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NOTHING IN THIS ELECTRONIC TRANSMISSION CONSTITUTES AN OFFER OF SECURITIES FOR SALE IN THE UNITED STATES OR ANY OTHER JURISDICTION WHERE IT IS UNLAWFUL TO DO SO. THE SECURITIES HAVE NOT BEEN AND WILL NOT BE REGISTERED UNDER THE US SECURITIES ACT OR WITH ANY SECURITIES REGULATORY AUTHORITY OF ANY STATE OR OTHER JURISDICTION OF THE UNITED STATES AND MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED IN THE UNITED STATES EXCEPT (1) IN ACCORDANCE WITH RULE 144A TO A PERSON THAT THE HOLDER AND ANY PERSON ACTING ON ITS BEHALF REASONABLY BELIEVES IS A QIB, OR (2) IN AN OFFSHORE TRANSACTION IN ACCORDANCE WITH RULE 903 OR RULE 904 OF REGULATION S UNDER THE US SECURITIES ACT, IN EACH CASE IN ACCORDANCE WITH ANY APPLICABLE SECURITIES LAWS OF ANY STATE OF THE UNITED STATES OR PURSUANT TO AN EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE US SECURITIES ACT AND APPLICABLE STATE OR LOCAL SECURITIES LAWS.

Confirmation of your representation: By accessing or accepting electronic delivery of this document, you are deemed to have represented to the Issuer and the Underwriters that (i) you are acting on behalf of, or you are either (a) an institutional investor outside the United States (as defined in Regulation S under the US Securities Act), or (b) in the United States and a QIB that is acquiring securities for your own account or for the account of another QIB; (ii) if you are in the

United Kingdom, you are a Relevant Person; (iii) if you are in any member state of the EEA other than Belgium or the United Kingdom, you are a Qualified Investor; (iv) the securities acquired by you in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, any person in circumstances which may give rise to an offer of any securities to the public other than their offer or resale in Belgium or in any member state of the EEA which has implemented the European Prospectus Directive to Qualified Investors (as defined in the European Prospectus Directive); and (v) if you are outside the United States, United Kingdom and EEA (and the electronic mail addresses that you gave the Issuer and to which this document has been delivered are not located in such jurisdictions) you are a person into whose possession this document may lawfully be delivered in accordance with the laws of the jurisdiction in which you are located.

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The Underwriters are acting exclusively for the Issuer and no one else in connection with the offer. They will not regard any other person (whether or not a recipient of this document) as their respective client in relation to the offer and will not be responsible to anyone other than the Issuer for providing the protections afforded to their respective clients nor for giving advice in relation to the offer or any transaction or arrangement referred to herein.

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Sequana Medical NV

OFFERING OF UP TO 3,235,294 NEW SHARES

PRICE RANGE: €8.50 TO €9.00 PER OFFERED SHARE

This prospectus (the “**Prospectus**”) relates to the initial offering (the “**Offering**”) by Sequana Medical NV (the “**Issuer**” and, together with its consolidated subsidiaries, “**Sequana Medical**”), a limited liability company organised under the laws of Belgium, registered with the legal entities register (Ghent, division Ghent) under enterprise number 0707.821.866, and with registered office located at AA Tower, Technologiepark 122, 9052 Ghent, Belgium, of up to 3,235,294 new shares (the “**New Shares**” and each existing share or New Share representing the Issuer’s share capital a “**Share**”), without nominal value, of the Issuer, within a price range between €8.50 and €9.00 per New Share (the “**Price Range**”). The Offer Price (as defined below) may be set within the Price Range or below the lower end of the Price Range, but will not exceed the higher end of the Price Range.

The aggregate number of New Shares offered in the Offering may be increased by up to 15% of the aggregate number of New Shares initially offered (the “**Increase Option**”). Any decision to exercise the Increase Option will be communicated, at the latest, on the date of the announcement of the Offer Price (as defined below).

KBC Securities NV/SA, as stabilisation manager (the “**Stabilisation Manager**”), acting on behalf of the Underwriters (as defined herein), is expected to be granted a warrant to purchase additional new Shares in a number equal to up to 15% of the number of New Shares subscribed for in the Offering (including the new Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) at the Offer Price (as defined below) to cover over-allotments or short positions, if any, in connection with the Offering (the “**Over-allotment Option**”), and (i) the New Shares, (ii) the additional new Shares issued pursuant to the Increase Option and (iii) the additional new Shares issued pursuant to the Over-allotment Option collectively being referred to as the “**Offered Shares**”). The Over-allotment Option will be exercisable for a period of 30 calendar days following the Listing Date (as defined below). The Stabilisation Manager, acting on behalf of the Underwriters, may engage in transactions that stabilise, maintain or otherwise affect the price of the Shares during a period of 30 calendar days following the Listing Date (as defined below). These activities may support the market price of the Shares at a level higher than that which might otherwise prevail.

The Offering consists of: (i) a public offering to retail and institutional investors in Belgium; (ii) a private placement in the United States (the “**U.S.**”) to persons who are reasonably believed to be “qualified institutional buyers” (“**QIBs**”) as defined in Rule 144A (“**Rule 144A**”) under the U.S. Securities Act of 1933, as amended (the “**U.S. Securities Act**”), in reliance on Rule 144A; and (iii) private placements to certain qualified and/or institutional investors under applicable laws of the relevant jurisdiction in the rest of the world (those qualified and/or institutional investors together with the QIBs are collectively being referred to as the “**Institutional Investors**”). The Offering outside the U.S. will be made in compliance with Regulation S under the U.S. Securities Act (“**Regulation S**”). Private placements may take place in member states of the European Economic Area (“**EEA**”) pursuant to an exemption under the Directive 2003/71/EC of the European Parliament and of the Council of the European Union (as amended, including by Directive 2010/73/EU, the “**European Prospectus Directive**”) as implemented in the relevant EEA member state.

There is no minimum amount for the Offering. Certain existing shareholders of the Issuer and other investors (the “**Participating Investors**”) have irrevocably committed to subscribe for an aggregate amount of €20.5 million in the Offering at the Offer Price, subject to closing of the Offering (the “**Subscription Commitments**”). A portion of this amount has already been made available to the Issuer on 20 December 2018 by several Participating Investors in the form of bridge loans for an aggregate principal amount of €1,024,238.77. In the event of over-subscription of the Offering, the Subscription Commitments for an amount of ca. €12.5 million can be reduced in line with the allocation principles that will apply to the other investors that will subscribe in the Offering, whereas the Subscription Commitments for the remaining amount shall not be reduced but be allocated entirely. As there is no minimum amount of the Offering, if not all of the Offered Shares are subscribed for in the Offering, the net proceeds from the Offering could be limited, all or in part, to the net proceeds from Subscription Commitments.

The Shares have not been and will not be registered under the U.S. Securities Act or the applicable securities laws of any state or other jurisdiction of the U.S. and may not be offered, sold, pledged or transferred within the U.S., except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the U.S. Securities Act. Prospective purchasers are hereby notified that sellers of the Shares may be relying on the exemption from the provisions of Section 5 of the U.S. Securities Act provided by Rule 144A. For a description of certain restrictions on transfer of the Shares, see Part 15 – (Transfer restrictions).

This Prospectus does not constitute, and neither the Issuer nor the Underwriters are making, an offer to sell the Offered Shares or soliciting an offer to purchase any of the Offered Shares to any person in any jurisdiction where such an offer or solicitation is not permitted. The Offered Shares may not be offered or sold, directly or indirectly, and neither this Prospectus nor any other Offering related documents may be distributed or sent to any person or into any jurisdiction, except in circumstances that will result in the compliance with all applicable laws and regulations. Persons into whose possession this Prospectus may come are required to inform themselves about, and to observe all, such restrictions. Neither the Issuer nor the Underwriters accept any responsibility for any violation by any person, whether or not it is a prospective purchaser of Offered Shares, of any such restriction.

An investment in the Offered Shares involves substantial risks and uncertainties. Prospective investors should read the entire Prospectus, and, in particular, should see Part 2 – (Risk Factors) beginning on page 31 for a discussion of certain factors that should be considered in connection with an investment in the Offered Shares, including the risks that Sequana Medical has incurred operating losses, negative operating cash flows and an accumulated deficit since inception and may not be able to achieve or subsequently maintain profitability, that Sequana Medical’s future financial performance will depend on the commercial acceptance of the alfapump[®] (Sequana Medical’s only commercial-stage product at the date of this Prospectus), the alfapump[®] DSR and/or any future products in target markets, and that Sequana Medical will likely require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available when required or could significantly limit Sequana Medical’s access to additional capital. See Part 1 – (Summary), Section D – (Risks) and Part 2 – (Risk Factors). Not taking into account any proceeds of the Offering, the Issuer does not have sufficient working capital to meet its working capital needs for a period of at least 12 months from the date of the Prospectus. All of these factors should be considered before investing in the Offered Shares. Prospective investors must be able to bear the economic risk of an investment in the Offered Shares and should be able to sustain a partial or total loss of their investment.

The offering period (the “**Offering Period**”) will begin on 31 January 2019 and is expected to end no later than 4:00 p.m. (CET) on 7 February 2019, subject to early closing or extension, provided that the Offering Period will in any event be open for at least six business days as from the start of the Offering Period. Any early closing or extension of the Offering Period will be announced by means of a press release by the Issuer, and the dates for each of pricing and allocation, publication of the Offer Price and results of the Offering, “if-and-when-issued-and/or-delivered” trading and closing of the Offering will in such case be adjusted accordingly.

The price per Offered Share (the “**Offer Price**”) will be determined during the Offering Period through a book-building process in which only Institutional Investors may participate, taking into account various relevant qualitative and quantitative elements, including but not limited to the number of Offered Shares for which subscriptions are received, the size of subscription orders received, the quality of the investors submitting such subscription orders and the prices at which the subscription orders were made, as well as market conditions at that time. See Part 13 – (The Offering), section 13.4 (Offer Price) for further information.

The Offer Price, the number of Offered Shares placed in the Offering and the allocation of Offered Shares to Retail Investors (as defined herein) is expected to be made public on or about 8 February 2019 and in any event no later than the first business day after the end of the Offering Period. The Offer Price will be a single price in euro, exclusive of the Belgian tax on stock exchange transactions, and of costs, if any, charged by financial intermediaries for the submission of applications.

Prior to the Offering, there has been no public market for the Shares. An application has been made to list all of the Issuer’s existing Shares as well as newly issued Offered Shares on the regulated market of Euronext Brussels under the symbol “SEQUA”. Trading of the Shares on the regulated market of Euronext Brussels is expected to commence, on an “if-and-when-issued-and/or-delivered” basis, on or about 11 February 2019 (the “**Listing Date**”), provided that this may be accelerated in case of early closing.

Delivery of the Offered Shares is expected to take place in book-entry form against payment therefore in immediately available funds on or about 12 February 2019, provided that this may be accelerated in case of early closing (the “**Closing Date**”), to investors’ securities accounts via Euroclear Belgium, the Belgian central securities depository. See Part 13 – (The Offering).

This document constitutes an offer and listing prospectus for purposes of article 3 of the European Prospectus Directive and has been prepared in accordance with article 20 of the Belgian Act of 16 June 2006 on the public offering of securities and the admission of securities to trading on a regulated market, as amended (the “**Belgian Prospectus Act**”). The English language version of this Prospectus was approved by the Belgian Financial Services and Markets Authority (the “**FSMA**”) on 30 January 2019.

Joint Global Coordinators and Joint Bookrunners

Kempen & Co N.V.

Lead Manager
Mirabaud Securities Limited

KBC Securities NV/SA

PROSPECTUS DATED 30 JANUARY 2019

IMPORTANT INFORMATION

Responsibility statement

In accordance with article 61, §1 and §2 of the Belgian Prospectus Act, the Issuer, represented by its board of directors, assumes responsibility for the information contained in this Prospectus. Having taken all reasonable care to ensure that such is the case, the Issuer, represented by its board of directors, declares that, to the best of its knowledge, the information contained in this Prospectus is in accordance with the facts and contains no omission likely to affect its import.

Neither Kempen & Co N.V. or KBC Securities NV/SA (together the “**Joint Global Coordinators**”) or Mirabaud Securities Limited (together with the Joint Global Coordinators, the “**Underwriters**”), nor any of their respective directors, officers, or employees, makes any representation or warranty, express or implied, as to, or assumes any responsibility for, the accuracy or completeness or verification of the information in this Prospectus, and nothing in this Prospectus is, or shall be relied upon as, a promise or representation by the Underwriters or any of their respective directors, officers, or employees whether as to the past or the future. Accordingly, the Underwriters disclaim, to the fullest extent permitted by applicable law, any and all liability, whether arising in tort, contract or otherwise, in respect of this Prospectus or any such statement.

Prospectus approval

The FSMA approved the English language version of this Prospectus on 30 January 2019 in accordance with article 23 of the Belgian Prospectus Act. The FSMA's approval does not imply any opinion by the FSMA on the suitability and the quality of the Offering or on the status of the Issuer.

Language versions

This Prospectus (including the Summary) has been prepared in English and translated into Dutch. The Issuer is responsible for the consistency between the Dutch and English language versions of the Prospectus. Investors can rely on the Dutch language version of this Prospectus in their contractual relationship with the Issuer. In any event, in the case of discrepancies between the different language versions of this Prospectus, the English language version will prevail.

Supplements to the Prospectus

The information in this Prospectus is as of the date printed on the front cover, unless expressly stated otherwise. The delivery of this Prospectus at any time does not imply that there has been no change in Sequana Medical's business or affairs since the date hereof or that the information contained herein is correct as of any time subsequent to the date hereof. In accordance with article 34 of the Belgian Prospectus Act, in the event of a significant new development, or material mistake or inaccuracy relating to the information included in this Prospectus which is capable of affecting the assessment of the Offered Shares during the period from the date of approval of the Prospectus to the Listing Date, a supplement to this Prospectus shall be published. Any supplement is subject to approval by the FSMA, in the same manner as this Prospectus and must be made public in the same manner as this Prospectus.

If a supplement to the Prospectus is published, investors who have already agreed to subscribe for the Offered Shares before the supplement is published will have the right, exercisable within at least two business days after the publication of the supplement, to withdraw their subscription orders, provided that the significant new development, material mistake or inaccuracy referred to above arose before the closing of the Offering and the delivery of the Offered Shares.

The distribution of this Prospectus and the Offering may, in certain jurisdictions, be restricted by law, and this Prospectus may not be used for the purpose of, or in connection with, any offer or solicitation by anyone in any jurisdiction in which such offer or solicitation is not authorised or to any person to whom it is unlawful to make such offer or solicitation. This Prospectus does not constitute an offer to sell, or an invitation of an offer to purchase, any Shares in any jurisdiction in which such offer or invitation would be unlawful. The Issuer and the Underwriters require persons into whose possession this Prospectus comes to inform themselves of and observe all such restrictions. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction. None of the Issuer or the Underwriters accepts any legal

responsibility for any violation by any person, whether or not a prospective purchaser of Shares, of any such restrictions. The Issuer and the Underwriters reserve the right in their own absolute discretion to reject any offer to purchase Shares that the Issuer, the Underwriters or their respective agents believe may give rise to a breach or violation of any laws, rules or regulations.

Stabilisation

In connection with the Offering, KBC Securities NV/SA will act as Stabilisation Manager on behalf of itself and the Underwriters, and may engage in transactions that stabilise, maintain or otherwise affect the price of the Shares or any options, warrants or rights with respect to, or other interest in, the Shares or other securities of the Issuer for up to 30 calendar days from the Listing Date (the “**Stabilisation Period**”). These activities may support the market price of the Shares at a level higher than that which might otherwise prevail. Stabilisation will not be executed above the Offer Price. Such transactions may be effected on the regulated market of Euronext Brussels, in the over-the-counter markets or otherwise. The Stabilisation Manager and its agents are not required to engage in any of these activities and, as such, there is no assurance that these activities will be undertaken; if undertaken, the Stabilisation Manager or its agents may discontinue any of these activities at any time and they must terminate at the end of the 30 calendar day period mentioned above.

Within one week of the end of the Stabilisation Period, the following information will be made public: (i) whether or not stabilisation was undertaken; (ii) the date on which stabilisation started; (iii) the date on which stabilisation last occurred; (iv) the price range within which stabilisation was carried out, for each of the dates on which stabilisation transactions were carried out; (v) the trading venue(s) on which the stabilisation transactions were carried out (where applicable) and (vi) the final size of the Offering, including the result of the stabilisation and the exercise of the Over-allotment Option and the Increase Option, as the case may be.

Availability of this Prospectus

This Prospectus is available to prospective investors in Belgium. The Prospectus will be made available to prospective investors at no cost at the Issuer’s registered office, located at AA Tower, Technologiepark 122, 9052 Ghent, Belgium, and can be obtained by prospective investors in Belgium on request from KBC Securities NV/SA at www.kbc.be/sequana, www.bolero.be/nl/sequana and www.kbcsecurities.com.

Subject to country restrictions, the Prospectus is also available to prospective investors on the following website: www.sequanamedical.com.

The posting of the Prospectus or any summary thereof on the internet does not constitute an offer to sell or a solicitation of an offer to buy any of the Shares to or from any person in any jurisdiction in which it is unlawful to make such offer or solicitation to such person. The electronic version may not be copied, made available or printed for distribution. Although certain references are made to the Issuer’s website, information on the Issuer’s website (www.sequanamedical.com) (other than the Prospectus) or any other website does not form part of the Prospectus. This Prospectus is valid only if circulated in accordance with applicable law.

Further information regarding the Issuer

The Issuer was initially incorporated as a limited liability company organised in the form of an Aktiengesellschaft/société anonyme under the laws of Switzerland. In 2018, its registered office was transferred from Switzerland to Belgium (the “**Belgian Seat Transfer**”).

The Issuer must file its restated articles of association and all other deeds and resolutions that are to be published in the Annexes to the Belgian Official Gazette (*Belgisch Staatsblad/Moniteur Belge*) with the clerk’s office of the commercial court (and, as of 1 November 2018, the enterprise court) of Ghent, division Ghent, where they are available to the public. The Issuer is registered with the legal entities register (Ghent, division Ghent) under enterprise number 0707.821.866. A copy of the Issuer’s most recently restated articles of association and corporate governance charter will also be available on its website free of charge.

In accordance with Belgian law, the Issuer must prepare annual audited statutory and consolidated financial statements. The annual statutory and consolidated financial statements and the reports of the Issuer’s board of directors and statutory auditor relating thereto must be filed with the Belgian National Bank, where they are available to the public. Furthermore, as a company

with shares listed on the regulated market of Euronext Brussels, the Issuer will also be required to publish an annual financial report (which includes its audited statutory and consolidated financial statements, the report of its board of directors and the report of the statutory auditor) and an annual announcement preceding the publication of the annual financial report, as well as a half-yearly financial report on the first six months of its financial year (which includes a condensed set of financial statements and an interim management report). Copies of these documents will be made available on the Issuer's website and on STORI, the Belgian central storage mechanism, which is operated by the FSMA and can be accessed via stori.fsma.be or www.fsma.be.

The Issuer must also disclose inside information, information about its shareholder structure and certain other information to the public. In accordance with the Belgian Royal Decree of 14 November 2007 on the obligations of issuers of financial instruments that are admitted to trading on a regulated market and Regulation (EU) 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (the "**Market Abuse Regulation**") and related rules, as amended from time to time, such information and documentation will be made available through the Issuer's website, press releases, the communication channels of Euronext Brussels, on STORI, or a combination of these means. All press releases published by the Issuer will be made available on its website.

The Issuer has agreed that, for so long as any of the Shares are "restricted securities" within the meaning of Rule 144(a)(3) under the U.S. Securities Act, the Issuer will, during any period in which it is neither subject to Section 13 or 15(d) of the U.S. Securities Exchange Act of 1934 (the "**U.S. Exchange Act**") nor exempt from reporting pursuant to Rule 12g3-2(b) under the U.S. Exchange Act, provide to any holder or beneficial owner of such restricted securities or to any prospective purchaser of such restricted securities designated by such holder or beneficial owner, on the request of such holder, beneficial owner or prospective purchaser, the information required to be provided to such persons pursuant to Rule 144A(d)(4) under the U.S. Securities Act. The Issuer is not currently subject to the periodic reporting requirements of the U.S. Exchange Act.

NOTICE TO INVESTORS

This Prospectus is intended to provide information to potential investors in the context of and for the sole purpose of evaluating a possible investment in the Offered Shares. It contains selected and summarised information, does not express any commitment or acknowledgement or waiver, and does not create any right, express or implied, towards anyone other than a potential investor. Investors must assess, with their own advisers if necessary, whether the Offered Shares are a suitable investment for them, considering their personal income and financial situation. In case of any doubt about the risk involved in investing in the Offered Shares, investors should abstain from investing in the Offered Shares.

In making an investment decision, investors must rely on their own assessment, examination, analysis and enquiry of the Issuer, the terms of the Offering and the contents of this Prospectus, including the merits and risks involved. Any purchase of Shares should be based on the assessments that an investor may deem necessary, including the legal basis and consequences of the Offering, and including possible tax consequences that may apply, before deciding whether or not to invest in the Shares. In addition to their own assessment of the Issuer and the terms of the Offering, investors should rely only on the information contained in this Prospectus, including the risk factors described herein.

The summaries and descriptions of legal provisions, accounting principles or comparisons of such principles, legal company forms or contractual relationships reported in the Prospectus may under no circumstances be interpreted as a basis for credit or other evaluation, or as investment, legal or tax advice for prospective investors. Prospective investors are urged to consult their own financial adviser, accountant or other advisers concerning the legal, tax, economic, financial and other aspects associated with the trading or investment in the Shares.

Investors must also acknowledge that they have not relied on the Underwriters or any person affiliated with the Underwriters in connection with any investigation of the information contained in this Prospectus or their investment decision, and they have relied only on the information contained in this Prospectus, and that no person has been authorised to give any information or to make any representation concerning the Issuer or its subsidiary or the Shares (other than as contained in this

Prospectus) and, if given or made, any such other information or representation should not be relied upon as having been authorised by the Issuer or the Underwriters.

None of the Issuer or the Underwriters, or any of their respective representatives, is making any representation to any offeree or purchaser of the Shares regarding the legality of an investment in the Shares by such offeree or purchaser under the laws applicable to such offeree or purchaser. Each investor should consult with his or her own advisers as to the legal, tax, business, financial and related aspects of a purchase of the Shares.

No person has been authorised to give any information or to make any representation in connection with the Offering other than those contained in this Prospectus, and, if given or made, such information or representation must not be relied upon as having been authorised. Without prejudice to the Issuer's obligation to publish supplements to the Prospectus when legally required (as described below), neither the delivery of this Prospectus nor any sale made at any time after the date hereof shall, under any circumstances, create any implication that there has been no change in Sequana Medical's affairs since the date hereof or that the information set forth in this Prospectus is correct as of any time since its date.

The Underwriters are acting exclusively for the Issuer and no one else in connection with the Offering. They will not regard any other person (whether or not a recipient of this document) as their respective clients in relation to the Offering and will not be responsible to anyone other than the Issuer for providing the protections afforded to their respective clients nor for giving advice in relation to the Offering or any transaction or arrangement referred to herein.

NOTICE TO PROSPECTIVE INVESTORS IN THE UNITED STATES

The Shares have not been and will not be registered under the U.S. Securities Act and are being offered and sold: (i) outside the U.S. in compliance with Regulation S, and (ii) in the U.S. only to persons who are reasonably believed to be QIBs in reliance on Rule 144A. Prospective investors are hereby notified that sellers of the Shares may be relying on the exemption from the registration requirements of Section 5 of the U.S. Securities Act provided by Rule 144A. For certain restrictions on transfer of the Shares, see Part 15 -(Transfer restrictions).

The Shares have not been recommended by any U.S. federal or state securities commission or regulatory authority. Furthermore, the foregoing authorities have not confirmed the accuracy or determined the adequacy of this Prospectus. Any representation to the contrary is a criminal offense in the U.S.

In the U.S., this Prospectus is being furnished on a confidential basis solely for the purpose of enabling a prospective investor to consider subscribing for the particular securities described herein. The information contained in this Prospectus has been provided by the Issuer and other sources identified herein. Distribution of this Prospectus to any person other than the offeree specified by the Underwriters or their representatives, and those persons, if any, retained to advise such offeree with respect thereto, is unauthorised, and any disclosure of its contents, without the Issuer's prior written consent, is prohibited. Any reproduction or distribution of this Prospectus in the U.S., in whole or in part, and any disclosure of its contents to any other person is prohibited. This Prospectus is personal to each offeree and does not constitute an offer to any other person or to the public generally to subscribe for, or otherwise acquire, the Shares.

NOTICE TO PROSPECTIVE INVESTORS IN THE EUROPEAN ECONOMIC AREA

An offer to the public of any Shares may not be made in any Member State of the European Economic Area ("EEA") other than an offer to the public of Offered Shares in Belgium unless a prospectus has been (i) approved by the competent authority in such Member State or passported and (ii) published in accordance with the European Prospectus Directive as implemented in such Member State. This Prospectus has been prepared on the basis that all offers of Shares other than the offers contemplated in Belgium, will be made pursuant to an exemption under the European Prospectus Directive, as implemented in Member States of the EEA, from the requirement to produce a prospectus for offers of shares. Accordingly, any person making or intending to make any offer within the EEA of Shares which are the subject of the placement contemplated in this Prospectus should only do so in circumstances in which no obligation arises for the Issuer or any of the Underwriters to produce a prospectus for such offer. The Offering is

solely conducted by the Issuer, and neither the Issuer nor the Underwriters have authorised, nor do the Issuer or the Underwriters authorise, the making of any offer of Shares through any financial intermediary.

The Shares have not been, and will not be, offered to the public in any Member State of the European Economic Area, except for Belgium. Notwithstanding the foregoing, an offering of the Shares may be made in a Member State of the European Economic Area that has implemented the European Prospectus Directive (a “**Relevant Member State**”):

- to any legal entity that is a qualified investor as defined in the European Prospectus Directive;
- to fewer than 150 natural or legal persons (other than qualified investors as defined in the European Prospectus Directive) subject to obtaining the prior consent of the Underwriters for any such offer; or
- in any other circumstances falling within article 3(2) of the European Prospectus Directive, if applicable;

provided that no such offer of Shares shall result in a requirement for the publication by the Issuer or any Underwriter of a prospectus pursuant to article 3 of the European Prospectus Directive.

For the purposes of this provision, the expression an “offer to the public” in relation to any Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the Offering and the Shares so as to enable an investor to decide to purchase or subscribe for Shares, as that definition may be varied in that Relevant Member State by any measure implementing the European Prospectus Directive in that Relevant Member State, the expression “European Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the Directive 2010/73/EU), and includes any relevant implementing measure in the Relevant Member State.

NOTICE TO PROSPECTIVE INVESTORS IN THE UNITED KINGDOM

Offers of Offered Shares pursuant to the Offering are only being made to persons in the United Kingdom who are “qualified investors” or otherwise in circumstances which do not require publication by the Issuer of a prospectus pursuant to section 85(1) of the U.K. Financial Services and Markets Act 2000.

Any investment or investment activity to which the Prospectus relates is available only to, and will be engaged in only with, persons who (i) are investment professionals falling within article 19(5) or (ii) fall within article 49(2)(a) to (d) (“high net worth companies, unincorporated associations, etc.”) of the U.K. Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or other persons to whom such investment or investment activity may lawfully be made available (together, “**Relevant Persons**”). Persons in the U.K. who are not Relevant Persons should not take any action on the basis of the Prospectus and should not act or rely on it.

NOTICE TO PROSPECTIVE INVESTORS IN SWITZERLAND

The Shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“**SIX**”) or on any other stock exchange or regulated trading facility in Switzerland. Neither this Prospectus nor any other offering or marketing material relating to the Shares constitutes a prospectus or a similar notice as such terms are understood pursuant to article 652a, article 752 or article 1156 of the Swiss Code of Obligations or a listing prospectus within the meaning of Art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this Prospectus nor any other offering or marketing material relating to the Shares or the Offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this Prospectus nor any other offering or marketing material relating to the Offering, the Issuer or the Shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this Prospectus will not be filed with, and the Offering will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA. The Offering has not been and will not be authorised under the Swiss Federal Act on Collective Investment Schemes (“**CISA**”). The

investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of Shares.

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

Financial statements

This Prospectus contains the audited consolidated financial statements of the Issuer as of and for the years ended 31 December 2017, 2016 and 2015 (the “**Annual Financial Statements**”) and the unaudited consolidated interim financial statements of the Issuer as of and for the nine-month period ended 30 September 2018 (with comparative figures for the nine-month period ended 30 September 2017) (the “**Interim Financial Statements**”, and together with the Annual Financial Statements, the “**Financial Statements**”). The Annual Financial Statements were prepared in accordance with International Financial Reporting Standards, as adopted by the European Union (“**IFRS**”). The Interim Financial Statements were prepared in accordance with International Accounting Standard 34, as adopted by the European Union (“**IAS 34**”).

The Issuer’s Annual Financial Statements have been audited, and the Interim Financial Statements have been reviewed, by PricewaterhouseCoopers AG, with office address at St Jakobs-Strasse 25, CH-4002 Basel, Switzerland, represented by Thomas Brüderlin and Susanne Halimi, both Swiss audit experts, who rendered an unqualified audit report on the Annual Financial Statements with a matter of emphasis paragraph on going concern, which should be read in conjunction with the Annual Financial Statements. Following the completion of the Belgian Seat Transfer, PricewaterhouseCoopers Bedrijfsrevisoren BV CVBA, with registered office at Woluwedal 18, 1932 Sint-Stevens-Woluwe, Belgium, represented by Peter D’hondt, has been appointed at the extraordinary general shareholders’ meeting of the Issuer held on 1 October 2018 as the Issuer’s current statutory auditor for the statutory term of three years. For further information on the Issuer’s statutory auditor, see Part 17 – (Statutory auditor).

Share Consolidation

On the date of this Prospectus, the share capital of the Issuer amounts to €887,997.47. It is represented by 9,930,784 Shares, of which 3,194,913 common Shares and 6,735,871 preferred Shares. The 6,735,871 preferred Shares consist of 543,682 series A preferred Shares, 2,167,115 series B preferred Shares, 1,724,337 series C preferred Shares, 201,501 series D preferred Shares, and 2,099,236 series E preferred Shares. All Shares are fully paid up, and represent the same fraction of the Issuer’s share capital. In addition, there are a number of outstanding Convertible Loans (as defined below) that are convertible into series E preferred Shares, and a number of outstanding Share options that are exercisable for common Shares and series E preferred Shares (see also Part 12 – (Share capital and articles of association), section 12.4 (Outstanding Convertible Loans and Bridge Loans), section 12.5 (Outstanding Share options)). The Convertible Loans will all be converted into series E preferred Shares immediately prior to the closing of the Offering. The preferred Shares benefit from a specific priority that will be triggered upon the closing of the Offering and which will result in a conversion and consolidation of the outstanding Shares into a new number of outstanding Shares reflecting the priority among the current shareholders of the Issuer as a result of the Offering (not including the Offered Shares to be issued upon the closing of the Offering (including pursuant to the conversion of Bridge Loans) and the exercise of the Over-allotment Option). In addition, subject to and with effect as of the closing of the Offering and after having given effect to the aforementioned priority, all of the then existing Shares will be converted into ordinary Shares in such a manner that each Share shall be of the same type and class as the Offered Shares. The conversion and consolidation of Shares as result of the aforementioned priority and conversion into ordinary Shares is referred to as the “**Share Consolidation**”. Unless indicated otherwise, the number of Shares reported does not yet reflect the Share Consolidation. For further information on the Share Consolidation, see Part 12 – (Share capital and articles of association), section 12.3 (Share capital and shares), subsection (c) (Share Consolidation upon the closing of the Offering).

Rounding

Certain monetary amounts and other figures included in this Prospectus have been subject to rounding adjustments. Accordingly, any discrepancies in any tables between the totals and the sums of amounts listed are due to rounding.

Other Information

In this Prospectus, references to the “Issuer” are to Sequana Medical NV, and references to “Sequana Medical”, “we,” “us” or “our” are to the Issuer and its consolidated subsidiaries, Sequana Medical GmbH and Sequana Medical, Inc.

In this Prospectus, references to “euro”, “EUR” or “€” are references to the euro, the single currency of the participating member states in the Third Stage of European Economic and Monetary Union of the Treaty Establishing the European Community, as amended from time to time; references to “Swiss franc” or “CHF” are references to the Swiss franc, the lawful currency of Switzerland and Liechtenstein; references to “U.S. Dollar”, “USD”, “US\$” or “\$” are references to the U.S. Dollar, the lawful currency of the United States of America; references to “pound sterling”, “U.K. pound sterling”, “GBP” or “£” are references to the pound sterling, the official currency of the United Kingdom, Jersey, Guernsey, the Isle of Man, South Georgia and the South Sandwich Islands, the British Antarctic Territory, and Tristan da Cunha.

PRESENTATION OF INDUSTRY, MARKET AND OTHER INFORMATION

This Prospectus includes market, economic and industry data, which were obtained by Sequana Medical from scientific journals, industry publications, press releases, filings under various securities laws, data published by government agencies and industry reports prepared by consultants. These market data are primarily presented in Part 8 – (Business). The market, economic and industry data have primarily been derived and extrapolated from reports and articles provided by third parties such as GlobalData, the American Association for the Study of Liver Diseases, the European Association for the Study of the Liver, the U.S. Centers for Disease Control and Prevention, the New England Journal of Medicine, the Journal of the American College of Cardiology, the Journal of Clinical Gastroenterology, the Annals of Oncology and the American Journal of Gastroenterology. For further information, see Annex A (Sources).

The third-party sources Sequana Medical has used generally state that the information they contain has been obtained from sources believed to be reliable. Some of these third-party sources also state, however, that the accuracy and completeness of such information is not guaranteed and that the projections they contain are based on significant assumptions. As Sequana Medical does not have access to the facts and assumptions underlying such market data, or statistical information and economic indicators contained in these third party sources, Sequana Medical is unable to verify such information. Thus, while the information has been accurately reproduced with no omissions that would render it misleading, and Sequana Medical believes it to be reliable, Sequana Medical cannot guarantee its accuracy or completeness. The inclusion of this third-party industry, market and other information should not be considered as the opinion of such third parties as to the value of the Offered Shares or the advisability of investing in the Offered Shares.

In addition, certain information in this Prospectus is not based on published data obtained from independent third parties or extrapolations therefrom, but rather is based upon Sequana Medical’s best estimates, which are in turn based upon information obtained from trade and business organisations and associations, consultants and other contacts within the industries in which Sequana Medical competes, information published by Sequana Medical’s competitors and Sequana Medical’s own experience and knowledge of conditions and trends in the markets in which it operates.

Sequana Medical cannot assure that any of the assumptions it has made while compiling this data from third party sources are accurate or correctly reflect Sequana Medical’s position in the industry and none of Sequana Medical’s internal estimates have been verified by any independent sources. None of Sequana Medical or the Underwriters makes any representation or warranty as to the accuracy or completeness of this information. None of Sequana Medical or the Underwriters have independently verified this information and, while Sequana Medical believes it to be reliable, none of Sequana Medical or the Underwriters can guarantee its accuracy.

JURISDICTION AND SERVICE OF PROCESS IN THE UNITED STATES AND ENFORCEMENT OF FOREIGN JUDGMENTS IN BELGIUM

The Issuer is a limited liability company organised and existing under the laws of Belgium. All of the Issuer's directors and all members of its executive management team are non-residents of the U.S. Although the Issuer has a U.S. subsidiary, Sequana Medical Inc., the subsidiary does not have any operations at the date of this Prospectus. Other than this subsidiary, which is not currently operational, all of the Issuer's assets and all of the assets of these individuals are located outside the U.S. As a result, it may not be possible for investors to effect service of process within the U.S. upon these individuals or to enforce against these individuals or the Issuer judgments obtained in the U.S. whether or not based on the civil liability provisions of the U.S. securities laws or other laws of the U.S. or any state thereof.

Original actions or actions for the enforcement of judgments of U.S. courts relating to the civil liability provisions of the federal or state securities laws of the U.S. are not directly enforceable in Belgium. The U.S. and Belgium currently do not have a multilateral or bilateral treaty providing for reciprocal recognition and enforcement of judgments, other than arbitral awards, in civil and commercial matters. In order for a final judgment for the payment of money rendered by U.S. courts based on civil liability to produce any effect on Belgian soil, it is accordingly required that this judgment be recognised and be declared enforceable by a Belgian court pursuant to the relevant provisions of the 2004 Belgian Code of Private International Law. Recognition or enforcement does not imply a review of the merits of the case and is irrespective of any reciprocity requirement. A U.S. judgment will, however, not be recognised or declared enforceable in Belgium if it infringes upon one or more of the grounds for refusal which are exhaustively listed in article 25 of the 2004 Belgian Code of Private International Law. In addition to recognition or enforcement, a judgment by a federal or state court in the U.S. against the Issuer may also serve as evidence in a similar action in a Belgian court if it meets the conditions required for the authenticity of judgments according to the law of the state where it was rendered.

In addition, with regard to enforcements by legal proceedings in Belgium (including the recognition of foreign court decisions in Belgium), a registration tax at the rate of 3% of the amount of the judgment is payable by the debtor, if the sum of money which the debtor is ordered to pay by a Belgian court, or by a foreign court judgment that is either (i) automatically enforceable and registered in Belgium or (ii) rendered enforceable by a Belgian court, exceeds €12,500. The registration tax is payable by the debtor, it being understood that the Belgian State has a priority on any amounts payable pursuant to such judgment as a security for the effective payment of the registration tax. A stamp duty is payable for each original copy of an enforcement judgment rendered by a Belgian court, with a maximum of €1,450.

FORWARD-LOOKING STATEMENTS

All statements in this Prospectus that do not relate to historical facts and events are "forward-looking statements". Forward-looking statements can be found under the captions Part 1 – (Summary), Part 2 – (Risk Factors), Part 7 – (Operating and financial review and prospects), Part 8 – (Business) and in other sections of this Prospectus. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes," "estimates," "anticipates," "expects," "intends," "may," "will," "plans," "continue," "ongoing," "potential," "predict," "project," "target," "seek" or "should" or, in each case, their negative or other variations or comparable terminology or by discussions of strategies, plans, objectives, targets, goals, future events or intentions. These forward-looking statements appear in a number of places throughout this Prospectus. Forward-looking statements include statements regarding Sequana Medical's intentions, beliefs or current expectations concerning, among other things, its results of operations, prospects, growth, strategies and dividend policy and the industry in which Sequana Medical operates. In particular, certain statements are made in this Prospectus regarding management's estimates of future growth.

By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. Forward-looking statements are not guarantees of future performance. You should not place undue reliance on these forward-looking statements. Any forward-looking statements are made only as of the date of this Prospectus and, without prejudice to the Issuer's

obligations under applicable law in relation to disclosure and ongoing information, Sequana Medical does not intend, and does not assume any obligation, to update forward-looking statements set forth in this Prospectus.

Many factors may cause Sequana Medical's results of operations, financial condition, liquidity and the development of the industries in which Sequana Medical competes to differ materially from those expressed or implied by the forward-looking statements contained in this Prospectus.

These factors include, but are not limited to:

- commercial acceptance of existing and future products in target markets;
- acceptance and adoption by physicians of any existing and future products in target markets;
- uncertain, time consuming and expensive regulatory approvals;
- failure to obtain sufficient financing;
- changing regulatory regimes may delay, prohibit or reduce potential sales or create costs that are not economically attractive;
- disruption of supply chain for services and components used for manufacturing products;
- changes in government regulations, legislation and healthcare policies, including with respect to reimbursements;
- intense and increased competition from other companies;
- failure to comply with the loan agreement entered into between Sequana Medical and Bootstrap Europe S.C.Sp.;
- failure to fully protect and exploit intellectual property rights;
- difficulties in recruitment and attracting physicians;
- failure to manufacture or outsource manufacturing in a timely manner or at a cost that is not economically attractive;
- product liability claims and no adequate insurance coverage for such claims;
- product recalls for defective products;
- failure to attract and retain management and other personnel;
- failure to penetrate markets outside of Europe, the United States and Canada;
- information security breaches and disruptions;
- failure of information technology systems;
- misconduct or other improper activities of employees, independent contractors, Investigators, consultants, commercial collaborators, service providers, distributors and other counterparties;
- changes in currency exchange rates; and
- changes in tax laws and regulations.

These risks and others described under Part 2 – (Risk Factors) are not exhaustive. Other sections of this Prospectus describe additional factors that could adversely affect Sequana Medical's results of operations, financial condition, liquidity and the development of the sectors in which Sequana Medical operates. New risks can emerge from time to time, and it is not possible for Sequana Medical to predict all such risks, nor can Sequana Medical assess the impact of all such risks on its business or the extent to which any risks, or combination of risks and other factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, you should not rely on forward-looking statements as a prediction of actual results.

EXCHANGE RATES

In this Prospectus, unless otherwise indicated, all amounts are expressed in euro. The following tables set forth, for the periods and dates indicated, certain information regarding the daily reference exchange rates published by the European Central Bank (“**ECB Daily Reference Rate**”) for the euro and the Swiss franc, and the euro and the U.S. Dollar. On 29 January 2019, the ECB Average Daily Reference Rate was CHF1.1352 per €1 and USD1.1422 per €1. These rates may differ from the actual rates used in the preparation of the financial statements and other financial information appearing in this Prospectus. Inclusion of these exchange rates is not meant to suggest that the Swiss franc or U.S. Dollar amounts (as the case may be) actually represent such euro amounts or that such amounts could have been converted into euro at any particular rate, if any. The following tables have been set out solely for the purpose of convenience.

Swiss francs per one euro

	Period End ⁽¹⁾	Average ⁽²⁾	High	Low
Year				
2012.....	1.2072	1.2053	1.2196	1.2008
2013.....	1.2276	1.2311	1.2599	1.2087
2014.....	1.2024	1.2146	1.2383	1.2009
2015.....	1.0835	1.0679	1.2022	0.9816
2016.....	1.0739	1.0902	1.1169	1.0687
2017.....	1.1702	1.1117	1.1772	1.0637
2018.....	1.1269	1.1550	1.1986	1.1217
2019 (up to and including 29 January 2019)	1.1352	1.1286	1.1352	1.1219
Month				
January 2018.....	1.1631	1.1723	1.1799	1.1563
February 2018.....	1.1520	1.1542	1.1610	1.1500
March 2018.....	1.1779	1.1685	1.1801	1.1512
April 2018.....	1.1968	1.1890	1.1986	1.1775
May 2018.....	1.1526	1.1780	1.1965	1.1513
June 2018.....	1.1569	1.1562	1.1631	1.1496
July 2018.....	1.1592	1.1622	1.1704	1.1557
August 2018.....	1.1281	1.1413	1.1589	1.1281
September 2018.....	1.1316	1.1286	1.1376	1.1217
October 2018.....	1.1399	1.1413	1.1470	1.1354
November 2018.....	1.1340	1.1377	1.1460	1.1273
December 2018.....	1.1269	1.1293	1.1348	1.1227

Notes:

- (1) Represents the exchange rate on the last business day of the applicable period.
- (2) Represents the average of the ECB Daily Reference Rates on the last business day of each month during the relevant one-year and interim periods and, with respect to monthly information, the average of the ECB Daily Reference Rates on each business day for the relevant period.

U.S. Dollars per one euro

	Period End⁽¹⁾	Average⁽²⁾	High	Low
Year				
2012.....	1.3194	1.2848	1.3454	1.2089
2013.....	1.3791	1.3281	1.3814	1.2768
2014.....	1.2141	1.3285	1.3953	1.2141
2015.....	1.0887	1.1095	1.2043	1.0552
2016.....	1.0541	1.1069	1.1569	1.0364
2017.....	1.1993	1.1297	1.2060	1.0385
2018.....	1.1454	1.1810	1.2493	1.1261
2019 (up to and including 29 January 2019)	1.1422	1.1412	1.1535	1.1341
Month				
January 2018.....	1.2457	1.2200	1.2457	1.1932
February 2018.....	1.2214	1.2348	1.2493	1.2214
March 2018.....	1.2321	1.2336	1.2421	1.2171
April 2018.....	1.2079	1.2276	1.2388	1.2070
May 2018.....	1.1699	1.1812	1.2007	1.1558
June 2018.....	1.1658	1.1678	1.1836	1.1534
July 2018.....	1.1736	1.1686	1.1789	1.1588
August 2018.....	1.1651	1.1549	1.1710	1.1321
September 2018.....	1.1576	1.1659	1.1777	1.1562
October 2018.....	1.1318	1.1484	1.1606	1.1318
November 2018.....	1.1359	1.1367	1.1487	1.1261
December 2018.....	1.1454	1.1384	1.1454	1.1285

Notes:

- (1) Represents the exchange rate on the last business day of the applicable period.
- (2) Represents the average of the ECB Daily Reference Rates on the last business day of each month during the relevant one-year and interim periods and, with respect to monthly information, the average of the ECB Daily Reference Rates on each business day for the relevant period.

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PART 1 – SUMMARY

Summaries are made up of disclosure requirements known as “Elements”. These Elements are numbered in Sections A-E (A.1-E.7).

This summary contains all the Elements required to be included in a summary for this type of securities and issuer. Because some Elements are not required to be addressed, there may be gaps in the numbering sequence of the Elements.

Even though an Element may be required to be inserted in the summary because of the type of securities and issuer, it is possible that no relevant information can be given regarding the Element. In this case a short description of the Element is included in the summary with the mention of “not applicable”.

Section A – Introduction and warnings

Element	Disclosure requirement
A.1	<p>Introduction and warning</p> <p>This summary must be read as an introduction to this prospectus (the “Prospectus”) and is provided to aid investors when considering whether to invest in the Offered Shares (as defined below), but is not a substitute for this Prospectus. Any decision to invest in Offered Shares should be based on consideration of this Prospectus as a whole. No civil liability will attach to the persons responsible for this summary in any member state of the European Economic Area (the “EEA”) solely on the basis of this summary, including any translation thereof, unless it is misleading, inaccurate or inconsistent when read together with the other parts of this Prospectus or it does not provide, when read together with the other parts of this Prospectus, key information in order to aid investors when considering whether to invest in the Offered Shares. Where a claim relating to this Prospectus is brought before a court in a member state of the EEA, the plaintiff may, under the national legislation of the member state of the EEA where the claim is brought, be required to bear the costs of translating this Prospectus before the legal proceedings are initiated.</p>
A.2	<p>Consent for use of the Prospectus for subsequent resale</p> <p>Not applicable. Sequana Medical NV (the “Issuer” and, together with its consolidated subsidiaries, “Sequana Medical”) does not consent to the use of the Prospectus for the subsequent resale or final placement of securities by financial intermediaries.</p>

Section B – Issuer

Element	Disclosure requirement
B.1	<p>The legal and commercial name of the Issuer</p> <p>The legal name of the Issuer is Sequana Medical NV. It carries out its business under the name of Sequana Medical.</p>
B.2	<p>Domicile and legal form of the Issuer</p> <p>The Issuer is a limited liability company organised in the form of a <i>naamloze vennootschap/ société anonyme</i> under the laws of Belgium. The Issuer is registered with the legal entities register (Ghent, division Ghent) under enterprise number 0707.821.866. The Issuer’s registered office is located at AA Tower, Technologiepark 122, 9052 Ghent, Belgium. The Issuer was initially incorporated as a limited liability company organised in the form of an Aktiengesellschaft/société anonyme under the laws of Switzerland. In 2018, its registered office was transferred from Switzerland to Belgium (the “Belgian Seat Transfer”).</p>

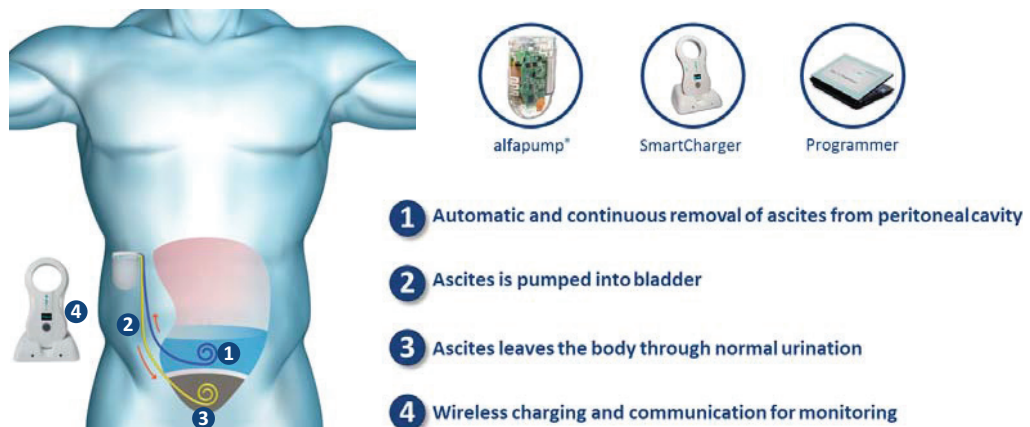
Current operations and principal activities of the Issuer and the principal markets in which it competes

Sequana Medical is a commercial stage medical device company focused on the development of innovative treatment solutions for the management of liver disease, heart failure, malignant ascites and other fluid imbalance disorders. Sequana Medical's core markets of liver disease and heart failure are large and growing, driven by unhealthy lifestyles and ageing populations.

Sequana Medical's **alfapump**[®] provides an innovative treatment solution for the long-term management of liver refractory ascites and malignant ascites with proven safety, efficacy and quality of life benefits demonstrated in multiple clinical studies and over 650 implants.

The **alfapump**[®] has received CE Mark approval for liver refractory ascites and malignant ascites. Since April 2018, the **alfapump**[®] has been included in the European Association for the Study of the Liver (the "**EASL**") clinical practice guidelines for the management of patients with decompensated cirrhosis, which management believes is a key step in the widespread commercial acceptance of the **alfapump**[®]. In January 2019, the U.S. Food and Drug Administration (the "**FDA**") granted Breakthrough Device designation for the **alfapump**[®] for the treatment of liver recurrent or refractory ascites.

The fully-implanted, programmable, wirelessly charged **alfapump**[®] automatically pumps ascites from the peritoneal cavity into the bladder, where the body can eliminate the ascites naturally through urination.



Sequana Medical has invested significant resources in clinical studies to demonstrate the safety and efficacy of the **alfapump**[®]. Key findings of selected **alfapump**[®] studies include:

- an approximately 90% reduction in the mean number of large volume paracentesis ("**LVP**") per month for liver refractory patients treated with the **alfapump**[®] versus patients treated with LVP standard of care;
- a clinically significant improvement in quality of life for patients treated with the **alfapump**[®] versus patients treated with LVP standard of care; and
- liver refractory ascites patients treated with the **alfapump**[®] demonstrated a clear nutritional benefit versus patients treated with LVP standard of care over 30-day and 90-day periods.

The **alfapump**[®] was also effective in palliative patients with malignant ascites and demonstrated the potential to improve quality of life and clinical outcomes for late-stage cancer patients.

There have been seven peer-reviewed publications regarding the **alfapump**[®], in addition to presentations of **alfapump**[®] studies at industry conferences.

The following table provides a summary of select **alfapump**[®] clinical studies that are ongoing or that Sequana Medical plans to conduct in the near future for the management of liver disease and malignant ascites:

Name of Study	Description ⁽¹⁾	2018	2019	2020	2021
Liver disease:					
ARIA Pump Study	Randomised, open-label health economic study in France in 90 liver refractory ascites patients to evaluate the cost utility of the alfapump [®] vs. standard of care (60 patients not waiting for liver transplant and 30 patients as bridge to transplant) over 12 months to support French reimbursement. ⁽²⁾				
POSEIDON (North American pivotal) Study	Pivotal study in the United States of America (the "U.S.") and Canada ("North America") in up to 100 patients with liver refractory and recurrent ascites to demonstrate the efficacy and cost-effectiveness of the alfapump [®] vs. standard of care (LVP). ⁽³⁾				
TOPMOST⁽⁴⁾	European registry study in cirrhosis patients that have been implanted with the alfapump [®] .				
Fitbit[®] Study⁽⁵⁾	Quality of life study in 20 patients to measure the impact of the alfapump [®] vs. standard of care on patient activity.				
Albumin Replacement Study	European study on the impact of albumin replacement therapy on clinical outcomes in 10-15 patients implanted with the alfapump [®] .				
Malignant ascites:					
Malignant Ascites CT	Controlled study in Europe to evaluate the efficacy and clinical impact of the alfapump [®] vs. standard of care in 25-30 malignant ascites patients.				

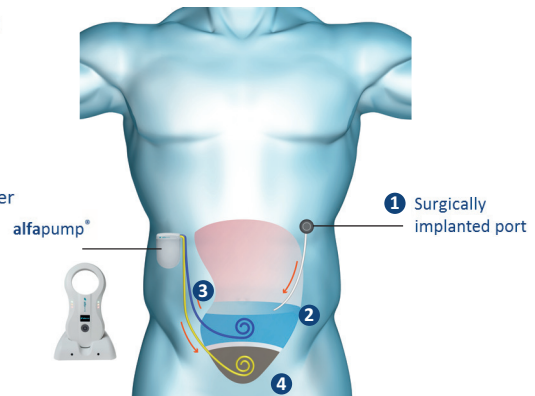
Notes:

- (1) The descriptions and timing of these studies reflect Sequana Medical's current expectations. These expectations are based on circumstances that may or may not occur in the future and remain subject to change and/or feedback from applicable regulatory authorities.
- (2) Funded by the French government and conducted by leading French clinicians.
- (3) Subject to feedback from the FDA.
- (4) The dashed shading of the arrow indicates that the study is expected to extend beyond 2021.
- (5) Fitbit[®] is not affiliated or associated with Sequana Medical, and Fitbit[®] is not affiliated with, and has not otherwise endorsed, the Fitbit[®] Study.

Sequana Medical has also developed Direct Sodium Removal ("**DSR**"), a novel and proprietary approach to the treatment of volume overload in heart failure. Animal studies have demonstrated DSR therapy to be both safe and effective. Sequana Medical has leveraged its **alfapump**[®] experience to develop **alfapump**[®] DSR, a fully implanted system to deliver what it believes is a commercially attractive approach to implement DSR therapy.

The **alfapump**[®] DSR combines three proven elements, (i) the **alfapump**[®] system, (ii) a surgically implanted port and (iii) DSR infusates. The DSR infusate is administered to the peritoneal cavity via the surgically implanted port, which allows for flexible dosing to remove the desired amount of sodium. The DSR infusate remains there for a pre-determined time before the DSR infusate and the extracted sodium is pumped to the bladder.

- 1 Administration of DSR infusate to peritoneal cavity via surgically implanted port
- 2 Sodium from systemic circulation diffuses into DSR infusate
- 3 **alfapump**[®] DSR clears sodium-rich fluid into the bladder
- 4 Body eliminates associated fluid through osmotic ultrafiltration & urination



The following table provides a summary of clinical studies that are ongoing or that Sequana Medical plans to conduct for the management of volume overload in heart failure using DSR:

Name of Study	Description ⁽¹⁾	2018	2019	2020	2021	2022	2023
Single Dose DSR Proof of Concept	First-in-human clinical study in approximately 20 patients to demonstrate the safety, tolerability and dynamics of a single dose of DSR therapy (no alfapump [®]). ⁽²⁾		➔				
Repeated Dose DSR Proof of Concept	Study in approximately 5-10 patients with volume overload in heart failure to demonstrate the safety, tolerability and efficacy (sodium and fluid removal) of the alfapump [®] DSR in connection with multiple dose DSR therapy over a 90-day period. ⁽³⁾		➔				
Multi-national Feasibility Study	Multi-national 3-month feasibility study to assess the safety and efficacy of the alfapump [®] DSR in patients with volume overload in heart failure.			➔			
Multi-national Pivotal Study	Multi-national pivotal study in patients with volume overload in heart failure to demonstrate the efficacy and cost-effectiveness of the alfapump [®] DSR vs. standard of care (LVP).					➔	

Notes:

(1) The descriptions and timing of these studies reflect Sequana Medical's current expectations. These expectations are based on circumstances that may or may not occur in the future and remain subject to change and/or feedback from applicable regulatory authorities.

(2) The Single Dose DSR Proof of Concept is being conducted in the U.S. at Yale University. Presentation of initial results anticipated in the first half of 2019.

(3) The Repeated Dose DSR Proof of Concept is expected to be conducted at clinical centres in Europe. Presentation of initial results anticipated in the second half of 2019, with presentation of full results anticipated in the first half of 2020.

	<p>Sequana Medical is led by an experienced management team, supported by renowned life science investors and its technology and approach has been endorsed by key opinion leaders (“KOLs”) in Europe and North America.</p> <p>Sequana Medical has produced more than 1,000 alfapump[®] systems at the date of this Prospectus, and has developed significant experience in the sub-component supply chain as well as production capacity that can accommodate expected growth in sales.</p> <p>Sequana Medical has obtained reimbursement for the alfapump[®] in Switzerland and Germany. Sequana Medical has expanded commercial activities in the U.K. following the improved guidance from NICE, which management believes will support broader commercial access. Management also believes that the successful completion of the multi-centre, open-label, randomised medico-economical clinical study being conducted in France (the “ARIA Pump Study”) will lead to French reimbursement. Sequana Medical has also entered into exclusive distribution agreements with Fresenius Medical Care Deutschland GmbH (“Fresenius”) in Belgium and the Netherlands, Vingmed Holding (“Vingmed”) in Denmark and Gamida Ltd. (“Gamida”) in Israel.</p>
B.4	<p>Significant recent trends affecting the Issuer and the industries in which it operates</p> <p><i>The growing importance of non-alcoholic steatohepatitis (“NASH”) as the cause of liver cirrhosis.</i> Cirrhosis, one of the leading manifestations of liver disease, is the progressive scarring of the liver. The key cause of liver cirrhosis is dramatically changing, with NASH serving as the leading growth driver and a major public health threat, in particular in the U.S.¹ While alcohol and viral hepatitis are regarded as impacting only a limited proportion of society, NASH will affect a much broader spectrum. Management believes that the growing importance of NASH as the cause of cirrhosis will transform attitudes to liver cirrhosis. In particular, the similar causes to coronary artery disease, e.g. obesity, poor diet and lack of exercise, will make liver cirrhosis a “mainstream” disease and result in the need for improved therapies, with a greater focus on quality of life for patients. Historically, Sequana Medical has generated substantially all of its sales of alfapump[®] systems in Europe as a result of the regulatory approval status and reimbursement arrangements described above. Going forward, however, it expects that the North American market will be a key driver of its alfapump[®] sales, subject to the receipt of regulatory approval and the conclusion of reimbursement arrangements. Management believes that the North American market has high growth potential given the relatively high incidence of NASH in the U.S.</p> <p><i>The growing number of hospitalisations for heart failure and the rates of patients discharged with residual fluid excess.</i> Volume overload in the body is a major clinical problem and the leading cause of hospitalisations for patients suffering from heart failure.² There are approximately 1 million people in the U.S. admitted annually to the hospital for heart failure, costing the U.S. approximately \$13 billion each year.³ Of these admissions, 90% are due to symptoms of volume overload.⁴ By 2026, it is estimated that there will be approximately 1.0 million hospitalisations in the U.S. and approximately 1.2 million hospitalisations across the U.K., France, Germany, Italy and Spain each year due to volume overload.⁵ It is estimated that nearly 50% of hospitalised patients with heart failure are discharged with residual fluid excess.⁶ By not truly addressing the volume overload problem, patients are being readmitted to the hospital too frequently, with 30-day readmission rates of 24%.⁷ There is a significant unmet medical need for a safe and effective, long-term treatment for volume overload caused by heart failure in diuretic resistant patients that is cost-effective, reducing the number of hospitalisations and improving patient quality of life.</p> <p><i>Pricing pressures from third party payers.</i> Third-party payers are continuing and increasing their efforts to contain or reduce the costs of healthcare. Sequana Medical expects to experience pricing pressures in connection with the sale of any of its products, due to the efforts of third-party payers, the trend towards managed healthcare costs, the increasing influence of health maintenance organisations and additional legislative changes. In seeking reimbursements in target markets, management believes that the alfapump[®] has a strong health-economics rationale because the elimination of the need for LVP leads to substantial costs reductions for hospitals and payers.</p>

	<p>Changes in the regulatory environment in the countries where Sequana Medical operates. Sequana Medical will be required to comply with the new Medical Devices Regulation (Regulation 2017/745) (the “Medical Devices Regulation”) in Europe, which will become applicable in May 2020. The new regulations may influence the way Sequana Medical conducts business in Europe, and will include, among other things, stricter rules for placing medical devices on the market (in particular implantable medical devices such as the alfapump[®] and the alfapump[®] DSR), increased transparency requirements and re-approval requirements for medical devices currently on the market in the EEA (such as the alfapump[®]).</p> <p>In addition, on 23 June 2016, the U.K. held a referendum pursuant to which voters approved an exit from the E.U., commonly referred to as “Brexit.” As a result of the referendum, the British government is negotiating the terms of the U.K.’s future relationship with the E.U. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the E.U. and, in particular, any arrangements for the U.K. to retain access to E.U. markets either during a transitional period or more permanently. Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for medical device companies in the U.K., which will be one of Sequana Medical’s focus markets. Furthermore, there have been judicial and Congressional challenges to certain aspects of the Patient Protection and Affordable Care Act (the “Affordable Care Act”), as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act and, such challenges and amendments may continue. These actions may adversely affect the healthcare industry in the U.S. and around the world. Sequana Medical cannot predict the likelihood, nature or extent of government regulation that may arise in the U.S. as a result of the Trump administration.</p>
B.5	<p>Description of the group and the Issuer’s position within the group</p> <p>Sequana Medical consists of Sequana Medical NV based in Ghent, Belgium and its consolidated subsidiaries, Sequana Medical GmbH based in München, Germany, and Sequana Medical, Inc. based in Delaware, U.S. References to “Sequana Medical” are to the Issuer and its consolidated subsidiaries.</p>
B.6	<p>Relationship with major shareholders</p> <p>The Issuer has a relatively widely held shareholder base, and no single shareholder controls the Issuer. For an overview of the Issuer’s existing shareholders, see also Element E.6.</p> <p>Currently, most of the existing shareholders of the Issuer have entered into a shareholders’ agreement (the “Shareholders’ Agreement”), containing, amongst others, terms regarding the Issuer’s business and governance, as well as pre-emptive rights and transfer restrictions regarding the Shares (as defined below). The Shareholders’ Agreement was entered into on 1 October 2018, and is an amendment and restatement of a previous shareholders’ agreement that had been entered into prior to the Belgian Seat Transfer. The Issuer is a party to this Shareholders’ Agreement. The Shareholders’ Agreement will be terminated effective as of the closing of the Offering. The Issuer is not aware of shareholders entering into a new shareholders’ agreement or agreeing to act in concert following the closing of the Offering (as defined below) (other than certain lock up arrangements as described in Element E.5).</p> <p>The Issuer entered into several transactions with related parties, including its principal shareholders. The most significant transactions with related parties for the period covered by the historical financial information and as of the date hereof are summarised below:</p> <ul style="list-style-type: none"> • The Issuer and certain of its shareholders have entered into a convertible loan agreement, dated 16 February 2018, pursuant to which shareholders provided a non-interest-bearing loan to the Issuer in an aggregate principal amount of CHF 1,996,742.00 (the “February 2018 Convertible Loan”). The loan was initially granted until 31 December 2018. The loan can be extended if lenders representing more than 50% of the principal amount of the loan, agree with the extension. On 20 December 2018, the loan was extended until 15 February 2019. The loan must be converted in a number of circumstances, including at the time of an initial public offering. The loan can be converted at any time prior to maturity on a voluntary basis, including prior to the

Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share if lenders representing more than 50% of the principal amount of the loan agree with the conversion.

- The Issuer and Participatiemaatschappij Vlaanderen NV (“**PMV**”) have entered into a convertible loan agreement, dated 6 June 2018, pursuant to which PMV granted a loan to the Issuer in a principal amount of €1,680,000, which loan was extended to a principal amount of €2,000,000 pursuant to an addendum dated 23 October 2018 (the “**PMV Convertible Loan**”). The loan was initially granted until 31 December 2018, and on 20 December 2018 the loan was extended until 15 February 2019. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. PMV is entitled to convert the loan and the accrued interest at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. The PMV Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.
- The Issuer and Federale Participatie- en Investeringsmaatschappij NV (“**FPIM**”) have entered into a convertible loan agreement, dated 27 July 2018, pursuant to which FPIM granted a loan to the Issuer in a principal amount of €2,000,000 (the “**FPIM Convertible Loan**”). The loan was initially granted until 31 December 2018, and on 20 December 2018 the loan was extended until 15 February 2019. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. FPIM is entitled to convert the loan and the accrued interest at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. In the event of an Offering, the loan and accrued interest are also subject to a mandatory conversion into share capital of the Issuer in consideration of new series E preferred Shares at CHF 10.48 per Share. The FPIM Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.
- The Issuer and Cofipalux Invest SA (“**Cofipalux**”) have entered into a convertible loan agreement, dated 30 August 2018, pursuant to which Cofipalux granted a loan to the Issuer in a principal amount of €500,000 (the “**Cofipalux Convertible Loan**”). The loan was initially granted until 31 December 2018, and on 20 December 2018 the loan was extended until 15 February 2019. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. Cofipalux is entitled to convert the loan and the accrued interest at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. In the event of an Offering, the loan and accrued interest are also subject to a mandatory conversion into share capital of the Issuer in consideration of new series E preferred Shares at CHF 10.48 per Share. The Cofipalux Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.
- The Issuer and Newton Biocapital I Pricav Privée SA (“**Newton**”) have entered into a convertible loan agreement, dated 11 October 2018, pursuant to which Newton granted a loan to the Issuer in a principal amount of €2,000,000 (the “**Newton Convertible Loan**”). The loan was initially granted until 31 December 2018, and on 20 December 2018 the loan was extended until 15 February 2019. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. Newton is entitled to convert the loan and the accrued interest at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. In the event of an Offering, the loan and accrued interest are also subject to a mandatory conversion into share capital of the Issuer in consideration of new series E preferred Shares at CHF 10.48 per Share. The Newton Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.
- The Issuer entered into three additional non-interest bearing convertible loan agreements (i) two of which under terms similar to the February 2018 Convertible Loan Agreement with, respectively, one individual shareholder and BioMedInvest LP (“**BioMed**”), dated, respectively, 25 October 2018 and 30 October 2018, pursuant to which the individual shareholder granted a loan to the Issuer in a principal amount of CHF 52,400 and BioMed granted a loan to the Issuer in a principal amount of CHF 198,000 (respectively, the “**Individual 1 Convertible Loan**” and the “**BioMed Convertible Loan**”), and (ii) one under terms similar to the Newton Convertible Loan

	<p>Agreement with an individual dated 2 November 2018 pursuant to which such individual granted a loan to the Issuer in a principal amount of CHF 100,000 (the “Individual 2 Convertible Loan”, and together with the February 2018 Convertible Loan, the PMV Convertible Loan, the FPIM Convertible Loan, and the Cofipalux Convertible Loan, the Newton Convertible Loan, the Individual 1 Convertible Loan, and the BioMed Convertible Loan the “Convertible Loans”). The loans were initially granted until 31 December 2018, and on 20 December 2018 they were extended until 15 February 2019.</p> <ul style="list-style-type: none"> • The Convertible Loans were amended and completed pursuant to several pre-IPO investment commitment agreements, dated 2 November 2018, by and between the Issuer and, respectively, the lenders under the Convertible Loans. The pre-IPO investment commitment agreements were amended and restated on 20 December 2018 (such amended and restated agreements, the “Pre-IPO Investment Commitment Agreements”). Pursuant to the Pre-IPO Investment Commitment Agreements, the lenders under the respective Convertible Loans (the “Participating Investors”) agreed to convert their Convertible Loans for new series E preferred Shares at the agreed conversion rate of CHF 10.48 per Share immediately prior to the closing of the Offering, and that the new Shares shall be converted and consolidated immediately thereafter into ordinary Shares pursuant to the Share Consolidation (as defined below). As an exception, payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91 will be converted into New Shares (as defined below) at the Offer Price (as defined below) in connection with the Offering. The conversions will be implemented by means of a contribution in kind of the outstanding payable amounts under the Convertible Loans. The Pre-IPO Investment Commitment Agreements with the lenders that are an existing shareholder of the Issuer also provide that these lenders will convert a number of their Shares other than series E preferred Shares into series E preferred Shares at a ratio of one existing Share per new series E preferred Share subscribed for through the conversion of their Convertible Loan. In addition, the Participating Investors, who are all lenders pursuant to the Convertible Loans, irrevocably committed pursuant to the respective Pre-IPO Investment Commitment Agreements to subscribe for an aggregate amount of €20.5 million in the Offering at the Offer Price, subject to the closing of the Offering (the “Subscription Commitments”). A portion of this amount has already been made available to the Issuer on 20 December 2018 by all of the respective Participating Investors (except three of them who are also each a lender under the February 2018 Convertible Loan) in the form of bridge loans for an aggregate principal amount of €1,024,238.77 (the “Bridge Loans”). The Bridge Loans were granted until 15 February 2019, and bear an interest of 8% per annum, payable at maturity. Pursuant to the Pre-IPO Investment Commitment Agreements, the relevant Participating Investors agreed to convert the principal amount and accrued interest of the Bridge Loans into New Shares at the Offer Price upon the closing of the Offering. The conversion will be implemented by means of a contribution in kind of the outstanding payable amounts under the Bridge Loans. The remaining portion of the Subscription Commitments (not including the amounts due pursuant to the Bridge Loans and the payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) will be subscribed for in cash upon the closing of the Offering. In the event of over-subscription of the Offering, the Subscription Commitments in cash for an amount of ca. €12.5 million (not including the amounts due pursuant to the Bridge Loans and the payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) can be reduced in line with the allocation principles that will apply to the other investors that will subscribe in the Offering (see Element E.3 below), whereas the Subscription Commitments for the remaining amount (including the amounts due pursuant to the Bridge Loans and the payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) shall not be reduced but be allocated entirely.
B.7	<p>Selected historical key financial information</p> <p>The financial data set forth below as at 31 December 2017, 2016 and 2015 and for the years then ended have been extracted without material adjustment from the audited consolidated financial statements of the Issuer as of and for the years ended 31 December 2017, 2016 and 2015 (the “Annual Financial Statements”) and the unaudited consolidated interim</p>

financial information of the Issuer as of and for the nine-month period ended 30 September 2018 (with comparative figures for the nine-month period ended 30 September 2017) (the “**Interim Financial Statements**”, and together with the Annual Financial Statements, the “**Financial Statements**”). The Annual Financial Statements have been prepared in accordance with International Financial Reporting Standards, as adopted by the European Union (“**IFRS**”). The Interim Financial Statements were prepared in accordance with International Accounting Standard 34, as adopted by the European Union (“**IAS 34**”). The Issuer’s functional and presentation currency is the euro.

Consolidated statements of profit and loss

	For the nine months ended 30 September		For the year ended 31 December		
	2018	2017	2017	2016	2015
	<i>(unaudited)</i>		<i>(in €000)</i>		
	<i>(unaudited)</i>		<i>(audited)</i>		
Revenue	686	957	1,304	1,489	1,685
Costs of goods sold	(107)	(198)	(212)	(321)	(360)
Gross margin	580	760	1,092	1,168	1,325
Sales and marketing	(1,479)	(1,091)	(1,506)	(3,337)	(2,988)
Clinical affairs	(1,040)	(1,310)	(1,749)	(3,325)	(2,790)
Quality and regulatory	(816)	(974)	(1,225)	(1,492)	(1,091)
Supply chain	(729)	(862)	(1,041)	(1,775)	(1,795)
Engineering	(885)	(743)	(1,004)	(1,146)	(995)
General and administration	(3,547)	(1,709)	(1,988)	(4,059)	(3,286)
Other income	—	—	3	21	264
Total operating expenses	(8,496)	(6,689)	(8,510)	(15,113)	(12,681)
Earnings before interest and taxes (EBIT)	(7,916)	(5,929)	(7,418)	(13,945)	(11,356)
Financial income	—	—	—	3	4
Financial expense	(670)	(487)	(636)	(190)	(89)
Foreign exchange gains/ (losses), net	(23)	(8)	(153)	198	(72)
Total net financial expense	(693)	(495)	(789)	11	(157)
Taxes	(25)	(12)	(18)	(41)	(44)
Net loss for the period ..	(8,634)	(6,436)	(8,225)	(13,975)	(11,557)

Consolidated statements of cashflows

	For the nine months ended 30 September		For the year ended 31 December		
	2018	2017	2017	2016	2015
	<i>(unaudited)</i>		<i>(in €000)</i>		
	<i>(unaudited)</i>		<i>(audited)</i>		
Net loss for the period	(8,634)	(6,436)	(8,225)	(13,975)	(11,557)
Income taxes	25	12	18	41	44
Financial result	693	495	789	(11)	157
Depreciation	54	58	78	80	47
Change in defined benefit plan	—	—	64	71	10
Share-based compensation	18	17	23	10	11
Changes in trade and other receivables	(87)	(58)	145	213	(451)
Changes in inventories	(182)	453	556	208	(622)
Changes in trade and other payables/provisions	1,437	(1,658)	(1,808)	656	1,146
Taxes paid	(9)	(12)	(18)	(41)	(44)
Cash flow used in operating activities	(6,686)	(7,129)	(8,378)	(12,748)	(11,259)
Investments in tangible assets	(3)	(7)	(7)	(215)	(89)
Investments in financial assets	(11)	(4)	(4)	(2)	(19)
Cash flow used in investing activities	(14)	(10)	(11)	(217)	(108)
Proceeds from capital increase	—	9,813	9,815	7,812	8,206
Exercise of employee options	2	—	—	71	34
Proceeds from financial debts	5,711	—	—	4,545	—
Transaction costs deducted from equity	(226)	—	—	—	—
Interest paid	(7)	(250)	(314)	(190)	(22)
Cash flow from financing activities	5,480	9,563	9,501	12,238	8,218
Net change in cash and cash equivalents	(1,219)	2,423	1,112	(727)	(3,149)
Cash and cash equivalents at beginning of period	1,684	797	797	1,427	4,091
Net effect of currency translation on cash and cash equivalents	76	(145)	(226)	97	485
Cash and cash equivalents at end of period	541	3,075	1,683	797	1,427

Summary analysis of selected profit and loss results

Revenue. Revenue decreased from €0.96 million in the nine months ended 30 September 2017 to €0.69 million in the nine months ended 30 September 2018 mainly as a result of a strategic decision to focus principally on Sequana Medical's focus markets in Europe, which are currently Switzerland, Germany, France and the U.K. Management also expects to begin pursuing reimbursement in Spain and Italy in 2019. Sequana Medical reduced its investment in commercial activities until the clinical results of the **alfapump**[®] have further improved, and following challenges in recruiting suitable members for the commercial team. Revenue decreased from €1.49 million in 2016 to €1.30 million in 2017 largely as a result of the decrease in revenue from Germany from €1.11 million in 2016 to €0.76 million in 2017. This was due to the restructuring undertaken by Sequana Medical in 2016, which resulted in a reduction in the number of hospitals on which it focused its commercial activities. The decrease in revenue from Germany was partially offset by an increase in revenue from the rest of the world from €0.14 million in 2016 to €0.35 million in 2017, which was mainly driven by higher sales in Israel and Belgium. Revenue decreased from €1.69 million in 2015 to €1.49 million in 2016 largely as a result of the decrease in revenue from Switzerland from €0.38 million in 2015 to €0.16 million in 2016, which was due to significant purchases by a hospital in 2015 and no subsequent purchase in 2016, and the decrease in revenue from the U.K. from €0.19 million in 2015 to €0.07 million in 2016. The decrease in revenue from Switzerland and the U.K. was partially offset by an increase in revenue from Germany from €1.02 million in 2015 to €1.11 million in 2016.

Cost of goods sold. Cost of goods sold decreased from €0.20 million in the nine months ended 30 September 2017 to €0.11 million in the nine months ended 30 September 2018 in line with the decrease in revenue. Costs of goods sold decreased from €0.36 million in 2015 to €0.32 million in 2016 and again to €0.21 million in 2017 in line with the decreases in revenue.

Sales and marketing. Sales and marketing expenses increased from €1.09 million in the nine months ended 30 September 2017 to €1.48 million in the nine months ended 30 September 2018 mainly as a result of the expansion of the commercial team, greater travel expenses and increased marketing activities. Sales and marketing expenses decreased from €3.34 million in 2016 to €1.51 million in 2017 largely as a result of the restructuring undertaken by Sequana Medical in 2016, which entailed a reduction in the commercial team and commercial activities. Sales and marketing expenses increased from €2.99 million in 2015 to €3.34 million in 2016 mainly as a result of investments in marketing support for Germany and trade shows.

Clinical affairs expenses. Clinical affairs expenses decreased from €1.31 million in the nine months ended 30 September 2017 to €1.04 million in the nine months ended 30 September 2018 principally as a result of lower expenses for the MOSAIC (North American IDE feasibility) Study in 2018 versus 2017, partly offset by higher expenses for the healthy pig and heart failure pig DSR proof of concept studies. Clinical affairs expenses decreased from €3.33 million in 2016 to €1.75 million in 2017 largely as a result of lower expenses for the MOSAIC (North American IDE feasibility) Study (as defined below) in 2017 as compared to 2016 and the completion of the six-month European randomised controlled trial on the **alfapump**[®] versus LVP for the treatment of liver refractory ascites (the "**European RCT**"). Clinical affairs expenses increased from €2.79 million in 2015 to €3.33 million in 2016 primarily as a result of the 12-month open-label, single-arm study in North America to assess the safety and efficacy of the **alfapump**[®] in patients with liver recurrent or refractory ascites (the "**MOSAIC (North American IDE feasibility) Study**") starting in 2015, partially offset by a decrease in costs related to other liver trials and a decreased use of consultants.

Supply chain expenses. Supply chain expenses decreased from €0.86 million in the nine months ended 30 September 2017 to €0.73 million in the nine months ended 30 September 2018 mainly as a result of the decrease in revenue. Supply chain expenses decreased from €1.78 million in 2016 to €1.04 million in 2017 in line with the decrease in revenue and as a result of the discontinuation of a project that Sequana Medical had undertaken to analyse the benefits of outsourcing certain aspects of production (which incurred consultancy and other expenses) as well as a decrease in shipping costs relating to the MOSAIC (North

American IDE feasibility) Study. Supply chain expenses were broadly flat from €1.80 million in 2015 to €1.78 million in 2016.

General and administration expenses. General and administration expenses increased from €1.71 million in the nine months ended 30 September 2017 to €3.55 million in the nine months ended 30 September 2018 mainly as a result of the transaction costs related to the preparation for the Offering. General and administration expenses decreased from €4.06 million in 2016 to €1.99 million in 2017 primarily as a result of severance payments made to former employees in 2016 and the restructuring that took place in that year. General and administration expenses increased from €3.29 million in 2015 to €4.06 million in 2016 mainly as a result of the expansion of the team and severance payments made in 2016.

Total net finance expense. Net finance result increased from €0.50 million expense in the nine months ended 30 September 2017 to €0.69 million in the nine months ended 30 September 2018 mainly as a result of the interest expenses related to the Convertible Loans received in 2018 that were denominated in CHF. The remainder of the costs relate to Sequana Medical's secured loan from Bootstrap Europe S.C.Sp. ("**Bootstrap**") that was signed in September 2016 (the "**Bootstrap Loan**"). Net finance result decreased from €0.01 million income in 2016 to €0.79 million expense in 2017 mainly due to the full year interest expense relating to the Bootstrap Loan. The decrease was also the result of fluctuations in the CHF/EUR foreign exchange rate. Net finance result increased from €0.16 million expense in 2015 to €0.01 million income in 2016 as a result of the Bootstrap Loan, offset by positive fluctuations in the CHF/EUR foreign exchange rate.

Earnings before interest and taxes. Earnings before interest and taxes increased from a loss of €5.93 million in the nine months ended 30 September 2017 to a loss of €7.92 million in the nine months ended 30 September 2018 largely due to transaction costs related to the preparation for the Offering, increased marketing activities and a lower gross margin due to a decrease in sales (partially offset by lower expenses in clinical affairs). Earnings before interest and taxes decreased from a loss of €13.95 million in 2016 to a loss of €7.42 million in 2017 largely due to the restructuring undertaken in 2016, severance payments to former employees and lower expenses for the MOSAIC (North American IDE feasibility) Study in 2017 as compared to 2016. Earnings before interest and taxes increased from a loss of €11.36 million in 2015 to a loss of €13.95 million in 2016 mainly as a result of an increase in sales and marketing expenses due to investments in marketing support for Germany and trade shows, clinical affairs expenses due to the MOSAIC (North American IDE feasibility) Study, quality and regulatory expenses due to testing for the North American market and quality studies and general and administrative expenses due to severance payments, as well as a decrease in revenue due to the restructuring of the commercial team.

Summary analysis of selected statements of cashflows

Cash flow used in operating activities. Cash flow used in operating activities decreased from €7.13 million in the nine months ended 30 September 2017 to €6.69 million in the nine months ended 30 September 2018, which corresponded with a general increase in the net loss for the period from €6.44 million in the nine months ended 30 September 2017 to €8.63 million in the nine months ended 30 September 2018. This overall increase in the net loss for the period was largely offset by a decrease in working capital during the nine months ended 30 September 2018 as compared to the nine months ended 30 September 2017, which was as a result of an increase in trade payables and accrued liabilities. Cash flow used in operating activities decreased from €12.75 million in 2016 to €8.38 million in 2017, which corresponded with a general decrease in the net loss for the period from €13.98 million in 2016 to €8.23 million in 2017. The overall decrease in the net loss for the period was partially offset by an increase in working capital in 2017 as compared to 2016. Working capital worsened as a result of the decreased trade payables and accrued liabilities. At the end of 2016, significant amounts related to clinical studies and severance payments remained outstanding. This effect was partially offset by a decrease in inventory and receivables in 2017. Cash flow used in operating activities increased from €11.26 million in 2015 to €12.75 million in 2016, which corresponded with a general increase in the net loss for the period from €11.56 million in 2015 to €13.98 million in 2016. The overall increase in the net loss for the period was partially offset by a decrease in working capital in 2016 as compared to 2015. In 2016 both inventory levels and outstanding receivables improved

	<p>compared to 2015. Additionally, in 2016 there were more outstanding trade payables and accruals, mainly related to the ongoing clinical studies and the severance payment provisions.</p> <p>Cash flow used in investing activities. Cash flow used for investing activities were broadly flat at €0.01 million for the nine months ended 30 September 2017 and the nine months ended 30 September 2018, with the amounts for the nine months ended 30 September 2018 mainly reflecting the down payment for the new office in Ghent, Belgium. Cash flow used for investing activities decreased from €0.22 million in 2016 to €0.01 million in 2017 as a result of a decrease in investments in tangible assets. Cash flow used for investing activities increased from €0.11 million in 2015 to €0.22 million in 2016 largely as a result of an increase in investments in tangible assets from €0.09 million in 2015 to €0.22 million in 2016, mainly in hardware and software.</p> <p>Cash flow from financing activities. Cash flow from financing activities decreased from €9.56 million in the nine months ended 30 September 2017 to €5.48 million in the nine months ended 30 September 2018 as a result of €9.81 million in proceeds from the issuance of Shares in 2017 and the proceeds of new Convertible Loans amounting to €5.71 million in 2018. Cash flow from financing activities decreased from €12.24 million in 2016, which was mainly comprised of €7.81 million in proceeds from the issuance of Shares and the drawdown of € 4.55 million (CHF 5 million) under the Bootstrap Loan, to €9.50 million in 2017, mainly comprised of €9.81 million in proceeds from the issuance of Shares. Cash flow from financing activities increased from €8.22 million in 2015, primarily from €8.21 million in proceeds from the issuance of Shares, to €12.24 million in 2016 largely as a result of a drawdown of €4.55 million (CHF 5.0 million) under the Bootstrap Loan and €7.81 million in proceeds from the issuance of Shares.</p>
B.8	<p>Selected key pro forma financial information</p> <p>Not applicable. No <i>pro forma</i> information has been included in the Prospectus.</p>
B.9	<p>Profit forecast or estimate</p> <p>Not applicable. No profit forecast or estimate has been included in the Prospectus or otherwise published by the Issuer.</p>
B.10	<p>A description of the nature of any qualifications in the audit report on the historical financial information</p> <p>The auditors have not qualified their report on the Annual Financial Statements; however, the auditors have included in their report a matter of emphasis paragraph on going concern given that, as described in note 2.5 to the Annual Financial Statements and note 4 to the Interim Financial Statements, that the Issuer's ability to continue operations depends on its ability to raise additional capital in order to fund operations and assure the solvency of the company until revenues reach a level to sustain positive cashflows. As such, there is significant doubt about Sequana Medical's ability to continue as a going concern if Sequana Medical would not succeed in raising additional capital.</p>
B.11	<p>Working capital</p> <p>On the date of this Prospectus, the Issuer is of the opinion that, taking into account its available cash and cash equivalents, it does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Prospectus.</p> <p>However, assuming a placement of the maximum number of New Shares in the Offering (excluding the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the lower end of the Price Range, the gross proceeds from the issue of the New Shares are estimated to be approximately €27.5 million. In the event the Offering is completed in full (including the conversion of the Bridge Loans in full, but excluding the exercise in full of the Increase Option and the Over-allotment Option), Sequana Medical is of the opinion that the proceeds of the Offering (together with its available cash and cash equivalents) will provide Sequana Medical with sufficient working capital to meet its present</p>

	<p>requirements and cover the working capital needs for a period of at least 12 months from the date of the Prospectus, even if the Offer Price is at the lower end of the Price Range.</p> <p>In case Sequana Medical would not be able to attract new funds (beyond its existing cash and cash equivalents), it expects to run out of working capital by mid February 2019. Sequana Medical's 12 month working capital shortfall in the event Sequana Medical would not be able to attract any such additional funds and if Sequana Medical in that event maintains its current strategy and development activities, is projected to be approximately €28.2 million at the end of January 2020 (which includes a shortfall for the repayment of outstanding Convertible Loans for an aggregate principal amount of €8.5 million and outstanding Bridge Loans for an aggregate principal amount of €1.0 million).</p>
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Section C – Shares

Element	Disclosure requirement
C.1	<p>Type and class of the securities being offered and admitted to trading</p> <p>As from the closing of the Offering, all of the shares representing the Issuer's share capital (the "Shares"), including the Offered Shares, will be ordinary shares of the Issuer, without nominal value. The Shares can be in registered or dematerialised form. The following ISIN code has been assigned to the Shares: BE0974340722.</p>
C.2	<p>Currency of the Shares</p> <p>The currency of the Shares is the euro.</p>
C.3	<p>Number of Shares issued</p> <p>On the date of this Prospectus, the share capital of the Issuer amounts to €887,977.47. It is represented by 9,930,784 Shares, of which 3,194,913 common Shares and 6,735,871 preferred Shares. The 6,735,871 preferred Shares consist of 543,682 series A preferred Shares, 2,167,115 series B preferred Shares, 1,724,337 series C preferred Shares, 201,501 series D preferred Shares, and 2,099,236 series E preferred Shares. All Shares are fully paid up, and represent the same fraction of the Issuer's share capital.</p> <p>In addition to the outstanding Shares, the Issuer has a number of outstanding options that are exercisable into new Shares, consisting of:</p> <ul style="list-style-type: none"> ● 752,500 Share options that were granted to employees and consultants of the Issuer, and that each entitle the holder thereof to subscribe for one new common Share subject to the terms and conditions that are set out in the Stock Option Plan Regulation 2011, dated 1 September 2011 (the "2011 Share Options"); ● 111,177 Share options that were granted in 2018 to members of the staff, as well as consultants of the Issuer, and that each entitle the holder thereof to subscribe for one new series E preferred Share subject to the terms and conditions that are determined by the board of directors (the "Executive Share Options"); and ● one warrant that entitles the holder thereof to, at the election of the holder, subscribe for a maximum of 104,961 series E preferred Shares prior to giving effect to the Share Consolidation, subject to the terms and conditions that are set out in the Warrant Agreement, dated 2 September 2016, between the Issuer and Bootstrap, as amended on 28 April 2017, 1 October 2018, and 20 December 2018 (the "Bootstrap Warrant"). <p>Subject to the closing of the Offering, the Issuer will issue a number of additional new Share options for directors, employees and other staff members of Sequana Medical (the "2018 Share Options"), equal to 10% of the number of outstanding Shares after the completion of the Offering (including upon exercise of the Increase Option (as defined below) and the Over-allotment Option (as defined below)).</p> <p>Furthermore, the Convertible Loans are convertible into new Shares, consisting of:</p> <ul style="list-style-type: none"> ● the February 2018 Convertible Loan; ● the PMV Convertible Loan; ● the FPIM Convertible Loan; ● the Cofipalux Convertible Loan;

- the Newton Convertible Loan;
- the Biomed Convertible Loan;
- the Individual 1 Convertible Loan; and
- the Individual 2 Convertible Loan.

The Convertible Loans were amended and completed pursuant to several Pre-IPO Investment Commitment Agreements. Pursuant to the Pre-IPO Investment Commitment Agreements, the Participating Investors, who are all lenders under the Convertible Loans, agreed to convert their loans for new series E preferred Shares at the agreed conversion rate of CHF 10.48 per Share immediately prior to the closing of the Offering, and that the new Shares shall be converted and consolidated immediately thereafter into ordinary Shares pursuant to the Share Consolidation (as defined below). As an exception, payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91 will be converted into New Shares at the Offer Price in connection with the Offering. The conversions will be implemented by means of a contribution in kind of the outstanding payable amounts under the Convertible Loans. The Pre-IPO Investment Commitment Agreement with the lenders that are an existing shareholder of the Issuer also provides that these lenders will convert a number of their Shares other than series E preferred Shares into series E preferred Shares at a ratio of one existing Share per new series E preferred Share subscribed for through the conversion of their Convertible Loan.

The preferred Shares benefit from a specific priority that will be triggered upon the closing of the Offering and which will result in a conversion and consolidation of the outstanding Shares into a new number of outstanding Shares reflecting the priority among the current shareholders of the Issuer as a result of the Offering (not including the Offered Shares to be issued upon the closing of the Offering and the exercise of the Over-allotment Option). In addition, subject to and with effect as of the closing of the Offering and after having given effect to the aforementioned priority, all of the then existing Shares will be converted into ordinary Shares in such a manner that each Share shall be of the same type and class as the Offered Shares. The conversion and consolidation of Shares will also be effected with respect to the outstanding Share options and Convertible Loans. The conversion and consolidation of Shares as result of the aforementioned priority and conversion into ordinary Shares is referred to as the “**Share Consolidation**”.

Pursuant to Pre-IPO Investment Commitment Agreements, all of the respective Participating Investors (except three of them who are also each a lender under the February 2018 Convertible Loan) also provided already to the Company a portion of their Subscription Commitments in the form of a Bridge Loan. Pursuant to the Pre-IPO Investment Commitment Agreements, the relevant Participating Investors agreed to convert the principal amount and accrued interest of the Bridge Loans into New Shares at the Offer Price upon the closing of the Offering. The conversion will be implemented by means of a contribution in kind of the outstanding payable amounts under the Bridge Loans. The New Shares issuable pursuant to the contribution in kind of the Bridge Loan payables shall not be subject to the Share Consolidation.

The New Shares in the Offering can also be subscribed for through a contribution in kind by Bootstrap of 50% of the payable due by the Issuer upon the closing of the Offering as an “Exit Fee” pursuant to the Bootstrap Loan. As provided for by the Bootstrap Loan, the Exit Fee shall not exceed a maximum of CHF 750,000. The portion of the Exit Fee payable that shall be so contributed in kind, but that cannot be used for the subscription for a whole number of New Shares at the Offer Price shall not be contributed in kind, but remains payable in cash (subject to the terms of the Bootstrap Loan).

In case of an over-subscription of the Offering, the allocation to the aforementioned lenders and Bootstrap of Shares in consideration of the respective contributions in kind in the Offering of the Convertible Loan, Bridge Loan and partial Exit Fee payables shall not be reduced.

In view hereof, upon closing of the Offering and after giving effect to the Share Consolidation, assuming a placement of the maximum number of New Shares in the Offering (including the conversion of the Bridge Loans in full, but excluding the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range (i.e. €8.75), the Issuer’s share capital will amount to

	<p>€1,306,939.52 as of the closing of the Offering, represented by 12,611,900 ordinary Shares, each with a fractional value of ca. €0.10 and each representing the same <i>pro rata</i> fraction of the share capital. Assuming a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option) and after giving effect to the Share Consolidation, the Issuer's share capital will amount to €1,415,033.89 as of the closing of the Offering, represented by 13,655,282 Shares, each with a fractional value of ca. €0.10 and each representing the same <i>pro rata</i> fraction of the share capital.</p>
C.4	<p>Rights attached to the Shares</p> <p>As from the closing of the Offering, all of the Shares will be of the same class and will have the same voting rights. All of the Shares will be profit sharing as from any distribution in respect of which the relevant record date or due date falls on or after the date of their issuance, including any distribution in relation to the financial year that has started on and after 1 January 2018, as the case may be.</p>
C.5	<p>Restrictions on the free transferability of the Shares</p> <p>As from the closing of the Offering, all Shares will be freely transferable, subject to any transactional restrictions. Please see E.5 for a description of the lock up.</p>
C.6	<p>Applications for admission to trading on a regulated market and identity of all the regulated markets where the Shares are or are to be traded</p> <p>An application has been made to list all Shares of the Issuer on the regulated market of Euronext Brussels under the symbol "SEQUA". Trading of the Shares on the regulated market of Euronext Brussels is expected to commence, on an "if-and-when-issued-and/or-delivered" basis, on or about 11 February 2019 (the "Listing Date").</p>
C.7	<p>Description of the dividend policy</p> <p>The Issuer has not declared or paid dividends on its Shares in the past. Currently, the board of directors of the Issuer expects to retain all earnings, if any, generated by the Issuer's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the foreseeable future.</p> <p>The Issuer's ability to distribute dividends is subject to the availability of sufficient distributable profits as defined under Belgian law on the basis of the Issuer's statutory unconsolidated financial statements.</p> <p>The amount of any dividends and the determination of whether to pay dividends in any year may be affected by a number of factors, including the Issuer's business prospects, cash requirements and financial performance, the condition of the market and the general economic climate and other factors, including tax and other regulatory considerations. As a consequence of these and other factors, there can be no assurance as to whether dividends or similar payments will be paid in the future nor, if they are paid, as to their amount.</p>

Section D – Risks

Element	Disclosure requirement
D.1	<p>Risks relating to the Issuer's industry and business</p> <p>The Issuer is subject to the following material risks, in addition to other risks that are mentioned in the Prospectus in relation to Sequana Medical's business and industry:</p> <p><i>Sequana Medical has incurred operating losses, negative operating cash flows and an accumulated deficit since inception and may not be able to achieve or subsequently maintain profitability.</i></p> <p>Sequana Medical has incurred operating losses and negative operating cash flows in each period since it was founded in 2006. As of 30 September 2018, Sequana Medical has a loss brought forward of €79.7 million. These losses have resulted principally from costs incurred</p>

in the development and commercialisation of the **alfapump**[®] technology, as well as from general and administrative costs associated with Sequana Medical's operations and manufacturing scale-up. Sequana Medical intends to fund the continued development of the **alfapump**[®] and the **alfapump**[®] DSR, to expand manufacturing capabilities, to seek further regulatory and marketing approvals for the **alfapump**[®], to secure reimbursement by payers, to maintain, protect and expand Sequana Medical's intellectual property portfolio and to expand sales and marketing activities. Sequana Medical expects to begin a pivotal study in the second half of 2019 on the **alfapump**[®] for the treatment of liver recurrent and refractory ascites in the U.S. and Canada (the "**POSEIDON (North American pivotal) Study**"), which management estimates will be completed in the second half of 2021 and cost around €11 million to complete and to acquire data to support reimbursement. Sequana Medical also plans to conduct additional clinical studies and as a result management expects that clinical affairs expenses will increase significantly over the next several years. These expenses, together with anticipated general and administrative expenses, will likely result in Sequana Medical incurring further losses for at least the next few years. There can be no assurance that Sequana Medical will achieve profitability, which could impair its ability to sustain operations or obtain any required additional funding. If Sequana Medical does achieve profitability in the future, it may not be able to sustain profitability in subsequent periods, and it may suffer net losses and/or negative operating cash flows in subsequent periods.

Sequana Medical's future financial performance will depend on the commercial acceptance of the alfapump[®] (Sequana Medical's only commercial-stage product at the date of this Prospectus), the alfapump[®] DSR and/or any future products in target markets.

At the date of this Prospectus, the **alfapump**[®] is the only product that has been commercialised by Sequana Medical. Furthermore, the **alfapump**[®] has only received regulatory approval in Europe (through a CE-Mark). The **alfapump**[®] received a CE-Mark for the treatment of liver refractory ascites (for a period of up to two years) in 2011, and in 2012 for the treatment of malignant ascites (for patients with a life expectancy of six months or less). The **alfapump**[®] was launched commercially in 2012, and to date has only been commercialised in a limited number of countries. Sales of the **alfapump**[®] have only generated limited revenue while Sequana Medical has been working to gain commercial market acceptance of the **alfapump**[®] in target markets. There can be no assurance that the **alfapump**[®], the **alfapump**[®] DSR and/or any future products launched by Sequana Medical will gain commercial acceptance in target markets. If Sequana Medical fails to gain and maintain commercial market acceptance of the **alfapump**[®] in its focus jurisdictions of Germany, Switzerland, France, the U.K., the U.S. and Canada, in particular if Sequana Medical fails to secure and maintain regulatory approval and reimbursement arrangements for the **alfapump**[®] (as further described below), the amount of revenue generated from sales of the **alfapump**[®] in the future could continue to be limited, and could even decrease. In addition, the **alfapump**[®] DSR has not received marketing approval in any jurisdictions and Sequana Medical's future financial performance will depend on the successful completion of its ongoing and planned clinical studies on the **alfapump**[®] DSR, including the ongoing first-in-human clinical study in approximately 20 patients in the U.S. at Yale University to demonstrate the safety, tolerability and dynamics of a single dose of DSR therapy (no **alfapump**[®]) (the "**Single Dose DSR Proof of Concept**"), the planned study that is expected to be conducted in clinical centres in Europe in approximately 5-10 patients with volume overload in heart failure to demonstrate the safety, tolerability and efficacy of the **alfapump**[®] DSR in connection with multiple dose DSR therapy over a 90-day period the ("**Repeated DSR Dose Proof of Concept**"), the planned multi-national 3-month feasibility study to assess the safety and efficacy of the **alfapump**[®] DSR in patients with volume overload in heart failure (the "**Multi-national Feasibility Study**") and the planned multi-national pivotal study in patients with volume overload in heart failure to demonstrate the efficacy and cost-effectiveness of the **alfapump**[®] DSR versus LVP standard of care (the "**Multi-national Pivotal Study**"). Many factors can influence market acceptance of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products. Failure, or any substantial delay, in gaining significant commercial market acceptance of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in target markets, on a timely basis or at all,

could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Sequana Medical will likely require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available when required or could significantly limit Sequana Medical's access to additional capital.

Sequana Medical anticipates using the proceeds of the Offering as described in Element E.2 (Use of Proceeds), including to fund:

- the POSEIDON (North American pivotal) Study, which management estimates will cost around €11 million to complete and to acquire data to support reimbursement;
- the Single Dose DSR Proof of Concept and the Repeated DSR Dose Proof of Concept, which management estimates will together cost around a total of €1 million to complete;
- the controlled study in Europe to evaluate the efficacy and clinical impact of the **alfapump**[®] versus standard of care in 50 malignant ascites patients (the "**Malignant Ascites CT**"), which management estimates will cost around €1 million to complete;
- the European registry study in cirrhosis patients that have been implanted with the **alfapump**[®] ("**TOPMOST**"), which management estimates will cost around €0.4 million annually and includes the quality of life study in 20 patients to measure the impact of the **alfapump**[®] vs. standard of care on patient activity (the "**Fitbit**[®] **Study**"); and
- the European study on the impact of albumin replacement therapy on clinical outcomes in 10-15 patients implanted with the **alfapump**[®] (the "**Albumin Replacement Study**"), which management estimates will cost around €0.25 million to complete.

Positive outcomes from these clinical studies will likely result in Sequana Medical requiring additional funding in the future in order to continue development and conduct regulatory approval activities, to expand marketing and sales capabilities, to expand manufacturing capabilities and to take advantage of new business opportunities. Sequana Medical may also strategically decide to seek additional capital if market conditions are favourable. In addition, while the above estimates reflect management's current expectations concerning the cost of Sequana Medical's planned clinical studies, these amounts are only estimates and there are many factors that could cause the actual costs of one or more of these clinical studies to be substantially greater than anticipated.

On the date of this Prospectus, Sequana Medical is of the opinion that, taking into account its available cash and cash equivalents (and excluding any proceeds of the Offering), it does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months from the date of the Prospectus. Furthermore, over the longer term, the net proceeds from the Offering, together with Sequana Medical's existing capital resources, will be insufficient to fund, among other things, the completion of the clinical development of the **alfapump**[®] DSR required to bring it to market in Europe and the U.S., including the Multi-national Feasibility Study or the Multinational Pivotal Study, to fund the commercial roll-out of the **alfapump**[®] in the U.S., if approved, or to pay in full the total CHF 5.90 million principal and interest outstanding under the secured loan from Bootstrap Europe S.C.Sp. ("**Bootstrap**") that was signed in September 2016, as amended (the "**Bootstrap Loan**").

Equity and/or debt financing might not be available when needed or, if available, might not be available on commercially favourable terms. If the necessary funds are not available, Sequana Medical may seek funds through collaboration and licensing arrangements, at an earlier stage than originally planned, at terms that are less favourable than those it might otherwise have obtained or at terms which may require it to reduce or relinquish significant rights to its programmes. Sequana Medical may also be required to significantly curtail, delay, reduce or terminate all or part of its development programmes or the commercialisation of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products, or it may be unable to take advantage of future business opportunities or to respond to certain business challenges, which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Seeking and obtaining regulatory approval for medical devices can be a long, expensive and uncertain process. Strict or changing regulatory regimes, government policies and legislation in any of Sequana Medical's target markets may delay, prohibit or reduce potential sales.

Applications for regulatory approval may require extensive pre-clinical, clinical and technical testing, all of which must be undertaken in accordance with the requirements of regulations established by the relevant regulatory agencies. The regulations to which Sequana Medical is subject are complex and have tended to become more stringent over time. Sequana Medical may be adversely affected by changes in government policy or legislation applying to active implantable medical devices ("AIMDs"). Sequana Medical is obliged to comply with regulatory requirements that include obtaining regulatory approval pursuant to the applicable laws and regulations before it can market or sell its products in each market.

At the date of this Prospectus, the **alfapump**[®] is the only product that has been commercialised by Sequana Medical. Furthermore, the **alfapump**[®] has only received regulatory approval in Europe (through a CE-Mark). The **alfapump**[®] DSR for the treatment of fluid overload in heart failure patients is in the early stage of development and will require substantial technical, pre-clinical and clinical development and testing prior to receiving marketing approval. There can be no assurance that using the **alfapump**[®] DSR will be safe and efficacious, or that the **alfapump**[®] DSR will receive regulatory approval in any market.

Review of Sequana Medical's regulatory submissions by regulatory agencies may result in requests to perform additional or repeat testing, to redesign one or more aspects of the **alfapump**[®], the **alfapump**[®] DSR or any future products, or to change materials. The regulatory approval process may delay or prevent the launch and/or commercialisation of the **alfapump**[®], the **alfapump**[®] DSR or any future products in target markets, which would negatively impact or prevent Sequana Medical's ability to achieve its milestones. If Sequana Medical fails to obtain approval of the **alfapump**[®], the **alfapump**[®] DSR or any future products in target markets, on a timely basis or at all, the marketing and sale of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in certain markets may be delayed or may not be achieved, which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Sequana Medical's success is largely contingent on third party payment from government providers, healthcare insurance providers or other public or private sources. Healthcare policy changes, including legislation to reform the U.S. healthcare system, could have a material adverse effect on Sequana Medical. Sequana Medical could fail to achieve or maintain reimbursement levels sufficient to support a commercial infrastructure or realise an appropriate return on its investment in product development, which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

The existence of coverage and adequate reimbursement for Sequana Medical's products by government and/or private payers will be critical to market adoption for the **alfapump**[®], the **alfapump**[®] DSR and/or any future products. Physicians and hospitals are unlikely to use the **alfapump**[®], the **alfapump**[®] DSR and/or any future products, at all or to a great extent, if they do not receive adequate reimbursement for the procedures utilising Sequana Medical's product, and potential patients may be unwilling to pay for the **alfapump**[®], the **alfapump**[®] DSR and/or any future products themselves. Failure to obtain attractive reimbursement may materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Sequana Medical expects to experience pricing pressures in connection with the sale of the **alfapump**[®], as well as the **alfapump**[®] DSR and/or any future products following the receipt of regulatory approval. Generally, hospitals, governments and third-party payers are increasingly exerting downward pressure on pricing and reviewing the cost-effectiveness of medical products, therapies and services. With this global pressure on healthcare costs, payers are attempting to contain costs by, for example, limiting coverage of and the level of reimbursement for new therapies.

In the U.S., the emphasis on managed care and the influence of health maintenance organisations has increased and is expected to continue to increase the pressure on

healthcare pricing. Hospitals are financially incentivised to improve the quality of care and consequent patient satisfaction, as well as patient throughput (the cycling of patients through a hospital's physical resource base). To contain costs, the Centers for Medicare & Medicaid Services and other third-party payers are increasingly challenging the price, scrutinising the medical necessity and reviewing the cost-effectiveness of medical treatments. Similar cost-containment initiatives are also being emphasised in Canada. In Europe, the downward pressure on healthcare costs has also become very intense, and as a result, increasingly high barriers are being erected to the entry of new products. In some countries, cross-border imports from lower-priced markets also exert a commercial pressure on pricing. Securing adequate or attractive reimbursement often depends on the successful outcome of a medical economics study, which is a clinical study designed to demonstrate the cost effectiveness of a product or procedure. For example, in order to obtain reimbursement in France, the ARIA Pump Study is being conducted by a group of French clinicians. There is no assurance that this study will demonstrate cost-effectiveness of the **alfapump**[®] in a timely manner or at all, which could leave the **alfapump**[®] without reimbursement in France and materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

The price that Sequana Medical may receive for, and the marketability of, the **alfapump**[®], the **alfapump**[®] DSR and/or any future products for which Sequana Medical receives regulatory approval may suffer if the government and/or third-party payers fail to provide adequate coverage and reimbursement or if further governmental cost containment or other health reform initiatives are adopted or implemented. Increasing downward pressure on healthcare pricing and/or any changes that lower reimbursements for Sequana Medical's products could result in product revenues generated from sales of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products being lower than anticipated. As a result, Sequana Medical could fail to achieve or maintain reimbursement levels sufficient to support a commercial infrastructure or realise an appropriate return on its investment in product development, which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Sequana Medical is also subject to the following risks, in addition to other risks mentioned in the Prospectus in relation to Sequana Medical's business and industry:

- Sequana Medical is required to conduct clinical studies for regulatory approvals and other purposes. Clinical studies require approvals, carry substantial risks and may be costly and time consuming, with uncertain results.
- Sequana Medical's manufacturing facilities and those of its third party suppliers are subject to significant regulations and approvals. If Sequana Medical or its third-party manufacturers or suppliers fail to comply with these regulations or maintain these approvals, Sequana Medical's business will be materially harmed.
- Sequana Medical depends on third party suppliers for services and components used in the production of the **alfapump**[®] and **alfapump**[®] DSR, and some of those services and components are supplied from a single source. Disruption of the supply chain, unavailability of third party services required for the production of the **alfapump**[®] and **alfapump**[®] DSR, component modifications or failure to achieve economies of scale could have a material adverse effect on Sequana Medical.
- Seeking and obtaining regulatory approval under the new Medical Devices Regulation can be an uncertain process, and Notified Bodies have limited resources and may experience backlogs in the transition period leading up to the May 2020 effective date of the new regulations.
- Changes in regulatory requirements, guidance from regulatory authorities or unanticipated events (including adverse events and/or severe adverse events) during Sequana Medical's clinical studies could necessitate changes to clinical study protocols or additional clinical study requirements, which would result in increased costs to Sequana Medical and delay the development timeline. Sequana Medical may not be able to afford such additional costs.
- Sequana Medical may not receive a German Diagnosis Related Group code for the **alfapump**[®] in Germany, a target European market.

- Competition from medical device companies, pharmaceutical companies, and medical device subsidiaries of large healthcare and pharmaceutical companies is intense and expected to increase.
- Sequana Medical has entered into a loan agreement with Bootstrap, which contains covenants that may limit Sequana Medical's ability (or require Bootstrap's prior consent) to take certain actions including the incurrence of certain additional indebtedness. Sequana Medical may not have cash available in an amount sufficient to enable Sequana Medical to make interest or principal payments on its indebtedness when due.
- Any inability to fully protect and exploit Sequana Medical's intellectual property may adversely impact Sequana Medical's financial performance and prospects.
- Attracting physicians and subjects to perform clinical studies and meet clinical study objectives is costly and uncertain. If Sequana Medical experiences delays or difficulties in the recruitment of Investigators or enrolment of subjects in clinical studies, its receipt of necessary regulatory approvals could be delayed or prevented.
- Even though Sequana Medical has obtained regulatory approval in Europe for the **alfapump**[®] in liver refractory ascites and malignant ascites, there is no guarantee that the **alfapump**[®] will perform as intended.
- Sequana Medical may not be able to manufacture or outsource manufacturing of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in sufficient quantities, in a timely manner or at a cost that is economically attractive.
- The success of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products depends on its acceptance and adoption by physicians.
- Active implantable medical devices such as the **alfapump**[®] and the **alfapump**[®] DSR carry risks associated with the surgical procedure for implant or removal of the device, use of the device, or the therapy delivered by the device.
- Sequana Medical faces an inherent risk of product liability claims and may not have adequate insurance coverage.
- If Sequana Medical's products are defective, or otherwise pose safety risks, the relevant governmental authorities could require their recall, or Sequana Medical may need to initiate a recall of its products voluntarily.
- Sequana Medical may be unable to attract and retain management and other personnel it needs to succeed.
- For the marketing of the **alfapump**[®], Sequana Medical will be largely dependent on Fresenius in Belgium and the Netherlands, Vingmed in Denmark and Gamida in Israel.
- If Sequana Medical is unable to expand its sales, marketing and distribution capabilities for the **alfapump**[®], the **alfapump**[®] DSR and/or any future products, whether it be with internal infrastructure or an arrangement with a commercial partner such as the ones that Sequana Medical has entered into with Fresenius, Vingmed and Gamida, Sequana Medical may not be successful in commercialising the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in its target markets, if and when they are approved.
- Sequana Medical's future profitability may depend on its ability to penetrate markets outside of Europe and North America, where Sequana Medical would be subject to additional regulatory burdens and other risks and uncertainties.
- The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about medical devices. If Sequana Medical is found to have made false or misleading claims about the **alfapump**[®] and/or the **alfapump**[®] DSR and/or any future products, or otherwise have violated promotion or advertising restrictions, Sequana Medical may become subject to significant fines and/or other liabilities.
- Compliance with regulations for quality systems for medical device companies is difficult, time consuming and costly. Sequana Medical may be found to be non-compliant, for example as a result of future changes in or interpretation of the regulations regarding quality systems in certain jurisdictions.
- Intellectual property rights do not necessarily address all potential threats to Sequana Medical's competitive advantage.

D.2	<p>Risks relating to the Shares and the Offering</p> <p>The Shares and Offering are subject to the following material risks, in addition to other risks that are mentioned in the Prospectus in relation to the Shares and the Offering:</p> <ul style="list-style-type: none"> ● The fact that no minimum amount is set for the Offering may affect Sequana Medical's investment plan and the liquidity of the Shares. ● There has been no prior public market for the Shares and an active market for the Shares may not develop. ● The market price of the Shares may fluctuate widely in response to various factors. ● Future sales of substantial amounts of Shares, or the perception that such sales could occur, could adversely affect the market value of the Shares. ● The Issuer has no fixed dividend policy and will probably not be in a capacity to pay dividends in the foreseeable future. ● Certain significant shareholders of the Issuer after the Offering may have different interests from the Issuer and may be able to control the Issuer, including the outcome of shareholder votes. ● Any future capital increase by the Issuer could have a negative impact on the price of the Shares and could dilute the interests of existing shareholders.
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Section E – The Offering

Element	Disclosure requirement
E.1	<p>Expenses and net proceeds of the Offering</p> <p>The aggregate of the administrative, legal, tax and audit expenses as well as the other costs in connection with the Offering (including but not limited to legal publications, printing and translation of the Prospectus and Offering related documents, and expenses incurred by the KBC Securities NV/SA and Kempen & Co N.V. (the “Joint Global Coordinators”) and Mirabaud Securities Limited (together with the Joint Global Coordinators, the “Underwriters”) (which are estimated at €50,000)) and the remuneration of the Belgian Financial Services and Markets Authority (the “FSMA”) (which is estimated at €20,000) and Euronext Brussels, is expected to amount to approximately €3 million. Additionally, fees and commissions payable to the Underwriters (as defined below) by the Issuer are expected to be maximum €1.9 million assuming a placement of the maximum number of New Shares in the Offering (including the conversion of the Bridge Loans in full, but excluding the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price (as defined below) is at the midpoint of the Price Range (as defined below), or maximum €2.7 million assuming a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range.</p> <p>Assuming a placement of the maximum number of New Shares in the Offering (excluding the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range, the gross proceeds from the issue of the New Shares are estimated to be approximately €28,308,822.50. Assuming a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range, the gross proceeds from the issue of the Offered Shares are estimated to be approximately €37,438,415.00.</p> <p>Based on the aforementioned assumptions, the Issuer estimates to receive net proceeds of approximately €23.4 million in case of a placement of the maximum number of New Shares in the Offering (including the conversion of the Bridge Loans in full, but excluding the exercise in full of the Increase Option and the Over-allotment Option) and approximately €31.8 million in case of a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option).</p>

Use of proceeds

The principal purpose of the Offering is to obtain additional capital to support the execution of Sequana Medical's strategy. In particular, the Issuer intends to use the net proceeds of the Offering to fund:

- the POSEIDON (North American pivotal) Study (which management estimates will cost around €11 million to complete and to acquire data to support reimbursement);
- the European commercial roll-out;
- the development of the **alfapump**[®] DSR, including the Single Dose DSR Proof of Concept and Repeated Dose DSR Proof of Concept (which management estimates will together cost around €1 million to complete);
- other clinical programmes, including the Malignant Ascites CT (which management estimates will cost around €1 million to complete), TOPMOST (which management estimates will cost around €0.4 million annually and includes the Fitbit[®] Study) and the Albumin Replacement Study (which management estimates will cost around €0.25 million to complete);
- partial repayment of the principal outstanding under the Bootstrap Loan, equal to a maximum of €1.5 million, payment of €0.44 million in accrued and unpaid interest on the Bootstrap Loan and payment of up to €0.33 million for the portion of the 'Exit Fee' under the Bootstrap Loan that is payable in cash; and
- general corporate purposes.

The Issuer intends to fund the European commercial roll-out with most of the net proceeds of the Offering that are not allocated to the clinical studies or the payments on the Bootstrap Loan described above. The Issuer intends to fund its commercial operations directly in the form of payments to the commercial team and sales and marketing expenses, as well as to indirectly fund commercial operations through significant investments in general corporate purposes to establish the infrastructure necessary to enable growth in Sequana Medical's commercial operations, such as investments in quality assurance and regulatory affairs and general and administrative personnel to provide critical support to Sequana Medical's commercial operations. The European commercial roll-out will also be funded by revenues from sales of the **alfapump**[®], but the amount of revenues that the **alfapump**[®] will generate is uncertain.

The Issuer cannot predict with certainty all of the particular uses for the proceeds from the issuance of the Offered Shares, or the amounts that it will actually spend on the uses set forth above. The amounts and timing of the Issuer's actual expenditures will depend upon numerous factors, including the progress, costs, timing and results of its further development of the **alfapump**[®] and the **alfapump**[®] DSR, regulatory or competitive developments, the net proceeds actually raised by it in the Offering, amounts received by way of revenues and the Issuer's operating costs and expenditures. As such, the Issuer's management assumes significant flexibility in applying the net proceeds from the issue of the Offered Shares and may change the allocation of these proceeds as a result of these and other contingencies. Pending the use of the proceeds from this Offering, the Issuer intends to invest the net proceeds in interest bearing, cash and cash equivalents instruments or short-term certificates of deposit. Furthermore, the Issuer has the right to proceed with a capital increase in a reduced amount, corresponding to a number of Shares lower than the maximum number of Offered Shares in the Offering. In the event that the Issuer would proceed with the capital increase in a reduced amount, it may be required to raise additional capital in order to meet the funding requirements of the above proposed uses.

Prior the closing of the Offering, the outstanding Convertible Loans will be converted into share capital via a contribution in kind. In addition, some Convertible Loan payables, the outstanding payables pursuant to the Bridge Loans, and 50% of the Exit Fee payable will be contributed in kind in the Offering (see also Element C.3). No additional cash will be contributed for the amount of the loans and payables that will be so contributed in kind.

Terms and conditions of the Offering

The offering (the “**Offering**”) consists of: (i) a public offering to retail and institutional investors in Belgium; (ii) a private placement in the U.S. to persons who are reasonably believed to be “qualified institutional buyers” (“**QIBs**”) as defined in Rule 144A (“**Rule 144A**”) under the U.S. Securities Act of 1933, as amended (the “**U.S. Securities Act**”), in reliance on Rule 144A; and (iii) private placements to certain qualified and/or institutional investors under applicable laws of the relevant jurisdiction in the rest of the world (those qualified and/or institutional investors together with the QIBs are collectively being referred to as the “**Institutional Investors**”). The Offering outside the U.S. will be made in compliance with Regulation S under the U.S. Securities Act. Private placements may take place in member states of the EEA pursuant to an exemption under the European Prospectus Directive as implemented in the relevant EEA member state.

The Offering is an offering of up to 3,235,294 new Shares (the “**New Shares**”).

The aggregate number of Shares sold in the Offering may be increased by up to 15% of the aggregate number of New Shares initially offered (the “**Increase Option**”). Any decision to exercise the Increase Option will be communicated, at the latest, on the date of the announcement of the Offer Price.

KBC Securities NV/SA, as stabilisation manager (the “**Stabilisation Manager**”), acting on behalf of the Underwriters, is expected to be granted by the Issuer an option, in the form of a warrant, to subscribe for additional new Shares for an aggregate number equal to up to 15% of the New Shares (including the New Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) subscribed for in the Offering at the Offer Price to cover over-allotments or short positions, if any, in connection with the Offering (the “**Over-allotment Option**”, and the additional new Shares issued pursuant to (i) the Increase Option and (ii) the Over-allotment Option and the New Shares collectively being referred to as the “**Offered Shares**”). The Over-allotment Option will be exercisable for a period of 30 calendar days following the Listing Date.

The closing date is expected to be 12 February 2019 (the “**Closing Date**”) unless the Offering Period is closed earlier. The Offer Price must be paid by investors by authorising their financial institutions to debit their bank accounts with such amount for value on the Closing Date.

There is no minimum amount for the Offering. The Participating Investors, who are all lenders pursuant to the Convertible Loans, have irrevocably committed pursuant to their Subscription Commitments to subscribe for an aggregate amount of €20.5 million at the Offer Price, subject to the closing of the Offering. As there is no minimum amount of the Offering, if not all of the Offered Shares are subscribed for in the Offering, the net proceeds from the Offering could be limited, all or in part, to the net proceeds from Subscription Commitments.

The New Shares in the Offering can also be subscribed for through a contribution in kind of payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91, and a contribution in kind of the outstanding payables under the Bridge Loans for an aggregate principal amount of €1,024,238.77 (to be increased with accrued interests). Furthermore, the New Shares in the Offering can be subscribed for through a contribution in kind by Bootstrap of 50% of the payable due by the Issuer upon the closing of the Offering as an “Exit Fee” pursuant to the Bootstrap Loan. The remaining portion of the Exit Fee shall be repaid in cash by the Issuer following closing of the Offering. As provided for by the Bootstrap Loan, the Exit Fee shall not exceed a maximum of CHF 750,000. The portion of the Exit Fee that shall be so contributed in kind, but that cannot be used for the subscription for a whole number of New Shares at the Offer Price shall not be contributed in kind, but remains payable in cash (subject to the terms of the Bootstrap Loan). In case of an over-subscription of the Offering, the allocation to the aforementioned lenders and Bootstrap of Shares in the Offering in consideration of the respective contributions in kind of their Convertible Loan, Bridge Loan and partial Exit Fee payables shall not be reduced. As the aforementioned Convertible Loan, Bridge Loan and partial Exit Fee payables will be contributed in kind in the Offering, no additional cash will be contributed for the amount of these payables in the Offering.

The offering period (the “**Offering Period**”) will begin on 31 January 2019 and is expected to end no later than 4:00 p.m. (CET) on 7 February 2019, subject to early closing or extension, provided that the Offering Period will in any event be open for at least six business days as from the start of the Offering Period. Any early closing or extension of the Offering Period will be announced by means of a press release by the Issuer, and the dates for each of pricing and allocation, publication of the Offer Price and results of the Offering, “if-and-when-issued-and/or-delivered” trading and closing of the Offering will in such case be adjusted accordingly. In the event the Offering Period is extended, this will be announced by means of a press release by the Issuer. If the Offering Period is extended with more than five business days, this will also be published in a supplement to the Prospectus. Prospective investors can submit their subscription orders during the Offering Period. Taking into account the fact that the Offering Period may be closed early, investors are invited to submit their applications as promptly as possible.

The price per Offered Share (the “**Offer Price**”) will be determined within the Price Range on the basis of a book-building process in which only Institutional Investors can participate, taking into account various relevant qualitative and quantitative elements, including but not limited to the number of Offered Shares for which subscriptions are received, the size of subscription orders received, the quality of the investors submitting such subscription orders and the prices at which the subscription orders were made, as well as market conditions at that time. The Offer Price is expected to be between €8.50 and €9.00 per Offered Share (the “**Price Range**”). The Offer Price may be set within the Price Range or below the lower end of the Price Range but will not exceed the higher end of the Price Range.

The Issuer reserves the right to increase or decrease the lower limit of the Price Range or to decrease the upper limit of the Price Range. If the Price Range is narrowed through an increase of the lower limit and/or a decrease of the upper limit, or if the Price Range is narrowed to a single price, the change will be published in the financial press and by means of a press release, through electronic information services such as Reuters or Bloomberg. Other changes to the Price Range will also be published in the financial press and by means of a press release, through electronic information services, as well as in a supplement to the Prospectus. Investors who have submitted subscription orders will not be notified individually. The Offer Price for investors shall not, however, exceed the higher end of the Price Range.

In accordance with article 34 of the Belgian Prospectus Act, in the event of a significant new development, or material mistake or inaccuracy relating to the information included in this Prospectus which is capable of affecting the assessment of the Offered Shares during the period from the date of approval of the Prospectus to the Listing Date, a supplement to this Prospectus shall be published. Any supplement is subject to approval by the FSMA, in the same manner as this Prospectus and must be made public in the same manner as this Prospectus. Investors who have already agreed to subscribe for the Offered Shares before the supplement is published will have the right, exercisable within at least two business days after the publication of the supplement, to withdraw their subscription orders, provided that the significant new development, material mistake or inaccuracy referred to above arose before the closing of the Offering and the delivery of the Offered Shares. A supplement to this Prospectus will be published in accordance with article 34 of the Belgian Prospectus Act (i) in the event the Offer Price is set below the lower end of the Price Range, (ii) if the Price Range is changed (other than in the event of a narrowing of the Price Range through an increase of the lower limit and/or a decrease of the upper limit of the Price Range), (iii) if the Offering Period is extended with more than five business days, (iv) if the maximum number of Offered Shares is reduced, including due to an early closing of the Offering Period without placement of the total number of New Shares, (v) if the Underwriting Agreement is not executed or is executed but subsequently terminated or (vi) to the extent required, if the Offering is withdrawn.

The Offer Price will apply to all investors, whether Retail Investors (i.e. an individual person resident in Belgium or a legal entity located in Belgium that does not qualify as a “qualified investor” (*gekwalificeerde belegger/investisseur qualifié*) as defined in article 10, §1 of the Belgian Prospectus Act) or Institutional Investors.

The number of Offered Shares allotted to investors will be determined at the end of the Offering Period by the Issuer in agreement with the Underwriters on the basis of the

	<p>respective demand of both Retail Investors and Institutional Investors and on the quantitative, and, for Institutional Investors only, the qualitative analysis of the order book, in accordance with Belgian regulations relating to allocation to Retail Investors and Institutional Investors.</p> <p>In accordance with Belgian regulations, a minimum of 10% of the Offered Shares shall be allocated to Retail Investors, subject to sufficient retail demand. However, the proportion of Offered Shares allocated to Retail Investors may be increased or decreased in an equal manner if subscription orders received from them exceed or do not reach, respectively, 10% of the Offered Shares effectively allocated.</p> <p>In case of over-subscription of the Offered Shares reserved for Retail Investors, the allocation to Retail Investors will be made on the basis of objective and quantitative allocation criteria, whereby all Retail Investors will be treated equally. The criteria that may be used for this purpose are the preferential treatment of applications submitted by Retail Investors at the counters of KBC Bank and KBC Securities NV/SA in Belgium, and at the counters of the affiliate of Kempen & Co N.V. in Belgium (i.e. Van Lanschot), and the number of Shares for which applications are submitted by Retail Investors.</p> <p>In the event of over-subscription of the Offering, the Subscription Commitments of the Participating Investors in cash for an amount of ca. €12.5 million (not including the amounts due pursuant to the Bridge Loans and the payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) can be reduced in line with the allocation principles that will apply to the other investors that will subscribe in the Offering, whereas the Subscription Commitments for the remaining amount (including the amounts due pursuant to the Bridge Loans and the payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) shall not be reduced but be allocated entirely. The allocation to the aforementioned lenders and Bootstrap of Shares in the Offering in consideration of the respective contributions in kind of their Convertible Loan, Bridge Loan and partial Exit Fee payables shall not be reduced.</p>
E.4	<p>Material interests to the Offering</p> <p>Assuming a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option), the fees, and commissions payable to the Underwriters will be maximum €2.7 million. The Issuer has also agreed to reimburse the Underwriters for certain expenses incurred by them in connection with the Offering (which are estimated at around €50,000).</p>
E.5	<p>Lock up</p> <p>The current shareholders (excluding certain minority shareholders holding in the aggregate less than ca. 0.01% of the outstanding Shares after giving effect to the contribution in kind of the Convertible Loan payables (with the exception of certain payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91 that will be converted into New Shares at the Offer Price in connection with the Offering) and the Share Consolidation) and the Participating Investors have entered into a lock up arrangement with the Underwriters in respect of (i) any of their Shares in the Issuer prior to the Offering, (ii) any of the Shares that they will receive through the contribution in kind of their Convertible Loan payables (with the exception of certain payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91 that will be converted into New Shares at the Offer Price in connection with the Offering), (iii) all of the Shares into which the aforementioned Shares will be converted, exchanged and consolidated pursuant to the Share Consolidation, and (iv) all their securities or rights issued or agreed to by the Issuer that are convertible into or exercisable or exchangeable for Shares of the Issuer (including the shares into which such securities or rights are converted, exercised or exchanged) (together the “Locked Securities”). The definition of Locked Securities does not include any of the New Shares that will be subscribed for in the Offering at the Offering Price pursuant to the Subscription Commitments (including pursuant to the conversion of outstanding amounts pursuant to the Bridge Loans) or pursuant to the contribution in kind of payables under the February 2018 Convertible Loan for an aggregate principal amount of</p>

€6,340.91. Pursuant to the lock up arrangement, the holders of Locked Securities will not, for a period ending 360 days after the Listing Date, (i) directly or indirectly, issue, offer, pledge, exchange, lend, assign by way of security, grant any right “in rem”, deliver or market, sell, contract to sell, sell or grant any option, right, warrant or contract to purchase, exercise any option to sell, purchase any option or contract to sell, or lend or otherwise transfer or dispose of any of their Locked Securities, (ii) enter into any swap, any arrangement, any derivative transaction or issue any instruments that transfer (conditionally or unconditionally, now or in the future) to a third party all or part of the economic risk, benefits, rights or ownership of any Locked Securities, or (iii) publicly announce such an intention to effect any such transaction. The restrictions do not prohibit holders of Locked Securities from (i) accepting a general take-over or tender offer on all of the ordinary share capital of the Issuer, giving an irrevocable commitment to accept such an offer, or disposing of Locked Securities to an offeror or potential offeror during the period of such an offer; (ii) proceeding with any disposal required by law, regulation or a court of competent jurisdiction; (iii) transferring Locked Securities intra-group or to one or more legal successors pursuant to a merger, liquidation, concursus, de-merger, transfer of a branch of activity or transfer of a universality (for holders of Locked Securities that are a legal entity), or intra-family or to one or more legal successors pursuant to the death of the shareholder (for holders of Locked Securities who are a natural person), provided that each such transferee shall continue to be bound by the restrictions for the remaining period of the restrictions; or (iv) lending a number of Locked Shares to one of the Joint Global Coordinators in the framework of the Offering. In addition, starting as from the 181th day after the first day of trading of the Shares on Euronext Brussels until the end of the restriction period, transfers of Locked Securities shall be permitted provided that (x) one or more Participating Investors holding in the aggregate at least 5% of the outstanding share capital of the Issuer at the time the request is made, shall have requested and obtained the prior written approval of the Joint Global Coordinators (acting on behalf of the Underwriters) and (y) any such transfer for which such prior written consent has been given shall solely be effected through a coordinated sale.

Any transfer of (any part of) the 18,468 common Shares (before giving effect to the Share Consolidation, representing less than 59 Shares after giving effect to the Share Consolidation and assuming that the Offer Price is at the midpoint of the Price Range (i.e. €8.75)) that were issued on 9 July 2018 and all of the Shares that will be issued upon conversion of the Convertible Loans (other than the Shares that will be issued at the Offer Price in connection with the Offering through contribution in kind of payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) will (subject to limited exceptions in the context of a public takeover bid), as from and until one year after the closing of the Offering, require a prior approval by the FSMA in accordance with the statutory lock up provisions of article 11 of the Belgian Royal Decree of 17 May 2007 on primary market practices, as amended.

The Shares that Bootstrap acquires upon the exercise of the Bootstrap Warrant will not be subject to a transfer restriction. However, Bootstrap entered into a lock-up arrangement with the Issuer and the Joint Global Coordinators with respect to the Shares that it will acquire through the contribution in kind of 50% of the Exit Fee in the Offering. Pursuant to the lock up arrangement, Bootstrap will not, for a period ending 180 days after the Listing Date (the “**Bootstrap Lock-up Period**”), (i) directly or indirectly, issue, offer, pledge, exchange, lend, assign by way of security, grant any right “in rem”, deliver or market, sell, contract to sell, sell or grant any option, right, warrant or contract to purchase, exercise any option to sell, purchase any option or contract to sell, or lend or otherwise transfer or dispose of any of the Shares that it will acquire through the contribution in kind of 50% of the Exit Fee in the Offering, (ii) enter into any swap, any arrangement, any derivative transaction or issue any instruments that transfer (conditionally or unconditionally, now or in the future) to a third party all or part of the economic risk, benefits, rights or ownership of any such Shares, or (iii) publicly announce such an intention to effect any such transaction. The restrictions do not prohibit Bootstrap from (i) accepting a general take-over or tender offer on all of the ordinary share capital of the Issuer, giving an irrevocable commitment to accept such an offer, or disposing of Shares to an offeror or potential offeror during the period of such an offer; (ii) proceeding with any disposal required by law, regulation or a court of competent jurisdiction; or (iii) transferring any of the Shares that it will acquire through the contribution in kind of 50% of the Exit Fee in the Offering to its limited partners that have an interest in Bootstrap,

	<p>provided that prior to such transfer such limited partner confirms in writing to the Joint Global Coordinators that it shall be bound by the transfer restriction for the remainder of the Bootstrap Lock-Up Period with respect to any of such Shares so to be transferred to it.</p>
<p>E.6</p>	<p>Dilution resulting from the Offering</p> <p>The following table presents the undiluted ownership of the Shares immediately prior to the Share Consolidation and the closing of the Offering (including the conversion of the Bridge Loans in full); immediately after the closing of the Offering assuming a placement of the maximum number of New Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option, but without exercise of the Over-allotment Option) and after giving effect to the Share Consolidation; and immediately after the closing of the Offering assuming a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option) and after giving effect to the Share Consolidation. An assumption has been made that the existing shareholders will not participate in the Offering in addition to pre-commitments by the Participating Investors (see Element C.3). The natural persons holding less than 1% of the outstanding Shares prior to the closing of the Offering have been presented under “other”.</p>

Shareholder/Investor	Shares owned before the closing of the Offering and before the Share Consolidation on an undiluted basis⁽¹⁾		Shares owned assuming full placement of the New Shares and the Share Consolidation⁽²⁾		Shares owned assuming full placement of the Offered Shares and the Share Consolidation		Shares owned on a fully diluted basis assuming full placement of the Offered Shares and the Share Consolidation⁽³⁴⁾	
	<i>(Number)</i>	<i>(%)</i>	<i>(Number)</i>	<i>(%)</i>	<i>(Number)</i>	<i>(%)</i>	<i>(Number)</i>	<i>(%)</i>
NeoMed ^{(3) (4)}	3,567,733 ⁽⁷⁾	35.93%	4,126,250	31.50%	4,126,250	30.22%	4,126,250	26.38%
LSP Health Economics Fund Management B.V. ⁽⁴⁾	1,077,148 ⁽⁸⁾	10.85%	1,424,456	10.88%	1,424,456	10.43%	1,424,456	9.11%
Venture Incubator AG ⁽⁴⁾	994,137 ⁽⁹⁾	10.01%	511,954	3.91%	511,954	3.75%	511,954	3.27%
VI Partners ⁽⁴⁾	22,874 ⁽²⁵⁾	0.23%	10,546	0.08%	10,546	0.08%	10,546	0.07%
Entrepreneurs Fund LP	869,159 ⁽¹⁰⁾	8.75%	4	0.00%	4	0.00%	4	0.00%
BioMedInvest II LP ⁽⁴⁾	816,227 ⁽¹¹⁾	8.22%	225,194	1.72%	225,194	1.65%	225,194	1.44%
Capricorn Health-tech Fund NV ⁽⁴⁾	803,186 ⁽¹²⁾	8.09%	237,039	1.81%	237,039	1.74%	237,039	1.52%
Brynjulf Gran Jensen	207,109 ⁽¹³⁾	2.09%	90,014	0.69%	90,014	0.66%	90,014	0.58%
Quest for Growth NV ⁽⁴⁾	204,366 ⁽¹⁴⁾	2.06%	360,168	2.75%	360,168	2.64%	360,168	2.30%
Nayereh Ladjevardi ⁽⁴⁾	192,511 ⁽¹⁵⁾	1.94%	306,207	2.34%	306,207	2.24%	306,207	1.96%
John A. Kazour	192,511 ⁽¹⁶⁾	1.94%	258,622	1.97%	258,622	1.89%	258,622	1.65%
BGJ Holding AS	158,927 ⁽¹⁷⁾	1.60%	68,664	0.52%	68,664	0.50%	68,664	0.44%
Johs. Hansen Rederi AS ⁽⁴⁾	144,626 ⁽¹⁸⁾	1.46%	120,207	0.92%	120,207	0.88%	120,207	0.77%
Schroeder & Co. Bank AG	84,520 ⁽¹⁹⁾	0.85%	5	0.00%	5	0.00%	5	0.00%
Zürcher Kantonalbank	73,030 ⁽²⁰⁾	0.74%	44,096	0.34%	44,096	0.32%	44,096	0.28%
N5 Investments AS ⁽⁴⁾	64,218 ⁽²¹⁾	0.65%	83,232	0.64%	83,232	0.61%	83,232	0.53%
Active Invest-Sweden AB ⁽⁴⁾	57,759 ⁽²²⁾	0.58%	125,207	0.96%	125,207	0.92%	125,207	0.80%
Hookipa AG ⁽⁴⁾	29,912 ⁽²³⁾	0.30%	19,419	0.15%	19,419	0.14%	19,419	0.12%
Codlam	24,556 ⁽²⁴⁾	0.25%	14,826	0.11%	14,826	0.11%	14,826	0.09%
TheraNova LLC	19,250 ⁽²⁶⁾	0.19%	1	0.00%	1	0.00%	1	0.00%
Art of Technology	10,665 ⁽²⁷⁾	0.11%	6,442	0.05%	6,442	0.05%	6,442	0.04%
IDEO	500 ⁽²⁸⁾	0.01%	1	0.00%	1	0.00%	1	0.00%
WS Investments	500 ⁽²⁸⁾	0.01%	1	0.00%	1	0.00%	1	0.00%
Bootstrap	0 ⁽²⁹⁾	0.00%	34,409	0.26%	34,409	0.25%	337,213	2.16%
PMV ⁽⁵⁾	0 ⁽²⁹⁾	0.00%	1,092,806	8.34%	1,092,806	8.00%	1,092,806	6.99%
FPIM ⁽⁵⁾	0 ⁽²⁹⁾	0.00%	1,091,793	8.34%	1,091,793	8.00%	1,091,793	6.98%
Cofipalux ⁽⁵⁾	0 ⁽²⁹⁾	0.00%	272,571	2.08%	272,571	2.00%	272,571	1.74%
Newton Biocapital ⁽⁵⁾	0 ⁽²⁹⁾	0.00%	1,089,076	8.32%	1,089,076	7.98%	1,089,076	6.96%
Victor Röhm ⁽⁵⁾	0 ⁽³⁰⁾	0.00%	47,533	0.36%	47,533	0.35%	47,533	0.30%
Other ⁽⁶⁾	315,361 ⁽³¹⁾	3.18%	95,213	0.73%	95,213	0.70%	1,781,494	11.39%
Free float	0 ⁽³²⁾	0.00%	1,341,238	10.24%	1,899,326	13.91%	1,899,326	12.14%
Total	9,930,784⁽³³⁾	100	13,097,194	100.00%	13,655,282	100.00%	15,644,367	100.00%

Notes:

- (1) The number of Shares reflects the aggregate number of Shares held by the relevant shareholder before giving effect to the Share Consolidation, and refers to common Shares as well as preferred Shares.
- (2) For the purpose of the Share Consolidation, it is assumed that the Offer Price is at the midpoint of the Price Range (i.e. at €8.75).
- (3) The shareholders NeoMed IV Extension L.P. and NeoMed Innovation V L.P. are together referred to as "NeoMed".
- (4) These shareholders are Participating Investors.
- (5) These investors are Participating Investors.
- (6) Including Participating Investors.
- (7) Of which 1,003,695 common Shares, 356,893 series A preferred Shares, 699,863 series B preferred Shares, 400,412 series C preferred Shares, 0 series D preferred Shares and 1,106,870 series E preferred Shares.
- (8) Of which 390,610 are common Shares, 0 series A preferred Shares, 0 series B preferred Shares, 304,858 series C preferred Shares, 0 series D preferred Shares and 381,680 series E preferred Shares.
- (9) Of which 312,485 are common Shares, 111,317 series A preferred Shares, 245,798 series B preferred Shares, 198,764 series C preferred Shares, 30,353 series D preferred Shares and 95,420 series E preferred Shares.
- (10) Of which 281,235 are common Shares, 0 series A preferred Shares, 315,974 series B preferred Shares, 202,241 series C preferred Shares, 69,709 series D preferred Shares and 0 series E preferred Shares.
- (11) Of which 256,437 are common Shares, 0 series A preferred Shares, 315,974 series B preferred Shares, 177,443 series C preferred Shares, 66,373 series D preferred Shares and 0 series E preferred Shares.
- (12) Of which 240,289 are common Shares, 0 series A preferred Shares, 315,974 series B preferred Shares, 161,295 series C preferred Shares, 23,260 series D preferred Shares and 62,368 series E preferred Shares.
- (13) Of which 63,807 are common Shares, 4,428 series A preferred Shares, 69,962 series B preferred Shares, 37,712 series C preferred Shares, 0 series D preferred Shares and 31,200 series E preferred Shares.

	<p>(14) Of which 68,966 are common Shares, 0 series A preferred Shares, 0 series B preferred Shares, 40,248 series C preferred Shares, 0 series D preferred Shares and 95,152 series E preferred Shares.</p> <p>(15) Of which 68,965 are common Shares, 0 series A preferred Shares, 0 series B preferred Shares, 33,900 series C preferred Shares, 0 series D preferred Shares and 89,645 series E preferred Shares.</p> <p>(16) Of which 68,965 are common Shares, 0 series A preferred Shares, 0 series B preferred Shares, 33,900 series C preferred Shares, 0 series D preferred Shares and 89,645 series E preferred Shares.</p> <p>(17) Of which 50,131 are common Shares, 0 series A preferred Shares, 58,116 series B preferred Shares, 26,880 series C preferred Shares, 0 series D preferred Shares and 23,800 series E preferred Shares.</p> <p>(18) Of which 35,767 are common Shares, 17,041 series A preferred Shares, 48,771 series B preferred Shares, 12,781 series C preferred Shares, 0 series D preferred Shares and 30,266 series E preferred Shares.</p> <p>(19) Of which 29,310 are common Shares, 17,706 series A preferred Shares, 12,021 series B preferred Shares, 19,898 series C preferred Shares, 5,585 series D preferred Shares and 0 series E preferred Shares.</p> <p>(20) Of which 14,592 are common Shares, 29,613 series A preferred Shares, 13,541 series B preferred Shares, 0 series C preferred Shares, 0 series D preferred Shares and 15,284 series E preferred Shares.</p> <p>(21) Of which 21,696 are common Shares, 0 series A preferred Shares, 0 series B preferred Shares, 20,194 series C preferred Shares, 0 series D preferred Shares and 22,328 series E preferred Shares.</p> <p>(22) Of which 20,689 are common Shares, 0 series A preferred Shares, 0 series B preferred Shares, 10,164 series C preferred Shares, 0 series D preferred Shares and 26,905 series E preferred Shares.</p> <p>(23) Of which 9,140 are common Shares, 0 series A preferred Shares, 8,976 series B preferred Shares, 5,536 series C preferred Shares, 0 series D preferred Shares and 6,260 series E preferred Shares.</p> <p>(24) Of which 6,901 are common Shares, 0 series A preferred Shares, 8,976 series B preferred Shares, 3,541 series C preferred Shares, 0 series D preferred Shares and 5,138 series E preferred Shares.</p> <p>(25) Of which 6,901 are common Shares, 0 series A preferred Shares, 8,976 series B preferred Shares, 4,657 series C preferred Shares, 566 series D preferred Shares and 1,774 series E preferred Shares.</p> <p>(26) Of which 19,250 are common Shares, 0 series A preferred Shares, 0 series B preferred Shares, 0 series C preferred Shares, 0 series D preferred Shares and 0 series E preferred Shares.</p> <p>(27) Of which 3,267 are common Shares, 0 series A preferred Shares, 4,509 series B preferred Shares, 657 series C preferred Shares, 0 series D preferred Shares and 2,232 series E preferred Shares.</p> <p>(28) Which are all common Shares.</p> <p>(29) This company does not own any Shares before the closing of the Offering.</p> <p>(30) This individual does not own any Shares before the closing of the Offering.</p> <p>(31) Of which 220,815 are common Shares, 6,684 series A preferred Shares, 39,684 series B preferred Shares, 29,255 series C preferred Shares, 5,655 series D preferred Shares and 13,268 series E preferred Shares.</p> <p>(32) There is no free float before the closing of the Offering.</p> <p>(33) Of which 3,194,913 are common Shares, 543,682 series A preferred Shares, 2,167,115 series B preferred Shares, 1,724,337 series C preferred Shares, 201,501 series D preferred Shares and 2,099,236 series E preferred Shares.</p> <p>(34) Assumes the exercise in full of existing Share options, including the 2018 Share Options to be created at the time of the closing of the Offering.</p>
E.7	<p>Estimated expenses charged to the investor by the Issuer</p> <p>Not applicable. No fees or expenses in connection with the Offering will be charged to investors by the Issuer.</p>

PART 2 – RISK FACTORS

The following risk factors may affect the future operating and financial performance of Sequana Medical and the value of an investment in the Shares. Examples of past experience have been included where material in aiding the understanding of the risk. Investors should carefully consider the following risk factors, as well as the other information contained in this Prospectus, before making an investment decision. These risks and uncertainties are not the only ones Sequana Medical faces. Additional risks and uncertainties not presently known, or that management currently believes to be immaterial, may also affect Sequana Medical's business, financial condition and results of operations. If any of those risks or uncertainties occurs, the price of the Offered Shares may decline and investors could lose all or part of their investment.

In addition to considering carefully the risk factors set out below and this entire Prospectus, prospective investors should also consult, before making an investment decision with respect to the Offered Shares, their own financial, legal and tax advisers to carefully review the risks associated with an investment in the Offered Shares and consider such an investment decision in light of their personal circumstances.

2.1 Risks related to Sequana Medical's business and industry

(a) *Sequana Medical has incurred operating losses, negative operating cash flows and an accumulated deficit since inception and may not be able to achieve or subsequently maintain profitability.*

Sequana Medical has incurred operating losses and negative operating cash flows in each period since it was founded in 2006. As of 30 September 2018, Sequana Medical has a loss brought forward of €79.7 million. These losses have resulted principally from costs incurred in the development and commercialisation of the **alfapump**[®] technology, as well as from general and administrative costs associated with Sequana Medical's operations and manufacturing scale-up. Sequana Medical intends to fund the continued development of the **alfapump**[®] and the **alfapump**[®] DSR, to expand manufacturing capabilities, to seek further regulatory and marketing approvals for the **alfapump**[®], to secure reimbursement by payers, to maintain, protect and expand Sequana Medical's intellectual property portfolio and to expand sales and marketing activities. Sequana Medical expects to begin a pivotal study in the second half of 2019 on the **alfapump**[®] for the treatment of liver recurrent and refractory ascites in the United States (the "U.S.") and Canada (the "**POSEIDON (North American pivotal) Study**"), which management estimates will be completed in the second half of 2021 and cost around €11 million to complete and to acquire data to support reimbursement. Sequana Medical also plans to conduct the additional clinical studies described under Part 7 – (Operating and Financial Review and Prospects), section 7.2 (Factors affecting results of operations), subsection (e) (Clinical affairs expenses) and as a result management expects that clinical affairs expenses will increase significantly over the next several years. These expenses, together with anticipated general and administrative expenses, will likely result in Sequana Medical incurring further losses for at least the next few years.

As a consequence of the losses incurred, the consolidated balance sheet as at 30 September 2018 shows a negative equity in the amount of €13.3 million. As a result of the negative net equity also at non-consolidated level, the Issuer had to comply with the procedure under article 633 of the Belgian Companies Code, which provides that if, as a result of losses incurred, the ratio of the Issuer's net assets (determined in accordance with Belgian legal and accounting rules for non-consolidated financial statements) to share capital is less than 50%, the board of directors must convene an extraordinary general shareholders' meeting within two months as of the date upon which the board of directors discovered or should have discovered this undercapitalisation, to resolve on either the continuation or the dissolution of the Issuer. In addition, pursuant to article 634 of the Belgian Companies Code, if the amount of the Issuer's net assets is below €61,500 (the minimum amount of share capital of a corporation with limited liability organised under the laws of Belgium (*naamloze vennootschap/société anonyme*)), any interested party is entitled to request the competent court to dissolve the Issuer. The court can order the dissolution of the Issuer or grant a grace period within which the Issuer is to remedy the situation. Notwithstanding the negative net equity, the Issuer's general shareholders' meeting held on 20 November 2018 resolved, in accordance with article 633 of the Belgian Companies Code, to continue the Issuer's activities, and not to dissolve the Issuer. Upon completion of the Offering, the Issuer's net equity will again be positive, and the Issuer will no longer fall within the scope of articles 633 and 634 of the Belgian Companies Code upon closing of the Offering.

There can be no assurance that Sequana Medical will achieve profitability, which could impair its ability to sustain operations or obtain any required additional funding. If Sequana Medical does achieve profitability in the future, it may not be able to sustain profitability in subsequent periods, and it may suffer net losses and/or negative operating cash flows in subsequent periods.

It is possible that Sequana Medical will experience fluctuating revenues, operating results and cash flows. In that case, as a result, period-to-period comparisons of financial results are not necessarily meaningful, and results of operations in prior periods should not be relied upon as an indication of future performance.

(b) *Sequana Medical's future financial performance will depend on the commercial acceptance of the alfapump[®] (Sequana Medical's only commercial-stage product at the date of this Prospectus), the alfapump[®] DSR and/or any future products in target markets.*

At the date of this Prospectus, the alfapump[®] is the only product that has been commercialised by Sequana Medical. Furthermore, the alfapump[®] has only received regulatory approval in Europe (through a CE-Mark). The alfapump[®] received a CE-Mark for the treatment of liver refractory ascites (for a period of up to two years) in 2011, and in 2012 for the treatment of malignant ascites (for patients with a life expectancy of six months or less). The alfapump[®] was launched commercially in 2012, and to date has only been commercialised in a limited number of countries. Sales of the alfapump[®] have only generated limited revenue while Sequana Medical has been working to gain commercial market acceptance of the alfapump[®] in target markets. There can be no assurance that the alfapump[®], the alfapump[®] DSR and/or any future products launched by Sequana Medical will gain commercial acceptance in target markets. If Sequana Medical fails to gain and maintain commercial market acceptance of the alfapump[®] in its focus jurisdictions of Germany, Switzerland, France, the U.K., the U.S. and Canada, in particular if Sequana Medical fails to secure and maintain regulatory approval and reimbursement arrangements for the alfapump[®] (as further described below), the amount of revenue generated from sales of the alfapump[®] in the future could continue to be limited, and could even decrease. In addition, the alfapump[®] DSR has not received marketing approval in any jurisdictions and Sequana Medical's future financial performance will depend on the successful completion of its planned clinical studies on the alfapump[®] DSR.

Many factors can influence market acceptance of the alfapump[®], the alfapump[®] DSR and/or any future products, including:

- approval from the appropriate regulatory authorities or unavailability of Sequana Medical's products due to regulatory barriers (see subsection (d) (Seeking and obtaining regulatory approval for medical devices can be a long and uncertain process. Strict or changing regulatory regimes, government policies and legislation in any of Sequana Medical's target markets may delay, prohibit or reduce potential sales));
- price and reimbursement levels from third party payers (see subsection (j) (Sequana Medical's success is largely contingent on third party payment from government providers, healthcare insurance providers or other public or private sources. Healthcare policy changes, including legislation to reform the U.S. healthcare system, could have a material adverse effect on Sequana Medical. Sequana Medical could fail to achieve or maintain reimbursement levels sufficient to support a commercial infrastructure or realise an appropriate return on its investment in product development, which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects));
- successful completion of the clinical development of the alfapump[®] DSR, including the ongoing first-in-human clinical study in approximately 20 patients in the U.S. at Yale University to demonstrate the safety, tolerability and dynamics of a single dose of DSR therapy (no alfapump[®] (the "**Single Dose DSR Proof of Concept**"), the planned study that is expected to be conducted in clinical centres in Europe in approximately 5-10 patients with volume overload in heart failure to demonstrate the safety, tolerability and efficacy of the alfapump[®] DSR in connection with multiple dose DSR therapy over a 90-day period the ("**Repeated DSR Dose Proof of Concept**"), the planned multi-national 3-month feasibility study to assess the safety and efficacy of the alfapump[®] DSR in patients with volume overload in heart failure (the "**Multi-national Feasibility Study**")

and the planned multi-national pivotal study in patients with volume overload in heart failure to demonstrate the efficacy and cost-effectiveness of the **alfapump**[®] DSR versus LVP standard of care (the “**Multi-national Pivotal Study**”);

- the timing of the launch in a particular market;
- inclusion in clinical practice guidelines;
- the availability of clinical evidence through studies and registries;
- accurate anticipation of patients’, healthcare providers’ and payers’ needs and emerging technology trends;
- frequency and/or severity of complications or side effects, and/or market perception of the reliability and quality (see subsection (s) (Active implantable medical devices such as the **alfapump**[®] and the **alfapump**[®] DSR carry risks associated with the surgical procedure for implant or removal of the device, use of the device, or the therapy delivered by the device));
- competition, the convenience and ease of use compared to competing products and other potential advantages and disadvantages over alternative products and services (see subsection (l) (Competition from medical device companies, pharmaceutical companies, and medical device subsidiaries of large healthcare and pharmaceutical companies is intense and expected to increase));
- production barriers such as interruptions to the supply of materials or sub-components or Sequana Medical’s manufacturing activities being suspended by regulatory authorities (see subsection (g) (Sequana Medical depends on third party suppliers for services and components used in the production of the **alfapump**[®] and **alfapump**[®] DSR, and some of those services and components are supplied from a single source. Disruption of the supply chain, unavailability of third party services required for the production of the **alfapump**[®] and **alfapump**[®] DSR, component modifications or failure to achieve economies of scale could have a material adverse effect on Sequana Medical) and subsection (aa) (Compliance with regulations for quality systems for medical device companies is difficult, time consuming and costly. Sequana Medical may be found to be non-compliant, for example as a result of future changes in or interpretation of the regulations regarding quality systems in certain jurisdictions));
- limitations on approved uses;
- the quality of the service that Sequana Medical establishes in order to support customers;
- the ability to demonstrate to physicians and other potential customers the benefits and cost-effectiveness relative to other products available on the market (see subsection (r) (The success of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products depends on its acceptance and adoption by physicians));
- the ability of Sequana Medical to maintain relationships with key opinion leaders in the medical community;
- entrance into additional markets or indications and the scope of the indications approved by regulatory authorities (see subsection (d) (Seeking and obtaining regulatory approval for medical devices can be a long and uncertain process. Strict or changing regulatory regimes, government policies and legislation in any of Sequana Medical’s target markets may delay, prohibit or reduce potential sales) and subsection (y) (Sequana Medical’s future profitability may depend on its ability to penetrate markets outside of Europe and the United States and Canada (“**North America**”), where Sequana Medical would be subject to additional regulatory burdens and other risks and uncertainties));
- tariffs, trade barriers and other trade protection measures, import or export licensing requirements and any other restrictive actions by the U.S. or other governments; and
- the ability of Sequana Medical to hire new sales and marketing personnel and their effectiveness in executing its business strategy (see subsection (x) (If Sequana Medical is unable to expand its sales, marketing and distribution capabilities for the **alfapump**[®], the **alfapump**[®] DSR and/or any future products, whether it be with internal infrastructure or an arrangement with a commercial partner such as the ones that Sequana Medical has entered into with Fresenius Medical Care Deutschland GmbH (“**Fresenius**”)),

Vingmed Holding (“**Vingmed**”) and Gamida Ltd. (“**Gamida**”), Sequana Medical may not be successful in commercialising the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in its target markets, if and when they are approved)).

These and other factors present obstacles to commercial market acceptance of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in target markets. Failure, or any substantial delay, in gaining significant commercial market acceptance of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in target markets, on a timely basis or at all, could materially and adversely affect Sequana Medical’s business, financial condition, results of operations and prospects.

(c) Sequana Medical will likely require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available when required or could significantly limit Sequana Medical’s access to additional capital.

Sequana Medical anticipates using the proceeds of the Offering as described under Part 3 – (Use of Proceeds), including to fund:

- the POSEIDON (North American pivotal) Study, which management estimates will cost around €11 million to complete and to acquire data to support reimbursement;
- the Single Dose DSR Proof of Concept and the Repeated DSR Dose Proof of Concept, which management estimates will together cost around a total of €1 million to complete;
- the randomised controlled study in Europe to evaluate the efficacy and clinical impact of the **alfapump**[®] versus standard of care in 50 malignant ascites patients (the “**Malignant Ascites CT**”), which management estimates will cost around €1 million to complete;
- the European registry study in cirrhosis patients that have been implanted with the **alfapump**[®] (“**TOPMOST**”), which management estimates will cost around €0.4 million annually and includes the quality of life study in 20 patients to measure the impact of the **alfapump**[®] vs. standard of care on patient activity (the “**Fitbit**[®] **Study**”); and
- the European study on the impact of albumin replacement therapy on clinical outcomes in 10-15 patients implanted with the **alfapump**[®] (the “**Albumin Replacement Study**”), which management estimates will costs around €0.25 million to complete.

Positive outcomes from these clinical studies will likely result in Sequana Medical requiring additional funding in the future in order to continue development and conduct regulatory approval activities, to expand marketing and sales capabilities, to expand manufacturing capabilities and to take advantage of new business opportunities. Sequana Medical may also strategically decide to seek additional capital if market conditions are favourable. In addition, while the above estimates reflect management’s current expectations concerning the cost of Sequana Medical’s planned clinical studies, these amounts are only estimates and there are many factors that could cause the actual costs of one or more of these clinical studies to be substantially greater than anticipated, such as extensive delays or difficulty receiving approval in advance by the applicable regulatory authorities, as further described below in subsection (e) (Sequana Medical is required to conduct clinical studies for regulatory approvals and other purposes. Clinical studies require approvals, carry substantial risks and may be costly and time consuming, with uncertain results).

Sequana Medical’s future capital requirements will depend on many factors, including but not limited to:

- progress with pre-clinical studies (for example, to enhance the efficacy of direct sodium removal in animal models) and clinical studies (for example, to gain approvals or reimbursement in new markets);
- regulatory requirements of clinical studies and changes in the regulatory environment including those potentially caused by Brexit (as defined below), the Medical Devices Regulation (Regulation 2017/745) (the “**Medical Devices Regulation**”) and the E.U. General Data Protection Regulation (the “**GDPR**”);
- the time and costs involved in obtaining and renewing regulatory approvals and market access (including pricing and reimbursement status);
- the costs involved in filing and pursuing patent applications, enforcing patent claims, or engaging in interference proceedings or other patent litigation;
- competing technological and market developments;

- addressing any complications or side effects associated with use of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products;
- the establishment of partnerships and strategic alliances;
- the achievement of sales targets;
- the cost of commercialisation activities and arrangements; and
- continued progress, and the magnitude and complexity, of Sequana Medical's development programmes.

In addition, for purposes of designing and conducting the POSEIDON (North American pivotal) Study, there is a significant body of clinical evidence available on the **alfapump**[®] for the management of liver refractory ascites. For purposes of designing a pivotal study in the U.S. on the **alfapump**[®] DSR, given that a similar body of clinical evidence will likely not be available for the treatment of volume overload in heart failure, the FDA is likely to require the **alfapump**[®] DSR pivotal study to be larger and therefore the costs of a pivotal study on the **alfapump**[®] DSR will likely exceed the estimated costs of the POSEIDON (North American pivotal) Study.

On the date of this Prospectus, the Issuer is of the opinion that, taking into account its available cash and cash equivalents (and excluding any proceeds of the Offering), it does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months from the date of the Prospectus. Furthermore, over the longer term, the net proceeds from the Offering, together with Sequana Medical's existing capital resources, will be insufficient to fund, among other things, the completion of the clinical development of the **alfapump**[®] DSR required to bring it to market in Europe and the U.S., including the Multi-national Feasibility Study or the Multi-national Pivotal Study, to fund the commercial roll-out of the **alfapump**[®] in the U.S., if approved, or to pay in full the total CHF 5.90 million in principal and interest outstanding under the secured loan from Bootstrap Europe S.C.Sp. ("**Bootstrap**") that was signed in September 2016, as amended (the "**Bootstrap Loan**").

Equity and/or debt financing might not be available when needed or, if available, might not be available on commercially favourable terms. In addition, to the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in the dilution of the interests of Sequana Medical's existing shareholders. In addition, these securities may be sold at a discount from the market price of Sequana Medical's shares.

Furthermore, at the date of this Prospectus, the Bootstrap Loan also includes covenants, which may limit Sequana Medical's ability or require Bootstrap's prior consent to, among other things, incur certain additional indebtedness (see subsection (m) (Sequana Medical has entered into a loan agreement with Bootstrap, which contains covenants that may limit Sequana Medical's ability (or require Bootstrap's prior consent) to take certain actions including the incurrence of certain additional indebtedness. Sequana Medical may not have cash available in an amount sufficient to enable Sequana Medical to make interest or principal payments on its indebtedness when due) below).

If the necessary funds are not available, Sequana Medical may seek funds through collaboration and licensing arrangements, at an earlier stage than originally planned, at terms that are less favourable than those it might otherwise have obtained or at terms which may require it to reduce or relinquish significant rights to its programmes. Sequana Medical may also be required to significantly curtail, delay, reduce or terminate all or part of its development programmes or the commercialisation of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products, or it may be unable to take advantage of future business opportunities or to respond to certain business challenges, which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(d) Seeking and obtaining regulatory approval for medical devices can be a long, expensive and uncertain process. Strict or changing regulatory regimes, government policies and legislation in any of Sequana Medical's target markets may delay, prohibit or reduce potential sales.

Applications for regulatory approval may require extensive pre-clinical, clinical and technical testing, all of which must be undertaken in accordance with the requirements of regulations established by the relevant regulatory agencies. The regulations to which Sequana Medical is subject are complex and have tended to become more stringent over time. Sequana Medical may

be adversely affected by changes in government policy or legislation applying to active implantable medical devices (“**AIMDs**”). Sequana Medical is obliged to comply with regulatory requirements that include obtaining regulatory approval pursuant to the applicable laws and regulations before it can market or sell its products in each market.

At the date of this Prospectus, the **alfapump**[®] is the only product that has been commercialised by Sequana Medical. Furthermore, the **alfapump**[®] has only received regulatory approval in Europe (through a CE-Mark). The **alfapump**[®] DSR for the treatment of fluid overload in heart failure patients is in the early stage of development and will require substantial technical, pre-clinical and clinical development and testing prior to receiving marketing approval. There can be no assurance that using the **alfapump**[®] DSR will be safe and efficacious, or that the **alfapump**[®] DSR will receive regulatory approval in any market.

In Europe, regulatory approval for the **alfapump**[®] (and potentially in the future, regulatory approval for the **alfapump**[®] DSR and any future products) is obtained via the CE Mark process according to the European Active Implantable Medical Devices Directive 90/385/EEC and subsequent amendments (the “**AIMD Directive**”), which provides approval for the European Economic Area (the “**EEA**”, which includes the European Union (the “**E.U.**”), Iceland, Liechtenstein and Norway) and is accepted by certain other non-EEA countries, including Switzerland. Sequana Medical has received a CE-Mark on the **alfapump**[®] for single patient use in patients with liver refractory ascites for a period of up to 2 years and in patients with malignant ascites with a life expectancy of six months or less. Patients must be at least 18 years or older and may not be pregnant. This approval is limited to those indications and the jurisdictions that accept the CE-Mark. The CE Mark must be renewed every five years, with Sequana Medical’s next renewal being required in 2021; however, medical devices currently on the market in the EEA (such as the **alfapump**[®]) will need to be re-evaluated and re-approved in accordance with the new Medical Devices Regulation (see subsection (h) (Seeking and obtaining regulatory approval under the new Medical Devices Regulation can be an uncertain process, and Notified Bodies have limited resources and may experience backlogs in the transition period leading up to the May 2020 effective date of the new regulations).

In Europe, the **alfapump**[®] and the **alfapump**[®] DSR fall within the scope of radio equipment and are therefore also subject to the Radio Equipment Directive 2014/53/EU (the “**RED**”), which imposes requirements for safety and health, electromagnetic compatibility, and the efficient use of the radio spectrum.

Sequana Medical will also be required to comply with the new Medical Devices Regulation in Europe. On April 5, 2017, the European Parliament passed the Medical Devices Regulation, which repeals and replaces the AIMD Directive. Unlike directives, which must be implemented into the national laws of the member states of the EEA (the “**EEA Member States**”), the new regulations will be directly applicable (i.e., without the need for adoption of EEA member state laws implementing them) in all EEA Member States and are intended to eliminate current differences in the regulation of medical devices among EEA Member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation will become applicable three years after publication (in May 2020). The new regulations may influence the way Sequana Medical conducts business in Europe, and will include, among other things, the following:

- stricter rules for placing devices on the market with increased requirements for CE-Marking, as well as subsequent post-market surveillance and clinical follow-up once they are available;
- explicit provisions on the responsibilities of manufacturers and other supply chain actors for the follow-up of the quality, performance and safety of devices placed on the market;
- better traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- a central database and increased transparency requirements to provide patients, healthcare professionals and the public with comprehensive information on products available in the E.U.;

- stricter rules for the assessment of certain high-risk devices, such as implantable medical devices like the **alfapump**[®] and the **alfapump**[®] DSR, which may have to undergo additional testing (for example, on safety or efficacy) and may be subject to additional scrutiny by independent experts before they are placed on the market; and
- re-approval requirements for medical devices currently on the market in the EEA (such as the **alfapump**[®]) and for the organisations responsible for assessing whether manufacturers and their medical devices meet applicable regulatory requirements (the “**Notified Bodies**”) (see subsection (h) (Seeking and obtaining regulatory approval under the new Medical Devices Regulation can be an uncertain process, and Notified Bodies have limited resources and may experience backlogs in the transition period leading up to the May 2020 effective date of the new regulations) below);

Furthermore, on 23 June 2016, the U.K. held a referendum pursuant to which voters approved an exit from the E.U., commonly referred to as “**Brexit**.” As a result of the referendum, the British government is negotiating the terms of the U.K.’s future relationship with the E.U. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the E.U. and, in particular, any arrangements for the U.K. to retain access to E.U. markets either during a transitional period or more permanently. Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for medical device companies. The U.K. will be one of Sequana Medical’s focus markets, and the additional uncertainties arising from Brexit could adversely affect the ability of Sequana Medical to conduct and expand its operations in the U.K.

In the U.S., regulatory approval for the **alfapump**[®] (and potentially the **alfapump**[®] DSR and/or any future products) is obtained via pre-market approval (“**PMA**”) from the U.S. Food and Drug Administration (the “**FDA**”). The **alfapump**[®] has not yet received a PMA. Timing for regulatory approval via a PMA by the FDA is uncertain, as it depends on the design of the clinical studies to be agreed between Sequana Medical and the FDA, including parameters such as number of subjects and duration of follow-up. The process is expected to take significantly longer than obtaining a CE-Mark and there is a risk that the **alfapump**[®] may not receive a PMA at all. Once granted, the PMA does not have an expiry date, however regulatory approvals may be withdrawn if, for example, a new and unexpected risk emerges which would make continued marketing of the relevant product no longer acceptable. The Federal Communications Commission must also determine that wireless medical devices, such as the **alfapump**[®] and the **alfapump**[®] DSR, are compatible with other uses of the spectrum on which the device operates, and that power levels and the frequency spectrum of the wireless energy transfer comply with applicable regulations. In addition, certain policies of the Trump administration in the U.S. may impact the medical device industry. There have been judicial and Congressional challenges to certain aspects of the Patient Protection and Affordable Care Act (the “**Affordable Care Act**”), as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act and, such challenges and amendments may continue. These actions may adversely affect the healthcare industry in the U.S. and around the world. Sequana Medical cannot predict the likelihood, nature or extent of government regulation that may arise in the U.S. as a result of the Trump administration.

In addition to the U.S. and Europe, Sequana Medical is obliged to comply with regulatory requirements (including obtaining regulatory approval pursuant to the applicable laws and regulations) before it can market or sell its products in each target market. For example, in Canada, medical devices are regulated by Health Canada, the department of the government of Canada with responsibility for national public health, which reviews medical devices to assess their safety, effectiveness, and quality based on clinical data before authorising their sale in Canada according to the Medical Devices Regulation SOR/98-282. Prior to marketing the **alfapump**[®], the **alfapump**[®] DSR and/or any future product in Canada, Sequana Medical must obtain a medical device licence from Health Canada and fulfil the necessary quality requirements established under the Medical Devices Single Audit Program (the “**MDSAP**”). Health Canada also monitors medical devices after they are placed on the market to ensure their continued safety and effectiveness. If a medical device is found to no longer be safe and effective, its medical device license can be suspended or the manufacturer may be requested to recall or refurbish the medical device.

In Israel, European companies importing medical devices must generally request a pre-marketing approval from the Israel Ministry of Health (the “**IMOH**”), and such request is based on an existing CE-Mark. The Israel Ministry of Communication (the “**IMOC**”) also imposes certification requirements on medical devices that transmit and/or receive data in order to protect

the frequency spectrum and telecommunications networks of Israel. IMOH certifications have a five-year validity period; however, if critical components in a product are modified, the updated product must be resubmitted for approval to the IMOH. Sequana Medical has received a pre-marketing approval from the IMOH but has not yet received a certification from the IMOC. Instead Sequana Medical has received a temporary special permission from the IMOC to use a limited number of pumps within Israel. The IMOC may withdraw this special permission at any time, in which case Sequana Medical would not be permitted to market the **alfapump**[®] in Israel without receiving certification from the IMOC. Furthermore, the IMOC has informed Sequana Medical that in order for the **alfapump**[®] to be certified, Sequana Medical will be required to modify the frequency on which the **alfapump**[®] operates. This modification may be costly and time-consuming to implement, and if Sequana Medical is unable to implement this modification on a timely, cost-effective basis, or at all, Sequana Medical may be unable to continue marketing the **alfapump**[®] in Israel.

Sequana Medical may at some time request that the indications for use of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products be expanded, and that expansion of indications is likely to also require regulatory approval. Any change or modification to a device may also require further approvals and must be made in compliance with appropriate regulations. Review of Sequana Medical's regulatory submissions by regulatory agencies may result in requests to perform additional or repeat testing, to redesign one or more aspects of the **alfapump**[®], the **alfapump**[®] DSR or any future products, or to change materials. The regulatory approval process may delay or prevent the launch and/or commercialisation of the **alfapump**[®], the **alfapump**[®] DSR or any future products in target markets, which would negatively impact or prevent Sequana Medical's ability to achieve its milestones. If Sequana Medical fails to obtain approval of the **alfapump**[®], the **alfapump**[®] DSR or any future products in target markets, on a timely basis or at all, the marketing and sale of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in certain markets may be delayed or may not be achieved, which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(e) *Sequana Medical is required to conduct clinical studies for regulatory approvals and other purposes. Clinical studies require approvals, carry substantial risks and may be costly and time consuming, with uncertain results.*

Sequana Medical is required to conduct clinical studies for regulatory approvals and other purposes as described under Part 8 – (Business), section 8.11 (Quality assurance and regulatory affairs), subsection (d) (Clinical studies). Clinical studies may be long, expensive and unpredictable processes that can be subject to extensive delays. Clinical studies may require notification and/or approval in advance by the applicable regulatory authorities, and are subject to approval from institutional review boards and/or ethics committees. These approvals are increasingly difficult to obtain due to, among other things, evolving regulations leading to enhanced levels of scrutiny in the evaluation of study protocols, increasingly complex submission forms and procedures when preparing protocols for review and limited resources available to the regulatory authorities, institutional review boards and/or ethics committees responsible for approval. Clinical studies remain subject to ongoing review and monitoring throughout the duration of the study, and with certain exceptions, changes made to the study protocols after approval is received must also be approved prior to implementation. Failure to obtain or maintain the approvals required to conduct a clinical study on the **alfapump**[®], the **alfapump**[®] DSR and/or any future products could significantly delay or prevent the completion of such study, necessitate additional testing or a re-design of the clinical study, incur significant additional time and costs and/or prevent Sequana Medical from achieving or maintaining profitability.

Clinical studies (including registries such as TOPMOST and the Post Marketing Surveillance Registry (the “PMSR”)) may not produce the anticipated clinical efficacy outcomes, or may uncover previously unknown safety issues or risks. Interim results of clinical studies do not necessarily predict final results, and success in pre-clinical testing and early clinical studies does not ensure that later clinical studies will be successful. Further studies of the **alfapump**[®] or the **alfapump**[®] DSR may uncover product design issues not yet discovered by previous pre-clinical or clinical testing, which could lead to delays or suspension of the clinical studies or market approval while unexpected issues are resolved. In particular, the **alfapump**[®] DSR has not yet been studied in humans and the ongoing Single Dose DSR Proof of Concept is the first in-human study using DSR therapy. As a result the Single Dose DSR Proof of Concept and/or the Repeated Dose DSR Proof of Concept first-in-human studies could uncover issues not previously discovered in pre-clinical

animal models. Even if Sequana Medical obtains final approval to market the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in target markets, future studies or clinical studies may uncover previously unknown safety issues or risks or suggest that the **alfapump**[®], the **alfapump**[®] DSR and/or any future products do not significantly improve clinical outcomes. Such results would slow or possibly stop the adoption of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products, would substantially reduce Sequana Medical's ability to achieve sales estimates and could prevent Sequana Medical from achieving or maintaining profitability.

The performance and/or efficacy of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products may not be demonstrated to the satisfaction of regulatory bodies to allow regulatory approval. For approval to market an AIMD in the U.S., the FDA generally requires a prospective clinical study with results that meet pre-specified endpoints for safety and efficacy. Sequana Medical and the FDA may not agree on a clinical study design or, if a clinical study design is accepted, one or more clinical study endpoints may not be achieved, and that may undermine support for PMA approval. Failure to meet the endpoints may necessitate additional testing or a re-design of the clinical study, incur significant additional time and costs and/or prevent Sequana Medical from achieving or maintaining profitability.

The outcomes of clinical studies are by their nature uncertain and dependent on a number of variables inherent to clinical development, such as the suitability of the clinical study subjects for the therapy, the experience and the expertise of the referring and implanting physicians, the ability and willingness of the clinical study subjects to perform the activities required from their participation in the study, the quality of the clinical follow-up, and the adherence to the study protocol.

Adverse events, both anticipated and unanticipated, occur in clinical studies. Adverse events may be associated with the **alfapump**[®], the **alfapump**[®] DSR and/or any future products, or may be incorrectly ascribed to the **alfapump**[®], the **alfapump**[®] DSR and/or any future products. For example, patients with liver refractory ascites generally have significant co-occurring diseases or disorders and due to their ongoing disease progression experience a significant rate of adverse events such as acute kidney injury (“AKI”) and infections. It can be difficult to determine whether these adverse events are the result of the **alfapump**[®] or are instead due to the co-occurring diseases and disorders that are prevalent in liver refractory ascites patients, and as a result adverse events may be incorrectly ascribed to the **alfapump**[®].

Prior clinical studies involving treatment with the **alfapump**[®] have resulted in patients experiencing serious adverse events, including renal dysfunction and infection. Although it did not affect overall survival at 6 months, in the European Randomised Controlled Trial (the “**European RCT**”) on the **alfapump**[®] versus large volume paracentesis (“LVP”) for the treatment of liver refractory ascites, adverse events and serious adverse events were more common in the **alfapump**[®] group versus the LVP standard of care group and there were significantly more AKI events in the **alfapump**[®] group versus the LVP standard of care group. In addition, prior clinical studies have also resulted in technical complications with the **alfapump**[®], including blockages. While Sequana Medical has enhanced the design of the **alfapump**[®] to improve its technical performance, further technical complications and adverse events may arise in the future. In addition, although Sequana Medical provides training, instructions for use (labelling), and oversight by Sequana Medical's personnel, adverse events resulting from the failure of a physician to follow the instructions for use are out of Sequana Medical's control, have occurred in the past, and may occur again in the future.

Any technical complications and/or adverse events in the clinical studies that are ascribed to the **alfapump**[®], the **alfapump**[®] DSR and/or any future products could result in damage to Sequana Medical's reputation, lawsuits, enrolment difficulties, suspension of clinical studies and/or failure to obtain marketing approval, and/or prevent the **alfapump**[®], the **alfapump**[®] DSR and/or any future products from achieving commercial market acceptance. For example, if the rates of serious adverse events such as AKI in the POSEIDON (North American pivotal) Study are significantly higher in patients during treatment with the **alfapump**[®] as compared to LVP standard of care, the **alfapump**[®] could fail to receive regulatory approval in the U.S. and could fail to gain and/or maintain commercial market acceptance in target markets in Europe.

Furthermore, Sequana Medical is required to fund clinical studies. In particular, Sequana Medical is planning to fund the POSEIDON (North American pivotal) Study, the ongoing Single Dose DSR Proof of Concept, the Repeated Dose DSR Proof of Concept, the Malignant Ascites

CT, the ongoing TOPMOST registry and the Albumin Replacement Study over the next few years (as described about in subsection (c) (Sequana Medical will likely require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available when required or could significantly limit Sequana Medical's access to additional capital). This includes the payment of site costs, professional fees for physicians, fees for one or more contract research organisations (“CROs”), data collection, retention and management, fees for consultants to run committees, and clinical study insurance premiums. Developers of medical devices are usually required to provide products and services at no charge during planned clinical studies, and therefore Sequana Medical does not attract revenue from product sales during such clinical studies. The costs of the clinical studies are high and may exceed the resources available to Sequana Medical, possibly resulting in delayed completion, cost overruns, or failure to complete. Any delay or termination of clinical studies may delay the filings of regulatory submissions and may ultimately impact the ability to commercialise products in target markets and prevent Sequana Medical from achieving or maintaining profitability.

Moreover, at the conclusion of these and future studies, Sequana Medical intends to publish the results. There is a risk that physicians or other parties may prematurely publish clinical results prior to conclusion of the study, which may adversely affect future study enrolment, may have adverse regulatory impact, may prevent Sequana Medical from securing patent protection and may result in diminished competitive position, or damage the reputation of Sequana Medical. Moreover, clinical studies are often conducted by CROs and the failure of the CROs to adequately perform may negatively impact the outcomes of a clinical study (see subsection (ff) (Sequana Medical relies on third parties to conduct its clinical studies, perform data collection and analysis, and provide marketing, regulatory advice and other services that are crucial to its business) below).

Should any of these events occur, they could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(f) *Sequana Medical's manufacturing facilities and those of its third party suppliers are subject to significant regulations and approvals. If Sequana Medical or its third-party manufacturers or suppliers fail to comply with these regulations or maintain these approvals, Sequana Medical's business will be materially harmed.*

Sequana Medical currently manufactures the **alfapump**[®] and the **alfapump**[®] DSR, and has entered into an agreement with third party suppliers to manufacture and supply certain components of the **alfapump**[®] and the **alfapump**[®] DSR. The manufacturing practices of Sequana Medical and its third-party suppliers are subject to ongoing regulation and periodic inspection. Any failure to follow and document the adherence to regulatory requirements (including having in place an adequate quality management system (“QMS”) in line with the most up-to-date standards and regulations) by Sequana Medical or its third party suppliers may lead to significant delays in the availability of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products for commercial sale or clinical studies, may result in the termination of or a hold on a clinical study, or may delay or prevent filing or approval or maintenance of marketing applications for the **alfapump**[®], the **alfapump**[®] DSR and/or any future products.

Failure to comply with applicable regulations could also result in regulatory authorities taking various actions, including:

- levying fines and other civil penalties;
- imposing consent decrees or injunctions;
- requiring Sequana Medical to suspend or put on hold one or more of Sequana Medical's clinical studies;
- suspending or withdrawing regulatory approvals;
- delaying or refusing to approve pending applications or supplements to approved applications;
- requiring Sequana Medical to suspend manufacturing activities, sales, imports or exports of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products;
- requiring Sequana Medical to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, and other issues involving the **alfapump**[®], the **alfapump**[®] DSR and/or any future products;
- mandating product recalls or seizing products;

- imposing operating restrictions; and
- seeking criminal prosecutions.

Any of the foregoing actions could be detrimental to Sequana Medical's reputation and materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(g) *Sequana Medical depends on third party suppliers for services and components used in the production and operation of the alfapump[®] and alfapump[®] DSR, and some of those services and components are supplied from a single source. Disruption of the supply chain, unavailability of third party services required for the production of the alfapump[®] and alfapump[®] DSR, component modifications or failure to achieve economies of scale could have a material adverse effect on Sequana Medical.*

If Sequana Medical has to switch to a replacement supplier for any of its product components or for certain services required for the production and operation of the **alfapump[®]** or the **alfapump[®] DSR** (for example, the sterilisation and coating of the product components), or if Sequana Medical has to commence its own manufacturing to satisfy market demand, it may face additional delays, and the manufacture and delivery of the **alfapump[®]** or the **alfapump[®] DSR** could be interrupted for an extended period of time, which could delay completion of its clinical studies or commercialisation and prevent Sequana Medical from achieving or maintaining profitability. Alternative suppliers may be unavailable, may be unwilling to supply, may not have the necessary regulatory approvals, or may not have in place an adequate QMS. Furthermore, modifications to a service or component made by a third party supplier could require new approvals from the relevant regulatory authorities before the modified service or component may be used.

A third party supplier may be subject to circumstances which impact its ability to supply, including enforcement action by regulatory authorities, natural disasters (e.g. hurricanes and earthquakes), industrial action (e.g. strikes), financial difficulties including insolvency, among a variety of other internal or external factors. Before any products can be considered for marketing approval in the U.S., Europe or elsewhere, Sequana Medical's suppliers may have to pass an audit by the applicable regulatory agencies. Sequana Medical is dependent on the cooperation of its suppliers and the ability of its suppliers to pass such audits. The audits and any audit remediation may be costly. Any identified manufacturing or quality issue may require extensive rework of products or a complete scrapping of the inventory of affected product and could also require suspension of distribution of products or products to be returned for modification.

The **alfapump[®]** and the **alfapump[®] DSR** require customised components and services that are currently available from a limited number of sources. For a number of critical components, Sequana Medical relies on single source suppliers. If these suppliers decide not to supply, are unable to supply, or if they provide Sequana Medical with components or services of insufficient quality, this could harm Sequana Medical's reputation and business. There can be no assurance that Sequana Medical's suppliers will be able or willing to continue to provide Sequana Medical with the components or services it needs, at suitable prices or in sufficient quantity or quality. If any of Sequana Medical's existing suppliers are unable or unwilling to meet its demand for components or services, or if the services or components that they supply do not meet quality and other specifications, clinical studies or sales of the **alfapump[®]** or the **alfapump[®] DSR** could be delayed or halted, which could prevent Sequana Medical from achieving or maintaining profitability. Sequana Medical's suppliers, in turn, depend on their own suppliers and supply chain. For instances where Sequana Medical relies on a single source supplier for a critical component, even if additional suppliers are available to provide a secondary source for these critical components, the addition of a new supplier to the production process generally requires extensive evaluations, testing and regulatory approval, making it difficult and costly for Sequana Medical to diversify its exposure to single source suppliers.

In addition, Sequana Medical's suppliers may discontinue their supply of components or services upon which Sequana Medical relies before the end of the product life of the **alfapump[®]**, the **alfapump[®] DSR** and/or any future products. In the past, a supplier has discontinued its supply of certain components after it deemed Sequana Medical's purchase requirements to be of insufficient volume to justify the enhanced regulatory obligations that affect manufacturers of medical device components. The timing of a discontinuation may not allow Sequana Medical sufficient time to develop and obtain regulatory approval for replacement components or services

before Sequana Medical exhausts its inventory. If suppliers discontinue their supply of components or services, Sequana Medical may have to pay premium prices to its suppliers to keep their production or service lines open or to obtain alternative suppliers, buy substantial inventory to last until the scheduled end of life of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products or through such time as Sequana Medical has an alternative component developed and approved by the regulatory authorities or temporarily cease supplying the **alfapump**[®], the **alfapump**[®] DSR and/or any future products once its inventory of the affected component is exhausted. In the past, Sequana Medical has also been required to purchase excess volumes of inventory for certain components in order to meet minimum volume requirements and/or achieve volume-dependent purchase discounts. Holding large volumes of inventories may increase the risk that Sequana Medical's product component inventory becomes obsolete.

In addition Sequana Medical expects to be required to significantly increase manufacturing volumes as clinical studies on the **alfapump**[®] and/or the **alfapump**[®] DSR are expanded, as the commercialisation of the **alfapump**[®] is expanded and/or the **alfapump**[®] DSR reaches commercialisation, and/or as any future products undergo clinical studies or reach commercialisation. The large majority of the sub-components of the **alfapump**[®] including the batteries, printed circuit board, motor, charger, docking station, catheter and surgical accessories are sourced externally, from approximately 70 suppliers. Most of these suppliers will need to increase their scale of production to meet the projected needs for commercial manufacturing, the satisfaction of which on a timely basis may not be met. If Sequana Medical is unable to secure an adequate supply of sub-components, Sequana Medical may be unable to achieve or maintain successful commercialisation in target markets. In addition, although Sequana Medical's current business expectation is that the cost of goods sold will decline over time as the cumulative volume manufactured grows, Sequana Medical will be required to manage its relationships with approximately 70 suppliers to ensure these suppliers can increase their scale of production to meet the projected needs for manufacturing. Time spent managing these relationships could impose a strain on Sequana Medical's management and resources and diminish any cost efficiencies that are otherwise gained through the cumulative growth in manufacturing volume.

Any of these interruptions to the supply of services or components could result in a substantial reduction in Sequana Medical's available inventory and an increase in its production costs, which may materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(h) *Seeking and obtaining regulatory approval under the new Medical Devices Regulation can be an uncertain process, and Notified Bodies have limited resources and may experience backlogs in the transition period leading up to the May 2020 effective date of the new regulations.*

Notified Bodies are designated by the EEA Member State (the "**Competent Authority**") in which they are based to assess whether manufacturers and their medical devices meet the regulatory requirements in the EEA. Notified Bodies must submit applications for re-designation under the new Medical Devices Regulation to the Competent Authority and the European Commission Medical Device Coordination Group (the body tasked with assisting the European Commission and EEA Member States in ensuring a harmonised implementation of the new Medical Devices Regulation), which may be a lengthy and uncertain process. In these applications, Notified Bodies are required to demonstrate increased technical expertise in their scope of designation, as well as improved quality management systems, as compared to the designation application requirements under the AIMD Directive. Due to the new designation process, the Notified Bodies have been experiencing backlogs during the transition period leading up to the May 2020 effective date of the new regulations. There is also a risk that some Notified Bodies will be judged unfit for re-designation, which would further exacerbate these backlogs as the number of Notified Bodies capable of assessing the sufficiency of medical devices under the Medical Devices Regulation would be further diminished and the workload would need to be absorbed by the remaining Notified Bodies.

Furthermore, any modification to an existing medical device may also require approvals from a Notified Body that the modification has been made in compliance with appropriate regulations. Due to the limited resources of the Notified Bodies during the transition period leading up to the May 2020 effective date of the Medical Devices Regulation, there are likely to be significant delays in the approval process for any modifications made to existing medical devices. Therefore, any

modification to the **alfapump**[®] that would require approval from a Notified Body could delay or prevent the marketing and sale of the **alfapump**[®] in target markets, which would negatively impact or prevent Sequana Medical's ability to achieve its milestones and adversely affect Sequana Medical's ability to generate revenues. In addition to new medical devices, devices currently on the market in the EEA (such as the **alfapump**[®]) will need to be re-evaluated and re-approved in accordance with the new Medical Devices Regulation, which has also further contributed to the backlog of the Notified Bodies. Management believes that Sequana Medical is on track to meeting the new requirements by the deadlines set forth in the Medical Devices Regulation; however, in the event the **alfapump**[®] is not re-approved under the Medical Devices Regulation, on a timely basis or at all, the marketing and sale of the **alfapump**[®] in EEA Member States may be temporarily or permanently prohibited.

Moreover, Sequana Medical's third party distributors in the EEA Member States will also need to be compliant with the new Medical Devices Regulation. If any of Sequana Medical's third party distributors in EEA Member States (such as Fresenius in Belgium and the Netherlands or Vingmed in Denmark) fail to meet the requirements of the new Medical Devices Regulation, on a timely basis or at all, the marketing and sale of the **alfapump**[®] in those EEA Member States by the affected distributor or distributors may be temporarily or permanently prohibited.

Any of the foregoing could be detrimental to Sequana Medical's reputation and materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

- (i) ***Changes in regulatory requirements, guidance from regulatory authorities or unanticipated events (including adverse events and/or severe adverse events) during Sequana Medical's clinical studies could necessitate changes to clinical study protocols or additional clinical study requirements, which would result in increased costs to Sequana Medical and delay the development timeline. Sequana Medical may not be able to afford such additional costs.***

Changes in regulatory requirements, or guidance from the regulatory authorities, or unanticipated events (including adverse events and/or severe adverse events) during Sequana Medical's clinical studies, may force Sequana Medical to amend clinical study protocols. The regulatory authorities could also impose additional clinical study requirements. Amendments to Sequana Medical's clinical study protocols would require resubmission to the competent ethics committees/ethics review boards and may require resubmission to the regulatory authorities for review and approval, which may adversely impact the cost, timing or successful completion of a clinical study and thereby delay or prevent the launch and/or commercialisation of the **alfapump**[®], the **alfapump**[®] DSR or any future products in target markets. If Sequana Medical experiences delays in completing, or if Sequana Medical terminates, any of its clinical studies, or if Sequana Medical is required to conduct additional clinical studies, the costs of the clinical studies are high and may exceed the resources available to Sequana Medical. Any delay or termination of clinical studies may delay the filings of regulatory submissions and may ultimately impact the ability to commercialise products in target markets and prevent Sequana Medical from achieving or maintaining profitability.

- (j) ***Sequana Medical's success is largely contingent on third party payment from government providers, healthcare insurance providers or other public or private sources. Healthcare policy changes, including legislation to reform the U.S. healthcare system, could have a material adverse effect on Sequana Medical. Sequana Medical could fail to achieve or maintain reimbursement levels sufficient to support a commercial infrastructure or realise an appropriate return on its investment in product development, which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.***

The existence of coverage and adequate reimbursement for Sequana Medical's products by government and/or private payers will be critical to market adoption for the **alfapump**[®], the **alfapump**[®] DSR and/or any future products. Physicians and hospitals are unlikely to use the **alfapump**[®], the **alfapump**[®] DSR and/or any future products, at all or to a great extent, if they do not receive adequate reimbursement for the procedures utilising Sequana Medical's product, and potential patients may be unwilling to pay for the **alfapump**[®], the **alfapump**[®] DSR and/or any future products themselves.

In many countries, payment for the **alfapump**[®], the **alfapump**[®] DSR and/or any future products will be dependent on obtaining a “reimbursement code” for the procedure and product. Obtaining a reimbursement code can be a lengthy process (months to years) and there is no guarantee that such a code can be obtained at satisfactory levels, or at all. Following the grant of a “reimbursement code” payers (e.g. national healthcare systems or health insurance companies) have to agree to provide coverage for the procedure(s) that use the **alfapump**[®], the **alfapump**[®] DSR and/or any future products. Failure to obtain attractive reimbursement may materially and adversely affect Sequana Medical’s business, financial condition, results of operations and prospects. In addition, the U.S. will be one of Sequana Medical’s target markets if the **alfapump**[®] and/or the **alfapump**[®] DSR receive marketing authorisation from the FDA. There is a risk that a portion of the patients in the U.S. suffering from recurrent or refractory liver ascites or fluid volume overload in heart failure will not have any form of health insurance, and therefore that those patients will not seek treatment for their conditions, which could have a negative impact on the estimated market sizes for these indications.

In February 2014, the National Institute for Health and Care Excellence (“**NICE**”) in the U.K. issued guidance on the use of the **alfapump**[®] for the treatment of liver refractory and recurrent ascites, recommending that the **alfapump**[®] be used only in the context of research in the U.K. given the limited amount of evidence on the safety and efficacy of the **alfapump**[®] when the guidance was issued. In 2018, NICE initiated a further consultation on the safety and efficacy of the **alfapump**[®], and issued a final recommendation in November 2018 that the **alfapump**[®] be used for the treatment of liver refractory ascites only with special arrangements for clinical governance, consent, and audit or research. The new recommendation was based on evidence from prior studies with key efficacy outcomes to be reduction in need for paracentesis and improvement in quality of life, and key safety outcomes to be incidences of device failure, infection and AKI. NICE recommendations are intended to encourage physicians in the National Health Service (the “**NHS**”) to consider newer procedures that they may not have otherwise used, and to protect patients by advising on the risks and benefits of their use. There is no legal requirement for the NHS to comply with NICE’s recommendations. This means that even though NICE has issued guidance recommending the use of **alfapump**[®] with special arrangements, physicians in the NHS are not legally obligated to use the **alfapump**[®] when treating patients with liver refractory ascites.

Sequana Medical expects to experience pricing pressures in connection with the sale of the **alfapump**[®], as well as the **alfapump**[®] DSR and/or any future products following the receipt of regulatory approval. Generally, hospitals, governments and third-party payers are increasingly exerting downward pressure on pricing and reviewing the cost-effectiveness of medical products, therapies and services. With this global pressure on healthcare costs, payers are attempting to contain costs by, for example, limiting coverage of and the level of reimbursement for new therapies.

In the U.S., following the receipt of regulatory approval, the **alfapump**[®] would be purchased primarily by hospitals or other healthcare providers, with those customers then billing various third-party payers for covered services. There is no uniform policy of coverage and reimbursement among third-party payers. Accordingly, Sequana Medical will be dependent on private insurers approving reimbursement for the **alfapump**[®], as well as the Centers for Medicare & Medicaid Services (the agency responsible for administering the Medicare programme) issuing favourable national coverage for treatment using the **alfapump**[®]. Third-party payers often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process, and therefore coverage and reimbursement policies can differ significantly from payer to payer. The emphasis on managed care and the influence of health maintenance organisations in the U.S. has increased and is expected to continue to increase the pressure on healthcare pricing. Hospitals are financially incentivised to improve the quality of care and consequent patient satisfaction, as well as patient throughput (the cycling of patients through a hospital’s physical resource base). To contain costs, the Centers for Medicare & Medicaid Services and other third-party payers are increasingly challenging the price, scrutinising the medical necessity and reviewing the cost-effectiveness of medical treatments. Similar cost-containment initiatives are also being emphasised in Canada.

In Europe, reimbursement systems vary by country and governments influence the price of medical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. The downward pressure on healthcare costs has also become very intense in Europe, and as a result, increasingly high

barriers are being erected to the entry of new products. In some countries, cross-border imports from lower-priced markets also exert a commercial pressure on pricing. Securing adequate or attractive reimbursement often depends on the successful outcome of a medical economics study, which is a clinical study designed to demonstrate the cost effectiveness of a product or procedure. For example, in order to obtain reimbursement in France, a multi-centre, open-label, randomised medico-economical clinical study (the “**ARIA Pump Study**”) is being conducted in France. The study is being organised and run by a group of French clinicians and Sequana Medical is not funding this study or otherwise involved in the conduct of this study. There is no assurance that this study will demonstrate cost-effectiveness of the **alfapump**[®] in a timely manner or at all, which could leave the **alfapump**[®] without reimbursement in France and materially and adversely affect Sequana Medical’s business, financial condition, results of operations and prospects.

The price that Sequana Medical may receive for, and the marketability of, the **alfapump**[®], the **alfapump**[®] DSR and/or any future products for which Sequana Medical receives regulatory approval may suffer if the government and/or third-party payers fail to provide adequate coverage and reimbursement or if further governmental cost containment or other health reform initiatives are adopted or implemented. From time to time, legislation is enacted that could significantly change the statutory provisions governing the clearance or approval, manufacture, marketing or taxation of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products. In addition, regulations and guidance are often revised or reinterpreted in ways that may significantly affect the **alfapump**[®], the **alfapump**[®] DSR and/or any future products. It is impossible to predict whether legislation changes will be enacted or regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. Sequana Medical cannot predict what healthcare programmes and regulations will be ultimately implemented at the U.S. federal or state level, or at the E.U. level, or within the implementing legislation of the individual E.U. Member States, or the effect of any future legislation or regulation. However, these types of provisions, as adopted, could materially change the way healthcare is delivered and financed, and may materially impact numerous aspects of Sequana Medical’s business. Increasing downward pressure on healthcare pricing and/or any changes that lower reimbursements for Sequana Medical’s products could result in product revenues generated from sales of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products being lower than anticipated. As a result, Sequana Medical could fail to achieve or maintain reimbursement levels sufficient to support a commercial infrastructure or realise an appropriate return on its investment in product development, which could materially and adversely affect Sequana Medical’s business, financial condition, results of operations and prospects.

(k) Sequana Medical may not receive a German Diagnosis Related Group (“G-DRG”) code for the **alfapump[®] in Germany, a target European market.**

In Germany, medical devices are reimbursed according to G-DRG codes, but the receipt of a G-DRG code requires the submission of data collected through usage of the device. To encourage entry of new medical devices into the German healthcare system, there is a short-term, intermediate reimbursement mechanism known as the Neue Untersuchungs- und Behandlungsmethoden (the “**NUB**”) New Research and Treatment Methods) application that provides hospitals with financial incentives to use a new medical device before it is reimbursed under the G-DRG system. Hospitals using the new medical device must submit an application for reimbursement, which (if approved) is available only to those hospitals that applied. NUB reimbursement must be renewed each year.

Although there is an existing NUB reimbursement for the **alfapump**[®] in Germany, Sequana Medical has not yet received and is currently pursuing a G-DRG code for the **alfapump**[®]. The Institut für das Entgeltsystem im Krankenhaus (Institute for the Hospital Remuneration System), which is the organisation responsible for maintaining and developing the G-DRG system, rejected the acceptance of the **alfapump**[®] in the 2016 G-DRG catalogue due to a lack of peer-reviewed papers on the **alfapump**[®] at the time that the proposal for inclusion was submitted. There is no guarantee that a G-DRG code can be obtained, or that if obtained it will provide reimbursement adequate to enable Sequana Medical to build a profitable business selling the **alfapump**[®] in Germany. Failure to obtain an attractive G-DRG code or failure of hospitals to obtain NUB renewals may leave the **alfapump**[®] without reimbursement in Germany and materially and adversely affect Sequana Medical’s business, financial condition, results of operations and prospects.

(l) Competition from medical device companies, pharmaceutical companies, and medical device subsidiaries of large healthcare and pharmaceutical companies is intense and expected to increase.

Sequana Medical may face intense competition from a number of companies that offer solutions and technologies in its target markets and competitors may develop new products or adapt existing products for the same patients that Sequana Medical targets with the **alfapump**[®], the **alfapump**[®] DSR and/or any future products. There can be no assurance that Sequana Medical will be able to compete successfully against its current and future competitors, including competitors with more resources and experience.

Any competitors' products currently in clinical studies or in development or developed in the future could have superior clinical results, could be easier to implement clinically, could be more convenient for patients and/or less expensive than the **alfapump**[®], the **alfapump**[®] DSR and/or any future products or could reach commercialisation sooner in certain target markets. In addition, products are generally provided at no charge during clinical studies. Entry by a competitive product into clinical studies while the **alfapump**[®], the **alfapump**[®] DSR and/or any future products are being commercialised could have an adverse effect on Sequana Medical's sales. Such occurrences could adversely affect Sequana Medical's ability to generate sufficient revenues to sustain its business and/or prevent Sequana Medical from achieving or maintaining profitability.

For the treatment of liver ascites, there are a number of products in development for non-alcoholic steatohepatitis ("NASH"), many of which are being developed by pharmaceutical companies that are far larger, with significantly greater resources than Sequana Medical. It is not clear how these new therapeutics may impact Sequana Medical's target markets, and if any of these products effectively prevent the development of NASH-related ascites, the **alfapump**[®] may be rendered non-competitive or obsolete for the treatment of ascites resulting from NASH.

In addition, the commercial availability of any approved competing product could potentially inhibit recruitment and enrolment in Sequana Medical's clinical studies. Sequana Medical may successfully conclude its clinical studies and obtain final regulatory approval, but may fail to compete against competitors or alternative treatments that may be available or developed for the relevant indication. Alternative treatments include drugs, devices and surgery, among others. New treatment options, or modifications of existing treatments, may emerge which yield clinical results equal to or better than those achieved with the **alfapump**[®], the **alfapump**[®] DSR and/or any future products, possibly at a lower cost. Emergence of such new therapies may inhibit Sequana Medical's ability to develop and grow the market for the **alfapump**[®], the **alfapump**[®] DSR and/or any future products. Furthermore, new entrants into the markets in which Sequana Medical operates could also decide to more aggressively compete on price, requiring Sequana Medical to reduce prices in an effort to maintain market share. Any inability by Sequana Medical to compete effectively against other medical device companies, pharmaceutical companies, or medical device subsidiaries of large healthcare and pharmaceutical companies, or to effectively manage the risks related to competition may materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(m) Sequana Medical has entered into a loan agreement with Bootstrap, which contains covenants that may limit Sequana Medical's ability (or require Bootstrap's prior consent) to take certain actions including the incurrence of certain additional indebtedness. Sequana Medical may not have cash available in an amount sufficient to enable Sequana Medical to make interest or principal payments on its indebtedness when due.

In 2016, Sequana Medical entered into the Bootstrap Loan for up to an aggregate of CHF 10.0 million. Sequana Medical has pledged to Bootstrap its intellectual property as well as the related assets as security for the Bootstrap Loan. The agreement for the Bootstrap Loan was amended in 2017, and again thereafter in 2018 as described under Part 7 – (Operating and financial review and prospects), section 7.4 (Liquidity and capital resources), subsection (a) (General).

The New Shares in the Offering can also be subscribed for through a contribution in kind by Bootstrap of 50% of the payable due by the Issuer upon the closing of the Offering as an "Exit Fee" pursuant to the Bootstrap Loan. The remaining portion of the Exit Fee shall be repaid in cash by the Issuer following the closing of the Offering. As provided for by the Bootstrap Loan, the Exit Fee shall not exceed a maximum of CHF 750,000. The portion of the Exit Fee payable that shall be so contributed in kind, but that cannot be used for the subscription for a whole number of New

Shares at the Offer Price shall not be contributed in kind, but remains payable in cash (subject to the terms of the Bootstrap Loan). In case of an over-subscription of the Offering, the allocation to Bootstrap of Shares in consideration of the contribution in kind of 50% of the Exit Fee payable shall not be reduced.

At the date of this Prospectus, CHF 5.9 million in principal and interest is outstanding. Up to €1.5 million of the proceeds from the Offering will be used for the repayment of outstanding principal and €0.44 million will be used for the payment of accrued and unpaid interest on the Bootstrap Loan. The remaining principal amount will then be due in four substantially equal consecutive instalments on each of 31 December 2020, 31 January 2021, 28 February 2021 and 31 March 2021. Management expects that it will need to raise additional indebtedness for the repayment of these amounts. As a result, the Bootstrap Loan may create additional financial risk for Sequana Medical, particularly if Sequana Medical's business or prevailing financial market conditions are not conducive to refinancing, or alternatively paying off, the outstanding debt obligations on or before 31 December 2020 when the principal repayments on the Bootstrap Loan start becoming payable.

Failure of Sequana Medical to satisfy its current and future debt obligations under the Bootstrap Loan could result in an event of default. Sequana Medical has failed to make payments when due on the Bootstrap Loan in the past, and there is a risk that Sequana Medical could fail to make payments when due in the future.

Furthermore, at the date of this Prospectus, the Bootstrap Loan also includes covenants, which may limit Sequana Medical's ability (or require Bootstrap's prior consent) to:

- incur or guarantee financial indebtedness from a lender other than Bootstrap, unless such indebtedness is fully subordinated to the Bootstrap Loan, a finance lease, bank debt, rental agreement or similar instrument or form of loan finance up to an aggregate amount of CHF 5 million, trade credit of 90 days or less or other unsecured non-interest bearing debt arising in the ordinary course of business;
- make certain investments or acquisitions;
- create liens or otherwise grant security on certain assets;
- lend funds from the Issuer to one of its subsidiaries;
- restructure, consolidate, merge, sell, transfer, lease or otherwise dispose of all or any substantial part of its assets; and
- make distributions by way of dividends or otherwise.

The Bootstrap Loan does not limit the Issuer's ability to issue additional Shares; however, it does prohibit the Issuer from permitting any of its subsidiaries to issue securities of any kind other than to Bootstrap or employee stock options. If Sequana Medical fails to comply with any of the covenants to take or avoid the actions specified above, this could result in an event of default.

If an event of default occurs, Bootstrap could accelerate all of the amounts due. In the event of an acceleration of amounts due as a result of an event of default, Sequana Medical may not have sufficient funds or may be unable to arrange for additional financing to repay its indebtedness while still pursuing its current business strategy. In addition, Bootstrap could seek to enforce their security interests in the collateral securing the Bootstrap Loan. Sequana Medical's success depends significantly on its ability to protect and maintain its intellectual property related to the **alfapump**[®] and the **alfapump**[®] DSR. Enforcement by Bootstrap of their security interests in the pledged collateral securing the Bootstrap Loan could result in Bootstrap taking ownership of Sequana Medical's intellectual property and related assets, which could prevent Sequana Medical from, among other things, marketing the **alfapump**[®], pursuing the further development of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products or otherwise using technology that is based on the pledged collateral, and which would materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

The Bootstrap Loan contains events of default that are customary for facilities of this type, including, but not limited to, non-payment of principal, interest or other amounts when due, failure of any representation or warranty to be true in any material respect when made or deemed made, violation of covenants, cross default, bankruptcy events, invalidity of the loan documents and events or circumstances having a material adverse effect. Upon the occurrence of an event of

default, the outstanding obligations under the Bootstrap Loan may be accelerated and become due and payable immediately or Bootstrap could seek to enforce their security interests.

Moreover, the Bootstrap Loan provides that Bootstrap may cancel any undrawn part of the facility and declare all outstanding amounts under the Bootstrap Loan immediately due and payable if a change of control occurs, whereby “change of control” is to be understood as the key shareholders collectively ceasing to directly hold or have the power to cast, or control the cast of, at least 50.1% of (i) the issued share capital or (ii) the voting rights relating to the issued share capital, or any sale of (a) any or all assets related to the Issuer’s liver or heart business with a minimum net value of at least CHF 10 million or (b) all or substantially all of the assets or business of the Issuer.

If any of these factors materialise, Sequana Medical’s business, results of operations, financial condition and prospects could be materially and adversely affected.

(n) Any inability to fully protect and exploit Sequana Medical’s intellectual property may adversely impact Sequana Medical’s financial performance and prospects.

Sequana Medical’s success will depend significantly on its ability to protect its proprietary rights, including the intellectual property related to the **alfapump**[®] and the **alfapump**[®] DSR. Sequana Medical relies on a combination of patent protection, trademarks and trade secrets, and Sequana Medical uses non-disclosure, confidentiality and other contractual agreements to protect its proprietary technology. Sequana Medical generally seeks patent protection where possible for those aspects of its technology and products that it believes provide significant competitive advantages. However, Sequana Medical may be unable to adequately protect its intellectual property rights (see subsection (bb) (Intellectual property rights do not necessarily address all potential threats to Sequana Medical’s competitive advantage) below) or may become subject to a claim of infringement or misappropriation, which it is unable to settle on commercially acceptable terms (see subsection (cc) (Sequana Medical could become subject to intellectual property litigation that could be costly, result in the diversion of management’s time and efforts, require Sequana Medical to pay damages, prevent Sequana Medical from marketing the **alfapump**[®] and/or reduce the margins for the **alfapump**[®]) below). Sequana Medical cannot be certain that patents will be issued with respect to Sequana Medical’s pending or future patent applications. In addition, Sequana Medical does not know whether any issued patents will be upheld as valid or proven enforceable against alleged infringers or that they will prevent the development of competitive patents or provide meaningful protection against competitors or against competitive technologies.

The process of obtaining patents involves filing applications in multiple jurisdictions, and may take many years. Success in one jurisdiction does not guarantee success in another jurisdiction, particularly as different jurisdictions may apply different legal principles. For example, it is possible to obtain a patent for a medical method in the U.S., but such patents cannot be obtained in Europe. Therefore, there may be circumstances where an invention is patentable in one jurisdiction but a patent cannot be obtained in other jurisdictions.

In responding to a patent application, a patent office may reject one or more claims of the application. This may lead to an extensive and time consuming dialogue between Sequana Medical and the patent office in an effort by Sequana Medical to reach agreement with regard to the issuance of some of its claims. There is no assurance that such efforts will successfully result in issued patent claims, whether or not of any value.

There is no assurance that Sequana Medical’s intellectual property rights will not be challenged, invalidated, circumvented or rendered unenforceable. Sequana Medical’s competitors or other third parties may successfully challenge and invalidate or render unenforceable Sequana Medical’s issued patents, including any patents that may be issued in the future. This could prevent or limit Sequana Medical’s ability to stop competitors from marketing products that are identical or substantially equivalent to the **alfapump**[®], the **alfapump**[®] DSR and/or any future products. In addition, competitors may be able to design around Sequana Medical’s patents or develop products that provide outcomes that are comparable to the **alfapump**[®], the **alfapump**[®] DSR and/or any future products but that are not covered by Sequana Medical’s patents. Much of Sequana Medical’s value is in its intellectual property, and any challenge to Sequana Medical’s intellectual property portfolio (whether successful or not) may impact its value. Non-specific claims of inventorship have been made with respect to the **alfapump**[®] and the **alfapump**[®] DSR by a former officer and director of Sequana Medical, but these were non-specific and no evaluation thereof could be made.

Sequana Medical decides on a case by case basis the countries in which to seek patent protection. It is not economically feasible or practical to seek patent protection in every country, and it is possible that one or more third parties may develop and market devices similar or identical to the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in countries where Sequana Medical has not obtained patent protection. Sequana Medical may not be able to prevent such third party action, which may limit Sequana Medical's ability to pursue those markets.

(o) *Attracting physicians and subjects to perform clinical studies and meet clinical study objectives is costly and uncertain. If Sequana Medical experiences delays or difficulties in the recruitment of Investigators or enrolment of subjects in clinical studies, its receipt of necessary regulatory approvals could be delayed or prevented.*

Performing clinical studies requires the engagement of many hospitals, clinics, and clinicians. In particular, Sequana Medical must engage a physician at each clinical study centre to maintain overall responsibility for conduct of the clinical study (the "**Investigator**"). Each Investigator may have additional physicians working under his or her direction to conduct a study. Sequana Medical may not be able to attract sufficient qualified Investigators to conduct clinical studies within an adequate time, and those Investigators may not be able to attract or enrol sufficient subjects to meet Sequana Medical's clinical study objectives.

Clinical study subjects may be sourced from the Investigator's own practice clinic or hospital, or may be referred from another physician. Potential clinical study subjects must sign an informed consent before undergoing certain clinical tests to determine whether the subject meets the enrolment criteria for the clinical study (inclusion and exclusion). Once a subject is enrolled in the clinical study, the subject must comply with the study requirements and undergo tests. Some subjects may not comply with the requirements of the study, thereby leading to poor or unusable data, or may withdraw from the study, which may compromise the results of the clinical study.

Sequana Medical may not be able to initiate or continue clinical studies if it is unable to locate and enrol a sufficient number of eligible subjects within the required recruitment period to participate in these studies as required by the applicable regulatory authorities in the U.S., Europe, Canada and any other applicable jurisdictions.

Subject enrolment may be affected by other factors including:

- the fact that the **alfapump**[®] and the **alfapump**[®] DSR are implantable devices requiring clinical study subjects to undergo surgery;
- the severity of the disease under investigation;
- the subject eligibility criteria for the study in question;
- the perceived risks and benefits of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products for the indication under study;
- the referral practices of physicians;
- the ability to monitor subjects adequately during and after treatment;
- the proximity and availability of clinical study sites for prospective subjects;
- the approval of other devices or therapeutics for target indications; and
- other clinical studies for the same target patient group.

Any difficulties in enrolling a sufficient number of subjects for any of its clinical studies could result in significant delays and could require Sequana Medical to abandon one or more clinical studies altogether. Enrolment delays in Sequana Medical's clinical studies may result in increased development costs that may exceed the resources available to Sequana Medical and in delays to commercially launching the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in target markets, if approved. If any of these factors materialise, Sequana Medical's business, results of operations, financial condition and prospects could be materially and adversely affected.

(p) *Even though Sequana Medical has obtained regulatory approval in Europe for the alfapump[®] in liver refractory ascites and malignant ascites, there is no guarantee that the alfapump[®] will perform as intended.*

Even though Sequana Medical has obtained final regulatory approval in Europe for the **alfapump**[®] in liver refractory ascites and malignant ascites, the performance of the **alfapump**[®] in the market may be different from the performance observed during the clinical studies for a

number of reasons, including less control on the selection of people suitable for use of the products, use by physicians with different experience and/or training, and failure to adhere to a follow-up regimen in the absence of clinical study enrolment and oversight.

Furthermore, issues with product performance may subsequently be identified once a product is in the market. In the EEA, Sequana Medical must comply with the E.U. Medical Device Vigilance System. Under this system, incidents must be reported to the relevant authorities of the Member States of the EEA, and manufacturers may be required to take Field Safety Corrective Actions (“FSCAs”) to reduce the risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to, or might have led to, the death of a patient, user or other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

In addition, the FDA requires medical device manufacturers to monitor and report adverse events as part of the medical device reporting (“MDR”) regulations so that safety issues can be identified and addressed quickly. When such issues are identified, the FDA may require corrective actions – such as modifying labelling or instructions for use, improving training, or removing the device from the market – to ensure proper use or patient safety. Any of these could result in significant time and expense to correct and may harm the reputation of Sequana Medical. Such issues may result in the need for the **alfapump**[®] to be suspended from sale or withdrawn from the market. In these circumstances the **alfapump**[®] may require substantial redesign and/or re-engineering to address any identified issues. This may result in Sequana Medical needing to undertake further clinical studies to re-establish the safety and efficacy of the revised product, which would be costly and time consuming and may exceed the resources of Sequana Medical. Similar reporting requirements exist for devices approved within the regulatory frameworks of other countries.

Moreover, as part of or following the FDA grant of a PMA for the **alfapump**[®] in the U.S., the FDA may require Sequana Medical to conduct one or more post-approval studies (“PAS”), which could be extensive, expensive and take additional time, effort and capital to complete. The PAS may uncover problems with the **alfapump**[®] and may result in a need to redesign certain aspects of the **alfapump**[®], a need to conduct additional studies and/or possible suspension from sale. The requirement for corrective actions in response to MDRs, as well as a PAS may delay or inhibit Sequana Medical’s ability to market the **alfapump**[®] in target markets.

The **alfapump**[®] is subject to extensive testing to international technical standards. Testing may uncover problems or non-compliance with standards that may require a substantial product redesign, resulting in extensive delays and additional costs. Changes in standards may require re-testing of the **alfapump**[®], and there is no assurance that compliance with an earlier standard will also mean compliance with a more recent version of a standard. Such consequences could materially and adversely affect Sequana Medical’s business, financial condition, results of operations and prospects.

(q) Sequana Medical may not be able to manufacture or outsource manufacturing of the **alfapump[®], the **alfapump**[®] DSR and/or any future products in sufficient quantities, in a timely manner or at a cost that is economically attractive.**

Sequana Medical’s revenues and other operating results will depend, in large part, on its ability to manufacture and sell the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in sufficient quantities and quality, in a timely manner, and at a cost that is economically attractive.

Although Sequana Medical has produced more than 1,000 **alfapump**[®] systems at the date of this Prospectus, Sequana Medical expects to be required to significantly increase manufacturing volumes as clinical studies on the **alfapump**[®] and/or the **alfapump**[®] DSR are expanded, as the commercialisation of the **alfapump**[®] is expanded and/or the **alfapump**[®] DSR reaches commercialisation, and/or as any future products undergo clinical studies or reach commercialisation. In order to support future demand for the **alfapump**[®], the **alfapump**[®] DSR and/or any future products, Sequana Medical would likely need to expand its manufacturing capacity, which could require relocating to a new facility or outsourcing to a third party contract manufacturing organisation (a “CMO”). Relocating to a new manufacturing facility could involve

significant additional expenses, including for the construction of a new facility, the movement and installation of key manufacturing equipment, the modification of manufacturing processes, and for the recruitment and training of new team members. In addition, Sequana Medical must also notify, and in most cases obtain approval from, regulatory authorities of any changes or modifications to its manufacturing facilities and processes, and there can be no assurance that the regulatory authorities will authorise Sequana Medical to proceed. Any failure by Sequana Medical to expand or to outsource its manufacturing capacity to meet future demand could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Furthermore, if Sequana Medical outsources production to a CMO, there can be no assurance that the contracted CMO will be able to manufacture Sequana Medical's products in sufficient quantities, to the same exacting standards and at an economically attractive cost, or at all. In all of these cases, the commercialisation of the **alfapump**[®], the **alfapump**[®] DSR and/or any future product may be material and adversely affected, which could prevent Sequana Medical from achieving or maintaining profitability.

Sequana Medical manufactures the **alfapump**[®] and the **alfapump**[®] DSR according to manufacturing best practices applicable to medical devices and to specifications approved by the applicable regulatory authorities. If the **alfapump**[®] or the **alfapump**[®] DSR is found to be non-compliant, Sequana Medical would be required to manufacture the **alfapump**[®] and/or the **alfapump**[®] DSR again, which would entail additional costs and may prevent delivery of the **alfapump**[®] or the **alfapump**[®] DSR to patients on time.

In addition, Sequana Medical's current business expectation is that the cost of goods sold will decline over time as the cumulative volume manufactured grows. However, there is no guarantee that Sequana Medical and/or its suppliers will be able to increase yields and/or decrease manufacturing costs with time, and in fact costs may increase, which could prevent Sequana Medical from achieving or maintaining profitability.

Any of the foregoing could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(r) *The success of the alfapump[®], the alfapump[®] DSR and/or any future products depends on its acceptance and adoption by physicians.*

The success of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products will require acceptance and adoption by physicians. Such acceptance will depend on physicians being convinced of the distinctive characteristics, clinical performance, benefits, safety and cost-effectiveness of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products and being prepared to undertake special training in certain cases. Furthermore, physicians will most likely not adopt the **alfapump**[®], the **alfapump**[®] DSR and/or any future products unless they determine, based on experience, clinical data, and published peer-reviewed journal articles, that the **alfapump**[®], the **alfapump**[®] DSR and/or any future products are an attractive treatment solution.

Even if the safety and efficacy of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products is established, physicians may be hesitant to change their medical treatment practices or accept and adopt the **alfapump**[®], the **alfapump**[®] DSR and/or any future products, including for the following reasons:

- general conservatism about the adoption of new treatment practices;
- history of adverse events and severe adverse events;
- lack or perceived lack of long-term evidence supporting additional patient benefits;
- perceived liability risks associated with the use of new products and procedures;
- limited or lack of reimbursement and coverage within healthcare payment systems;
- cost associated with the purchase of new products and equipment;
- other procedures competing for physician time and attention;
- the fact that the **alfapump**[®] and the **alfapump**[®] DSR are implantable devices requiring surgery for implantation;
- the time commitment that may be required for special training;
- insufficient level of commercial attractiveness to physicians;
- the extent of ongoing support required by the clinician; and

- the extent of ongoing involvement of the patient in therapy.

Economic, psychological, ethical and other concerns may also limit general acceptance and adoption of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products. Lack of acceptance and adoption of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products by a sufficient number of relevant physicians would substantially reduce Sequana Medical's ability to achieve sales estimates, prevent Sequana Medical from achieving or maintaining profitability and materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(s) *Active implantable medical devices such as the alfapump[®] and the alfapump[®] DSR carry risks associated with the surgical procedure for implant or removal of the device, use of the device, or the therapy delivered by the device.*

The **alfapump**[®] and the **alfapump**[®] DSR are medical devices with complex electronic circuits and software. It is not possible to design and build electronic medical devices that are 100% reliable, as all electronic devices carry a risk of failure. Furthermore, all surgical procedures carry risks and the effectiveness of any medical therapy varies between patients. The consequences of failure of the **alfapump**[®] and/or the **alfapump**[®] DSR, complications arising through product use and associated surgical procedures can range from minor to life-threatening effects and even death.

All medical devices have associated risks. Regulatory authorities regard AIMDs as the highest risk category of medical devices, and accordingly, AIMDs are subject to the highest level of scrutiny when seeking regulatory approval. The risks include, among others, risks associated with any surgical procedure, such as infection, allergic reaction, and consequences of anaesthesia and risks associated with any implantable medical device such as device movement, electromagnetic interference, device failure, tissue damage including nerve damage, pain, and psychological effects. Comprehensive lists of the risks associated with the **alfapump**[®] are included in the documentation (labelling) provided with the device to both physicians and patients. Prior clinical studies involving treatment with the **alfapump**[®] have resulted in patients experiencing serious adverse events, including renal dysfunction and infection, as further described above under subsection (e) (Sequana Medical is required to conduct clinical studies for regulatory approvals and other purposes. Clinical studies require approvals, carry substantial risks and may be costly and time consuming, with uncertain results).

Adverse events associated with these risks may lead some patients to blame Sequana Medical, the physician or other parties for such occurrences. This may result in product liability lawsuits, medical malpractice lawsuits, investigations by regulatory authorities, adverse publicity, criminal charges or other harmful circumstances for Sequana Medical. Any of those circumstances may have a material adverse effect on Sequana Medical's ability to conduct its business, to continue selling the **alfapump**[®], to achieve revenue objectives, or to develop the **alfapump**[®] DSR and/or future products.

(t) *Sequana Medical faces an inherent risk of product liability claims and may not have adequate insurance coverage.*

Medical device manufacturers are exposed to the risk of potential product liability claims arising from device failures and malfunctions, product use and associated surgical procedures. A product liability claim may be raised as a result of factors outside the control of the manufacturer, such as off-label use of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products, or failure of the medical practitioners or patients to follow the instructions for use. Consolidation of product liability claims into a class action lawsuit may require large dedication of resources for defence, which will be time consuming, costly, and a major distraction from the running of the business. It is possible that a product liability lawsuit may be lost through no fault of Sequana Medical, which could result in reputation risk, increased insurance premiums, and depression of future sales, all of which may materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Sequana Medical maintains product liability insurance at levels which management believes are in line with market practice. To date, no product liability claim has been initiated against Sequana Medical. However, Sequana Medical cannot provide any assurance that it will be able to maintain sufficient insurance coverage on commercially acceptable terms in the future, or that its insurance coverage will provide adequate protection against all potential risks. As a consequence,

Sequana Medical might have to face liabilities for a claim that may not be covered by its insurance or its liabilities could exceed the limits of its insurance. In addition, Sequana Medical's insurance policies will not protect Sequana Medical against any reputational harm that it may suffer if the market perceives its products to be unreliable or defective. Any of the foregoing could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(u) *If Sequana Medical's products are defective, or otherwise pose safety risks, the relevant governmental authorities could require their recall, or Sequana Medical may need to initiate a recall of its products voluntarily.*

AIMDs are characterised by a complex manufacturing process, requiring adherence to demanding product specifications. The **alfapump**[®] and the **alfapump**[®] DSR use many disciplines including electrical, mechanical, software, biomaterials, and other types of engineering. Device failures discovered during the clinical study phase may lead to suspension or termination of the study, which could have a material adverse effect on Sequana Medical. In addition, device failures and malfunctions may result in a recall of the product, which may relate to a specific manufacturing lot or may impact all products in the field. Recalls may occur at any time during the life cycle of a device once regulatory approval has been obtained for the commercial distribution of the device. For example, engineers employed by Sequana Medical undertaking development or manufacturing activities may make an incorrect decision or make a decision during the engineering phase without the benefit of long term experience, and the impact of such wrong decisions may not be felt until well into a product's life cycle. The relevant governmental authorities may require the recall of commercialised products in the event of material deficiencies, or defects in design or manufacture, or in the event that a product poses an unacceptable risk to health. Manufacturers, on their own initiative, may recall a product if any material deficiency in a device is found. A government mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labelling defects or other deficiencies and issues.

Recalls of the **alfapump**[®], the **alfapump**[®] DSR and/or any future products would divert managerial and financial resources, can result in damaged relationships with regulatory authorities such as the FDA, lead to loss of market share to competitors and materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects. In addition, any product recall may result in irreparable harm to Sequana Medical's reputation. Any product recall could impair Sequana Medical's ability to produce products in a cost-effective and timely manner in order to meet Sequana Medical's customers' demands. Sequana Medical may also be required to bear other costs, or take other actions that may have a negative impact on future revenue and could prevent Sequana Medical from achieving or maintaining profitability.

(v) *Sequana Medical may be unable to attract and retain management and other personnel it needs to succeed.*

Sequana Medical relies on the expertise and experience of the board of directors, management and other key employees and contractors in management, engineering, manufacturing, clinical and regulatory matters, sales and marketing, and other functions. The retention and performance of the board of directors, senior management and other key employees are therefore significant factors in Sequana Medical's ability to achieve its objectives. The departure of any of these individuals (in particular the Chief Executive Officer) from Sequana Medical without timely and adequate replacement or the loss of any of Sequana Medical's senior management or other key employees may materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects, and there can be no assurance that Sequana Medical would be able to find and attract other individuals with similar levels of expertise and experience or similar relationships with commercial partners and other market participants. In addition, Sequana Medical's competitive position could be materially and adversely affected if a member of senior management transferred to a competitor.

Sequana Medical currently expects to expand its operations and grow its clinical development, manufacturing, administrative and commercial operations. Sequana Medical's growth will require hiring a number of qualified clinical, scientific, commercial and administrative personnel. Competition for skilled personnel is intense and may limit Sequana Medical's ability to hire and retain highly qualified personnel on acceptable terms or at all. Competitors may have greater financial and other resources, different risk profiles and a longer history than Sequana Medical. If

Sequana Medical is unable to identify, attract, retain and motivate these highly skilled personnel, it may be unable to continue its development, commercialisation or growth. In addition, Sequana Medical relies on consultants who may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to Sequana Medical.

(w) For the marketing of the *alfapump*[®], Sequana Medical will be largely dependent on Fresenius in Belgium and the Netherlands, Vingmed in Denmark and Gamida in Israel.

For the marketing of the *alfapump*[®], Sequana Medical has entered into exclusive distribution agreements with Fresenius in Belgium and the Netherlands, Vingmed in Denmark and Gamida in Israel. The marketing and commercial success of the *alfapump*[®] in these countries will be largely driven by the efforts of Fresenius, Vingmed and Gamida and will depend on marketing and commercial efforts deployed by these third parties. Although the *alfapump*[®] has not received reimbursement in these countries, Sequana Medical's distribution partners are able to secure payment for the *alfapump*[®] systems that are sold via special innovation or other funds that have been established in these countries.

Sequana Medical expects that its product revenues would be adversely impacted with the loss or transition of these or any future distributors of the *alfapump*[®], the *alfapump*[®] DSR and/or any future products. If Sequana Medical chooses to terminate any of its distribution agreements, Sequana Medical would either need to reach an agreement with, qualify, train and supply a replacement distributor or supply and service customer accounts in those territories itself, and there can be no assurance that this would happen in a timely manner or at all. These factors may be disruptive for Sequana Medical's customers, and Sequana Medical's reputation may be damaged as a result. Sequana Medical's distributors may have more established relationships with potential customers than a new distributor or Sequana Medical may have in particular territories, which could adversely impact Sequana Medical's ability to successfully commercialise the *alfapump*[®], the *alfapump*[®] DSR and/or any future products in these territories. In addition, it may take longer for Sequana Medical to be paid if payment timing and terms in these new arrangements are less favourable to Sequana Medical than those in Sequana Medical's existing distribution arrangements. Current or transitioning distributors may irreparably harm relationships with local existing and prospective customers and Sequana Medical's standing with the medical device community in general. In the event that Sequana Medical is unable to find alternative distributors or mobilise its own sales efforts in the territories in which a particular distributor operates, Sequana Medical's customer supply and reputation may be negatively affected which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(x) If Sequana Medical is unable to expand its sales, marketing and distribution capabilities for the *alfapump*[®], the *alfapump*[®] DSR and/or any future products, whether it be with internal infrastructure or an arrangement with a commercial partner such as the ones that Sequana Medical has entered into with Fresenius, Vingmed and Gamida, Sequana Medical may not be successful in commercialising the *alfapump*[®], the *alfapump*[®] DSR and/or any future products in its target markets, if and when they are approved.

Sequana Medical will need to expand its internal sales and marketing organisation to commercialise the *alfapump*[®], the *alfapump*[®] DSR and/or any future products in markets that it will target directly. There are risks involved with expanding Sequana Medical's own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay launch. In addition, Sequana Medical may experience challenges in recruiting qualified sales and marketing personnel.

Furthermore, Sequana Medical intends to enter into additional distribution agreements to distribute its products in other markets. If Sequana Medical is unable to find suitable distribution partners, loses these distribution partners or if Sequana Medical's distribution partners fail to sell its products in sufficient quantities, on commercially viable terms or in a timely manner, the commercialisation of the *alfapump*[®], the *alfapump*[®] DSR and/or any future products could be materially harmed, which could prevent Sequana Medical from achieving or maintaining profitability.

Further factors that may inhibit Sequana Medical's efforts to commercialise the *alfapump*[®], the *alfapump*[®] DSR and/or any future products in target markets include the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any of Sequana Medical's future products, and the lack of complementary products to be offered

by sales personnel, which may put Sequana Medical at a competitive disadvantage relative to companies with more products.

If Sequana Medical is unable to expand its own sales, marketing and distribution capabilities or enter into arrangements with other third parties to perform these services, Sequana Medical's revenue and profitability may be negatively affected which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(y) *Sequana Medical's future profitability may depend on its ability to penetrate markets outside of Europe and North America, where Sequana Medical would be subject to additional regulatory burdens and other risks and uncertainties.*

Sequana Medical's future profitability may depend on its ability to commercialise the **alfapump**[®] in markets outside of Europe and North America. If Sequana Medical commercialises the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in markets outside of Europe and North America, Sequana Medical would be subject to additional risks and uncertainties, including:

- economic weakness, including inflation, or political instability in particular economies and markets;
- the burden of complying with complex and changing regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs affecting acceptance in the marketplace;
- tariffs and trade barriers;
- other trade protection measures, import or export licensing requirements or other restrictive actions by the U.S. or other governments;
- longer accounts receivable collection times;
- longer lead times for shipping;
- compliance with tax, employment, immigration and labour laws for employees living or traveling abroad;
- workforce uncertainty in countries where labour unrest is common;
- language barriers for technical training;
- reduced protection of intellectual property rights in some countries outside of Europe, and related prevalence of generic alternatives to therapeutics;
- currency exchange rate fluctuations and currency controls;
- differing reimbursement landscapes;
- uncertain and potentially inadequate reimbursement of Sequana Medical's products; and
- the interpretation of contractual provisions governed by the laws of countries outside of Europe and North America in the event of a contract dispute.

These risks could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(z) *The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about medical devices. If Sequana Medical is found to have made false or misleading claims about the alfapump[®] and/or the alfapump[®] DSR and/or any future products, or otherwise have violated promotion or advertising restrictions, Sequana Medical may become subject to significant fines and/or other liabilities.*

In Sequana Medical's target markets, Sequana Medical's promotional materials and training methods must comply with numerous applicable laws and regulations. Use of a device outside of its cleared or approved indication is known as "off-label" use. Sequana Medical has only a limited influence over its distribution partners' marketing activities. Although Sequana Medical trains its distribution partners not to promote its products for "off-label" uses, and Sequana Medical's instructions for use in all markets specify that its products are not intended for use outside of those indications cleared for use, it cannot provide any assurance that no competent regulatory agency will hold Sequana Medical responsible for engaging in "off-label" promotion. If a relevant governmental authority determines that Sequana Medical's promotional materials or training constitute promotion of an "off-label" use, it could request modifications to Sequana Medical's

training or promotional materials or subject Sequana Medical to regulatory or enforcement actions, which may include the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. U.S, E.U. or other applicable governmental authorities might also take action if they consider Sequana Medical's promotional or training materials to constitute promotion of an un-cleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, Sequana Medical's reputation could be damaged and adoption of Sequana Medical's products could be impaired. If Sequana Medical was held so responsible, this may materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(aa) Compliance with regulations for quality systems for medical device companies is difficult, time consuming and costly. Sequana Medical may be found to be non-compliant, for example as a result of future changes in or interpretation of the regulations regarding quality systems in certain jurisdictions.

Sequana Medical has developed and maintains a QMS to ensure quality of Sequana Medical's products and activities. The system is designed to be in compliance with regulations in many different jurisdictions, including the Quality Systems Regulations (QSR) mandated by the FDA, and the requirements of the AIMD Directive, including the international standard ISO13485 required by the countries in Europe that recognise the CE Mark and Israel. In some circumstances, the requirements of regulations and standards may be different.

In the past, medical devices sold in Canada had to have their QMS assessed under the Canadian Medical Devices Conformity Assessment System ("CMDCAS"). This option will not be available from January 2019 onwards. From 1 January 2019 any manufacturer commercialising medical devices into Canada must be part of the MDSAP.

Compliance with regulations for quality systems for medical device companies is difficult, time consuming and costly, and there are changes in the regulations from time to time. For example, ISO13485:2016 (the latest version of ISO13485) aims to harmonise the requirements of ISO13485 with the requirements of the AIMD. Manufacturers (including Sequana Medical's external critical sub-contractors) must be certified according to the requirements of new ISO 13485:2016 by 28 February 2019. While management believes that Sequana Medical is compliant with existing QMS regulations for medical device companies at the date of this Prospectus, it is possible that Sequana Medical may be found to be non-compliant with new or existing regulations in the future. In addition, Sequana Medical may be found to be non-compliant as a result of future changes in, or interpretation of, the regulations for quality systems. If Sequana Medical does not achieve compliance or subsequently becomes non-compliant, the regulatory authorities may, require that Sequana Medical takes appropriate action to address non-conformance issues identified in the audit, withdraw marketing clearance, or require product recall or take other enforcement action.

Sequana Medical's external vendors must, in general, also comply with the QSR and ISO13485. Any of its external vendors may become non-compliant with QSR or ISO13485, which could result in enforcement action by regulatory authorities, including by way of example a warning letter from the FDA or a requirement to withdraw from the market or suspend distribution, or export or use of products manufactured by one or more of Sequana Medical's vendors.

Any change or modification to a device (including changes to the manufacturing process) may require further approvals (depending on the jurisdiction) and must be made in compliance with appropriate regulations (such as the QSR for the U.S. and the AIMD Directive for Europe), which compliance may cause interruption to or delays in the marketing and sale of Sequana Medical's products. Regulations and laws regarding the manufacture and sale of AIMDs are subject to future changes, as are administrative interpretation and policies of regulatory agencies. If Sequana Medical fails to comply with such laws and regulations where Sequana Medical would intend to market the **alfapump**[®], the **alfapump**[®] DSR and/or any future products, Sequana Medical could be subject to enforcement action including recall of its device, withdrawal of approval or clearance and civil and criminal penalties. If any of these events occur, it may materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(bb) Intellectual property rights do not necessarily address all potential threats to Sequana Medical's competitive advantage.

The degree of protection afforded by Sequana Medical's intellectual property rights is uncertain because intellectual property rights are limited, and may not adequately protect Sequana

Medical's business or permit it to maintain its competitive advantage or its ability to sell its products. For example:

- others may be able to develop, make and sell products that are similar to or different from that deliver similar therapeutic benefits to the **alfapump**[®], the **alfapump**[®] DSR and/or any future products without infringing claims of the Sequana Medical patents or other Sequana Medical intellectual property rights;
- pending patent applications may not lead to issued patents;
- issued patents may not provide Sequana Medical with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges;
- Sequana Medical's competitors might conduct research and development activities in countries where Sequana Medical does not have patent rights and sell the resulting competitive products in such countries, or use the information learned from such activities to develop competitive products for sale in major commercial markets;
- Bootstrap may seek to enforce their security interests in Sequana Medical's intellectual property and related assets securing the Bootstrap Loan;
- Sequana Medical may develop intellectual property that is not patentable; and/or
- the patents of others may dominate the patents of Sequana Medical, thereby preventing their use, or have an adverse effect on Sequana Medical's business.

Should any of these events occur, they could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(cc) Sequana Medical could become subject to intellectual property litigation that could be costly, result in the diversion of management's time and efforts, require Sequana Medical to pay damages, prevent Sequana Medical from marketing the alfapump[®], the alfapump[®] DSR and/or any future products, and/or reduce the margins for the alfapump[®] and/or the alfapump[®] DSR and/or any future products.

The medical device industry is characterised by rapidly changing products and technologies and there is intense competition to establish intellectual property and proprietary rights covering the use of these new products and the related technologies. This vigorous pursuit of intellectual property and proprietary rights has resulted and will continue to result in extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, and the outcome of such disputes is often uncertain. There may be existing patents of which Sequana Medical is unaware that are inadvertently infringed by the **alfapump**[®], the **alfapump**[®] DSR and/or any future products. Competitors may have or develop patents and other intellectual property that they assert are infringed by the **alfapump**[®], the **alfapump**[®] DSR and/or any future products.

Any infringement claim against Sequana Medical, even if without merit, may cause Sequana Medical to incur substantial costs, and could place a significant strain on Sequana Medical's financial resources and/or divert the time and efforts of management from the conduct of Sequana Medical's business. In addition, any intellectual property litigation could force Sequana Medical to do one or more of the following: (i) stop selling the **alfapump**[®], the **alfapump**[®] DSR and/or any future products or using technology that contains the allegedly infringing intellectual property; (ii) forfeit the opportunity to license Sequana Medical's technology to others or to collect royalty payments based upon successful protection and assertion of its intellectual property rights against others; (iii) pay substantial damages to the party whose intellectual property rights Sequana Medical may be found to be infringing; or (iv) redesign those products that contain or utilise the allegedly infringing intellectual property. Any of these circumstances may materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

The requirement to obtain licenses to third party intellectual property could also arise in the future. If Sequana Medical needs to license any third party intellectual property, it could be required to pay lump sums or royalties on its products. In addition, there can be no assurance that, if Sequana Medical is required to obtain licenses to third party intellectual property, it will be able to obtain such licenses on commercially reasonable terms or at all. Sequana Medical's inability to obtain required third party intellectual property licenses on commercially reasonable terms or at all could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(dd) Sequana Medical may focus its limited financial and managerial resources on a particular market or indication resulting in a failure to capitalise on markets or indications that may be more profitable or for which there is a greater likelihood of success.

To grow its business in the future with limited financial and managerial resources, Sequana Medical will have to carefully choose which markets to target based on parameters such as market size, competition, and the type of product. Accordingly, it will need to carefully focus its limited financial and managerial resources on the development of products for such target markets.

Sequana Medical makes projections on the number of people for its target markets. These projections are derived from a variety of sources, including, but not limited to, scientific literature, governmental statistics and market research but are highly contingent on a number of variables that are difficult to predict and may prove to be too high, resulting in a smaller population of patients who could benefit from the **alfapump**[®], the **alfapump**[®] DSR or any future products than Sequana Medical anticipates, which would result in lower potential revenue for Sequana Medical.

If as a result of these or other factors the market for the **alfapump**[®], the **alfapump**[®] DSR or any future products does not develop as currently anticipated, Sequana Medical's ability to generate revenue could be materially adversely affected. If Sequana Medical uses its limited financial and managerial resources to promote a particular indication that is not ultimately sufficiently commercially successful, it could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(ee) Sequana Medical depends on confidentiality agreements with third parties to maintain confidential information.

Sequana Medical relies upon unpatented confidential and proprietary information, including technical information, and other trade secrets to develop and maintain the competitive position of Sequana Medical, the **alfapump**[®], the **alfapump**[®] DSR, and/or any future products. While Sequana Medical generally enters into confidentiality and invention assignment agreements with its employees and other third parties to protect its intellectual property, there can be no assurance that such agreements will not be breached, that they will provide meaningful protection for Sequana Medical's trade secrets and proprietary information or that adequate remedies will be available in the event of an unauthorised use or disclosure of such information. Unauthorised use or disclosure of Sequana Medical's confidential and proprietary information may materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(ff) Sequana Medical relies on third parties to conduct its clinical studies, perform data collection and analysis, and provide marketing, regulatory advice and other services that are crucial to its business.

Sequana Medical relies, and will rely in the future, on medical institutions, Investigators, CROs, contract laboratories and collaborators to perform data collection and analysis and to carry out Sequana Medical's clinical studies. Sequana Medical's development activities or clinical studies conducted in reliance on third parties may be delayed, suspended, or terminated if:

- the third parties do not devote a sufficient amount of time or effort to Sequana Medical's activities or otherwise fail to successfully carry out their contractual duties or to meet regulatory obligations or expected deadlines;
- Sequana Medical replaces a third party;
- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons including the loss of data; or
- the third party enters bankruptcy or liquidation.

Sequana Medical generally would not have the ability to control the performance of third parties in their conduct of their activities. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or in the event of a default, bankruptcy or shutdown of, or a dispute with, a third party, Sequana Medical would be required to find a replacement third party to conduct the required activities. Sequana Medical may be unable to enter into a new agreement with another third party on commercially acceptable terms. Furthermore, if the quality or accuracy of the data obtained by the third party is compromised, or if data is otherwise lost, Sequana Medical would be required to repeat the affected study. Third-party

performance failures may increase Sequana Medical's development costs, delay Sequana Medical's ability to obtain regulatory approval, and delay or prevent the commercialisation of the **alfapump**[®], the **alfapump**[®] DSR or any future products in target markets. In addition, Sequana Medical's third-party agreements usually contain a clause limiting such third party's liability, such that Sequana Medical may not be able to obtain full compensation for any losses that Sequana Medical may incur in connection with the third party's performance failures. While Sequana Medical believes that there are alternative sources to provide these services, in the event that Sequana Medical seeks such alternative sources, Sequana Medical may not be able to enter into replacement arrangements without incurring delays or additional costs.

In order to carry out its business, Sequana Medical also depends heavily on third party consultants, contractors, distributors, suppliers, agents and numerous other partners for core and non-core services and functions, including management functions, applications for regulatory approval, manufacturing activities and other services and functions that may involve interactions with government and quasi-government authorities. As a result, if any of these parties fails to perform as promised or intended, Sequana Medical's performance and/or plans for obtaining final regulatory approval for the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in its target markets may suffer, and its business may be materially and adversely affected.

(gg) Security breaches and other disruptions could compromise Sequana Medical's information and expose Sequana Medical to liability, which would cause Sequana Medical's business and reputation to suffer.

Sequana Medical, the **alfapump**[®] and the **alfapump**[®] DSR collect and store confidential and sensitive information. This information includes, among other things, intellectual property and proprietary information, the confidential information of any of Sequana Medical's future collaborators and licensees, the personally identifiable information of Sequana Medical employees, and data from patients using the **alfapump**[®] or the **alfapump**[®] DSR. It is important to Sequana Medical that this information remains secure and is perceived to be secure. Despite security measures, however, Sequana Medical's IT and network infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance, or other disruptions. Any such attack or breach could compromise Sequana Medical's networks and stored information could be accessed, publicly disclosed, lost, or stolen. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, delays and impediments to Sequana Medical's development efforts, and damage to Sequana Medical's reputation. The loss of pre-clinical or clinical study data from completed, ongoing or planned studies could result in delays in Sequana Medical's regulatory approval efforts and significantly increase Sequana Medical's costs to recover or reproduce the data. In addition, Sequana Medical's may rely on third parties to store confidential and sensitive information and it is important that these third parties also take adequate measures to secure this information, such as ensuring compliance with the GDPR. The GDPR is a comprehensive update to the data protection regime in the EEA that became effective in May 2018 and imposes new requirements relating to, among other things, consent to process personal data of individuals, the information provided to individuals regarding the processing of their personal data, the security and confidentiality of personal data, notifications in the event of data breaches and use of third party processors. If Sequana Medical or the third parties on which it relies fails to comply with these standards, Sequana Medical could be subject to criminal penalties and civil sanctions, including fines and penalties for non-compliance with the GDPR.

Sequana Medical may, in the future, inadvertently gain access, or be determined to have access, to personal information that is subject to a number of U.S. federal and state, E.U., and other laws of applicable countries protecting the confidentiality of certain patient health or other private information, including patient records, and will need to restrict the use and disclosure of that protected information.

(hh) Information technology forms a key support requirement within Sequana Medical's business. Any failure of Sequana Medical's IT systems could present a substantial risk to its business continuity.

The efficient operation of Sequana Medical's business and the use of the **alfapump**[®] and the **alfapump**[®] DSR depend on information technology ("IT") systems. Sequana Medical relies on its information technology systems for the collection of pump performance data using DirectLink

technology and to effectively manage its marketing, accounting and financial functions, manufacturing processes, and its development functions. The regulatory and legal environment of Sequana Medical's industry requires Sequana Medical to maintain records for long periods of time, sometimes forever. In most cases, those records are kept in electronic form, and without paper copies.

Sequana Medical uses third party suppliers to provide computing, communication, data storage and backup services, and failure of any of those third party suppliers may have an adverse effect on Sequana Medical's ability to operate. Although industry standard practices are in place for regular information backup, failure of Sequana Medical's IT systems infrastructure may result in the inability to continue business until the records are recreated. These events could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Sequana Medical's employees and contractors may also work from home offices, in particular employees or contractors who need to be close to the customer base to enable rapid support (for example, field clinical specialists). This requires strong IT infrastructure support (telephone, e-mail, internet access), which must be continuously maintained. Sequana Medical's employees frequently utilise portable computers, smartphones, and tablets. Loss, theft or damage to a portable computer, smartphone, or tablet could result in loss of key information (in some cases to a competitor). Failure of Sequana Medical's IT infrastructure, a security breach by a malicious third party, or loss of critical information may materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(ii) *Sequana Medical may be unable to successfully manage its growth.*

During the next few years, Sequana Medical expects to significantly expand its operations with regard to clinical activities, sales and the manufacturing. Sequana Medical expects this expansion to continue to an even greater degree as it seeks regulatory approval from the FDA and, if such approval is received, the commercial launch of the **alfapump**[®] in the U.S. Growth may place a significant strain on Sequana Medical's management, operating and financial systems and sales, marketing and administrative resources. Growth may cause Sequana Medical's operating costs to escalate faster than planned, and some of Sequana Medical's internal systems and processes, including those related to manufacturing the **alfapump**[®], may need to be enhanced, updated or replaced. If Sequana Medical cannot effectively manage its expanding operations, manufacturing capacity and costs, including scaling to meet increased demand, Sequana Medical may not be able to continue to grow or may grow at a slower pace than expected.

(jj) *Sequana Medical's employees, independent contractors, Investigators, consultants, commercial collaborators, service providers, distributors and other counterparties may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which may result in the imposition of significant fines or other sanctions and have an adverse effect on Sequana Medical's results of operations.*

Sequana Medical is exposed to the risk that its employees and contractors, including Investigators, consultants, commercial collaborators, service providers, distributors and other counterparties may engage in fraudulent or other illegal activity. Acts or omissions of any of the parties Sequana Medical relies on could potentially cause Sequana Medical to incur liability under applicable laws and regulations, such as the U.S. Foreign Corrupt Practices Act (the "**FCPA**"), the U.K. Bribery Act, the OECD Anti-Bribery Convention and other anti-bribery laws and regulations, export and import control laws in the E.U., U.S. and other jurisdictions, and sanctions programmes, including those administered by the U.S. Office of Foreign Asset Controls ("**OFAC**") and the European Commission. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorised activities that violate laws and regulations, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; healthcare fraud and abuse and health regulatory laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical studies, creating fraudulent data in Sequana Medical's pre-clinical studies or clinical studies or illegal misappropriation of therapeutic materials, which could result in regulatory sanctions and serious harm to Sequana Medical's reputation.

Sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programmes and other business arrangements. For example, Sequana Medical's dependence on the distribution efforts of Fresenius, Vingmed and Gamida creates the risk of non-compliance by these and other future distributors with local anti-corruption laws, the FCPA, and other local and international regulations. It is not always possible to identify and deter third-party misconduct, and the precautions Sequana Medical takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting Sequana Medical from governmental investigations or civil or criminal liability, fines and/or prohibitions stemming from a failure to be in compliance with such laws or regulations.

Additionally, Sequana Medical is subject to the risk that a person or government could allege fraud or other misconduct, even if none occurred. If any such actions are instituted against Sequana Medical, and Sequana Medical is not successful in defending itself or asserting its rights, those actions could have a significant impact on Sequana Medical's business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in healthcare programmes (such as Medicare and Medicaid) and tenders, reputational harm, diminished profits and future earnings, and curtailment of Sequana Medical's operations, any of which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(kk) *Sequana Medical is subject to healthcare fraud and abuse and other laws applicable to Sequana Medical's business activities. If Sequana Medical is unable to comply with such laws, it could face substantial penalties.*

Upon the planned launch of operations in the U.S., Sequana Medical's operations will be subject to various federal and state fraud and abuse laws. Such laws include the federal and state anti-kickback statutes, physician payment transparency laws and false claims laws. These laws may impact, among other things, Sequana Medical's proposed sales and marketing and education programmes and require it to implement additional internal systems for tracking certain marketing expenditures and to report to governmental authorities. In addition, Sequana Medical may be subject to patient privacy and security regulations by both the federal government and the states in which Sequana Medical conducts its business. The laws that may affect Sequana Medical's ability to operate include, *inter alia*:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly or wilfully soliciting, receiving, offering or paying any remuneration, overtly or covertly, directly or indirectly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order, arrange for, or recommendation of, any good, facility, item or services for which payment may be made, in whole or in part, under a federal healthcare program;
- federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from or approval by a governmental payer program that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, which established new federal crimes for, among other things, knowingly and wilfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, wilfully obstructing a criminal investigation of a healthcare offense, concealing a material fact, or making materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;
- an increasing number of state "sunshine" laws that require manufacturers to provide reports to state governments on pricing and marketing information. Several states have enacted legislation requiring medical device companies to, among other things, establish marketing compliance programmes, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, and to prohibit or limit certain other sales and marketing practices; and

- a federal law known as the Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals, and medical supplies to report annually to the Centres for Medicare & Medicaid Services information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

Sequana Medical is also subject to various fraud and abuse laws in jurisdictions outside of the U.S. For example, pursuant to the Belgian 'Sunshine Act' (the Belgian Act of 18 December 2016 and its implementing Royal Decree of 14 June 2017), manufacturers of medical devices are required to document and disclose all direct or indirect premiums and benefits granted to healthcare professionals, healthcare organisations and patient organisations with a practice or a registered office in Belgium.

If Sequana Medical's operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to it, it may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of Sequana Medical's operations, the exclusion from participation in government healthcare programmes and individual imprisonment, any of which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

(II) *Sequana Medical faces risks related to environmental matters and animal testing activities.*

Sequana Medical's facilities are subject to a broad range of environmental laws and requirements, including those governing discharges to the air and water, remediation of contamination associated with the release of any hazardous substances at Sequana Medical's facilities and offsite disposal locations and occupational safety and health. Sequana Medical is also subject to strict laws and requirements governing the handling or disposal of solid and hazardous substances and wastes. For example, Sequana Medical must process non-functioning pumps that have been explanted from patients, including patients with hepatitis and other serious diseases, to identify the cause of the pump failure. Sequana Medical has made, and will continue to make, expenditures to comply with such laws and requirements. Future events, such as changes in existing laws and regulations, or the enforcement thereof, or the discovery of contamination at Sequana Medical's facilities, may give rise to additional compliance or remediation costs that could have a material adverse effect on Sequana Medical's business, financial condition, results of operations and prospectus. Such laws and requirements are constantly changing, are different in every jurisdiction and can impose substantial fines and sanctions for violations. As a manufacturer, Sequana Medical is exposed to some risk of claims with respect to environmental matters, and there can be no assurance that material costs or liabilities will not be incurred in connection with any such claims.

In addition, Sequana Medical has been required to use animals to test the **alfapump**[®] and the **alfapump**[®] DSR, and may be required to use animals to test future products. Animal testing activities have been the subject of controversy and adverse publicity. Testing on animals can be vital for the development of a product. If applicable regulations were to ban this practice, or if, due to pressure from animal welfare groups, Sequana Medical is no longer able to source animals to perform such tests, it would be difficult and in some cases impossible to develop products in certain jurisdictions under the applicable marketing authorisations. In addition, negative publicity regarding Sequana Medical's use, or the industry's use, of animal subjects could harm Sequana Medical's reputation.

(mm) *Sequana Medical has entered into an exclusive distribution agreement with Gamida in Israel (the "Gamida Distribution Agreement"). In the event there is (i) more than a 50% change of ownership of Sequana Medical or (ii) a direct or indirect change of control of Sequana Medical, Gamida would be entitled to terminate the Gamida Distribution Agreement with written notice.*

Gamida is entitled to terminate the Gamida Distribution Agreement with written notice in the event there is (i) more than a 50% change of ownership of Sequana Medical or (ii) a direct or indirect change of control of Sequana Medical. If such termination takes place and Sequana Medical is unable to enter into a replacement distribution agreement with a suitable distribution partner in Israel, Sequana Medical's revenue and profitability may be negatively affected (see subsection (x) (If Sequana Medical is unable to expand its sales, marketing and distribution capabilities for the **alfapump**[®], the **alfapump**[®] DSR and/or any future products, whether it be with

internal infrastructure or an arrangement with a commercial partner such as the ones that Sequana Medical has entered into with Fresenius, Vingmed and Gamida, Sequana Medical may not be successful in commercialising the **alfapump**[®], the **alfapump**[®] DSR and/or any future products in its target markets, if and when they are approved)).

(nn) Sequana Medical faces risks related to work safety matters

Although Sequana Medical is committed to providing a safe work environment for all of its employees and contractors, it cannot be guaranteed that the equipment, infrastructure and processes at all times meet all applicable requirements to work safety. If critical issues are identified by any authority, Sequana Medical may be required to halt **alfapump**[®] and **alfapump**[®] DSR production until such deficiencies have been addressed.

(oo) Changes in currency exchange rates could have a material negative impact on the profitability of Sequana Medical.

Sequana Medical is and will in the future be exposed to exchange rate fluctuations including among others, the euro, U.S. Dollar, Swiss franc, and pound sterling. Fluctuations of exchange rates outside a budgeted range may affect revenues, expenses, or the ability to raise future capital if it is needed, and may materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects. The relationships between different currencies may be volatile and vary based on a number of interrelated factors, including the supply and demand for each currency, political, economic, legal, financial, accounting and tax matters and other actions that Sequana Medical cannot control.

(pp) Sequana Medical's operating results could be materially adversely affected by unanticipated changes in tax laws and regulations, adjustments to its tax provisions, exposure to additional tax liabilities, or forfeiture of its tax assets.

The determination of Sequana Medical's provision for income taxes and other future tax liabilities requires significant judgment, including the adoption of certain accounting policies. The complexity of in particular international tax systems, as well as changes in the current practice of tax authorities and courts, may lead to incomplete and inaccurate tax declarations which may result in additional tax payments. Although management believes its estimates and judgment are reasonable, they remain subject to review by the relevant tax authorities. Sequana Medical cannot guarantee that its interpretation will not be questioned by the relevant tax authorities, or that the relevant tax laws and regulations, or the interpretation thereof by the relevant tax authorities, will not be subject to change, including changes that may have a retroactive effect. Any adverse outcome of such a review may lead to adjustments in the amounts recorded in Sequana Medical's financial statements. Furthermore, Sequana Medical could incur additional tax liabilities as a result of moving its registered office to Belgium. While management does not believe that any such additional taxes would have a significant impact on Sequana Medical, there can be no guarantee that Sequana Medical's interpretations and estimates of its potential tax liabilities will not be questioned by tax authorities or that any such amounts will not be material. Any adjustments to the amounts recorded in Sequana Medical's financial statements and/or any significant tax liabilities so incurred could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Sequana Medical's effective tax rates could be adversely affected by changes in tax laws, treaties and regulations, both internationally and domestically, including changes to the patent income deduction regime, possible changes to the wage withholding tax incentive for qualified research and development personnel in Belgium, possible changes to other tax incentives and possible changes in tax laws in the context of the future implementation of the actions defined by the Organization for Economic Cooperation and Development (the "OECD") under its "Base Erosion and Profit Shifting" (the "BEPS") project, in the context of the European Commission's "Anti Tax Avoidance Package" (the "ATAP"), and in the context of a possible Belgian corporate income tax reform discussed by the Belgian government. An increase of the effective tax rates could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

2.2 Risks relating to the Shares and the Offering

(a) *The fact that no minimum amount is set for the Offering may affect Sequana Medical's investment plan and the liquidity of the Shares.*

The Issuer has the right to proceed with a capital increase in a reduced amount, corresponding to a number of Offered Shares that is lower than the maximum number of Offered Shares in the Offering. As there is no minimum amount of the Offering, if not all of the Offered Shares are subscribed for in the Offering, the net proceeds from the Offering could be limited, all or in part, to the net proceeds from Subscription Commitments. The actual number of Shares subscribed for, or placed, will be confirmed on Sequana Medical's website and by way of a press release together with the Offer Price. As a result only a number of Shares that is lower than the maximum number of Offered Shares in the Offering could be available for trading on the market, which could limit the liquidity of the Shares. Furthermore, Sequana Medical's financial means in view of the uses of proceeds as described in Part 3 – (Use of proceeds) would in such case also be reduced. If this were to be the case, Sequana Medical may have to reduce its level of investments or look for further external funding.

(b) *There has been no prior public market for the Shares and an active market for the Shares may not develop.*

Prior to the Offering, there has been no public trading market for the Shares. No assurance can be given that an active trading market for the Shares will develop or, if developed, can be sustained or will be sufficiently liquid following the closing of the Offering. Furthermore, the Offer Price is not necessarily indicative of the prices at which the Shares will subsequently trade on the stock exchange. If an active trading market is not developed or maintained, the liquidity and trading price of the Shares could be adversely affected.

(c) *The market price of the Shares may fluctuate widely in response to various factors.*

Publicly traded securities from time to time experience significant price and volume fluctuations that may be unrelated to the results of operation or the financial condition of the companies that have issued them. In addition, the market price of the Shares may prove to be highly volatile and may fluctuate significantly in response to a number of factors, many of which are beyond Sequana Medical's control, including:

- announcements of technological innovations, clinical data in relation to existing or new products or collaborations by Sequana Medical or its competitors;
- market expectations for Sequana Medical's financial performance;
- actual or anticipated fluctuations in Sequana Medical's business, results of operations and financial condition;
- changes in the estimates of Sequana Medical's results of operations, downgrades of recommendations, or cessation of publication of research reports on Sequana Medical by securities analysts;
- potential or actual sales of blocks of Shares in the market or short selling of Shares, future issues or sales of Shares, and stock market price and volume fluctuations in general;
- the entrance of new competitors or new products in the markets in which Sequana Medical operates;
- volatility in the market as a whole or investor perception of Sequana Medical's markets and competitors;
- changes in market valuation of similar companies;
- announcements by Sequana Medical or its competitors of significant contracts;
- acquisitions, strategic alliances, joint ventures, capital commitments or new products or services;
- additions or departures of key personnel;
- litigation;
- developments regarding intellectual property rights, including patents;

- regulatory, pricing and reimbursement developments in Europe, the U.S. and other jurisdictions, and new government regulation in general;
- general economic, financial and political conditions; and
- the risk factors mentioned above.

The market price of the Shares may be adversely affected by most of the preceding or other factors regardless of Sequana Medical's actual results of operations and financial condition.

(d) *Future sales of substantial amounts of Shares, or the perception that such sales could occur, could adversely affect the market value of the Shares.*

A sale of a significant number of Shares on the public markets, or the perception that such sale will occur, may adversely affect the market price of the Shares. The Issuer cannot make any predictions as to the sale or perception on the market price of the Shares. The current shareholders (excluding certain minority shareholders holding in the aggregate less than ca. 0.01% of the outstanding Shares after giving effect to the contribution in kind of the Convertible Loan payables (with the exception of certain payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91 that will be converted into New Shares at the Offer Price in connection with the Offering) and the Share Consolidation) and the Participating Investors have entered into a lock up arrangement with the Underwriters with respect to certain of their Shares and other rights or securities issued by the Issuer for a period of 360 days after the Listing Date, subject to certain exceptions, as described in Part 14 – (Plan of distribution), section 14.3 (Lock up).

The Shares that Bootstrap acquires upon the exercise of the Bootstrap Warrant (as defined in Part 12 – (Share capital and articles of association), section 12.5 (Outstanding Share options), subsection (b) (Bootstrap Warrant)) will not be subject to a transfer restriction. However, Bootstrap entered into a lock-up arrangement with the Issuer and the Joint Global Coordinators with respect to the Shares that it will acquire through the contribution in kind of 50% of the Exit Fee in the Offering for a period of 180 days after the Listing Date, subject to certain exceptions, as described in Part 14 – (Plan of distribution), section 14.3 (Lock up).

Following the expiration of these respective lock up provisions, potential future sales of Shares by the relevant existing shareholders or the relevant Share option holders, or the perception that such sales could occur, may adversely affect the market price of the Shares.

(e) *The Issuer has no fixed dividend policy and will probably not be in a capacity to pay dividends in the foreseeable future.*

The Issuer has not declared or paid dividends on its Shares in the past. In the future, the Issuer's dividend policy will be determined and may change from time to time by determination of the Issuer's board of directors. Any declaration of dividends will be based upon the Issuer's earnings, financial condition, capital requirements and other factors considered important by the board of directors. Belgian law and the Issuer's articles of association do not require the Issuer to declare dividends.

Currently, the board of directors of the Issuer expects to retain all earnings, if any, generated by the Issuer's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the foreseeable future.

The maximum amount of the dividend that can be paid is determined by reference to the Issuer's stand-alone statutory accounts prepared in accordance with generally applicable accounting rules and principles in Belgium ("**Belgian GAAP**").

In addition, under Belgian law and the Issuer's articles of association, before it can pay dividends, the Issuer must allocate an amount of 5% of its Belgian GAAP annual net profit (nettowinst/bénéfices nets) to a legal reserve in its stand-alone statutory accounts until the reserve equals 10% of the Issuer's share capital. The Issuer's legal reserve currently does not meet this requirement nor will it meet the requirement at the time of the closing of the Offering. Accordingly, 5% of its Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, limiting the Issuer's ability to pay out dividends to its shareholders. As a consequence of these factors, there can be no assurance as to whether dividends or similar payments will be paid out in the future nor, if they are paid, as to their amount. Furthermore, financial restrictions and other limitations may be contained in future credit agreements.

(f) *Certain significant shareholders of the Issuer after the Offering may have different interests from the Issuer and may be able to control the Issuer, including the outcome of shareholder votes.*

Following the closing of the Offering and listing of its Shares, the Issuer will have a number of significant shareholders. For an overview of the Issuer's current significant shareholders see Part 10 – (Principal shareholders).

Currently, most of the existing shareholders of the Issuer and the Issuer have entered into a shareholders' agreement (the "**Shareholders' Agreement**"), containing, amongst others, terms regarding the Issuer's business and governance, as well as pre-emptive rights and transfer restrictions regarding the Shares. The Shareholders' Agreement will be terminated effective as of the closing of the Offering. The Issuer is not aware of shareholders entering into a new shareholders' agreement or agreeing to act in concert following the closing of the Offering (other than certain lock up arrangements as described above in subsection (d) (Future sales of substantial amounts of the Shares, or the perception that such sales could occur, could adversely affect the market value of the Shares). Nevertheless, they could, alone or together, have the ability to elect or dismiss directors, and, depending on how broadly the Issuer's other Shares are held, take certain other shareholders' decisions that require at least 50%, 75% or 80% of the votes of the shareholders that are present or represented at general shareholders' meetings where such items are submitted to voting by the shareholders. Alternatively, to the extent that these shareholders have insufficient votes to impose certain shareholders' decisions, they could still have the ability to block proposed shareholders' resolutions that require at least 50%, 75% or 80% of the votes of the shareholders that are present or represented at general shareholders' meetings where such decisions are submitted to voting by the shareholders. Any such voting by the shareholders may not be in accordance with the interests of the Issuer or the other shareholders of the Issuer.

(g) *Any future capital increases by the Issuer could have a negative impact on the price of the Shares and could dilute the interests of existing shareholders.*

The Issuer is expected to agree pursuant to the Underwriting Agreement (as defined below) (which is expected to be entered into on or about 8 February 2019) to a standstill on the issuance of new Shares and issuance of new securities that are substantially similar to Shares, including but not limited to any securities that are convertible into or exchangeable for, or that represent the right to receive, Shares or any such substantially similar securities, for a period of 360 days following the Closing Date, as described in Part 14 – (Plan of distribution), section 14.2 (Standstill). The standstill would not apply to the issue of new Shares upon exercise of existing outstanding warrants or Share options. After such period, or within that period with the Joint Global Coordinator's consent, the Issuer may increase its share capital against cash or contributions in kind to finance any future acquisition or other investment or to strengthen its balance sheet. The Issuer may also issue warrants that are exercisable into new Shares, or raise capital through public or private convertible debt or equity securities, or rights to acquire these securities. In connection with such transactions, the Issuer may, subject to certain conditions, limit or disapply the preferential subscription rights of the existing shareholders otherwise applicable to capital increases through contributions in cash, while no preferential subscription rights apply to capital increases through contributions in kind. Such transactions could therefore dilute the stakes in the Issuer's share capital held by the shareholders at that time and could have a negative impact on the Share price, earnings per Share and net asset value per Share.

(h) *If securities or industry analysts do not publish research reports about the Issuer, or if they change their recommendations regarding the Issuer's Shares in an adverse way, the market price of the Shares may fall and the trading volume may decline.*

The trading market for the Issuer's Shares may be influenced by the research reports that industry or securities analysts publish about the Issuer or its industry. If one or more of the analysts who cover the Issuer or its industry, downgrades its recommendation, the market price of the Issuer's Shares may fall. If one or more of the analysts ceases to cover the Issuer or fails to publish research reports about the Issuer on a regular basis, the Issuer may lose visibility in the financial markets, which in turn could cause the market price of the Issuer's Shares or trading volume to decline. This decline could be exacerbated due to the Issuer's limited market capitalisation.

(i) *Investors resident in countries other than Belgium may suffer dilution if they are unable to participate in future preferential subscription rights offerings.*

Under Belgian law and the Issuer's constitutional documents, shareholders have a waivable and cancellable preferential subscription right to subscribe *pro rata* to their existing shareholdings to the issuance, against a contribution in cash, of new Shares or other securities entitling the holder thereof to new Shares, unless such rights are limited or cancelled by resolution of the Issuer's general shareholders' meeting or, if so authorised by a resolution of such meeting, the board of directors. The exercise of preferential subscription rights by certain shareholders not residing in Belgium (including those in the U.S., Australia, Canada or Japan) may be restricted by applicable law, practice or other considerations, and such shareholders may not be entitled to exercise such rights, unless the rights and Shares are registered or qualified for sale under the relevant legislation or regulatory framework. In particular, there can be no assurance that the Issuer will be able to establish an exemption from registration under the U.S. Securities Act, and the Issuer is under no obligation to file a registration statement with respect to any such preferential subscription rights or underlying securities or to endeavour to have a registration statement declared effective under the U.S. Securities Act. Shareholders in jurisdictions outside Belgium who are not able or not permitted to exercise their preferential subscription rights in the event of a future preferential subscription rights, equity or other offering may suffer dilution of their shareholdings.

(j) *Takeover provisions in Belgian national law may complicate a change in management and discourage potential takeover attempts.*

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as the obligation to disclose important shareholdings, merger control and authorised capital, that may apply to the Issuer and which may make an unsolicited tender offer, merger, change in management or other change in control, more difficult. These provisions could discourage potential takeover attempts that third parties may consider and that other shareholders may consider to be in their best interest and could adversely affect the market price of the Shares. These provisions may also deprive the shareholders of the opportunity to sell their Shares at a premium (which is typically offered in the framework of a takeover bid).

(k) *Shareholders in jurisdictions with currencies other than the euro face additional investment risk from currency exchange rate fluctuations in connection with their holding of Shares.*

The Shares will be quoted only in euro and any future payments of dividends on Shares, as the case may be, will be denominated in euro. An investment in the Shares by an investor whose principal currency is not euro exposes such investor to currency exchange rate risk which may impact the value of the investment in the Shares or of any dividends.

(l) *Any future sale, purchase or exchange of Shares may become subject to the Financial Transaction Tax.*

On 14 February 2013, the EU Commission adopted a proposal for a Council Directive (the "**Draft Directive**") on a common financial transaction tax ("**FTT**"). The intention is for the FTT to be implemented via an enhanced cooperation procedure between, currently, 10 Member States (Austria, Belgium, France, Germany, Greece, Italy, Portugal, Spain, Slovakia and Slovenia, together, the "**Participating Member States**").

Pursuant to the Draft Directive, the FTT would be payable on financial transactions provided at least one party to the financial transaction is established or deemed established in a Participating Member State and there is a financial institution established or deemed established in a Participating Member State which is a party to the financial transaction, or is acting in the name of a party to the transaction. The FTT would, however, not apply to (*inter alia*) primary market transactions referred to in article 5(c) of Regulation (EC) No 1287/2006, including the activity of underwriting and subsequent allocation of financial instruments in the framework of their issue.

The rates of the FTT would be fixed by each Participating Member State but for transactions involving financial instruments other than derivatives shall amount to at least 0.1% of the taxable amount. The taxable amount for such transactions would in general be determined by reference to the consideration paid or owed in return for the transfer or the market price (whichever is higher). The FTT should be payable by each financial institution established or deemed established in a

Participating Member State which is either a party to the financial transaction, or acting in the name of a party to the transaction or where the transaction has been carried out on its account. Where the FTT due has not been paid within the applicable time limits, each party to a financial transaction, including persons other than financial institutions, would become jointly and severally liable for the payment of the FTT due.

Investors should therefore note, in particular, that in case of implementation any sale, purchase or exchange of Shares would become subject to the FTT at a minimum rate of 0.1% provided the above mentioned prerequisites are met. The investor may be liable to pay this charge or reimburse a financial institution for the charge, and/or the charge may affect the value of the Shares. The issuance of New Shares would not be subject to the FTT.

The Draft Directive remains subject to further negotiations between the Participating Member States. It may therefore be altered prior to any implementation, of which the eventual timing and fate remains unclear. Additional EU Member States may decide to participate or drop out of the negotiations. If the number of Participating Member States would fall below nine, it would put an end to the project. Moreover, once the Draft Directive would be adopted (the “**Directive**”), it would need to be implemented into the respective domestic laws of the Participating Member States and the domestic provisions implementing the Directive might deviate from the Directive itself.

Investors should consult their own tax advisers in relation to the consequences of the FTT associated with subscribing for, purchasing, holding and disposing of the Shares.

(m) *Investors’ rights as shareholders of the Issuer will be governed by Belgian law and may differ in some respects from the rights granted to shareholders in other companies under the laws of other jurisdictions.*

The Issuer is a limited liability company (société anonyme/naamloze vennootschap) organised under the laws of Belgium. The rights of holders of the Shares are governed by Belgian law and by the Issuer’s articles of association. These rights may differ in material respects from the rights of shareholders in companies organised outside of Belgium.

(n) *Investors may not be able to recover in civil proceedings for U.S. securities laws violations.*

The Issuer’s directors and members of senior management may not be resident in the jurisdiction of investors and the Issuer’s assets and the assets of its directors and senior management may be located outside the jurisdiction of investors. As a result, it may be difficult for investors to prevail in a claim against the Issuer or to enforce liabilities predicated upon the securities laws of jurisdictions outside of Belgium and, in general, for investors outside of Belgium to serve process on or enforce foreign judgments against the Issuer, its directors or its senior management. In addition, there is uncertainty as to the enforceability in Belgium of original actions or in actions for enforcement of judgments of U.S. courts of civil liabilities predicated solely upon the federal securities laws of the U.S. See page viii (Jurisdiction and service of process in the U.S. and enforcement of foreign judgments in Belgium).

(o) *The Shares will be listed and traded on the regulated market of Euronext Brussels on an “if-and-when-issued-and/or-delivered” basis from the Listing Date until the Closing Date. Euronext Brussels may annul all transactions effected in the Shares if they are not issued and delivered on the Closing Date.*

From the Listing Date until the Closing Date, the Shares will be listed and traded on the regulated market of Euronext Brussels on an “if-and-when-issued-and/or-delivered” basis, meaning that trading of the Shares will begin prior to the closing of the Offering. The Closing Date is expected to occur on the first Euronext Brussels trading day following the Listing Date. Investors that wish to enter into transactions in the Shares prior to the Closing Date, whether such transactions are effected on the regulated market of Euronext Brussels or otherwise, should be aware that the closing may not take place on the expected date, or at all, if certain conditions or events referred to in the Underwriting Agreement (as defined below) are not satisfied or waived or do not occur on or prior to such date. Euronext Brussels may annul all transactions effected in the Shares if they are not issued and delivered on the Closing Date. Euronext Brussels cannot be held liable for any damage arising from the listing and trading on an “if-and-when-issued-and/or-delivered” basis as of the Listing Date until the Closing Date.

(p) *The Issuer may become a passive foreign investment company, which could result in adverse U.S. federal income tax consequences for U.S. investors.*

The Issuer does not believe that it was a passive foreign investment company (a “**PFIC**”) for U.S. federal income tax purposes for its most recent taxable year. However, because the Issuer’s status as a PFIC must be determined annually and depends upon the nature of the Issuer’s income as well as upon the manner and rate at which the Issuer utilises the proceeds of the Offering, the composition and quarterly average value of the Issuer’s assets and the market price of the Shares, there is no assurance that the Issuer will not be a PFIC for the current taxable year or any future taxable year. If the Issuer were treated as a PFIC for any taxable year during which a U.S. investor held the Shares, certain adverse U.S. federal tax consequences could apply to such U.S. investor. Further information about the PFIC rules is set out in Part 18 – (Taxation of Shares), section 18.8 (Certain material U.S. federal income tax considerations), subsection (d) (Passive foreign investment company rules).

PART 3 – USE OF PROCEEDS

3.1 Expenses of the Offering

The aggregate of the administrative, legal, tax and audit expenses as well as the other costs in connection with the Offering (including but not limited to legal publications, printing and translation of the Prospectus and Offering related documents, and expenses incurred by the Underwriters (which are estimated at €50,000)) and the remuneration of the FSMA (which is estimated at €20,000) and Euronext Brussels, is expected to amount to approximately €3 million. Additionally, fees and commissions payable to the Underwriters by the Issuer are expected to be maximum €1.9 million assuming a placement of the maximum number of New Shares in the Offering (including the conversion of the Bridge Loans in full, but excluding the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range, or €2.7 million assuming a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range.

3.2 Use of proceeds

Assuming a placement of the maximum number of New Shares in the Offering (including the conversion of the Bridge Loans in full, but excluding the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range, the gross proceeds from the issue of the New Shares are estimated to be approximately €28.3 million. Assuming a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range, the gross proceeds from the issue of the Offered Shares are estimated to be approximately €37.4 million.

Based on the aforementioned assumptions and the expenses of the Offering (see section 3.1 (Expenses of the Offering) above), the Issuer estimates to receive net proceeds of approximately €23.4 million in case of a placement of the maximum number of New Shares in the Offering (including the conversion of the Bridge Loans in full, but excluding the exercise in full of the Increase Option and the Over-allotment Option) and approximately €31.8 million in case of a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option). The principal purpose of the Offering is to obtain additional capital to support the execution of Sequana Medical's strategy (as described in Part 8 – (Business), section 8.3 (Strategy)). In particular, the Issuer intends to use the net proceeds of the Offering to fund:

- the POSEIDON (North American pivotal) Study (which management estimates will cost around €11 million to complete and to acquire data to support reimbursement);
- the European commercial roll-out;
- the development of the **alfapump**[®] DSR, including the Single Dose DSR Proof of Concept and Repeated Dose DSR Proof of Concept (which management estimates will together cost around €1 million to complete);
- other clinical programmes, including the Malignant Ascites CT (which management estimates will cost around €1 million to complete), TOPMOST (which management estimates will cost around €0.4 million annually and includes the Fitbit[®] Study) and the Albumin Replacement Study (which management estimates will cost around €0.25 million to complete);
- partial repayment of the principal outstanding under the Bootstrap Loan, equal to a maximum of €1.5 million, payment of €0.44 million in accrued and unpaid interest on the Bootstrap Loan and payment of up to €0.33 million for the portion of the 'Exit Fee' under the Bootstrap Loan that is payable in cash (as described in Part 7 – (Operating and financial review and prospectus), section 7.4 (Liquidity and capital resources), subsection (a) (General)); and
- general corporate purposes.

The Issuer intends to fund the European commercial roll-out with most of the net proceeds of the Offering that are not allocated to the clinical studies or the payments on the Bootstrap Loan described above. The Issuer intends to fund its commercial operations directly in the form of

payments to the commercial team and sales and marketing expenses, as well as to indirectly fund commercial operations through significant investments in general corporate purposes to establish the infrastructure necessary to enable growth in Sequana Medical's commercial operations, such as investments in quality assurance and regulatory affairs and general and administrative personnel to provide critical support to Sequana Medical's commercial operations. The European commercial roll-out will also be funded by revenues from sales of the **alfapump**[®], but the amount of revenues that the **alfapump**[®] will generate is uncertain.

The Issuer cannot predict with certainty all of the particular uses for the proceeds from the issuance of the Offered Shares, or the amounts that it will actually spend on the uses set forth above. The amounts and timing of the Issuer's actual expenditures will depend upon numerous factors, including the progress, costs, timing and results of its further development of the **alfapump**[®] and the **alfapump**[®] DSR, regulatory or competitive developments, the net proceeds actually raised by it in the Offering, amounts received by way of revenues and the Issuer's operating costs and expenditures. As such, the Issuer's management assumes significant flexibility in applying the net proceeds from the issue of the Offered Shares and may change the allocation of these proceeds as a result of these and other contingencies. Pending the use of the proceeds from this Offering, the Issuer intends to invest the net proceeds in interest bearing, cash and cash equivalents instruments or short-term certificates of deposit. Furthermore, the Issuer has the right to proceed with a capital increase in a reduced amount, corresponding to a number of Shares lower than the maximum number of Offered Shares in the Offering. In the event that the Issuer would proceed with the capital increase in a reduced amount, it may be required to raise additional capital in order to meet the funding requirements of the above proposed uses.

Prior the closing of the Offering, the outstanding Convertible Loans will be converted into share capital via a contribution in kind. In addition, some Convertible Loan payables, the outstanding payables pursuant to Bridge Loans (as defined below), and 50% of the Exit Fee payable will be contributed in kind in the Offering. No additional cash will be contributed for the amount of the loans and payables that will be so contributed in kind. See also Part 12 – (Share capital and articles of association), section 12.4 (Outstanding Convertible Loans and Bridge Loans), and PART 13 – (The Offering), section 13.3 (Contribution in kind of certain payables in the Offering).

PART 4 – DIVIDEND AND DIVIDEND POLICY

4.1 Dividends

As of the closing of the Offering, all of the Shares, including the Offered Shares, will entitle the holder thereof to an equal right to participate in dividends declared after the Closing Date, in respect of the financial year ending 31 December 2018 and future years. All of the Shares participate equally in the Issuer's profits (if any). Pursuant to the Belgian Companies Code, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the annual general shareholders' meeting, based on the most recent statutory audited financial statements, prepared in accordance with Belgian GAAP and based on a (non-binding) proposal of the Issuer's board of directors. The Issuer's articles of association also authorise the board of directors to declare interim dividends without shareholder approval. The right to pay such interim dividends is, however, subject to certain legal restrictions.

The Issuer's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of the Issuer's stand-alone statutory accounts prepared in accordance with Belgian GAAP. In particular, dividends can only be distributed if following the declaration and issuance of the dividends the amount of the Issuer's net assets on the date of the closing of the last financial year as follows from the statutory non-consolidated financial statements (i.e. summarised, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all in accordance with Belgian accounting rules), decreased with the non-amortised costs of incorporation and extension and the non-amortised costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased with the amount of non-distributable reserves.

In addition, pursuant to Belgian law and the Issuer's articles of association, the Issuer must allocate an amount of 5% of its Belgian GAAP annual net profit (nettowinst/bénéfices nets) to a legal reserve in its stand-alone statutory accounts, until the legal reserve amounts to 10% of the Issuer's share capital. The Issuer's legal reserve currently does not meet this requirement nor will it meet the requirement at the time of the closing of the Offering. Accordingly, 5% of its Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, limiting the Issuer's ability to pay out dividends to its shareholders.

Additional financial restrictions and other limitations may be contained in future credit agreements.

Assuming that the Offer Price is at the mid-point of the Price Range and all Offered Shares are placed (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option), the Issuer's share capital will amount to €1,415,033.89. There will be no distributable reserves nor will there be a legal reserve, as of the closing of the Offering.

4.2 Dividend policy

The Issuer has not declared or paid dividends on its Shares in the past. In the future, the Issuer's dividend policy will be determined and may change from time to time by determination of the Issuer's board of directors. Any declaration of dividends will be based upon the Issuer's earnings, financial condition, capital requirements and other factors considered important by the board of directors. Belgian law and the Issuer's articles of association do not require the Issuer to declare dividends.

Currently, the board of directors of the Issuer expects to retain all earnings, if any, generated by the Issuer's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the foreseeable future.

As a consequence of all of these factors, there can be no assurance as to whether dividends or similar payments will be paid out in the future nor, if they are paid, as to their amount.

PART 5 – CAPITALISATION AND INDEBTEDNESS

5.1 Capitalisation and indebtedness

The following tables set forth Sequana Medical's consolidated capitalisation and net financial indebtedness as at 30 November 2018 (i) on an actual basis and (ii) as adjusted to give effect to (a) the conversion of Convertible Loans, (b) the Share Consolidation, (c) the entering into and conversion of Bridge Loans, (d) the Offering (assuming a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range), and (e) the partial repayment of the principal and the payment of €0.41 million in accrued and unpaid interest outstanding under the Bootstrap Loan with the net proceeds of the Offering. This table should be read in conjunction with Part 6 – (Selected financial information), Part 7 – (Operating and financial review and prospects), and the Interim Financial Statements as of and for the nine-month period ended 30 September 2018, including the notes thereto. Other than as set forth below, there have been no material changes to Sequana Medical's consolidated capitalisation and net financial indebtedness since 30 November 2018.

	As at 30 November 2018	Adjustments	As Adjusted
	<i>(in €000)</i>		
Total current debt	10,653	(10,216)	437
Guaranteed	—	—	—
Secured	2,259 ⁽¹⁾	(1,822) ⁽²⁾	437 ⁽³⁾
Unguaranteed/unsecured	8,394 ⁽⁴⁾	(8,394) ⁽⁵⁾	—
Total non-current debt	2,901	0	2,901
Guaranteed	—	—	—
Secured	2,901	0 ⁽²⁾	2,901
Unguaranteed/unsecured	—	—	—
Total indebtedness	13,554	(10,216)	3,338
Shareholders' equity			
Share capital	856	527 ⁽⁶⁾⁽⁷⁾	1,383
Other equity	184	(184)	—
Own shares	0	0	—
Share premium	65,064	45,528 ⁽⁶⁾⁽⁷⁾	110,592
Reserves	(390)	—	(390)
Loss brought forward	(82,565)	—	(82,565)
Cumulative translation adjustment	721	—	721
Total equity	(16,130)	45,871	29,741

Notes:

- (1) Amounts payable to Bootstrap under the Bootstrap Loan. Sequana Medical has pledged to Bootstrap its intellectual property as well as the related assets as security for the Bootstrap Loan. Sequana Medical may prepay any or all outstanding amounts on the Bootstrap Loan without penalties.
- (2) Assumes a maximum partial repayment of the Bootstrap Loan of €1.5 million pursuant to the amendment signed on 1 October 2018, which provides that 5% of the proceeds of the Offering must be used for a partial repayment of the principal outstanding under the facility. The entire outstanding principal amount of the Bootstrap Loan not already paid from the 5% of the Offering proceeds would be equal to €2.9 million (assuming a maximum partial repayment of €1.5 million) and shall be due in four substantially equal consecutive instalments on each of 31 December 2020, 31 January 2021, 28 February 2021 and 31 March 2021. This amount has been classified as non-current debt. The adjustment also reflects the payment of €0.41 million in accrued and unpaid interest in respect of the period from 1 January 2018 to 31 October 2018, which shall be made within 10 business days of the Closing Date.
- (3) Reflects €0.44 million of (i) a reclassification of accrued and unpaid interest in respect of the period from 1 May 2017 to 31 December 2017 to current debt and (ii) €0.08 million in interest that has been added to provide Bootstrap with a 12% per annum return on the extended term for the repayment of principal under the October 2018 and December 2018 amendments and given that the repayment of principal under the 2017 amendment to the Bootstrap Loan had been scheduled to begin in February 2018. The €0.44 million is payable in instalments on the last day of each month from 28 February 2019 to 31 July 2019.
- (4) Consists of Convertible Loans (as defined and described in PART 11 – (Related Party Transactions)) denominated in CHF and in EUR.

- (5) This reflects the conversion of the Convertible Loans pursuant to several Pre-IPO Investment Commitment Agreements entered into on 2 November 2018 by and between the Issuer and the lenders under the Convertible Loans, pursuant to which the lenders under the respective Convertible Loans agreed to convert their loans for new series E preferred Shares immediately prior to the closing of the Offering, and that the new Shares shall be converted and consolidated immediately thereafter into ordinary Shares pursuant to the Share Consolidation. As an exception, payables under the February 2018 Convertible Loan (as defined and described in PART 11 – (Related Party Transactions)) will be converted into New Shares at the Offer Price in connection with the Offering. The conversions will be implemented by means of a contribution in kind of the outstanding payable amounts under the Convertible Loans. See PART 11 – (Related party transactions) for more information.
- (6) It is contemplated that immediately prior to the closing of the Offering, the Convertible Loans will be converted into new Series E Shares at the agreed conversion rate of CHF 10.48. Of this amount, a portion of ca. €0.09 (representing the current fractional value of the Issuer's shares being the amount of the Issuer's current share capital, divided by the total number of the Issuer's currently outstanding Shares) will be booked as share capital, whereas the balance shall be booked as share premium. As an exception, payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91 will be converted into New Shares at the Offer Price in connection with the Offering, as described in note 7.
- (7) This reflects (i) the Offering, assuming a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range; (ii) the Share Consolidation (as described in Part 12 – (Share Capital and Articles of Association), section 12.3 (Share capital and Shares)), following which all existing Shares will have been converted into ordinary Shares; and (iii) subscription through a contribution in kind by Bootstrap of 50% of the payable due by the Issuer upon the closing of the Offering as an "Exit Fee" pursuant to the Bootstrap Loan. On the basis of this assumption, the Issuer's shares would each have a fractional value of ca. €0.10 per New Shares. In that scenario, of the Offer Price, an amount equal to the fractional value would be booked as share capital, whereas the balance shall be booked as share premium. See also Part 12 – (Share Capital and Articles of Association), section 12.3 (Share capital and Shares), subsection (d) (Capital increase and other changes to the Shares and the Share Capital upon closing of the Offering).

The following table sets out the net financial indebtedness of Sequana Medical as at 30 November 2018:

	As at 30 November 2018	Adjustments	As Adjusted
	<i>(in €000)</i>		
Cash and cash equivalents	1,486	37,131	38,617
Trading securities	—	—	—
Total liquidity	1,486	37,131	38,617
Current financial receivable	—	—	—
Current bank debt	—	—	—
Current portion of non-current debt	—	—	—
Other financial debt	10,653	(10,216)	437
Current financial debt	10,653	(10,216)	437
Net current financial indebtedness	9,167	(47,347)	(38,180)
Non-current bank loans	—	—	—
Bonds issued	—	—	—
Other non-current loans	2,901	0	2,901
Non-current financial indebtedness	2,901	0	2,901
Net financial indebtedness	12,068	(47,347)	(35,279)

As at 30 November 2018, Sequana Medical has no contingent or indirect indebtedness.

5.2 Working capital statement

On the date of this Prospectus, Sequana Medical is of the opinion that, taking into account its available cash and cash equivalents, it does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Prospectus.

However, assuming a placement of the maximum number of New Shares in the Offering (excluding the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the lower end of the Price Range, the gross proceeds from the issue of the New Shares are estimated to be approximately €27.5 million. In the event the Offering is completed in full (including the conversion of the Bridge Loans in full, but excluding the exercise in full of the

Increase Option and the Over-allotment Option), Sequana Medical is of the opinion that the proceeds of the Offering (together with its available cash and cash equivalents) will provide Sequana Medical with sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months from the date of the Prospectus, even if the Offer Price is at the lower end of the Price Range.

In case Sequana Medical would not be able to attract new funds (beyond its existing cash and cash equivalents), it expects to run out of working capital by mid February 2019. Sequana Medical's 12 month working capital shortfall in the event Sequana Medical would not be able to attract any such additional funds and if Sequana Medical in that event maintains its current strategy and development activities, is projected to be approximately €28.2 million at the end of January 2020 (which includes a shortfall for the repayment of outstanding Convertible Loans for an aggregate principal amount of €8.5 million and outstanding Bridge Loans for an aggregate principal amount of €1.0 million).

In addition, the net proceeds from the Offering, together with Sequana Medical's existing capital resources, will be insufficient to fund, among other things, the completion of the clinical development of the **alfapump**[®] DSR required to bring it to market in Europe and the U.S., the commercial roll-out of the **alfapump**[®] in the U.S., if approved, or to pay in full the total CHF 5.90 million in principal and interest outstanding under the Bootstrap Loan, as further described under Part 2 (Risk Factors), section 2.1 (Risks related to Sequana Medical's business and industry), subsection (c) (Sequana Medical will likely require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available when required or could significantly limit Sequana Medical's access to additional capital).

PART 6 – SELECTED FINANCIAL INFORMATION

The following selected financial information should be read together with the other information contained in this Prospectus, including Part 7 – (Operating and financial review and prospects) and the Financial Statements included elsewhere in this Prospectus. This financial information is historical and not necessarily indicative of results to be expected in any future period.

The following selected financial information has been derived from the Financial Statements included elsewhere in this Prospectus and should be read in conjunction with these Financial Statements. The Annual Financial Statements have been prepared in accordance with IFRS and the Interim Financial Statements have been prepared in accordance with IAS 34 in each case as in effect at the time of preparing the relevant financial statements. For more information, see the subsection “Financial Statements” of the section titled “Presentation of financial and other information” on page vi of this Prospectus.

6.1 Consolidated statements of profit and loss

	For the nine months ended 30 September		For the year ended 31 December		
	2018	2017	2017	2016	2015
			<i>(in €000)</i>		
	<i>(unaudited)</i>			<i>(audited)</i>	
Revenue	686	957	1,304	1,489	1,685
Cost of goods sold	(107)	(198)	(212)	(321)	(360)
Gross margin	580	760	1,092	1,168	1,325
Sales and marketing	(1,479)	(1,091)	(1,506)	(3,337)	(2,988)
Clinical affairs	(1,040)	(1,310)	(1,749)	(3,325)	(2,790)
Quality and regulatory	(816)	(974)	(1,225)	(1,492)	(1,091)
Supply chain	(729)	(862)	(1,041)	(1,775)	(1,795)
Engineering	(885)	(743)	(1,004)	(1,146)	(995)
General and administration	(3,547)	(1,709)	(1,988)	(4,059)	(3,286)
Other income	—	—	3	21	264
Total operating expenses	(8,496)	(6,689)	(8,510)	(15,113)	(12,681)
Earnings before interest and taxes (EBIT)	(7,916)	(5,929)	(7,418)	(13,945)	(11,356)
Financial income	—	—	—	3	4
Financial expense	(670)	(487)	(636)	(190)	(89)
Foreign exchange gains/ (losses), net	(23)	(8)	(153)	198	(72)
Total net financial expense	(693)	(495)	(789)	11	(157)
Taxes	(25)	(12)	(18)	(41)	(44)
Net loss for the period	(8,634)	(6,436)	(8,225)	(13,975)	(11,557)

6.2 Consolidated balance sheet

	As of	As of		
	30 September	2017	2016	2015
	2018			
		(in €000)		
	<i>(unaudited)</i>		<i>(audited)</i>	
Tangible fixed Assets	170	206	299	160
Laboratory	8	10	16	17
Information Technology (IT)	154	186	268	136
RD Tools	8	10	15	7
Financial assets	51	42	104	102
Financial assets – Rental deposit	51	42	46	45
Loans to related parties	—	—	58	57
Total non-current assets	221	248	403	262
Trade Receivables	120	165	225	258
Trade Receivables – Third parties	120	165	225	258
Other Receivables	284	152	419	591
Other Receivables – Third parties	170	130	193	245
Other Receivables – Related parties	—	9	153	103
Other Receivables – Prepaid expenses	115	13	73	243
Inventory	1,453	1,271	1,964	2,144
Inventory	1,453	1,271	1,964	2,144
Cash and cash equivalents	541	1,684	797	1,427
Cash and cash equivalents	541	1,684	797	1,427
Total current assets	2,398	3,272	3,405	4,420
TOTAL ASSETS	2,620	3,519	3,808	4,682
Total equity	(13,349)	(4,611)	(6,667)	(284)
Share Capital	956	955	860	4,411
Other equity	184	—	—	—
Own shares	(193)	(193)	—	—
Share premium	65,157	65,157	55,438	48,623
Reserves	(390)	(183)	(335)	(307)
Loss brought forward	(79,716)	(71,082)	(62,856)	(53,501)
Cumulative translation adjustment	653	736	226	490
Long term financial debts	—	1,757	4,664	—
Long term financial debts	—	1,757	4,664	—
Retirement benefit obligation	875	819	969	846
Retirement benefit obligation	875	819	969	846
Total non-current liabilities	875	2,576	5,633	846
Short term financial debts	10,923	2,820	—	—
Short term financial debts	10,923	2,820	—	—
Trade Payables	2,190	2,012	3,224	2,766
Trade Payables – Third parties	1,175	909	1,803	1,304
Contract liabilities	1,015	1,103	1,421	1,462
Other payables	18	270	182	571
Other payables – Third parties	18	270	182	571
Accrued liabilities	1,962	451	1,436	783
Accrued liabilities – Provision warranty	62	29	54	49
Accrued liabilities – Third parties	1,901	422	1,383	734
Total current liabilities	15,093	5,554	4,842	4,120
TOTAL EQUITY AND LIABILITIES	2,620	3,519	3,808	4,682

6.3 Consolidated statements of cash flows

	For the nine months ended 30 September		For the year ended 31 December		
	2018	2017	2017	2016	2015
			<i>(in €000)</i>		
	<i>(unaudited)</i>			<i>(audited)</i>	
Net loss for the period	(8,634)	(6,436)	(8,225)	(13,975)	(11,557)
Income taxes	25	12	18	41	44
Financial result.....	693	495	789	(11)	157
Depreciation.....	54	58	78	80	47
Change in defined benefit plan.....	—	—	64	71	10
Share-based compensation	18	17	23	10	11
Changes in trade and other receivables.....	(87)	(58)	145	213	(451)
Changes in inventories	(182)	453	556	208	(622)
Changes in trade and other payables/provisions.....	1,437	(1,658)	(1,808)	656	1,146
Taxes paid	(9)	(12)	(18)	(41)	(44)
Cash flow used in operating activities	(6,686)	(7,129)	(8,378)	(12,748)	(11,259)
Investments in tangible assets.....	(3)	(7)	(7)	(215)	(89)
Investments in financial assets.....	(11)	(4)	(4)	(2)	(19)
Cash flow used in investing activities	(14)	(10)	(11)	(217)	(108)
Proceeds from capital increase	—	9,813	9,815	7,812	8,206
Exercise of employee options.....	2	—	—	71	34
Proceeds from financial debts	5,711	—	—	4,545	—
Transaction costs deducted from equity	(226)	—	—	—	—
Interest paid.....	(7)	(250)	(314)	(190)	(22)
Cash flow from financing activities	5,480	9,563	9,501	12,238	8,218
Net change in cash and cash equivalents	(1,219)	2,423	1,112	(727)	(3,149)
Cash and cash equivalents at beginning of period	1,684	797	797	1,427	4,091
Net effect of currency translation on cash and cash equivalents	76	(145)	(226)	97	485
Cash and cash equivalents at end of period	541	3,075	1,683	797	1,427

PART 7 – OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following is a review of Sequana Medical's financial condition and results of operations as of and for the nine-month periods ended 30 September 2018 and 2017 and the three years ended 31 December 2017, 2016 and 2015. This section should be read in conjunction with the section entitled "Selected financial information" and the Financial Statements included elsewhere in this Prospectus. The figures used in this section have been derived from these Financial Statements. The Annual Financial Statements have been prepared in accordance with IFRS, and the Interim Financial Statements have been prepared in accordance with IAS 34. Certain statements in this section are forward-looking and should be read in conjunction with "Forward-looking statements" on page viii of this Prospectus.

7.1 Overview

Sequana Medical is a commercial stage medical device company focused on the development of innovative treatment solutions for the management of liver disease, heart failure, malignant ascites and other fluid imbalance disorders. Sequana Medical's core markets of liver disease and heart failure are large and growing, driven by unhealthy lifestyles and aging populations.

Sequana Medical's **alfapump**[®] provides an innovative treatment solution for the long-term management of liver refractory ascites and malignant ascites with proven safety, efficacy and quality of life benefits demonstrated in multiple clinical studies and over 650 implants. The **alfapump**[®] has received CE Mark approval for liver refractory ascites and malignant ascites. Since April 2018, the **alfapump**[®] has been included in the European Association for the Study of the Liver (the "**EASL**") clinical practice guidelines for the management of patients with decompensated cirrhosis, which management believes is a key step in the widespread commercial acceptance of the **alfapump**[®].

Sequana Medical has developed Direct Sodium Removal ("**DSR**"), a novel and proprietary approach to the treatment of volume overload in heart failure. Animal studies have demonstrated DSR therapy to be both safe and effective. Sequana Medical has built on the **alfapump**[®] platform to deliver **alfapump**[®] DSR, a convenient and fully implanted system for DSR therapy.

Sequana Medical is led by an experienced management team, supported by renowned life science investors and its technology and approach has been endorsed by key opinion leaders ("**KOLs**").

7.2 Factors affecting results of operations

Set forth below is a discussion of factors that management believes have affected and will continue to affect the results of operations of Sequana Medical.

(a) Sales of **alfapump**[®] systems

Sequana Medical derives its revenues solely from the sale of **alfapump**[®] systems to customers primarily located in Germany, as well as in Switzerland and other European countries. Sequana Medical recognises revenue at the time the **alfapump**[®] is implanted in the patient. See section 7.6 (Critical accounting policies), subsection (a) (Revenue recognition) for further detail. For direct sales (i.e., sales to hospitals), the timing between delivery and implantation is typically very brief, meaning that the invoice is issued upon delivery of the implant, and payable within 30 days from the date of implant. In some cases, customers make an advance payment for the full sales price, which results in Sequana Medical recognising a receivable and/or cash inflow and corresponding contract liability, which is reversed only at the time the performance obligation (i.e. implantation in the patient) has been satisfied.

The following table provides a breakdown of revenue derived from the sale of **alfapump**[®] systems by geography for the nine months ended 30 September 2018 and 2017 and the years ended 31 December 2017, 2016 and 2015:

	For the nine months ended 30 September		For the year ended 31 December		
	2018	2017	2017	2016	2015
			<i>(in €000)</i>		
	<i>(unaudited)</i>			<i>(audited)</i>	
Switzerland	55	106	125	164	383
Germany	427	456	764	1,108	1,021
U.K.....	68	69	69	73	186
Rest of the world	136	326	346	144	95
Total	686	957	1,304	1,489	1,685

(i) Regulatory approvals

Sequana Medical's revenues from the sale of **alfapump**[®] systems are driven to a great extent by the status of regulatory approval in the countries in which its customers are located. The **alfapump**[®] received a CE-Mark in Europe for the treatment of liver refractory ascites in 2011, and in 2012 for the treatment of malignant ascites. Sequana Medical has not yet received regulatory approval for the **alfapump**[®] in North America. However, it expects to begin the POSEIDON (North American pivotal) Study in the second half of 2019, with the aim of receiving such approval.

(ii) Reimbursement arrangements

Reimbursement arrangements in the countries where Sequana Medical commercialises the **alfapump**[®] also have a significant impact on revenues. In Switzerland and Germany, Sequana Medical has existing reimbursement arrangements, which facilitate the sale of **alfapump**[®] systems on a larger scale in comparison with countries for which it has no such arrangements. In Switzerland, Sequana Medical has reimbursement for the **alfapump**[®] through a Swiss Diagnosis Related Group ("DRG") code. In Germany, medical devices are reimbursed according to G-DRG codes. There has been reimbursement for the **alfapump**[®] since 2012 pursuant to a short-term, intermediate reimbursement mechanism known as the NUB application, which must be renewed each year. Sequana Medical is actively pursuing a G-DRG code for the **alfapump**[®]. Management estimates that the **alfapump**[®] will acquire a G-DRG code in the first half of 2020. This will enable Sequana Medical to expand the scale of its operations in Germany.

In France, Sequana Medical intends to commercially launch following the completion of the ARIA Pump Study and estimates that the **alfapump**[®] will receive a DRG code in France in 2022 on the assumption that the study results in satisfactory French reimbursement. Sequana Medical is expanding into the U.K. market following the updated NICE guidance. Management estimates that the **alfapump**[®] will receive a DRG code in the Netherlands in mid-2019 and Belgium in the first half of 2020 in cooperation with Fresenius, its distributor in those markets.

In the US, following the receipt of regulatory approval, the **alfapump**[®] would be purchased primarily by hospitals or other healthcare providers, with those customers then billing various third-party payers for covered services provided to patients. Accordingly, Sequana Medical will be dependent on private insurers approving reimbursement for the **alfapump**[®], as well as the Centers for Medicare & Medicaid Services, the agency responsible for administering the Medicare programme, issuing favourable national coverage for treatment using the **alfapump**[®]. In Canada, reimbursement will largely depend on individual hospitals and physicians making favourable coverage decisions for the **alfapump**[®].

See Part 8 – (Business), section 8.7 (Commercial operations), subsection (c) (Reimbursement) for further detail of the reimbursement arrangements applicable to sales of the **alfapump**[®].

(iii) Opportunities for revenue growth

During the periods under review, Sequana Medical has generated substantially all of its sales of **alfapump**[®] systems in Europe as a result of the regulatory approval status and reimbursement arrangements described above. Going forward, however, it expects that the North American market will be a key driver of its **alfapump**[®] sales, subject to the receipt of regulatory approval and the conclusion of reimbursement arrangements. Management believes that the North American market has high growth potential given the relatively high incidence of NASH in the U.S., and estimates that sales in the U.S. would peak prior to sales in Europe given the slower onset of NASH in Europe. See Part 8 – (Business), section 8.1 (Overview), subsection (a) (Large and growing market opportunities), subsection (i) Chronic liver disease/NASH for further detail regarding the U.S. market opportunity.

At the same time, Sequana Medical expects that its revenues in its currently most significant European markets, in particular Germany and Switzerland, will continue to grow as it further penetrates those markets. The further penetration of the German market depends to a great extent on the receipt of a G-DRG code as described above under (subsection (ii) (Reimbursement arrangements)). Sequana Medical also is expanding into the U.K. market following the updated NICE guidance and intends to expand into France, assuming reimbursement is obtained following completion of the ARIA Pump Study, which would contribute to additional revenues.

Furthermore, Sequana Medical intends to intensify its commercial and clinical activity in malignant ascites. This will include investing in prospective clinical studies and establishing a KOL group to support market acceptance as has been done in the liver ascites market. Management estimates, subject to the results of the study being positive, that **alfapump**[®] sales to malignant ascites patients will increase following the release of the results of the Malignant Ascites CT, which are expected to be available in mid-2021.

Moreover, during the periods under review, all of Sequana Medical's revenues have been attributable to sales of **alfapump**[®] systems. Going forward, subject to successful development and the receipt of regulatory approval, Sequana Medical may potentially derive revenues from the sale of **alfapump**[®] DSR systems and associated consumables, which leverage the **alfapump**[®] platform to deliver a potential novel and patent-pending treatment for fluid overload caused by heart failure. Sequana Medical may also explore the use of the **alfapump**[®] in other indications, which could present additional revenue opportunities.

(b) Pricing for **alfapump**[®]

As described above under subsection (a) (Sales of **alfapump**[®] systems), subsection (ii) (Reimbursement arrangements), Sequana Medical is dependent upon the conclusion of reimbursement arrangements with the relevant "payer" in the countries where it currently sells, and intends to sell, the **alfapump**[®]. Pricing for the **alfapump**[®] and the **alfapump**[®] DSR is determined pursuant to these reimbursement arrangements. In Germany, for instance, the Germany NUB mechanism provides for a centrally determined price which applies to hospitals using the **alfapump**[®], which must submit an application for reimbursement.

In other countries, such as France, prices are negotiated directly with the government. In the United States, the **alfapump**[®] and **alfapump**[®] DSR would be purchased primarily by hospitals or other healthcare providers, who will then bill third-party payers such as federal healthcare programmes (e.g., Medicare and Medicaid), state healthcare programmes, and private health insurance companies. See Part 8 – (Business), section 8.7 (Commercial operations), subsection (c) (Reimbursement) for further details of these arrangements. As a result, the payment Sequana Medical receives for the **alfapump**[®] (and will potentially receive in the future for its **alfapump**[®] DSR) is usually determined through negotiations as part of the reimbursement process. At the date of this Prospectus, the German NUB mechanism provides reimbursement of €27,000 and the Swiss DRG code provides reimbursement of approximately CHF 30,000, in each case covering both the pump and the implantation procedure.

Pricing for the **alfapump**[®] (and potentially in the future the **alfapump**[®] DSR) may in the future evolve due to developments in government spending or the regulatory environment in the countries into which Sequana Medical sells the **alfapump**[®]. In the United States, for example, the federal government and Congress review and adjust reimbursement rates annually, and from time to time consider various Medicare and other healthcare reform proposals that could significantly affect both private and public reimbursement for healthcare services. In addition, state government

reimbursement for services is determined pursuant to each state's Medicaid plan, which is established by state law and regulations, subject to requirements of federal law and regulations.

(c) Cost of goods sold

Sequana Medical assembles and tests the **alfapump**[®] and **alfapump**[®] DSR and manufactures selected components at its facilities in Switzerland. The large majority of sub-components including the batteries, printed circuit board, motor, charger, docking station, catheter and surgical accessories are sourced externally, from approximately 70 suppliers. Sequana Medical includes the cost of producing the **alfapump**[®] and **alfapump**[®] DSR (including labour expenses of approximately 6 man-hours per **alfapump**[®]) in cost of goods sold.

Sequana Medical is working to improve the technical performance of the **alfapump**[®] as well as reduce the cost of the system. It is exploring production cost reductions by optimising the design for manufacturing and assembly and through the realisation of purchasing efficiencies as production volumes increase. While management believes that Sequana Medical has sufficient capacity to meet volume projections up to 2,000 pumps annually, it has also undertaken an evaluation of the feasibility of outsourcing its manufacturing in the future and has determined that it has the ability to outsource manufacturing if sufficient demand volumes are achieved.

(d) Sales and marketing expenses

Sequana Medical's commercial team is focused on the successful penetration of Germany and Switzerland and on follow-on expansion into the U.K. (following the updated guidance from NICE) and France (subject to the completion of the ARIA Pump Study). The commercial team also supports Sequana Medical's distributors in Belgium, the Netherlands, Denmark and Israel. Sequana Medical intends to establish direct commercial activities in the U.S. and Canada, and will either establish a direct commercial presence or work with distributors in other markets. In those countries covered by distributors, Sequana Medical typically sells the **alfapump**[®] to the distributor at a price which is lower than the price paid by the end user. As a result, in the countries where it has distribution agreements, it will typically have a lower gross margin compared to Germany and Switzerland, where it has direct sales and marketing activities.

In 2016, Sequana Medical undertook a significant restructuring of its commercial team, which entailed scaling down its commercial efforts and reducing the number of hospitals on which it focused its commercial activities. As a result of this restructuring, sales and marketing expenses decreased significantly from 2016 to 2017.

In addition to the direct costs associated with its sales force, Sequana Medical conducts promotional activities using both conventional and social media tools to raise awareness of the **alfapump**[®] amongst the medical community, patients and their relatives. These costs are recorded directly within sales and marketing expense.

(e) Clinical affairs expenses

Sequana Medical has invested significant resources in clinical studies to demonstrate the safety and efficacy of the **alfapump**[®]. See Part 8 – (Business), section 8.6 (Clinical and pre-clinical studies) for further detail of these studies. These costs primarily include:

- employee-related expenses, including salaries, benefits, bonuses and travel expenses;
- the cost of pre-clinical and clinical study activities performed by third parties, including hospitals, laboratories and physicians;
- the cost of outside consultants who assist with pre-clinical and clinical studies and medical affairs; and
- the cost of the **alfapump**[®] systems used in the clinical studies.

Sequana Medical expenses the costs associated with its clinical studies as incurred and records them within clinical affairs expenses.

In 2018, Sequana Medical completed the MOSAIC (North American IDE feasibility) Study, which was a 12-month open-label, single-arm study in North America to assess the safety and efficacy of the **alfapump**[®] in patients with liver recurrent or refractory ascites.

Clinical studies will continue to be central to Sequana Medical's business model. Sequana Medical expects that clinical affairs expenses will increase significantly over the next several years as it will conduct the following clinical studies: (i) the POSEIDON (North American pivotal) Study

for the purposes of obtaining regulatory approval for the **alfapump**[®] in North America; (ii) the TOPMOST registry; (iii) the study on the impact of albumin replacement therapy on clinical outcomes in patients implanted with the **alfapump**[®] (the “**Albumin Replacement Study**”); (iv) the study to measure the impact of the **alfapump**[®] on patient quality of life (the “**Fitbit**[®] **Study**”); and (v) the Malignant Ascites CT. Sequana Medical also plans to commence clinical studies for DSR and **alfapump**[®] DSR in 2018 and 2019, respectively. See Part 8 – (Business), section 8.6 (Clinical and pre-clinical studies) for further detail of these studies. The duration, costs and timing of clinical studies, and accordingly, Sequana Medical’s clinical affairs expenses, will depend on a variety of factors that include, but are not limited to:

- the number of clinical studies required for approval.
- the clinical study costs per patient.
- the number of patients that participate in the clinical studies.
- the number of sites included in clinical studies and the type of site. In the U.S., there is significant variability in cost across potential clinical sites.
- the countries in which the clinical studies are conducted. Hospital care costs are generally much more expensive in the U.S. versus Europe, and vary significantly within Europe as well. This has an impact on the clinical study cost per patient which is approximately 15% higher in the U.S. than in EU.
- the length of time required to enrol eligible patients.
- the drop-out or discontinuation rates of patients.
- the potential additional safety monitoring or other studies requested by the relevant regulatory authorities.
- the duration of any patient follow-up. For example, it is likely that reduction in hospitalisation rates over a fixed period (such as 12 months) will drive reimbursement for the **alfapump**[®] DSR, which would likely require a pivotal study on the **alfapump**[®] DSR for the treatment of volume overload in heart failure to last longer than the POSEIDON (North American pivotal) Study and result in additional costs.
- the timing and receipt of regulatory approvals.
- the efficacy and safety profile of the **alfapump**[®] in the clinical studies.

(f) Quality and regulatory expenses

The costs of obtaining and maintaining regulatory approval for the **alfapump**[®] (and potentially in the future the **alfapump**[®] DSR) are included within quality and regulatory expenses. Employee-related costs, such as salaries, benefits and travel expenses, of Sequana Medical employees are a key part of quality and regulatory expenses. The cost of regular audits and regulatory filings, internal and external costs related to testing and validation, as well as costs associated with external consultants, are also included within quality and regulatory expenses. Changes in regulations or standards (including, for example, the introduction of the Medical Devices Regulation and ISO 13485:2016) may lead to additional quality and regulatory expenses.

(g) Supply chain expenses

The cost of supply chain primarily includes employee-related costs, such as salaries and benefits of Sequana Medical employees, as well as external suppliers’ services. Additionally, yield loss costs and material costs for internal use are included in supply chain expenses.

(h) Engineering expenses

Sequana Medical’s engineering expenses primarily include employee-related costs, such as salaries, benefits and travel expenses, of Sequana Medical employees, as well as external consultants and suppliers, involved in the design of the **alfapump**[®] and **alfapump**[®] DSR. For the **alfapump**[®] DSR, Sequana Medical will use both internal resources and external consultants.

(i) General and administrative expenses

The principal components of general and administrative expenses are salaries and related costs for personnel and external consultants in executive, finance, accounting, tax, audit, legal and human resources functions and their respective external advisers. General and administrative

expenses also include the costs related to the general information and communication technologies as well as lease, rental, insurance and general maintenance expenses. General and administrative expenses are expected to increase as a result of becoming a public company and in line with the expansion of Sequana Medical's business.

(j) Total net financial expense

Sequana Medical's finance costs include interest costs less interest income and also include foreign exchange gains/losses related to its borrowings as well as other finance expenses. For detail of Sequana Medical's financing arrangements, see section 7.4 (Liquidity and capital resources).

(k) Taxation

Since its inception, Sequana Medical has not made profits and, as a result, has not paid any material corporate income taxes. While it had accumulated losses for taxation purposes in Switzerland, it will not be permitted to carry these forward as a result of the relocation to Belgium.

7.3 Analysis of operating results

The following table includes information relating to Sequana Medical's operating results for the nine months ended 30 September 2018 and 2017 and the years ended 31 December 2017, 2016 and 2015.

(a) Consolidated statements of profit and loss

	For the nine months ended 30 September		For the year ended 31 December		
	2018	2017	2017	2016	2015
			<i>(in €000)</i>		
	<i>(unaudited)</i>		<i>(audited)</i>		
Revenue	686	957	1,304	1,489	1,685
Cost of goods sold.....	(107)	(198)	(212)	(321)	(360)
Gross margin	580	760	1,092	1,168	1,325
Sales and marketing.....	(1,479)	(1,091)	(1,506)	(3,337)	(2,988)
Clinical affairs.....	(1,040)	(1,310)	(1,749)	(3,325)	(2,790)
Quality and regulatory.....	(816)	(974)	(1,225)	(1,492)	(1,091)
Supply chain.....	(729)	(862)	(1,041)	(1,775)	(1,795)
Engineering.....	(885)	(743)	(1,004)	(1,146)	(995)
General and administration.....	(3,547)	(1,709)	(1,988)	(4,059)	(3,286)
Other income.....	—	—	3	21	264
Total operating expenses	(8,496)	(6,689)	(8,510)	(15,113)	(12,681)
Earnings before interest and taxes (EBIT)	(7,916)	(5,929)	(7,418)	(13,945)	(11,356)
Financial income.....	—	—	—	3	4
Financial expense.....	(670)	(487)	(636)	(190)	(89)
Foreign exchange gains/ (losses), net.....	(23)	(8)	(153)	198	(72)
Total net financial expense	(693)	(495)	(789)	11	(157)
Taxes.....	(25)	(12)	(18)	(41)	(44)
Net loss for the period	(8,634)	(6,436)	(8,225)	(13,975)	(11,557)

(b) Revenue

The table below provides a breakdown of Sequana Medical's revenue by geographical market for the nine months ended 30 September 2018 and 2017 and the years ended 31 December 2017, 2016 and 2015:

	For the nine months ended 30 September		For the year ended 31 December		
	2018	2017	2017	2016	2015
			<i>(in €000)</i>		
	<i>(unaudited)</i>		<i>(audited)</i>		
Geographical market:					
Switzerland	55	106	125	164	383
Germany	427	456	764	1,108	1,021
U.K.	68	69	69	73	186
Rest of the world	136	326	346	144	95
Total revenue	686	957	1,304	1,489	1,685

Revenue decreased from €0.96 million in the nine months ended 30 September 2017 to €0.69 million in the nine months ended 30 September 2018 mainly as a result of a strategic decision to focus principally on Sequana Medical's focus markets in Europe, which are currently Switzerland, Germany, France and the U.K. Management also expects to begin pursuing reimbursement in Spain and Italy in 2019. Sequana Medical reduced its investment in commercial activities until the clinical results of the **alfapump**[®] have further improved, and following challenges in recruiting suitable members for the commercial team.

Revenue decreased from €1.49 million in 2016 to €1.30 million in 2017 largely as a result of the decrease in revenue from Germany from €1.11 million in 2016 to €0.76 million in 2017. This was due to the restructuring undertaken by Sequana Medical in 2016, which resulted in a reduction in the number of hospitals on which it focused its commercial activities. The decrease in revenue from Germany was partially offset by an increase in revenue from the rest of the world from €0.14 million in 2016 to €0.35 million in 2017, which was mainly driven by higher sales in Israel and Belgium.

Revenue decreased from €1.69 million in 2015 to €1.49 million in 2016 largely as a result of the decrease in revenue from Switzerland from €0.38 million in 2015 to €0.16 million in 2016, which was due to significant purchases by a hospital in 2015 and no subsequent purchase in 2016, and the decrease in revenue from the U.K. from €0.19 million in 2015 to €0.07 million in 2016. The decrease in revenue from Switzerland and the U.K. was partially offset by an increase in revenue from Germany from €1.02 million in 2015 to €1.11 million in 2016.

(c) Cost of goods sold

Cost of goods sold decreased from €0.20 million in the nine months ended 30 September 2017 to €0.11 million in the nine months ended 30 September 2018 in line with the decrease in revenue.

Cost of goods sold decreased from €0.36 million in 2015 to €0.32 million in 2016 and again to €0.21 million in 2017 in line with the decreases in revenue.

(d) Sales and marketing expenses

Sales and marketing expenses increased from €1.09 million in the nine months ended 30 September 2017 to €1.48 million in the nine months ended 30 September 2018 mainly as a result of the expansion of the commercial team, greater travel expenses and increased marketing activities.

Sales and marketing expenses decreased from €3.34 million in 2016 to €1.51 million in 2017 largely as a result of the restructuring undertaken by Sequana Medical in 2016, which entailed a reduction in the commercial team and commercial activities.

Sales and marketing expenses increased from €2.99 million in 2015 to €3.34 million in 2016 mainly as a result of investments in marketing support for Germany and trade shows.

(e) Clinical affairs expenses

Clinical affairs expenses decreased from €1.31 million in the nine months ended 30 September 2017 to €1.04 million in the nine months ended 30 September 2018 principally as a result of lower expenses for the MOSAIC (North American IDE feasibility) Study in 2018 versus 2017, partly offset by higher expenses for the healthy pig and heart failure pig DSR proof of concept studies.

Clinical affairs expenses decreased from €3.33 million in 2016 to €1.75 million in 2017 largely as a result of lower expenses for the MOSAIC (North American IDE feasibility) Study in 2017 as compared to 2016 and the completion of the RCT.

Clinical affairs expenses increased from €2.79 million in 2015 to €3.33 million in 2016 primarily as a result of the MOSAIC (North American IDE feasibility) Study starting in 2015, partially offset by a decrease in costs related to other liver trials and a decreased use of consultants.

(f) Quality and regulatory expenses

Quality and regulatory expenses decreased from €0.97 million in the nine months ended 30 September 2017 to €0.82 million in the nine months ended 30 September 2018 as a result of multiple minor changes, including additional external advice regarding the POSEIDON (North American pivotal) Study and preparation for the new Medical Device Regulation.

Quality and regulatory expenses decreased from €1.49 million in 2016 to €1.23 million in 2017 largely as a result of the completion of the usability/safety testing performed for the MOSAIC (North American IDE feasibility) Study and the CE-Mark renewal process.

Quality and regulatory expenses increased from €1.09 million in 2015 to €1.49 million in 2016 mainly as a result of the aforementioned factors in relation to 2016.

(g) Supply chain expenses

Supply chain expenses decreased from €0.86 million in the nine months ended 30 September 2017 to €0.73 million in the nine months ended 30 September 2018 mainly as a result of the decrease in revenue.

Supply chain expenses decreased from €1.78 million in 2016 to €1.04 million in 2017 in line with the decrease in revenue and as a result of the discontinuation of a project that Sequana Medical had undertaken to analyse the benefits of outsourcing certain aspects of production (which incurred consultancy and other expenses) as well as a decrease in shipping costs relating to the MOSAIC (North American IDE feasibility) Study.

Supply chain expenses were broadly flat from €1.80 million in 2015 to €1.78 million in 2016.

(h) Engineering expenses

Engineering expenses increased from €0.74 million in the nine months ended 30 September 2017 to €0.89 million in the nine months ended 30 September 2018 largely as a result of the costs related to the further development of improvements to the **alfapump**[®] and costs related to preparation for the new Medical Device Regulation.

Engineering expenses decreased from €1.15 million in 2016 to €1.00 million in 2017 largely as a result of minor reduction in the size of the engineering team.

Engineering expenses increased from €1.00 million in 2015 to €1.15 million in 2016 primarily as a result of a minor expansion of the engineering team.

(i) General and administration expenses

General and administration expenses increased from €1.71 million in the nine months ended 30 September 2017 to €3.55 million in the nine months ended 30 September 2018 mainly as a result of the transaction costs related to the preparation for the Offering.

General and administration expenses decreased from €4.06 million in 2016 to €1.99 million in 2017 primarily as a result of severance payments made to former employees in 2016 and the restructuring that took place in that year.

General and administration expenses increased from €3.29 million in 2015 to €4.06 million in 2016 mainly as a result of the expansion of the team and severance payments made in 2016.

(j) Earnings before interest and taxes (EBIT)

Earnings before interest and taxes increased from a loss of €5.93 million in the nine months ended 30 September 2017 to a loss of €7.92 million in the nine months ended 30 September 2018 largely due to transaction costs related to the preparation for the Offering, increased marketing activities and a lower gross margin due to a decrease in sales (partially offset by lower expenses in clinical affairs).

Earnings before interest and taxes decreased from a loss of €13.95 million in 2016 to a loss of €7.42 million in 2017 largely due to the restructuring undertaken in 2016, severance payments to former employees and lower expenses for the MOSAIC (North American IDE feasibility) Study in 2017 as compared to 2016.

Earnings before interest and taxes increased from a loss of €11.36 million in 2015 to a loss of €13.95 million in 2016 mainly as a result of an increase in sales and marketing expenses due to investments in marketing support for Germany and trade shows, clinical affairs expenses due to the MOSAIC (North American IDE feasibility) Study, quality and regulatory expenses due to testing for the North American market and quality studies and general and administrative expenses due to severance payments, as well as a decrease in revenue due to the restructuring of the commercial team.

(k) Total net finance expense

	For the nine months ended 30 September		For the year ended 31 December		
	2018	2017	2017	2016	2015
			<i>(in €000)</i>		
	<i>(unaudited)</i>			<i>(audited)</i>	
Interest income	—	—	—	3	4
Interest cost	(670)	(487)	(636)	(190)	(89)
Foreign exchange gains / (losses)	(23)	(8)	(153)	198	(72)
Net financial result	(693)	(495)	(789)	11	(157)

Net finance result increased from €0.50 million expense in the nine months ended 30 September 2017 to €0.69 million in the nine months ended 30 September 2018 mainly as a result of the interest expenses related to the Convertible Loans received in 2018 that were denominated in CHF. The remainder of the costs relate to the Bootstrap Loan. For further details of the Bootstrap Loan, see section 7.4 (Liquidity and capital resources).

Net finance result decreased from €0.01 million income in 2016 to €0.79 million expense in 2017 mainly due to the full year interest expense relating to the Bootstrap Loan (the agreement for which was signed in September 2016). The decrease was also the result of fluctuations in the CHF/EUR foreign exchange rate. For further details of the Bootstrap Loan, see section 7.4 (Liquidity and capital resources).

Net finance result increased from €0.16 million expense in 2015 to €0.01 million income in 2016 as a result of the Bootstrap Loan referred to in the previous paragraph, offset by positive fluctuations in the CHF/EUR foreign exchange rate.

(l) Taxes

Tax expense was broadly flat at €0.01 million in the nine months ended 30 September 2017 and €0.03 million in the nine months ended 30 September 2018. These amounts largely reflected taxes payable in Germany.

Tax expense was broadly flat at €0.04 million in 2016 and €0.02 million in 2017. These amounts largely reflected taxes payable in Germany.

Tax expense remained stable at €0.04 million in 2015 and 2016.

(m) Net loss for the period

The net loss for the period increased from €6.44 million in the nine months ended 30 September 2017 to €8.63 million in the nine months ended 30 September 2018 due to the factors described under subsection (j) (Earnings before interest and taxes (EBIT)).

The net loss for the period decreased from a loss of €13.98 million in 2016 to a loss of €8.23 million in 2017 due to the factors described under subsection (j) (Earnings before interest and taxes (EBIT)).

The net loss for the period increased from a loss of €11.56 million in 2015 to a loss of €13.98 million in 2016 due to the factors described under subsection (j) (Earnings before interest and taxes (EBIT)).

7.4 Liquidity and capital resources

(a) General

Sequana Medical's liquidity requirements relate primarily to the funding of clinical studies, sales and marketing, regulatory compliance and quality assurance, its supply chain, engineering and general and administrative expenses, capital expenditures and working capital requirements. Historically, Sequana Medical was funded from equity capital and loans.

In 2016, Sequana Medical entered into a secured loan agreement with Bootstrap in the amount of up to CHF 10 million and made a drawdown of CHF 5 million. The nominal interest rate was set at 12% per annum. In addition, as an inducement for Bootstrap to enter into the secured loan agreement, the Issuer and Bootstrap entered into the Bootstrap Warrant Agreement (as described in Part 12 – (Share capital and articles of association), section 12.5 (Outstanding Share options), subsection (b) (Bootstrap Warrant)). Sequana Medical has pledged to Bootstrap its intellectual property as well as the related assets as security for the Bootstrap Loan.

In 2017, following the significant restructuring of Sequana Medical's commercial team that drove a decrease in revenues from 2017 to 2016, the agreement for the Bootstrap Loan was amended whereby, in exchange for Bootstrap waiving potential events of default, the second advance of CHF 5 million was cancelled, the terms of the Bootstrap Warrant were also amended (see Part 12 – (Share capital and articles of association, section 12.5 (Outstanding Share options), subsection (b) (Bootstrap Warrant)), and Bootstrap was granted an "Exit Fee" initially to be payable in cash upon the occurrence of certain exit events (including in the event of a listing), which was further amended in October 2018 as described below.

In October and December 2018, the Issuer and Bootstrap agreed to further amend the Bootstrap Loan, as well as the terms of the Bootstrap Warrant (see Part 12 – (Share capital and articles of association, section 12.5 (Outstanding Share options), subsection (b) (Bootstrap Warrant)). The "Exit Fee" was amended whereby instead of the "Exit Fee" being payable in cash, the New Shares in the Offering can be subscribed for through a contribution in kind by Bootstrap of 50% of the payable due by the Issuer upon the closing of the Offering (as described in Table 1 below). The remaining portion of the Exit Fee shall be repaid in cash by the Issuer following the closing of the Offering. As provided for by the Bootstrap Loan, the Exit Fee shall not exceed a maximum of CHF 750,000. The portion of the Exit Fee payable that shall be so contributed in kind, but that cannot be used for the subscription for a whole number of New Shares at the Offer Price shall not be contributed in kind, but remains payable in cash (subject to the terms of the Bootstrap Loan). In case of an over-subscription of the Offering, the allocation to Bootstrap of Shares in consideration of the contribution in kind in the Offering of 50% of the Exit Fee payable shall not be reduced. Table 1 below summarises the payments of principal, interest and fees to be made pursuant to the terms of the amended Bootstrap Loan.

At the date of this Prospectus, CHF 5.9 million in principal and interest is outstanding.

Table 1
Payments of principal, interest and fees
on the Bootstrap Loan

Payment description	Amount	Payment date(s)
5% of the proceeds of the Offering must be used for a partial repayment of the principal outstanding	a minimum of €0.75 million and a maximum of €1.5 million	Closing Date
Remaining outstanding principal amount not already paid from the 5% of the proceeds of the Offering	four substantially equal consecutive instalments	31 December 2020; 31 January 2021; 28 February 2021; 31 March 2021
Unpaid interest from 1 January 2018 through 31 October 2018	€0.44 million (CHF 0.50 million)	10 business days after Closing Date
Unpaid interest from 1 May 2017 to 31 December 2017 plus additional interest charge following the October 2018 and December 2018 amendments	€0.44 million (CHF 0.50 million); ⁽¹⁾ to be paid in six equal instalments	The last day of each month from 28 February 2019 to 31 July 2019
Interest from 1 November 2018 to 31 March 2021	12% per annum payable monthly	The last day of each month from 31 October 2018 to 31 March 2021
New Shares in the Offering can be subscribed for by Bootstrap through a contribution in kind by Bootstrap of 50% of the payable due by the Issuer as an “Exit Fee” with the remaining portion of the Exit Fee payable in cash	Up to CHF 0.75 million (CHF 0.38 million in cash) ⁽²⁾	Closing Date

Notes:

- (1) Reflects €0.44 million of (i) accrued and unpaid interest in respect of the period from 1 May 2017 to 31 December 2017 to current debt and (ii) €0.08 million in interest that has been added to provide Bootstrap with a 12% per annum return on the extended term for the repayment of principal under the October 2018 and December 2018 amendments and given that the repayment of principal under the 2017 amendment to the Bootstrap Loan had been scheduled to begin in February 2018. The total amount remains subject to minor adjustments by Bootstrap.
- (2) This Exit Fee was an additional incentive granted to Bootstrap as an inducement to enter into the amendments to the Bootstrap Loan and is separate from, and not included in, the CHF 5.9 million in principal and interest outstanding on the Bootstrap Loan. The portion of the Exit Fee payable that shall be so contributed in kind, but that cannot be used for the subscription for a whole number of New Shares at the Offer Price shall not be contributed in kind, but remains payable in cash (subject to the terms of the Bootstrap Loan).

Sequana Medical may prepay any or all outstanding amounts on the Bootstrap Loan without penalties.

The maximum amount that Sequana Medical could be required to pay on the Bootstrap Loan at the completion of the Offering is €1.5 million (CHF 1.7 million) for the partial repayment of principal plus €0.44 million (CHF 0.5 million) for the repayment of interest accrued from 1 January 2018 through 1 October 2018 and up to €0.33 million (CHF 0.38 million) for the portion of the Exit Fee payable in cash. In the event that the maximum amount of €1.5 million (CHF 1.7 million) of the net proceeds is used for the partial repayment of the Bootstrap Loan, the amount of principal outstanding on the Bootstrap Loan immediately after the closing of the Offering would be approximately €2.9 million, which is equal to the principal amount outstanding at the date of this Prospectus of CHF 5 million (or €4.4 million) minus the €1.5 million payment from the net proceeds.

The agreement for the Bootstrap Loan contains covenants that may limit Sequana Medical's ability to take certain actions. See Part 2 – (Risk factors), section 2.1 (Risks related to Sequana Medical's business and industry), subsection (m) (Sequana Medical has entered into a loan agreement with Bootstrap, which contains covenants that may limit Sequana Medical's ability (or require Bootstrap's prior consent) to take certain actions including the incurrence of certain

additional indebtedness. Sequana Medical may not have cash available in an amount sufficient to enable Sequana Medical to make interest or principal payments on its indebtedness when due).

Following the Offering and the application of the proceeds as described in Part 3 – (Use of Proceeds), Sequana Medical's principal sources of funds are expected to be cash on hand and cash generated from revenues.

Furthermore, Bootstrap entered into a lock-up arrangement with the Issuer and the Joint Global Coordinators with respect to the Shares that it will acquire through the contribution in kind of 50% of the Exit Fee in the Offering for a period of 180 days after the Listing Date, subject to certain exceptions, as described in Part 14 – (Plan of distribution), section 14.3 (Lock up).

(b) Consolidated statements of cash flows

The following table includes information relating to Sequana Medical's cash flow statements for the nine months ended 30 September 2018 and 2017 and the years ended 31 December 2017, 2016 and 2015.

	For the nine months ended 30 September		For the year ended 31 December		
	2018	2017	2017	2016	2015
			<i>(in €000)</i>		
	<i>(unaudited)</i>			<i>(audited)</i>	
Net loss for the period	(8,634)	(6,436)	(8,225)	(13,975)	(11,557)
Income taxes	25	12	18	41	44
Financial result.....	693	495	789	(11)	157
Depreciation.....	54	58	78	80	47
Change in defined benefit plan.....	—	—	64	71	10
Share-based compensation	18	17	23	10	11
Changes in trade and other receivables.....	(87)	(58)	145	213	(451)
Changes in inventories	(182)	453	556	208	(622)
Changes in trade and other payables/provisions.....	1,437	(1,658)	(1,808)	656	1,146
Taxes paid	(9)	(12)	(18)	(41)	(44)
Cash flow used in operating activities	(6,686)	(7,129)	(8,378)	(12,748)	(11,259)
Investments in tangible assets.....	(3)	(7)	(7)	(215)	(89)
Investments in financial assets.....	(11)	(4)	(4)	(2)	(19)
Cash flow used in investing activities	(14)	(10)	(11)	(217)	(108)
Proceeds from capital increase	—	9,813	9,815	7,812	8,206
Exercise of employee options.....	2	—	—	71	34
Proceeds from financial debts	5,711	—	—	4,545	—
Transaction costs deducted from equity	(226)	—	—	—	—
Interest paid	(7)	(250)	(314)	(190)	(22)
Cash flow from financing activities	5,480	9,563	9,501	12,238	8,218
Net change in cash and cash equivalents	(1,219)	2,423	1,112	(727)	(3,149)
Cash and cash equivalents at beginning of period	1,684	797	797	1,427	4,091
Net effect of currency translation on cash and cash equivalents	76	(145)	(226)	97	485
Cash and cash equivalents at end of period	541	3,075	1,683	797	1,427

(i) Cash flow used in operating activities

Cash flow used in operating activities decreased from €7.13 million in the nine months ended 30 September 2017 to €6.69 million in the nine months ended 30 September 2018, which corresponded with a general increase in the net loss for the period from €6.44 million in the nine months ended 30 September 2017 to €8.63 million in the nine months ended 30 September 2018. This overall increase in the net loss for the period was largely offset by a decrease in working capital during the nine months ended 30 September 2018 as compared to the nine months ended 30 September 2017, which was as a result of an increase in trade payables and accrued liabilities.

Cash flow used in operating activities decreased from €12.75 million in 2016 to €8.38 million in 2017, which corresponded with a general decrease in the net loss for the period from €13.98 million in 2016 to €8.23 million in 2017. The overall decrease in the net loss for the period was partially offset by an increase in working capital in 2017 as compared to 2016. Working capital worsened as a result of the decreased trade payables and accrued liabilities. At the end of 2016, significant amounts related to clinical studies and severance payments remained outstanding. This effect was partially offset by a decrease in inventory and receivables in 2017.

Cash flow used in operating activities increased from €11.26 million in 2015 to €12.75 million in 2016, which corresponded with a general increase in the net loss for the period from €11.56 million in 2015 to €13.98 million in 2016. The overall increase in the net loss for the period was partially offset by a decrease in working capital in 2016 as compared to 2015. In 2016 both inventory levels and outstanding receivables improved compared to 2015. Additionally, in 2016 there were more outstanding trade payables and accruals, mainly related to the ongoing clinical studies and the severance payment provisions.

(ii) Cash flow used in investing activities

Cash flow used for investing activities were broadly flat at €0.01 million for the nine months ended 30 September 2017 and the nine months ended 30 September 2018, with the amounts for the nine months ended 30 September 2018 mainly reflecting the down payment for the new office in Ghent, Belgium.

Cash flow used for investing activities decreased from €0.22 million in 2016 to €0.01 million in 2017 as a result of a decrease in investments in tangible assets, mainly in hardware and software.

Cash flow used for investing activities increased from €0.11 million in 2015 to €0.22 million in 2016 largely as a result of an increase in investments in tangible assets from €0.09 million in 2015 to €0.22 million in 2016, mainly in hardware and software.

(iii) Cash flow from financing activities

Cash flow from financing activities decreased from €9.56 million in the nine months ended 30 September 2017 to €5.48 million in the nine months ended 30 September 2018 as a result of €9.81 million in proceeds from the issuance of Shares in 2017 and the proceeds of new Convertible Loans amounting to €5.71 million in 2018.

Cash flow from financing activities decreased from €12.24 million in 2016, which was mainly comprised of €7.81 million in proceeds from the issuance of Shares and the drawdown of €4.55 million (CHF 5 million) under the Bootstrap Loan, to €9.50 million in 2017, mainly comprised of €9.81 million in proceeds from the issuance of Shares.

Cash flow from financing activities increased from €8.22 million in 2015, primarily from €8.21 million in proceeds from the issuance of Shares, to €12.24 million in 2016 largely as a result of a drawdown of €4.55 million (CHF 5.0 million) under the Bootstrap Loan and €7.81 million in proceeds from the issuance of Shares.

7.5 Disclosures about market and liquidity risk

The nature of Sequana Medical's business and its global presence exposes Sequana Medical to market risks and liquidity risks. The board of directors is responsible for overseeing Sequana Medical's internal control system, which addresses risks to which Sequana Medical is exposed. These systems provide appropriate security against significant inaccuracies and material losses. Management is responsible for identifying and assessing risks that are of significance for the respective country.

(a) Market risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. The market risks consist primarily of foreign currency risks and, to a lesser degree, interest rate risks. Main currency exposures are the Swiss franc and the euro. Sequana Medical is not hedging any of these risks.

Foreign currency translation risks. Translation exposure arises from the consolidation of the foreign currency denominated financial statements of Sequana Medical's subsidiaries. This is reported as currency translation effects in other comprehensive income. Translation risk can be significant to its equity base. Currency translation risks are not hedged.

The following table shows the sensitivity to foreign exchange rate changes (CHF/EUR and USD/EUR), with all other variables held constant, of Sequana Medical's income statement and equity:

	Impact on income statement and equity as at 31 December		
	2017	2016	2015
	<i>(in €000)</i>		
5% decrease of average foreign exchange rate	(395)	(760)	(610)
5% increase of average foreign exchange rate.....	380	690	550

The USD/EUR rate does not have a material impact on Sequana Medical's income statement or equity. Accordingly, in the table above, substantially all of the impact on the income statement and equity is due to changes in the CHF/EUR exchange rate.

Interest rate risks. Interest rate risks arise from changes in interest rates, which have negative repercussions on Sequana Medical's asset and earnings situation. Interest rate fluctuations lead to changes in interest income and interest expense on interest-bearing assets and liabilities.

The following table shows the sensitivity to interest rate changes, with all other variables held constant, of Sequana Medical's income statement and equity:

	Impact on income statement and equity as at 31 December	
	2017	2016
	<i>(in €000)</i>	
50 basis points increase / decrease	-/+ 22	-/+ 14

An asset is current when it is:

- expected to be realised or intended to be sold or consumed in the normal operating cycle,
- held primarily for the purpose of trading,
- expected to be realized within twelve months after the reporting period, or
- cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period.

All other assets are classified as non-current.

A liability is current when:

- it is expected to be settled in the normal operating cycle,
- it is held primarily for the purpose of trading,
- it is due to be settled within twelve months after the reporting period, or
- there is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period.

Sequana Medical classifies all other liabilities as non-current.

(d) Foreign currency translation

Sequana Medical's consolidated financial statements are presented in euros. For each entity, Sequana Medical determines the functional currency and items included in the financial statements of each entity are measured using that functional currency. Consequently, the functional currency of the subsidiaries does not necessarily correspond to the functional currency of the parent.

Transactions in foreign currencies are initially recorded by Sequana Medical's entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition. Items of income and cash flow statements are measured by entities at the date of transaction. For practical reasons the average exchange rate of the period is applied for the translation of the income statement and the cash flow statement. Differences arising on settlement or translation of monetary items are recognized in profit or loss.

The results and financial position of foreign operations that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet,
- income and expenses for each statement of profit or loss and statement of comprehensive income are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions), and
- all resulting exchange differences are recognised in other comprehensive income.

On consolidation, exchange differences arising from the translation of any net investment in foreign entities are recognised in other comprehensive income. When a foreign operation is sold, the associated exchange differences are reclassified to profit or loss, as part of the gain or loss on sale.

See Note 9 to the audited financial statements for the year ended 31 December 2017 for the foreign exchange rates that were applied for the consolidated financial statements at 31 December 2017 and the comparative periods.

(e) Employee benefits

Sequana Medical has both defined contribution plans and defined benefit plans.

In the case of defined contribution plans, contributions are paid to publicly or privately administered pension plans on a statutory, contractual, or voluntary basis. Sequana Medical has no further payment obligations once the contributions have been paid. The contributions are recognised as personnel expenses.

Defined benefit plans require Sequana Medical to make contributions to individual plans, for which the ultimate benefit to the employee is based on a defined benefit, e.g., based on a final salary level, defined performance of the plan, etc. For defined benefit plans, Sequana Medical obtains actuarial valuations to determine the required defined benefit pension obligation.

(i) General

Wages, salaries, social security contributions, paid annual leave and sick leave, bonuses, and non-monetary benefits are accrued in the year in which the associated services are rendered by employees of Sequana Medical.

(ii) Pension obligations

The cost of providing benefits under the defined benefit plan is determined using the projected unit credit method. Re-measurements, comprising of actuarial gains and losses, the effect of the asset ceiling, excluding net interest and the return on plan assets (excluding net interest), are recognised immediately in the balance sheet with a corresponding debit or credit to retained earnings through other comprehensive income in the period in which they occur. Re-measurements are not reclassified to profit or loss in subsequent periods.

Past service costs are recognised in profit or loss on the earlier of:

- the date of the plan amendment or curtailment, and
- the date that Sequana Medical recognises restructuring-related costs.

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset and is disclosed in the respective expense by function.

Sequana Medical recognises the service costs comprising current service costs, past-service costs, gains and losses on curtailments and non-routine settlements in the net defined benefit obligation under the respective expenses by function.

(f) Significant accounting estimates and judgments

For the preparation of the consolidated financial statements it is necessary to make judgments, estimates and assumptions to form the basis of presentation, recognition and measurement of the Sequana Medical's assets, liabilities, items of income statements, accompanying disclosures and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

In the process of applying Sequana Medical's accounting policies, management has made various judgments. Those which management has assessed to have the most significant effect on the amounts recognised in the consolidated financial statements have been discussed in the individual notes of the related financial statement line items.

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial years, are also described in the note 2.5 to Annual Financial Statements and note 3 to the Interim Financial Statements.

Sequana Medical based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Sequana Medical. Such changes are reflected in the assumptions when they occur.

Sequana Medical is subject to risks and uncertainties which may lead to actual results differing from these estimates, both positively and negatively. Sequana Medical's specific estimates including tax, pension liabilities or provisions are discussed in the relevant sections of the management's review and in the notes.

Significant estimates and judgments of Sequana Medical include the following:

- Pensions (International Accounting Standard 19) – key assumptions for measuring defined benefit for measuring post-employment benefit expense for a period and the defined benefit obligation at the period end.

- Going concern – key assumptions on the company’s ability to continue as a going concern.

(i) Post-employment benefits

The aggregate of the present value of the defined benefit obligation and the fair value of plan assets for each plan is recognised in the balance sheet as a net defined benefit liability or net defined benefit asset. The defined benefit obligation is determined annually by independent actuaries using the projected unit credit method. Employee contributions are recognised in the period in which the related service is rendered. Plan assets are not available to the creditors of Sequana Medical.

Pension costs consist of three elements: service costs, net interest, and re-measurements of employee benefits.

- Service costs are part of personnel expenses and consist of current service costs, past service costs (gains/losses from plan amendments or curtailments), and gains/losses from plan settlements.
- Net interest is recorded in the financial result and is determined by applying the discount rate to the net defined benefit liability or net defined benefit asset that exists at the beginning of the year.
- Gains and losses resulting from the actuarial valuation are recorded in other comprehensive income as re-measurements of employee benefits. The return on plan assets (excluding interest based on the discount rate) and any change in the effect of an asset ceiling are also recorded in other comprehensive income.
- Significant other non-current employee benefits (mainly jubilee benefits) are also measured using the projected unit credit method, however re-measurements are recorded in the consolidated income statement.

Detailed information about the assumptions and measurement of post-employment benefits are included in Note 6.7 to the audited financial statements for the year ended 31 December 2017.

Termination benefits are recognised on the date on which Sequana Medical can no longer withdraw the offer of this type of benefit or on which restructuring provisions are recorded.

(ii) Going concern

Sequana Medical is still in its start-up phase and subject to various risks and uncertainties, including but not limited to the timing of achieving profitability and the substantial uncertainty of the development process. Sequana Medical’s ability to continue operations also depends on its ability to raise additional capital in order to fund operations and assure the solvency of Sequana Medical until revenues reach a level to sustain positive cash flows. These conditions indicate the existence of material uncertainties, which may also cast significant doubt about Sequana Medical’s ability to continue as a going concern.

The consolidated balance sheet as at 30 September 2018 shows a negative equity in the amount of €13.3 million. Throughout the year, Sequana Medical successfully gathered external funds to finance its business. In October 2018, additional funds amounting to €2.6 million have been raised. Sequana Medical continues to evaluate equity financing options, including discussions with existing investors. On the basis of these discussions, the board of directors remains confident that the liquidity requirements for the next 12 months, estimated to be €14 million, can be secured. In case the financing is endangered, the going concern of Sequana Medical can most probably no longer be ensured. However, management and the board of directors remain confident that the strategic direction, comprising financing measures such as additional financing rounds or capital market transactions, will be successful and therefore considers the preparation of the present financial statements on a going concern basis as appropriate.

Notwithstanding the negative net equity, the Issuer’s general shareholders’ meeting held on 20 November 2018 resolved, in accordance with article 633 of the Belgian Companies Code, to continue the Issuer’s activities, and not to dissolve the Issuer. Upon completion of the Offering, the Issuer’s net equity will again be positive. See further in section (d) (Rights regarding liquidation) of section 12.8 (Rights Attached to the Shares) of Part 12 – (Share Capital and Articles of Association).

(iii) Fair value of financial instruments

The fair value of financial instruments that are not traded in an active market is determined by using valuation techniques. Sequana Medical uses its judgment to select a variety of methods and make assumptions that are mainly based on market conditions existing at the end of each reporting period.

1. Valuation of the Convertible Loans denominated originally in CHF:

The initial fair value of the liability component of the bond was determined using a market interest rate of 12%, which represents the market interest rate for similar bonds having no conversion rights at the issue date. One of the conversion options represents a fixed amount of the Issuer's shares for a fixed amount of cash. See Note 10 to the Interim Financial Statements for further information on the accounting treatment.

2. Valuation of the Convertible Loans denominated originally in EUR:

The initial fair value of the liability portion of the bond was determined using a market interest rate of 12%, which represents the market interest rate for similar bonds having no conversion rights at the issue date. The corresponding fair value of the conversion option was determined using the expected Share price range multiplied by the number of Shares capable to be converted. The Share price range is based on the expected gross amount of proceeds of €35 million, whereas probability weighted scenarios between €9.3 and €11 per Share have been applied. Based on Sequana Medical's assumptions regarding the estimates described, the resulting fair value of the conversion option is insignificant to the Interim Financial Statements. See Note 10 to the Interim Financial Statements for further information on the accounting treatment.

7.7 Off-balance sheet arrangements

Sequana Medical does not have any off-balance sheet arrangements.

7.8 Events after the balance sheet

Except for those described below, there have been no other events occurring after the reporting period which would have a material effect on the financials of Sequana Medical as of 30 September 2018.

(a) Transfer of registered address

Sequana Medical relocated its registered office and certain functions from Switzerland to Belgium, allowing Sequana Medical to strengthen its commercial ties within the E.U. In 2018, Sequana Medical's registered address was transferred to AA Tower, Technologiepark 19, 9052 Ghent, Belgium, which changed to AA Tower, Technologiepark 122, 9052 Ghent, Belgium effective as from 1 January 2019.

(b) Executive Share Options

In October 2018, 111,177 Share options were granted to members of the staff, as well as consultants of the Issuer, and each entitle the holder thereof to subscribe for one new series E preferred Share subject to the terms and conditions that are determined by the board of directors (see Part 9 – (Management and corporate governance), section 9.6 (Description of Share Plans)).

(c) Amendment to Bootstrap Loan

In October and December 2018, the Bootstrap Loan was amended as described above in section 7.4 (Liquidity and capital resources), subsection (a) (General).

(d) Convertible Loans, Bridge Loans and the Pre-IPO Investment Commitment Agreements

On 11 October 2018, the Issuer and Newton Biocapital I Pricav Privée SA ("**Newton**") entered into a convertible loan agreement pursuant to which Newton granted a loan to the Issuer in a principal amount of €2,000,000. See Part 11 – (Related party transactions) for more information.

On 23 October 2018, the Issuer and Participatiemaatschappij Vlaanderen ("**PMV**") amended the PMV Convertible Loan (as defined and described in Part 11 – (Related Party Transactions)),

pursuant to which the principal amount of the loan was increased from €1,680,000 from to €2,000,000. See Part 11 – (Related party transactions) for more information.

The Issuer entered into three additional convertible loan agreements, dated 25 October 2018, 30 October 2018 and 2 November 2018, respectively, with two individuals and BioMedInvest II LP (“**BioMed**”) pursuant to which BioMed granted the BioMed Convertible Loan (as defined and described in Part 11 – (Related Party Transactions)) in a principal amount of CHF 198,000 and the two individuals each granted loans to the Issuer in a principal amount of CHF 100,000 and CHF 52,400, respectively. See Part 11 – (Related party transactions) for more information.

On 2 November 2018, the Convertible Loans (as defined and described in Part 11 – (Related Party Transactions)) were amended and completed pursuant to several Pre-IPO investment commitment agreements by and between the Issuer and, respectively, the lenders under the Convertible Loans. The pre-IPO investment commitment agreements were amended and restated on 20 December 2018 pursuant to several Pre-IPO Investment Commitment Agreements (as defined in Part 11 – (Related Party Transactions)). Pursuant to the Pre-IPO Investment Commitment Agreements, the lenders under the respective Convertible Loans agreed to convert their Convertible Loans for new series E preferred Shares immediately prior to the closing of the Offering, and that the new Shares shall be converted and consolidated immediately thereafter into ordinary Shares pursuant to the Share Consolidation. As an exception, payables under the February 2018 Convertible Loan (as defined and described in Part 11 – (Related Party Transactions)) for an aggregate principal amount of €6,340.91 will be converted into New Shares at the Offer Price in connection with the Offering. The conversions will be implemented by means of a contribution in kind of the outstanding payable amounts under the Convertible Loans. See Part 11 – (Related party transactions) for more information.

In addition, pursuant to the Pre-IPO Investment Commitment Agreements, the Participating Investors, who are all lenders pursuant to the Convertible Loans, provided a Subscription Commitment (as defined in Part 11 – (Related Party Transactions)) to subscribe for an aggregate amount of €20.5 million in the Offering at the Offer Price, subject to the closing of the Offering. A portion of this amount was made available to the Issuer on 20 December 2018 by all of the respective Participating Investors (except three of them who are also each a lender under the February 2018 Convertible Loan) in the form of Bridge Loans (as defined in Part 11 – (Related Party Transactions)) for an aggregate principal amount of €1,024,238.77. Pursuant to the Pre-IPO Investment Commitment Agreements, the relevant Participating Investors agreed to convert the principal amount and accrued interest of the Bridge Loans into New Shares at the Offer Price upon the closing of the Offering. The conversion will be implemented by means of a contribution in kind of the outstanding payable amounts under the Bridge Loans.

PART 8 – BUSINESS

8.1 Overview

Sequana Medical is a commercial stage medical device company focused on the development of innovative treatment solutions for the management of liver disease, heart failure, malignant ascites and other fluid imbalance disorders. Sequana Medical's core markets of liver disease and heart failure are large and growing, driven by unhealthy lifestyles and ageing populations.

Sequana Medical's **alfapump**[®] provides an innovative treatment solution for the long-term management of liver refractory ascites and malignant ascites with proven safety, efficacy and quality of life benefits demonstrated in multiple clinical studies and over 650 implants. The **alfapump**[®] has received CE Mark approval for liver refractory ascites and malignant ascites. Since April 2018, the **alfapump**[®] has been included in the EASL clinical practice guidelines for the management of patients with decompensated cirrhosis, which management believes is a key step in the widespread commercial acceptance of the **alfapump**[®]. In January 2019, the FDA granted Breakthrough Device designation for the **alfapump**[®] for the treatment of liver recurrent or refractory ascites.

Sequana Medical has also developed DSR, a novel and proprietary approach to the treatment of volume overload in heart failure. Animal studies have demonstrated DSR therapy to be both safe and effective. Sequana Medical has built on the **alfapump**[®] platform to deliver **alfapump**[®] DSR, a convenient and fully implanted system for DSR therapy.

Sequana Medical is led by an experienced management team, supported by renowned life science investors and its technology and approach have been endorsed by KOLs.

(a) Large and growing market opportunities

(i) Chronic liver disease/NASH

Liver disease is a large and growing market. In 2015, more than 3.9 million U.S. adults were living with a chronic liver disease diagnosis.⁸ Cirrhosis, one of the leading manifestations of liver disease, is the progressive scarring of the liver. Key causes include alcoholic liver disease, viral hepatitis and more recently, NASH. Chronic liver disease and cirrhosis are one of the fastest growing leading causes of death in the U.S.⁹

NASH is a severe disease associated with obesity and its prevalence has been growing dramatically, particularly in the U.S. NASH was the most rapidly growing indication for liver transplantation in the U.S. in 2017.¹⁰ Management estimates there will be between three and four million people in the U.S. suffering from liver cirrhosis due to NASH in the near- to medium-term based on the current prevalence of NASH in the U.S. population and the observed rates at which NASH patients develop cirrhosis.¹¹ The NASH market has similarities to the coronary artery disease market, as both are driven by poor diet, lack of exercise and ageing. Management believes that the growth in the prevalence of liver disease due to NASH will transform attitudes to chronic liver disease and will drive demand for modern therapies that focus on disease management and patient quality of life.

A key complication of liver cirrhosis is "**ascites**", the accumulation of fluid within the abdomen. Ascites has a dramatic negative impact on patient quality of life including difficulties eating, moving, breathing and sleeping. Patients with ascites suffer from malnutrition, withdrawal from society, nausea, serious infection risks, swelling and tension. When drug therapy and dietary restriction are no longer effective, the common treatment is drainage ("**paracentesis**"). Patients may accumulate as much as 10-15 litres of fluid within the abdomen every 15 days. Paracentesis of more than 5 litres is referred to as LVP. In addition to being a painful, burdensome and costly procedure, paracentesis has the severe limitation of only providing temporary relief of symptoms. Management estimates that patients undergoing recurrent cycles of fluid build-up and paracentesis are only able to experience a normal life for one-third of the time before the debilitating symptoms of ascites return.

Managements estimates there are approximately 18,000 liver refractory ascites patients in the U.S. and 17,000 across the U.K., France, Germany, Italy and Spain (the "**EU5**") based on historical rates of liver cirrhosis in the U.S. and the EU5¹² and the observed rates at which patients with cirrhosis develop ascites¹³ and refractory ascites.¹⁴ Management estimates that within the next ten to twenty years the number of liver refractory ascites patients will grow to 151,000 in the U.S. (with 145,000 due to NASH) and 89,000 in the EU5 (with 83,000 due to NASH) based on the

estimated prevalence of refractory ascites patients with alcoholic liver disease,¹⁵ the estimated prevalence of liver cirrhosis due to NASH in the current population¹⁶ and the observed rates at which patients with cirrhosis develop ascites¹⁷ and refractory ascites.¹⁸ The estimated market size for 2030 takes into consideration the estimated growth in the prevalence for NASH but excludes refractory ascites patients with viral hepatitis as management expects this market to disappear by 2030.¹⁹

(ii) Malignant ascites

In addition to liver disease, ascites is also caused by certain late-stage cancers (“**malignant ascites**”). Although life expectancy for many malignant ascites patients is short (less than 3 months), ovarian and breast cancer patients often have longer life expectancies. Management believes based on discussions with clinicians that, in addition to improving the quality of life for these patients, a long-term treatment for malignant ascites could enhance their ability to withstand additional cancer treatments and increase their chances of survival. Management estimates the prevalence of malignant ascites due to ovarian and breast cancer to be approximately 16,000 cases in the U.S. and 18,000 cases across the EU5 based on the incidence of breast and ovarian cancers in the U.S. and EU5²⁰ and the observed rates of malignant ascites in breast and ovarian cancer patients.²¹

(iii) Heart failure

Volume overload in heart failure is a major clinical problem. There are 6.5 million adults in the U.S. age 20 and over suffering from heart failure and this number is forecasted to grow to 8.0 million by 2030.²² There are over one million hospitalisations in the U.S. each year due to heart failure and 90% are due to volume overload.²³ The treatment options are severely limited in those patients whom diuretic therapy is no longer effective. This limitation is evident from the 24% hospital re-admission rate at 30 days from discharge.²⁴ The cost of heart failure-related hospitalisations in the U.S. is \$13 billion a year.²⁵

(b) The alfapump[®] for the management of liver refractory ascites and malignant ascites

Sequana Medical’s **alfapump[®]** provides an innovative treatment solution for the long-term management of liver refractory ascites and malignant ascites with proven safety, efficacy and quality of life benefits demonstrated in multiple clinical studies. The **alfapump[®]** received a CE-Mark in Europe for the treatment of liver refractory ascites in 2011, and in 2012 for the treatment of malignant ascites. Over 650 **alfapump[®]** systems have been implanted at the date of this Prospectus. In January 2019, the **alfapump[®]** received Breakthrough Device designation from the FDA for the treatment of liver recurrent or refractory ascites.

The **alfapump[®]** is a fully-implantable, wirelessly charged system that automatically and continuously pumps ascites from the abdominal cavity into the bladder, where the body eliminates the ascites naturally through urination. The **alfapump[®]** system’s DirectLink technology allows physicians to monitor pump performance and more effectively manage their patients. Through eliminating the need for routine paracentesis and delivering improvements to patient quality of life, management believes that the **alfapump[®]** offers a strong health economics rationale for hospitals and payers.

(i) Completed studies

Sequana Medical has invested significant resources in clinical studies to demonstrate the safety and efficacy of the **alfapump**[®]. There have been seven peer-reviewed publications regarding the **alfapump**[®], in addition to presentations of **alfapump**[®] studies at industry conferences. Sequana Medical has established a strong network of KOLs in Europe and North America that support the clinical development of the **alfapump**[®].

The following table provides a summary of selected **alfapump**[®] studies for the management of liver disease, each of which have been presented or published prior to the date of this Prospectus:

Name of Study	Description	Number of Patients
PIONEER Study	Prospective, multi-centre, open-label, uncontrolled study to assess the safety and performance of the alfapump [®] in patients with liver refractory ascites and diuretic resistance (completed in 2013).	40
Gines Study	Prospective, single-centre, uncontrolled study to evaluate the effects of the alfapump [®] on kidney and circulatory function in patients with liver cirrhosis and refractory ascites.	10
European RCT	6-month open-label, randomised and controlled study in Europe on the alfapump [®] versus LVP for the treatment of liver refractory ascites (completed in 2016).	58
Post Marketing Surveillance Registry ("PMSR")	Multi-centre, open-label observational study in Europe designed to follow patients implanted with an alfapump [®] for up to 24 months (completed in 2018).	100 ⁽¹⁾
Retrospective Study at Hannover Medical School	Retrospective, single-centre study at Hannover Medical School to investigate the alfapump [®] as an alternative for LVP in a real-world setting (published in 2018).	21
MOSAIC (North American IDE feasibility) Study	12-month open-label, single-arm study in the United States and Canada (" North America ") to assess the safety and efficacy of the alfapump [®] in patients with liver recurrent or refractory ascites (completed in 2018).	30

Notes:

(1) Data on initial 56 patients has been published. Data on all 100 patients is intended to be submitted for publication in the first half of 2019.

Key findings of the selected **alfapump**[®] studies presented in the table above include:

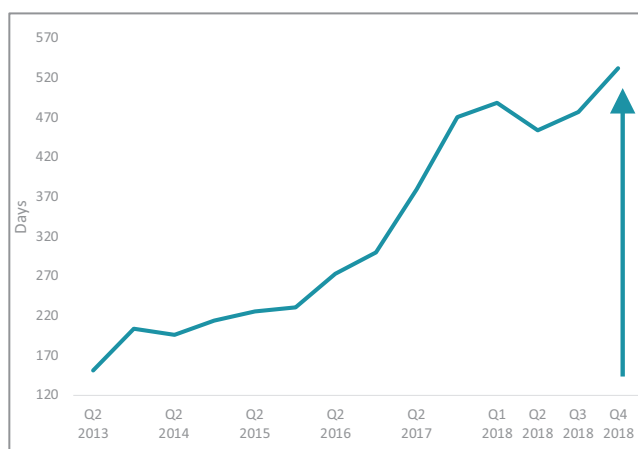
- an approximately 90% reduction in the mean number of LVPs per month for liver refractory patients treated with the **alfapump**[®] versus patients treated with LVP standard of care;
- a clinically significant improvement in quality of life for patients treated with the **alfapump**[®] versus patients treated with LVP standard of care; and

- liver refractory ascites patients treated with the **alfapump**[®] demonstrated a clear nutritional benefit versus patients treated with LVP standard of care over 30-day and 90-day periods.

Management believes that these clinical studies have demonstrated that the **alfapump**[®] dramatically reduces the need for LVP and increases patient quality of life.

Through the significant experience gained from clinical studies and extensive commercial use, Sequana Medical continually works to improve **alfapump**[®] results and there has been a clear increase in clinical outcomes. The average duration of **alfapump**[®] therapy per patient increased from 151 days in the second quarter of 2013 to 533 days in the fourth quarter of 2018, as demonstrated in Figure 1 below.

Figure 1
Average duration of alfapump[®] therapy



Source: Sequana Medical internal statistical analysis of market feedback/implant duration

Following completion of these studies, the **alfapump**[®] was included in the EASL clinical practice guidelines for decompensated cirrhosis in April 2018 and received Breakthrough Device designation from the FDA for the treatment of liver recurrent or refractory ascites in January 2019.

The following table provides a summary of the completed **alfapump**[®] study for the management of malignant ascites:

Name of Study	Description	Number of Patients
Retrospective Malignant Ascites Study	Retrospective open-label study in Europe to assess the performance and safety of the alfapump [®] for the treatment of malignant ascites (completed in 2017).	17

The study demonstrated that the **alfapump**[®] appears to be effective in treating palliative patients with malignant ascites and improving their quality of life.

(ii) Ongoing/planned studies

The following table provides a summary of select **alfapump**[®] clinical studies that are ongoing or that Sequana Medical plans to conduct in the near future for the management of liver disease and malignant ascites:

Name of Study	Description ⁽¹⁾	2018	2019	2020	2021
Liver disease:					
ARIA Pump Study	Randomised, open-label health economic study in France in 90 liver refractory ascites patients to evaluate the cost utility of the alfapump [®] vs. standard of care (60 patients not waiting for liver transplant and 30 patients as bridge to transplant) over 12 months to support French reimbursement. ⁽²⁾				
POSEIDON (North American pivotal) Study	North American pivotal study in up to 100 patients with liver refractory and recurrent ascites to demonstrate the efficacy and cost-effectiveness of the alfapump [®] vs. standard of care (LVP). ⁽³⁾				
TOPMOST⁽⁴⁾	European registry study in cirrhosis patients that have been implanted with the alfapump [®] .				
Fitbit[®] Study⁽⁵⁾	Quality of life study in 20 patients to measure the impact of the alfapump [®] vs. standard of care on patient activity.				
Albumin Replacement Study	European study on the impact of albumin replacement therapy on clinical outcomes in 10-15 patients implanted with the alfapump [®] .				
Malignant ascites:					
Malignant Ascites CT	Controlled study in Europe to evaluate the efficacy and clinical impact of the alfapump [®] vs. standard of care in 25-30 malignant ascites patients.				

Notes:

- (1) The descriptions and timing of these studies reflect Sequana Medical’s current expectations. These expectations are based on circumstances that may or may not occur in the future and remain subject to change and/or feedback from applicable regulatory authorities.
- (2) Funded by the French government and conducted by leading French clinicians.
- (3) Subject to FDA feedback.
- (4) The dashed shading of the arrow indicates that the study is expected to extend beyond 2021.
- (5) Fitbit[®] is not affiliated or associated with Sequana Medical, and Fitbit[®] is not affiliated with, and has not otherwise endorsed, the Fitbit[®] Study.

(c) alfapump[®] DSR for the treatment of volume overload in heart failure

DSR is Sequana Medical’s proprietary therapy for the management of volume overload in heart failure. This breakthrough approach involves removing sodium from the body using diffusion via the peritoneal cavity with the use of a “sodium-free” solution (“**infusate**”). Once the sodium has been removed, the body eliminates excess fluid via urination and osmotic ultrafiltration, resulting in a sustained fluid reduction.

(i) Completed studies

The following animal studies have been completed for the management of volume overload in heart failure using DSR:




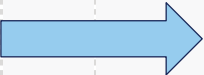
Name of Study	Description	Number of Animals
Healthy pig DSR proof of concept study	Single dose, single arm proof of concept study to assess impact of direct sodium removal therapy in healthy pigs.	15
Heart failure pig DSR proof of concept study	Single dose, single arm proof of concept study to assess impact of direct sodium removal therapy in pigs with experimentally induced heart failure via tamponade.	5

The key findings of these prospective, uncontrolled proof of concept studies include:

- administration of 1 litre of “sodium-free” infusate in healthy pigs resulted in the removal of 2 litres of fluid and 4 grams of sodium (on average);
- administration of 1 litre of “sodium-free” infusate in the pigs with experimentally induced heart failure resulted in the removal of 5 litres of fluid and 14 grams of sodium (on average); and
- serum-sodium levels were virtually unchanged in both healthy and heart failure pigs.

(ii) Ongoing/Planned studies

The following table provides a summary of clinical studies that are ongoing or that Sequana Medical plans to conduct for the management of volume overload in heart failure using DSR:

Name of Study	Description ⁽¹⁾	2018	2019	2020	2021	2022	2023
Single Dose DSR Proof of Concept⁽²⁾	First-in-human clinical study in approximately 20 patients to demonstrate the safety, tolerability and dynamics of a single dose of DSR therapy (no alfapump [®]). ⁽³⁾						
Repeated Dose DSR Proof of Concept⁽²⁾	Study in approximately 5-10 patients with volume overload in heart failure to demonstrate the safety, tolerability and efficacy (sodium and fluid removal) of the alfapump [®] DSR in connection with multiple dose DSR therapy over a 90-day period. ⁽⁴⁾						
Multi-national Feasibility Study	Multi-national 3-month feasibility study to assess the safety and efficacy of the alfapump [®] DSR in patients with volume overload in heart failure.						
Multi-national Pivotal Study	Multi-national pivotal study in patients with volume overload in heart failure to demonstrate the efficacy and cost-effectiveness of the alfapump [®] DSR vs. standard of care (LVP).						

Notes:

- (1) The descriptions and timing of these studies reflect Sequana Medical's current expectations. These expectations are based on circumstances that may or may not occur in the future and remain subject to change and/or feedback from applicable regulatory authorities.
- (2) Management estimates that the Single Dose DSR Proof of Concept and the Repeated Dose DSR Proof of Concept will cost around a total of €1 million to complete.
- (3) The Single Dose DSR Proof of Concept is being conducted in the U.S. at Yale University. Presentation of initial results anticipated in the first half of 2019.
- (4) The Repeated Dose DSR Proof of Concept is expected to be conducted at clinical centres in Europe. Presentation of initial results anticipated in the second half of 2019, with presentation of full results anticipated in the first half of 2020.

(d) Commercial operations and reimbursement

Sequana Medical has obtained reimbursement for the **alfapump**[®] in Switzerland and Germany at the date of this Prospectus. Sequana Medical has expanded commercial activities in the U.K. following the improved guidance from NICE, which management believes will support broader commercial access. Management also believes that the successful completion of the ARIA Pump Study will lead to reimbursement in France.

Sequana Medical has a team of 11 to support commercialisation of the **alfapump**[®] in Switzerland, Germany and the U.K., as well as to support the ARIA Pump Study in France and Sequana Medical's distributors in Israel, Denmark, Belgium and the Netherlands. Sequana Medical's focus on specialist centres allows coverage of the market with a lean commercial organisation. In addition, Sequana Medical invests in promotional activities using both conventional and digital media to raise awareness of the **alfapump**[®] therapy amongst clinicians, patients and their relatives.

(e) Manufacturing and product development

Sequana Medical has developed significant experience and expertise in the production of the **alfapump**[®], and has developed a supply chain and production capability that can accommodate the forecast growth in sales. Management believes that this proven capability to reliably manufacture the **alfapump**[®] is an important asset of the company. Through the development of the **alfapump**[®], Sequana Medical has built and accumulated extensive expertise in the hardware, software and production aspects of the system, as well as requirements around engineering, test methods and creating/maintaining technical documentation to fulfil regulatory requirements.

Sequana Medical continues to use its experience in developing the **alfapump**[®] to (i) improve **alfapump**[®] performance (e.g. extend **alfapump**[®] life through improving the production process and minor design modifications), (ii) deliver enhanced DirectLink capabilities, enabling a broader range of parameter monitoring including sensors inside and outside of the body to deliver a disease-management platform, and (iii) reduce production cost through optimised design and purchasing efficiencies.

(f) Intellectual property

In addition to its proven production capability, and know-how associated with the design, development and use of the **alfapump**[®], Sequana Medical has a patent portfolio. Sequana Medical has 73 patents granted across 14 patent-families and a further 16 patent applications pending.

(g) History

Sequana Medical was founded in 2006 and established operations in Zurich, Switzerland. In 2018, Sequana Medical relocated its registered office and certain functions from Switzerland to Belgium, allowing Sequana Medical to strengthen its commercial ties within the E.U. In addition, Sequana Medical's office in Belgium is located in an area that is known for its dynamic university spin-offs, highly trained and educated staff members, experienced management and networks of specialised investors. Since inception, Sequana Medical has received equity financing and bridge loans totalling nearly €90 million.

8.2 Strengths

Sequana Medical's competitive strengths are supported by its technologies, expertise and business strategy, and include the following:

(a) *Sequana Medical has a focus on liver disease and heart failure, which are large and growing markets with unmet medical needs*

In the U.S. alone, more than 3.9 million adults were living with a chronic liver disease diagnosis in 2015,²⁶ and chronic liver disease and cirrhosis are one of the fastest growing leading causes of death in the U.S.²⁷ The key cause of liver cirrhosis is dramatically changing, with NASH serving as the leading growth driver and a major public health threat, in particular in the U.S.²⁸ While alcohol and viral hepatitis are regarded as impacting only a limited proportion of society, NASH will affect a much broader spectrum and as such management believes that liver disease will become a "mainstream" disease. There are limited treatment options available for ascites, a key complication of cirrhosis, and management believes that the growth in the prevalence of NASH, as well as the severe limitations of treatment options, will drive the demand for modern therapies that focus on patient quality of life.

There are 6.5 million adults in the U.S. age 20 and over suffering from heart failure and this number is forecasted to grow to 8.0 million by 2030.²⁹ Volume overload is a major clinical problem and the leading cause of hospitalisations in this patient group.³⁰ There is a clear need for better treatment options for those patients that are no longer effectively treated with diuretics, as evidenced by the hospital re-admission rates of 24% at 30 days from discharge³¹ and the cost of heart failure-related hospitalisations of \$13 billion a year in the U.S.³²

(b) *alfapump*[®] is a proven step change in the management of liver refractory ascites and malignant ascites

- ***The alfapump*[®] has received regulatory approval in Europe and offers significant benefits over existing treatments.** **alfapump**[®] has received a CE-Mark for the treatment of liver refractory ascites and malignant ascites and is commercially available in Europe.

Other treatments provide only short-term symptomatic relief, have the risk of significant or life-threatening side effects or have very limited availability. This creates a significant opportunity for safe and effective long-term treatment alternatives, such as the **alfapump**[®], that dramatically reduces the need for repeated invasive procedures and improves patient quality of life. In addition, for malignant ascites patients, use of the **alfapump**[®] has the potential to improve clinical outcomes through (i) enabling greater anti-cancer treatment intensity and (ii) therapeutic monitoring via liquid biopsies.

- ***The alfapump***[®] ***has received Breakthrough Device designation from the FDA for the treatment of liver recurrent or refractory ascites.***

The FDA's Breakthrough Devices Program is designed to facilitate the development and expedite the review of devices that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and to provide patients and healthcare providers with timely access to these medical devices. Devices that receive this designation are eligible for more frequent interactions with the FDA's experts to identify areas of agreement in a timely way and are eligible for prioritised review of the submission package to obtain regulatory approval in the U.S. The designation of Breakthrough Device status by the FDA is a recognition both of the high unmet medical need in patients with recurrent or refractory ascites and the potential for the **alfapump**[®] to improve the lives of these patients.

- ***Over 650 alfapump***[®] ***implants completed.*** Sequana Medical has strong clinical and commercial experience that has been derived from the implantation of more than 650 **alfapumps**[®] at the date of this Prospectus. Sequana Medical's significant body of clinical evidence on the **alfapump**[®] provides extensive safety and efficacy data that has allowed management to develop and implement technical and clinical improvements to make the **alfapump**[®] safer, more effective and convenient for patients and physicians.
- ***Peer-reviewed publications and inclusion in the EASL clinical practice guidelines.*** Seven articles on the **alfapump**[®] have been published in renowned, peer-reviewed journals. Since April 2018, the **alfapump**[®] has also been included in the EASL clinical practice guidelines for the management of patients with decompensated cirrhosis. Historically, medical devices that have been included in clinical practice guidelines have gained enhanced adoption and reimbursement.
- ***Endorsed by renowned key opinion leaders.*** Sequana Medical works in close collaboration with, and the **alfapump**[®] is endorsed by, an established international network of leading clinicians in the hospitals where the **alfapump**[®] systems are implanted.

(c) *alfapump*[®] ***DSR offers a breakthrough approach to the treatment of volume overload in heart failure and is built on the proven alfapump***[®] ***platform***

DSR therapy is a breakthrough approach to the major clinical challenge of volume overload in diuretic-resistant heart failure patients. Animal studies have demonstrated the approach to be both safe and clinically effective.

The **alfapump**[®] DSR leverages the technical and clinical experience of the validated **alfapump**[®] system to deliver a convenient and fully implanted system for DSR therapy. Management believes this experience significantly reduces the risks of developing the **alfapump**[®] DSR and will enhance adoption of this breakthrough approach.

(d) *Sequana Medical is a strong organisation led by an experienced leadership team, has proven capabilities to produce the alfapump*[®] ***and has a strong IP position***

- ***Experienced leadership team.*** Sequana Medical has a multi-disciplinary management team with strong clinical, engineering, production, regulatory and commercial experience and expertise in bringing a product from concept phase through to commercialisation. Each member of the team has also been involved in the establishment, development or management of medical device, life science or investment banking companies, including Circassia Pharmaceuticals, Johnson & Johnson, Boston Scientific, Sanofi, Jefferies, Philips Medical, Myriad Genetics, Fagron and Thommen Medical.

- **Proven capabilities to produce the alfapump®.** Sequana Medical assembles the alfapump® and alfapump® DSR at its facilities in Switzerland, incorporating sub-components from a number of suppliers. Sequana Medical has produced more than 1,000 alfapump® systems at the date of this Prospectus. In addition, Sequana Medical's production organisation and supply chain is lean and adaptable to rising order volumes.
- **Intellectual property position.** Sequana Medical's technology has protection through a patent portfolio consisting of 73 patents granted across 14 patent families, with a further 16 patent applications pending. Furthermore, intellectual property barriers are also achieved through the complexities of the design of the alfapump®. Many of the components within the alfapump® cannot be physically accessed unless the device is destroyed, and several of the components are uniquely manufactured for Sequana Medical and are not otherwise available for purchase. The alfapump® requires extensive development and manufacturing experience, and replication of the performance of the alfapump® or the alfapump® DSR is difficult due to the complex interaction of the system components and would require significant experience and extensive testing. Sequana Medical's proprietary software cannot be retrieved from the device. As a result of these factors, the design and functionality provide significant barriers for any attempts to replicate the alfapump® and alfapump® DSR.

8.3 Strategy

Sequana Medical focuses on three growth platforms – the European market for liver disease and malignant ascites, the North American market for liver disease and malignant ascites, and the heart failure market in Europe and North America. Management believes this strategically balances perceived risks and estimated rewards with an aim of maximising the potential of these growth platforms and intends to:

- Continue the commercial rollout of the alfapump® in target European markets.** Sequana Medical has established a commercial team focussed on the successful penetration of its target European markets. At the date of this Prospectus, these are Switzerland and Germany where the alfapump® is already reimbursed. Sequana Medical is expanding into the U.K. market following the updated guidance by NICE from “research only” to “special arrangements for clinical governance, consent, and audit or research”. Sequana Medical intends to commercially launch in France following the completion of the ARIA Pump Study (health economic study to support French reimbursement) on the assumption that the study results in satisfactory French reimbursement. Sequana Medical continues to support its distributors Fresenius, Vingmed and Gamida in Belgium and the Netherlands, Denmark and Israel, respectively. Sequana Medical continuously evaluates the opportunity to enter other markets based on commercial potential and the opportunity for reimbursement.
- Secure regulatory approval in North America for the alfapump®.** Following the completion of the MOSAIC (North American IDE feasibility) Study, Sequana Medical expects to begin the POSEIDON (North American pivotal) Study in the second half of 2019. Management believes that the increasing prevalence of NASH and the high expectation of healthcare and quality of life make North America a significant market opportunity. Sequana Medical held a pre-submission meeting with the FDA in October 2018 regarding the POSEIDON (North American pivotal) Study.
- Move into recurrent ascites patients.** The alfapump® CE-Mark is for the treatment of “**liver refractory ascites**” patients, i.e., those patients whose ascites is unresponsive to a sodium-restricted diet and high-dose diuretic treatment or that recurs rapidly after paracentesis. Management believes that the alfapump® can provide significant benefit to “**liver recurrent ascites**” patients, i.e., those whose ascites recurs on at least 3 occasions within a 12-month period despite prescription of dietary sodium restriction and adequate diuretic dosage. Management believes that the liver recurrent ascites market is twice the size of the liver refractory ascites market. Sequana Medical plans to work with its KOLs and regulatory bodies to expand the CE-Mark into the recurrent ascites market. The POSEIDON (North American pivotal) Study will be targeting both refractory and recurrent ascites, building upon the MOSAIC (North American IDE feasibility) Study in the same patient population.
- Expand penetration of malignant ascites market.** To date, Sequana Medical has focussed on the liver ascites market. Despite having a CE-Mark for malignant ascites, there have been very limited implants and clinical activity in this market to date. Following the publication of

the retrospective study of malignant ascites patients with the **alfapump**[®], Sequana Medical intends to intensify its commercial and clinical activity in malignant ascites. This will include investing in prospective clinical studies and establishing a KOL group to support market acceptance as has been done in the liver ascites market.

- (e) **Successfully develop DSR therapy for the treatment of volume overload in heart failure.** Sequana Medical aims to advance the clinical development of the **alfapump**[®] DSR for the treatment of volume overload in heart failure. A first-in-human study of DSR therapy at Yale University began in the second half of 2018.
- (f) **Explore additional applications of alfapump[®] technology platform.** Sequana Medical intends to continue leveraging the unique capabilities of its proprietary **alfapump**[®] technology platform to explore innovative treatment solutions for other fluid imbalance disorders with significant unmet medical need (such as pleural effusion). Sequana Medical will do this itself or via out-licencing to partners.
- (g) **Further develop monitoring capabilities of the alfapump[®] to deliver patient management solutions.** The **alfapump**[®] already enables the monitoring of key performance parameters through the proprietary DirectLink system. Sequana Medical intends to build upon the existing monitoring capabilities to integrate additional parameters (using sensors outside the body, eg. weighing scales and blood pressure monitors, and/or inside the body, eg. pressure sensors in the **alfapump**[®] and biosensors) to deliver patient management solutions for clinicians. Management believes this will deliver improved clinical outcomes and lower care costs for high acuity patient groups.
- (h) **Continue to improve the technical performance and reduce the cost of the alfapump[®].** Through the technical know-how of the Sequana Medical team and its partners, Sequana Medical is working to improve the technical performance of the **alfapump**[®] as well as reduce the cost of the system. Sequana Medical is exploring production cost reductions by optimising the design for manufacturing and assembly and through the realisation of purchasing efficiencies as production volumes increase.

8.4 Market opportunity and limitations of current therapies

(a) Liver disease

The liver is the largest internal organ and its proper function is vital for many critical bodily functions, including cleaning the blood by helping to remove or process waste products and toxins, aiding the digestion of food through the production of bile, regulating blood sugar and cholesterol levels, the production of important proteins, including those involved in blood clotting and the production and functioning of important components of the innate immune system. As a result, liver disease can be highly debilitating and life-threatening unless effectively treated.

Chronic liver disease is a large and growing market with more than 3.9 million U.S. adults living with a chronic liver disease diagnosis in 2015.³³ Cirrhosis is one of the leading manifestations of liver disease, and deaths related to liver cirrhosis globally have increased approximately 54% from 838,000 in 1990 to 1.3 million in 2015.³⁴ Chronic liver disease and cirrhosis were the 12th leading cause of death in the U.S. in 2013 and are one of the fastest growing leading causes of death in the U.S.³⁵

The early stage of chronic liver disease starts with inflammation of the liver. As the disease progresses over time, and inflammation continues, this can result in fibrotic scar tissue replacing healthy liver tissue. Fibrotic scar tissue can affect the ability of the liver to function properly and this can lead to cirrhosis, with liver function continuing to decline as liver cirrhosis becomes progressively worse. People with cirrhosis in the U.S. have a mortality rate of 26% during a two-year period.³⁶

Key causes of chronic liver disease include viral infections, such as hepatitis B and hepatitis C, chronic excessive alcohol use, and more recently, NASH. NASH is a severe form of non-alcoholic fatty liver disease (“**NAFLD**”) with a poor prognosis and extremely limited treatment options.

NAFLD is the most prevalent form of chronic liver disease in the world³⁷ and is characterised by an accumulation of fat in the liver and associated with obesity, high fat, fructose-rich diets and a sedentary lifestyle. Management estimates that NAFLD affects approximately one-third of adults in the U.S.,³⁸ having an economic and clinical burden of \$103 billion per annum,³⁹ and that

approximately one-fourth to one-third of NAFLD cases are classified as NASH, a reflection of both disease progression and an aging population.⁴⁰ Management estimates there will be between three and four million people in the U.S. suffering from liver cirrhosis due to NASH in the near- to medium-term based on the current prevalence of NASH in the U.S. population and the observed rates at which NASH patients develop cirrhosis.⁴¹

NASH is a “silent disease”, which means it is difficult to diagnose until the disease is significantly developed and therefore intervention at an early stage to prevent the fibrosis and scarring is clinically challenging. The gold standard for detecting NASH in most markets is an invasive liver biopsy. In addition, NASH is a multi-faceted disease,⁴² which makes it difficult to identify a key approach to prevent the progression of the disease. This makes the development of drugs for NASH difficult as the scarring of the liver is generally very advanced by the time NASH is diagnosed, and management believes that drugs currently in development will likely only slow the onset of cirrhosis and ascites. There are a number of drugs in clinical development by biotechnology and pharmaceutical companies for the treatment of NASH, including Ocaliva from Intercept Pharmaceuticals, Elafibranor from Genfit, Selonsertib from Gilead Sciences and Cenicriviroc Mesylate from Allergan, that may receive marketing approval in the coming years. Management does not expect a significant impact from any newly approved treatments for NASH in the near future.

Recent studies suggest that whereas NAFLD can be a benign condition, NASH may lead to progressive fibrosis that dramatically increases the risk of late-stage severe liver diseases, such as cirrhosis, carcinoma and end-stage liver disease. Studies have indicated that the risk that a person with NASH will suffer a liver disease-related death is ten-times higher than that of the general population.⁴³

The U.S. prevalence of NASH is expected to increase by 63% from 2015 to 2030.⁴⁴ The increasing prevalence of NASH is attributed to the growing obesity epidemic and the disease is often diagnosed in patients who have diabetes, high cholesterol or high triglycerides. NASH is estimated to develop in 25-30% of obese people and in 30-50% of people with diabetes.⁴⁵ It is expected that the impact of rising obesity will create a dramatic increase in NASH-related liver transplant waitlist additions in the U.S. over the next 15 years, likely making NASH the dominant indication for liver transplant in the U.S.⁴⁶ NASH was the most rapidly growing indication for liver transplantation in the U.S. in 2017.⁴⁷ NASH is the leading cause for liver transplant for women and the second leading cause for men (following alcoholic liver disease) in the U.S.⁴⁸ The NASH therapeutics market across the U.S., Japan and EU5 is expected to grow to \$25 billion between 2016 and 2026.⁴⁹

Management believes that the growing importance of NASH as the cause of cirrhosis (versus alcoholic liver disease and viral hepatitis) will transform attitudes to liver cirrhosis. In particular, the similar causes to coronary artery disease, e.g. obesity, poor diet and lack of exercise, will make liver cirrhosis a “mainstream” disease and result in the need for improved therapies, with a greater focus on quality of life for patients.

A key complication of liver cirrhosis is ascites, the accumulation of ascitic fluid in the abdomen. This has a dramatic negative impact on patient quality of life. Ascitic fluid is the protein-containing fluid that leaks from the liver as a result of advanced cirrhosis. Patients may accumulate as much as 10-15 litres of fluid within the abdomen every 15 days. The result is a severe swelling of the abdomen, resulting in pain, difficulty breathing, sleeping and eating, severe nausea and constipation as well as increased risk of severe infection including spontaneous bacterial peritonitis. Approximately 50% of cirrhotic patients develop ascites within 10 years of the diagnosis of cirrhosis.⁵⁰

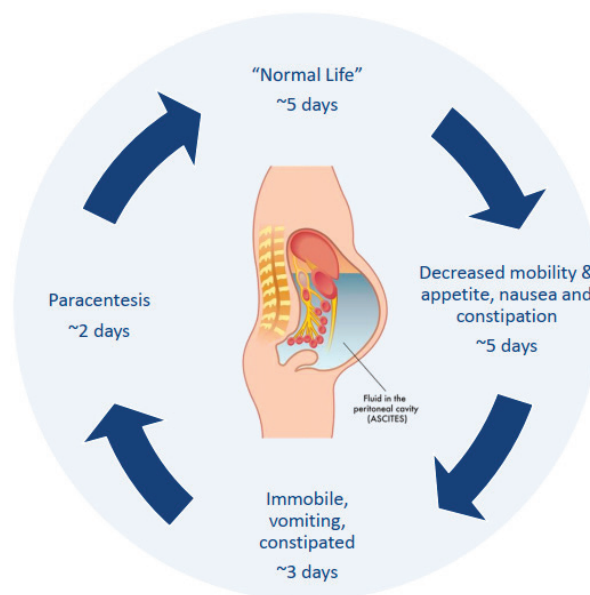
Management of ascites is based on low-sodium diet and diuretic treatment. However, approximately 7.5% of patients with cirrhosis and ascites will develop liver refractory ascites,⁵¹ which is ascites that is unresponsive to a sodium-restricted diet and high-dose diuretic treatment or that recurs rapidly after paracentesis. Management estimates there are approximately 18,000 liver refractory ascites patients in the U.S. and 17,000 across the EU5 based on historical rates of liver cirrhosis in the U.S. and the EU5⁵² and the observed rates at which patients with cirrhosis develop ascites⁵³ and refractory ascites.⁵⁴ Management estimates that within the next ten to twenty years the number of liver refractory ascites patients will grow to 151,000 in the U.S. (with 145,000 due to NASH) and 89,000 in the EU5 (with 83,000 due to NASH) based on the estimated prevalence of refractory ascites patients with alcoholic liver disease,⁵⁵ the estimated prevalence of liver cirrhosis

due to NASH in the current population⁵⁶ and the observed rates at which patients with cirrhosis develop ascites⁵⁷ and refractory ascites.⁵⁸ The estimated market size for 2030 takes into consideration the estimated growth in the prevalence for NASH but excludes refractory ascites patients with viral hepatitis as management expects this market to disappear by 2030.⁵⁹ Existing treatment options for refractory ascites carry the risk of significant or life-threatening side effects, provide only short-term symptomatic relief or have very limited availability.

Recurrent or recidivant ascites is a severe stage prior to further progression to refractory ascites and is defined as ascites that recurs on at least 3 occasions within a 12-month period despite prescription of dietary sodium restriction and adequate diuretic dosage.⁶⁰ Management estimates the recurrent or recidivant ascites market to be double the size of the refractory ascites market.

The standard of care for refractory ascites is LVP with albumin infusion to decrease the risk of paracentesis-induced circulatory dysfunction. Although LVP is generally considered safe, it is a painful and burdensome procedure which only provides short-term symptomatic relief, requiring hospital visits and placing a significant burden on the healthcare system and patient quality of life. Management estimates that patients undergoing recurrent cycles of fluid build-up and paracentesis are only able to experience a normal life for one-third of the time of each cycle until the debilitating symptoms of ascites return. The LVP treatment cycle is depicted in Figure 2 below:

Figure 2
Large volume paracentesis treatment cycle



Source: Dr. Rajiv Jalan

In selected patients with refractory ascites, a therapeutic alternative to repeated LVPs is the use of a transjugular intrahepatic portosystemic shunt (“TIPS”), an artificial channel within the liver that establishes a connection between the inflow portal vein and the outflow hepatic vein. There are a wide variety of complications that can be encountered with TIPS, such as haemorrhage, hepatic encephalopathy (which develops in 30% to 50% of patients),⁶¹ heart failure, TIPS blockage, and liver failure. The hepatic encephalopathy complications arise primarily from the significant reduction in the cleaning of the blood by the liver and the consequent accumulation of toxins that particularly impact the brain. Development of hepatic encephalopathy, one of the main drawbacks of TIPS, causes devastating physical and mental changes such as mood and personality changes, anxiousness, concentration deficit, loss of orientation, dementia-like memory loss, tremor, and may ultimately lead to coma. The risk of developing hepatic encephalopathy increases with age. As a result, TIPS carries significant risks for patients over 65 years old,⁶² which many patients with ascites from NASH are forecast to be.

The only curative treatment for liver disease is a liver transplantation. Liver transplants are very limited in availability and result in large healthcare costs. Lifelong use of immunosuppression drugs is required to reduce the risk that the recipient's body will reject the transplant.

There is a high unmet medical need for a long-term, cost-effective therapy to manage ascites that meaningfully improves patient quality of life. Management believes that despite significant investments in the development of therapeutics for NASH, there will be a strong, growing need for ascites treatments.

(b) Malignant ascites

Ascites is also a common complication of certain late-stage cancers as a result of fluid accumulation in the peritoneal cavity due to a number of causes including draining of the lymph system. While life expectancy for many cancer patients with malignant ascites is short (less than 3 months), ovarian and breast cancer patients often have longer life expectancies.⁶³ There will be an estimated 232,000 and 269,000 new cases of breast cancer diagnosed in each of the U.S. and EU5, respectively, in 2018.⁶⁴ In addition, there will be an estimated 24,000 and 26,000 new cases of ovarian cancer diagnosed in the U.S. and EU5, respectively, in 2018.⁶⁵ Management estimates the prevalence of malignant ascites due to ovarian and breast cancer to be approximately 16,000 cases in the U.S. and 18,000 cases across the EU5 based on the incidence of breast and ovarian cancers in the U.S. and EU5⁶⁶ and the observed rates of malignant ascites in breast and ovarian cancer patients.⁶⁷

As with ascites due to liver disease, paracentesis is used to eliminate the ascites that accumulates when drugs are not effective. The impact of ascites on patient health reduces their ability to withstand anti-cancer therapies, thereby potentially reducing survival, and places a burden on the patient through a significant reduction in quality of life through regular hospital visits and impact on daily life.

There is a significant unmet medical need for a minimally invasive therapy to manage malignant ascites that does not cause a further detriment to quality of life among patients with an already poor prognosis. In addition to improving the quality of life for these patients, a long-term treatment for malignant ascites could enhance their ability to withstand additional cancer treatments and increase their chances of survival.

(c) Heart failure

Heart failure is a progressive disease that results in the heart being unable to pump enough blood and thereby supply oxygen to support other organs in the body. The American Heart Association estimates that 6.5 million adults in the U.S. age 20 and over are affected by heart failure and that number is expected to rise to 8.0 million adults by 2030.⁶⁸ It is estimated that at least 26 million people are living with heart failure worldwide.⁶⁹ Total direct medical costs for the U.S. heart failure market are projected to reach \$53 billion in 2030.⁷⁰

Physicians usually classify heart failure according to the severity of their symptoms. The New York Heart Association Functional Classification (the "NYHAFC") is one of the most commonly used classifications. Class III heart failure under the NYHAFC is categorised as a marked limitation of physical activity (comfortable at rest) where less than ordinary activity causes fatigue, palpitation or dyspnea. Class IV heart failure under the NYHAFC is categorised as being unable to carry on any physical activity without discomfort (symptoms of heart failure at rest), and if any physical activity is undertaken, discomfort increases. It is estimated that there are 1.7 million Class III and Class IV heart failure patients in the U.S. (based on the NYHAFC).⁷¹

Heart failure can disturb the normal functioning of the kidney, diminishing its ability to excrete sodium from the body and triggering compensatory mechanisms that cause water retention resulting in volume overload. Patients with heart failure commonly experience shortness of breath, fatigue, difficulty exercising and swelling of the legs. The increase in fluid volume increases the burden on the weakened heart, further exacerbating the problem clinically.

Volume overload, which presents in Class III and IV patients under the NYHAFC, is currently treated through the administration of diuretics, which frequently cause patients to develop kidney failure and an estimated 40% of heart failure patients experience diuretic resistance or intolerance.⁷² Once patients become resistant or intolerant to diuretics or begin to experience kidney failure, clinical alternatives are limited (eg. ultrafiltration) and have significant limitations.

Volume overload in the body is a major clinical problem and the leading cause of hospitalisations for patients suffering from heart failure.⁷³ There are approximately 1 million people in the U.S. admitted annually to the hospital for heart failure, costing the U.S. approximately \$13 billion each year.⁷⁴ Of these admissions, 90% are due to symptoms of volume overload,⁷⁵ with an average length of stay of 5 days.⁷⁶ By 2026, it is estimated that there will be 2.0 million Class III and Class IV heart failure patients (based on the NYHAFC) in each of the U.S. and the EU5,⁷⁷ and that there will be approximately 1.0 million hospitalisations in the U.S. and approximately 1.2 million hospitalisations in the EU5 each year due to volume overload.⁷⁸

According to a study of over 100,000 patients in the U.S. suffering from acute decompensated heart failure, over 37% of patients discharged were still symptomatic and about one-third of the patients were discharged with less than five pounds lost and 16% had actually gained weight,⁷⁹ demonstrating that current volume overload treatments are not effective in these patients. It is estimated that nearly 50% of hospitalised patients with heart failure are discharged with residual fluid excess.⁸⁰ By not truly addressing the volume overload problem, patients are being readmitted to the hospital too frequently, with 30-day readmissions of 24%.⁸¹

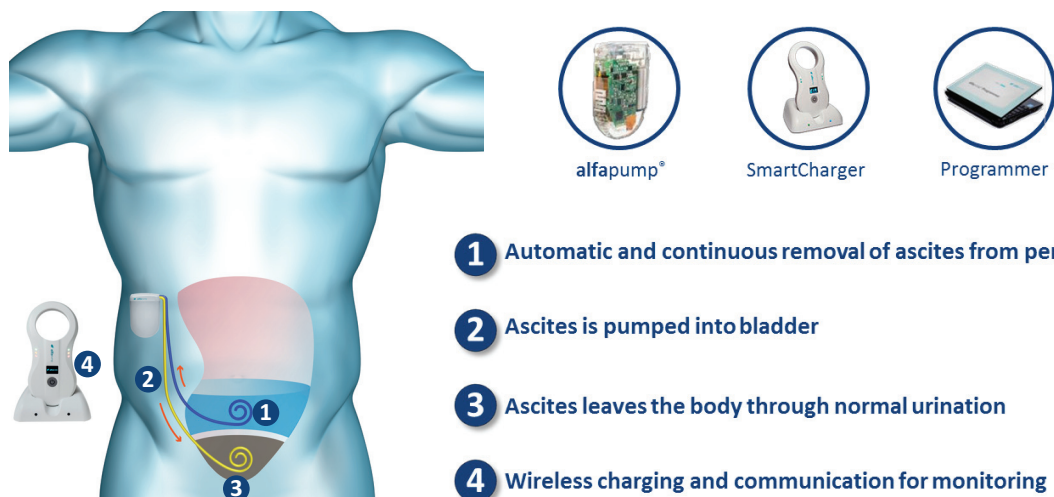
There is a significant unmet medical need for a safe and effective, long-term treatment for volume overload caused by heart failure in diuretic resistant patients that is cost-effective, reducing the number of hospitalisations and improving patient quality of life.

8.5 Sequana Medical's solution

(a) Liver and malignant ascites – **alfapump**[®]



The automated low-flow ascites pump, or **alfapump**[®], provides a safe and effective innovative treatment solution for the management of liver refractory ascites and malignant ascites. The fully-implanted, programmable, wirelessly charged **alfapump**[®] automatically pumps ascites from the peritoneal cavity into the bladder, where the body can eliminate the ascites naturally through urination.



The **alfapump**[®] was developed with the aim to eliminate the need for repeated invasive procedures. The **alfapump**[®] DirectLink technology allows Sequana Medical's data specialists to receive pump performance information (eg. volume pumped and pump charging) 24 hours a day, seven days a week, and report this information to clinicians to enable them to more effectively manage patients through closer monitoring and notification of changes in the patient's condition. Physicians are able to tailor and update the pump settings based on the specific and evolving needs of the individual patient allowing for fewer in-person, follow-up visits.

A further benefit of the **alfapump**[®] in malignant ascites is that the physician is able to conduct regular liquid biopsies through the analysis of urine samples. These will contain significant material direct from the peritoneal cavity, including cancer cells.

The **alfapump**[®] is implanted via a procedure that lasts approximately 45 minutes. The procedure is generally performed under general anaesthesia but can also be performed under local anaesthesia with sedation. Pump placement is generally performed by a general surgeon or by an interventional radiologist. Because the **alfapump**[®] is fully implanted, patients are able to retain normal mobility and activity. The **alfapump**[®] prevents fluid build-up and its possible complications, providing a basis for improvements to patient quality of life and nutrition, and reduced hospital visits and potentially healthcare costs to hospitals and payers.

In addition, the **alfapump**[®] can serve as a bridge to liver transplantation. Due to the high cost of the liver transplantation procedure and the scarcity of donor organs, the **alfapump**[®] provides support for patients waiting for a liver transplantation and can also improve patient condition ahead of transplant.

For commercial patients, there are no formal warranty terms and conditions in place with customers in relation to the duration of the **alfapump**[®]. On a voluntary basis, if an **alfapump**[®] needs to be replaced, Sequana Medical pays for the replacement **alfapump**[®]. In no circumstance would Sequana Medical be responsible for any healthcare costs, and the healthcare system bears the cost of the replacement procedure.

The **alfapump**[®] is fully programmable, for example it can also be inactive at night in order to ensure that the patient receives rest. Furthermore, the **alfapump**[®] has internal sensors that monitor the pressure in the peritoneal cavity and the bladder in order to stop pump operation if there is no ascites in the peritoneal cavity or if the bladder is already full.

The housing of the pump is made of biocompatible plastic, which enables efficient wireless charging and communications. The only patient interaction is the need to recharge the battery each day with a wireless charger through the skin for approximately 20 minutes (depending on the amount of fluid extracted each day).

The **alfapump**[®] programmer is a medical-grade notebook with proprietary FlowControl software that is used to change the pump setting. The FlowControl software enables the quick and easy adaption of a fluid-transport program that is specific to the individual patient. The **alfapump**[®] is also accompanied with a surgical kit that is provided to facilitate the implantation procedure and enable the customisation of the catheters to the anatomy of the patient,

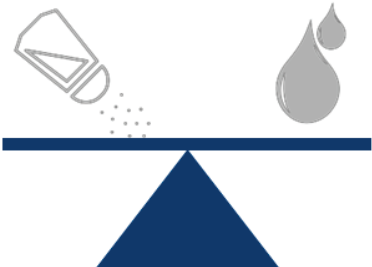
The **alfapump**[®] received a CE-Mark in Europe for the treatment of liver refractory ascites in 2011, and in 2012 for the treatment of malignant ascites. In January 2019, the FDA granted Breakthrough Device designation for the **alfapump**[®] for the treatment of liver recurrent or refractory ascites. Over 650 **alfapump**[®] systems have been implanted at the date of this Prospectus.

Management believes that the **alfapump**[®] also has the potential to provide significant benefit to recurrent ascites patients, which management estimates to be double the size of the refractory ascites market.


(b) Heart failure – alfapump[®] DSR

Sequana Medical's proprietary Direct Sodium Removal (DSR) therapy is a breakthrough in the management of volume overload in heart failure.

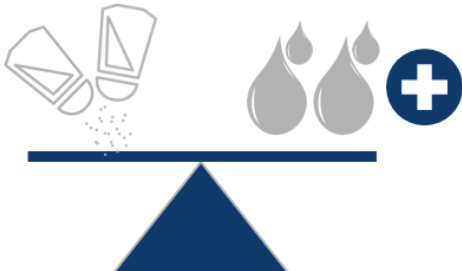
Maintaining a constant concentration of sodium in the body is a key physiological parameter that is vital to patient health. A concentration that is too high will result in hypernatremia and a concentration that is too low will result in hyponatremia.



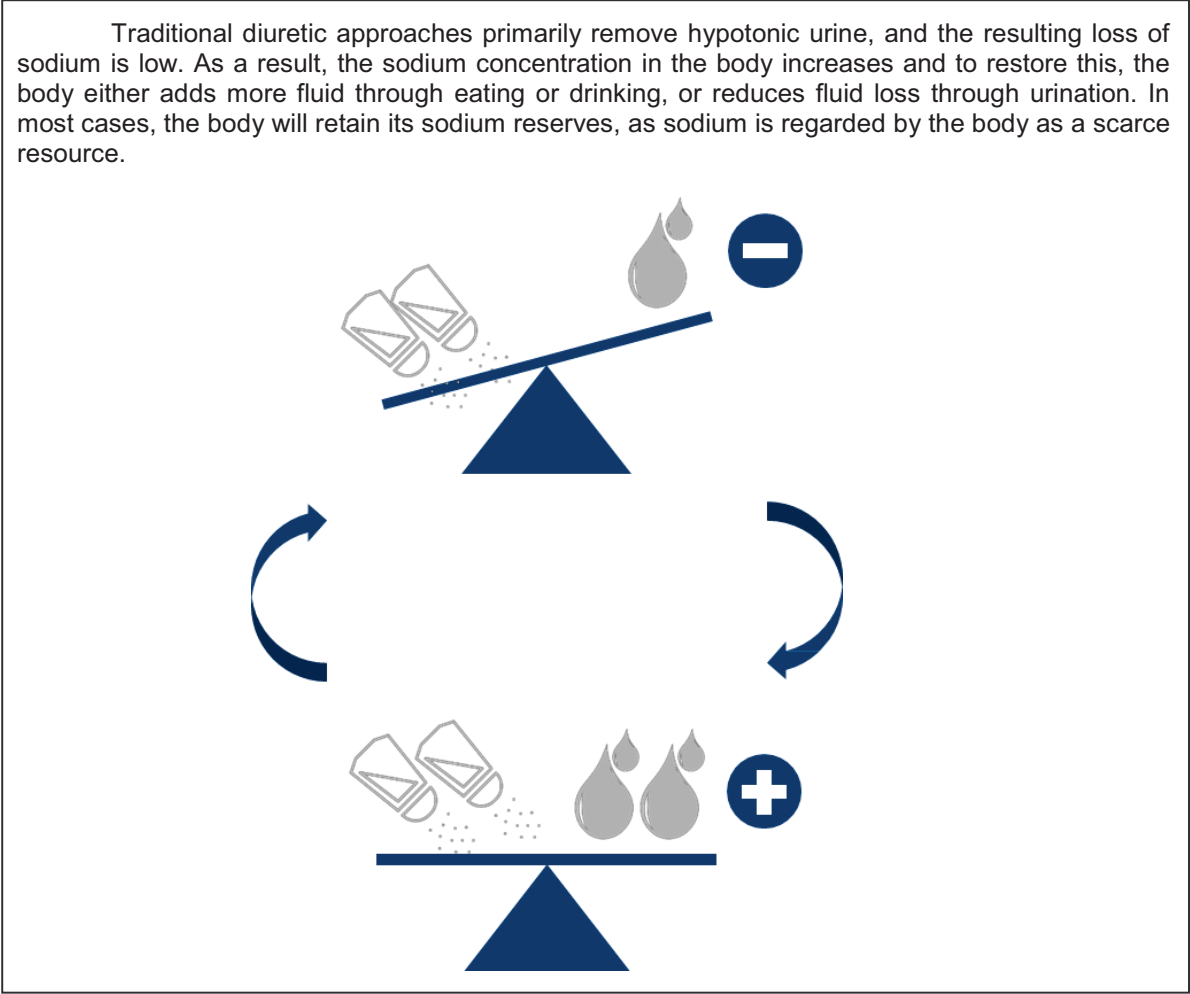
The body's response to heart failure causes sodium levels to increase:



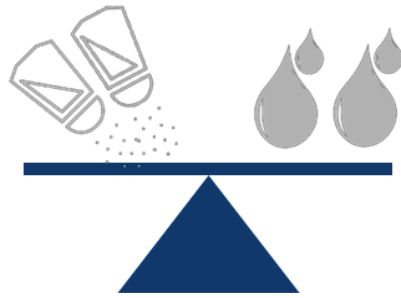
To restore the balance, the body retains water, leading to volume overload and an increased burden on the heart:



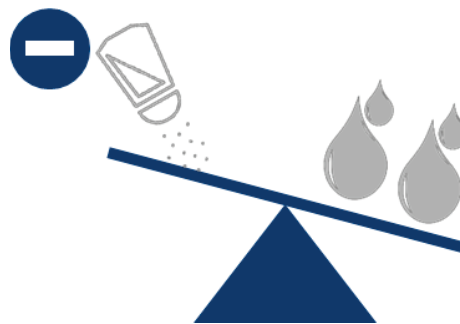
The key challenge in addressing volume overload is that removal of water from the body without the removal of the associated amount of sodium only results in a temporary reduction in fluid volumes.



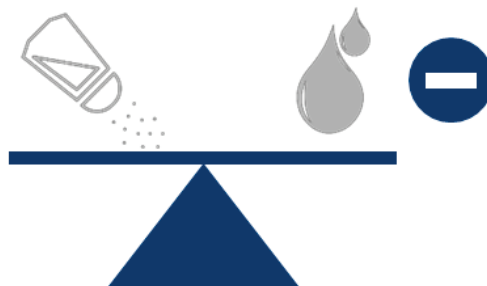
The sodium concentration in patients with volume overload is in balance but there is too much sodium and too much fluid in the blood.



Sequana Medical's approach is to remove excess sodium in patients with residual renal function.



As a result, the body acts to restore the sodium concentration in the body by eliminating fluid through urination and osmotic ultrafiltration, resulting in a sustained level of fluid loss.



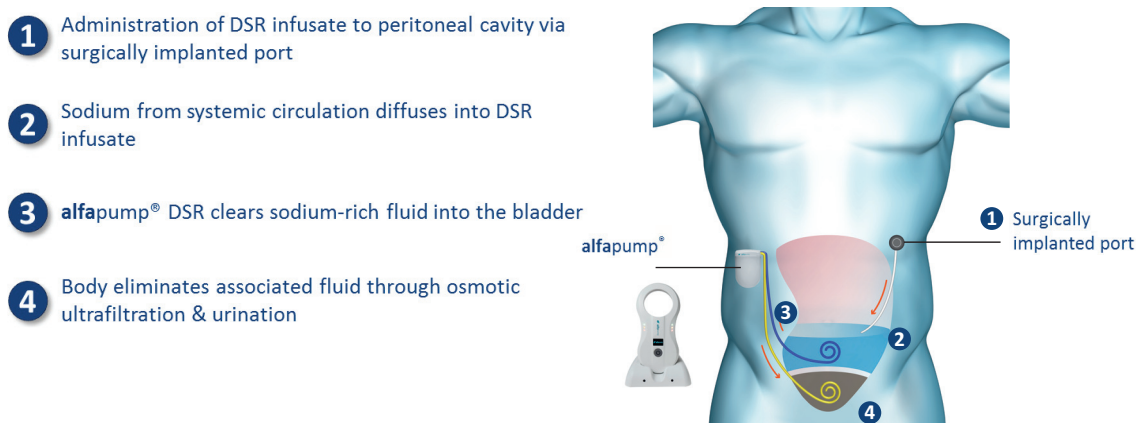
Sequana Medical's DSR therapy involves the use of the peritoneal cavity for the removal of sodium via diffusion. The peritoneal cavity has a rich blood supply and thin walls, which makes it highly effective in removing soluble compounds from the blood stream. The utility of the peritoneal cavity is supported by the long-standing technique of peritoneal dialysis, for the removal of toxins from the blood of patients with renal failure.

In DSR, the objective is to remove sodium instead of toxins. To do this, a "sodium-free" infusate is administered to the abdomen and allowed to dwell for a pre-defined period. During this time, sodium diffuses from the body down a steep diffusion gradient into the infusate. Circulation keeps the effective blood sodium concentration high. The infusate and the extracted sodium are then removed, resulting in a removal of sodium from the body. The body responds by eliminating the associated fluid via osmotic ultrafiltration (the movement of water, together with sodium, from the bloodstream to the peritoneal cavity) and/or urination.

Sequana Medical has leveraged its **alfapump**[®] experience to develop **alfapump**[®] DSR, a fully implanted system to deliver what it believes is a commercially attractive approach to implement DSR therapy. The **alfapump**[®] DSR combines three proven elements, (i) the **alfapump**[®] system, (ii)

a surgically implanted port and (iii) DSR infusates. The DSR infusate is administered to the peritoneal cavity via the surgically implanted port, which allows for flexible dosing to remove the desired amount of sodium. The DSR infusate remains there for a pre-determined time before the DSR infusate and the extracted sodium is pumped to the bladder. Management believes that the accumulated experience of over 650 implanted **alfapump**[®] systems significantly de-risks the technical and clinical development of **alfapump**[®] DSR.

In addition to the direct removal of the sodium and associated elimination of fluid, management believes that the ability of **alfapump**[®] DSR to remove any spontaneous accumulation of fluid (which is likely to be isotonic to the body) in the abdomen will further enhance the efficacy of the **alfapump**[®] DSR. Furthermore, the ability of the **alfapump**[®] DSR to monitor changes in the rate of spontaneous accumulation of fluid in the abdomen and changes in intra-abdominal pressure will deliver significant diagnostic information to clinicians, potentially providing advance warning of decompensation. It has been demonstrated that integrated monitoring systems have the potential to extend and improve patients' lives while decreasing the burden of care and reducing costs.



(c) Other potential applications

Through the development and optimisation of the **alfapump**[®] for liver ascites and malignant ascites, Sequana Medical has developed a system with a range of important capabilities. These include a pump capable of pumping up to 4 litres of biologic matter per day for over one year without clogging and being charged wirelessly. The system does not cause significant heating of the body and the system can be controlled wirelessly.

Management believes that this combination of capabilities can be applied to applications such as pleural effusion/hydrothorax. Initial clinical work has been undertaken in pleural effusion with positive results.

Sequana Medical intends to continue leveraging its proprietary **alfapump**[®] technology to explore innovative treatment solutions for other fluid imbalance disorders with unmet medical need in order to maximise the potential of Sequana Medical's innovative and patented technology. Sequana Medical may either undertake such development itself or seek to partner or out-license the **alfapump**[®] technology for specific applications.

8.6 Clinical and pre-clinical studies

Sequana Medical has invested significant resources in clinical studies to demonstrate the safety and efficacy of the **alfapump**[®] in liver refractory ascites patients. As of the date of this Prospectus, seven articles on clinical study results have been published in peer-reviewed journals, which management believes are essential to support acceptance of the **alfapump**[®].

Key findings of these studies include:

- an approximately 90% reduction in the mean number of LVPs per month for liver refractory ascites patients treated with the **alfapump**[®] versus patients treated with LVP standard of care;
- a clinically significant improvement in quality of life for patients treated with the **alfapump**[®] versus patients treated with LVP standard of care; and

- liver refractory ascites patients treated with the **alfapump**[®] demonstrated a clear nutritional benefit versus patients treated with LVP standard of care over 30-day and 90-day periods.

The **alfapump**[®] was also effective in palliative patients with malignant ascites and demonstrated the potential to improve quality of life and clinical outcomes for late-stage cancer patients.

Animal studies have shown that DSR therapy is both effective at removing clinically significant amounts of sodium and fluid, and safe.

(a) Liver disease

(i) Completed studies

The following **alfapump**[®] studies have been completed for the management of liver disease:

Name of Study	Description	Number of Patients
PIONEER Study	Prospective, multi-centre, open-label, uncontrolled study to assess the safety and performance of the alfapump [®] in patients with liver refractory ascites and diuretic resistance (completed in 2013).	40
Gines Study	Prospective, single-centre, uncontrolled study to evaluate the effects of the alfapump [®] on kidney and circulatory function in patients with liver cirrhosis and refractory ascites.	10
European RCT	6-month open-label, randomised and controlled study in Europe on the alfapump [®] versus LVP for the treatment of liver refractory ascites (completed in 2016).	58
Post Marketing Surveillance Registry ("PMSR")	Multi-centre, open-label observational study in Europe designed to follow patients implanted with an alfapump [®] for up to 24 months (completed in 2018).	100 ⁽¹⁾
Retrospective Study at Hannover Medical School	Retrospective, single-centre study at Hannover Medical School to investigate the alfapump [®] as an alternative for LVP in a real-world setting (published in 2018).	21
MOSAIC (North American IDE feasibility) Study	12-month open-label, single-arm study in the United States and Canada (" North America ") to assess the safety and efficacy of the alfapump [®] in patients with liver recurrent or refractory ascites (completed in 2018).	30

Note:

(1) Data on initial 56 patients has been published. Data on all 100 patients is intended to be submitted for publication in the first half of 2019.

1. PIONEER Study

Study design

The PIONEER study was a prospective, multi-centre, open-label uncontrolled study to assess the efficacy and safety of the **alfapump**[®] in patients with liver refractory ascites. In total, 40

patients were enrolled at 9 sites across Spain, Germany, Belgium and Bulgaria. The **alfapump**[®] was successfully implanted in all patients.

The primary endpoint included safety of the **alfapump**[®] evaluated by the incidence and severity of device and procedure-related serious adverse events at 6 months. Key secondary endpoints included the need for paracentesis and device function. Data was collected from each patient over a follow-up period of 24 months.

Key findings

The **alfapump**[®] removed 90% of the ascites and significantly reduced the median number of LVPs per month, from 3.4 in the month preceding the **alfapump**[®] implantation to 0.2 after implantation.

Procedure-related complications were mostly related to dislocation of the bladder catheter which was easily resolved by adjusting the design of the catheter and its implant procedure. Two patients developed pump pocket infections refractory to antibiotic therapy. The number and type of cirrhosis-related adverse events were in line with what was reported in literature and decreased along follow-up.

In the first cohort of patients enrolled, a significant number of infectious events were detected. As a result, antibiotic prophylaxis was implemented in all remaining patients and this remains a treatment recommendation.

About one third (n=13) of the **alfapump**[®] systems needed to be removed, most often due to infection, followed by catheter dislodgement or consecutive withdrawal of consent by the patient.

Based on these findings, a CE-Mark was granted for the **alfapump**[®] for single patient use in patients with refractory ascites due to liver cirrhosis, for a period of up to 2 years.

The results of this study have been published in the Journal of Hepatology (Bellot et al., 2013).⁸²

2. Gines Study

Study design

In 2011, the first patient was enrolled in the Gines Study, which was a prospective, single-center, uncontrolled study to evaluate the effects of the **alfapump**[®] on kidney and circulatory function in patients with liver cirrhosis and refractory ascites. Primary outcomes included changes in GFR, as assessed by isotopic techniques, and changes in circulatory function assessed by arterial pressure, cardiac output, and activity of vasoconstrictor systems. Secondary outcomes included the need for LVP and adverse events. Between November 2011 and June 2013, 10 patients with cirrhosis and refractory ascites were enrolled. Patients were followed up to 12 months after **alfapump**[®] implantation.

Key findings

Treatment with the **alfapump**[®] system was associated with marked activation of endogenous vasoconstrictor systems and impairment of kidney function, as shown by a reduction in GFR. The chronological relationship observed between kidney impairment and vasoconstrictor systems activation after device insertion suggests a cause-effect relationship, raising the possibility that treatment with the **alfapump**[®] impairs effective arterial blood volume mimicking a postparacentesis circulatory dysfunction syndrome. Long-term follow-up demonstrated that 4 out of the 10 (40%) patients did not require more LVP after **alfapump**[®] implantation. Overall there was a mean requirement of 7.5 LVPs per patient during the 3 months preceding study enrollment. After **alfapump**[®] implantation, mean LVP requirement in 3-month intervals was significantly reduced to respectively 1.8 (at 0-3 months), 3.7 (at 3-6 months), 3.2 (at 6-9 months), and 2.4 (at 9-12 months) during the follow-up periods. The main reasons for LVP requirements were technical problems precluding the correct functioning of the **alfapump**[®] (see below) or cirrhosis-related adverse events that did not allow an adequate increase in the volume of ascites removed.

Overall, there were 15 device- or procedure-related adverse events in 7 patients, which resulted in 6 surgical re-interventions.

During follow-up, albumin administration was only given if patients required a LVP or in case of spontaneous bacterial peritonitis or development of AKI with serum creatinine of more than

1.5mg/dL. No more albumin was given throughout the Gines Study. In this context, the potential role of albumin in counter-acting these effects should be investigated in future studies.

The results of this study have been published in Liver Transplantation (Solà et al., 2017).⁸³

3. European RCT

Study design

In April 2016, Sequana Medical completed the European RCT, a prospective, multi-centre, open-label, randomised, controlled study to evaluate the safety and efficacy of the **alfapump**[®] in patients with liver refractory ascites versus LVP standard of care. The European RCT was conducted at seven sites across the U.K., France, Austria, Italy and Spain. Sixty patients were enrolled, of which 58 had data for safety and efficacy.

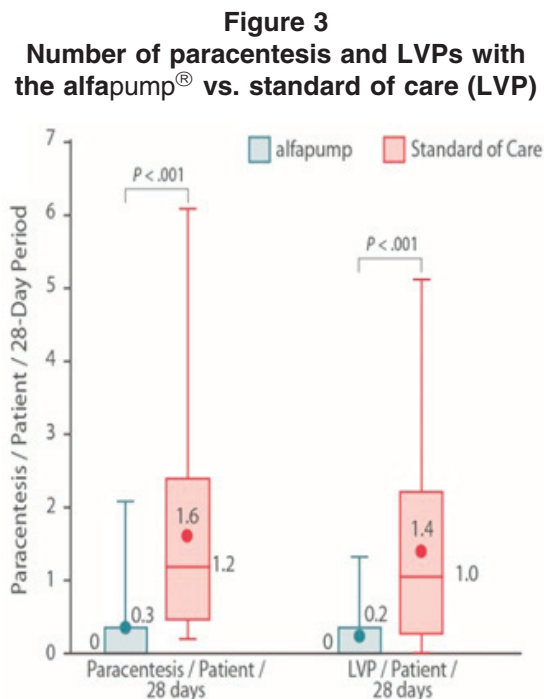
Patients were randomised 1:1 to either the **alfapump**[®] group or the LVP standard of care group. The primary endpoint of time to first LVP was evaluated at 6 months post-randomisation.

Key secondary outcomes included requirement for therapeutic paracentesis, safety, health-related quality of life and survival. An exploratory sub-study was performed on the first 16 patients, to investigate the effects of the **alfapump**[®] on nutrition, hemodynamics and renal injury biomarkers after 3 months.

Key findings

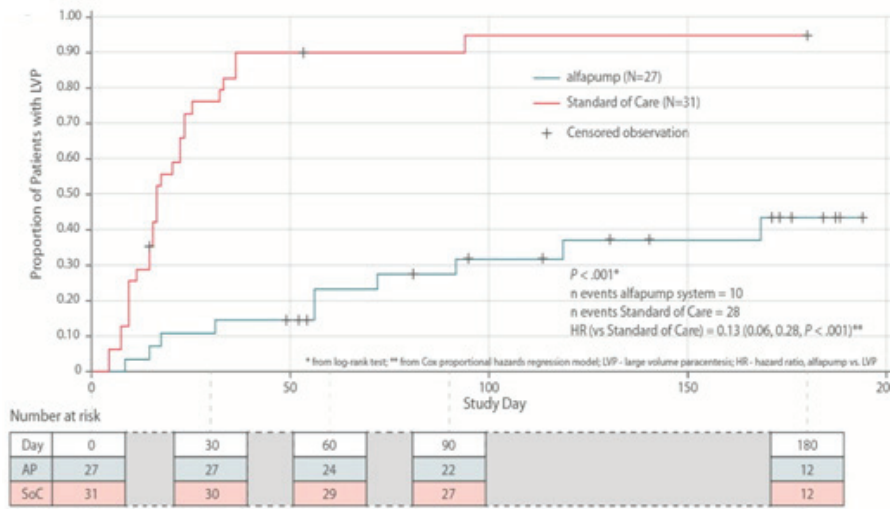
The study achieved the primary endpoint by demonstrating a statistically significant difference in time to first LVP in **alfapump**[®] patients versus LVP standard of care patients.

The mean number of LVPs per patient per 28-day period was 0.2 in the **alfapump**[®] group versus 1.4 in the LVP standard of care group ($p < 0.001$), as demonstrated in Figure 3 below.



The median time to LVP was more than 6 months in the **alfapump**[®] group versus 15 days in the LVP standard of care group ($p < 0.001$), as demonstrated in Figure 4 below.

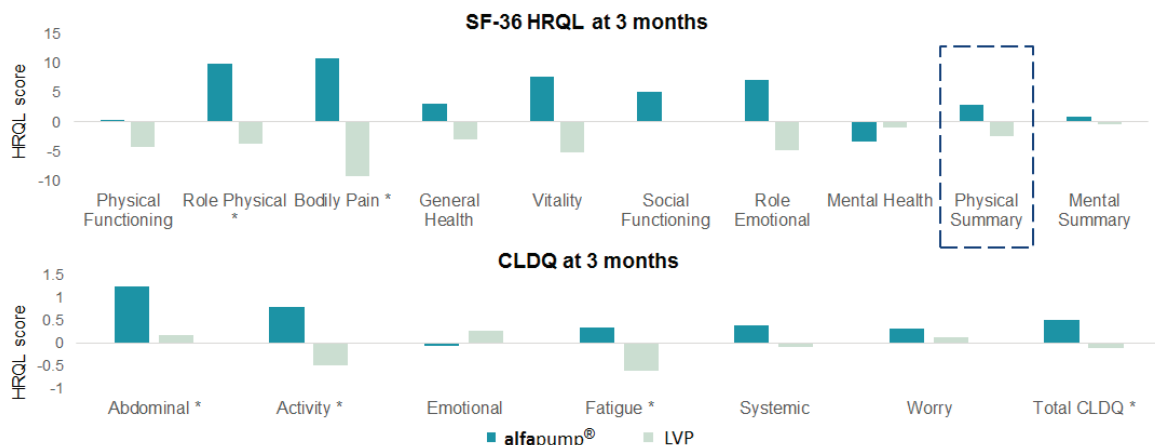
Figure 4
Kaplan-Meier plot of time to first LVP



The **alfapump**[®] patients also showed significantly improved health-related quality of life scores compared to the LVP standard of care group as measured by two widely used scales: the 36-Item Short Form Survey (the “**SF-36**”) and the Chronic Liver Disease Questionnaire (the “**CLDQ**”). The CLDQ is more focused on the most frequently observed health-related impairments associated with chronic liver disease.

Figure 5 below shows the scores in both quality of life methodologies at 3 months (N=49). In a subgroup analysis of those who also completed the 6 months questionnaires (N=28), a similar pattern was observed. The superiority of health-related quality of life in **alfapump**[®] patients remained significant even after controlling for other known predictors of health related quality of life (“**HRQL**”) scores.⁸⁴

Figure 5
alfapump[®] vs. standard of care (LVP)
quality of life scores



Notes: *($P < 0.05$)

The benefit seen in the physical component scores is of particular importance since a poor physical component of quality of life is associated with increased mortality as demonstrated in a study of over 400 difficult-to-treat and refractory ascites patients.⁸⁵ Figure 6 below shows data from this study where patients were stratified by survival after one year follow-up: patients that

survived follow-up for 1 year were associated with a higher median physical component score (a “PCS”).

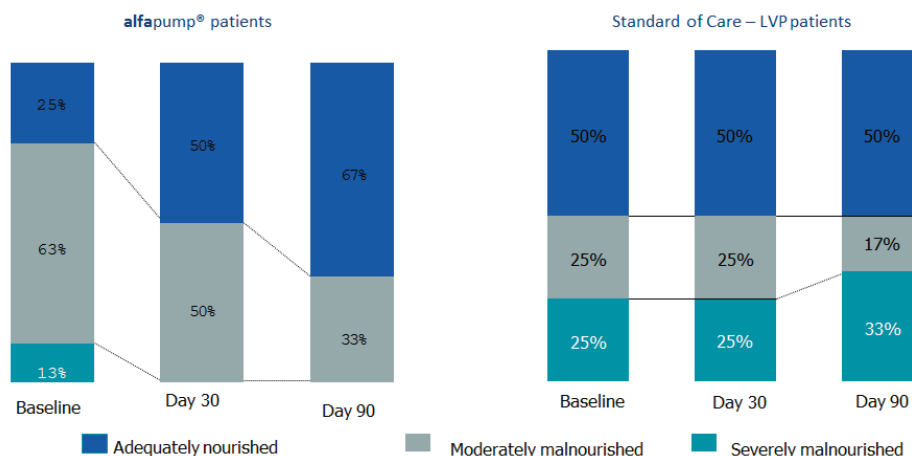
Figure 6
Importance of physical component score (PCS) (one year follow-up)

Physical component score (range)	PCS of patients who died during follow-up	PCS of patients who survived follow-up	P-value
Physical component score	34 (24-49)	41 (29-53)	0.01
Physical function	45 (25-65)	50 (30-70)	0.42
Role Physical	0 (0-25)	0 (0-50)	0.05
Bodily pain	42 (22-80)	54 (41-74)	0.05
General health	35 (27-50)	40 (30-55)	0.12

Source: MacDonald et al., J. Hepatology , V68 , S726-7 (2018) ⁸⁶

In a sub-study of 16 patients, clear improvements in nutritional status were seen in **alfapump**[®] patients compared to patients treated with LVP from baseline to day 90, as demonstrated in Figure 7 below. Nutrition is a key clinical objective for refractory ascites patients as many patients are malnourished as a result of the condition and the sodium-restricted diet.

Figure 7



More patients in the **alfapump**[®] group compared to the LVP standard of care group reported adverse events (respectively 96.3% and 77.4%) and serious adverse events (respectively 85.2% and 45.2%). Adverse events consisted predominantly of AKI in the immediate post-operative period, and re-intervention for pump-related issues, and were treatable in most cases. Although serious adverse events were more common in the **alfapump**[®] group, these were generally limited and did not affect the overall survival at 6 months.

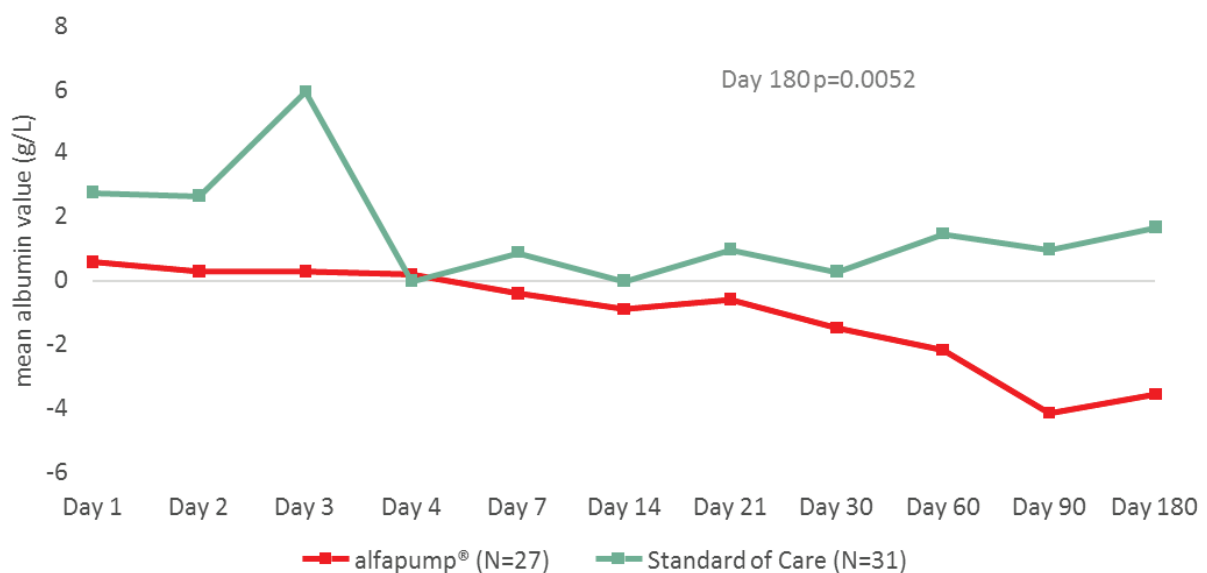
The total number of infectious complications was similar between groups. There were significantly more AKI events in the **alfapump**[®] group than in the LVP standard of care group (respectively 30 versus 11). This difference was significantly reduced if the first 7 post-operative days were excluded (respectively 17 versus 11). The AKI events occurring within the first 7 days

following the implantation may have been related to sterile inflammation induced by the surgical procedure or related to manipulation of the abdominal wall and rapidly changing abdominal pressures, or a combination of these factors.

Although there was no difference between groups in the number of adverse events related to AKI and hyponatremia occurring more than 7 days post-implantation, more of these events required hospitalisation in the **alfapump**[®] group. It was hypothesised that this could be related to albumin depletion, resulting in circulatory dysfunction demonstrated by an increase in plasma renin activity, since the study design did not include the systematic administration of albumin in the **alfapump**[®] group. Administration of albumin after LVP is routine to address paracentesis-induced circulatory dysfunction, which is widely acknowledged to impact survival.

Figure 8 below shows changes in plasma albumin over time after treatment for the **alfapump**[®] group and LVP standard of care group. Patients in the **alfapump**[®] group received significantly less cumulative albumin post-implant (versus routine albumin replacement in the LVP standard of care group following each LVP), and the change in albumin from baseline was more pronounced in the **alfapump**[®] group compared to LVP standard of care group.

Figure 8
Change in plasma albumin from baseline over time after treatment



Despite receiving less systematic albumin replacement in the **alfapump**[®] group, mortality was unchanged. Sequana Medical plans to initiate a study to evaluate the impact of albumin replacement therapy in patients implanted with the **alfapump**[®] (see subsection (iii) (Ongoing / Planned studies), subsection 5 (Albumin Replacement Study)).

The results of this study have been published in the Journal of Hepatology (Bureau et al., 2017)⁸⁷ and Quality of Life Research (Stepanova et al., 2018).⁸⁸

4. The PMSR study

Study design

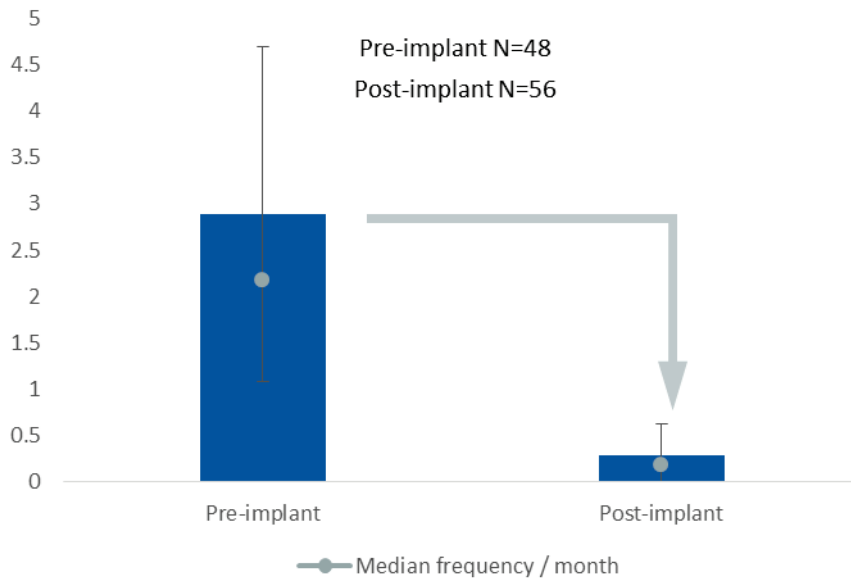
This prospective, multi-centre, open-label, observational study was initiated in 2012 to evaluate the data of 100 liver refractory ascites patients with a contra-indication to TIPS and therefore treated with an **alfapump**[®] across 10 European referral centres in Germany, Switzerland, the U.K. and Spain.

After implantation of the **alfapump**[®], patients were followed for at least 12 months, with a maximum of 24 months. The aim of this study was to assess the safety and efficacy of the **alfapump**[®] by collecting information about LVP, hepatic decompensations, infections, death, adverse device events and liver transplants.

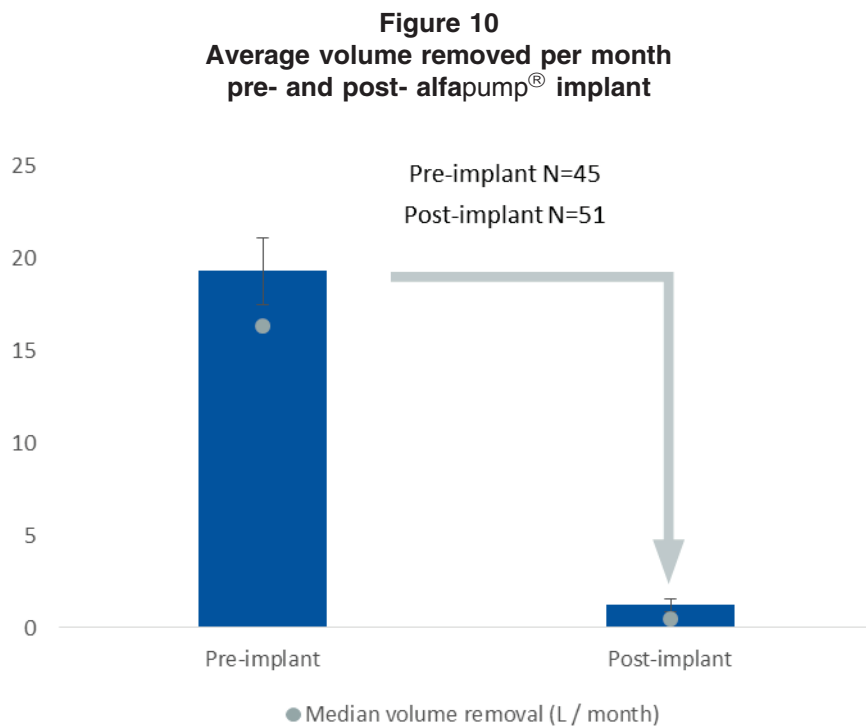
Key findings

These real-world data of patients with refractory ascites followed over a longer period of time reinforce the results of the European RCT. The study demonstrated that the **alfapump**[®] is effective in decreasing the need for paracentesis by more than 90% from a median of 2.2 times per month to a median of 0.2 times per month as shown in Figure 9 below. For patients implanted with the **alfapump**[®], 66% remained free of LVP and the majority of paracenteses performed post-implantation were necessary because of clogging, charger or pump programming issues.

Figure 9
Average paracentesis frequency per month
pre- and post- alfapump[®] implant



The study also demonstrated a decrease of 97.5% in the volume of fluid removed per month through paracentesis from a median volume of 16.3 litres per month to a median volume of 0.41 litres per month as shown in Figure 10 below.



The most frequently observed device deficiency was obstruction of the peritoneal catheter by proteinaceous debris and/or fibrin clots and aspiration of the omentum, requiring its exchange (21 events in 13 patients). In 5 patients, the peritoneal catheter was either displaced, disconnected or twisted. Of the 127 paracentesis that were performed post-implantation of the **alfapump[®]**, 55 (43%) were related to pump or catheter issues. As noted in a paper by Solbach et al. regarding the Hannover study (Retrospective Study at Hannover Medical School),⁸⁹ replacing the older peritoneal catheter with the Medionics peritoneal catheter has dramatically reduced instances of obstruction.

Bacterial infections occurred in roughly one-third of patients, which is similar to the infection rate typically seen in cirrhotic patients who are hospitalised (25%-35% in recently published studies).⁹⁰ Pump pocket infections led to two pump explantations.

The survival rate was consistent with that of patients treated with LVP as reported in a meta-analysis of recent studies investigating TIPS versus LVP for refractory ascites. The mean actuarial survival time was 12.8 months.

Results of the first 56 patients were published in *Alimentary Pharmacology & Therapeutics* (Stirnemann et al., 2017).⁹¹ Data from all 100 patients is intended to be submitted for publication in the first half of 2019.

5. Retrospective study at Hannover Medical School – the **alfapump[®]** in a real-world setting: complications and outcomes

Study design

This study retrospectively analysed the data of 21 patients who had been implanted with an **alfapump[®]** at the Hannover Medical School, a tertiary transplant centre in Germany, between December 2012 and May 2016. The aim of this study was to investigate the **alfapump[®]** as an alternative for LVP in patients with liver refractory ascites with a contraindication for TIPS or liver transplant.

Data was collected up to 12 weeks post-implantation, including requirement for LVP, infection rate, overall survival, and pump-related complications.

Key findings

After implantation of the **alfapump**[®], diuretic dosages were significantly reduced and the number of paracentesis declined from 2.3 (+/- 2.7) to none per week.

Infections related to the **alfapump**[®] occurred in 11 patients (52%) and 4 **alfapump**[®] systems were removed due to bacterial or fungal infections. It was noted that the higher rate of bacterial infections might be linked to the patient cohort with more advanced cirrhosis.

The mean duration of the **alfapump**[®] *in situ* was 194.8 days (n=18).

Overall, 33 complications related to the **alfapump**[®] were observed in 15 patients (71%) and 21 surgical interventions were needed in 15 patients (71%). It is important to note that the high complication rate was significantly reduced in those patients where instead of the original peritoneal catheter, a Medionics catheter (normally used for peritoneal dialysis) was used.

The results of this study were published in the European Journal of Gastroenterology & Hepatology (Solbach et al., 2018).⁹²

6. MOSAIC (North American IDE feasibility) Study

Study design

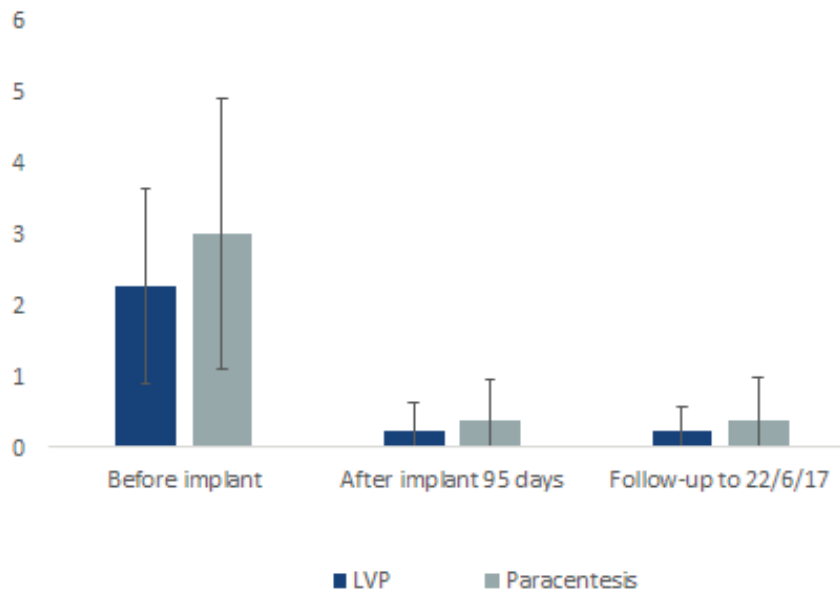
The MOSAIC (North American IDE feasibility) Study was a prospective, multi-centre, open-label, uncontrolled feasibility study to evaluate the safety and efficacy in patients with recurrent or refractory liver ascites not eligible for TIPS. In total, 30 patients were enrolled across 6 centres in the U.S. and Canada. Of the 30 **alfapump**[®] systems, 29 were implanted using interventional radiology techniques.

The primary objective of the study was to assess the safety of the **alfapump**[®] through evaluation of the incidence and the severity of device and procedure-related serious adverse events and survival. Secondary objectives included evaluation of the efficacy of the **alfapump**[®] through the overall requirement for LVP, change in nutritional status and quality of life, and device function. An initial analysis was performed at 3 months with an extended safety follow-up at 12 and 24 months.

Key Findings

The study demonstrated a 91% reduction in the average number of required LVP (from 2.4 per month per patient at baseline to 0.2 per month per patient at 3 months) as shown in Figure 11 below. There were a total of 34 paracentesis/LVPs required across 11 patients post-implantation, which were attributable to the peritoneal catheter becoming blocked or dislodged (38%), low pump volume settings due to concerns with the patient's kidney function (29%), the **alfapump**[®] becoming blocked (3%) and instances where there were no known issues with the **alfapump**[®] (29%) such as a low battery. Management believes that subsequent improvements in pump protocols could eliminate more than 95% of LVPs.

Figure 11
Average number of LVPs and paracenteses per patient per month



The study also demonstrated a clinically significant improvement in the mean quality of life, as measured by the CLDQ scores (3.88 at baseline versus 4.88 at 3 months – a higher score indicates improvement) and Ascites-Q scores (51.7 at baseline versus 32.2 at 3 months – a lower score indicates improvement), as demonstrated in Figures 12 and 13 below.

Figure 12
Mean CLDQ score
(Higher is better)

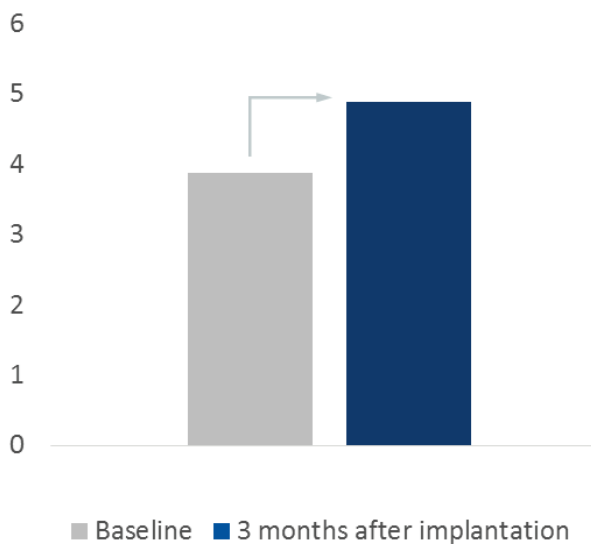
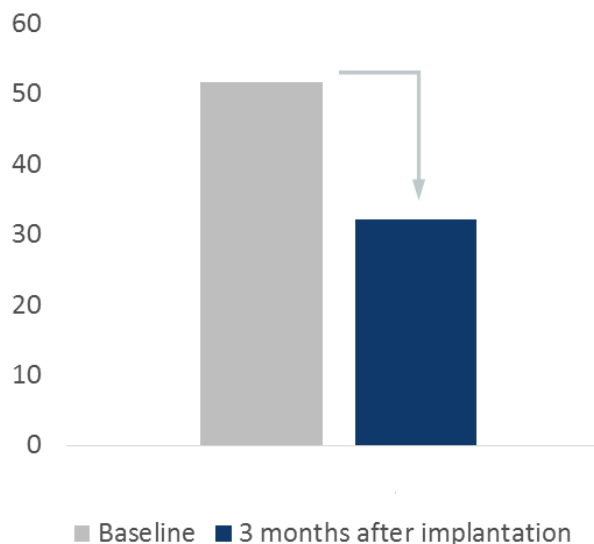


Figure 13
Mean Ascites-Q score
(Lower is better)



The large majority of **alfapump**[®] patients experienced a clinically relevant improvement in quality of life over a period of 12 months, as demonstrated in Figures 14 and 15 below.

Figure 14
Median change in CLDQ overall score compared to baseline

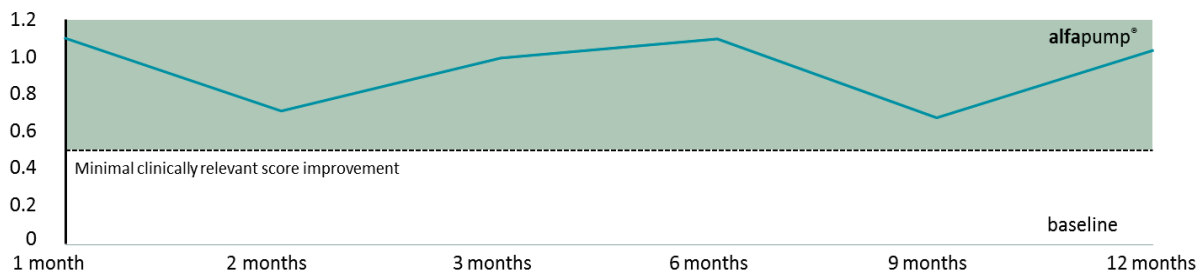
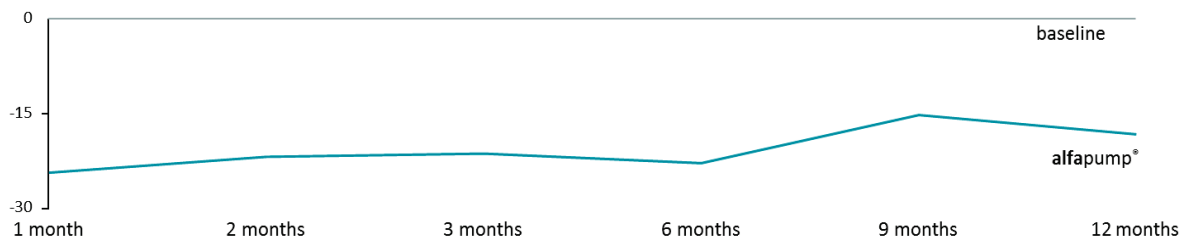


Figure 15
Median change in Ascites-Q total score from baseline



The mean overall survival was estimated at 15.1 months which was greater than expected as compared to prior publications. In addition, the overall survival rate was 96.7% at three months and 88.3% at twelve months.

The nutrition of **alfapump**[®] patients improved, on the basis of mean pre-albumin levels, from 87.8 mg/L to 102.9 mg/L. Surviving **alfapump**[®] patients experienced improved nutritional status.

Re-interventions occurred in 4 patients; 3 due to leaking, kinked or blocked peritoneal catheters, and 1 due to a pump malfunction (exchanged during initial implant procedure). The study used the original peritoneal catheter.

In the follow-up to June 2017, the **alfapump**[®] had been replaced in 8 patients. Causes of the additional **alfapump**[®] replacements were pump or bladder catheter blockage (2 patients) and a pump communication defect (2 patients). In addition, there were 8 catheter replacements (2 of which were simultaneous with replacement of the **alfapump**[®]).

Safety analysis reported 11 renal dysfunction events in 8 patients including 6 AKI events in 4 patients (majority resolved with or without sequelae). In total, 24 infections were reported in 14 patients including 1 spontaneous bacterial peritonitis (despite antibiotic prophylaxis) and 6 urinary tract infections (all resolved).

The initial results of the MOSAIC (North American IDE feasibility) Study were presented at the American Association for the Study of Liver Disease (AASLD) annual meeting in October 2017 and long-term follow-up results were presented at the AASLD annual meeting in November 2018. For these results, all protocol-required follow-up data (at least one year of data) was available. These results confirm the previously presented data and demonstrate that a significant reduction in the number of LVPs is maintained for up to 12 months, in addition to improved nutritional status and quality of life during follow-up. The data from the study is expected to be submitted for publication in the first quarter of 2019.

(ii) Improvement in clinical outcomes

Through the significant experience gained from clinical studies and extensive commercial use, Sequana Medical has continually worked on improvements to the **alfapump**[®]. Management believes that there is always a “learning curve” with new medical therapies, and this has been the case for the **alfapump**[®]. To deliver improved clinical outcomes, Sequana Medical focused on improvement in (i) pump performance, (ii) patient selection, and (iii) the procedure (before implant, during implant and after implant). This has resulted in an improvement in clinical outcomes and an improvement in the average time patients spend on the **alfapump**[®].

These improvements include:

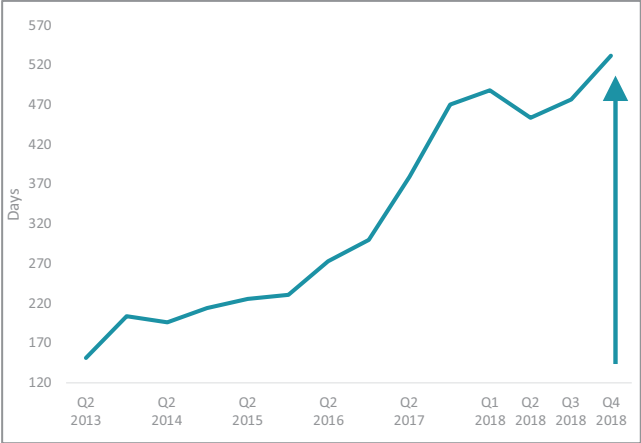
- Modifications to the bladder catheter design to reduce kinking and dislocation. The current bladder catheter was introduced in mid-2011.
- Replacement of the original peritoneal catheter with a Medionics catheter (normally used for peritoneal dialysis), which has dramatically reduced instances of blockage, dislocation and fluid leakage. The Medionics catheter has been used in all commercial patients in Europe since the fourth quarter of 2016, and was introduced for patients in Israel in May 2017 (once it received regulatory approval in Israel)
- Modifications to the **alfapump**[®] control algorithms to address pump blockage (e.g. “boost”, “shake” and “jog” modes).
- Use of antibiotic prophylaxis to reduce infection rates (due to the poor clinical condition of cirrhotic patients).
- Optimisation of the implant procedure to address issues including leakage, skin erosion and wound dehiscence (recognising that many cirrhotic patients are malnourished and have poor wound-healing ability). The current surgical procedures were implemented in the second and third quarters of 2017.

Meetings with experienced **alfapump**[®] surgeons and hepatologists were organised to share their experience and to discuss and find consensus upon standard of care protocols and generate recommendations for the use of the **alfapump**[®] in liver cirrhosis patients with refractory or recurrent ascites.

Sequana Medical is currently working to extend the **alfapump**[®] life to approximately 18 months through improvements to the production process and minor modifications to the pump design. A number of clinicians have confirmed that 18 months would be a sufficient lifespan for the **alfapump**[®]. This extended life will be increasingly important for earlier stage cirrhotic patients (e.g. individuals with recurrent ascites) and for the **alfapump**[®] DSR.

Following these improvements to the design of the **alfapump**[®] and the implantation procedures including pre- and post- implant care, there has been a clear increase in clinical outcomes. The average duration of **alfapump**[®] therapy per patient increased from 151 days in the second quarter of 2013 to 533 days in the fourth quarter of 2018, as demonstrated in Figure 17 below.

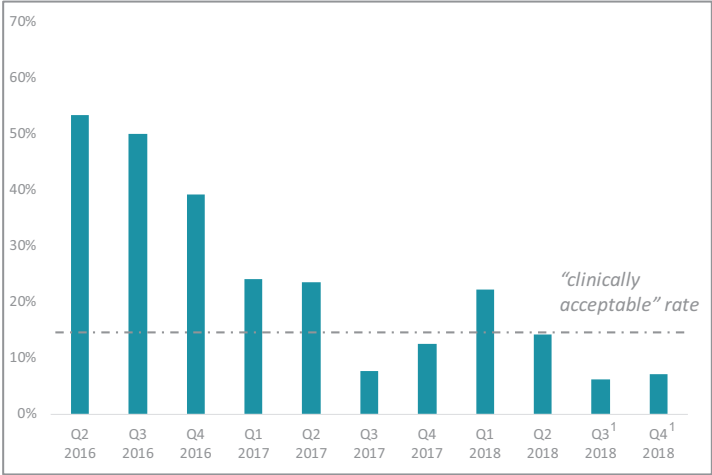
Figure 17
Average duration of alfapump[®] therapy



Source: Sequana Medical internal statistical analysis of market feedback/implant duration

In addition, there was a strong decline in the number of **alfapump**[®] systems requiring surgical re-intervention or explantation within 6 months after implantation as demonstrated in Figure 18 below: from 53% in the second quarter of 2016 to 7% in the fourth quarter of 2018. The dotted line represents the re-intervention and explant rate of 15% that clinicians have confirmed to be acceptable in their discussions with Sequana Medical.

Figure 18
Number of surgical reinterventions/explants
within 6 months (%)



Note: (1) Cohorts have not completed 6 months follow-up
 Source: Sequana Medical internal statistical analysis of market feedback/surgical reinterventions

(iii) Ongoing / planned studies

The following table provides a summary of select **alfapump**[®] clinical studies that are ongoing or that Sequana Medical plans to conduct in the near future for the management of liver disease:

Name of Study	Description ⁽¹⁾	2018	2019	2020	2021
Ongoing:					
ARIA Pump Study	Randomised, open-label health economic study in France in 90 liver refractory ascites patients to evaluate the cost utility of the alfapump [®] vs. standard of care (60 patients not waiting for liver transplant and 30 patients as bridge to transplant) over 12 months to support French reimbursement. ⁽²⁾				
Planned:					
TOPMOST ⁽⁴⁾	European registry study in cirrhosis patients that have been implanted with the alfapump [®] .				
POSEIDON (North American pivotal) Study	North American pivotal study in up to 100 patients with liver refractory and recurrent ascites to demonstrate the efficacy and cost-effectiveness of the alfapump [®] . ⁽³⁾				
Fitbit [®] Study ⁽⁵⁾	Quality of life study in 20 patients to measure the impact of the alfapump [®] vs. standard of care on patient activity.				
Albumin Replacement Study	European study on the impact of albumin replacement therapy on clinical outcomes in 10-15 patients implanted with the alfapump [®] .				

Notes:

- (1) The descriptions and timing of these studies presented in this table and in subsections 1 (Aria Pump Study) to 5 (Albumin Replacement Study) below reflect Sequana Medical's current expectations. These expectations are based on circumstances that may or may not occur in the future and remain subject to change and/or feedback from applicable regulatory authorities.
- (2) Funded by the French government and conducted by leading French clinicians.
- (3) Subject to FDA feedback.
- (4) The dashed shading of the arrow indicates that the study is expected to extend beyond 2021.
- (5) Fitbit[®] is not affiliated or associated with Sequana Medical, and Fitbit[®] is not affiliated with, and has not otherwise endorsed, the Fitbit[®] Study.

1. ARIA Pump Study

The ARIA Pump Study, a multi-centre, randomised health economics clinical study, began in the first half of 2018. The government of France is funding the study which is being conducted and sponsored by leading clinicians across seven centres in France. The study consists of two study populations including 60 patients with liver refractory ascites who are not waiting for a liver transplant and 30 patients with refractory ascites who are waiting for a liver transplant, both randomised 1:1 to either the **alfapump**[®] or the LVP standard of care group.

The primary outcome of the ARIA Pump Study is the incremental cost utility ratio of the **alfapump**[®] versus LVP standard of care over a period of one year. HRQL is measured through EQ-5D questionnaires every three months. Each patient is followed for up to two years. Key secondary endpoints include clinical and economic outcomes and evaluation of a budget impact model. Prior to commencing patient enrolment, the study centres were required to complete a

training phase whereby the clinicians that will complete the study are required to gain experience treating a group of liver refractory ascites patients with the **alfapump**[®]. The ARIA Pump Study began in the first half of 2018, and the study centres are expected to begin collecting data from prospectively enrolled patients once the training cases have been completed. No interim results for the ARIA Pump Study are planned.

2. TOPMOST

This European registry, TOPMOST, is ongoing to collect data from prospectively enrolled patients that have been implanted with the **alfapump**[®] and accepted to participate, across all commercial centres in Europe. The registry is supported by key opinion leaders and will assess the adverse event profile of the **alfapump**[®] following the technical improvements in product design and care protocols, as well as the effectiveness in “real world” circumstances. Patients will be enrolled on a continual basis and interim readouts will take place at regular time points, and the data will be captured in a detailed electronic data collection system and source data will be verified to ensure scientific validity.

Management believes that this real-world data will be important for healthcare providers and payers and to increase awareness of the **alfapump**[®], and will demonstrate the ongoing improvement in clinical outcomes and reductions in complications/adverse events. Management estimates that TOPMOST will cost up to €0.4 million annually.

3. POSEIDON (North American pivotal) Study

Following the MOSAIC (North American IDE feasibility) Study, Sequana Medical plans to launch the POSEIDON (North American pivotal) Study, a multi-centre, single arm, open-label, crossover controlled pivotal study in the second half of 2019 in U.S. and Canada for approval of the **alfapump**[®] in North America. A pre-submission meeting with the FDA took place in October 2018 to discuss the design of this study. Sequana Medical incorporated the feedback from this meeting and a further pre-submission meeting with the FDA is scheduled for March 2019.

Subject to FDA feedback, Sequana Medical plans to enrol up to 100 patients with liver refractory or recurrent ascites. These patients will first undergo 3 months of treatment on LVP standard of care. Thereafter, the patients will be “crossed over”, ie implanted and treated with the **alfapump**[®]. This will permit Sequana Medical to observe how the same individual responds to treatment with the **alfapump**[®] versus LVP standard of care.

Subject to FDA feedback, the co-primary outcomes of the study will be i) on a per-patient basis, the post-implant versus pre-implant ratio for average monthly requirements for therapeutic paracentesis, and ii) proportion of subjects with at least 50% reduction in number of therapeutic paracenteses from the 3-month pre-implant observation period to the 3-month post-implant observation period (months 4 – 6 after implant). Patients will be followed for up to 2 years for analysis of secondary outcome measurements including safety (device and/or procedure-related adverse events), patients’ nutritional status, quality of life, health economics and overall survival. For the quality of life analysis, Sequana Medical plans to use both generic (SF-36) and disease-specific (Ascites Q) quality of life questionnaires. In addition, Sequana Medical plans to collect specific healthcare utilisation costs (e.g., costs related to interventional procedures, hospitalisation, concomitant medications and adverse events) to determine the impact of the **alfapump**[®] on the healthcare system. These measurements will provide valuable insights for healthcare policy makers and payers about the value and benefit of the **alfapump**[®] for the patient and support future reimbursement discussions.

Management believes that in the event the FDA requires substantially less than 100 patients, it may be possible to complete the POSEIDON (North American pivotal) Study before mid-2021 which would allow for earlier submission for regulatory approval. However, management believes that a number of U.S. reimbursement groups are likely to require i) clinical trial data from at least 100 **alfapump**[®] patients, and ii) comparison data from LVP standard of care patients (an “**LVP SOC Registry**”), to evaluate the **alfapump**[®] for reimbursement. Therefore, Sequana Medical intends to file for regulatory approval based upon the study size that will be agreed with the FDA, and then if necessary continue to enrol patients to reach the required patient numbers for the reimbursement groups, and in addition to collect the data from the LVP standard of care patient group. Management estimates that the cost of the POSEIDON Study (including the cost of recruiting any additional **alfapump**[®] patients for reimbursement purposes) and the LVP SOC Registry will be around €11 million in total.

In the future, Sequana Medical may also consider submitting an additional clinical study protocol on the **alfapump**[®] for the treatment of malignant ascites which could have the potential to be linked to the POSEIDON (North American pivotal) Study.

4. Fitbit[®] Study

The Fitbit[®] Study is a quality of life study that will be conducted in selected centres participating in the TOPMOST registry to measure the impact of the **alfapump**[®] on patient activity. The study will enrol 20 patients. The industry-accepted measures of quality of life such as SF-36, CLDQ and AscitesQ are not readily understood by patients and their families. Through the use of a well-understood activity monitor, management believes that the impact of the **alfapump**[®] on patient lives can be more clearly appreciated.

Fitbit[®] is not affiliated or associated with Sequana Medical, and Fitbit[®] is not affiliated with, and has not otherwise endorsed, the Fitbit[®] Study.

5. Albumin Replacement Study

Sequana Medical plans to initiate a prospective study in mid 2019 to evaluate the impact of albumin replacement therapy in patients implanted with the **alfapump**[®]. Based on current discussions with potential Investigators, the study is expected to enrol 10-15 patients across sites in Europe and patients will be followed for up to one year.

Through recent publications including the ANSWER study, the role of albumin replacement in improving outcomes for cirrhotic patients is becoming increasingly clear. The routine replacement of albumin in LVP patients is well accepted, but the impact on outcomes in **alfapump**[®] patients has not yet been systematically investigated. Management believes that regular albumin replacement will have a significant impact on AKI and potentially survival.

Initial findings from the Albumin Replacement Study are expected in the first half of 2020. Management estimates that the Albumin Replacement Study will cost around €0.25 million to complete.

(b) Malignant ascites

(i) Completed study

The following table shows the clinical study that has been completed in patients with malignant ascites:

Name of Study	Description	Number of Patients
Retrospective Malignant Ascites Study	Retrospective open-label study in Europe to assess the performance and safety of the alfapump [®] for the treatment of malignant ascites (completed in 2017).	17

1. Retrospective Malignant Study

Study design

In July 2017, Sequana Medical conducted a 6-month, retrospective, multi-centre study in 17 patients with malignant ascites that had been implanted with the **alfapump**[®] in centres across Switzerland, Germany, and the U.K. The patients represented 13 different tumour types. Patients were implanted with the **alfapump**[®] in the period from January 2013 to November 2016.

The primary objective was to evaluate the effectiveness of the **alfapump**[®] in reducing the need for LVP as measured by time to first LVP up to 6 months after implantation. Secondary objectives included evaluation of the safety and tolerability of the **alfapump**[®] and frequency and duration of hospitalisation of patients implanted with the **alfapump**[®].

Medical safety endpoints included infection rate, renal function deterioration including development of AKI, and procedure-related problems. Technical safety endpoints included technical failures of the **alfapump**[®] and required re-interventions or removal of the **alfapump**[®].

Key findings

The Retrospective Malignant Study demonstrated that the **alfapump**[®] was effective in palliative patients with malignant ascites and improving their quality of life.

The median daily volume of ascites removed with the **alfapump**[®] was 304 millilitres and the median total ascitic volume drained with the **alfapump**[®] was 28 litres.

In a physician-reported quality of life questionnaire, 71% of patients experienced an improvement post-implantation of at least one of the following quality of life parameters: tiredness, pain and bloating, sleeping, appetite and nutritional status.

The median patient survival was 111 days (range 10 to 715).

Management believes these findings demonstrated the potential of the **alfapump**[®] to improve clinical outcomes for late-stage cancer patients through enabling enhanced anti-cancer treatment.

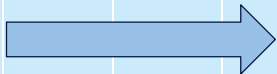
Data was presented at two conferences in September 2018 (International Gynecologic Cancer Society congress in Kyoto and Pelvic Surgeons Annual Meeting in Romania), and will be submitted for a publication in a peer-reviewed journal.

(ii) Planned study

1. Malignant Ascites CT

The following table shows the clinical study that Sequana Medical plans to conduct in the near future in patients with malignant ascites:

Name of Study	Description ⁽¹⁾	2018	2019	2020	2021
Malignant Ascites CT	Controlled study in Europe to evaluate the efficacy and clinical impact of the alfapump [®] vs. standard of care in 25-30 malignant ascites patients.				



Notes:

(1) The descriptions and timing of this study presented in this table and the paragraph below reflects Sequana Medical's current expectations. These expectations are based on circumstances that may or may not occur in the future and remain subject to change and/or feedback from applicable regulatory authorities.

Following positive results in the Retrospective Malignant Study, Sequana Medical expects to begin a prospective, controlled study in selected European countries in the first half of 2019 to confirm the efficacy and clinical impact of the **alfapump**[®] in patients with malignant ascites in a controlled manner. Based on discussions with potential Investigators, the study is expected to enrol 25-30 patients with gynaecologic malignancies (ovarian, breast). Management estimates that the Malignant Ascites CT will cost around €1 million to complete.

(c) Heart failure

(i) Completed studies

The following animal studies have been completed for the management of volume overload in heart failure using DSR therapy:

Name of Study	Description	Number of Animals
Healthy pig DSR proof of concept study	Single dose, single arm proof of concept study to assess impact of direct sodium removal therapy in healthy pigs.	15
Heart failure pig DSR proof of concept study	Single dose, single arm proof of concept study to assess impact of direct sodium removal therapy in pigs with experimentally induced heart failure via tamponade.	5

1. Healthy pig DSR proof of concept study

Study design

This study was a prospective, uncontrolled proof of concept animal study to evaluate the impact of DSR therapy in healthy pigs. In total 15 pigs were included in the study, of which 5 “protocol refinement” pigs were used to investigate the dynamics of the DSR therapy, in order to optimise the protocol used for the 10 “protocol” pigs. Each of the protocol pigs weighed approximately 80 kilograms.

The objective of the study was to investigate the impact of administering a “sodium-free” infusate to the abdominal cavity, including subsequent removal of sodium and fluid, as well as the impact on serum sodium levels.

In both the “protocol refinement” and “protocol” groups, 1 litre of “sodium-free” infusate was administered as a single dose to the peritoneal cavity of the pigs. The infusate was D10, 10% glucose in water. In the protocol refinement group, the infusate dwelled in the peritoneal cavity for 6 hours before removal. The evolution of fluid removed from the peritoneal cavity is shown in Figure 19 below.

Figure 19
Protocol refinement pigs: fluid removal from the peritoneal cavity over time

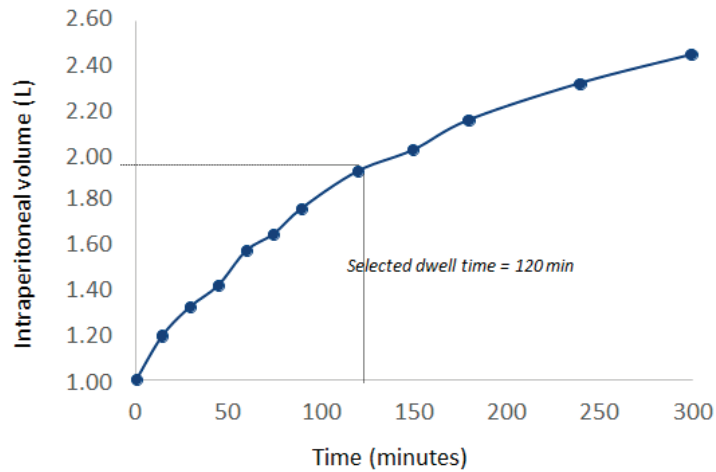
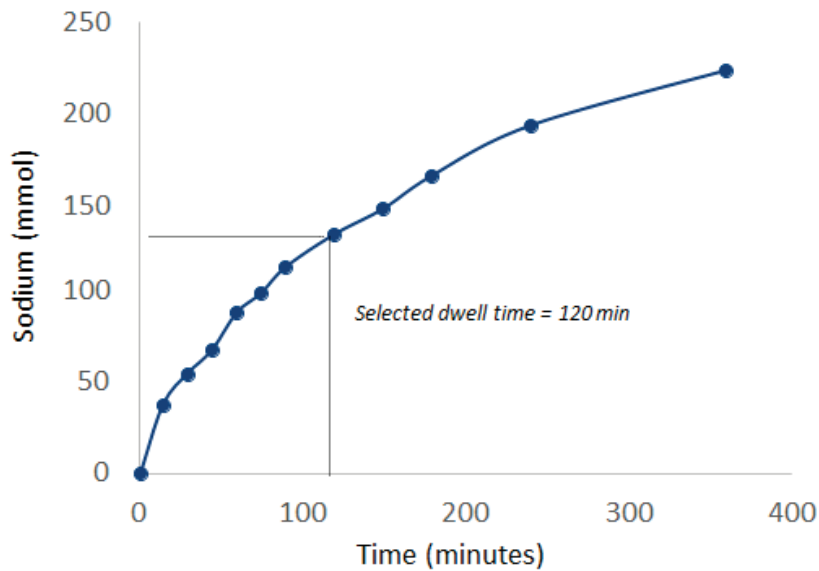


Figure 20 below shows the effective absolute sodium removal in the protocol refinement pigs over the course of the 6-hour dwell time.

Figure 20
Protocol refinement pigs: absolute sodium removal over time



As a result of the findings from the protocol refinement group, the infusate in protocol pigs dwelled in the peritoneal cavity for 2 hours before removal as it was determined that 2 hours was the optimum dwell time. In both groups, the amount of fluid and sodium accumulating in the peritoneal cavity was analysed, together with the impact on serum sodium concentration.

Key findings

In the protocol pigs, the study demonstrated that with the administration of 1 litre of the “sodium-free” infusate and a 2-hour dwell period, approximately 2 litres of fluid on average was removed from the peritoneal cavity (i.e., a net of 1 litre was removed) as shown in Figure 21

below. This 2 litres of fluid was determined to contain approximately 4,000 milligrams of sodium on average as shown in Figure 22 below. This amount of sodium is considered to be clinically relevant as it represents two days recommended daily intake of sodium for adults in the U.S. Management believes that this demonstrates the efficacy of the DSR method for sodium removal.

Figure 21
Protocol pigs: volume removed after 2 hour dwell

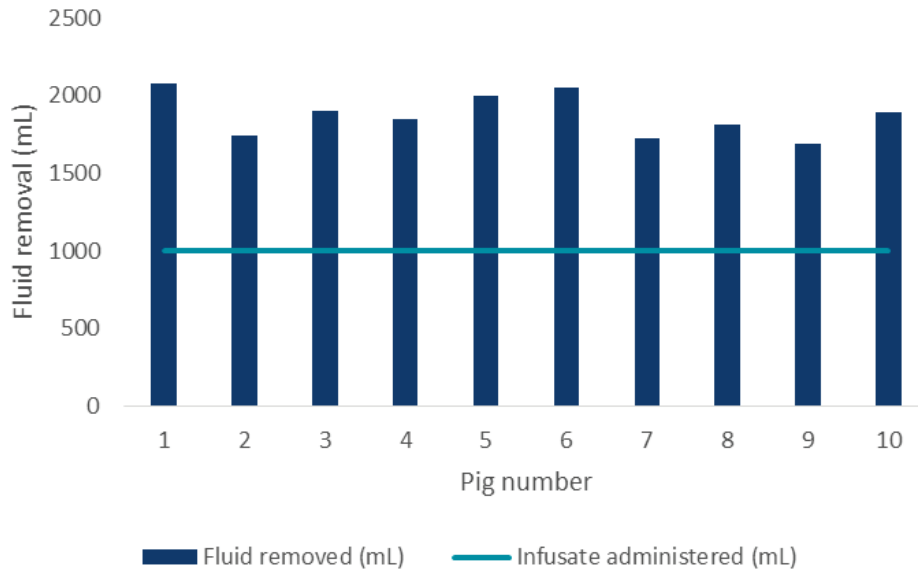
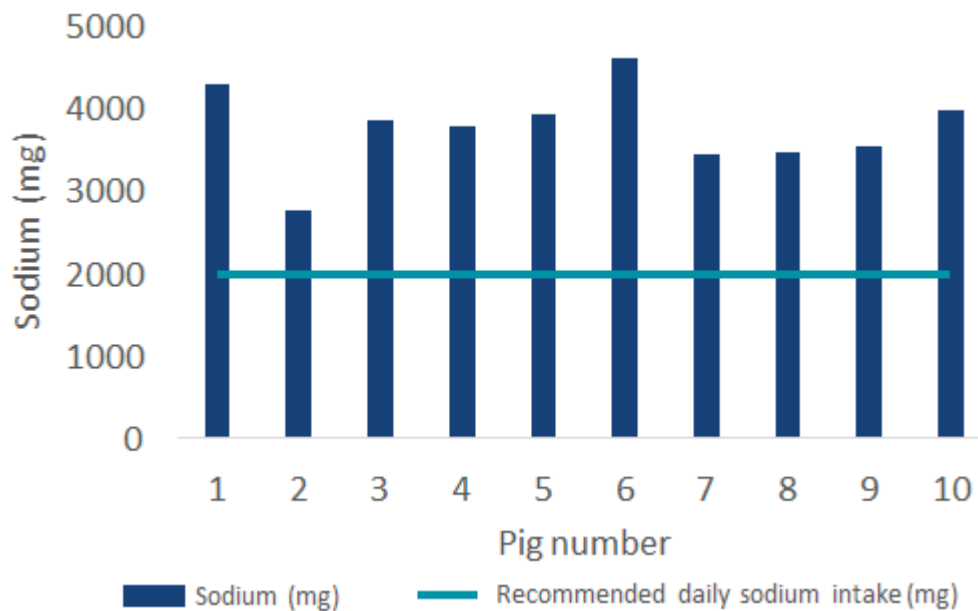
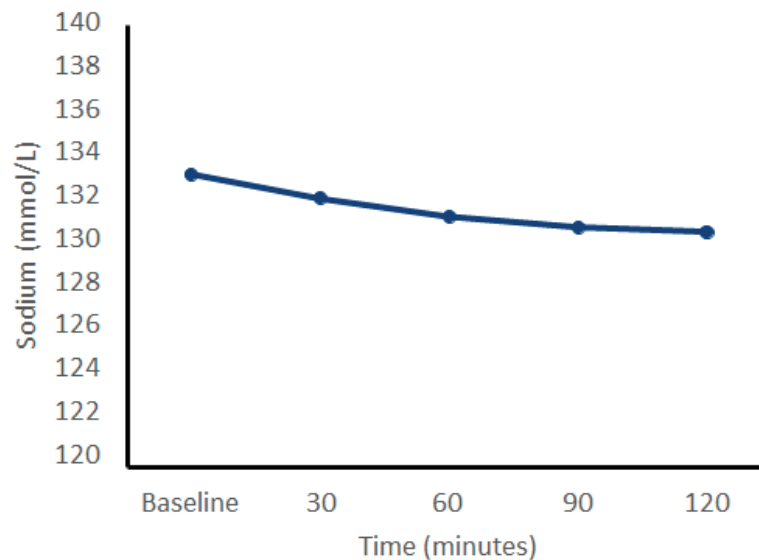


Figure 22
Protocol pigs: sodium removal after 2 hour dwell



The serum sodium levels for the protocol pigs were analysed and Figure 23 below shows that there was a negligible impact on the concentration of sodium in the bloodstream of the protocol pigs. Management believes that this demonstrates that DSR can remove meaningful amounts of sodium without significantly impacting the serum sodium concentration, a key safety parameter.

Figure 23
Protocol pigs: serum sodium concentrations over 2-hour dwell



The uptake of glucose resulting from the use of D10 was in line with the experience of peritoneal dialysis in diabetic patients. Management does not expect this to significantly impact use in the diabetic population as the uptake can be addressed clinically, as well as through the development of specific infusates.

2. “Heart failure” pig DSR proof of concept study

Study Design

This study was a prospective, uncontrolled proof of concept animal study to evaluate the impact of DSR therapy in pigs with experimentally induced heart failure. In this study, heart failure was simulated through the induction of tamponade, the accumulation of fluid in the pericardial sac around the heart. The pressure within the pericardium prevents the heart from expanding fully and as a result a significantly reduced amount of blood circulates within the body. Four litres of fluids were administered to the pigs during the preparation phase, and during the procedure additional fluids were given to maintain the right atrial pressure of greater than 20 mmHg. The study included 5 pigs.

The objective of the study was to investigate the impact of administering a “sodium-free” infusate to the abdominal cavity, including subsequent removal of sodium and fluid, as well as the impact on serum sodium levels.

As with the healthy “protocol pigs”, the infusate was D10, 10% glucose in water and the infusate dwelled in the peritoneal cavity for 2 hours before removal.

In both groups, the amount of fluid and sodium accumulating in the peritoneal cavity was analysed, together with the impact on serum sodium concentration.

Key Findings

The study demonstrated that with the administration of 1 litre of the “sodium-free” infusate and a 2-hour dwell period, approximately 5 litres of fluid on average was removed from the peritoneal cavity (i.e., a net of 4 litres was removed) as shown in Figure 24 below. This 5 litres of fluid was determined to contain approximately 14 grams of sodium as shown in Figure 25 below.

Figure 24
Volume of ultrafiltration
after 2 hour dwell

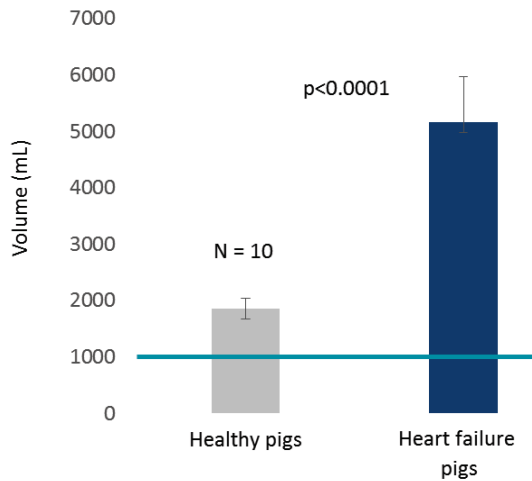
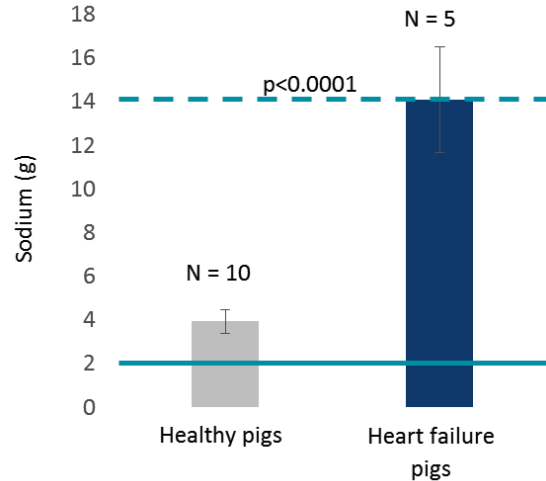





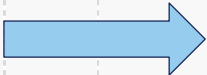
Figure 25
Absolute sodium removal
after 2 hour dwell



This amount of sodium is considered to be clinically relevant as it represents 7 days recommended daily intake of sodium for adults in the U.S. Management believes that this demonstrates that DSR therapy is potentially even more effective in patients with volume overload due to heart failure. The serum sodium levels for the protocol pigs were analysed regularly during the 2-hour dwell period and there was a negligible impact on the concentration of sodium in the bloodstream of the pigs.

(ii) Ongoing/Planned studies

The following table provides a summary of clinical studies that are ongoing or that Sequana Medical plans to conduct for the management of volume overload in heart failure:

Name of Study	Description ⁽¹⁾	2018	2019	2020	2021	2022	2023
Single Dose DSR Proof of Concept⁽²⁾	First-in-human clinical study in approximately 20 patients to demonstrate the safety, tolerability and dynamics of a single dose of DSR therapy (no alfapump [®]). ⁽³⁾						
Repeated Dose DSR Proof of Concept⁽²⁾	Study in approximately 5-10 patients with volume overload in heart failure to demonstrate the safety, tolerability and efficacy (sodium and fluid removal) of the alfapump [®] DSR in connection with multiple dose DSR therapy over a 90-day period. ⁽⁴⁾						
Multi-national Feasibility Study	Multi-national 3-month feasibility study to assess the safety and efficacy of the alfapump [®] DSR in patients with volume overload in heart failure.						
Multi-national Pivotal Study	Multi-national pivotal study in patients with volume overload in heart failure to demonstrate the efficacy and cost-effectiveness of the alfapump [®] DSR vs. standard of care (LVP).						

Notes:

- (1) The descriptions and timing of these studies reflect Sequana Medical's current expectations. These expectations are based on circumstances that may or may not occur in the future and remain subject to change and/or feedback from applicable regulatory authorities.
- (2) Management estimates that the Single Dose DSR Proof of Concept and the Repeated Dose Proof of Concept will cost around a total of €1 million to complete.
- (3) The Single Dose DSR Proof of Concept is being conducted in the U.S. at Yale University. Presentation of initial results anticipated in the first half of 2019.
- (4) The Repeated Dose DSR Proof of Concept is expected to be conducted at clinical centres in Europe. Presentation of initial results anticipated in the second half of 2019, with presentation of full results anticipated in the first half of 2020.

8.7 Commercial operations

(a) Customers

Sequana Medical's products are primarily targeted at the specialist clinician treating the patient. In the case of the **alfapump**[®] for liver refractory or recurrent ascites it is usually the hepatologist, and for malignant ascites it is the oncologist. The heart failure specialist and/or cardiologist would be the appropriate clinician for the **alfapump**[®] DSR. This focus on specialist clinicians enables the use of a focused commercial organisation targeting a limited number of hospitals.

For any company commercialising a novel treatment approach, it is essential that medical practitioners are supportive of the approach, the product and the clinical use. Sequana Medical has established strong relationships with KOLs in Europe and North America. Sequana Medical actively uses its network of KOLs to support the development of the **alfapump**[®] and the **alfapump**[®] DSR.

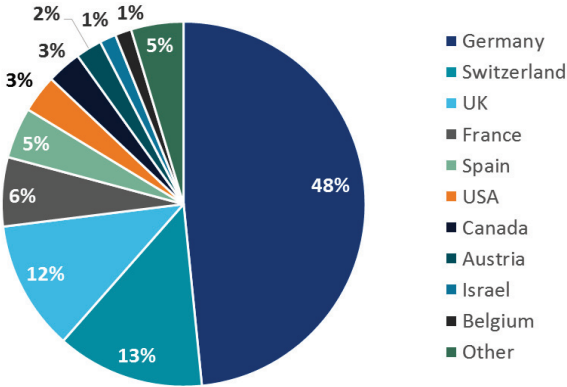
(b) Sales and marketing

Sequana Medical currently has established a commercial team of 11 to focus on the successful penetration of its focus European markets of Germany and Switzerland, to support expansion into the U.K. (following the updated guidance by NICE from “research only” to “special arrangements for clinical governance, consent, and audit or research”) and France (subject to successful completion of the ARIA Pump Study), and to support its distributors Fresenius, Vingmed and Gamida in Belgium and the Netherlands, Denmark and Israel, respectively. The European liver disease market is concentrated across 174 European liver transplant specialist centres,⁹³ and Sequana Medical’s focus on specialist centres allows coverage of the market with a lean commercial organisation. In addition, the commercial team also covers selected large secondary hospitals/referral centres and community hepatologists/gastroenterologists through “awareness events” and direct calling activities. These leverage the contacts with the specialist centres to expand the network of potential patients. Sequana Medical plans to increase its commercial organisation over time to increase the contact with such centres and hepatologists/gastroenterologists as the **alfapump**[®] becomes more established and penetration of the specialist centres increases.

Sequana Medical continuously evaluates the opportunity to enter other markets based on commercial potential and the opportunity for reimbursement. Sequana Medical also intends to establish direct commercial activities in the U.S., Canada, Spain and Italy, and will either establish a direct commercial presence or work with distributors in other markets. By concentrating on the 140⁹⁴ liver transplant centres in the United States, management believes that it can effectively commercialise the **alfapump**[®] with a lean commercial organisation.

Over 650 **alfapump**[®] systems have been implanted at the date of this Prospectus, of which 79% were commercial implants and 21% were implants in connection with a clinical study. Figure 26 below provides a percentage breakdown for the countries in which the **alfapump**[®] systems were sold or used in clinical studies.

Figure 26
alfapump[®] placement by country



In addition, Figures 27 and 28 below provide percentage breakdowns for the countries in which the **alfapump**[®] systems were sold or used in clinical studies, respectively.

Figure 27
Clinical use of alfapump[®] by country

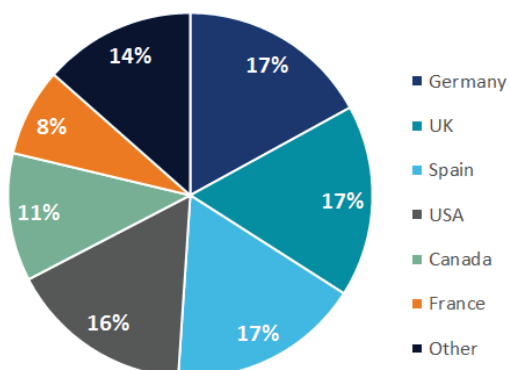
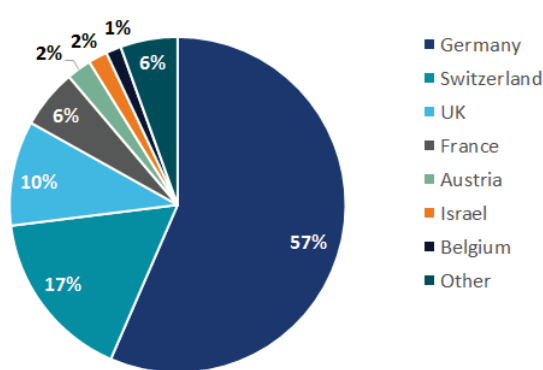


Figure 28
Commercial sale of alfapump[®] by country



In addition, Sequana Medical actively invests in promotional activities using both conventional and social media, such as Facebook and YouTube, and shares testimonials provided by patients and clinicians in order to raise awareness of the **alfapump**[®] therapy amongst clinicians, patients and their relatives. Sequana Medical also raises awareness amongst clinicians through participation in specialist conferences and supporting clinical studies. It has two websites (www.sequanamedical.com) and (www.alfapump.com), which provide information to patients, their families and clinicians on the **alfapump**[®]. Sequana Medical's YouTube videos on the **alfapump**[®] have received more than 300,000 views.

Sequana Medical's sales representatives implement consumer marketing programmes and provide physicians and nurses with educational patient materials. Sequana Medical's print campaign has reached more than 12 million people. Sequana Medical also markets to potential referral source clinicians in order to build awareness.

As with the **alfapump**[®], the focus markets of the **alfapump**[®] DSR will be Switzerland, Germany, France, the U.K., the U.S. and Canada. If the **alfapump**[®] DSR receives marketing authorisation in the U.S., management also intends to implement a targeted and specialised salesforce to focus on cardiologists and other heart failure specialists, with an initial focus on key cardiology centres that specialise in the treatment of heart failure.

(c) Reimbursement

Once a medical device is approved for sale, arrangements must be made for payment. The term "payer" refers to the organisation which eventually provides the payment for a medical therapy.

In most countries, a series of codes is used to classify diagnoses and clinical procedures. These are usually combined to describe an episode of care which forms the basis of the payment to the healthcare provider. Most of these systems aim to have a single code and associated tariff to cover the total care package including any implants used. The reimbursement amounts associated with each of the codes typically will be adjusted periodically based on actual procedure resource utilisation and product cost data.

(i) Reimbursement for the alfapump[®]

1. Europe

In Switzerland, the payer is a social insurance company and medical devices are reimbursed according to Swiss DRG codes. Sequana Medical has reimbursement for the **alfapump**[®] through a Swiss DRG code for a reimbursement of approximately CHF 30,000, which covers both the pump and the implantation procedure.

In Germany, the payer is a social insurance company and medical devices are reimbursed according to G-DRG codes. The receipt of a G-DRG code requires the submission of data collected through usage of the device. To encourage entry of new medical devices into the German healthcare system, there is a short-term, intermediate reimbursement mechanism known

as the NUB application that provides hospitals with financial incentives to use a new medical device before it is properly reimbursed under the G-DRG system. Hospitals using the new medical device must submit an application for reimbursement, which (if approved) is available only to those hospitals that applied. NUB reimbursement must be renewed each year. There has been NUB reimbursement for the **alfapump**[®] in Germany since 2012, and Sequana Medical is actively pursuing a G-DRG code for the **alfapump**[®]. Management estimates that the **alfapump**[®] will acquire a G-DRG code in the first half of 2020. At the date of this Prospectus, the German NUB mechanism provides reimbursement of €27,000, which covers both the pump and the implantation procedure. Management estimates that there are approximately 5,100 refractory ascites patients in Germany based on historical rates of liver cirrhosis in Germany⁹⁵ and the observed rates at which patients with cirrhosis develop ascites⁹⁶ and refractory ascites.⁹⁷

In France, the payer is a social insurance company and prices for reimbursable implants are negotiated with the government. The ARIA Pump Study, a health-economics study, is underway in France. Successful completion of this study is required for the receipt of French reimbursement. Sequana Medical intends to commercially launch in France assuming the successful completion of the ARIA Pump Study. On the assumption that the ARIA Pump Study results in satisfactory French reimbursement, Sequana Medical estimates that the **alfapump**[®] will receive a DRG code in France in 2022.

In the U.K., the payer is a state provided system whereby the NHS provides healthcare for the population, mostly free of charge at the point of use. There is also a parallel private health insurance system that citizens can choose to pay for access to products and services not available from the state provided system. In the U.K., the **alfapump**[®] is reviewed by NICE as part of its Interventional Procedures Programme. An independent advisory committee, composed of health professionals and people familiar with the matters affecting patients and carers, drafts the interventional procedure guidance including recommendations for use. Recommendations are based on the efficacy and safety of the procedure and consist of 4 levels: 1) do not use; 2) use only in research; 3) use with special arrangements for clinical governance, consent and audit and 4) use with standard arrangements for clinical governance, consent and audit. NICE recommendations are intended to encourage physicians in the NHS to consider newer procedures that they may not have otherwise used, and to protect patients by advising on the risks and benefits of their use. There is no legal requirement for the NHS to comply with NICE's recommendations. In February 2014, NICE issued guidance on the use of the **alfapump**[®] for the treatment of refractory and recurrent ascites, recommending that the **alfapump**[®] should be used only in the context of research in the U.K. given the limited amount of evidence on the safety and efficacy of the **alfapump**[®] at the time of the guidance. In March 2018, NICE initiated a further consultation on the safety and efficacy of the **alfapump**[®], and issued a final recommendation in November 2018 that the **alfapump**[®] be used for the treatment of refractory ascites only with special arrangements for clinical governance, consent, and audit or research. The new guidance recommends patient selection for the **alfapump**[®] to be done in specialist centres, by clinicians experienced in managing liver disease and in the various options available for managing ascites. Sequana Medical is expanding into the U.K. market following the updated guidance by NICE. Although there is no formal reimbursement for the **alfapump**[®] in the U.K., management believes that the "special arrangements" recommendation will enable constructive reimbursement discussions with the NHS-payer groups. Management estimates that there are approximately 2,800 refractory ascites patients in the U.K. based on historical rates of liver cirrhosis in the U.K.⁹⁸ and the observed rates at which patients with cirrhosis develop ascites⁹⁹ and refractory ascites.¹⁰⁰

In those markets where the **alfapump**[®] is not reimbursed such as the Netherlands, Denmark, Belgium and Israel, Sequana Medical and its distributors seek alternative funding sources including innovation funds, hospital budgets, arrangements with insurance funds, and direct payment by patients. Management estimates that the **alfapump**[®] will receive a DRG code in the Netherlands (where discussions with insurance companies are ongoing) in mid-2019 and Belgium (where management expects to generate a value dossier with market access specialists and KOLs) in the first half of 2020 in cooperation with Fresenius, its distributor in those markets.

Because reimbursement in Italy and Spain is determined at a regional and local (i.e., hospital) level, Sequana Medical expects to conduct a market research study in both countries to further understand the key hospitals, key decision makers, current standard of care and existing pricing environment. Based on the results of this market study, Sequana Medical expects to begin pursuing reimbursement in Spain and Italy in 2019.

Sequana Medical continuously evaluates the opportunity to enter other markets based on commercial potential and the opportunity for reimbursement.

In seeking reimbursements in target markets, management believes that the **alfapump**[®] has a strong health-economics rationale because the elimination of the need for LVP leads to substantial costs reductions for hospitals and payers. The typical patient requires 2-3 LVPs per month.¹⁰¹ Based on the existing NUB reimbursement in Germany of €27,000 and assuming there are no serious adverse events, management estimates that treatment with the **alfapump**[®] will lead to costs savings in (i) less than 4 months for patients that otherwise require 3 LVPs per month and (ii) less than 7 months for patients that otherwise require 2 LVPs per month.

2. North America

In the United States, the **alfapump**[®] and **alfapump**[®] DSR would be purchased primarily by hospitals or other healthcare providers. Customers will then bill various third-party payers for covered services provided to patients. These payers, which include federal healthcare programmes (e.g., Medicare and Medicaid), state healthcare programmes, private health insurance companies, and managed care organisations, then reimburse Sequana Medical's customers based on established payment formulas that take into account part or all of the cost associated with these devices and the related procedures performed. Therefore, favourable reimbursement in the U.S. will largely depend on the Centers for Medicare & Medicaid Services, the agency responsible for administering the Medicare program, issuing a favourable national coverage for treatment using the **alfapump**[®] and **alfapump**[®] DSR and private insurers approving reimbursement for the **alfapump**[®] and **alfapump**[®] DSR.

Furthermore, in the U.S., purchase of medical supplies including medical devices may be done through a Group Purchasing Organisation (a "GPO") which negotiates on behalf of a group of customers with vendors to obtain best possible prices. Sequana Medical intends to engage with GPOs at the appropriate time to negotiate prices and payment for its products.

In Canada, decisions to reimburse medical devices are de-centralised. The reimbursement decisions for market-approved products are largely made at the level of the hospitals, which typically receive general funding for providing services. In the majority of provinces, budgets are allocated to hospitals through a geographic or operational health region or authority, and are bound by provincial legislation. In this scheme, hospitals are separate legal not-for-profit entities that administer services through their centres and associated facilities. Regional or national consensus by physicians through existing professional networks can be a strong influence on decisions regarding whether or not to reimburse technology. Therefore, reimbursement in Canada will largely depend on individual hospitals and physicians making favourable coverage decisions for the **alfapump**[®] and **alfapump**[®] DSR.

Health Technology Assessment ("HTA") of medical devices is becoming increasingly common in the reimbursement procedure in Canada, although the presence of HTA bodies within hospitals and health regions across Canada varies. Typically, an HTA is initiated when a specialist physician requests a new technology. Information requirements vary by hospital and/or region, but typically consider: 1) local need; 2) evidence of positive clinical benefit and provider consensus regarding the procedure, 3) supplier information; 4) feasibility of implementation; and 5) budget impact (price and utilisation). There are currently only a limited number of HTAs conducted relative to the number of new medical devices entering the market. For hospitals and regions without HTA bodies, decisions to fund a new medical device are made by hospital administrators without a formal HTA process to support decision-making.

(ii) Reimbursement for existing treatments for refractory ascites

For paracentesis, the average reimbursed hospital costs are estimated at around €850 per procedure in the U.K., €600 in France, €2,275 in Germany (where an in-patient hospital stay is required), and €3,700 in Switzerland (out-patient procedure).¹⁰² In the U.S., the average cost for paracentesis is estimated to be around \$1,000 per procedure.¹⁰² However, many patients that undergo paracentesis require emergency medical treatment for complications that result in significant emergency room costs (in the U.S. it is estimated that up to \$5,000 may be spent on the complications stemming from a single episode).¹⁰² While the overall costs related to patients undergoing LVP is difficult to verify in light of the need for emergency care and other treatments, many physicians have communicated their belief that the treatment of LVP patients is on average a loss-generating activity. Therefore, management believes that reimbursement arrangements for

paracentesis are not likely to present a major barrier to entry given that the reimbursement income received for performing the paracentesis versus the costs and resources used to perform the procedure is not believed to be significant.

In Europe, the average reimbursed cost for TIPS treatment is estimated to be €8,000 across France, the U.K. and Germany, and up to €12,000 in Switzerland.¹⁰² In the U.S., the average TIPS procedure is estimated to cost \$23,000.¹⁰² Management estimates that interventional radiologists, the specialist physicians that perform TIPS and **alfapump**[®] implantations, would receive similar revenues for their services under both procedures, but the **alfapump**[®] would provide interventional radiologists with the opportunity to treat a broader patient group given the risk of hepatic encephalopathy for patients that are over 65 years old and treated with TIPS.

8.8 Engineering

Throughout the development of the **alfapump**[®], Sequana Medical has built and accumulated extensive expertise in the hardware, software and production aspects of the system, as well as requirements engineering, test methods and creating/maintaining technical documentation to fulfil regulatory requirements. Sequana Medical continues to use this experience to improve the clinical performance and capabilities of the **alfapump**[®].

(a) Improve **alfapump**[®] performance

The **alfapump**[®] has clearly demonstrated its unique capabilities, including the ability to pump significant quantities of biological matter over extended periods of time with wireless-charging and adjustment.

Sequana Medical is working to further extend the life of the **alfapump**[®] through improving the production process and minor design adaptations. This will become more important in ascites patients at an earlier stage of their disease (e.g. recurrent ascites) and for **alfapump**[®] DSR.

(b) Enhance DirectLink capabilities

The **alfapump**[®] DirectLink technology enables the monitoring of pump performance parameters. This regular reporting to clinicians is an important aspect of the **alfapump**[®] system's benefits. Sequana Medical is working to further enhance the monitoring capabilities of the **alfapump**[®] to deliver greater clinical benefits.

Through integrating additional monitoring parameters, such as temperature, blood pressure, and weight, clinicians can more closely monitor their patients, optimise care, and potentially identify adverse events earlier. The **alfapump**[®] can incorporate sensors either outside the body (e.g. weighing scales or blood pressure monitor), or inside the body (eg. **alfapump**[®] pressure sensors or biosensors) by leveraging the wireless charging and communication capabilities of the **alfapump**[®].

(c) Reduce production cost

The current cost of goods sold for each **alfapump**[®] system is €3,700, with the cost of goods sold in prior years being largely similar. Sequana Medical is seeking ways to reduce the production cost of the **alfapump**[®] by optimising the design for manufacturing and through the realisation of purchasing efficiencies as production volumes increase.

In the future, Sequana Medical may also explore modifications to the design of the **alfapump**[®] that would allow Sequana Medical to produce variations of the **alfapump**[®] with more limited functionality at a lower price point suitable for cost-sensitive markets with a significant demand for liver disease and heart failure treatments, such as parts of Asia and Latin America.

8.9 Manufacturing

Sequana Medical has produced more than 1,000 **alfapump**[®] systems at the date of this Prospectus, and has developed significant experience in the sub-component supply chain as well as production capacity that can accommodate expected growth in sales.

Sequana Medical assembles and tests the **alfapump**[®] and **alfapump**[®] DSR and manufactures certain components at its facilities in Switzerland. The large majority of sub-components including the batteries, printed circuit board, motor, charger, docking station, catheter and surgical accessories are sourced externally, from a total of approximately 70 suppliers. In Sequana Medical's opinion, the suppliers of the critical components of the **alfapump**[®] are experienced and well-respected manufacturers with multiple customers and have existing quality control programmes

and registrations with the appropriate regulatory authorities. Sequana Medical verifies key vendors' quality systems with periodic audits.

Sequana Medical's manufacturing and production organisation is scalable and readily adaptable to rising order volumes, and management believes that its current suppliers will have sufficient capacity to meet the scale-up required for the further commercial roll-out of the **alfapump**[®] based on the size and reputations of the suppliers. Sequana Medical has the potential to add additional capacity by hiring additional manufacturing personnel to run extra shifts and adding an additional manufacturing suite. Sequana Medical has a current manufacturing capacity of 200 units and management believes that Sequana Medical has sufficient capacity to meet volume projections of up to 2,000 units with limited investment. Sequana Medical has undertaken an evaluation of the feasibility of outsourcing its manufacturing in the future and has determined that it has the ability to outsource manufacturing if sufficient demand volumes are achieved.

8.10 Intellectual property

Patents, trademarks, and other intellectual property rights are important in the medical device industry in which Sequana Medical operates. Sequana Medical has implemented an intellectual property protection policy with the objective of obtaining protection for key aspects of the technology embodied in the **alfapump**[®], the **alfapump**[®] DSR and certain methods of use. Sequana Medical's portfolio of patents, patent applications, and other intellectual property related matters are managed by its US and European patent counsel. Sequana Medical may, from time to time, file patent applications for inventions that may be of importance to its future business.

Sequana Medical may license or acquire rights to patents, patent applications, or other intellectual property owned by third parties, academic partners or commercial companies which are of interest to Sequana Medical. Further, Sequana Medical may decide, from time to time, to license its intellectual property to other parties, for example, in exchange for cash, marketing collaboration, or other valuable consideration to Sequana Medical. As of the date of this Prospectus, Sequana Medical has not in-licensed or out-licensed any of the patents or applications for inventions embodied in its intellectual property.

In addition to patents, Sequana Medical also relies on a combination of trade secrets, design rights, copyright laws, non-disclosure agreements and other contractual provisions and technical measures that help it maintain and develop its competitive position with respect to intellectual property. Sequana Medical may pursue legal action to protect or defend its intellectual property rights including patent rights, trade secrets, or know-how from infringement by others. Any such legal action could be costly and time consuming for Sequana Medical, and Sequana Medical cannot be certain of the outcome. Invalidation of key patents or proprietary rights of Sequana Medical or an unsuccessful outcome in such a lawsuit could have a material adverse effect on Sequana Medical's financial condition and results of operations and/or impair Sequana Medical's ability to prevent copying by competitors of inventions embodied in the **alfapump**[®] system.

Sequana Medical's policy is that employees and contractors of Sequana Medical execute a propriety information and inventions assignment agreement, which protects proprietary information and assigns to Sequana Medical all inventions created by an employee during the term of employment. Where possible and appropriate, agreements with third parties (e.g., consultants and vendors) contain language designed to protect Sequana Medical's intellectual property and confidential information, and to provide for assignment to Sequana Medical of new inventions related to Sequana Medical's business. There can be no assurance, however, that such agreements have been executed in all circumstances or that such agreements will not be breached or will provide meaningful protection for Sequana Medical's trade secrets and proprietary information or that adequate remedies will be available in the event of an unauthorised use or disclosure of such information.

(a) Patents

Sequana Medical's patent portfolio consists of 14 patent families, of which 73 patents have been granted and 16 patent applications are pending at the date of this Prospectus. The table below provides an overview of Sequana Medical's patents and patent applications.

Patent Family No.	Name	Summary Description⁽⁵⁾	Key Jurisdictions⁽⁴⁾	Key Expiry Dates⁽¹⁾
1	Vesicular shunt for the drainage of excess fluid	Vesicular shunt including a hollow cylinder configured to be anchored to the bladder, a pump, a flexible tube between the cylinder and the pump, and an electric valve. The valve opens responsive to an electric signal to permit fluid to flow therethrough	U.S. U.K. Canada Germany Switzerland France Belgium	2023 – 2024
2	Dialysis implant and methods of use	Peritoneal dialysis system including an implantable pump, reservoir, and conduits. The pump pumps fluid from the reservoir to the peritoneal cavity and then pumps the fluid from the peritoneal cavity to the bladder through the conduits	U.S. U.K. Canada Germany Switzerland France	2025 – 2030
3	Implantable fluid management system for the removal of excess fluid	Implantable fluid management system for treating ascites, pleural effusion, or pericardial effusion. The system includes an implantable pump, a conduit between the pump and a first cavity (e.g., peritoneal cavity, pleural cavity, pericardial cavity), and another conduit between the pump and a second cavity (e.g., bladder, gastro-intestinal tract). The pump pumps fluid from the first cavity to the second cavity. The pump employs inductive coupling circuitry for receipt of power and communications transdermally from an external controller	U.S.	2023 – 2024
4	Implantable fluid management device for the removal of excess fluid	Implantable fluid management system for treating ascites, pleural effusion, or pericardial effusion. The system includes an implantable pump, a conduit between the pump and a first cavity (e.g., peritoneal cavity, pleural cavity, pericardial cavity), another conduit between the pump and a second cavity (e.g., bladder, gastro-intestinal tract), and a reservoir	U.S. U.K. Canada Germany	2023 – 2035
5	Apparatus and methods for treating intracorporeal fluid accumulation	Describes the current alfapump design and is directed to a fluid management system for the treatment of ascites, pleural effusion, or pericardial effusion. The system includes an implantable pump, a charging and communication system for periodically charging the battery of the pump and retrieving data from the pump, and software for configuring and controlling operation of the pump and the charging and communication system. The implantable pump includes a number of features that provide automated movement of fluid to the bladder with reduced risk of clogging and with no patient involvement other than occasional recharging of the battery of the pump. The software permits the treating physician to interact with the implantable pump via the charging and communication system	U.S. Canada	2032-2033

Patent Family No.	Name	Summary Description ⁽⁵⁾	Key Jurisdictions ⁽⁴⁾	Key Expiry Dates ⁽¹⁾
6	Method of using fluid management system/ Systems and methods for treating chronic liver failure based on peritoneal dialysis.....	<p>A method of using a fluid management system comprising:</p> <p>introducing a peritoneal dialysis fluid from a reservoir to a patient's peritoneum; pumping, using an implantable device, the peritoneal dialysis fluid in the peritoneum to the patient's bladder via a peritoneal catheter and a bladder catheter; transferring data from the implantable device to a charging and communication system; providing the data from the charging and communication system to monitoring and control software running on a computer separate from the charging and communication system; and communicating operational parameters from the monitoring and control software to the implantable device via the charging and communication system to control the pumping.</p> <p>An artificial liver system for treating liver failure that includes a reservoir to provide albumin-containing dialysis fluid to the patient's peritoneum, an implantable device including a pump to pump the fluid from the peritoneum to the bladder via respective catheters, control circuitry, battery and transceiver; a charging and communication system configured to periodically charge the battery and communicate with the implantable device to retrieve data reflective of the patient's health; and monitoring and control software, suitable for use with conventional personal computers, for configuring and controlling operation of the implantable device and charging and communication system. The monitoring and control software allows a treating physician to remotely adjust the volume, time, and frequency with which fluid is pumped from the peritoneal cavity to the bladder based on the data reflective of the patient's health.</p>	U.S. U.K. Canada Germany France)	2032 – 2035
7, 8, 9	Catheter with staggered slits.....	Catheter having a plurality of septa defining a plurality of lumens along the catheter. The catheter includes a plurality of slits that vary in length to reduce the risk of clogging and permit fluid to flow in the catheter	U.S.	2029-2033
10	Systems and methods for regulating inductive energy transfer to an implantable system	Devices for regulating the inductive transfer of energy between an implantable device and an external charging system. The energy transfer rate is regulated by varying the operating frequency of the inductive energy transfer circuit of the implantable device	U.S. U.K. Canada Germany France	2033 – 2034
11	Implantable fluid management system having clog resistant catheters, and methods of using the same	Mechanisms and methods for minimizing catheter clogging in an implantable fluid management system for treating fluid accumulations, such as ascites, pleural effusion, and pericardial effusion. Clog resistant mechanisms and methods include clog resistant catheters and programmed routines configured to cycle fluid out inflow catheters	U.S. ⁽³⁾	2036 ⁽²⁾

Patent Family No.	Name	Summary Description ⁽⁵⁾	Key Jurisdictions ⁽⁴⁾	Key Expiry Dates ⁽¹⁾
12	Apparatus and methods for non-invasive monitoring of cancerous cells	Implantable pumping system for moving fluid containing cancerous cells from a body cavity (e.g., peritoneal cavity, pleural cavity, pericardial cavity) to the bladder such that the fluid may be excreted during urination, collected, and analysed to assess progress of the cancer or efficacy of a cancer treatment program	U.S.	2033
13	Systems and methods for managing data generated by and implantable device	Directed to the DirectLink system having an implantable medical device and a data analyst device in direct or indirect communication with the implantable device, and configured to analyse data generated by the implantable device	U.S. ⁽³⁾	2037 ⁽²⁾
14	Direct sodium removal method, solution and apparatus to reduce fluid overload in heart failure patients.....	Method of treating patients with heart failure using a no or low sodium dialysate.	U.S. ⁽³⁾	2038 ⁽²⁾

Notes:

- (1) Before any extension due to a patent term extension.
- (2) Patent is currently pending. Indicates expiration in the event patent is granted.
- (3) Patent Cooperation Treaty application pending.
- (4) Additional patents may have issued and/or additional applications may be pending in other jurisdictions
- (5) These descriptions are merely indicative of the features discussed in the patents. The scope of the patents is determined by the issued claims.

The selection of countries in which to pursue such patent applications is based, in part, on Sequana Medical's assessments of the importance of such future markets. Securing a patent typically involves negotiation between Sequana Medical and the governmental authority that issues the patent, e.g., the United States Patent and Trademark Office (the "USPTO") or the European Patent Office. In the course of such negotiation, the examining authority may initially reject the patent application claims, for example, based on its interpretation of prior art, and, from time to time, may issue a "final" ruling rejecting certain patent application claims. Sequana Medical, in conjunction with its patent attorneys in the pertinent jurisdiction, may modify or delete claims, or accept suggested claim amendments offered by the examining authority, to secure issuance of a patent. Alternatively, Sequana Medical may continue to pursue the same or similar patent application claims by way of a continuation application, a request for continued examination, or a divisional application, depending upon the applicable jurisdiction.

In general, patents describe an "apparatus" and/or a "method." European law prohibits the patenting of method of medical treatment claims, and, from time to time, Sequana Medical may seek to obtain method claims in a patent application in the U.S. without pursuing a corresponding patent application in Europe.

The term of a US patent for an application filed on or after June 7, 1995, generally is 20 years from the earliest effective filing date claimed by the patent application, subject to patent term adjustment (additional time added to a patent's lifespan based on delays that occur from the USPTO during the patenting process), patent term extension (additional time added to a patent's lifespan as a result of regulatory delay in marketing approval of a product embodying the patented invention), and payment of applicable maintenance fees. The actual protection afforded by a patent outside the US, which can vary from country to country, depends upon the type of patent, the scope of its coverage, and the availability of legal remedies in the country.

Patent applications may be kept secret until published by the USPTO. In some cases, the number of application claims filed in a patent application may include claims of various scope or directed to different inventions and, after interaction with the relevant patent examining authority, Sequana Medical may elect to file divisional applications, continuation applications, or other types of applications to pursue patents of varied scope.

Sequana Medical can give no assurance that any of Sequana Medical's patent rights, whether issued or pending, will not be circumvented or invalidated by others. Furthermore, there are many existing patents and pending patent applications directed to numerous aspects of medical products. There can be no assurance that Sequana Medical's existing or planned products do not or will not infringe such rights or that others will not claim infringement of their patents. No assurance can be given that Sequana Medical will be able to prevent competitors from challenging Sequana Medical's patents or entering markets Sequana Medical intends to serve with competing products.

As Sequana Medical continues to innovate, new patent applications may be filed from time to time, and it is anticipated that Sequana Medical's intellectual property portfolio will grow. Sequana Medical does not intend to make announcements as new patent applications are filed for commercial and competitive reasons.

In addition to patent protection, the **alfapump**[®] benefits from enhanced protection from the complexity of its design. The device needs to be completely destroyed in order to access many of the components, several of the components are not available on the open market, and the **alfapump**[®] software cannot be retrieved from the device.

(b) Trademarks

Sequana Medical uses its corporate name, Sequana Medical, and associated logo in creating awareness of its expertise and in marketing its **alfapump**[®] system technology. Sequana Medical uses the trademark **alfapump**[®] to identify its **alfapump**[®] platform.

Sequana Medical has obtained registration for the Sequana Medical name and the **alfapump**[®] trademark in Australia, Canada, China, Colombia, the E.U., Hong Kong, Israel, Japan, New Zealand, Norway, Russia, Saudi Arabia, Singapore, South Korea, Switzerland, Turkey, the United Arab Emirates and the U.S., and has obtained registration for the Sequana Medical name in India.

(c) Confidential information and trade secrets

The success of Sequana Medical's business depends, in part, on maintenance of confidential information and trade secrets, generally referred to as proprietary information. Sequana Medical has implemented procedures, where appropriate, to maintain the confidentiality of its proprietary information. Sequana Medical's policy is that employees and contractors enter into confidentiality agreements with Sequana Medical, and, where appropriate, that confidentiality agreements are executed before confidential information is revealed to any third party. Confidentiality provisions are also present in consulting agreements and supplier agreements in certain cases where the consultant or supplier may be exposed to confidential information.

8.11 Quality assurance and regulatory affairs

(a) Regulatory oversight for market access

The marketing and sale of medical devices is subject to regulatory oversight. The regulatory pathway is different in each of Sequana Medical's key target markets, but with elements in common.

In general, regulatory approval of AIMDs requires submission of data generated from clinical studies. Such data may also be used to drive reimbursement and market adoption. Sequana Medical conducts its clinical studies with a combination of in-house resources and one or more external CROs. All human clinical studies are to be conducted according to the international standard covering clinical studies, ISO14155:2011.

Any clinical study which generates data that Sequana Medical intends to submit to the U.S. FDA as part of an application for regulatory approval must meet the U.S. FDA requirements. At the time of application for regulatory approval in any jurisdiction (e.g.: CE Marking for Europe or PMA for U.S.), Sequana Medical reports all relevant clinical experience to the date of the submission as part of the submission. Registration of clinical studies in a public registry such as www.clinicaltrials.gov is mandated for any clinical study involving human subjects for which the clinical results are to be presented or published.

(b) CE Mark for Europe

In Europe (the EEA and Switzerland based on mutual recognition), the **alfapump**[®] is an AIMD and regulatory approval must be received prior to commercialisation through the granting of the appropriate CE certificates, which certify (i) compliance of the design of the product with the

applicable harmonised standards and essential requirements of the AIMD Directive and (ii) the QMS (including that of critical suppliers) is in conformity with the requirements under the AIMD Directive. These CE certificates are issued by a Notified Body and allow the manufacturer to draw up a declaration of conformity (with the AIMD Directive) and to apply the CE Mark (Conformité Européenne) to the medical device. The classification of the **alfapump**[®] DSR is unknown at the date of this Prospectus, but the **alfapump**[®] DSR may also potentially be classified as an AIMD. The CE Mark is granted by a Notified Body with authority designated by a Competent Authority. Sequana Medical has engaged The British Standards Institution (“**BSI**”) as its Notified Body.

The key steps to obtaining a CE-Mark are:

- submission of a clinical evaluation review;
- submission of a technical dossier with extensive details;
- certification of the quality system to the international standard ISO13485; and
- if necessary, agreement to a programme of a post-market clinical follow-up (i.e., proactively collecting and evaluating clinical data related to the use of a CE marked device already on the market), with the purpose of monitoring long term performance of an approved device in a larger population, and to gather data on residual risks.

Sequana Medical has received a CE-Mark on the **alfapump**[®] for single patient use and for a period of up to 2 years in patients with refractory ascites due to liver cirrhosis or malignant ascites with a life expectancy of 6 months or less. The CE Mark must be renewed every five years. The last renewal occurred in 2016.

Sequana Medical will also be required to comply with the new Medical Devices Regulation in Europe. On April 5, 2017, the European Parliament passed the Medical Devices Regulation, which repeals and replaces the AIMD Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the new regulations will be directly applicable (i.e., without the need for adoption of EEA member state laws implementing them) in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA Member States and strengthen the oversight of medical devices in the EEA. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The Medical Devices Regulation will generally become applicable three years after publication (in May 2020) although some specific transition timelines apply. Sequana Medical has been actively working to meet the requirements under the new Medical Devices Regulation since 2017 and management believes that Sequana Medical is on track to meeting the new requirements by the deadlines set forth in the Medical Devices Regulation.

The regulatory authorities in Europe monitor medical devices after they are placed on the market to ensure their continued safety and effectiveness. If a medical device is found to no longer be safe and effective, its CE-Mark can be suspended or the manufacturer may be requested to recall or refurbish the medical device.

In Europe, the **alfapump**[®] and the **alfapump**[®] DSR fall within the scope of radio equipment and are therefore also subject to the radio communication directive (RED 2014/53/EU), which imposes requirements for safety and health, electromagnetic compatibility, and the efficient use of the radio spectrum, and requires an additional compliance certification that BSI is not able to provide. Sequana Medical has appointed Phoenix Testlab (“**Testlab**”) as an additional Notified Body to audit and certify compliance with the radio communication directive requirements. The current CE certificate covering full quality assurance under the RED Directive for the **alfapump**[®] was issued in June 2017 and is valid until June 2022.

(c) Pre-market approval for North America

(i) United States

In the U.S., the FDA regulates medical device design, development, pre-clinical and clinical testing, PMA, registration and listing, manufacturing, labelling, storage, advertising and promotion, sales and distribution, export and import, and post market surveillance pursuant to the Federal Food, Drug and Cosmetic Act (the “**FDCA**”) and its implementing regulations. The **alfapump**[®] is regulated as a Class III medical device.

Unless an exemption applies, in order to be commercially distributed in the U.S. each Class III medical device requires marketing authorisation from the FDA prior to distribution. To obtain FDA approval to market the **alfapump**[®], the FDA requires proof of safety and efficacy in human clinical studies performed under an Investigational Device Exemption (an “**IDE**”). Usually, an IDE application must contain pre-clinical test data, such as animal and laboratory testing results, supporting the safety of the product for human investigational use, information on manufacturing processes and procedures, proposed clinical protocols and other information. If the IDE application is approved, human clinical studies may begin. The studies consist of a feasibility study (to provide proof of principle and initial clinical safety data) and a pivotal study (definitive evidence of the safety and effectiveness of a device for a specified intended use, typically in a statistically justified number of subjects) and must be conducted in compliance with FDA regulations and with the approval of institutional review boards. Clinical studies are subject to central registration requirements. The results obtained from these studies are submitted to the FDA in support of a PMA application.

FDA approval of an IDE allows clinical testing to go forward but does not bind the FDA to accept the results of the study as sufficient to prove the product’s safety and efficacy, even if the study meets its intended success criteria. With certain exceptions, changes made to an investigational plan after an IDE is approved must be submitted in an IDE supplement and approved by FDA (and by governing institutional review boards when appropriate) prior to implementation.

All clinical studies must be conducted in accordance with regulations and requirements collectively known as Good Clinical Practices (“**GCP**”). GCPs include the FDA’s IDE regulations, which describe the conduct of clinical studies with medical devices, including the recordkeeping, reporting and monitoring responsibilities of sponsors and investigators, and labelling of investigational devices. They also prohibit promotion, test marketing or commercialization of an investigational device and any representation that such a device is safe or effective for the purposes being investigated. GCPs also include the FDA’s regulations for institutional review board approval and for protection of human subjects (such as informed consent), as well as disclosure of financial interests by clinical investigators.

The **alfapump**[®] has received Breakthrough Device designation from the FDA for the treatment of liver recurrent or refractory ascites. The FDA’s Breakthrough Devices Program is a voluntary program for certain medical devices that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the Breakthrough Devices Program is to provide patients and healthcare providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for regulatory approval, consistent with the FDA’s mission to protect and promote public health. The Breakthrough Devices Program replaces the Expedited Access Pathway and Priority Review for medical devices. The Breakthrough Devices Program offers manufacturers an opportunity to interact with FDA’s experts through several different programme options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission.

Once regulatory approval has been received, products must be manufactured in registered establishments and in accordance with Quality System Regulations (“**QSR**”). Furthermore, the FDA may at any time after regulatory approval has been received inspect Sequana Medical’s facilities or the facilities of Sequana Medical’s suppliers to determine whether Sequana Medical or its suppliers comply with FDA regulations, including the QSR, which requires manufacturers to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process. The FDA monitors medical devices after they are placed on the market to ensure their continued safety and effectiveness. If a medical device is found to no longer be safe and effective, its marketing approval can be suspended or the manufacturer may be requested to recall or refurbish the medical device.

Sequana Medical and its suppliers are also subject to regulation by various state authorities, which may inspect the facilities and manufacturing processes of Sequana Medical or its suppliers and enforce state regulations. Failure to comply with applicable state regulations may result in seizures, injunctions or other types of enforcement actions.

(ii) Canada

In Canada, medical devices are regulated by Health Canada, the department of the government of Canada with responsibility for national public health, which reviews medical devices to assess their safety, effectiveness, and quality based on clinical data before authorising their sale in Canada according to the Medical Devices Regulation SOR/98-282. Prior to placing the **alfapump**[®] or the **alfapump**[®] DSR on the Canadian market, Sequana Medical must obtain a medical device licence from Health Canada and fulfil the necessary quality requirements set under the MDSAP. Health Canada also monitors medical devices after they are placed on the market to ensure their continued safety and effectiveness. If a medical device is found to no longer be safe and effective, its medical device license can be suspended or the manufacturer may be requested to recall or refurbish the medical device.

(iii) Other countries

In addition to North America and Europe, Sequana Medical is also obliged to comply with regulatory requirements in other target markets that include obtaining regulatory approval pursuant to the applicable laws and regulations before it can place its products on each market. Furthermore, if a medical device receives marketing approval but is found to no longer be safe and effective, its marketing approval can be suspended.

In Israel, European companies importing medical devices must request a PMA from the IMOH, and such request is based on the CE-Mark. The IMOC also imposes certification requirements on medical devices that transmit and/or receive data in order to protect the frequency spectrum and telecommunications networks of Israel. IMOH certifications have a five-year validity period; however, if critical components in a product are modified, the updated product must be resubmitted for approval to the IMOH.

Sequana Medical has received a pre-marketing approval from the IMOH but has not yet received a certification from the IMOC. Instead the IMOC has granted temporary special permission to two hospitals to use a limited number of pumps within Israel. The IMOC may withdraw this special permission at any time, in which case Sequana Medical would not be permitted to market the **alfapump**[®] in Israel without receiving a certification from the IMOC. Furthermore, the IMOC has informed Sequana Medical that in order for the **alfapump**[®] to be certified, Sequana Medical will be required to modify the frequency on which the **alfapump**[®] operates.

(d) Clinical studies

(i) Europe

Although placing medical devices on the market in the EEA is regulated under the AIMD Directive, the rules governing the conduct of clinical studies in the EU are fragmented, and clinical studies are subject to approval on a country by country basis. Sequana Medical is required to obtain approval from the ethics committees in any EEA Member State where it intends to carry out clinical investigations and may need to obtain approval from or notify the competent regulatory authorities depending on the type of study and the relevant EEA Member State.

(ii) North America

In the U.S., clinical studies are regulated by the FDA (see subsection (c) (Pre-market approval for North America), subsection (i) (United States) above). In Canada, in-man medical device research is evaluated through the Device Evaluation Division of the Medical Devices Bureau of Health Canada. An application is submitted and evaluated according to the Investigational Testing Authorization program governing the use of Class II, III, and IV medical devices. Following a favourable Health Canada review of the Application for Investigational Testing a “No Objection Letter” is issued indicating Health Canada’s agreement to conduct the research. Health Canada requires notification of ethics clearance for the study through a Research Ethics Board prior to issuing a No Objection Letter.

(e) Quality management systems

Many of Sequana Medical’s activities are subject to a QMS. Sequana Medical’s QMS is designed to be in compliance with international standards (such as ISO13485) and the QSR. ISO13485 and QSR requirements are similar but not identical.

Although ISO13485 certification is not a direct requirement for CE-Marking medical devices under the AIMD Directive, it is recognised as a harmonised standard by the European Commission and accepted as a basis for CE marking in the E.U. ISO13485:2016 (the latest version of ISO13485) aims to further harmonise the requirements of ISO13485 with the applicable requirements of the AIMD Directive. Manufacturers (including Sequana Medical and its external critical sub-contractors) must be certified according to the requirements of new ISO 13485:2016 by 28 February 2019. Although outside the U.S. compliance with ISO13485 is well-established to show the establishment of a QMS, in the U.S. compliance with the FDA QSR is required.

Currently, medical devices sold in Canada must have their quality management system assessed under the CMDCAS system. This option will not be available from January 2019 onwards. From 1 January 2019 any manufacturer commercialising medical devices into Canada must be part of the MDSAP. Sequana must be compliant to the MDSAP in order to gain access to the Canadian market.

Sequana Medical's QMS is implemented on a computer-based document management platform. Sequana Medical believes that it has put in place back-up systems necessary to protect its integrity and security. Sequana Medical conducts periodic internal audits of its QMS and that of its subcontractors, and uses external auditors from time-to-time.

The QMS is subject to audit and enforcement by regulatory authorities such as the U.S. FDA and a Notified Body that certifies fulfilment of ISO13485. Compliance with ISO13485 is assessed by a Notified Body and Sequana Medical has engaged BSI as its Notified Body to audit the compliance of Sequana Medical and its subcontractors with ISO13485 and provide certification. Furthermore, the **alfapump**[®] and **alfapump**[®] DSR are subject to the E.U. radio communication directive (RED 2014/53/EU). Sequana Medical has appointed Testlab as an additional Notified Body to audit and certify compliance with the radio communication requirements. Sequana Medical's QMS will also be audited by the U.S. FDA for the compliance with the QSRs prior to and/or after any granting of a PMA to allow sales of the **alfapump**[®] or **alfapump**[®] DSR in the U.S.

Sequana Medical maintains a post-market surveillance system, which is designed to be in compliance with QSR and ISO13485. The purpose of the post-market surveillance system is to receive, record and respond to feedback from the field including reports of suspected device failure, recommendations for device modifications or design changes, and reports of inadequate labelling or other documentation (collectively called "**Customer Complaints**"). All Customer Complaints are logged, and trends are tracked. A Customer Complaint may result in a corrective and preventive action (a "**CAPA**"). At least annually, Sequana Medical conducts a management review of its QMS during which the history of Customer Complaints is analysed and appropriate actions (if any) are initiated.

Customer Complaints logged into the Sequana Medical's post-market surveillance system may result in a report to a regulatory authority. The E.U. employs a vigilance reporting system as described in MEDDEV 2.12-1, Rev 8 (Guidelines on a Medical Devices Vigilance System) with obligations for incident reporting, investigation of incidents by the manufacturer, follow-up reporting and possible field safety corrective actions. Many of these obligations are incorporated in the new Medical Device Regulation. In the U.S., the FDCA requires the submission of medical device reports to the FDA to report device-related deaths, serious injuries and malfunctions of medically approved products that could result in death or serious injury if they were to recur. The FDA uses this information to identify and respond to problems associated with medical devices. Other countries have generally similar obligations for reporting adverse events to the appropriate regulatory authority.

8.12 Environmental and health and safety

Sequana Medical is committed to providing a safe and healthy work environment for all of its employees, contractors and visitors. This commitment also extends to ensuring that its operations do not place local communities or the environment at risk of injury, illness or damage. In the event a device explanted (removed) from a patient is required to be returned to Sequana Medical for analysis, instructions and certified packaging materials are supplied for compliant transport. Such devices are decontaminated by Sequana Medical before analysis by specifically trained employees.

Sequana Medical has not been the subject of any significant environmental prosecutions for violating environmental regulations, licences or other requirements during the past five financial years.

8.13 Insurance

Sequana Medical maintains insurance to cover its potential exposure for a number of claims and losses, including product liability insurance to help pay for the defence of product liability lawsuits and clinical study insurance helps cover defence of lawsuits relating to products which are the subject of clinical studies. Management believes that the insurance coverage that Sequana Medical has is adequate in light of the risks that Sequana Medical faces.

8.14 Employees

Management believes that one of Sequana Medical's key strengths is its employee base, which has extensive know-how across manufacturing, quality-control, engineering, software programming and marketing and sales.

As at 30 September 2018, Sequana Medical employed 34 full-time equivalents, which included employees and consultants. The following table presents a breakdown of Sequana Medical's full-time equivalents as at 31 December 2015, 2016 and 2017 and as at 30 September 2018.

	As at	As at 31 December		
	30 September 2018	2017	2016 ⁽¹⁾	2015
Clinical	1.6	1.6	3.0	4.0
Engineering and production	9.3	9.0	10.6	10.0
Quality assurance and regulatory affairs	4.0	5.0	4.0	4.0
Commercial	10	7.0	7.0	10.8
General and administrative	7.6	5.4	5.4	7.8
Total	34.0	28.0	30.0	36.6

Notes:

(1) Full time equivalents excluding individuals within the employment termination notice period.

In 2016, Sequana Medical undertook a significant restructuring of its commercial team, which entailed scaling down its commercial efforts and reducing the number of hospitals on which it focused its commercial activities. This resulted in a decreased from 10.8 full-time equivalents in 2015 to 7.0 full-time equivalents in 2016.

Management expects that the clinical team will expand by at least 2 full-time equivalents in 2019 in order to support the POSEIDON (North American pivotal) Study and TOPMOST, and that that over the next few years employee expansion will be focused on the clinical and commercial teams, as well as the production team in order to scale-up manufacturing.

Currently, 6 full-time equivalents are allocated to Sequana Medical's focus markets of Germany and Switzerland. If the **alfapump**[®] secures reimbursement in additional European markets such as the U.K., France, Spain and Italy, management estimates that a commercial team of approximately 20 full-time equivalents would be required to support the sales and marketing activities in those markets. Management expects to begin pursuing reimbursement in Spain and Italy in 2019.

If the **alfapump**[®] secures reimbursement in the U.S., management estimates that an additional commercial team of approximately 20 full-time equivalents would first be required to support the sales and marketing activities directed at the specialist transplant centres in the U.S., with an addition of approximately 30 full-time equivalents thereafter to support the sales and marketing activities directed at referral centres in the U.S.

8.15 Material agreements

(a) Supplier agreements

The large majority of sub-components of the **alfapump**[®] and **alfapump**[®] DSR including the batteries, printed circuit board, motor, charger, docking station, catheter and surgical accessories are sourced externally, from a total of approximately 70 external suppliers. Sequana Medical's

suppliers are predominantly headquartered in Europe and the U.S. and range from large multinational companies to smaller private companies. In Sequana Medical's opinion, the suppliers of the critical components of the **alfapump**[®] are experienced and well-respected manufacturers with multiple customers and have existing quality control programmes and registrations with the appropriate regulatory authorities.

The tenure of Sequana Medical's relationships with suppliers usually extends beyond a single contract term with automatic agreement renewals for successive one-year periods over the life of the relationship. Sequana Medical determines whether it is appropriate to have a long term or short term agreement in place with a supplier on a case by case basis. Both Sequana Medical and each supplier can typically terminate the relevant supplier agreement with six months' advance notice prior to the expiration of the initial term of the agreement or the relevant renewal period.

The prices of the supplier components and/or services are set in Sequana Medical's supplier agreements, in some cases for the period of the contract and in other cases agreed per each purchase order placed by Sequana Medical.

(b) Distribution agreements

For the marketing and sale of the **alfapump**[®], Sequana Medical has entered into exclusive distribution agreements with Fresenius in Belgium and the Netherlands, Vingmed in Denmark and Gamida in Israel. The terms of these agreements range from two years to ten years. The prices of the **alfapump**[®] are generally set in the distribution agreements, in some cases for the period of the contract and in other cases subject to regular review. In those countries covered by distributors, Sequana Medical typically sells the **alfapump**[®] to the distributor at a price which is lower than the price paid by the end user. As a result, in the countries where it has distribution agreements, it will typically have a lower gross margin compared to Germany and Switzerland, where it has direct sales and marketing activities.

The agreements are renewable by mutual agreement between Sequana Medical and the applicable distributor. Both Sequana Medical and the distributors can terminate the distribution agreements for cause. Sequana Medical has the right to terminate an agreement if the distributor fails to meet pre-established sales thresholds for a specified number of consecutive quarters (typically 2-3), subject to the payment by Sequana Medical of any applicable pre-agreed termination fees based on the number of **alfapump**[®] systems sold in the jurisdiction covered by the terminated agreement. To date, Sequana Medical has not exercised this right of termination in instances where a distributor did not meet the pre-established sales threshold. The provisions of these agreements may temporarily constrain Sequana Medical's ability to convert certain jurisdictions from a distributor to a direct sales model.

The distribution agreements contain a confidentiality clause whereby the distributor is prohibited from disclosing or using for any other purpose than the execution of the distribution agreement any information which is confidential.

In addition, the Gamida Distribution Agreement contains a change of control provision. Gamida is entitled to terminate the Gamida Distribution Agreement with written notice in the event there is (i) more than a 50% change of ownership of Sequana Medical or (ii) a direct or indirect change of control of Sequana Medical. In order to exercise this termination right, Gamida must provide Sequana Medical with written notice of termination with immediate effect.

(c) Contract research organisations

Sequana Medical has entered into contracts with CROs, primarily in connection with clinical studies and the development of the **alfapump**[®]. These contracts with CROs are generally entered into for the duration of the clinical study or limited period of time (up to 3 years), with early termination options for both parties, including for convenience (but subject to the payment of some or part of the costs and fees already, or to be, incurred by the CRO).

All of the contracts with CROs contain confidentiality and intellectual property rights clauses. The confidentiality clauses in these contracts generally remain applicable for a period which varies between the different contracts and ranges from the duration of the contract to a period of up to 10 years after termination of the contract. The intellectual property rights clauses in these contracts grant Sequana Medical all proprietary rights with respect to the results of the study and the performance of the agreement.

(d) Bootstrap Loan

See Part 7 – (Operating and financial review and prospectus), section 7.4 (Liquidity and capital resources), subsection (a) (General) for a description of the loan agreement between Sequana Medical and Bootstrap.

8.16 Legal proceedings

There are no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which Sequana Medical is aware), during the previous 12 months which may have, or have had in the recent past, significant effects on Sequana Medical and/or Sequana Medical’s financial position or profitability.

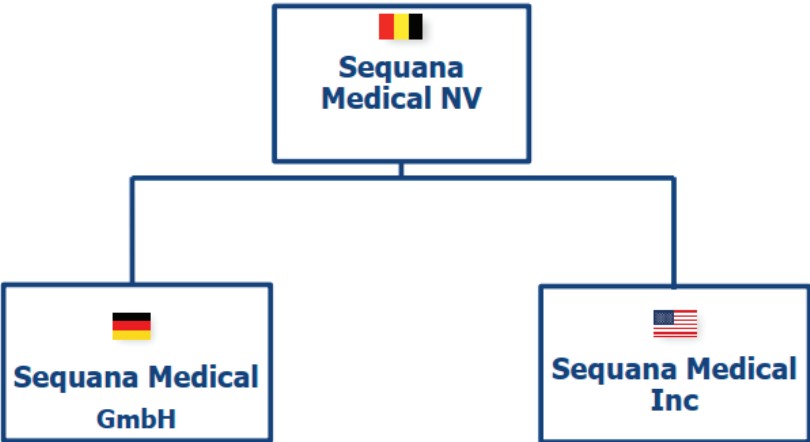
8.17 Facilities

Sequana Medical NV (the parent) operates out of a leased site in Ghent, Belgium, which gives home to Sequana Medical’s corporate, commercial and clinical activities, and a leased site in Zurich, Switzerland, where Sequana Medical’s production, engineering and quality assurance and regulatory affairs activities are located. The lease for the site in Zurich, Switzerland expires on 31 March 2020. Sequana Medical also leases warehouse space in Germany that is used for the distribution of the **alfapump**® to countries within the E.U.

8.18 Group structure

Sequana Medical is comprised of Sequana Medical NV and its wholly owned subsidiaries: Sequana Medical GmbH, which includes marketing and distribution activities in Germany; and Sequana Medical Inc., which is located in the U.S. and does not have any operations at the date of this Prospectus.

The following chart represents Sequana Medical’s structure at the date of this Prospectus:



8.19 Grants and subsidies

Sequana Medical has not received any grant monies to date. Following its relocation to Belgium, Sequana Medical intends to apply for grant support from various institutions in the future.

PART 9 – MANAGEMENT AND CORPORATE GOVERNANCE

9.1 Overview

The Issuer has the legal form of a limited liability company (naamloze vennootschap/société anonyme) organised under the laws of Belgium. The Issuer was established as a limited liability company (Aktiengesellschaft/société anonyme) organised under the laws of Switzerland in 2007, and transferred its registered office, without liquidation or dissolution, from Switzerland to Belgium in 2018. As a result of the Belgian Seat Transfer, the Issuer became a limited liability company organised under the laws of Belgium.

This section summarises the rules and principles by which the Issuer's corporate governance will be organised, and which are contained in the Belgian Companies Code, other relevant legislation and the Issuer's articles of association and corporate governance charter effective as of the closing of the Offering.

9.2 Corporate governance

The Issuer has adopted a corporate governance charter that is in line with the Belgian Code on Corporate Governance of 12 March 2009 and that will enter into force upon the closing of the Offering. The Issuer's board of directors approved the charter on 28 January 2019, subject to and with effect as of the closing of the Offering. The corporate governance charter describes the main aspects of the corporate governance of the Issuer, including its governance structure, the terms of reference of the board of directors and its committees and other important topics. The corporate governance charter must be read together with the Issuer's articles of association.

The Issuer will apply the nine corporate governance principles contained in the Belgian Code on Corporate Governance and will comply with the corporate governance provisions set forth in the Belgian Code on Corporate Governance, except in relation to the following.

- Although at the date of this Prospectus, no Share options have been granted to non-executive directors, the Issuer intends to award Share-based incentives to the non-executive directors, upon advice of the remuneration and nomination committee. This is contrary to provision 7.7 of the Belgian Code on Corporate Governance that provides that non-executive directors should not be entitled to performance-related remuneration such as, amongst others, share-related long-term incentive schemes. The Issuer believes that this provision of the Belgian Code on Corporate Governance is not appropriate and adapted to take into account the realities of companies in the biotech and life sciences industry that are still in a development phase. Notably, the ability to remunerate non-executive directors with Share options allows Sequana Medical to limit the portion of remuneration in cash that the Issuer would otherwise need to pay to attract or retain renowned experts with the most relevant skills, knowledge and expertise. The Issuer is of the opinion that granting non-executive directors the opportunity to be remunerated in part in Share-based incentives rather than all in cash enables the non-executive directors to link their effective remuneration to the performance of Sequana Medical and to strengthen the alignment of their interests with the interests of the Issuer's shareholders. This is in the interest of the Issuer and its stakeholders. Furthermore, this is customary for directors active in companies in the life sciences industry. In any event, the Issuer intends that the portion of the remuneration payable in Share options will be limited.
- Pursuant to article 520ter of the Belgian Companies Code and the guideline to provision 7.13 of the Belgian Code on Corporate Governance, shares should not vest and share options should not be exercisable within three years as of their granting. The Issuer's board of directors has been explicitly authorised in the Issuer's articles of association to deviate from this rule in connection with stock based incentive plans, compensations, awards and issuances to employees, directors and service providers of the Issuer and/or its subsidiaries (from time to time). The Issuer is of the opinion that this allows for more flexibility when structuring share-based awards. For example, it is customary for option plans to provide for a vesting in several instalments over a well-defined period of time, instead of vesting after three years only. This seems to be more in line with prevailing practice.

- At the closing of the Offering, there will only be two independent directors on the Issuer's board of directors. This is contrary to provision 2.3 of the Belgian Code on Corporate Governance which provides that at least one half of the board should comprise non-executive directors and at least three of the non-executive directors should be independent directors. The Issuer is currently in discussions with potential candidates and expects to strengthen its board with a third independent director after the closing of the Offering.

What constitutes good corporate governance will evolve with the changing circumstances of a company and with the standards of corporate governance globally, and must be tailored to meet those changing circumstances. The board of directors intends to update the corporate governance charter as often as required to reflect changes to the Issuer's corporate governance.

The articles of association and the corporate governance charter will be made available on the Issuer's website (www.sequanamedical.com) and can be obtained free of charge at the Issuer's registered office after closing of the Offering.

9.3 Board of directors

(a) Powers and responsibilities of the board of directors

The Issuer has a "one tier" governance structure whereby the board of directors is the ultimate decision making body, with the overall responsibility for the management and control of the Issuer, and is authorised to carry out all actions that are considered necessary or useful to achieve the Issuer's purpose. The board of directors has all powers except for those reserved to the general shareholders' meeting by law or the Issuer's articles of association. The board of directors acts as a collegiate body.

Pursuant to the Issuer's corporate governance charter, the role of the board of directors is to pursue the long term success of the Issuer by providing entrepreneurial leadership and enabling risks to be assessed and managed. The board of directors decides on the Issuer's values and strategy, its risk appetite and key policies.

The board of directors is assisted by a number of committees in relation to specific matters. The committees advise the board of directors on these matters, but the decision making remains with the board of directors as a whole (see also subsection (e) (Committees of the board of directors) below).

The board of directors has the power to appoint and remove the chief executive officer. The role of the chief executive officer is to implement the mission, strategy and targets set by the board of directors and to assume responsibility for the day-to-day management of the Issuer. The chief executive officer reports directly to the board of directors.

Pursuant to the Belgian Companies Code and the Issuer's articles of association, the board of directors must consist of at least three directors. The Issuer's corporate governance charter provides that the composition of the board of directors should ensure that decisions are made in the corporate interest. It should be determined on the basis of diversity, as well as complementary skills, experience and knowledge. Pursuant to the Belgian Code on Corporate Governance, at least half of the directors must be non-executive and at least three directors must be independent in accordance with the criteria set out in the Belgian Companies Code and in the Belgian Code on Corporate Governance. As stated in section 9.2 (Corporate Governance), at the closing of the Offering, there will only be two independent directors on the Issuer's board of directors. By 1 January 2024, at least one third of the members of the board of directors must be of the opposite gender.

The directors are elected by the Issuer's general shareholders' meeting. The term of the directors' mandates cannot exceed four (4) years. Resigning directors can be re-elected for a new term. Proposals by the board of directors for the appointment or re-election of any director must be based on a recommendation by the remuneration and nomination committee. In the event the office of a director becomes vacant, the remaining directors can appoint a successor temporarily filling the vacancy until the next general shareholders' meeting.

The general shareholders' meeting can dismiss the directors at any time.

The board of directors elects a chairperson from among its non-executive members on the basis of his knowledge, skills, experience and mediation strength. The chairperson is responsible for the leadership and the proper and efficient functioning of the board of directors. On the date of

this Prospectus, Dr Rudy Dekeyser is chairperson of the board of directors and Mr Ian Crosbie is the chief executive officer. With effect as of the closing of the Offering, Mr Pierre Chauvineau, will be chairperson of the board of directors. If the board of directors envisages appointing a former chief executive officer as chairperson, it should carefully consider the positive and negative aspects of such a decision and disclose why such appointment is in the best interest of the Issuer.

The board of directors should meet as frequently as the interest of the Issuer requires, or at the request of one or more directors. In principle, the board of directors will meet sufficiently regularly and at least five (5) times per year. The decisions of the board of directors are made by a simple majority of the votes cast. The chairperson of the board of directors will have a casting vote.

(b) Pre-Offering composition of the board of directors

As of the date of this Prospectus, the board of directors is composed of three directors. The table below gives an overview of the members of the Issuer’s board of directors and their term of office as at the date of this Prospectus:

Name	Age	Position	Start of Term	End of Term
Rudy Dekeyser ⁽¹⁾	56	Chairperson, Non-Executive Director	2018	2019
Erik Amble ⁽²⁾	67	Non-Executive Director	2018	2019
Diego Braguglia ⁽³⁾	52	Non-Executive Director	2018	2019

Notes:

- (1) Appointed upon proposal of LSP Health Economics Fund Management B.V.
- (2) Appointed upon proposal of NeoMed IV Extension L.P. and NeoMed Innovation V L.P.
- (3) Appointed upon proposal of Venture Incubator AG.

Dr Rudy Dekeyser is a non-executive director and the chairperson of the Issuer’s board of directors. He is managing partner of the LSP Health Economics Fund II, a €280 million fund investing in medical device, diagnostic and digital health companies in Europe and the US. Besides serving on the Issuer’s board of directors, Dr Dekeyser currently also serves on the board of directors of Curetis, reMYND, Celyad and EMBLEM and has served on many other biotech boards such as Ablynx (acquired by Sanofi), Devgen (acquired by Syngenta), CropDesign (acquired by BASF), Actogenix (acquired by Intrexon) and Multiplicom (acquired by Agilent). Prior to joining LSP, he was one of the co-founders of VIB and co-managing director of this leading life sciences research institute for 17 years, during which he was also responsible for the business development. Under his leadership VIB has built a patent portfolio exceeding 200 patent families, signed 800 R&D and license agreements, spun out twelve companies and laid the foundation for bio-incubators, bio-accelerators and the biotech association FlandersBio. Dr Dekeyser holds a Ph.D in molecular biology from the University of Ghent where he was also professor innovation management until 2012.

Dr Erik Amble is a non-executive director of the Issuer. Dr Amble is the chairman and founder of NeoMed Management in 1997. Prior to that, he has been Chairman and controlling shareholder of NeoMed AS, providing investment advisory services, specializing in small and medium sized companies in the pharmaceutical, medical device and diagnostic industries. From 1993 to 1997, NeoMed AS co-managed two private equity investment companies, KS Nordic Healthcare Partners and Viking Medical Ventures Limited. Dr Amble has served as a board member of Clavis Pharma AS, GenoVision AS/Qiagen AS, Thommen Medical AG, Vessix Vascular Inc. and Sonendo Inc., and currently serves on the board of directors of JenaValve Technology Inc., CorFlow Therapeutics AG and Axonics Modulation Technologies Inc. He is a founder and former Chairman of the Norwegian Venture Capital Association. He holds a Dr. scient. degree in organic chemistry from the University of Oslo and a Master of Science degree in Management from the Graduate School of Business, Stanford University, U.S.A.

Dr Diego Braguglia is a non-executive director of the Issuer. He has over 20 years of experience in life science, medical devices and pharmaceuticals in Europe and the U.S. Prior to his entry as General Partner for VI Partners, a leading Swiss venture capital firm, Dr Braguglia has held various managerial positions in the pharmaceuticals and medical devices sectors. In addition to his role in Sequana Medical, Dr Braguglia presently represents VI Partners in various biotech

start-ups companies. He holds a M.Sc. in Microbiology from the Biocenter of the University of Basel and a Ph.D. in Molecular and Cellular Biology from the Swiss Cancer Research Institute (ISREC) in Lausanne and the University of Lausanne.

The business address of each of the directors for the purpose of their mandate is the address of the Issuer's registered office.

(c) Post-Offering composition of the board of directors

With effect as of the closing of the Offering, the board of directors will be composed of five directors. The table below gives an overview of the members of the Issuer's board of directors and their terms as at the closing of the Offering:

Name	Age	Position	Start of Term	End of Term
Pierre Chauvineau	54	Chair, Independent Non-Executive Director	2018	2022
Ian Crosbie	50	CEO, Executive Director	2018	2022
Rudy Dekeyser	56	Non-Executive Director	2018	2022
Erik Amble	66	Non-Executive Director	2018	2022
Wim Ottevaere ⁽¹⁾	62	Independent Non-Executive Director	2018	2022

Notes:

(1) Acting as permanent representative of WIOT BVBA.

Mr Pierre Chauvineau will be an independent non-executive director and the chairperson of the Issuer's board of directors subject to and with effect as from the closing of the Offering. Mr Chauvineau has over 26 years of international business leadership in corporate and start-up companies within the medical technology industry. He started his career with Medtronic where he spent 20 years living in Belgium, France, Switzerland, the U.K. and Ireland consistently demonstrating leadership in developing high performance teams and growing the business faster than the market. In 2010, Mr Chauvineau joined Cameron Health, a VC-funded medical device company based in California where he was responsible for commercialising their innovative implantable defibrillator across international markets. Cameron Health was acquired by Boston Scientific two years later in June 2012, after which Mr Chauvineau went on to lead Boston Scientific's largest European Business Unit for 5 years. Today, Mr Chauvineau continues to work for Boston Scientific as an executive advisor on a part-time basis. He is also an executive board member with U.K. based Creavo Medical Technologies. Pierre Chauvineau holds an MBA degree in International Management from the Monterey Institute of International Studies (Monterey, California, U.S.A.) and a BA degree from IPAG (Paris, France).

Mr Ian Crosbie will be an executive director of the Issuer subject to and with effect as from the closing of the Offering. He is the Issuer's chief executive officer. Mr Crosbie has over 25 years of experience in the healthcare sector, both in-house at medical device and pharmaceutical companies, and as an investment banker at leading global firms. He has extensive expertise and a strong track record in capital markets, licensing and strategic transactions. Prior to joining Sequana Medical, Mr Crosbie was Chief Financial Officer of GC Aesthetics Ltd. Before that, he was Senior Vice President, Corporate Development at Circassia Pharmaceuticals plc, a late-stage biopharmaceutical company focused on allergy immunotherapy where he led the execution of the company's £210 million IPO, as well as the M&A and licensing activities. Prior to Circassia, Mr Crosbie enjoyed a 20-year career in corporate finance, including Managing Director, Healthcare Investment Banking at Jefferies International Limited and Director, Healthcare Investment Banking at Deutsche Bank. He has a degree in Engineering, Economics and Management from Oxford University.

Mr Wim Ottevaere will be an independent non-executive director of the Issuer subject to and with effect as from the closing of the Offering. Mr Ottevaere was the chief financial officer of Ablynx until September 2018, a Belgian biopharmaceutical company engaged in the development of proprietary therapeutic proteins based on single-domain antibody fragments. Ablynx was listed on Euronext Brussels and Nasdaq and acquired by Sanofi in June 2018. From 1992 until joining Ablynx in 2006, Mr Ottevaere was Chief Financial Officer of Innogenetics (now Fujirebio Europe), a biotech company that was listed on Euronext Brussels at the time. From 1990 until 1992, he

served as Finance Director of Vanhout, a subsidiary of the Besix group, a large construction enterprise in Belgium. From 1978 until 1989, Mr Ottevaere held various positions in finance and administration within the Dossche group. Wim Ottevaere holds a Master's degree in Business Economics from the University of Antwerp, Belgium.

The business address of each of the directors for the purpose of their mandate will be the address of the Issuer's registered office.

(d) Share ownership and intention of the directors to participate in the Offering

Immediately prior to the closing of the Offering, none of the non-executive directors (based on the post-Offering composition of the board of directors) or, in case the non-executive directors are legal entities, their permanent representatives, own Shares or Share options. The Issuer has not received any indication that any of its non-executive directors (based on the post-Offering composition of the board of directors) or, in case the non-executive directors are legal entities, their permanent representatives, intends to purchase any Offered Shares.

Although at the date of this Prospectus, no Share options have been granted to non-executive directors, the Issuer intends to award Share-based incentives to the non-executive directors, upon advice of the remuneration and nomination committee.

For an overview of the Share and Share option ownership of the chief executive officer, see section 9.4 (Executive management), subsection (d) (Share ownership and intention of the members of the executive management to participate in the Offering).

(e) Committees of the board of directors

The board of directors has established two board committees subject to and with effect as of the closing of the Offering, which are responsible for assisting the board of directors and making recommendations in specific fields: the audit committee (in accordance with article 526bis of the Belgian Companies Code and provision 5.2 of the Belgian Code on Corporate Governance) and the remuneration and nomination committee (in accordance with article 526quater of the Belgian Companies Code and provision 5.3 and 5.4 of the Belgian Code on Corporate Governance). The terms of reference of these board committees are primarily set out in the corporate governance charter.

(f) Audit committee

The audit committee consists of three directors. According to the Belgian Companies Code, all members of the audit committee must be non-executive directors, and at least one member must be independent within the meaning of article 526ter of the Belgian Companies Code. The chairperson of the audit committee is to be appointed by the members of the audit committee. Subject to and with effect as of the closing of the Offering, the following directors will be the members of the audit committee: Mr Wim Ottevaere, Mr Pierre Chauvineau and Dr Erik Amble. The composition of the audit committee complies with the Belgian Code on Corporate Governance, which requires that a majority of the members of the audit committee are independent.

The members of the audit committee must have a collective competence in the business activities of Sequana Medical as well as in accounting, auditing and finance, and at least one member of the audit committee must have the necessary competence in accounting and auditing. According to the board of directors, the members of the audit committee satisfy this requirement, as evidenced by the different senior management and director mandates that they have held in the past and currently hold (see also section 9.8 (Other mandates) below).

The role of the audit committee is to:

- inform the board of directors of the result of the audit of the financial statements and the manner in which the audit has contributed to the integrity of the financial reporting and the role that the audit committee has played in that process;
- monitor the financial reporting process, and to make recommendations or proposals to ensure the integrity of the process,
- monitor the effectiveness of the internal control and risk management systems, and the Issuer's internal audit process and its effectiveness;
- monitor the audit of the financial statements, including the follow-up questions and recommendations by the statutory auditor;

- assess and monitor the independence of the statutory auditor, in particular with respect to the appropriateness of the provision of additional services to Sequana Medical. More specifically, the audit committee analyses, together with the statutory auditor, the threats for the statutory auditor's independence and the security measures taken to limit these threats, when the total amount of fees exceeds the criteria specified in article 4 §3 of Regulation (EU) No 537/2014; and
- make recommendations to the board of directors on the selection, appointment and remuneration of the statutory auditor of Sequana Medical in accordance with article 16 §2 of Regulation (EU) No 537/2014.

The audit committee should have at least four regularly scheduled meetings each year. The audit committee regularly reports to the board of directors on the exercise of its missions, and at least when the board of directors approves the financial statements and the condensed or short form financial information that will be published. The members of the audit committee have full access to the executive management and to any other employee to whom they may require access in order to carry out their responsibilities.

Without prejudice to the statutory provisions which determine that the statutory auditor must address reports or warnings to the corporate bodies of the Issuer, the statutory auditor must discuss, at the request of the statutory auditor, or at the request of the audit committee or of the board of directors, with the audit committee or with the board of directors, essential issues which are brought to light in the exercise of the statutory audit of the financial statements, which are included in the additional statement to the audit committee, as well as any meaningful shortcomings discovered in the internal financial control system of the Issuer.

(g) Remuneration and nomination committee

The remuneration and nomination committee consists of at least three directors. In line with the Belgian Companies Code and the Belgian Code on Corporate Governance (i) all members of the remuneration and nomination committee are non-executive directors, (ii) the remuneration and nomination committee consists of a majority of independent directors and (iii) the remuneration and nomination committee is chaired by the chairperson of the board of directors or another non-executive director appointed by the committee. Subject to and with effect as of the closing of the Offering, the following directors will be the members of the remuneration and nomination committee: Dr Rudy Dekeyser, Mr Wim Ottevaere and Mr Pierre Chauvineau.

Pursuant to the Belgian Companies Code, the remuneration and nomination committee must have the necessary expertise in terms of remuneration policy, which is evidenced by the experience and previous roles of its current members.

Pursuant to the Belgian Code on Corporate Governance, the chief executive officer participates in the meetings of the remuneration and nomination committee in an advisory capacity each time the remuneration of another member of the executive management is being discussed.

The role of the remuneration and nomination committee is to make recommendations to the board of directors with regard to the appointment and remuneration of directors and members of the executive management and, in particular, to:

- identify, recommend and nominate, for the approval of the board of directors, candidates to fill vacancies in the board of directors and executive management positions as they arise. In this respect, the remuneration and nomination committee must consider and advise on proposals made by relevant parties, including management and shareholders;
- advise the board of directors on any proposal for the appointment of the chief executive officer and on the chief executive officer's proposals for the appointment of other members of the executive management;
- draft appointment procedures for members of the board of directors and the chief executive officer;
- ensure that the appointment and re-election process is organised objectively and professionally;
- periodically assess the size and composition of the board of directors and make recommendations to the board of directors with regard to any changes;
- consider issues related to succession planning;

- make proposals to the board of directors on the remuneration policy for directors and members of the executive management and the persons responsible for the day-to-day management of Sequana Medical, as well as, where appropriate, on the resulting proposals to be submitted by the board of directors to the shareholders' meeting;
- make proposals to the board of directors on the individual remuneration of directors and members of the executive management, and the persons responsible for the day-to-day management of Sequana Medical, including variable remuneration and long-term incentives, whether or not share-related, in the form of share options or other financial instruments, and arrangements on early termination, and where applicable, on the resulting proposals to be submitted by the board of directors to the shareholders' meeting;
- prepare a remuneration report to be included by the board of directors in the annual corporate governance statement;
- present and provide explanations in relation to the remuneration report at the annual shareholders' meeting; and
- report regularly to the board of directors on the exercise of its duties.

In principle, the remuneration and nomination committee meets as frequently as necessary for carrying out its duties, but at least two times a year.

(h) Independent directors

A director will only qualify as an independent director if he or she meets at least the criteria set out in article 526ter of the Belgian Companies Code, which can be summarised as follows:

- Not being an executive member of the board of directors, exercising a function as a member of the executive management or as a person entrusted with the daily management of the Issuer or a company or person affiliated with the Issuer, and not having been in such a position during the previous five years before his or her nomination.
- Not having served for more than three terms as a non-executive director of the board of directors, without exceeding a total term of more than twelve years.
- Not being an employee of the senior management (as defined in article 19, 2° of the Belgian Act of 20 September 1948 regarding the organisation of the business industry) of the Issuer or a company or person affiliated with the Issuer and not having been in such a position for the previous three years before his or her nomination.
- Not receiving, or having received, any significant remuneration or other significant advantage of a financial nature from the Issuer or a company or person affiliated with the Issuer, other than any bonus or fee (tantièmes) he or she receives or has received as a non-executive member of the board of directors.
- Not holding (directly or via one or more companies under his or her control) any shareholder rights representing 10% or more of the Shares or of a class of the Shares (as the case may be), and not representing a shareholder meeting this condition.
- If the shareholder rights held by the director (directly or via one or more companies under his or her control) represent less than 10%, the disposal of such Shares or the exercise of the rights attached thereto may not be subject to contracts or unilateral undertakings entered into by the director. The director may also not represent a shareholder meeting this condition.
- Not having, or having had within the previous financial year, a significant business relationship with the Issuer or a company or person affiliated with the Issuer, either directly or as partner, shareholder, member of the board of directors, member of the senior management (as defined in article 19, 2° of the aforementioned Belgian Act of 20 September 1948) of a company or person who maintains such a relationship.
- Not being or having been within the last three years, a partner or employee of the current or former statutory auditor of the Issuer or a company or person affiliated with the current or former statutory auditor of the Issuer.

- Not being an executive director of another company in which an executive director of the Issuer is a non-executive member of the board, and not having other significant links with executive directors of the Issuer through involvement in other companies or bodies.
- Not being a spouse, legal partner or close family member (by marriage or birth) to the second degree of a member of the board of directors, a member of the executive management, a person charged with the daily management, or a member of the senior management (as defined in article 19, 2° of the aforementioned Belgian Act of 20 September 1948) of the Issuer or a company or person affiliated with the Issuer, or of a person who finds him or herself in one or more of the circumstances described in the previous bullets.

The resolution appointing the director must mention the reasons on the basis of which the capacity of independent director is granted.

In the absence of guidance in the law or case law, the board of directors has not further quantified or specified the aforementioned criteria set out in article 526ter of the Belgian Companies Code. The Issuer is of the view that the independent directors that will enter into office at the closing of the Offering comply with each of the criteria of the Belgian Companies Code and Belgian Code on Corporate Governance. The board of directors will also disclose in its annual report which directors it considers to be independent directors. An independent director who ceases to satisfy the requirements of independence must immediately inform the board of directors thereof.

Subject to and with effect as of the closing of the Offering, Mr Pierre Chauvineau and Mr Wim Ottevaere will be the Issuer's independent directors.

(i) Performance review of the board of directors

The board of directors evaluates its own size, composition, performance and interaction with executive management and that of its committees on a continuous basis.

The evaluation assesses how the board of directors and its committees operate, checks that important issues are effectively prepared and discussed, evaluates each director's contribution and constructive involvement, and assesses the composition of the board of directors and its committees against the desired composition. This evaluation takes into account the members' general role as director, and specific roles as chairperson or member of a committee of the board of directors, as well as their relevant responsibilities and time commitment.

Non-executive directors assess their interaction with the executive management on a continuous basis.

9.4 Executive management

(a) Powers and responsibilities of the executive management

The executive management is composed of two members and is led by the chief executive officer. Its members are appointed by the board of directors on the basis of a recommendation by the remuneration and nomination committee. The Issuer's executive management does not constitute a directiecomité/comité de direction within the meaning of article 524bis of the Belgian Companies Code. The executive management is responsible and accountable to the board of directors for the discharge of its responsibilities.

The executive management is responsible for:

- operating the Issuer;
- implementing the policy and plans of the Issuer as defined by the board of directors and in accordance with its instructions;
- executing the decisions made by the board of directors;
- assessing the achievement of the targets for the business of the Issuer and its subsidiary;
- preparing corporate policies, strategies and strategic plans for the attention of and approval by the board of directors or its committees;
- promoting an active internal and external communications policy;
- ensuring that management capacity, financial and other resources are provided and used efficiently;

- submitting to the board of directors or to one of its committees for approval or advice in accordance with such regulations and standards as are promulgated by the board of directors from time to time: (a) capital investment, financial measures and acquisition or divestiture of companies, participations and businesses of material significance, and (b) material agreements with third parties and engagement in new business activities;
- preparing the Issuer's yearly business plan and yearly budget to be submitted to the board of directors;
- establishing an independent internal audit function with resources and skills adapted to the company's nature, size and complexity. If the Issuer does not have an internal audit function, the need for one shall be reviewed at least annually by the audit committee;
- setting up the Issuer's internal control and risk management systems and submit them for approval to the board of directors;
- promulgating guidelines, including guidelines for planning, controlling, reporting, finance, personnel, information and other technologies; and
- dealing with such other matters as are delegated by the board of directors from time to time.

(b) Chief executive officer

The chief executive officer is responsible for the day-to-day management of the Issuer. He may be granted additional well-defined powers by the board of directors. He has direct operational responsibility for the Issuer and oversees the organisation and day-to-day management of subsidiaries, affiliates and joint ventures. The chief executive officer is responsible for the execution and management of the outcome of all decisions of the board of directors.

The chief executive officer leads the executive management within the framework established by the board of directors and under its ultimate supervision. The chief executive officer is appointed and removed by the board of directors and reports directly to it.

(c) Composition of the executive management

Subject to and with effect as of the closing of the Offering, the executive management will consist of the following members:

Name	Age	Position
Ian Crosbie	50	Chief Executive Officer
Kirsten Van Bockstaele ⁽¹⁾	43	Chief Financial Officer

Notes:

(1) Acting through Fin-2K BVBA.

The senior management team of Sequana Medical consists of the members of the executive management, together with Mr Martijn Blom, Dr Gijs Klarenbeek, Mr Timur Resch and Mr Dirk Fengels. The biographies of each of the members of the senior management team are set forth below.

Mr Ian Crosbie is the chief executive officer and a director of Sequana Medical. Please see his biography under section 9.3 (Board of directors), subsection (c) (Post-Offering composition of the board of directors) above.

Mrs Kirsten Van Bockstaele is the chief financial officer of Sequana Medical. She is a seasoned finance executive with extensive international experience in the healthcare industry. Mrs Van Bockstaele joined Sequana Medical from Fagron (formerly Arseus), an international pharmaceutical compounding company. Within Fagron, she held a number of senior financial roles, most recently as Vice President of Finance, North America. In this role, Mrs Van Bockstaele was responsible for creating and overseeing the company's financial strategy and policy, positioning Fagron's North American companies for growth. She also played a pivotal role in building out the North American headquarters, supporting the financial integration of acquisitions and assisting in redirecting the company's strategy. Mrs Van Bockstaele previously served as Chief Financial Officer for Arseus Dental & Medical Solutions, where she was instrumental in the coordination, support and control of financial activities in key European countries. Her previous roles include

Financial Controller at Omega Pharma and Audit Manager at PwC. Kirsten Van Bockstaele has a degree in Business Economics from EHSAL and a degree in Financial and Fiscal Sciences from the University of Antwerp, Belgium.

Dr Gijs Klarenbeek is the Chief Medical Officer of Sequana Medical. Dr Klarenbeek has over 14 years academic and healthcare industry experience. After his training in abdominal surgery at the University of Leuven, he held multiple positions in Medical Affairs, Clinical and Marketing at large pharmaceutical (Sanofi, AstraZeneca) and medical device companies. These include roles as Director of Medical Affairs Europe at Boston Scientific, providing leadership to the medical support for the portfolio of products in the Structural Heart and Medical / Surgical divisions, and as Worldwide Medical Director Clinical Research at Johnson & Johnson's medical device division (Cordis and Cardiovascular Care Franchise), supporting the clinical development of different products through regulatory submission (CE mark & IDE), post-market commitments and development. Dr Klarenbeek holds an MD from the University of Leuven, Belgium and a degree in Business Administration from the Institute for Pharmaceutical Business Administration (IFB).

Mr. Martijn Blom is the Chief Commercial Officer of Sequana Medical. Mr. Blom has over 15 years' experience in the life sciences industry. Most recently he was the Director of International Marketing at Myriad Genetics, responsible for the marketing development of genetic testing in the international markets. Previous to Myriad, he worked as Director of Marketing and Market Development at PulmonX, a start up from Redwood City focusing on developing and marketing minimally-invasive medical devices and technologies to expand and improve treatment options for emphysema patients. Prior to this he was Director International Marketing at Alere where he spent more than 7 years leading the marketing, training and marketing communications teams, for all of their business units: Cardiology, Women's Health, Oncology, Infectious Diseases, Blood Borne Pathogens, Toxicology and Health Management. Mr. Blom studied economics at the MEAO in Breda and specialised at de Rooi Pannen in Marketing and Sales management.

Mr Timur Resch is the Global Vice President Quality Management and Regulatory Affairs of Sequana Medical. Mr Resch has 10 years of experience within quality management and regulatory affairs in the regulated medical device industry. In 2010 Mr Resch graduated as an engineer in medical technology from the University of Applied Sciences in Lübeck, Germany and began his professional career as a process and management consultant at Synspace AG. Thereafter, Mr Resch continued as Head of Quality Management & Regulatory Affairs at Schaerer Medical AG and prior to joining Sequana Medical held the position of Manager & Team Leader Regulatory Affairs at Medela AG. His experience includes the establishment of quality management systems, auditing, international product registrations for Class I to Class III medical devices, ensuring compliance with applicable regulatory requirements as well as being the liaison to Notified Bodies and health authorities. Mr. Resch serves as member of quality and regulatory task forces and expert groups within Germany and Switzerland. Prior to Mr Resch being appointed as the Global Vice President Quality Management and Regulatory Affairs of Sequana Medical, this position was held by Mr Orlando Antunes.

Mr Dirk Fengels is the Global Vice President Engineering and Manufacturing of Sequana Medical. He has over 15 years experience in research and development and spent the majority of his career in a multidisciplinary high-tech environment. Mr Fengels has extensive expertise in developing innovative solutions for the medical device industry. Prior to joining Sequana Medical, he led the Sensors & Systems group at the Swiss Center for Electronics and Microtechnology (CSEM) for 10 years, where his team specialised in developing innovative sensors, mechatronic systems and automated fluid handling solutions to create unique selling propositions on behalf of various industry partners. In his role, Mr Fengels was also responsible for aligning the research strategy in the automation field with industry needs and he mentored research and industry projects. Prior to CSEM, he was responsible for the development of next generation products in two medical start-up companies, one in Switzerland and one in Silicon Valley. Mr Fengels holds a Master's degree in Electrical Engineering from the Swiss Federal Institute of Technology, Zürich (ETH).

The business address of each of the members of the executive management for the purpose of their mandate is the address of the Issuer's registered office.

(d) Share ownership and intention of the members of the executive management to participate in the Offering

On the date of this Prospectus no member of the executive management holds any Shares of the Issuer.

The table below provide an overview of the number of Shares which each member of the executive management is entitled to acquire upon exercise of the 2011 Share Options and the Executive Share Options that are held by him or her on the date of this Prospectus (before and after giving effect to the Share Consolidation, assuming an Offer Price at the midpoint of the Price Range).

Name	2011 Share Options					
	Vested options		Unvested options		Total options	
	Before Share Consolidation	After Share Consolidation	Before Share Consolidation	After Share Consolidation	Before Share Consolidation	After Share Consolidation
Ian Crosbie	63,563	1	49,437	1	113,000	1
Kirsten Van Bockstaele ⁽¹⁾	0	0	0	0	0	0

Notes:

(1) Acting through Fin-2K BVBA.

Name	Executive Share Options					
	Vested options		Unvested options		Total options	
	Before Share Consolidation	After Share Consolidation	Before Share Consolidation	After Share Consolidation	Before Share Consolidation	After Share Consolidation
Ian Crosbie	0	0	75,025	216,442	75,025	216,442
Kirsten Van Bockstaele ⁽¹⁾	0	0	2,158	6,226	2,158	6,226

Notes:

(1) Acting through Fin-2K BVBA.

For an overview of the features of the Issuer's Share option plans, see also section 9.6 (Description of Share plans) below.

The Issuer has not received any indication that the members of the executive management intend to purchase Offered Shares.

9.5 Remuneration and benefits

(a) Remuneration policy

The Issuer's remuneration policy is designed to:

- enable the Issuer to attract and retain talented employees,
- promote continuous improvement in the business, and
- reward performance in order to motivate employees to deliver increased shareholder value through superior business results.

The remuneration policy that has been determined in relation to the directors and members of the executive management is further described below in section (b) (Directors) and section 9.4 (Executive management) respectively.

(b) Directors

(i) General

Upon recommendation and proposal of the remuneration and nomination committee, the board of directors determines the remuneration of the directors to be proposed to the general shareholders' meeting.

Pursuant to Belgian law, the general shareholders' meeting approves the remuneration of the directors, including *inter alia*, each time as relevant:

- (i) in relation to the remuneration of executive and non-executive directors, the exemption from the rule that Share-based awards can only vest after a period of at least three years as of the grant of the awards;
- (ii) in relation to the remuneration of executive directors, the exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years;
- (iii) in relation to the remuneration of non-executive directors, any variable part of the remuneration; and
- (iv) any service agreements to be entered into with executive directors providing for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, eighteen months' remuneration).

Notwithstanding point (i) above, pursuant to the Issuer's articles of association, the board of directors is explicitly authorised to deviate from the provisions of article 520ter of the Belgian Companies Code in connection with Share-based incentive plans, compensation, awards or issues to employees, directors and service providers of the Issuer and/or its subsidiaries. The Issuer believes this allows for more flexibility when structuring Share-based awards. For example, it is customary for option plans to provide for a vesting in several instalments over a well-defined period of time, instead of vesting after three years only. This seems to be more in line with prevailing practice.

The general shareholders' meeting of the Issuer has not approved any of the matters referred to in paragraphs (i) to (iv) with respect to the remuneration of the directors of the Issuer upon closing of the Offering, except for the following matters:

- The general shareholders' meeting approved that Share options issued pursuant to the Issuer's Share option plans can, under certain conditions, vest earlier than three years as of their grant, as referred to in paragraph (i) above.
- The general shareholders' meeting approved that the Share options under the respective Share option plans will not qualify as variable remuneration nor as annual remuneration for the purpose of the application of the rule set out in paragraph (ii) above.
- With respect to the matter in paragraph (iii) above, although at the date of this Prospectus, no Share options have been granted to non-executive directors, the Issuer intends to award stock-based incentives to the non-executive directors, upon advice of the remuneration and nomination committee. See also subsection (iii) (Remuneration and compensation as of the closing of the Offering) below.

(ii) Remuneration and compensation in 2017

During 2017, no remuneration or compensation was paid to the directors, other than (i) €70,883.33 paid to Rolf Classon, and (ii) the reimbursement of travel and hotel expenses incurred by the directors in connection with their attendance of meetings of the board of directors.

(iii) Remuneration and compensation as of the closing of the Offering

The remuneration and compensation of the non-executive directors for the current financial year, which has been determined by the general shareholders' meeting and will become effective upon the closing of the Offering, is as follows:

- Annual fixed fees:
 - The chairperson of the board of directors will receive an annual fixed fee of €40,000.
 - The chairperson of the audit committee will receive an annual fixed fee of €15,000.
 - The chairperson of the remuneration and nomination committee will receive an annual fixed fee of €15,000.
 - The other independent non-executive directors will receive an annual fixed fee of €25,000.

- The members of the audit committee and the remuneration and nomination committee (other than the chairpersons of such committees) will receive an annual fixed fee of €10,000.
- Share based awards: Each independent director will be entitled to receive Share options or warrants. Part of the 2018 Share options will be used for this purpose. See also Part 9 – (Management and corporate governance), section 9.2 (Corporate governance).

There are currently no plans to change the remuneration policy or remuneration of non-executive directors. However, the Issuer will continuously review the remuneration of non-executive directors against market practice.

The Issuer also intends to award Share-based incentives to the non-executive directors, upon advice of the remuneration and nomination committee. This is contrary to provision 7.7 of the Belgian Code on Corporate Governance that provides that non-executive directors should not be entitled to performance-related remuneration such as, amongst others, stock-related long-term incentive schemes. The Issuer believes that this provision of the Belgian Code on Corporate Governance is not appropriate and adapted to take into account the realities of companies in the biotech and life sciences industry that are still in a development phase.

The Issuer also reimburses reasonable out of pocket expenses of directors (including travel expenses) incurred in performing the activity of director. Without prejudice to the powers granted by law to the general shareholders' meeting, the board of directors sets and revises the rules for reimbursement of directors' business-related out of pocket expenses.

The directors who will also be a member of the executive management will be remunerated for the executive management mandate, but not for their director mandate.

(c) Executive management

(i) General

The remuneration of the chief executive officer and the other member of the executive management is based on recommendations made by the remuneration and nomination committee. The chief executive officer participates in the meetings of the remuneration and nomination committee in an advisory capacity each time the remuneration of another member of the executive management is being discussed.

The remuneration is determined by the board of directors. As an exception to the foregoing rule, Belgian law provides that the general shareholders' meeting must approve, as relevant:

- (i) in relation to the remuneration of members of the executive management and other executives, an exemption from the rule that Share-based awards can only vest after a period of at least three years as of the grant of the awards,
- (ii) in relation to the remuneration of members of the executive management and other executives, an exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years, and
- (iii) any service agreements to be entered into with members of the executive management and other executives (as the case may be) providing for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, eighteen months' remuneration).

Notwithstanding point (i) above, the Issuer's board of directors has been explicitly authorised in the Issuer's articles of association to deviate from this rule in connection with Share-based incentive plans, compensations, awards and issuances to employees, directors and service providers of the Issuer and/or its subsidiaries. The Issuer believes that this allows for more flexibility when structuring Share-based awards (see also section 9.5 (Remuneration and benefits), subsection (b) (Directors), subsection (i) (General) above).

In relation to point (ii) above, the Issuer takes the view that share options generally do not qualify as variable remuneration nor as annual remuneration for the purpose of the application of

the rule set out in point (ii) above. This has been approved by the Issuer's general shareholders' meeting with respect to Share-based awards that are outstanding on the date of this Prospectus (see also section 9.5 Remuneration and benefits), subsection (b) (Directors), subsection (i) (General) above). The general shareholders' meeting also approved that the variable remuneration of the members of the executive management can deviate from the principle described in point (ii) above.

An appropriate proportion of the remuneration package should be structured so as to link rewards to corporate and individual performance, thereby aligning the interest of the executive management with the interests of the Issuer and its shareholders. The chief executive officer will determine whether the targets for the variable remuneration of the members of the executive management, as set by the board of directors, are met. In the past, approval by the general shareholders' meeting has been obtained in relation to the Share plans (see section 9.6 (Description of Share plans) below).

The remuneration of the executive management was amended in view of the contemplated Offering and currently consists of the following main remuneration components:

- annual base salary/fee (fixed);
- participation in Share option plans; and
- a performance bonus.

The members of the executive management have a variable remuneration (i.e. remuneration linked to performance criteria) amounting to up to 50% of the base salary/fee for on target performance. The chief executive officer is entitled to pension benefits. The contributions by Sequana Medical to the pension scheme amount to 5% of the annual salary.

The members of the executive management are also reimbursed for certain costs and expenses made in the performance of their function.

There are currently no plans to change the remuneration policy or remuneration of members of the executive management. However, the Issuer will continuously review the remuneration of members of the executive management against market practice.

(ii) Remuneration and compensation in 2017

The following remuneration and compensation was paid to the chief executive officer:

	Chief executive officer (EUR)
Annual base salary	281,838.82
Pension/group insurance	14,165.54
Car lease/transport allowance	10,879.10
Medical plan	
Life insurance	1,139.72
Health insurance	3,504.43
Bonus plan	40,058.74
Total	351,586.35

There were no other members of the executive management other than the chief executive officer in 2017.

(iii) Payments upon termination

The employment agreement with the chief executive officer provides that the agreement can be terminated by either the Issuer or the chief executive officer subject to four months' notice. If within six months after the completion of an "Exit Transaction" the chief executive officer is (i) no longer the chief executive officer of the Issuer, or (ii) required to change his current work pattern (the events in (i) and (ii) shall be an "Enforced Redundancy"), the chief executive officer shall be entitled to resign and shall no longer be required to work or perform until the end of the four

months' notice period. The term "Exit Transaction" has been defined as (i) a transfer of more than 50% of the Issuer's shares or more than 50% of the voting rights to a third party or a group of persons exercising joint control in one or a series of related transactions to a propose acquirer who wishes to acquire a controlling majority of the shares, voting rights or assets pursuant to a *bona fide* purchase offer, (ii) the sale, lease, transfer, license or other disposition of all or substantially all of the Issuer's assets, or (iii) the consolidation or merger of the Issuer in which the Issuer is not the surviving entity or any other event pursuant to which the shareholders of the Issuer will have less than 50% plus one share of the voting power and/or of the shares of the surviving or acquiring company. In the event of an Enforced Redundancy, the chief executive officer will be entitled to a *pro rata* bonus. In the event of an Enforced Redundancy, the chief executive officer may also, at his sole discretion, elect to terminate the employment agreement with immediate effect and the Issuer shall then be required to make a payment in lieu of a notice equivalent to the basic salary only (but not the other benefits) to which the chief executive officer would have been entitled. The employment agreement also provides for a number of instances in which the agreement can be immediately terminated by the Issuer, including for cause.

The services agreement with the chief financial officer of the Issuer provides that it has been entered into for an unlimited term, and that it may be terminated in mutual agreement by the Issuer and the chief executive officer at any time. In case of termination of the agreement by Sequana Medical, the chief financial officer is entitled to three months' notice or to the payment of a quarter of the annual compensation in lieu of notice, or the payment of a *pro rata* part of one quarter of the fixed annual compensation in lieu of part of the notice. The agreement may be terminated by the chief executive officer subject to a notice period of three months. The agreement may be terminated by either the Issuer or the chief executive officer with immediate effect and without notice period (or, in case of termination by the Issuer, without notice period or indemnity) in case of wilful or serious breach or violation by a party of any of its covenants, obligations or duties under the agreement, or any wilful or serious neglect of or refusal to perform any of such covenants, obligations or duties.

(d) Indemnification and insurance of directors and executive management

As permitted by the Issuer's articles of association, the Issuer has entered into indemnification arrangements with the directors and relevant members of the executive management and has implemented directors' and officers' insurance coverage in order to cover liability they may incur in the exercise of their mandates.

9.6 Description of Share plans

The Issuer has currently outstanding Share options pursuant to two outstanding stock based incentive plans, namely (i) Share options that were granted to employees and consultants of the Issuer pursuant the Stock Option Plan Regulation 2011 (the "**2011 Share Options**"), and (ii) Share options that were granted in 2018 to members of the staff, as well as consultants of the Issuer (the "**Executive Share Options**"). In addition, subject to the closing of the Offering, the Issuer will create new Share options for directors, employees and other staff members of Sequana Medical (the "**2018 Share Options**"). There is no obligation for the holders of the 2011 Share Options and Executive Share Options to exercise the Share options prior to the closing of the Offering. All of the Share options will be subject to the Share Consolidation (see also Part 12 – (Share capital and articles of association), section 12.3 (Share capital and shares), subsection (c) (Share Consolidation upon the closing of the Offering)).

(a) Currently outstanding Share options

The number of 2011 Share Options and Executive Share Options that have been granted and remain outstanding on the date of this Prospectus can be summarised as follows:

Type of Share Option Plan	Number of Share Options	Issue date	Expiration date	Exercise price per Share option (CHF)	Type of Share issuable per option
2011 Share Options	752,500	1 September 2011	1 September 2021	CHF 0.10	1 common Share per Share option
Executive Share Options	111,177	28 September 2018	28 September 2028	CHF 10.48 / CHF 1.05 ⁽¹⁾	1 series E preferred Share per Share option
	<u>863,677</u>				

Notes:

(1) The 75,025 Executive Share Options held by the Chief Executive Officer have an exercise price of CHF 1.05 per option.

Subject to the closing of the Offering, the Share options will be adjusted as a result of the Share Consolidation (see also Part 12 – (Share capital and articles of association), section 12.3 (Share capital and shares), subsection (c) (Share Consolidation upon the closing of the Offering). As result hereof, after giving effect to the Share Consolidation (assuming an Offer Price at the midpoint of the Price Range):

- the 2011 Share Options will be diluted in such a manner, that each holder of 2011 Share Options will only be entitled to subscribe for one ordinary Share when exercising all of his or her Share options, or an aggregate of up to one ordinary Share for all of his or her outstanding 2011 Share Options; and
- each holder of an Executive Share Option will be entitled to subscribe to ca. 2.88 ordinary Shares when exercising one Executive Share Option, or an aggregate of up to 320,737 ordinary Shares for all outstanding Executive Share Options.

The exercise price of the respective Share options will not be amended as a result of the Share Consolidation. This entails that the 2011 Share Options will no longer have economic value.

(b) Terms of the 2011 Share Options

The key features of the 2011 Share Options can be summarised as follows:

- The 2011 Share Options could be granted to the employees, consultants and directors of the Issuer or its subsidiaries.
- The Share options are in registered form.
- Exercisable Share options are freely transferable. Share options granted to members of the board of directors, whether or not exercisable, can only be transferred after approval by the plan administrator.
- Each Share option can be exercised for one new common Share, before giving effect to the Share Consolidation.
- The Share options are granted for free, i.e. no consideration is due upon the grant of the Share options.
- Unless determined otherwise by the plan administrator, the Share options expire 10 years after the date of grant.
- Unless determined otherwise by the plan administrator, 25% of the Share options granted vest 12 months from the date of grant, after which the balance of Share options will vest in equal parts on the first calendar date of each quarter over the subsequent three years, such that 100% of the Share options are vested on the fourth anniversary of the date of grant. However, there is an accelerated vesting of the Share options in the event of (i) a transfer of securities possessing more than 50% of the total combined voting power of the Issuer's outstanding securities to a person or persons (other than purely financial investors) that are different from the persons holding those securities

immediately prior to such transfer without such person(s) having at least 50% of the total combined voting power prior to such transaction; and (ii) the sale, transfer or other disposition of all or substantially all of the Issuer's assets (together with (i), and for the purposes of this paragraph, a "**Change of Control Transaction**"). Notwithstanding the above, there is no accelerated vesting if (i) the Share options, in connection with the Change of Control Transaction, are either to be assumed by the successor corporation or parent thereof, or to be replaced with a similar option to purchase equity of the successor corporation or parent thereof, (ii) the Share options as to be replaced with a cash incentive program of the successor corporation which preserves the economic value applicable to the Share options under the 2011 SOP, or (iii) the Share options are repurchased by the Issuer or a third party designated by the Issuer for a cash consideration equivalent to the economic value applicable to the Share options under the 2011 SOP. Furthermore, the board of directors may decide upon an acceleration of the vesting in the event of an initial public offering of the Issuer, such as the present Offering, or in the event of any transaction that would result in a Change of Control Transaction.

- The Share options of beneficiaries that are no longer employed by or in function with Sequana Medical can lapse.
- The terms of the Share options are governed by the laws of Switzerland.

(c) Terms of the Executive Share Options

The key features of the Executive Share Options can be summarised as follows:

- The Executive Share Options could be granted to the employees, consultants and directors of the Issuer or its subsidiaries.
- The Share options are in registered form.
- The Executive Share Options are in principle non-transferable, and the holders of the Executive Share Options are not permitted to transfer the Executive Share Options nor the underlying Shares issuable upon exercise of the Executive Share Options for a period of two years as from the Offering, except as provided otherwise in the grant agreement or by the board of directors, and except in case of death of the beneficiary and in the context of inheritance planning by the beneficiary. In case of death, only Executive Share Options that have vested prior to the time of death can be transferred.
- Each Share option can be exercised for one new series E preferred Share, before giving effect to the Share Consolidation.
- The exercise price of the Executive Share Options shall be determined by the board of directors of the Issuer, taking into account applicable laws.
- Pursuant to Belgian company law, the Executive Share Options have a maximum term of 10 years as of their issuance.
- Unless determined otherwise in a separate sub-plan or share option agreement with the beneficiary, 50% of the Share options granted vest upon the closing of the Offering, after which the balance of Share options will vest in equal parts on the last calendar date of each of the thirty-six months following the month in which the closing of the Offering falls, it being understood that any Share options that have not vested on the third anniversary of the date of grant shall immediately vest on that date. However, unless determined otherwise in the grant agreement or by the board of directors, there is accelerated vesting of the 2018 Share Options in the event of a sale or other transfer of at least 50% of all of the then outstanding Shares of the Issuer, whereby an (internal) reorganisation in which the Shares of the Issuer would be transferred to a person in which the then existing shareholders of the Issuer were to hold shares or other interest in a similar proportion as the proportion held by each of them in the Issuer will not result in accelerated vesting. Notwithstanding the foregoing, the board of directors can at all times decide to accelerate the vesting of (all or part of) the 2018 Share Options and determine the conditions of such accelerated vesting.

- The Executive Share Options, whether vested or not, of beneficiaries of whom the employment agreement, consultancy agreement or directorship with Sequana Medical is terminated for serious cause, breach of contract or breach of director responsibilities, shall automatically and immediately lapse and become null and void.
- The terms of the Share options are governed by the laws of Belgium.

(d) Terms of the 2018 Share Options

Subject to the closing of the Offering, the Issuer will issue a number of 2018 Share Options for directors, employees and other staff members of Sequana Medical, equal to 10% of the number of outstanding Shares after the completion of the Offering (including upon exercise of the Increase Option and the Over-allotment Option).

The key features of the 2018 Share Options can be summarised as follows:

- The 2018 Share Options are warrants in registered form.
- The 2018 Share Options are in principle non-transferable, except as provided otherwise in the grant agreement or by the board of directors, and except in case of death of the beneficiary and in the context of inheritance planning by the beneficiary. In case of death, only 2018 Share Options that have vested prior to the time of death can be transferred.
- Each 2018 Share Option can be exercised for one new Share.
- The exercise price of the 2018 Share Options shall be determined by the board of directors of the Issuer, taking into account applicable laws.
- The 2018 Share Options are granted for free, i.e. no consideration is due upon the grant of the 2018 Share Options, unless the grant agreement provides otherwise.
- Pursuant to Belgian company law, the 2018 Share Options have a maximum term of 10 years as of their issuance.
- Unless stipulated otherwise in the grant agreement, one third of the 2018 Share Options granted to a beneficiary shall vest one year after the date of grant, the remaining two thirds will vest in 8 equal instalments, whereby on each first calendar day of the 8 quarters following first anniversary of the date of grant falls, 1/8 of the total number of unvested 2018 Share Options granted to a beneficiary shall vest. However, unless determined otherwise in the grant agreement or by the board of directors, there is accelerated vesting of the 2018 Share Options in the event of a sale or other transfer of at least 50% of all of the then outstanding Shares of the Issuer, whereby an (internal) reorganisation in which the Shares of the Issuer would be transferred to a person in which the then existing shareholders of the Issuer were to hold shares or other interest in a similar proportion as the proportion held by each of them in the Issuer will not result in accelerated vesting. Notwithstanding the foregoing, the board of directors can at all times decide to accelerate the vesting of (all or part of) the 2018 Share Options and determine the conditions of such accelerated vesting.
- The 2018 Share Options, whether vested or not, of beneficiaries of whom the employment agreement, consultancy agreement or directorship with Sequana Medical is terminated for serious cause, breach of contract or breach of director responsibilities, shall automatically and immediately lapse and become null and void.
- The 2018 Share Option Plan is governed by the laws of Belgium.

9.7 Other Information

(a) Conflicts of interest

Directors are expected to arrange their personal and business affairs so as to avoid conflicts of interest with the Issuer. Any director with a conflicting financial interest (as contemplated by article 523 of the Belgian Companies Code) on any matter before the board of directors must bring it to the attention of both the statutory auditor and fellow directors, and take no part in any deliberation or voting related thereto. The corporate governance charter contains the procedure for transactions between Sequana Medical and the directors which are not covered by the legal provisions on conflicts of interest. The corporate governance charter contains a similar procedure for transactions between Sequana Medical and members of the executive management.

To the knowledge of the Issuer, there are, on the date of this Prospectus, no potential conflicts of interests between any duties to the Issuer of the members of the board of directors upon closing of the Offering and members of the executive management upon closing of the Offering and their private interests and/or other duties.

There are no outstanding loans granted by the Issuer to any of the members of the board of directors upon closing of the Offering and members of the executive management upon closing of the Offering, nor are there any guarantees provided by the Issuer for the benefit of any of the members of the board of directors upon closing of the Offering and members of the executive management upon closing of the Offering.

None of the members of the board of directors upon closing of the Offering and members of the executive management upon closing of the Offering has a family relationship with any other of the members of the board of directors upon closing of the Offering and members of the executive management upon closing of the Offering.

(b) Dealing code

With a view to preventing market abuse (insider dealing and market manipulation), the board of directors has established a dealing code subject to and with effect as of the closing of the Offering. The dealing code describes the declaration and conduct obligations of directors, members of the executive management, certain other employees and certain other persons with respect to transactions in Shares and other financial instruments of the Issuer. The dealing code sets limits on carrying out transactions in Shares and other financial instruments of the Issuer, and allows dealing by the above mentioned persons only during certain windows. The dealing code is attached to the Issuer's corporate governance charter.

(c) Disclosure policy

As a company listed on Euronext Brussels, and with a view to ensuring investors in Shares have available all information necessary to ensure the transparency, integrity and good functioning of the market, the board of directors has established an information disclosure policy. The information disclosure policy is aimed at ensuring that inside information of which the Issuer is aware, is as soon as possible disclosed to the public. In addition, the information disclosure policy is aimed at ensuring information that is disclosed is fair, precise and sincere, and will enable the holders of Shares in the Issuer and the public to assess the influence of the information on the Issuer's position, business and results.

(d) Scientific advisory board

In connection with the Newton Convertible Loan, the Issuer agreed to establish a scientific advisory board that will advise the Issuer within the framework of its DSR program. The scientific advisory board will be composed of at least three members who will be selected on the basis of their international proven track record in the field. As long as the payment under the Newton Convertible Loan is due, or Newton is a shareholder of the Issuer, Newton will have the right to appoint one of its representatives as a member of the scientific advisory board. The Issuer agreed that, upon establishment of the scientific advisory board, Guy Heynen, senior clinical and regulatory partner at Newton shall be a member of the scientific advisory board. The scientific advisory board will convene at least two times per year to discuss amongst others the clinical and regulatory progress and plans of the DSR program. The members of the scientific advisory board and the terms of reference of the scientific advisory board will be determined after the closing of the Offering. The scientific advisory board will be an informal body that will provide advice to the Issuer. It will not be a part of the board of directors.

(e) Other

Each of the directors (based on the post-Offering composition of the board of directors) and each of the members of executive management, confirmed to the Issuer that neither he or she nor the company through which he or she acts (as the case may be) was subject to (i) any convictions in relation to fraudulent offenses during the past five years or (ii) any official public incrimination and/or sanctions of such members by statutory or regulatory authorities (including designated professional bodies), or disqualification by a court from acting as a member of the administrative, management or supervisory bodies of an issuer or from acting in the management or conduct of the affairs of any issuer during the past five years. In addition, each of them has confirmed to the

Issuer that neither he or she nor the company through which he or she acts (as the case may be) is subject to any bankruptcies, receiverships or liquidations of any entities in which he, she or it held any office, directorships, or partner or senior management positions during the past five years, other than the following. Diego Braguglia is currently acting as chairman and liquidator in the voluntary liquidations of Covalys Bioscience AG and Stemergie SA.

9.8 Other mandates

In the five years preceding the date of this Prospectus, the directors (based on the membership before and after the closing of the Offering) and members of the executive management have held the following directorships (apart from their functions within Sequana Medical) and memberships of administrative, management or supervisory bodies and/or partnerships:

Name	Current	Past
Rudy Dekeyser	Celyad SA Remynd NV Curetis AG Emblem GmbH Life Sciences Partners R.A.D. Life Sciences BVBA	N/A
Erik Amble	NeoMed Management Ltd JenaValve Technology GmbH CorFlow Therapeutics AG Axonics Modulation Technologies Inc.	Sonendo Inc. Index Pharmaceuticals AB
Diego Braguglia	VI Partners AG Stemergie Biotechnology SA (in liquidation) Amal Therapeutics SA Covalys Biosciences AG (in liquidation) DBA Partners Sàrl	N/A
Wim Ottevaere ⁽¹⁾	Woconsult BVBA Vlaams Instituut voor Biotechnologie	Ablynx NV ⁽¹⁾
Pierre Chauvineau	Creavo Medical Technologies Ltd Pathena	Boston Scientific Inc.
Ian Crosbie	N/A	GC Aesthetics Ltd Circassia Pharmaceuticals plc
Kirsten Van Bockstaele ⁽²⁾	Fin-2K BVBA	Fagron Inc

Notes:

(1) Acting as permanent representative of Woconsult BVBA.

(2) Acting through Fin-2K BVBA.

PART 10 – PRINCIPAL SHAREHOLDERS

The following table presents the undiluted ownership of the Shares immediately prior to the Share Consolidation and the closing of the Offering (including the conversion of the Bridge Loans in full); immediately after the closing of the Offering assuming a placement of the maximum number of New Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option, but without exercise of the Over-allotment Option) and after giving effect to the Share Consolidation; and immediately after the closing of the Offering assuming a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option) and after giving effect to the Share Consolidation. An assumption has been made that the existing shareholders will not participate in the Offering in addition to Subscription Commitments that were provided by the Participating Investors (see also Part 13 – (The Offering), section 13.2 (Pre-commitment by the Participating Investors)). The natural persons holding less than 1% of the outstanding Shares prior to the closing of the Offering have been presented under “other”.

Shareholder/Investor	Shares owned before the closing of the Offering and before the Share Consolidation on an undiluted basis ⁽¹⁾		Shares owned assuming full placement of the New Shares and the Share Consolidation ⁽²⁾		Shares owned assuming full placement of the Offered Shares and the Share Consolidation		Shares owned on a fully diluted basis assuming full placement of the Offered Shares and Share Consolidation ^(3,4)	
	(Number)	(%)	(Number)	(%)	(Number)	(%)	(Number)	(%)
NeoMed ⁽³⁾ ⁽⁴⁾	3,567,733 ⁽⁷⁾	35.93%	4,126,250	31.50%	4,126,250	30.22%	4,126,250	26.38%
LSP Health Economics Fund Management B.V. ⁽⁴⁾	1,077,148 ⁽⁸⁾	10.85%	1,424,456	10.88%	1,424,456	10.43%	1,424,456	9.11%
Venture Incubator AG ⁽⁴⁾	994,137 ⁽⁹⁾	10.01%	511,954	3.91%	511,954	3.75%	511,954	3.27%
VI Partners ⁽⁴⁾	22,874 ⁽²⁵⁾	0.23%	10,546	0.08%	10,546	0.08%	10,546	0.07%
Entrepreneurs Fund LP	869,159 ⁽¹⁰⁾	8.75%	4	0.00%	4	0.00%	4	0.00%
BioMedInvest II LP ⁽⁴⁾	816,227 ⁽¹¹⁾	8.22%	225,194	1.72%	225,194	1.65%	225,194	1.44%
Capricorn Health-tech Fund NV ⁽⁴⁾	803,186 ⁽¹²⁾	8.09%	237,039	1.81%	237,039	1.74%	237,039	1.52%
Brynjulf Gran Jensen	207,109 ⁽¹³⁾	2.09%	90,014	0.69%	90,014	0.66%	90,014	0.58%
Quest for Growth NV ⁽⁴⁾	204,366 ⁽¹⁴⁾	2.06%	360,168	2.75%	360,168	2.64%	360,168	2.30%
Nayereh Ladjevardi ⁽⁴⁾	192,511 ⁽¹⁵⁾	1.94%	306,207	2.34%	306,207	2.24%	306,207	1.96%
John A. Kazour	192,511 ⁽¹⁶⁾	1.94%	258,622	1.97%	258,622	1.89%	258,622	1.65%
BGJ Holding AS	158,927 ⁽¹⁷⁾	1.60%	68,664	0.52%	68,664	0.50%	68,664	0.44%
Johs. Hansen Rederi AS ⁽⁴⁾	144,626 ⁽¹⁸⁾	1.46%	120,207	0.92%	120,207	0.88%	120,207	0.77%
Schroeder & Co. Bank AG	84,520 ⁽¹⁹⁾	0.85%	5	0.00%	5	0.00%	5	0.00%
Zürcher Kantonalbank	73,030 ⁽²⁰⁾	0.74%	44,096	0.34%	44,096	0.32%	44,096	0.28%
N5 Investments AS ⁽⁴⁾	64,218 ⁽²¹⁾	0.65%	83,232	0.64%	83,232	0.61%	83,232	0.53%
Active Invest-Sweden AB ⁽⁴⁾	57,759 ⁽²²⁾	0.58%	125,207	0.96%	125,207	0.92%	125,207	0.80%
Hookipa AG ⁽⁴⁾	29,912 ⁽²³⁾	0.30%	19,419	0.15%	19,419	0.14%	19,419	0.12%
Codlam	24,556 ⁽²⁴⁾	0.25%	14,826	0.11%	14,826	0.11%	14,826	0.09%
TheraNova LLC	19,250 ⁽²⁶⁾	0.19%	1	0.00%	1	0.00%	1	0.00%
Art of Technology	10,665 ⁽²⁷⁾	0.11%	6,442	0.05%	6,442	0.05%	6,442	0.04%
IDEO	500 ⁽²⁸⁾	0.01%	1	0.00%	1	0.00%	1	0.00%
WS Investments	500 ⁽²⁸⁾	0.01%	1	0.00%	1	0.00%	1	0.00%
Bootstrap	0 ⁽²⁹⁾	0.00%	34,409	0.26%	34,409	0.25%	337,213	2.16%
PMV ⁽⁵⁾	0 ⁽²⁹⁾	0.00%	1,092,806	8.34%	1,092,806	8.00%	1,092,806	6.99%
FPIM ⁽⁵⁾	0 ⁽²⁹⁾	0.00%	1,091,793	8.34%	1,091,793	8.00%	1,091,793	6.98%
Cofipalux ⁽⁵⁾	0 ⁽²⁹⁾	0.00%	272,571	2.08%	272,571	2.00%	272,571	1.74%
Newton Biocapital ⁽⁵⁾	0 ⁽²⁹⁾	0.00%	1,089,076	8.32%	1,089,076	7.98%	1,089,076	6.96%
Victor Röhm ⁽⁵⁾	0 ⁽³⁰⁾	0.00%	47,533	0.36%	47,533	0.35%	47,533	0.30%
Other ⁽⁶⁾	315,361 ⁽³¹⁾	3.18%	95,213	0.73%	95,213	0.70%	1,781,494	11.39%
Free float	0 ⁽³²⁾	0.00%	1,341,238	10.24%	1,899,326	13.91%	1,899,326	12.14%
Total	9,930,784⁽³³⁾	100	13,097,194	100.00%	13,655,282	100.00%	15,644,367	100.00%

Notes:

- (1) The number of Shares reflects the aggregate number of Shares held by the relevant shareholder before giving effect to the Share Consolidation, and refers to common Shares as well as preferred Shares.
- (2) For the purpose of the Share Consolidation, it is assumed that the Offer Price is at the midpoint of the Price Range (i.e. at €8.75). See also Part 12 – (Share capital and articles of association), section 12.3 (Shares capital and Shares), subsection (c) (Share Consolidation upon the closing of the Offering).

- (3) The shareholders NeoMed IV Extension L.P. and NeoMed Innovation V L.P. are together referred to as "NeoMed".
- (4) These shareholders are Participating Investors.
- (5) These investors are Participating Investors.
- (6) Including Participating Investors.
- (7) Of which 1,003,695 common Shares, 356,893 series A preferred Shares, 699,863 series B preferred Shares, 400,412 series C preferred Shares, 0 series D preferred Shares and 1,106,870 series E preferred Shares.
- (8) Of which 390,610 are common Shares, 0 series A preferred Shares, 0 series B preferred Shares, 304,858 series C preferred Shares, 0 series D preferred Shares and 381,680 series E preferred Shares.
- (9) Of which 312,485 are common Shares, 111,317 series A preferred Shares, 245,798 series B preferred Shares, 198,764 series C preferred Shares, 30,353 series D preferred Shares and 95,420 series E preferred Shares.
- (10) Of which 281,235 are common Shares, 0 series A preferred Shares, 315,974 series B preferred Shares, 202,241 series C preferred Shares, 69,709 series D preferred Shares and 0 series E preferred Shares.
- (11) Of which 256,437 are common Shares, 0 series A preferred Shares, 315,974 series B preferred Shares, 177,443 series C preferred Shares, 66,373 series D preferred Shares and 0 series E preferred Shares.
- (12) Of which 240,289 are common Shares, 0 series A preferred Shares, 315,974 series B preferred Shares, 161,295 series C preferred Shares, 23,260 series D preferred Shares and 62,368 series E preferred Shares.
- (13) Of which 63,807 are common Shares, 4,428 series A preferred Shares, 69,962 series B preferred Shares, 37,712 series C preferred Shares, 0 series D preferred Shares and 31,200 series E preferred Shares.
- (14) Of which 68,966 are common Shares, 0 series A preferred Shares, 0 series B preferred Shares, 40,248 series C preferred Shares, 0 series D preferred Shares and 95,152 series E preferred Shares.
- (15) Of which 68,965 are common Shares, 0 series A preferred Shares, 0 series B preferred Shares, 33,900 series C preferred Shares, 0 series D preferred Shares and 89,645 series E preferred Shares.
- (16) Of which 68,965 are common Shares, 0 series A preferred Shares, 0 series B preferred Shares, 33,900 series C preferred Shares, 0 series D preferred Shares and 89,645 series E preferred Shares.
- (17) Of which 50,131 are common Shares, 0 series A preferred Shares, 58,116 series B preferred Shares, 26,880 series C preferred Shares, 0 series D preferred Shares and 23,800 series E preferred Shares.
- (18) Of which 35,767 are common Shares, 17,041 series A preferred Shares, 48,771 series B preferred Shares, 12,781 series C preferred Shares, 0 series D preferred Shares and 30,266 series E preferred Shares.
- (19) Of which 29,310 are common Shares, 17,706 series A preferred Shares, 12,021 series B preferred Shares, 19,898 series C preferred Shares, 5,585 series D preferred Shares and 0 series E preferred Shares.
- (20) Of which 14,592 are common Shares, 29,613 series A preferred Shares, 13,541 series B preferred Shares, 0 series C preferred Shares, 0 series D preferred Shares and 15,284 series E preferred Shares.
- (21) Of which 21,696 are common Shares, 0 series A preferred Shares, 0 series B preferred Shares, 20,194 series C preferred Shares, 0 series D preferred Shares and 22,328 series E preferred Shares.
- (22) Of which 20,689 are common Shares, 0 series A preferred Shares, 0 series B preferred Shares, 10,164 series C preferred Shares, 0 series D preferred Shares and 26,905 series E preferred Shares.
- (23) Of which 9,140 are common Shares, 0 series A preferred Shares, 8,976 series B preferred Shares, 5,536 series C preferred Shares, 0 series D preferred Shares and 6,260 series E preferred Shares.
- (24) Of which 6,901 are common Shares, 0 series A preferred Shares, 8,976 series B preferred Shares, 3,541 series C preferred Shares, 0 series D preferred Shares and 5,138 series E preferred Shares.
- (25) Of which 6,901 are common Shares, 0 series A preferred Shares, 8,976 series B preferred Shares, 4,657 series C preferred Shares, 566 series D preferred Shares and 1,774 series E preferred Shares.
- (26) Of which 19,250 are common Shares, 0 series A preferred Shares, 0 series B preferred Shares, 0 series C preferred Shares, 0 series D preferred Shares and 0 series E preferred Shares.
- (27) Of which 3,267 are common Shares, 0 series A preferred Shares, 4,509 series B preferred Shares, 657 series C preferred Shares, 0 series D preferred Shares and 2,232 series E preferred Shares.
- (28) Which are all common Shares.
- (29) This company does not own any Shares before the closing of the Offering.
- (30) This individual does not own any Shares before the closing of the Offering.
- (31) Of which 220,815 are common Shares, 6,684 series A preferred Shares, 39,684 series B preferred Shares, 29,255 series C preferred Shares, 5,655 series D preferred Shares and 13,268 series E preferred Shares.
- (32) There is no free float before the closing of the Offering.
- (33) Of which 3,194,913 are common Shares, 543,682 series A preferred Shares, 2,167,115 series B preferred Shares, 1,724,337 series C preferred Shares, 201,501 series D preferred Shares and 2,099,236 series E preferred Shares.
- (34) Assumes the exercise in full of existing Share options, including the 2018 Share Options to be created at the time of the closing of the Offering.

All of the Shares have the same voting rights. For further details of the Issuer's share capital as well as outstanding Share options that can be exercised into Shares and the Convertible Loans (as defined below), see Part 12 – (Share capital and articles of association).

On 1 October 2018, the Issuer and certain of the existing shareholders of the Issuer entered into the Shareholders' Agreement, which sets out certain arrangements regarding the operation of, the management of and the shareholding in the Issuer, and which is an amendment and restatement of a previous shareholders' agreement that had been entered into prior to the Belgian Seat Transfer. The Shareholders' Agreement will be terminated effective as of the closing of the Offering. The Issuer is not aware of shareholders entering into a new shareholders' agreement or agreeing to act in concert following the closing of the Offering (other than certain lock up arrangements as described in Part 14 – (Plan of distribution), section 14.3 (Lock up)).

PART 11 – RELATED PARTY TRANSACTIONS

As part of its business, Sequana Medical has entered into several transactions with related parties, including its principal shareholders. The following is a summary of Sequana Medical's most significant transactions with related parties for the period covered by the historical financial information and as of the date hereof. For further detail on related party transactions, see note 8 to the Annual Financial Statements and note 15 to the Interim Financial Statements.

- Currently, most of the existing shareholders of the Issuer and the Issuer itself have entered into the Shareholders' Agreement, containing, amongst others, terms regarding the Issuer's business and governance, as well as pre-emptive rights and transfer restrictions regarding the Shares. The Shareholders' Agreement was entered into on 1 October 2018, and is an amendment and restatement of a previous shareholders' agreement that had been entered into prior to the Belgian Seat Transfer. The Shareholders' Agreement will be terminated effective as of the closing of the Offering. The Issuer is not aware of shareholders entering into a new shareholders' agreement or agreeing to act in concert following the closing of the Offering (other than certain lock up arrangements as described in Part 14 – (Plan of distribution), section 14.3 (Lock up)).
- The Issuer and certain of its shareholders have entered into a convertible loan agreement, dated 16 February 2018, pursuant to which shareholders provided a non-interest-bearing loan to the Issuer in an aggregate principal amount of CHF 1,996,742.00 (the "**February 2018 Convertible Loan**"). The loan was initially granted until 31 December 2018. The loan can be extended if lenders representing more than 50% of the principal amount of the loan, agree with the extension. On 20 December 2018, the loan was extended until 15 February 2019. The loan must be converted in a number of circumstances, including at the time of an initial public offering. The loan can be converted at any time prior to maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share if lenders representing more than 50% of the principal amount of the loan agree with the conversion.
- The Issuer and PMV have entered into a convertible loan agreement, dated 6 June 2018, pursuant to which PMV granted a loan to the Issuer in a principal amount of €1,680,000, which loan was extended to a principal amount of €2,000,000 pursuant to an addendum dated 23 October 2018 (the "**PMV Convertible Loan**"). The loan was initially granted until 31 December 2018, and on 20 December 2018 the loan was extended until 15 February 2019. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. PMV is entitled to convert the loan and the accrued interest at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. The PMV Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.
- The Issuer and Federale Participatie- en Investeringsmaatschappij NV ("**FPIM**") have entered into a convertible loan agreement, dated 27 July 2018, pursuant to which FPIM granted a loan to the Issuer in a principal amount of €2,000,000 (the "**FPIM Convertible Loan**"). The loan was initially granted until 31 December 2018, and on 20 December 2018 the loan was extended until 15 February 2019. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. FPIM is entitled to convert the loan and the accrued interest at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. In the event of an Offering, the loan and accrued interest are also subject to a mandatory conversion into share capital of the Issuer in consideration of new series E preferred Shares at CHF 10.48 per Share. The FPIM Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.
- The Issuer and Cofipalux Invest SA ("**Cofipalux**") have entered into a convertible loan agreement, dated 30 August 2018, pursuant to which Cofipalux granted a loan to the Issuer in a principal amount of €500,000 (the "**Cofipalux Convertible Loan**"). The loan was initially granted until 31 December 2018, and on 20 December 2018 the loan was extended until 15 February 2019. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. Cofipalux is entitled to convert the loan and the

accrued interest at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. In the event of an Offering, the loan and accrued interest are also subject to a mandatory conversion into share capital of the Issuer in consideration of new series E preferred Shares at CHF 10.48 per Share. The Cofipalux Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.

- The Issuer and Newton have entered into a convertible loan agreement, dated 11 October 2018, pursuant to which Newton granted a loan to the Issuer in a principal amount of €2,000,000 (the “**Newton Convertible Loan**”). The loan was initially granted until 31 December 2018, and on 20 December 2018 the loan was extended until 15 February 2019. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. Newton is entitled to convert the loan and the accrued interest at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. In the event of an Offering, the loan and accrued interest are also subject to a mandatory conversion into share capital of the Issuer in consideration of new series E preferred Shares at CHF 10.48 per Share. The Newton Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.
- The Issuer entered into three additional non-interest bearing convertible loan agreements (i) two of which under terms similar to the February 2018 Convertible Loan Agreement with, respectively one individual shareholder and BioMedInvest LP (“**BioMed**”), dated, respectively 25 October 2018 and 30 October 2018, pursuant to which the individual shareholder granted a loan to the Issuer in a principal amount of CHF 52,400 and BioMed granted a loan to the Issuer in a principal amount of CHF 198,000 (respectively, the “**Individual 1 Convertible Loan**” and the “**BioMed Convertible Loan**”), and (ii) one under terms similar to the Newton Convertible Loan Agreement with an individual dated 2 November 2018 pursuant to which such individual granted a loan to the Issuer in a principal amount of CHF 100,000 (the “**Individual 2 Convertible Loan**”, and together with the February 2018 Convertible Loan, the PMV Convertible Loan, the FPIM Convertible Loan, and the Cofipalux Convertible Loan, the Newton Convertible Loan, the Individual 1 Convertible Loan, and the BioMed Convertible Loan the “**Convertible Loans**”). The loans were initially granted until 31 December 2018, and on 20 December 2018 they were extended until 15 February 2019.
- The Convertible Loans were amended and completed pursuant to several pre-IPO investment commitment agreements, dated 2 November 2018, by and between the Issuer and, respectively, the lenders under the Convertible Loans. The pre-IPO investment commitment agreements were amended and restated on 20 December 2018 (such amended and restated agreements, the “**Pre-IPO Investment Commitment Agreements**”). Pursuant to the Pre-IPO Investment Commitment Agreements, the lenders under the respective Convertible Loans (the “**Participating Investors**”) agreed to convert their Convertible Loans for new series E preferred Shares at the agreed conversion rate of CHF 10.48 per Share immediately prior to the closing of the Offering, and that the new Shares shall be converted and consolidated immediately thereafter into ordinary Shares pursuant to the Share Consolidation. As an exception, payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91 will be converted into New Shares at the Offer Price in connection with the Offering. The conversions will be implemented by means of a contribution in kind of the outstanding payable amounts under the Convertible Loans. The Pre-IPO Investment Commitment Agreements with the lenders that are an existing shareholder of the Issuer also provide that these lenders will convert a number of their Shares other than series E preferred Shares into series E preferred Shares at a ratio of one existing Share per new series E preferred Share subscribed for through the conversion of their Convertible Loan. In addition, the Participating Investors, who are all lenders pursuant to the Convertible Loans, irrevocably committed pursuant to the respective Pre-IPO Investment Commitment Agreements to subscribe for an aggregate amount of €20.5 million in the Offering at the Offer Price, subject to the closing of the Offering (the “**Subscription Commitments**”). A portion of this amount has already been made available to the Issuer on 20 December 2018 by all of the respective Participating Investors (except

three of them who are also each a lender under the February 2018 Convertible Loan) in the form of bridge loans for an aggregate principal amount of €1,024,238.77 (the “**Bridge Loans**”). The Bridge Loans were granted until 15 February 2019, and bear an interest of 8% per annum, payable at maturity. Pursuant to the Pre-IPO Investment Commitment Agreements, the relevant Participating Investors agreed to convert the principal amount and accrued interest of the Bridge Loans into New Shares at the Offer Price upon the closing of the Offering. The conversion will be implemented by means of a contribution in kind of the outstanding payable amounts under the Bridge Loans. The remaining portion of the Subscription Commitments (not including the amounts due pursuant to the Bridge Loans and the payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) will be subscribed for in cash upon the closing of the Offering. In the event of over-subscription of the Offering, the Subscription Commitments in cash for an amount of ca. €12.5 million (not including the amounts due pursuant to the Bridge Loans and the payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) can be reduced in line with the allocation principles that will apply to the other investors that will subscribe in the Offering (see also Part 13 – (The Offering), section 13.10 (Allocation)), whereas the Subscription Commitments for the remaining amount (including the amounts due pursuant to the Bridge Loans and the payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) shall not be reduced but be allocated entirely.

- In 2017, due to the passing of the former CEO, the Issuer and its subsidiaries signed a settlement agreement with the wife of the former CEO, in relation to among others the outstanding payment of wages, severance and bonuses for a total amount of USD 308,446. In addition, the Issuer and its subsidiaries signed a stock option and share purchase agreement with the wife of the former CEO to acquire his 117,569 Shares and 90,845 Share options by offsetting outstanding payables by the Issuer in the amount of CHF 226,161 (€211,000 as of December 31, 2016).

Other than these agreements, Sequana Medical has not undertaken any related party transactions except the compensation paid to its board of directors and executive management (see also Part 9 – (Management and corporate governance), section 9.5 (Remuneration and benefits), subsection (b) (Directors) and subsection (c) (Executive management)). See also Part 10 – (Principal shareholders).

PART 12 – SHARE CAPITAL AND ARTICLES OF ASSOCIATION

12.1 General

The Issuer has the legal form of a limited liability company (naamloze vennootschap/société anonyme) organised under the laws of Belgium. The Issuer was established as a limited liability company (*Aktiengesellschaft/société anonyme*) organised under the laws of Switzerland in 2006, and transferred its registered office, without liquidation or dissolution, from Switzerland to Belgium in 2018. As a result of the Belgian Seat Transfer, the Issuer became a limited liability company organised under the laws of Belgium.

Pursuant to the provisions of the Belgian Companies Code, the liability of the shareholders of the Issuer is in principle limited to the amount of their respective committed contribution to the capital of the Issuer. The Issuer is registered with the legal entities register (Ghent) under enterprise number 0707.821.866. The Issuer's registered office is located at AA Tower, Technologiepark 122, 9052 Ghent, Belgium.

This section summarises information relating to the Issuer's share capital, the articles of association, certain material rights of its shareholders under Belgian law and the Issuer's articles of association. The contents of this section are derived primarily from the Issuer's articles of association, which were adopted by the general shareholders' meeting of 18 January 2019, and which will enter into force subject to and effective as of the closing of the Offering.

The description provided hereafter is only a summary and does not purport to provide a complete overview of the articles of association or the relevant provisions of Belgian law. Neither should it be considered as legal advice regarding these matters.

12.2 Corporate purpose

The corporate purpose of the Issuer is set forth in article 3 of its articles of association. The corporate purpose reads (in translation from the Dutch original text) as follows:

"The company's corporate purpose is to carry out the following activities, for its own account or for third parties, internally as well as abroad:

- the design, research, development, production, manufacturing, marketing, sale, distribution, exploitation and commercialisation of (a) medical devices for the transportation of liquids inside the human body and (b) other medical devices, products, expertise, advice, techniques, drugs, treatments and services in the pharmaceutical, medical, biological and chemical field directly or indirectly in relation to the health or conditions of humans and animals, whether of a diagnostic, therapeutic or other nature; and
- the acquisition, purchase, sale, transfer, exploitation, operation, administration, management, giving of licenses, taking of licenses of all patents, trademarks, service marks, designs, copyrights, corporate names, trade names, logos, know-how, trade secrets, proprietary or confidential information, inventions, discoveries, processes, formulae, compositions, works, scientific, technical, engineering and marketing data, customer lists, and all other intellectual property rights and all other rights and forms of protection of a similar nature or having equivalent effect, whether registered or unregistered, and including registrations and applications therefor.

In addition, the company may, directly and indirectly, for its own account or for third parties, internally as well as abroad:

- carry out all industrial, commercial, movable, real estate, or financial transactions likely to directly or indirectly support or contribute to its activities or business;
- take an interest or participation, by any means or via a merger, in any business, enterprise, institution, association, undertaking or company, whether already existing or still to be incorporated, without any distinction, both internally and abroad, having an identical, analogous, similar or related corporate purpose or which is likely to promote the development of its activities or business;
- manage, increase the value of, and liquidate such participations or interests;
- participate in the control, management, administration, supervision and liquidation of any such business, enterprise, institution, association, undertaking or company;

- establish subsidiaries, operating seats, branch offices and agencies;
- provide guarantees, act as agent or representative, and grant advances, credit facilities or securities, including mortgages, to any business, enterprise, institution, association, undertaking, company or person.

Without prejudice to the foregoing, the company can carry out all acts and transactions that in any way whatsoever can contribute to the realisation of its corporate purpose.”

12.3 Share capital and Shares

(a) Current share capital and Shares

On the date of this Prospectus, the share capital of the Issuer amounts to €887,977.47 and is fully paid-up. It is represented by 9,930,784 Shares, of which 3,194,913 common Shares and 6,735,871 preferred Shares, each without nominal value and each representing the same *pro rata* fraction of the share capital. The 6,735,871 preferred Shares consist of 543,682 series A preferred Shares, 2,167,115 series B preferred Shares, 1,724,337 series C preferred Shares, 201,501 series D preferred Shares, and 2,099,236 series E preferred Shares. All Shares are fully paid up, and represent the same fraction of the Issuer's share capital. In addition, there are a number of outstanding Convertible Loans that are convertible into series E preferred Shares, a number of Bridge Loans that will be converted into New Shares upon the closing of the Offering, and a number of outstanding Share options that are exercisable for common Shares and series E preferred Shares (see also section 12.4 (Outstanding Convertible Loans and Bridge Loans) and section 12.5 (Outstanding Share options).

(b) Changes in the share capital since 2015

The changes to the Issuer's actual share capital since 1 January 2015 can be summarised as follows:

Date	Transaction	Increase (reduction) of share capital (CHF)	Number of Shares issued	Class of Shares issued	Issue price per Share (CHF, rounded) / Nominal value per Share	Resulting share capital (CHF)	Existing Shares
2 October 2015	Capital increase	620,715	620,715	Series C preferred Shares	14.50 / 1.00	5,196,899	5,196,899
25 April 2016	Conversion of selected preferred shares into common shares ⁽¹⁾	—	—	—	— / 1.00	5,196,899	5,196,899
25 April 2016	Capital increase ⁽²⁾	112,725	112,725	Common Shares	— / 1.00	5,309,624	5,309,624
25 April 2016	Capital increase	780,432	780,432	Series D preferred Shares ⁽³⁾	10.48 / 1.00	6,090,056	6,090,056
8 August 2016	Capital reduction ⁽⁴⁾	5,481,050.40	—	—	— / 0.10	609,005.60	6,090,056
8 August 2016	Capital increase	289,021.10	2,890,211	Common Shares	0.10 / 0.10	898,026.70	8,980,267
16 March 2017	Capital increase	34,636.50	346,365	Series E preferred Shares	10.48 / 0.10	932,663.20	9,326,632
9 November 2017	Capital increase ⁽⁵⁾	34,636.50 and 35,688.80	346,365 and 356,888	Series E preferred Shares	Exercise prices / 0.10	1,002,988.50	10,029,885
9 July 2018	Capital increase	1,846.80	18,468	Common Shares	0.10 / 0.10	1,004,835.30	10,048,353
1 October 2018	Cancellation of treasury stock	—	(117,569) ⁽⁶⁾	Common Shares and series B, C and D preferred Shares	—	1,004,835.30 ⁽⁷⁾	9,930,784

Notes:

- (1) On 25 April 2016, the shareholders' meeting decided to convert 2,169 registered series A preferred Shares, 34,341 registered series B preferred Shares and 11,072 registered series C preferred Shares into registered common Shares.
- (2) During the period from March 2012 to April 2016, options and conversion rights have been exercised based on conditional capital. Therefore, the capital was increased in the amount of CHF 112,725.
- (3) A new category of registered preferred shares was created (series D preferred Shares).
- (4) On 25 April 2016, the shareholders' meeting decided to reduce the share capital in the amount of CHF 5,481,050.40 from CHF 6,090,056 to CHF 609,005.60. On 8 August 2016, the reduction of the capital was effected by reducing the nominal value per

share from CHF 1 to CHF 0.10 and the reduction amount was used for offsetting against loss carry-forwards (“Verwendung des Herabsetzungsbetrages zur Verrechnung mit Verlustvorträgen”).

- (5) During the period from 8 March 2017 to 17 October 2017, options and conversion rights were exercised based on conditional capital in the articles of association. Therefore, the board of directors increased the capital on 9 November 2017 based on Article 5e articles of association in the amount of CHF 34,636.50 and based on Article 5f articles of association in the amount of CHF 35,688.80. Therefore, the share capital was increased in the amount of CHF 70,325.30 in total.
- (6) On 1 October 2018, the shareholders’ meeting decided to cancel all treasury stock held by the Issuer, i.e. 107,196 common Shares, 4,773 series B preferred Shares, 1,600 series C preferred Shares, and 4,000 series D preferred Shares, without cancellation of share capital.
- (7) On 1 October 2018, the shareholders’ meeting decided to convert the share capital from CHF 1,004,835.30 into €887,977.47.

(c) Share Consolidation upon the closing of the Offering

Certain of the currently outstanding preferred Shares benefit from special governance rights (such as in relation to the appointment of candidate directors and special majorities for decisions by the board of directors and the general shareholders’ meeting). In addition, all of the preferred Shares benefit from a specific priority in case of Share transfers and in case of certain liquidity events such as a bankruptcy, liquidation or winding-up of the Issuer, a sale of the Issuer, a sale or divestment of all or substantially all of the assets of the Issuer, or a merger or consolidation of the Issuer. The preference will also be triggered upon closing of the Offering and will result in a conversion and consolidation of the outstanding Shares into a new number of outstanding Shares reflecting the priority among the current shareholders of the Issuer as a result of the Offering (not including the Offered Shares to be issued upon the closing of the Offering (including pursuant to the conversion of the Bridge Loans) and the exercise of the Over-allotment Option).

In particular, subject to and with effect as of the closing of Offering, the respective outstanding Shares will per series of Shares be converted and consolidated in a greater or smaller number of Shares that will reflect a value that each holder would have received if the Issuer had been sold in a sale at a valuation reflecting the Offer Price that will be determined in connection with the Offering. The preference will be applied in such a manner that:

- firstly, the series E preferred Shares will have a priority for a value of up to three times CHF 10.48 per series E preferred Share;
- secondly, the series D preferred Shares will have a priority for a value of up to the aggregate subscription price paid for the series D preferred Shares;
- thirdly, the series C preferred Shares will have a priority for a value of up to the aggregate subscription price paid for the series C preferred Shares;
- fourthly, the series B preferred Shares will have a priority for a value of up to half of the aggregate subscription price paid for the series B preferred Shares;
- fifthly, the series A preferred Shares will have a priority for a value of up to half of the aggregate subscription price paid for the series A preferred Shares; and
- finally, any remaining value would accrue to the common Shares and preferred Shares on a *pro rata* basis.

The Share Consolidation will be combined with a new renumbering of the outstanding Shares. The Share Consolidation will apply to all of the existing Shares of the Issuer that will be outstanding immediately prior to the issuance of the New Shares to be issued in connection with the Offering. The Share Consolidation will therefore also apply to the series E preferred Shares that will be issued upon conversion of the Convertible Loans and the series E preferred Shares into which certain existing Shares of the Participating Investors will be converted subject to the closing of the Offering (see further in section 12.4 (Outstanding Convertible Loans and Bridge Loans)).

Subject to and with effect as of the closing of the Offering and after having given effect to the aforementioned priority, all of currently existing Shares will be converted into ordinary Shares in such a manner that each Share shall be of the same type and class as the Offered Shares.

The conversion and consolidation of Shares will also be effected with respect to the outstanding Share options.

The special governance rights and priority rights as described above will therefore no longer apply as from the closing of the Offering.

The effect of the Share Consolidation consisting of the consolidation as a result of the aforementioned priority and conversion into ordinary Shares on the currently outstanding Shares

has been illustrated in the tables below, based on an Offer Price equal to €8.75 (being the midpoint of the Price Range).

Before the Share Consolidation

Type of Share	Before the Share Consolidation			
	On an undiluted basis ⁽¹⁾		On a fully diluted basis ⁽²⁾	
	Number of Shares	% of total Shares	Number of Shares	% of total Shares
Common shares.....	3,194,913	32.17%	3,947,413	33.35%
Series A preferred shares.....	543,682	5.47%	543,646	4.59%
Series B preferred shares.....	2,167,115	21.82%	2,161,859	18.26%
Series C preferred shares.....	1,724,337	17.36%	1,574,537	13.30%
Series D preferred shares.....	201,501	2.03%	142,869	1.21%
Series E preferred shares.....	2,099,236	21.14%	3,466,297	29.28%
Total	9,930,784	100.00%	11,836,621	100.00%

Notes:

- (1) It is assumed that (a) none of the outstanding Convertible Loans have been converted into new Shares, (b) none of the Shares other than series E preferred Shares of the Participating Investors have been converted into series E preferred Shares, and (c) none of the outstanding Share options have been exercised.
- (2) It is assumed that (a) all of the outstanding Convertible Loans have been converted into new Shares on the contemplated Closing Date for the Offering (other than payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91), (b) some of the Shares other than series E preferred Shares of the Participating Investors have been converted into series E preferred Shares and (c) all of the outstanding Share options have been exercised (consisting of the 2011 Share Options, the Executive Share Options, and the Bootstrap Warrant).

Share Consolidation based on an Offer Price of €8.75⁽¹⁾

Origin of Shares	On an undiluted basis, assuming full placement of the New Shares ⁽²⁾		On an undiluted basis, assuming full placement of the Offered Shares ⁽³⁾		On a fully diluted basis ⁽⁴⁾	
	Number of ordinary Shares	% of total ordinary Shares	Number of ordinary Shares	% of total of ordinary Shares	Number of ordinary Shares	% of total of ordinary Shares
Common shares.....	59	0.00%	59	0.00%	75	0.00%
Series A preferred shares ...	9	0.00%	9	0.00%	9	0.00%
Series B preferred shares ...	26	0.00%	26	0.00%	26	0.00%
Series C preferred shares ...	34	0.00%	34	0.00%	34	0.00%
Series D preferred shares ...	20	0.00%	20	0.00%	20	0.00%
Series E preferred shares ⁽⁵⁾	6,672,711	50.95%	6,672,711	48.87%	7,296,252	46.64%
Sub-total	6,672,859	50.95%	6,672,859	48.87%	7,296,416	46.64%
Conversion of Convertible Loans.....	2,703,747	20.64%	2,703,747	19.80%	2,703,747	17.28%
New Shares.....	3,720,588	28.41%	3,720,588	27.25%	3,720,588	23.78%
Exercise of Over-allotment Option.....	0	0.00%	558,088	4.09%	558,088	3.57%
Exercise of new 2018 Share Options.....	0	0.00%	0	0.00%	1,365,528	8.73%
Sub-total	6,242,335	49.05%	6,982,423	51.13%	8,347,951	53.36%
Total	13,097,194	100.00%	13,655,282	100.00%	15,644,367	100.00%

Notes:

- (1) The Offer Price of €8.75 is the midpoint of the Price Range.

- (2) It is assumed that (a) all of the 3,235,294 New Shares are placed in the Offering (including as a result of the exercise in full of the Increase Option), (b) all of the outstanding Convertible Loans have been converted into new Shares, and (c) none of the outstanding Share Options have been exercised.
- (3) It is assumed that (a) all of the 4,278,676 Offered Shares are placed in the Offering (including as a result of the exercise in full of the Increase Option and the Over-allotment Option), (b) all of the outstanding Convertible Loans have been converted into new Shares, and (c) none of the outstanding Share Options have been exercised.
- (4) It is assumed that (a) all of the 4,278,676 Offered Shares are placed in the Offering (including as a result of the exercise in full of the Increase Option and the Over-allotment Option), (b) all of the outstanding Convertible Loans have been converted into new Shares, and (c) all of the outstanding Share options have been exercised (consisting of the 2011 Share Options, the Executive Share Options, and the Bootstrap Warrant). This also takes into account the exercise of new 2018 Share Options, which will only be created upon the closing of the Offering (see also section 12.5 (Outstanding share options)).
- (5) Existing shareholders that have provided a Subscription Commitments to subscribe in the Offering, have the ability to convert a portion of their Shares other than series E preferred Shares into series E preferred shares that will benefit from the priority in the Share Consolidation upon the closing of the Offering (see also Part 12 – (Share capital and articles of association), section 12.4 (Outstanding Convertible Loans and Bridge Loans).

The aforementioned illustration reflects that as a result of the Share Consolidation, the series E preferred Shares will be converted into ordinary Shares at a ratio of ca. 2.88 per existing series E preferred Share and that the series D preferred Shares, series C preferred Shares, series B preferred Shares, series A preferred Shares and common Shares will be converted into new ordinary Shares at a ratio of ca. 0.00 (rounded) per existing series B preferred Share, series A preferred Share and common Share, respectively.

(d) Capital increase and other changes to the Shares and the Share Capital upon closing of the Offering

Subject to and with effect as of the closing of the Offering, the Issuer's share capital and outstanding Shares will change and be amended as follows:

Firstly, the Issuer's share capital will be increased as a result of the conversion of outstanding Convertible Loans (with the exception of certain payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91 that will be converted into New Shares at the Offer Price in connection with the Offering), with the issuance of new series E preferred shares. The conversion will be implemented by means of a contribution in kind of the outstanding payable amounts under the Convertible Loans. For further information in relation to the conversion of the Convertible Loans, see section 12.4 (Outstanding Convertible Loans and Bridge Loans).

Secondly, the lenders that are a party to the February 2018 Convertible Loan Agreement will convert a number of their Shares other than series E preferred Shares into series E preferred Shares at a ratio of one existing Share per new series E preferred Share subscribed for through the conversion of the February 2018 Convertible Loan Agreement. For further information in relation to the conversion of Shares by the lenders to the February 2018 Convertible Loan Agreement, see section 12.4 (Outstanding Convertible Loans and Bridge Loans).

Thirdly, the Share Consolidation will be effected with respect to all of the outstanding Shares, Share options and Bootstrap Warrant. For further information in relation to the Share Consolidation, see sub-section (b) (Bootstrap Warrant) of section 12.5 (Outstanding Share options).

Finally, the Issuer's share capital will be increased as a result the issuance of the New Shares placed in the Offering (including pursuant to the contribution in kind of the Bridge Loan payables).

In view hereof, upon closing of the Offering and after giving effect to the Share Consolidation, assuming a placement of the maximum number of New Shares in the Offering (including the conversion of the Bridge Loans in full, but excluding the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range (i.e. €8.75), the Issuer's share capital will amount to €1,306,939.52 as of the closing of the Offering, represented by 12,611,900 ordinary Shares, each with a fractional value of ca. €0.10 and each representing the same *pro rata* fraction of the share capital. Assuming a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option) and after giving effect to the Share Consolidation, the Issuer's share capital will amount to €1,415,033.89 as of the closing of the Offering, represented by 13,655,282 Shares, each with a fractional value of ca. €0.10 and each representing the same *pro rata* fraction of the share capital.

The aforementioned transactions have been approved by the extraordinary general shareholders' meeting of the Issuer held on 18 January 2019. The same extraordinary general shareholders' meeting also resolved, subject to and with effect of the closing of the Offering:

- to issue a warrant, called “Over-allotment Option”, which the Issuer may offer to the Stabilisation Manager (see also section 12.5 (Outstanding Share options), subsection (c) (Over-allotment Option) below); and
- to issue a number of 2018 Share Options, equal to 10% of the number of outstanding Shares after the completion of the Offering (including upon exercise of the Increase Option and the Over-allotment Option).

12.4 Outstanding Convertible Loans and Bridge Loans

The Issuer and the Participating Investors entered into the following Convertible Loans:

- the February 2018 Convertible Loan for an aggregate principal amount of CHF1,996,742, and not bearing any interest;
- the PMV Convertible Loan for an aggregate principal amount of €2 million, and bearing an interest of 2% per annum;
- the FPIM Convertible Loan for an aggregate principal amount of €2 million, and bearing an interest of 2% per annum;
- the Cofipalux Convertible Loan for an aggregate principal amount of €500,000, and bearing an interest of 2% per annum;
- the Newton Convertible Loan for an aggregate principal amount of €2,000,000, and bearing and interest of 2% per annum;
- the BioMed Convertible Loan for an aggregate principal amount of CHF 198,000, and not bearing any interest; and
- the Individual 1 Convertible Loan and the Individual 2 Convertible Loan for an aggregate principal amount of respectively CHF 52,400 and CHF 100,000 and not bearing any interest.

The Convertible Loans were amended pursuant to the several Pre-IPO Investment Commitment Agreements. The respective Pre-IPO Investment Commitment Agreements provide amongst other things for the following:

- The Participating Investors, who are all lenders pursuant to the Convertible Loans, agreed to convert their outstanding Convertible Loans for new series E preferred Shares at the agreed conversion rate of CHF 10.48 per Share immediately prior to the closing of the Offering. As an exception, payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91 will be converted into New Shares at the Offer Price in connection with the Offering. The conversions will be implemented by means of a contribution in kind of the outstanding payable amounts under the Convertible Loans.
- The Pre-IPO Investment Commitment Agreement with the lenders that are an existing shareholder of the Issuer also provides that these lenders will convert a number of their Shares other than series E preferred Shares into series E preferred Shares at a ratio of one existing Share per new series E preferred Share subscribed for through the conversion of their Convertible Loan. The Shares will be converted in the following order of priority: (a) firstly, the series D preferred Shares, (b) secondly, the series C preferred Shares, (c) thirdly, the series B preferred Shares, (d) fourthly, the series A preferred Shares, and (e) finally, the common Shares. If a Participating Investor has a number of existing Shares that is less than the number of series E preferred Shares to be subscribed for upon conversion of its Convertible Loan, only those existing Shares shall be converted into series E preferred Shares.
- The conversion of the Convertible Loans and the conversion of Shares other than series E preferred Shares will be subject to the closing of the Offering, and the Shares resulting from the conversions will be subject to the Share Consolidation.
- Finally, the Participating Investors irrevocably committed pursuant to the respective Pre-IPO Investment Commitment Agreements to subscribe for an aggregate amount of €20.5 million in the Offering at the Offer Price, subject to the closing of the Offering. A portion of this amount has already been made available to the Issuer on 20 December 2018 by all of the respective Participating Investors (except three of them who are also each a lender under the February 2018 Convertible Loan) in the form of Bridge Loans

for an aggregate principal amount of €1,024,238.77. Pursuant to the Pre-IPO Investment Commitment Agreements, the relevant Participating Investors agreed to convert the principal amount and accrued interest of the Bridge Loans into New Shares at the Offer Price upon the closing of the Offering. The conversion will be implemented by means of a contribution in kind of the outstanding payable amounts under the Bridge Loans. The New Shares issuable pursuant to the contribution in kind of the Bridge Loan payables shall not be subject to the Share Consolidation. The remaining portion of the Subscription Commitments (not including the amounts due pursuant to the Bridge Loans and the payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) will be subscribed for in cash upon the closing of the Offering. In the event of over-subscription of the Offering, the Subscription Commitments in cash for an amount of ca. €12.5 million (not including the amounts due pursuant to the Bridge Loans and the payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) can be reduced in line with the allocation principles that will apply to the other investors that will subscribe in the Offering (see also Part 13 – (The Offering), section 13.10 (Allocation)), whereas the Subscription Commitments for the remaining amount (including the amounts due pursuant to the Bridge Loans and the payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) shall not be reduced but be allocated entirely.

For further information, see Part 11 – (Related party transactions).

12.5 Outstanding Share options

(a) Share-based incentive plans

The Issuer has a number of Share options pursuant to several plans, consisting of the 2011 Share Options, the Executive Share Options, and the 2018 Share Options. For further information, see Part 9 – (Management and corporate governance), section 9.6 (Description of Share plans).

(b) Bootstrap Warrant

The Issuer issued one warrant to Bootstrap that entitles Bootstrap to subscribe for a maximum of 104,961 series E preferred Shares at an exercise price of CHF 10.48 per Share prior to giving effect to the Share Consolidation (the “**Bootstrap Warrant**”). Upon the closing of the Offering and after giving effect to the Share Consolidation, assuming the Offer Price is at the midpoint of the Price Range (i.e. €8.75), the Bootstrap Warrant gives an entitlement to subscribe for 302,804 ordinary Shares at an exercise price of (rounded) €3.21 per Share. The terms of the Bootstrap Warrant are set out in the Warrant Agreement, dated 2 September 2016, between the Issuer and Bootstrap, as amended on 28 April 2017, 1 October 2018 and 20 December 2018 (collectively the “**Bootstrap Warrant Agreement**”).

The Bootstrap Warrant can be exercised in whole or in part at one or several occasions. The terms of the Bootstrap Warrant allow for an exercise of the warrant for a reduced number of Shares by means of a cashless exercise mechanism in function of the price of the Issuer’s Shares on the market on which the Shares are then listed prior to the exercise of the warrant. The terms of the Bootstrap Warrant also allow for an exercise without the issuance of new Shares, whereby the Issuer pays the balance between the exercise price and the fair market value the Issuer’s shares on the market. This “net exercise” mechanism will not be triggered by the Offering, and as from the closing of the Offering, can only be exercised, in case of (a) a sale or transfer of the legal or beneficial interest in any shares of the Issuer conferring in aggregate 50% or more of the voting rights at that time to one or more persons acting in concert, (b) the sale by the Issuer of the whole or substantially the whole of its undertaking, or (c) a merger or comparable transaction in which the Issuer is not the surviving entity.

The Bootstrap Warrant has a term of five years as from 2 September 2016. The Issuer and Bootstrap agreed that in the event that, at the end of the aforementioned 5-year term, the rights of Bootstrap have not been exercised, waived or lapsed, the Issuer shall use its best efforts, to the extent legally permitted, to grant new warrants to Bootstrap which confer rights to Bootstrap equivalent to the rights granted in the Bootstrap Warrant Agreement (as amended from time to time) and which are exercisable on the terms and subject to equivalent conditions but not extending beyond a term of 10 years as from 2 September 2016 or, in case of an Offering, five years as from the completion of the Offering.

The terms of the Bootstrap Warrant are subject to adjustment in certain events, including in case of Share issues by the Issuer at a price below the exercise price of the warrant. This adjustment will not be triggered by the Offering. In addition, following the closing of the Offering, any further adjustments for capital increases, issuances of shares or distributions to shareholders of the Issuer or other transactions or operations shall not lead to an adjustment, provided that these transactions or operations are approved by the general shareholders' meeting of the Issuer or are implemented or occur on the basis of an authorisation that was provided or approved by the general shareholders' meeting (such as, but not limited to, the authorised capital).

(c) Over-allotment Option

On 18 January 2019, the extraordinary general shareholders' meeting of the Issuer resolved to issue the Over-allotment Option, in the form of a warrant. The Over-allotment Option is expected to be granted to the Stabilisation Manager, acting on behalf of the Underwriters, in connection with the Offering. The Over-allotment Option can only be exercised by the Stabilisation Manager, acting on behalf of the Underwriters, to subscribe for additional new Shares for an aggregate number equal to up to 15% of the New Shares (including the new Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) subscribed for in the Offering at the Offer Price to cover over-allotments or short positions, if any, in connection with the Offering. The Over-allotment Option will only be exercisable for a period of 30 calendar days following the Listing Date, after which they will automatically expire. See Part 14 – (Plan of distribution), section 14.4 (Over-allotment Option and price stabilisation).

12.6 Form and transferability of the Shares

Upon closing of the Offering, all of the Shares will belong to the same class of securities and will be in registered or dematerialised form. A register of registered Shares (which may be held in electronic form) is maintained at the Issuer's registered office. It may be consulted by any holder of Shares. A dematerialised Share will be represented by an entry on a personal account of the owner or holder, with a recognised account holder or clearing and settlement institution. Holders of Shares may elect, at any time, to have their registered Shares converted into dematerialised Shares, and vice versa, at their own expense. Upon closing of the Offering, the Offered Shares will be delivered in dematerialised form.

The Shares are freely transferable. This is without prejudice to certain restrictions that may apply pursuant to applicable securities laws requirements which are further described in Part 15 – (Transfer restrictions). In addition, certain existing shareholders and the Participating Investors entered into contractual restrictions. See Part 14 – (Plan of distribution), section 14.3 (Lock up).

12.7 Currency

The Issuer's Shares do not have a nominal value, but each reflect the same fraction of the Issuer's share capital, which is denominated in euro.

12.8 Rights attached to the Shares

(a) Voting rights attached to the Shares

Each shareholder of the Issuer is entitled to one vote per Share. Shareholders may vote by proxy, subject to the rules described below in subsection (b) (Right to attend and vote at general shareholders' meetings), subsection (vi) (Voting by proxy or remote voting).

Voting rights can be mainly suspended in relation to Shares:

- which are not fully paid up, notwithstanding the request thereto of the board of directors of the Issuer;
- to which more than one person is entitled, except in the event a single representative is appointed for the exercise of the voting right;
- which entitle their holder to voting rights above the threshold of 5%, 10%, 15%, 20% and any further multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Issuer on the date of the relevant general shareholders' meeting, in the event that the relevant shareholder has not notified the Issuer and the FSMA at least 20 calendar days prior to the date of the general shareholders' meeting in accordance with the applicable rules on disclosure of major shareholdings; and

- of which the voting right was suspended by a competent court or the FSMA.

Pursuant to the Belgian Companies Code, the voting rights attached to Shares owned by the Issuer, as the case may be, are suspended.

Generally, the general shareholders' meeting has sole authority with respect to:

- the approval of the annual financial statements of the Issuer;
- the distribution of profits (except interim dividends (see subsection (c) (Dividends) below);
- the appointment (at the proposal of the board of directors and upon recommendation by the remuneration and nomination committee) and dismissal of directors of the Issuer;
- the appointment (at the proposal of the board of directors and upon recommendation by the audit committee) and dismissal of the statutory auditor of the Issuer;
- the granting of release from liability to the directors and the statutory auditor of the Issuer;
- the determination of the remuneration of the directors and of the statutory auditor for the exercise of their mandate;
- the approval of the remuneration report included in the annual report of the board of directors and the determination of the following features of the remuneration or compensation of directors, members of the executive management and certain other executives (as the case may be): (i) in relation to the remuneration of executive and non-executive directors, members of the executive management and other executives, an exemption from the rule that Share based awards can only vest after a period of at least three years as of the grant of the awards, (ii) in relation to the remuneration of executive directors, members of the executive management and other executives, an exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years, (iii) in relation to the remuneration of non-executive directors, any variable part of the remuneration, and (iv) any service agreements to be entered into with executive directors, members of the executive management and other executives providing for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, eighteen (18) months' remuneration);
- the filing of a claim for liability against directors;
- the decisions relating to the dissolution, merger and certain other reorganisations of the Issuer; and
- the approval of amendments to the articles of association.

(b) Right to attend and vote at general shareholders' meetings

(i) Annual meetings of shareholders

The annual general shareholders' meeting is held at the registered office of the Issuer or at the place determined in the notice convening the general shareholders' meeting. The meeting is held every year on fourth Thursday of May. If this day is a public holiday, even if it is only a public holiday in one of the communities of Belgium, the meeting will be held on the next business day. At the annual general shareholders' meeting, the board of directors submits to the shareholders the audited non-consolidated and consolidated annual financial statements and the reports of the board of directors and of the statutory auditor with respect thereto.

The general shareholders' meeting then decides on the approval of the statutory annual financial statements, the proposed allocation of the Issuer's profit or loss, the release from liability of the directors and the statutory auditor, the approval of the remuneration report included in the annual report of the board of directors and, when applicable, the (re-)appointment or dismissal of the statutory auditor and/or of all or certain directors. In addition, as relevant, the general shareholders' meeting must also decide on the approval of the remuneration of the directors and

statutory auditor for the exercise of their mandate, and on the approval of provisions of service agreements to be entered into with executive directors, members of the executive management and other executives providing (as the case may be) for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, 18 months' remuneration) (see also subsection (a) (Voting rights attached to the Shares) above).

(ii) Special and extraordinary general shareholders' meetings

The board of directors or the statutory auditor (or the liquidators, if appropriate) may, whenever the interest of the Issuer so requires, convene a special or extraordinary general shareholders' meeting. Such general shareholders' meeting must also be convened every time one or more shareholders holding, alone or together, at least 20% of the Issuer's share capital so request. Shareholders that do not hold at least 20% of the Issuer's share capital do not have the right to have the general shareholders' meeting convened.

(iii) Right to put items on the agenda of the general shareholders' meeting and to table draft resolutions

Shareholders who hold alone or together with other shareholders at least 3% of the Issuer's share capital have the right to put additional items on the agenda of a general shareholders' meeting that has been convened and to table draft resolutions in relation to items that have been or are to be included in the agenda. This right does not apply to general shareholders' meetings that are being convened on the grounds that the quorum was not met at the first duly convened meeting (see subsection (vii) (Quorum and majorities) below). Shareholders wishing to exercise this right must prove on the date of their request that they own at least 3% of the outstanding share capital. The ownership must be based, for dematerialised Shares, on a certificate issued by the applicable settlement institution for the Shares concerned, or by a certified account holder, confirming the number of Shares that have been registered in the name of the relevant shareholders and, for registered Shares, on a certificate of registration of the relevant Shares in the share register book of the Issuer. In addition, the shareholder concerned must register for the meeting concerned with at least 3% of the outstanding share capital (see also subsection (v) (Formalities to attend the general shareholders' meeting) below). A request to put additional items on the agenda and/or to table draft resolutions must be submitted in writing, and must contain, in the event of an additional agenda item, the text of the agenda item concerned and, in the event of a new draft resolution, the text of the draft resolution. The request must reach the Issuer at the latest on the twenty second calendar day preceding the date of the general shareholders' meeting concerned. If the Issuer receives a request, it will have to publish at the latest on the fifteenth calendar day preceding the general shareholders' meeting an update of the agenda of the meeting with the additional agenda items and draft resolutions.

(iv) Notices convening the general shareholders' meeting

The notice convening the general shareholders' meeting must state the place, date and hour of the meeting and must include an agenda indicating the items to be discussed. The notice needs to contain a description of the formalities that shareholders must fulfil in order to be admitted to the general shareholders' meeting and exercise their voting right, information on the manner in which shareholders can put additional items on the agenda and table draft resolutions, information on the manner in which shareholders can ask questions during the general shareholders' meeting, information on the procedure to participate to the general shareholders' meeting by means of a proxy or to vote by means of a remote vote, and, as applicable, the registration date for the general shareholders' meeting. The notice must also mention where shareholders can obtain a copy of the documentation that will be submitted to the general shareholders' meeting, the agenda with the proposed resolutions or, if no resolutions are proposed, a commentary by the board of directors, updates of the agenda if shareholders have put additional items or draft resolutions on the agenda, the forms to vote by proxy or by means of a remote vote, and the address of the webpage on which the documentation and information relating to the general shareholders' meeting will be made available. This documentation and information, together with the notice and the total number of outstanding voting rights, must also be made available on the Issuer's website at the same time as the publication of the notice convening the meeting, for a period of five years after the relevant general shareholders' meeting.

The notice convening the general shareholders' meeting has to be published at least 30 calendar days prior to the general shareholders' meeting in the Belgian Official Gazette (Belgisch Staatsblad/Moniteur Belge), in a newspaper that is published nation-wide in Belgium and in media that can be reasonably relied upon for the dissemination of information within the EEA in a manner ensuring fast access to such information on a non-discriminatory basis. A publication in a nation-wide newspaper is not needed for annual general shareholders' meetings taking place on the date, hour and place indicated in the articles of association of the Issuer if the agenda is limited to the treatment of the financial statements, the annual report of the board of directors, the remuneration report and the report of the statutory auditor, the discharge from liability of the directors and statutory auditor, and the remuneration of directors. See also subsection (a) (Voting Rights attached to the Shares) above. In addition to this publication, the notice has to be distributed at least 30 calendar days prior to the meeting via the normal publication means that the Issuer uses for the publication of press releases and regulated information. The term of 30 calendar days prior to the general shareholders' meeting for the publication and distribution of the convening notice can be reduced to 17 calendar days for a second meeting if, as the case may be, the applicable quorum for the meeting is not reached at the first meeting, the date of the second meeting was mentioned in the notice for the first meeting and no new item is put on the agenda of the second meeting. See also further below under subsection (vii) (Quorum and majorities).

At the same time as its publication, the convening notice must also be sent to the holders of registered Shares, holders of registered bonds, holders of registered warrants, holders of registered certificates issued with the co-operation of the Issuer (if any), and, as the case may be, to the directors and statutory auditor of the Issuer. This communication needs to be made by letter unless the addressees have individually and expressly accepted in writing to receive the notice by another form of communication.

(v) Formalities to attend the general shareholders' meeting

All holders of Shares, warrants, profit-sharing certificates, non-voting Shares, bonds, subscription rights or other securities issued by the Issuer, as the case may be, and all holders of certificates issued with the co-operation of the Issuer (if any) can attend the general shareholders' meetings insofar as the law or the articles of association entitles them to do so and, as the case may be, gives them the right to participate in voting.

In order to be able to attend a general shareholders' meeting, a holder of securities issued by the Issuer must satisfy two criteria: being registered as holder of securities on the registration date for the meeting, and notify the Issuer:

- Firstly, the right to attend general shareholders' meetings applies only to persons who are registered as owning securities on the fourteenth calendar day prior to the general shareholders' meeting at midnight (Central European Time) via registration, in the applicable register book for the securities concerned (for registered securities) or in the accounts of a certified account holder or relevant settlement institution for the securities concerned (for dematerialised securities or securities in book-entry form).
- Secondly, in order to be admitted to the general shareholders' meeting, securities holders must notify the Issuer at the latest on the sixth calendar day prior to the general shareholders' meeting whether they intend to attend the meeting and indicate the number of Shares in respect of which they intend to do so. For the holders of dematerialised securities or securities in book-entry form, the notice should include a certificate confirming the number of securities that have been registered in their name on the record date. The certificate can be obtained by the holder of the dematerialised securities or securities in book-entry form with the certified account holder or the applicable settlement institution for the securities concerned.

The formalities for the registration of securities holders, and the notification of the Issuer must be further described in the notice convening the general shareholders' meeting.

(vi) Voting by proxy or remote voting

Each shareholder has, subject to compliance with the requirements set forth above under subsection (v) (Formalities to attend the general shareholders' meeting), the right to attend a general shareholders' meeting and to vote at the general shareholders' meeting in person or through a proxy holder, who need not be a shareholder. A shareholder may designate, for a given

meeting, only one person as proxy holder, except in circumstances where Belgian law allows the designation of multiple proxy holders. The appointment of a proxy holder may take place in paper form or electronically (in which case the form shall be signed by means of an electronic signature in accordance with applicable Belgian law), through a form which shall be made available by the Issuer. The signed original paper or electronic form must be received by the Issuer at the latest on the sixth calendar day preceding the meeting. The appointment of a proxy holder must be made in accordance with the applicable rules of Belgian law, including in relation to conflicts of interest and the keeping of a register.

The notice convening the meeting may allow shareholders to vote remotely in relation to the general shareholders' meeting, by sending a paper form or, if specifically allowed in the notice convening the meeting, by sending a form electronically (in which case the form shall be signed by means of an electronic signature in accordance with applicable Belgian law). These forms shall be made available by the Issuer. The original signed paper form must be received by the Issuer at the latest on the sixth calendar day preceding the date of the meeting. Voting through the signed electronic form may occur until the last calendar day before the meeting.

The Issuer may also organise a remote vote in relation to the general shareholders' meeting through other electronic communication methods, such as, among others, through one or several websites. The Issuer shall specify the practical terms of any such remote vote in the convening notice.

Holders of securities who wish to be represented by proxy or vote remotely must, in any case comply with the formalities to attend the meeting, as explained above under subsection (v) (Formalities to attend the general shareholders' meeting).

(vii) Quorum and majorities

In general, there is no attendance quorum requirement for a general shareholders' meeting and decisions are generally passed with a simple majority of the votes of the Shares present or represented. However, capital increases (other than those decided by the board of directors pursuant to the authorised capital), decisions with respect to the Issuer's dissolution, mergers, demergers and certain other reorganisations of the Issuer, amendments to the articles of association (other than an amendment of the corporate purpose), and certain other matters referred to in the Belgian Companies Code do not only require the presence or representation of at least 50% of the share capital of the Issuer but also a majority of at least 75% of the votes cast. An amendment of the Issuer's corporate purpose requires the approval of at least 80% of the votes cast at a general shareholders' meeting, which can only validly pass such resolution if at least 50% of the share capital of the Issuer and at least 50% of the profit certificates, if any, are present or represented. In the event where the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second general shareholders' meeting may validly deliberate and decide regardless of the number of Shares present or represented. The special majority requirements, however, remain applicable.

(viii) Right to ask questions

Within the limits of article 540 of the Belgian Companies Code, shareholders have a right to ask questions to the directors in connection with the report of the board of directors or the items on the agenda of such general shareholders' meeting. Shareholders can also ask questions to the statutory auditor in connection with its report. Such questions can be submitted in writing prior to the meeting or can be asked at the meeting. Written questions must be received by the Issuer no later than the sixth calendar day prior to the meeting. Written and oral questions will be answered during the meeting concerned in accordance with applicable law. In addition, in order for written questions to be considered, the shareholders who submitted the written questions concerned must comply with the formalities to attend the meeting, as explained above under subsection (v) (Formalities to attend the general shareholders' meeting).

(c) Dividends

As of the closing of the Offering, all of the Shares, including the Offered Shares, will entitle the holder thereof to an equal right to participate in dividends declared after the Closing Date, in respect of the financial year ending 31 December 2018 and future years. All of the Shares will participate equally in the Issuer's profits (if any). Pursuant to the Belgian Companies Code, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the

occasion of the annual general shareholders' meeting, based on the most recent statutory audited financial statements, prepared in accordance with Belgian GAAP and based on a (non-binding) proposal of the Issuer's board of directors. The Issuer's articles of association also authorise the board of directors to declare interim dividends without shareholder approval. The right to pay such interim dividends is, however, subject to certain legal restrictions.

The Issuer's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of the Issuer's stand-alone statutory accounts prepared in accordance with Belgian GAAP. In particular, dividends can only be distributed if following the declaration and issuance of the dividends the amount of the Issuer's net assets on the date of the closing of the last financial year as follows from the statutory non-consolidated financial statements (i.e. summarised, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all in accordance with Belgian accounting rules), decreased with the non-amortised costs of incorporation and extension and the non-amortised costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased with the amount of non-distributable reserves.

In addition, pursuant to Belgian law and the Issuer's articles of association, the Issuer must allocate an amount of 5% of its Belgian GAAP annual net profit (nettowinst/bénéfices nets) to a legal reserve in its stand-alone statutory accounts, until the legal reserve amounts to 10% of the Issuer's share capital. The Issuer's legal reserve currently does not meet this requirement nor will it meet the requirement at the time of the closing of the Offering. Accordingly, 5% of its Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, limiting the Issuer's ability to pay out dividends to its shareholders.

Furthermore, additional financial restrictions and other limitations may be contained in future credit agreements.

For further information in relation to the Issuer's dividend policy, see Part 4 – (Dividends and dividend policy).

(d) Rights regarding liquidation

The Issuer can only be dissolved by a shareholders' resolution passed with a majority of at least 75% of the votes cast at an extraordinary general shareholders' meeting where at least 50% of the share capital is present or represented.

Pursuant to article 633 of the Belgian Companies Code, if, as a result of losses incurred, the ratio of the Issuer's net assets (determined in accordance with Belgian legal and accounting rules for non-consolidated financial statements) to share capital is less than 50%, the board of directors must convene an extraordinary general shareholders' meeting within two months as of the date upon which the board of directors discovered or should have discovered this undercapitalisation. At this general shareholders' meeting the board of directors needs to propose either the dissolution of the Issuer or the continuation of the Issuer, in which case the board of directors must propose measures to redress the Issuer's financial situation. The board of directors must justify its proposals in a special report to the shareholders. Shareholders representing at least 75% of the votes validly cast at this meeting have the right to dissolve the Issuer, provided that at least 50% of the Issuer's share capital is present or represented at the meeting.

If, as a result of losses incurred, the ratio of the Issuer's net assets to share capital is less than 25%, the same procedure must be followed, it being understood, however, that in that event shareholders representing 25% of the votes validly cast at the meeting can decide to dissolve the Issuer.

Pursuant to article 634 of the Belgian Companies Code, if the amount of the Issuer's net assets has dropped below €61,500 (the minimum amount of share capital of a corporation with limited liability organised under the laws of Belgium (naamloze vennootschap/société anonyme)), any interested party is entitled to request the competent court to dissolve the Issuer. The court can order the dissolution of the Issuer or grant a grace period within which the Issuer is to remedy the situation.

If the Issuer is dissolved for any reason, the liquidation must be carried out by one or more liquidators appointed by the general shareholders' meeting and whose appointment has been ratified by the commercial court (or, as of 1 November 2018, by the enterprise court). Any balance remaining after discharging all debts, liabilities and liquidation costs must first be applied to reimburse, in cash or in kind, the paid-up capital of the Shares not yet reimbursed. Any remaining

balance shall be equally distributed amongst all the shareholders (see also Part 2 – (Risk factors), section 2.1 (Risks related to Sequana Medical’s business and industry), subsection (a) (Sequana Medical has incurred operating losses, negative operating cash flows and an accumulated deficit since inception and may not be able to achieve or subsequently maintain profitability)).

In view of the Issuer’s negative net equity, which was established *inter alia* on the basis of the Issuer’s non-consolidated financial statements for the financial year ended on 31 December 2017 which had been prepared in accordance with Swiss legal and accounting rules for non-consolidated financial statements, the Issuer’s general shareholders’ meeting held on 20 November 2018 resolved, in accordance with article 633 of the Belgian Companies Code, to continue the Issuer’s activities, and not to dissolve the Issuer. Upon completion of the Offering, the Issuer’s net equity will again be positive, and the Issuer will no longer fall within the scope of articles 633 and 634 of the Belgian Companies Code upon closing of the Offering.

(e) Changes to the share capital

(i) Changes to the share capital decided by the shareholders

In principle, changes to the share capital are decided by the shareholders. The general shareholders’ meeting may at any time decide to increase or reduce the share capital of the Issuer. Such resolution must satisfy the quorum and majority requirements that apply to an amendment of the articles of association, as described above under subsection (b) (Right to attend and vote at general shareholders’ meetings), subsection (vii) (Quorum and majorities).

(ii) Capital increases decided by the board of directors

Subject to the same quorum and majority requirements, the general shareholders’ meeting may authorise the board of directors, within certain limits, to increase the Issuer’s share capital without any further approval of the shareholders. This is the so-called authorised capital. This authorisation needs to be limited in time (i.e. it can only be granted for a renewable period of maximum five years) and scope (i.e. the authorised capital may not exceed the amount of the registered capital at the time of the authorisation).

On 18 January 2019, the Issuer’s general shareholders’ meeting authorised, subject to and with effect as from the closing of the Offering, the board of directors to increase the share capital of the Issuer within the framework of the authorised capital with a maximum of 100% of its amount as at the closing of the Offering.

The Issuer’s general shareholders’ meeting decided that the board of directors, when exercising its powers under the authorised capital, will be authorised to restrict or cancel the statutory preferential subscription rights of the shareholders (within the meaning of article 592 and following of the Belgian Companies Code). See also subsection (iii) (Preferential subscription right) below. This authorisation includes the restriction or suppression of preferential subscription rights for the benefit of one or more specific persons (whether or not employees of the Issuer or its subsidiaries). See section 12.9 (Legislation and jurisdiction), subsection (b) (Public takeover bids). The authorisation is valid for a term of five years as from the date of the publication of the authorisation in the Annexes to the Belgian State Gazette (Belgisch Staatsblad/Moniteur belge).

(iii) Preferential subscription right

In the event of a capital increase for cash with the issue of new Shares, or in the event of an issue of convertible bonds or warrants, the existing shareholders have a preferential right to subscribe, *pro rata*, to the new Shares, convertible bonds or warrants. These preferential subscription rights are transferable during the subscription period.

The general shareholders’ meeting may decide to limit or cancel this preferential subscription right, subject to special reporting requirements. Such decision by the general shareholders’ meeting needs to satisfy the same quorum and majority requirements as the decision to increase the Issuer’s share capital.

The shareholders may also decide to authorise the board of directors to limit or cancel the preferential subscription right within the framework of the authorised capital, subject to the terms and conditions set forth in the Belgian Companies Code. On 18 January 2019, the Issuer’s general shareholders’ meeting decided (subject to and with effect as from the closing of the Offering) that, when exercising its powers under the authorised capital, the board of directors will be authorised to restrict or cancel the statutory preferential subscription rights of the shareholders (within the

meaning of article 592 and following of the Belgian Companies Code) (see also subsection (ii) (Capital increases decided by the board of directors) above).

Generally, unless expressly authorised in advance by the general shareholders' meeting, the authorisation of the board of directors to increase the share capital of the Issuer through contributions in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to the Issuer by the FSMA of a public takeover bid on the financial instruments of the Issuer. The Issuer's general shareholders' meeting did not grant such express authorisation to the board of directors.

(iv) Purchase and sale of own Shares

In accordance with the Belgian Companies Code, the Issuer can, on or outside the stock market, purchase and sell its own Shares, profit certificates or associated certificates by virtue of a special shareholders' resolution approved by at least 80% of the votes validly cast at a general shareholders' meeting where at least 50% of the share capital and at least 50% of the profit certificates, if any, are present or represented. The prior approval by the shareholders is not required if the Issuer purchases the Shares to offer them to the Issuer's personnel.

In accordance with the Belgian Companies Code, an offer to purchase Shares must be made by way of an offer to all shareholders under the same conditions. Shares can also be acquired by the Issuer without offer to all shareholders under the same conditions, provided that the acquisition of the Shares is effected in the central order book of the regulated market of Euronext Brussels or, if the transaction is not effected via the central order book, provided that the price offered for the Shares is lower than or equal to the highest independent bid price in the central order book of the regulated market of Euronext Brussels at that time. Shares can only be acquired with funds that would otherwise be available for distribution as a dividend to the shareholders. The total amount of Shares held by the Issuer can at no time be more than 20% of its share capital. Voting rights attached to Shares held by the Issuer as treasury shares are suspended.

Generally, the general shareholders' meeting can authorise the board of directors to acquire on or outside the stock exchange a number of the Shares representing a maximum of 20% of the subscribed capital, determining the minimum and maximum price that the board of directors can pay for the Shares. This authorisation can also cover the acquisition on or outside the stock exchange by a direct subsidiary of the Issuer and can be valid for a term of up to five years as of the date of the approval of the proposed resolution. The Issuer's general shareholders' meeting did not grant such authorisation to the board of directors.

The board of directors may, without prior authorisation by the general shareholders' meeting, in accordance with article 622, §2 of the Belgian Companies Code, dispose of the Issuer's own Shares, profit certificates or associated certificates at a price it determines, on or outside the stock market or in the framework of its remuneration policy to employees, directors or consultants of the Issuer. This authorisation is valid without any restriction in time. This authorisation can also cover the disposal of the Shares on or outside the stock market by a direct subsidiary of the Issuer within the meaning of article 627 of the Belgian Companies Code.

As of the date of this Prospectus, the Issuer does not hold any own Shares. Prior to the Belgian Seat Transfer, the Issuer held 117,569 of its own Shares as treasury stock, consisting of 107,196 common Shares, 4,773 series B preferred Shares, 1,600 series C preferred Shares and 4,000 series D preferred Shares. These Shares were acquired in 2017 from the estate of the former chief executive officer. All of the treasury shares were cancelled on 1 October 2018, immediately following the Belgian Seat Transfer, in order to simplify the Issuer's capital structure.

12.9 Legislation and jurisdiction

(a) Notification of significant shareholdings

Pursuant to the Belgian Act of 2 May 2007 on the disclosure of significant shareholdings in issuers whose securities are admitted to trading on a regulated market and containing various provisions, as amended from time to time, a notification to the Issuer and to the FSMA is required by all natural persons and legal entities (i.e. legal person, enterprise without legal personality, or trust), in the following circumstances:

- an acquisition or disposal of voting securities, voting rights or financial instruments that are treated as voting securities;
- the reaching of a threshold by persons or legal entities acting in concert;

- the conclusion, modification or termination of an agreement to act in concert;
- the downward reaching of the lowest threshold;
- the passive reaching of a threshold;
- the holding of voting securities in the Issuer upon first admission thereof to trading on a regulated market;
- where a previous notification concerning the financial instruments treated as equivalent to voting securities is updated;
- the acquisition or disposal of the control of an entity that holds voting securities in the Issuer; and
- where the Issuer introduces additional notification thresholds in the articles of association,

in each case where the percentage of voting rights attached to the securities held by such persons reaches, exceeds or falls below the legal threshold, set at 5% of the total voting rights, and 10%, 15%, 20% and so on in increments of 5% or, as the case may be, the additional thresholds provided in the articles of association. Sequana Medical has provided for an additional threshold of 3% in its articles of association that will enter into force subject to, and with effect as from, the closing of the Offering.

The notification must be made promptly and at the latest within four trading days following the moment on which the person who is subject to the notification obligation received knowledge or could be deemed to have received knowledge of the acquisition or disposal of the voting rights triggering the reaching of the threshold. Where the Issuer receives a notification of information regarding the reaching of a threshold, it has to publish such information within three trading days following receipt of the notification. Subject to certain exceptions, no shareholder may, pursuant to article 545 of the Belgian Companies Code, cast a greater number of votes at a general shareholders' meeting of the Issuer than those attached to the rights and securities that it has notified in accordance with the aforementioned disclosure rules at least 20 calendar days prior to the date of the general shareholders' meeting.

The forms on which such notifications must be made, as well as further explanations, can be found on the website of the FSMA (www.fsma.be). Violation of the disclosure requirements may result in the suspension of voting rights, a court order to sell the securities to a third party and/or criminal liability. The FSMA may also impose administrative sanctions.

The Issuer is required to publicly disclose any notifications received regarding increases or decreases in a shareholder's ownership of the Issuer's securities, and must mention these notifications in the notes to its financial statements. A list as well as a copy of such notifications will be accessible on the Issuer's website (www.sequanamedical.com).

(b) Public takeover bids

Public takeover bids for the Shares and other securities giving access to voting rights (such as warrants or convertible bonds, if any) are subject to supervision by the FSMA. Any public takeover bid must be extended to all of the Issuer's voting securities, as well as all other securities giving access to voting rights. Prior to making a bid, a bidder must publish a prospectus which has been approved by the FSMA prior to publication.

Belgium has implemented the Thirteenth Company Law Directive (European Directive 2004/25/EC of 21 April 2004) by the **Belgian Act** of 1 April 2007 on public takeover bids, as amended (the "**Belgian Takeover Act**") and the Belgian Royal Decree of 27 April 2007 on public takeover bids, as amended (the "**Belgian Takeover Decree**"). The Belgian Takeover Act provides that a mandatory bid must be launched if a person, as a result of its own acquisition or the acquisition by persons acting in concert with it or by persons acting for their account, directly or indirectly holds more than 30% of the voting securities in a company having its registered office in Belgium and of which at least part of the voting securities are traded on a regulated market or on a multilateral trading facility designated by the Belgian Takeover Decree. The mere fact of exceeding the relevant threshold through the acquisition of shares will give rise to a mandatory bid, irrespective of whether the price paid in the relevant transaction exceeds the current market price. The duty to launch a mandatory bid does not apply in certain cases set out in the Belgian Takeover Decree such as (i) in case of an acquisition if it can be shown that a third party exercises control over the company or that such party holds a larger stake than the person holding 30% of the voting

securities or (ii) in case of a capital increase with preferential subscription rights decided by the Issuer's general shareholders' meeting.

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as the obligation to disclose significant shareholdings (see subsection (a) (Notification of significant shareholdings) above) and merger control, that may apply towards the Issuer and which may create hurdles to an unsolicited tender offer, merger, change in management or other change in control. These provisions could discourage potential takeover attempts that other shareholders may consider to be in their best interest and could adversely affect the market price of the Shares. These provisions may also have the effect of depriving the shareholders of the opportunity to sell their Shares at a premium.

In addition, pursuant to Belgian company law, the board of directors of Belgian companies may in certain circumstances, and subject to prior authorisation by the shareholders, deter or frustrate public takeover bids through dilutive issuances of equity securities (pursuant to the "authorised capital") or through share buy-backs (i.e. purchase of own shares). In principle, the authorisation of the board of directors to increase the share capital of the Issuer through contributions in kind or in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to the Issuer by the FSMA of a public takeover bid on the securities of the Issuer. The general shareholders' meeting can, however, under certain conditions, expressly authorise the board of directors to increase the capital of the Issuer in such case by issuing Shares in an amount of not more than 10% of the existing Shares at the time of such a public takeover bid. (see also section 12.8 (Rights attached to the Shares), subsection (e) (Changes to the share capital), subsection (ii) (Capital increases decided by the board of directors)).

The Issuer's articles of association do not provide for any specific protective mechanisms against public takeover bids.

The Issuer is a party to the following significant agreements or instruments which, upon a fundamental change in shareholders or change of control of the Issuer or following a takeover bid can be terminated by the other parties thereto:

- the Bootstrap Loan provides that Bootstrap may cancel any undrawn part of the facility and declare all outstanding amounts under the Bootstrap Loan immediately due and payable if a change of control occurs, whereby "change of control" is to be understood as the key shareholders collectively ceasing to directly hold or have the power to cast, or control the cast of, at least 50.1% of (i) the issued share capital or (ii) the voting rights relating to the issued share capital, or any sale of (a) any or all assets related to the Issuer's liver or heart business with a minimum net value of at least CHF 10 million or (b) all or substantially all of the assets or business of the Issuer;
- the exclusive distribution agreement between the Issuer and Gamida Ltd. provides that in case of a more than 50% change of ownership, or direct or indirect control of the Issuer occurs, both parties to the distribution agreement may terminate this agreement with immediate effect without curing procedures by written notice of termination. The agreement further provides that in such case, the Issuer shall use commercially reasonable efforts to convince the new owners of Sequana Medical of a new distribution agreement between Sequana Medical and Gamida Ltd. with terms that are similar to the terms of the current agreement.

In addition, the Issuer's Share option plans; the Bootstrap Warrant and the employment agreement with the chief executive officer (see Part 9 – (Management and Corporate Governance), section 9.5 (Remuneration and benefits), subsection (c) (Executive management), subsection (iii) (Payments upon termination)) also contain takeover protections.

(c) Squeeze-outs

Pursuant to article 513 of the Belgian Companies Code or the regulations promulgated thereunder, a person or legal entity, or different persons or legal entities acting alone or in concert, who own, together with the company, at least 95% of the securities with voting rights in a public company are entitled to acquire the totality of the securities with voting rights in that company following a squeeze-out offer. The securities that are not voluntarily tendered in response to such an offer are deemed to be automatically transferred to the bidder at the end of the procedure. At

the end of the squeeze-out procedure, the company is no longer deemed a public company, unless bonds issued by the company are still spread among the public. The consideration for the securities must be in cash and must represent the fair value (verified by an independent expert) as to safeguard the interests of the transferring shareholders.

A squeeze-out offer is also possible upon completion of a public takeover bid, provided that the bidder holds at least 95% of the voting capital and 95% of the voting securities of the public company. In such a case, the bidder may require that all remaining shareholders sell their securities to the bidder at the offer price of the takeover bid, provided that, in case of a voluntary takeover offer, the bidder has also acquired 90% of the voting capital to which the offer relates. The shares that are not voluntarily tendered in response to any such offer are deemed to be automatically transferred to the bidder at the end of the procedure.

(d) Sell-out right

Within three months after the end of an acceptance period related to a public takeover bid, holders of voting securities or of securities giving access to voting rights may require the offeror, acting alone or in concert, who owns at least 95% of the voting capital and 95% of the voting securities in a public company following a takeover bid, to buy their securities from them at the price of the bid, on the condition that, in case of a voluntary takeover offer, the offeror has acquired, through the acceptance of the bid, securities representing at least 90% of the voting capital subject to the takeover bid.

PART 13 – THE OFFERING

Certain key dates in connection with the Offering are summarised in the following table. These are all anticipated dates, which are subject to any unforeseen circumstances, withdrawal, or to an early closing or extension of the Offering Period.

31 January 2019	Expected start of the Offering Period
7 February 2019, 4:00 p.m. CET	Expected end of the Offering Period ⁽¹⁾
8 February 2019	Expected publication of the Offer Price and results of the Offering and communication of allocations
11 February 2019	Expected Listing Date (listing and start of “if-and-when-issued-and/or-delivered” trading)
12 February 2019	Expected Closing Date (payment, settlement and delivery of the Offered Shares)
13 March 2019	Expected last possible exercise date of the Over-allotment Option ⁽²⁾

Notes:

- (1) In the event of an early closing or extension of the Offering Period, these dates will be amended and published in the same manner as the announcement of the start of the Offering Period. If the Offering Period is extended with more than five business days, this will also be published in a supplement to the Prospectus.
- (2) To enable the Stabilisation Manager, acting on behalf of the Underwriters, to cover over-allotments or short positions, if any, resulting from the over-allotment, if any (for further information, see section 13.16 (Over-allotment Option)).

13.1 Conditions and nature of the Offering

The Offering consists of: (i) a public offering to retail and institutional investors in Belgium; (ii) a private placement in the U.S. to persons who are reasonably believed to be QIBs as defined in Rule 144A under the U.S. Securities Act, in reliance on Rule 144A; and (iii) private placements to certain qualified and/or institutional investors under applicable laws of the relevant jurisdiction in the rest of the world. The Offering outside the U.S. will be made in compliance with Regulation S under the U.S. Securities Act. Private placements may take place in member states of the EEA pursuant to an exemption under the European Prospectus Directive as implemented in the relevant EEA member state. The Offering is an offering of up to 3,235,294 new Shares in the Issuer.

The aggregate number of Shares sold in the Offering may, pursuant to the Increase Option, be increased by up to 15% of the aggregate number of New Shares initially offered. Any decision to exercise the Increase Option will be communicated, at the latest, on the date of the announcement of the Offer Price. See section 13.15 (Increase Option).

The Stabilisation Manager, acting on behalf of the Underwriters, is expected to be granted by the Issuer the Over-allotment Option, in the form of a warrant, which entitles the Stabilisation Manager, acting on behalf of the Underwriters, to subscribe for additional new Shares for an aggregate number equal to up to 15% of the New Shares (including the New Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) subscribed for in the Offering at the Offer Price (including the New Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) to cover over-allotments or short positions, if any, in connection with the Offering.

The Underwriters are Kempen & Co N.V., KBC Securities NV/SA and Mirabaud Securities Limited See Part 14 – (Plan of distribution).

The actual number of New Shares issued by the Issuer in the Offering will only be determined after the Offering Period and will be published in the financial press and by way of a press release of the Issuer, simultaneously with the publication of the Offer Price and the allocation of Shares to Retail Investors. Such publication is currently expected to be made on or about 8 February 2019 and in any event no later than the first business day after the end of the Offering Period.

There is no minimum amount for the Offering. If not all of the Offered Shares are subscribed for in the Offering, the net proceeds from the Offering could be limited, all or in part, to the net proceeds from Subscription Commitments. The Issuer reserves the right to withdraw the Offering or

to reduce the maximum number of Offered Shares at any time prior to the allocation of the Offered Shares. Any withdrawal of the Offering will be published in the financial press, by means of a press release, through electronic information services such as Reuters or Bloomberg. To the extent required, also a supplement will be published. In the event of a withdrawal of the Offering, all orders received will automatically be cancelled and withdrawn, and investors will not have any claim to the delivery of the Offered Shares or any compensation. A reduction in the number of Offered Shares prior to expiry of the Offering Period will be published in the financial press, by means of a press release, through electronic information services such as Reuters or Bloomberg, and in a supplement to the Prospectus. In the event of a publication of a supplement to the Prospectus, investors will have the right to withdraw their orders made prior to the publication of the supplement (see section 13.9 (Right to withdraw) below). Investors withdrawing their order will not have any claim to the delivery of the Offered Shares or any compensation.

13.2 Pre-commitments by the Participating Investors

The Participating Investors, who are all lenders pursuant to the Convertible Loans, have irrevocably committed pursuant to their Subscription Commitments to subscribe for an aggregate amount of €20.5 million at the Offer Price, subject to the closing of the Offering. A portion of this amount has already been made available to the Issuer on 20 December 2018 by all of the respective Participating Investors (except three of them who are also each a lender under the February 2018 Convertible Loan) in the form of Bridge Loans for an aggregate principal amount of €1,024,238.77. The principal amount and accrued interest under the Bridge Loans will be converted into New Shares at the Offer Price upon the closing of the Offering. The conversion will be implemented by means of a contribution in kind of the outstanding payable amounts under the Bridge Loans. The New Shares issuable pursuant to the contribution in kind of the Bridge Loan payables shall not be subject to the Share Consolidation. The remaining portion of the Subscription Commitments will be subscribed for in cash upon the closing of the Offering. In the event of over-subscription of the Offering, the Subscription Commitments for an amount of ca. €12.5 million can be reduced in line with the allocation principles that will apply to the other investors that will subscribe in the Offering (see section 13.10 (Allocation)), whereas the Subscription Commitments for the remaining amount shall not be reduced but be allocated entirely. See also Part 12 – (Share capital and articles of association), section 12.4 (Outstanding Convertible Loans and Bridge Loans).

13.3 Contribution in kind of certain payables in the Offering

The New Shares in the Offering can also be subscribed for through a contribution in kind of payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91, and a contribution in kind of the outstanding payables under the Bridge Loans for an aggregate principal amount of €1,024,238.77 (to be increased with accrued interests).

Furthermore, the New Shares in the Offering can be subscribed for through a contribution in kind by Bootstrap of 50% of the payable due by the Issuer upon the closing of the Offering as an “Exit Fee” pursuant to the Bootstrap Loan. The remaining portion of the Exit Fee shall be repaid in cash by the Issuer following the closing of the Offering. As provided for by the Bootstrap Loan, the Exit Fee shall not exceed a maximum of CHF 750,000. The portion of the Exit Fee payable that shall be so contributed, but that cannot be used for the subscription for a whole number of New Shares at the Offer Price shall not be contributed in kind, but remains payable in cash (subject to the terms of the Bootstrap Loan).

In case of an over-subscription of the Offering, the allocation to the aforementioned lenders and Bootstrap of Shares in the Offering in consideration of the respective contributions in kind of their Convertible Loan, Bridge Loan and partial Exit Fee payables shall not be reduced.

As the aforementioned Convertible Loan, Bridge Loan and partial Exit Fee payables will be contributed in kind in the Offering, no additional cash will be contributed for the amount of these payables in the Offering.

13.4 Offer Price

The Offer Price will be a single price in euro, exclusive of the Belgian tax on stock exchange transactions, if applicable (see Part 18 – (Taxation), section 18.5 (Belgian tax on stock exchange transactions)), and costs, if any, charged by financial intermediaries for the submission of applications, and will apply to all investors, whether Retail Investors or Institutional Investors.

The Offer Price will be determined within the Price Range on the basis of a book-building process in which only Institutional Investors can participate, taking into account various relevant qualitative and quantitative elements, including but not limited to the number of Offered Shares for which subscriptions are received, the size of subscription orders received, the quality of the investors submitting such subscription orders and the prices at which the subscription orders were made, as well as market conditions at that time.

The Price Range has been determined by the Issuer in agreement with the Underwriters, taking into account market conditions and factors including but not limited to:

- the condition of the financial markets;
- the Issuer's financial position;
- qualitative assessment of the demand for the Offered Shares; and
- all other factors deemed relevant.

The Issuer reserves the right to increase or decrease the lower limit of the Price Range or to decrease the upper limit of the Price Range. If the Price Range is narrowed through an increase of the lower limit and/or a decrease of the upper limit, or if the Price Range is narrowed to a single price, the change will be published in the financial press and by means of a press release, through electronic information services such as Reuters or Bloomberg. Other changes to the Price Range will also be published in the financial press and by means of a press release, through electronic information services, as well as in a supplement to the Prospectus. Investors who have submitted subscription orders will not be notified individually. The Offer Price for investors shall not, however, exceed the higher end of the Price Range. In the event of a publication of a supplement to the Prospectus, investors will have the right to withdraw their orders made prior to the publication of the supplement (see section 13.9 (Right to withdraw) below).

Retail Investors in Belgium can only acquire the Offered Shares at the Offer Price and are legally bound to acquire the number of Offered Shares indicated in their subscription order at the Offer Price, unless (i) the Offering has been withdrawn in which case the subscription orders will become null and void, (ii) in the event of the publication of a supplement to the Prospectus, in which case the Retail Investors will have the right to withdraw their orders made prior to the publication of the supplement or (iii) they exercise their withdrawal right as further specified below (see section 13.9 (Right to withdraw) below).

13.5 Dilution resulting from the Offering

See table, "Principal shareholders".

13.6 Offering Period

The Offering Period will begin on 31 January 2019 and is expected to close no later than 4:00 p.m. (CET) on 7 February 2019, subject to the possibility of an early closing or extension, provided that the Offering Period will in any event be open for at least six business days. The Prospectus will be made available as of the first calendar day of the Offering Period. The Offering Period can be closed, at the earliest, six business days after the start of the Offering Period and, hence, prospective investors can submit their orders at least during six business days after the start of the Offering Period.

Any extension or early closing of the Offering Period will be announced by means of a press release by the Issuer, and the dates for each of pricing, allocation, publication of the Offer Price and the results of the Offering, "as-if-and-when-issued-and/or-delivered" trading and closing of the Offering will in such case be adjusted accordingly.

In the event the Offering Period is extended with more than five business days, this will be published in a supplement to the Prospectus. Investors who have already agreed to subscribe for the Offered Shares before the supplement is published will have the right, exercisable within at least two business days after the publication of the supplement, to withdraw their subscription orders, provided that the significant new development, material mistake or inaccuracy referred to above arose before the closing of the Offering and the delivery of the Offered Shares. The Offering Period can only be closed earlier in case of a coordinated action between the Underwriters. In the event the Offering Period is extended with five business days or less, this will only be announced by means of a press release by the Issuer. Prospective investors can submit their subscription

orders during the Offering Period. Taking into account the fact that the Offering Period may be closed early, investors are invited to submit their applications as promptly as possible.

The timeline, validity and form of instructions to financial intermediaries in relation to the subscription for or purchase of Shares will be determined by each financial intermediary in accordance with its usual procedures or as otherwise notified to the investors. The Issuer is not liable for any action or failure to act by a financial intermediary in connection with any subscription or purchase, or purported subscription or purchase, of Shares.

Subscription orders by Retail Investors in Belgium may be submitted at the counters of KBC Bank and KBC Securities NV/SA in Belgium, and at the counters of the affiliate of Kempen & Co N.V. in Belgium (i.e. Van Lanschot), at no cost to the investor or alternatively through other than the aforementioned intermediaries. Applications are not binding upon the Issuer or the Underwriters as long as they have not been accepted in accordance with the allocation rules described below under section 13.10 (Allocation).

Investors wishing to place purchase orders for the Offered Shares through intermediaries other than KBC Bank, KBC Securities NV/SA and the affiliate of Kempen & Co N.V. in Belgium should request details of the costs which these intermediaries may charge, which they will have to pay themselves.

To be valid, the subscription orders must be submitted no later than 4:00 p.m. (CET) on 7 February 2019, unless the Offering Period is closed earlier or extended, in which case the subscription orders must be submitted no later than 4:00 p.m. (CET) at such earlier or extended closing date of the Offering Period.

13.7 Retail Investors

A Retail Investor shall mean an individual person resident in Belgium or a legal entity located in Belgium that does not qualify as a qualified investor (gekwalificeerde belegger/investisseur qualifié) as defined in article 10, § 1 of the Belgian Prospectus Act.

Retail Investors must indicate in their subscription orders the number of Offered Shares they are committing to subscribe for. Every order must be expressed in number of Offered Shares with no indication of price and shall be deemed placed at the Offer Price. Only one application per Retail Investor will be accepted. If the Underwriters determine, or have reason to believe, that a single Retail Investor has submitted several subscription orders, through one or more intermediaries, they may disregard such subscription orders. There is no minimum or maximum amount or number of Offered Shares that may be subscribed for in one subscription order. Subscription orders are subject to a possible reduction as described below in section 13.10 (Allocation).

KBC Securities NV/SA will act as centralisation agent for subscription orders by Retail Investors.

13.8 Institutional Investors

Institutional Investors must indicate in their subscription orders the number of Offered Shares or an amount they are committing to subscribe for, and the prices at which they are making such subscription orders during the book-building period. There is no minimum or maximum amount or number of Offered Shares that may be subscribed for in one subscription order. Subscription orders are subject to a possible reduction as described below in section 13.10 (Allocation). Only Institutional Investors can participate in the book-building process during the Offering Period.

13.9 Right to withdraw

Retail Investors in Belgium can only acquire the Offered Shares at the Offer Price and are legally bound to acquire the number of Offered Shares indicated in their subscription order at the Offer Price, unless (i) the Offering has been withdrawn in which case the subscription orders will become null and void, or (ii) in the event of the publication of a supplement to the Prospectus, in which case the Retail Investors will have the right to withdraw their orders made prior to the publication of the supplement.

In accordance with article 34 of the Belgian Prospectus Act, in the event of a significant new development, or material mistake or inaccuracy relating to the information included in this Prospectus which is capable of affecting the assessment of the Offered Shares during the period from the date of approval of the Prospectus to the Listing Date, a supplement to this Prospectus

shall be published. Any supplement is subject to approval by the FSMA, in the same manner as this Prospectus and must be made public in the same manner as this Prospectus.

Investors who have already agreed to subscribe for the Offered Shares before the supplement is published will have the right, exercisable within at least two business days after the publication of the supplement, to withdraw their subscription orders, provided that the significant new development, material mistake or inaccuracy referred to above arose before the closing of the Offering and the delivery of the Offered Shares.

A supplement to this Prospectus will be published in accordance with article 34 of the Belgian Prospectus Act (i) in the event the Offer Price is set below the lower end of the Price Range, (ii) if the Price Range is changed (other than in the event of a narrowing of the Price Range through an increase of the lower limit and/or a decrease of the upper limit of the Price Range), (iii) if the Offering Period is extended with more than five business days, (iv) if the maximum number of Offered Shares is reduced, including due to an early closing of the Offering Period without placement of the total number of New Shares, (v) if the Underwriting Agreement is not executed or is executed but subsequently terminated or (vi) to the extent required, if the Offering is withdrawn.

Retail Investors that wish to withdraw their subscription order should contact their financial intermediaries in order to check how their subscription order can be withdrawn.

13.10 Allocation

The number of Offered Shares allotted to investors will be determined at the end of the Offering Period by the Issuer in agreement with the Underwriters on the basis of the respective demand of both Retail Investors and Institutional Investors and on the quantitative, and, for Institutional Investors only, the qualitative analysis of the order book, in accordance with Belgian regulations relating to allocation to Retail Investors and Institutional Investors as set forth below.

In accordance with Belgian regulations, a minimum of 10% of the Offered Shares shall be allocated to Retail Investors, subject to sufficient retail demand. However, the proportion of Offered Shares allocated to Retail Investors may be increased or decreased in an equal manner if subscription orders received from them exceed or do not reach, respectively, 10% of the Offered Shares effectively allocated.

In case of over-subscription of the Offered Shares reserved for Retail Investors, the allocation to Retail Investors will be made on the basis of objective and quantitative allocation criteria, whereby all Retail Investors will be treated equally. The criteria that may be used for this purpose are the preferential treatment of applications submitted by Retail Investors at the counters of KBC Bank and KBC Securities NV/SA in Belgium, and at the counters of the affiliate of Kempen & Co N.V. in Belgium (i.e. Van Lanschot), and the number of Shares for which applications are submitted by Retail Investors.

The results of the Offering, the allocation for Retail Investors, the Offer Price, and the allocation criteria (in case of over-subscription) will be announced by the Issuer on or about 8 February 2019 and in any event no later than the first business day after the end of the Offering Period. In the event of the over-allotment of Offered Shares, the Underwriters will use reasonable efforts to deliver the newly issued Shares to individual persons residing in Belgium and to investors subject to Belgian income tax on legal entities (*rechtspersonenbelasting/impôt des personnes morales*), in this order of priority. No tax on stock exchange transactions is due on the subscription for newly issued Shares, but such tax could be due on the subscription for existing Shares (see Part 18 – (Taxation of Shares), section 18.5 (Belgian tax on stock exchange transactions)).

In the event of over-subscription of the Offering, the Subscription Commitments of the Participating Investors in cash for an amount of ca. €12.5 million (not including the amounts due pursuant to the Bridge Loans and the payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) can be reduced in line with the allocation principles that will apply to the other investors that will subscribe in the Offering, whereas the Subscription Commitments for the remaining amount (including the amounts due pursuant to the Bridge Loans and the payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) shall not be reduced but be allocated entirely. See also section 13.2 (Pre-commitments by the Participating Investors).

13.11 Payment and taxes

The Offer Price must be paid by the investors in full, in euro, together with any applicable stock exchange taxes and costs. No tax on stock exchange transactions is due on the subscription for newly issued Shares. For further information about applicable taxes, see Part 18 – (Taxation of Shares), section 18.1 (Belgian taxation).

The Closing Date is expected to be 12 February 2019 unless the Offering Period is closed earlier or extended. The Offer Price must be paid by investors by authorising their financial institutions to debit their bank accounts with such amount for value on the Closing Date.

13.12 Form of the Offered Shares and delivery

From their issue date, the Offered Shares will be subject to all provisions of the articles of association of the Issuer. The Offered Shares shall be of the same class as existing Shares, including as to voting and dividend rights, and will be profit sharing as from any distribution in respect of which the relevant record date or due date falls on or after the date of their issuance, including any distributions in relation to the financial year that started on and after 1 January 2018, as the case may be. The rights attached to the Shares are described in Part 12 – (Share capital and articles of association), section 12.8 (Rights attached to the Shares).

All Offered Shares will be delivered in dematerialised (book-entry) form only, and will be credited on or around the Closing Date to investors' securities accounts via Euroclear Belgium.

Investors who, after delivery, wish to have their Shares registered, should request that the Issuer record the Shares in the Issuer's share register.

Holders of registered Shares may request that their registered Shares be converted into dematerialised Shares and vice versa. Any costs incurred in connection with the conversion of Shares into another form will be borne by the shareholders.

All Offered Shares will be fully paid-up upon their delivery and freely transferable, subject to what is set forth under Part 14 – (Plan of distribution).

13.13 Trading and listing on the regulated market of Euronext Brussels

An application has been made for the listing and admission to trading on the regulated market of Euronext Brussels of all Shares, including the Offered Shares. The Shares are expected to be listed under the symbol "SEQUA" with ISIN code BE0974340722.

Trading is expected to commence on or about 11 February 2019 (unless in case of early closing or extension of the Offering Period) and will start at the latest on the Closing Date, when the Offered Shares are delivered to investors.

As of the Listing Date until the Closing Date and delivery of the Offered Shares, the Shares will be traded on the regulated market of Euronext Brussels on an "as-if-and-when issued and/or delivered" basis. Investors who wish to effect transactions in Shares prior to the Closing Date, whether such transactions are effected on the regulated market of Euronext Brussels or otherwise, should be aware that the issuance and delivery of the Offered Shares may not take place on the expected Closing Date, or at all, if certain conditions or events referred to in the Underwriting Agreement (as defined below) are not satisfied or waived or do not occur on or prior to such date. Euronext Brussels may annul all transactions effected in the Shares if the Offered Shares are not delivered on the Closing Date. See Part 2 – (Risk Factors), section 2.2 (Risks related to the Shares and the Offering), subsection (o) (The Shares will be listed and traded on the regulated market of Euronext Brussels on an "if-and-when-issued-and/or-delivered" basis from the Listing Date until the Closing Date. Euronext Brussels may annul all transactions effected in the Shares if they are not issued and delivered on the Closing Date). Euronext Brussels cannot be held liable for any damage arising from the listing and trading on an "if-and-when-issued-and/or-delivered" basis as of the Listing Date until the expected Closing Date.

13.14 Share lending

LSP Health Economics Fund Management B.V. and NeoMed IV Extension L.P. are expected to agree to lend to the Stabilisation Manager (acting on behalf of the Underwriters) a number of Shares equal to up to 15% of the number of New Shares subscribed for in the Offering (including the New Shares subscribed for pursuant to the effective exercise of the Increase Option, if any), in order to enable the Stabilisation Manager to settle any over-allotments.

13.15 Increase Option

Depending on the volume of demand, the aggregate number of New Shares offered in Offering may be increased by up to 15% of the aggregate number of New Shares initially offered. Any decision to exercise the Increase Option will be communicated, at the latest, on the date of announcement of the Offer Price, which is currently expected to be on or around 8 February 2019. To the extent that such Increase Option has been exercised and subject to entering into the Underwriting Agreement, the Underwriters will severally purchase the additional Shares in the same proportion as set forth in the table under Part 14 – (Plan of distribution), section 14.1 (Underwriting) below.

13.16 Over-allotment Option

The Issuer is expected to grant to the Stabilisation Manager, acting on behalf of the Underwriters, an Over-allotment Option, in the form of a warrant, which will entitle the Stabilisation Manager, acting on behalf of the Underwriters, to subscribe for additional new Shares for an aggregate number equal to up to 15% of the number of New Shares subscribed for in the Offering at the Offer Price to cover over-allotments or short positions, if any, in connection with the Offering. The Over-allotment Option will be exercisable for a period of 30 calendar days following Listing Date.

13.17 Authorisations

This Prospectus and the participation of the Issuer in the Offering were approved by the board of directors of the Issuer on 28 January 2019. The issuance of the Offered Shares and required amendments to the Issuer's articles of association, both of which are subject to the condition precedent of the closing of the Offering, were approved by the shareholders of the Issuer at their extraordinary general shareholders' meeting held on 18 January 2019.

13.18 Financial service

From the Listing Date, the financial service for the shares of the Issuer will be provided by KBC Bank NV, who will act as listing and paying agent of the Issuer. Should the Issuer alter its policy in this respect, this will be announced in accordance with applicable law.

13.19 Jurisdiction and competent courts

The Offering is subject to Belgian law and the courts of Brussels are exclusively competent to adjudicate any and all disputes with investors concerning the Offering.

PART 14 – PLAN OF DISTRIBUTION

14.1 Underwriting

The Underwriters are Kempen & Co N.V., having its registered office at Beethovenstraat 300, 1077, WZ Amsterdam, the Netherlands, KBC Securities NV/SA, having its registered office at Havenlaan 2, 1080, Brussels, Belgium, and Mirabaud Securities Limited, having its registered office at 10 Bressenden Place, SW1E 5DH, London, United Kingdom.

The Underwriters are expected (but have no obligation) to enter into an underwriting agreement (the “**Underwriting Agreement**”), upon the determination of the Offer Price, which is expected to take place on or about 8 February 2019. The entering into the Underwriting Agreement may depend on various factors including, but not limited to, market conditions and the result of the book-building process.

Subject to the terms and conditions to be set forth in the Underwriting Agreement, the Underwriters will severally but not jointly agree to subscribe and procure payment for the following percentage of the total number of New Shares (including the New Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) less those New Shares subscribed for by certain Participating Investors pursuant to a Subscription Commitment and the New Shares subscribed for through a contribution in kind in the Offering of certain Convertible Loan, Bridge Loan and partial Exit Fee payables (the “**Underwritten Shares**”), in their own name but for the account of the relevant subscribers in the Offering to whom those Underwritten Shares have been allocated:

	Percentage of Underwritten Shares to be subscribed for
Underwriters	
Kempen & Co N.V.....	40%
KBC Securities NV/SA	40%
Mirabaud Securities Limited	20%
Total percentage of the Underwritten Shares to be subscribed for	100%

The Underwriters shall have no obligation to underwrite any of the Underwritten Shares prior to the execution of the Underwriting Agreement (and then only in accordance with the terms and subject to the conditions set forth therein).

Immediately after receipt of the Underwritten Shares, the Underwriters will deliver such Underwritten Shares to the relevant subscribers in the Offering and the Underwriters shall guarantee to the Issuer the payment of the Offer Price.

In the Underwriting Agreement, the Issuer will make certain customary representations and warranties and the Issuer will agree to indemnify each of the Underwriters against certain liabilities in connection with the Offering, including liability under the U.S. Securities Act. If the Underwriting Agreement is not entered into, a supplement to the Prospectus to this effect will be published.

The Underwriting Agreement will provide that each Underwriter shall have the right to terminate the Underwriting Agreement before the realisation of the capital increase in relation to the Offering, if: (i) in the reasonable opinion of the Joint Global Coordinators any statement in any offering document is, or has become, or has been discovered to be, inaccurate or misleading in any material respect, or any matter has arisen which would, if the offering documents were to be issued at such time, constitute a material inaccuracy or omission from such offering document; (ii) any matter has arisen which would, in the reasonable opinion of the Joint Global Coordinators, require under Belgian law the publication of a supplement to the Prospectus or a supplement or addendum to the other offer documents and the relevant Joint Global Coordinator has not explicitly confirmed to the Issuer at the occasion of the publication of such addendum that it would waive such condition, (iii) there has been a breach in any material respect by the Issuer or its subsidiaries of any of the representations and warranties given by them and contained in the Underwriting Agreement, or the Issuer has not complied with its covenants and undertakings set forth in the Underwriting Agreement in all material respects; (iv) any of the Underwriters would

default in performing its underwriting obligations under the Underwriting Agreement (it being specified that the termination rights in that case accrue to the non-defaulting Underwriter(s) only); (v) any Joint Global Coordinator would terminate the Agreement in accordance with the termination events set forth in the Underwriting Agreement; (vi) in the reasonable opinion of the Joint Global Coordinators, there shall have been or it is likely that there will be a material adverse effect; (vii) any of the conditions precedent has not been satisfied, such as (a) the performance of the Participating Investors pursuant to the Subscription Commitments or (b) the delivery of the closing documents; (viii) the application for trading on Euronext Brussels is withdrawn or refused; (ix) the Issuer fails to issue at the relevant date(s) the number of Shares that it is obliged to issue under the Underwriting Agreement; or (x) there has been a force majeure event. Following termination of the Underwriting Agreement by an Underwriter, the other Underwriter will be authorised but is not obliged to further proceed with the Offering and the performance of the Underwriting Agreement without the involvement of the Underwriter who terminated the Underwriting Agreement.

In the event that the Underwriting Agreement is not executed or is executed but subsequently terminated, a supplement to this Prospectus shall be published. After publication of the supplement, the subscriptions for the Offered Shares will automatically be cancelled and withdrawn, and subscribers will not have any claim to delivery of the Offered Shares or to any compensation.

14.2 Standstill

The Issuer is expected to agree pursuant to the Underwriting Agreement (which is expected to be entered into on or about 8 February 2019) that it will not, and it will procure that its affiliates will not, for a period of 360 days from the Closing Date, otherwise than with the prior written consent of the Joint Global Coordinators: (i) issue, offer, sell, contract to sell or otherwise transfer, (attempt to) dispose of, lend, or solicit any offer to buy (or publicly announce such action), directly or indirectly, any Shares or securities of the Issuer that are substantially similar to the Shares, including but not limited to any securities that are convertible into or exchangeable for, or that represent the right to receive, Shares or any such substantially similar securities, (ii) grant or issue any options, warrants, convertible securities, other guaranty, or other rights to subscribe for or purchase shares in the Issuer, or enter into any swap, hedge or other arrangement pursuant to which the economic consequences of its ownership of Shares is transferred to any other person or entity, in whole or in part, whether any such transaction is to be settled by delivery of Shares or such other securities, or cash or otherwise, or (iii) submit to its shareholders or any other body a proposal to effect any of the foregoing. The foregoing undertaking shall not apply in relation to (1°) the New Shares, (2°) the Over allotment Option, (3°) the Option Shares, (4°) the new Shares (to be) issued upon the exercise of warrants, conversion rights or options that are outstanding or are contemplated to be issued as described in the Prospectus, and (5°) the granting of warrants or options under warrant or option plans that are outstanding or are contemplated to be issued as described in the Prospectus.

14.3 Lock up

The current shareholders (excluding certain minority shareholders holding in the aggregate less than ca. 0.01% of the outstanding Shares after giving effect to the contribution in kind of the Convertible Loan payables (with the exception of certain payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91 that will be converted into New Shares at the Offer Price in connection with the Offering) and the Share Consolidation) and the Participating Investors have entered into a lock up arrangement with the Underwriters in respect of (i) any of their Shares in the Issuer prior to the Offering, (ii) any of the Shares that they will receive through the contribution in kind of their Convertible Loan payables (with the exception of certain payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91 that will be converted into New Shares at the Offer Price in connection with the Offering), (iii) all of the Shares into which the aforementioned Shares will be converted, exchanged and consolidated pursuant to the Share Consolidation, and (iv) all their securities or rights issued or agreed to by the Issuer that are convertible into or exercisable or exchangeable for Shares of the Issuer (including the shares into which such securities or rights are converted, exercised or exchanged) (together the “**Locked Securities**”). The definition of Locked Securities does not include any of the New Shares that will be subscribed for in the Offering at the Offering Price pursuant to the Subscription Commitments (including pursuant to the conversion of outstanding amounts pursuant to the Bridge Loans) or pursuant to the contribution in kind of payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91.

Pursuant to the lock up arrangement, the holders of Locked Securities will not, for a period ending 360 days after the Listing Date, (i) directly or indirectly, issue, offer, pledge, exchange, lend, assign by way of security, grant any right “in rem”, deliver or market, sell, contract to sell, sell or grant any option, right, warrant or contract to purchase, exercise any option to sell, purchase any option or contract to sell, or lend or otherwise transfer or dispose of any of their Locked Securities, (ii) enter into any swap, any arrangement, any derivative transaction or issue any instruments that transfer (conditionally or unconditionally, now or in the future) to a third party all or part of the economic risk, benefits, rights or ownership of any Locked Securities, or (iii) publicly announce such an intention to effect any such transaction.

The restrictions do not prohibit holders of Locked Securities from (i) accepting a general take-over or tender offer on all of the ordinary share capital of the Issuer, giving an irrevocable commitment to accept such an offer, or disposing of Locked Securities to an offeror or potential offeror during the period of such an offer; (ii) proceeding with any disposal required by law, regulation or a court of competent jurisdiction; (iii) transferring Locked Securities intra-group or to one or more legal successors pursuant to a merger, liquidation, concursus, de-merger, transfer of a branch of activity or transfer of a universality (for holders of Locked Securities that are a legal entity), or intra-family or to one or more legal successors pursuant to the death of the shareholder (for holders of Locked Securities who are a natural person), provided that each such transferee shall continue to be bound by the restrictions for the remaining period of the restrictions; or (iv) lending a number of Locked Shares to one of the Joint Global Coordinators in the framework of the Offering. In addition, starting as from the 181th day after the first day of trading of the Shares on Euronext Brussels until the end of the restriction period, transfers of Locked Securities shall be permitted provided that (x) one or more Participating Investors holding in the aggregate at least 5% of the outstanding share capital of the Issuer at the time the request is made, shall have requested and obtained the prior written approval of the Joint Global Coordinators (acting on behalf of the Underwriters) and (y) any such transfer for which such prior written consent has been given shall solely be effected through a coordinated sale.

Any transfer of (any part of) the 18,468 common Shares (before giving effect to the Share Consolidation, representing less than 59 Shares after giving effect to the Share Consolidation and assuming that the Offer Price is at the midpoint of the Price Range (i.e. €8.75)) that were issued on 9 July 2018 and all of the Shares that will be issued upon conversion of the Convertible Loans (other than the Shares that will be issued at the Offer Price in connection with the Offering through contribution in kind of payables under the February 2018 Convertible Loan for an aggregate principal amount of €6,340.91) will (subject to limited exceptions in the context of a public takeover bid), as from and until one year after the closing of the Offering, require a prior approval by the FSMA in accordance with the statutory lock up provisions of article 11 of the Belgian Royal Decree of 17 May 2007 on primary market practices, as amended.

The Shares that Bootstrap acquires upon the exercise of the Bootstrap Warrant will not be subject to a transfer restriction. However, Bootstrap entered into a lock-up arrangement with the Issuer and the Joint Global Coordinators with respect to the Shares that it will acquire through the contribution in kind of 50% of the Exit Fee in the Offering. Pursuant to the lock up arrangement, Bootstrap will not, for a period ending 180 days after the Listing Date (the “Bootstrap Lock-up Period”), (i) directly or indirectly, issue, offer, pledge, exchange, lend, assign by way of security, grant any right “in rem”, deliver or market, sell, contract to sell, sell or grant any option, right, warrant or contract to purchase, exercise any option to sell, purchase any option or contract to sell, or lend or otherwise transfer or dispose of any of the Shares that it will acquire through the contribution in kind of 50% of the Exit Fee in the Offering, (ii) enter into any swap, any arrangement, any derivative transaction or issue any instruments that transfer (conditionally or unconditionally, now or in the future) to a third party all or part of the economic risk, benefits, rights or ownership of any such Shares, or (iii) publicly announce such an intention to effect any such transaction. The restrictions do not prohibit Bootstrap from (i) accepting a general take-over or tender offer on all of the ordinary share capital of the Issuer, giving an irrevocable commitment to accept such an offer, or disposing of Shares to an offeror or potential offeror during the period of such an offer; (ii) proceeding with any disposal required by law, regulation or a court of competent jurisdiction; or (iii) transferring any of the Shares that it will acquire through the contribution in kind of 50% of the Exit Fee in the Offering to its limited partners that have an interest in Bootstrap, provided that prior to such transfer such limited partner confirms in writing to

the Joint Global Coordinators that it shall be bound by the transfer restriction for the remainder of the Bootstrap Lock-Up Period with respect to any of such Shares so to be transferred to it.

14.4 Over-allotment Option and price stabilisation

In connection with the Offering, KBC Securities NV/SA will act as Stabilisation Manager on behalf of the Underwriters and may engage in transactions that stabilise, maintain or otherwise affect the price of the Shares or any options, warrants or rights with respect to, or other interest in, the Shares or other securities of the Issuer for up to 30 calendar days from the Listing Date. These activities may support the market price of the Shares at a level higher than that which might otherwise prevail. Stabilisation will not be executed above the Offer Price. Such transactions may be effected on the regulated market of Euronext Brussels, in the over-the-counter markets or otherwise. The Stabilisation Manager and its agents are not required to engage in any of these activities and, as such, there is no assurance that these activities will be undertaken; if undertaken, the Stabilisation Manager or its agents may discontinue any of these activities at any time and they must terminate at the end of the 30-calendar day period mentioned above.

Under the possible stabilisation measures, investors may, in addition to the New Shares being offered, be allocated up to 15% of the New Shares subscribed for in the Offering (including the New Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) as additional Shares as part of the allocation of the Shares to be placed. Within the scope of a possible over-allotment, the additional Shares will be provided for the account of the Stabilisation Manager, acting on behalf of the Underwriters, in the form of a securities loan from NeoMed IV Extension L.P. and LSP Health Economics Fund Management B.V. (directly and/or through their respective affiliates).

The Issuer is expected to grant to the Stabilisation Manager, acting on behalf of the Underwriters, an Over-allotment Option, in the form of a warrant, which will entitle the Stabilisation Manager, acting on behalf of the Underwriters, to subscribe for additional new Shares for an aggregate number equal to up to 15% of the New Shares subscribed for in the Offering at the Offer Price to cover over-allotments or short positions, if any, in connection with the Offering.

The Stabilisation Manager may elect to reduce any short position by exercising all or part of the Over-Allotment Option. The Over-Allotment Option will be exercisable for a period of 30 calendar days from the Listing Date. The Over-Allotment Option will be exercisable in whole or in part, and in one or in several times, to cover over-allotments or short positions, if any. The possibility to over-allot Shares in the Offering and to exercise the Over-Allotment Option will exist whether or not the Offering is fully subscribed.

If the Stabilisation Manager creates a short position in the Shares in connection with the Offering (i.e. over-allot additional Shares), they may reduce that short position by purchasing Shares or by exercising all or part of the Over-Allotment Option. Purchases of Shares to stabilize the trading price or to reduce a short position may cause the price of the Shares to be higher than it might be in the absence of such purchases. Neither the Issuer, nor the Underwriters make any representation or prediction as to the direction or the magnitude of any effect that the transactions described above may have on the price of the Shares.

Within one week of the end of the Stabilisation Period, the following information will be made public: (i) whether or not stabilisation was undertaken; (ii) the date on which stabilisation started; (iii) the date on which stabilisation last occurred; (iv) the price range within which stabilisation was carried out, for each of the dates on which stabilisation transactions were carried out; (v) the trading venue(s) on which the stabilisation transactions were carried out (where applicable) and (vi) the final size of the Offering, including the result of the stabilisation and the exercise of the Over-allotment Option and the Increase Option, as the case may be.

14.5 Other relationships with the Underwriters

In connection with the Offering, each of the Underwriters and any of their respective affiliates, acting as an investor for its own account, may take up Offered Shares in the Offering and in that capacity may retain, purchase or sell for its own account such securities and any Shares or related investments and may offer or sell such Shares or other investments otherwise than in connection with the Offering. Accordingly, references in the Prospectus to Shares being offered or placed should be read as including any offering or placement of Offered Shares to any of the Underwriters or any of their respective affiliates acting in such capacity. None of the Underwriters intend to

disclose the extent of any such investment or transactions otherwise than in accordance with any legal or regulatory obligation to do so. In addition certain of the Underwriters or their affiliates may enter into financing arrangements (including swaps) with investors in connection with which such Underwriters (or their affiliates) may from time to time acquire, hold or dispose of Shares.

Certain of the Underwriters and/or their respective affiliates have in the past provided, and may in the future, from time to time, engage in commercial banking, investment banking and financial advisory and ancillary activities in the ordinary course of their business with the Issuer or any parties related to it, in respect of which they may, in the past have received, or in the future receive, customary fees and commissions. As a result of these transactions, these parties may have interests that may not be aligned, or could possibly conflict with the interests of investors.

14.6 No public offering outside Belgium

No public offer is being made and no action has been or will be taken that would, or is intended to, permit a public offering of the Offered Shares, or the possession, circulation or distribution of this Prospectus or any other material relating to the Offered Shares, in any country or jurisdiction, other than Belgium, where any such action for that purpose is required. Accordingly, the Offered Shares may not be offered or sold, directly or indirectly, and neither this Prospectus nor any other offering material or advertisements in connection with the Offered Shares may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of such country or jurisdiction.

Purchasers of the Offered Shares may be required to pay stamp taxes and other charges in accordance with the laws and practices of the country of purchase in addition to the Offer Price.

14.7 Selling restrictions

(a) General

Persons into whose hands this Prospectus comes are required by the Issuer and the Underwriters to comply with all applicable laws and regulations in each country or jurisdiction in or from which they purchase, offer, sell or deliver Shares or have in their possession or distribute such offering material, in all cases at their own expense. Neither the Issuer or the Underwriters accept any legal responsibility for any violation by any person, whether or not a prospective subscriber or purchaser of any of the Shares, of any such restrictions.

(b) United States

The Shares have not been and will not be registered under the U.S. Securities Act or with any state securities regulatory authority for offer or sale as part of their distribution and may not be offered, sold, pledged or transferred within the U.S., except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the U.S. Securities Act.

The Shares may only be resold: (i) in the U.S. to QIBs in reliance on Rule 144A under the U.S. Securities Act or pursuant to another exemption from the registration requirements of the U.S. Securities Act; and (ii) outside the U.S. in offshore transactions in compliance with Regulation S under the U.S. Securities Act and in accordance with applicable law. Any offer or sale of Shares in reliance on Rule 144A or pursuant to another exemption from, or transaction not subject to, the registration requirements of the U.S. Securities Act will be made by broker-dealers who are registered as such under the U.S. Exchange Act. Terms used above shall have the meanings given to them by Regulation S and Rule 144A under the U.S. Securities Act. Resales of the Shares are restricted as described under Part 15 – (Transfer restrictions).

(c) European Economic Area

In relation to each Relevant Member State an offer to the public of any Shares may not be made in that Relevant Member State unless the Prospectus has been approved by the competent authority in such Relevant Member State or passported and published in accordance with the European Prospectus Directive as implemented in such Relevant Member State, except that the Shares may be offered to the public in that Relevant Member State at any time under the following exemptions under the European Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a qualified investor as defined in the European Prospectus Directive;

- by the Underwriters to fewer than 150 natural or legal persons (other than qualified investors as defined in the European Prospectus Directive); or
- in any other circumstances falling within article 3(2) of the European Prospectus Directive,

provided that no such offer of Shares shall result in a requirement for the publication by the Issuer or any Underwriter of a prospectus pursuant to article 3 of the European Prospectus Directive or supplement a prospectus pursuant to article 16 of the European Prospectus Directive and each person who initially acquires Shares or to whom any offer is made will be deemed to have represented, warranted and agreed to and with the Underwriters and the Issuer that it is a “qualified investor” within the meaning of the law in that Relevant Member State implementing article 2(1) of the European Prospectus Directive.

The Issuer, the Underwriters and their affiliates and others will rely upon the truth and accuracy of the foregoing representation, acknowledgement, and agreement. Notwithstanding the above, a person who is not a qualified investor and who has notified the Underwriters of such fact in writing may, with the consent of the Underwriters, be permitted to subscribe for Shares in the Offering.

(d) United Kingdom

Any offer or sale of the Shares may only be made to persons in the U.K. who are “qualified investors” or otherwise in circumstances which do not require publication by the Issuer of a prospectus pursuant to section 85(1) of the U.K. Financial Services and Markets Act 2000. Any investment or investment activity to which this Prospectus relates in the U.K. is available only to, and will be engaged in only with, investment professionals falling within article 19(5), or falling within section 49(2)(a) to (d) (“high net worth; unincorporated associations, etc.”), of the U.K. Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or other persons to whom such investment or investment activity may lawfully be made available (together, “**Relevant Persons**”). Persons in the U.K. who are not Relevant Persons should not take any action on the basis of this Prospectus and should not act or rely on it.

(e) Japan

The Shares have not been and will not be registered under the Financial Instruments and Exchange Act, as amended, or any successor legislation thereto (the “**FIEL**”). This document is not an offer of securities for sale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or entity organised under the laws of Japan) or to others for reoffer or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements under the FIEL and otherwise in compliance with such law and any other applicable laws, regulations and ministerial guidelines of Japan.

(f) Switzerland

The Shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“**SIX**”) or on any other stock exchange or regulated trading facility in Switzerland. This Prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this Prospectus nor any other offering or marketing material relating to the Shares or the Offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this Prospectus nor any other offering or marketing material relating to the Offering, the Issuer or the Shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this Prospectus will not be filed with, and the Offering will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the Offering has not been and will not be authorised under the Swiss Federal Act on Collective Investment Schemes (“**CISA**”). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of Shares.

(g) Israel

This Prospectus does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the “**Israeli Securities Law**”), and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this Prospectus is being distributed only to, and is directed only at, and any offer of the Offered Shares is directed only (i) at a limited number of persons (35 investors or fewer during any given 12 month period) in accordance with Section 15A(a)(1) of the Israeli Securities Law and/or (ii) to investors listed in the first schedule to the Israeli Securities Law (the “**Schedule**”), consisting primarily of joint investment in trust funds, provident funds, insurance companies, banking corporations, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and high net worth individuals, each as described in the Schedule (as it may be amended from time to time), collectively referred to as “qualified investors” (in each case purchasing for their own account or, where permitted under the Schedule, for the accounts of their clients who are investors listed in the Schedule). Qualified investors will be required to submit written confirmation that they fall within the scope of the Schedule, and that they are aware of the consequences of such designation and agree thereto.

PART 15 – TRANSFER RESTRICTIONS

The Shares have not been and will not be registered under the U.S. Securities Act or the applicable securities laws of any state or other jurisdiction of the U.S. and may not be offered, sold, pledged or transferred within the U.S., except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the U.S. Securities Act and applicable state securities laws. Terms defined in Rule 144A or Regulation S shall have the same meaning when used in this section.

Each purchaser and each subsequent purchaser of the Offered Shares outside the U.S. in compliance with Regulation S will be deemed to have represented and agreed that it has received a copy of this Prospectus and such other information as it deems necessary to make an informed investment decision and that:

- (1) the purchaser is authorised to consummate the purchase of the Offered Shares in compliance with all applicable laws and regulations;
- (2) the purchaser acknowledges that the Offered Shares have not been and will not be registered under the U.S. Securities Act, or with any securities regulatory authority of any state of the U.S., and, subject to certain exceptions, may not be offered or sold within the U.S.;
- (3) the purchaser and the person, if any, for whose account or benefit the purchaser is acquiring the Offered Shares, was located outside the U.S. at the time the buy order for the Offered Shares was originated and continues to be located outside the U.S. and has not purchased the Offered Shares for the account or benefit of any person in the U.S. or entered into any arrangement for the transfer of the Offered Shares or any economic interest therein to any person in the U.S.;
- (4) the purchaser is not an affiliate of the Issuer or a person acting on behalf of such affiliate;
- (5) the purchaser is aware of the restrictions on the offer and sale of the Offered Shares pursuant to Regulation S described in this Prospectus;
- (6) the Offered Shares have not been offered to it by means of any “directed selling efforts” as defined in Regulation S;
- (7) the purchaser acknowledges that the Issuer shall not recognise any offer, sale, pledge or other transfer of the Offered Shares made other than in compliance with the above-stated restrictions;
- (8) if it is acquiring any of the Offered Shares as a fiduciary or agent for one or more accounts, the purchaser represents that it has sole investment discretion with respect to each such account and that it has full power to make the foregoing acknowledgements, representations and agreements on behalf of each such account; and
- (9) the purchaser acknowledges that the Issuer, the Underwriters and their respective affiliates will rely upon the truth and accuracy of the foregoing acknowledgements, representations and agreements, and undertakes promptly to notify the Issuer and the Underwriters if, at any time prior to the purchase of the Offered Shares, any of the foregoing ceases to be true.

Each purchaser and each subsequent purchaser of the Offered Shares within the U.S. purchasing pursuant to an exemption from the registration requirements of the U.S. Securities Act will be deemed to have represented and agreed that it has received a copy of this Prospectus and such other information as it deems necessary to make an informed investment decision and that:

- (1) the purchaser is authorised to consummate the purchase of the Offered Shares in compliance with all applicable laws and regulations;
- (2) the purchaser acknowledges that the Offered Shares have not been and will not be registered under the U.S. Securities Act or with any securities regulatory authority of any state of the U.S. and are subject to restrictions on transfer;
- (3) the purchaser: (i) is a qualified institutional buyer (as defined in Rule 144A under the U.S. Securities Act); (ii) is aware that the sale to it is being made pursuant to an exemption from the registration requirements of the U.S. Securities Act; and (iii) is acquiring such Offered Shares for its own account or for the account of a qualified institutional buyer;
- (4) the purchaser is aware that the Offered Shares are being offered in the U.S. in a transaction not involving any public offering in the U.S. within the meaning of the U.S. Securities Act;

- (5) if in the future, the purchaser decides to offer, resell, pledge or otherwise transfer such Offered Shares, or any economic interest therein, such Offered Shares or any economic interest therein may be offered, sold, pledged or otherwise transferred only: (i) to a person whom the beneficial owner and/or any person acting on its behalf reasonably believes is a qualified institutional buyer in a transaction meeting the requirements of Rule 144A, (ii) in compliance with Regulation S under the U.S. Securities Act, (iii) in accordance with Rule 144 under the U.S. Securities Act (if available), or (iv) pursuant to an effective registration statement under the U.S. Securities Act, in each case in accordance with any applicable securities laws of any state of the U.S. or any other jurisdiction;
- (6) the purchaser is not an affiliate of the Issuer or a person acting on behalf of such affiliate;
- (7) the purchaser acknowledges that the Offered Shares are “restricted securities” within the meaning of Rule 144(a)(3) under the U.S. Securities Act and no representation is made as to the availability of the exemption provided by Rule 144 for resales of any Offered Shares;
- (8) the purchaser will not deposit or cause to be deposited such Offered Shares into any depository receipt facility established or maintained by a depository bank other than a Rule 144A restricted depository receipt facility, so long as such Offered Shares are “restricted securities” within the meaning of Rule 144(a)(3) under the U.S. Securities Act;
- (9) the purchaser acknowledges that the Issuer shall not recognise any offer, sale, pledge or other transfer of the Offered Shares made other than in compliance with the above-stated restrictions;
- (10) if it is acquiring any of the Offered Shares as a fiduciary or agent for one or more accounts, the purchaser represents that it has sole investment discretion with respect to each such account and that it has full power to make the foregoing acknowledgements, representations and agreements on behalf of such account; and
- (11) the purchaser acknowledges that the Issuer, the Underwriters and their respective affiliates will rely upon the truth and accuracy of the foregoing acknowledgements, representations and agreements, and undertakes promptly to notify the Issuer and the Underwriters if, at any time prior to the purchase of the Offered Shares, any of the foregoing ceases to be true.

In addition, until the end of the 40th calendar day after the commencement of the Offering, an offer or sale of the Shares within the U.S. by any dealer (whether or not participating in the Offering) may violate the registration requirements of the U.S. Securities Act if such offer or sale is made otherwise than in accordance with Rule 144A or another exemption from registration under the U.S. Securities Act.

Each person in a Relevant Member State, other than persons receiving offers contemplated in the Prospectus in Belgium, who receives any communication in respect of, or who acquires any Offered Shares under, the offers contemplated hereby will be deemed to have represented, warranted and agreed to and with each of the Underwriters and the Issuer that:

- (1) it is a qualified investor within the meaning of the law in that Relevant Member State implementing article 2(1) of the European Prospectus Directive; and
- (2) in the case of any Offered Shares acquired by it as a financial intermediary, as that term is used in article 3(2) of the European Prospectus Directive, (i) the Offered Shares acquired by it in the offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors, as that term is defined in the European Prospectus Directive, or in other circumstances falling within article 3(2) of the European Prospectus Directive and the prior consent of the Underwriters has been given to the offer or resale; or (ii) where Offered Shares have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of those Offered Shares to it is not treated under the European Prospectus Directive as having been made to such persons.

PART 16 – LEGAL MATTERS

Certain legal matters in connection with this Offering have been passed upon for the Issuer by Baker & McKenzie CVBA, with respect to the laws of Belgium and by Baker & McKenzie LLP, with respect to the laws of the U.S. Certain legal matters in connection with this Offering have been passed upon for the Underwriters by Linklaters LLP with respect to the laws of Belgium and the U.S.

PART 17 – STATUTORY AUDITOR

The Issuer's Annual Financial Statements have been audited, and the Interim Financial Statements have been reviewed, by PricewaterhouseCoopers AG, with office address at St Jakobs-Strasse 25, CH-4002 Basel, Switzerland, represented by Thomas Brüderlin and Susanne Halimi, both Swiss audit experts, who rendered an unqualified audit report on the Annual Financial Statements with a matter of emphasis paragraph on going concern, which should be read in conjunction with the Annual Financial Statements. PricewaterhouseCoopers AG is a member of EXPERTsuisse – Swiss Expert Association for Audit, Tax and Fiduciary.

Since the Belgian Seat Transfer, the Issuer's current statutory auditor is PricewaterhouseCoopers Bedrijfsrevisoren BV CVBA, with registered office at Woluwedal 18, 1932 Sint-Stevens-Woluwe, Belgium, represented by Peter D'hondt, auditor. PricewaterhouseCoopers Bedrijfsrevisoren BV CVBA is a member of the Instituut van de Bedrijfsrevisoren/Institut des Réviseurs d'Enterprises. The Issuer's current statutory auditor has been appointed effective as from 1 October 2018 for the statutory term of three years by the Issuer's extraordinary general shareholders' meeting held on 1 October 2018. Belgian law limits the auditor's liability to €3 million (for a non-listed company) and €12 million (for a listed company) for tasks reserved to auditors by Belgian law or in accordance with Belgian law, such as auditing financial statements such as those described above, other than liability due to fraud or other deliberate breach of duty.

PART 18 – TAXATION OF SHARES

18.1 Belgian taxation

The paragraphs below present a summary of certain Belgian federal income tax consequences of the ownership and disposal of the Shares by an investor that acquires such Shares in connection with this Offering. The summary is based on laws, treaties and regulatory interpretations in effect in Belgium on the date of this Prospectus, all of which are subject to change, including changes that could have retroactive effect.

Investors should appreciate that, as a result of evolutions in law or practice, the eventual tax consequences may be different from what is stated below.

This summary does not purport to address all tax consequences of the investment in, ownership in and disposal of the Shares, and does not take into account the specific circumstances of particular investors, some of which may be subject to special rules, or the tax laws of any country other than Belgium. This summary does not describe the tax treatment of investors that are subject to special rules, such as banks, insurance companies, collective investment undertakings, dealers in securities or currencies, persons that hold, or will hold, Shares as a position in a straddle, Share repurchase transaction, conversion transactions, synthetic security or other integrated financial transactions. This summary does not address the tax regime applicable to Shares held by Belgian tax residents through a fixed basis or a permanent establishment situated outside Belgium. This summary does in principle not address the local taxes that may be due in connection with an investment in the Shares, other than Belgian local surcharges which generally vary from 0 % to 9 % of the investor's income tax liability.

For purposes of this summary, a Belgian resident is an individual subject to Belgian personal income tax (i.e. an individual who is domiciled in Belgium or has his seat of wealth in Belgium or a person assimilated to a resident for purposes of Belgian tax law), a company subject to Belgian corporate income tax (i.e. a corporate entity that has its statutory seat, its main establishment, its administrative seat or seat of management in Belgium), an Organisation for Financing Pensions subject to Belgian corporate income tax (i.e. a Belgian pension fund incorporated under the form of an Organisation for Financing Pensions), or a legal entity subject to Belgian income tax on legal entities (i.e. a legal entity other than a company subject to Belgian corporate income tax, that has its statutory seat, its main establishment, its administrative seat or seat of management in Belgium).

A non-resident is any person that is not a Belgian resident. Investors should consult their own advisers regarding the tax consequences of an investment in the Shares in the light of their particular circumstances, including the effect of any state, local or other national laws.

18.2 Belgian taxation of dividends on Shares

For Belgian income tax purposes, the gross amount of all benefits paid on or attributed to the Shares is generally treated as a dividend distribution. By way of exception, the repayment of capital carried out in accordance with the Belgian Companies Code is not treated as a dividend distribution to the extent that such repayment is imputed to the fiscal capital. This fiscal capital includes, in principle, the actual paid-up statutory share capital and, subject to certain conditions, the paid-up issuance premiums and the cash amounts subscribed to at the time of the issue of profit sharing certificates. However, a repayment of capital decided upon by the shareholder's meeting as of 1 January 2018 and which is carried out in accordance with the Belgian Companies Code is partly considered to be a dividend distribution, more specifically with respect to the portion that is deemed to be the distribution of the existing taxed retained earnings (irrespective of whether they are incorporated into the capital) and/or of the tax-free retained earnings incorporated into the capital. Such portion is determined on the basis of the ratio of the taxed retained earnings (except for the legal reserve up to the legal minimum and certain unavailable retained earnings) and the tax-free retained earnings incorporated into the capital (with a few exceptions) over the aggregate of such retained earnings and the fiscal capital.

Belgian withholding tax of 30% is normally levied on dividends, subject to such relief as may be available under applicable domestic or tax treaty provisions.

In case of redemption of the Shares, the redemption gain (i.e. the redemption proceeds after deduction of the portion of fiscal capital represented by the redeemed Shares) will be treated as a dividend subject to a Belgian withholding tax of 30%, subject to such relief as may be available

under applicable domestic or tax treaty provisions. No withholding tax will be triggered if such redemption is carried out on Euronext or a similar stock exchange and meets certain conditions.

In case of liquidation of the Issuer, the liquidation gain (i.e. the amount distributed in excess of the fiscal capital) will in principle be subject to Belgian withholding tax at a rate of 30%, subject to such relief as may be available under applicable domestic or tax treaty provisions.

Non-Belgian dividend withholding tax, if any, will neither be creditable against any Belgian income tax due nor reimbursable to the extent that it exceeds Belgian income tax due.

(a) Belgian resident individuals

For Belgian resident individuals who acquire and hold the Shares as a private investment, the Belgian dividend withholding tax fully discharges their personal income tax liability. They may nevertheless elect to report the dividends in their personal income tax return. Where such individual opts to report them, dividends will normally be taxable at the lower of the generally applicable 30% withholding tax rate on dividends or at the progressive personal income tax rates applicable to the taxpayer's overall declared income (local surcharges will not apply). The first €800 (amount applicable for income year 2019) of reported ordinary dividend income will be exempt from tax. For the avoidance of doubt, all reported dividends (hence, not only dividends distributed on the Shares) are taken into account to assess whether said maximum amount is reached. In addition, if the dividends are reported, the dividend withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, provided that the dividend distribution does not result in a reduction in value of or a capital loss on the Shares. This condition is not applicable if the individual can demonstrate that he has held the Shares in full legal ownership for an uninterrupted period of twelve months prior to the attribution of the dividends.

For Belgian resident individuals who acquire and hold the Shares for professional purposes, the Belgian withholding tax does not fully discharge their personal income tax liability. Dividends received must be reported by the investor and will, in such case, be taxable at the investor's personal income tax rate increased with local surcharges. Withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, subject to two conditions: (1) the taxpayer must own the Shares in full legal ownership on the day the beneficiary of the dividend is identified¹ and (2) the dividend distribution may not result in a reduction in value of or a capital loss on the Shares. The latter condition is not applicable if the investor can demonstrate that he has held the full legal ownership of the Shares for an uninterrupted period of twelve months prior to the attribution of the dividends.

(b) Belgian resident companies

(i) Corporate income tax

For Belgian resident companies, the dividend withholding tax does not fully discharge the corporate income tax liability. For such companies, the gross dividend income (including the withholding tax) must be declared in the corporate income tax return and will be subject to a corporate income tax rate of 29.58%² as of assessment year 2019 for financial years starting on or after 1 January 2018. The standard corporate income tax rate will be reduced to 25% as of assessment year 2021 for financial years starting on or after 1 January 2020. Subject to certain conditions, a reduced corporate income tax rate may apply.³

(1) The Belgian Parliament recently adopted a law pursuant to which full legal ownership of the Shares needs to be held on the day the beneficiary of the dividend is identified. This law entered into force as of its date of publication in the Belgian State Gazette, i.e. on 22 January 2019.

(2) The dividends received during a financial year starting before 1 January 2018 or ending before 31 December 2018 will be subject to the standard corporate income tax rate of 33.99%, unless the reduced corporate income tax rates apply.

(3) Subject to certain conditions, a reduced corporate income tax rate of (i) 20.4% (including the 2% crisis surcharge) as of 2018 (i.e. for financial years starting on or after 1 January 2018) and of (ii) 20% as of 2020 (i.e. for financial years starting on or after 1 January 2020) applies for Small and Medium Sized Enterprises (as defined by Article 15, §1 to §6 of the Belgian Companies Code) on the first € 100,000 of taxable profits.

Any Belgian dividend withholding tax levied at source may be credited against the corporate income tax due and is reimbursable to the extent that it exceeds the corporate income tax due, subject to two conditions: (1) the taxpayer must own the Shares in full legal ownership on the day the beneficiary of the dividend is identified⁴; and (2) the dividend distribution may not result in a reduction in value of or a capital loss on the Shares. The latter condition is not applicable (a) if the company can demonstrate that it has held the Shares in full legal ownership for an uninterrupted period of twelve months prior to the attribution of the dividends; or (b) if, during said period, the Shares never belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the Shares in a permanent establishment (“PE”) in Belgium.

As a general rule, Belgian resident companies can (subject to certain limitations) deduct, as of assessment year 2019, 100%⁵ of gross dividends received from their taxable income (dividend received deduction), provided that at the time of a dividend payment or attribution: (1) the Belgian resident company holds Shares representing at least 10% of the share capital of the Issuer or a participation in the Issuer with an acquisition value of at least €2,500,000; (2) the Shares have been held or will be held in full ownership for an uninterrupted period of at least one year; and (3) the conditions relating to the taxation of the underlying distributed income, as described in article 203 of the Belgian Income Tax Code (the “**Article 203 ITC Taxation Condition**”) are met (together, the “**Conditions for the application of the dividend received deduction regime**”). Under certain circumstances the conditions referred to under (1) and (2) do not need to be fulfilled in order for the dividend received deduction to apply.

The Conditions for the application of the dividend received deduction regime depend on a factual analysis, upon each distribution, and for this reason the availability of this regime should be verified upon each distribution.

(ii) Withholding tax

Dividends distributed to a Belgian resident company will be exempt from Belgian withholding tax provided that the Belgian resident company holds, upon payment or attribution of the dividends, at least 10% of the share capital of the Issuer and such minimum participation is held or will be held during an uninterrupted period of at least one year.

In order to benefit from this exemption, the Belgian resident company must provide the Issuer or its paying agent with a certificate confirming its qualifying status and the fact that it meets the required conditions. If the Belgian resident company holds the required minimum participation for less than one year, at the time the dividends are paid on or attributed to the Shares, the Issuer will levy the withholding tax but will not transfer it to the Belgian Treasury provided that the Belgian resident company certifies its qualifying status, the date from which it has held such minimum participation, and its commitment to hold the minimum participation for an uninterrupted period of at least one year. The Belgian resident company must also inform the Issuer or its paying agent if the one-year period has expired or if its shareholding will drop below 10% of the share capital of the Issuer before the end of the one-year holding period. Upon satisfying the one-year shareholding requirement, the dividend withholding tax which was temporarily withheld, will be refunded to the Belgian resident company.

Please note that the above described dividend received deduction and withholding tax exemption will not be applicable to dividends which are connected to an arrangement or a series of arrangements (“rechtshandeling of geheel van rechtshandelingen”/“acte juridique ou un ensemble d’actes juridiques”) for which the Belgian tax administration, taking into account all relevant facts and circumstances, has proven, unless evidence to the contrary, that this arrangement or this series of arrangements is not genuine (“kunstmatig”/“non authentique”) and has been put in place for the main purpose or one of the main purposes of obtaining the dividend received deduction, the above dividend withholding tax exemption or one of the advantages of the EU Parent-Subsidiary Directive of 30 November 2011 (2011/96/EU) (“**Parent-Subsidiary Directive**”) in another EU Member State. An arrangement or a series of arrangements is regarded as not genuine to the extent that they are not put into place for valid commercial reasons which reflect economic reality.

(4) The Belgian Parliament recently adopted a law pursuant to which full legal ownership of the Shares needs to be held on the day the beneficiary of the dividend is identified. This law enters into force as of its date of publication in the Belgian State Gazette, i.e. on 22 January 2019.

(5) 95% for dividends received during a financial year starting before 1 January 2018 or ending before 31 December 2018.

(c) Belgian resident organisations for financing pensions

For organisations for financing pensions (“**OFPs**”), i.e. Belgian pension funds incorporated under the form of an OFP (“*organismen voor de financiering van pensioenen*”/“*organismes de financement de pensions*”) within the meaning of article 8 of the Belgian Act of 27 October 2006, the dividend income is generally tax exempt.

Subject to certain limitations, any Belgian dividend withholding tax levied at source may be credited against the corporate income tax due and is reimbursable to the extent that it exceeds the corporate income tax due.

The Belgian Parliament recently adopted a law pursuant to which Belgian (or foreign) OFPs not holding the Shares – which give rise to dividends – for an uninterrupted period of 60 days in full ownership amounts to a rebuttable presumption that the arrangement or series of arrangements (“*rechtshandeling of geheel van rechtshandelingen*”/“*acte juridique ou un ensemble d’actes juridiques*”) which are connected to the dividend distributions, are not genuine (“*kunstmatig*”/“*non authentique*”). The withholding tax exemption will in such case not apply and/or any Belgian dividend withholding tax levied at source on the dividends will in such case not be credited against the corporate income tax, unless counterproof is provided by the OFP that the arrangement or series of arrangements are genuine. The law enters into force as of its date of publication in the Belgian State Gazette (“*Belgisch Staatsblad*”/“*Moniteur belge*”), i.e. on 22 January 2019.

(d) Other Belgian resident legal entities subject to Belgian legal entities tax

For taxpayers subject to the Belgian income tax on legal entities, the Belgian dividend withholding tax in principle fully discharges their income tax liability.

(e) Non-resident individuals or non-resident companies

(i) Non-resident income tax

For non-resident individuals and companies, the dividend withholding tax will be the only tax on dividends in Belgium, unless the non-resident holds the Shares in connection with a business conducted in Belgium through a fixed base in Belgium or a Belgian PE.

If the Shares are acquired by a non-resident in connection with a business in Belgium, the investor must report any dividends received, which will be taxable at the applicable non-resident personal or corporate income tax rate, as appropriate. Belgian withholding tax levied at source may be credited against non-resident personal or corporate income tax and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (1) the taxpayer must own the Shares in full legal ownership at the time the dividends are paid or attributed and (2) the dividend distribution may not result in a reduction in value of or a capital loss on the Shares. The latter condition is not applicable if (a) the non-resident individual or the non-resident company can demonstrate that the Shares were held in full legal ownership for an uninterrupted period of twelve months prior to the attribution of the dividends or (b) with regard to non-resident companies only, if, during said period, the Shares have not belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the Shares in a Belgian PE.

Non-resident companies whose Shares are invested in a Belgian PE may deduct 100% of the gross dividends received from their taxable income if, at the date the dividends are paid or attributed, the Conditions for the application of the dividend received deduction regime are met. See subsection (b) (Belgian resident companies). Application of the dividend received deduction regime depends, however, on a factual analysis to be made upon each distribution and its availability should be verified upon each distribution.

(ii) Belgian dividend withholding tax relief for non-residents

Dividends distributed to non-resident individuals who do not use the Shares in the exercise of a professional activity, may be eligible for the newly introduced tax exemption with respect to ordinary dividends in an amount of up to €800 (amount applicable for income year 2019) per year. For the avoidance of doubt, all dividends paid or attributed to such non-resident individual (and hence not only dividends paid or attributed on the Shares) are taken into account to assess whether said maximum amount is reached. Consequently, if Belgian withholding tax has been levied on dividends paid or attributed to the Shares, such non-resident individual may request in its Belgian non-resident income tax return that any Belgian withholding tax levied on up to such an

amount be credited and, as the case may be, reimbursed. However, if no Belgian non-resident income tax return has to be filed by the non-resident individual, any Belgian withholding tax levied on up to such an amount could in principle be reclaimed by filing a request thereto addressed to the tax official to be appointed in a Royal Decree. Such a request has to be made at the latest on 31 December of the calendar year following the calendar year in which the relevant dividend(s) have been received, together with an affidavit confirming the non-resident individual status and certain other formalities which are still to be determined in a Royal Decree.

Under Belgian tax law, withholding tax is not due on dividends paid to a foreign pension fund which satisfies the following conditions: (i) it is a non-resident saver within the meaning of Article 227, 3° of the Belgian Income Tax Code which implies that it has separate legal personality and has its tax residence outside of Belgium; (ii) whose corporate purpose consists solely in managing and investing funds collected in order to pay legal or complementary pensions; (iii) whose activity is limited to the investment of funds collected in the exercise of its corporate purpose, without any profit making aim; (iv) which is exempt from income tax in its country of residence; and (v) provided that it is not contractually obliged to redistribute the dividends to any ultimate beneficiary of such dividends for whom it would manage the Shares, nor obliged to pay a manufactured dividend with respect to the Shares under a securities borrowing transaction. The exemption will only apply if the foreign pension fund provides a certificate confirming that it is the full legal owner or usufruct holder of the Shares and that the above conditions are satisfied. The organisation must then forward that certificate to the Issuer or its paying agent.

The Belgian Parliament recently adopted a law pursuant to which a pension fund not holding the Shares – which give rise to dividends – for an uninterrupted period of 60 days in full ownership amounts to a rebuttable presumption that the arrangement or series of arrangements (“*rechtshandeling of geheel van rechtshandelingen*”/“*acte juridique ou un ensemble d’actes juridiques*”) which are connected to the dividend distributions, are not genuine (“*kunstmatig*”/“*non authentique*”). The withholding tax exemption will in such case be rejected, unless counterproof is provided by the OFP that the arrangement or series of arrangements are genuine. The law enters into force as of its date of publication in the Belgian State Gazette (“*Belgisch Staatsblad*”/“*Moniteur belge*”), i.e. on 22 January 2019.

Dividends distributed to non-resident qualifying parent companies established in a Member State of the EU or in a country with which Belgium has concluded a double tax treaty that includes a qualifying exchange of information clause, will, under certain conditions, be exempt from Belgian withholding tax provided that the Shares held by the non-resident company, upon payment or attribution of the dividends, amount to at least 10% of the share capital of the Issuer and such minimum participation is held or will be held during an uninterrupted period of at least one year. A non-resident company qualifies as a parent company provided that (i) for companies established in a Member State of the EU, it has a legal form as listed in the annex to the EU Parent-Subsidiary Directive, as amended from time to time, or, for companies established in a country with which Belgium has concluded a qualifying double tax treaty, it has a legal form similar to the ones listed in such annex; (ii) it is considered to be a tax resident according to the tax laws of the country where it is established and the double tax treaties concluded between such country and third countries; and (iii) it is subject to corporate income tax or a similar tax without benefiting from a tax regime that derogates from the ordinary tax regime. In order to benefit from this exemption, the non-resident company must provide the Issuer or its paying agent with a certificate confirming its qualifying status and the fact that it meets the required conditions.

If the non-resident company holds a minimum participation for less than one year at the time the dividends are attributed to the Shares, the Issuer must levy the withholding tax but does not need to transfer it to the Belgian Treasury provided that the non-resident company provides the Issuer or its paying agent with a certificate confirming, in addition to its qualifying status, the date as of which it has held the minimum participation, and its commitment to hold the minimum participation for an uninterrupted period of at least one year. The non-resident company must also inform the Issuer or its paying agent when the one-year period has expired or if its shareholding drops below 10% of the Issuer’s share capital before the end of the one-year holding period. Upon satisfying the one-year holding requirement, the dividend withholding tax which was temporarily withheld, will be refunded to the non-resident company.

Please note that the above withholding tax exemption will not be applicable to dividends which are connected to an arrangement or a series of arrangements (“*rechtshandeling of geheel van rechtshandelingen*”/“*acte juridique ou un ensemble d’actes juridiques*”) for which the tax

Belgian tax administration, taking into account all relevant facts and circumstances, has proven, unless evidence to the contrary, that this arrangement or this series of arrangements is not genuine (“kunstmatig”/“non authentique”) and has been put in place for the main purpose or one of the main purposes of obtaining the dividend received deduction, the above dividend withholding tax exemption or one of the advantages of the Parent-Subsidiary Directive in another EU Member State. An arrangement or a series of arrangements is regarded as not genuine to the extent that they are not put into place for valid commercial reasons which reflect economic reality.

Dividends distributed by a Belgian company to non-resident companies on a share participation of less than 10% will under certain conditions be subject to an exemption from withholding tax, provided that the non-resident companies (i) are either established in another Member State of the EEA or in a country with which Belgium has concluded a double tax treaty, where that treaty, or any other treaty concluded between Belgium and that jurisdiction, includes a qualifying exchange of information clause; (ii) have a legal form as listed in Annex I, Part A to the Parent-Subsidiary Directive as amended from time to time, or a legal form similar to the legal forms listed in the aforementioned annex and which is governed by the laws of another Member State of the EEA or a similar legal form in a country with which Belgium has concluded a double tax treaty; (iii) hold a share participation in the Belgian dividend distributing company, upon payment or attribution of the dividends, of less than 10% of the Issuer's share capital but with an acquisition value of at least €2,500,000; (iv) hold or will hold the Shares which give rise to the dividends in full legal ownership during an uninterrupted period of at least one year; and (v) are subject to the corporate income tax or a tax regime similar to the corporate income tax without benefiting from a tax regime which deviates from the ordinary regime. The exemption from withholding tax is only applied to the extent that the Belgian withholding tax, which would be applicable absent the exemption, could not be credited nor reimbursed at the level of the qualifying, dividend receiving, company. The non-resident company must provide the Issuer or its paying agent with a certificate confirming, in addition to its full name, legal form, address and fiscal identification number (if applicable), its qualifying status and the fact that it meets the required conditions mentioned under (i) to (v) above, and indicating to which extent the withholding tax, which would be applicable absent the exemption, is in principle creditable or reimbursable on the basis of the law as applicable on 31 December of the year preceding the year during which the dividend is paid or attributed.

Belgian dividend withholding tax is subject to such relief as may be available under applicable tax treaty provisions. Belgium has concluded tax treaties with more than 95 countries, reducing the dividend withholding tax rate to 20%, 15%, 10%, 5% or 0% for residents of those countries, depending on conditions, among others, related to the size of the shareholding and certain identification formalities. Such reduction may be obtained either directly at source or through a refund of taxes withheld in excess of the applicable treaty rate.

Prospective holders of Shares should consult their own tax advisers to determine whether they qualify for a reduction in withholding tax upon payment or attribution of dividends, and, if so, to understand the procedural requirements for obtaining a reduced withholding tax upon the payment of dividends or for making claims for reimbursement.

18.3 Belgian taxation of capital gains and losses on Shares

(a) Belgian resident individuals

In principle, Belgian resident individuals acquiring the Shares as a private investment should not be subject to Belgian capital gains tax on the disposal of the Shares and capital losses will not be tax deductible.

However, capital gains realised by a Belgian resident individual are taxable at 33% (plus local surcharges) if the capital gain on the Shares is deemed to be realised outside the scope of the normal management of the individual's private estate (e.g. in case of speculation). Capital losses are, however, not tax deductible.

Moreover, capital gains realised by Belgian resident individuals on the disposal of the Shares, outside the exercise of a professional activity, to a non-resident company (or body constituted in a similar legal form), to a foreign State (or one of its political subdivisions or local authorities) or to a non-resident legal entity, each time established outside the EEA, are in principle taxable at a rate of 16.5% (plus local surcharges) if, at any time during the five years preceding the sale, the Belgian resident individual has owned, directly or indirectly, alone or with his/her spouse or with

certain relatives, a substantial shareholding in the Issuer (i.e. a shareholding of more than 25% in the Issuer). Capital losses are, however, not tax deductible in such event.

Capital gains realised by Belgian resident individuals upon redemption of the Shares or upon liquidation of the Issuer will generally be taxable as a dividend. See section 18.2 (Belgian Taxation of dividends on Shares), subsection (a) (Belgian resident individuals).

Belgian resident individuals who hold the Shares for professional purposes are taxable at the ordinary progressive personal income tax rates (plus local surcharges) on any capital gains realised upon the disposal of the Shares, except for the Shares held for more than five years, which are taxable at a separate rate of 10% (capital gains realised in the framework of the cessation of activities under certain circumstances) or 16.5% (other), plus local surcharges. . Capital losses on the Shares incurred by Belgian resident individuals who hold the Shares for professional purposes are in principle tax deductible.

(b) Belgian resident companies

Belgian resident companies are normally not subject to Belgian capital gains taxation on gains realised upon the disposal of the Shares provided that the Conditions for the application of the dividend received deduction regime are met⁶.

If the one-year minimum holding period condition is not met but the other Conditions for the application of the dividend received deduction regime are met, the capital gains realised upon the disposal of the Shares by Belgian resident companies are taxable at a separate corporate income tax rate of 25.50%⁷. As of assessment year 2019 (for financial years starting as of 1 January 2018) this separate rate may be reduced to 20.40% for certain SMEs. This separate rate will be abolished as of assessment year 2021 (for financial years starting as of 1 January 2020), and the ordinary corporate income tax rate (or, if applicable, the reduced corporate income tax rate) will apply.

If one or more of the Conditions for the application of the dividend received deduction regime are not met (other than the one-year minimum holding period condition), any capital gain realised would be taxable at the standard corporate income tax rate of 29.58%⁸, unless the reduced corporate income tax rate of 20.4% applies. The standard corporate income tax rate will be reduced to 25%, and the reduced corporate income tax rate will be further reduced to 20% as of assessment year 2021 for financial years starting as of 1 January 2020.

Capital losses on the Shares incurred by Belgian resident companies (both non-SMEs and SMEs) are as a general rule not tax deductible.

Shares held in the trading portfolios of Belgian qualifying credit institutions, investment enterprises and management companies of collective investment undertakings are subject to a different regime. The capital gains on such Shares are taxable at the ordinary corporate income tax rate of 29.58%, unless the reduced corporate income tax rate of 20.4% applies, and the capital losses on such Shares are tax deductible. The standard corporate income tax rate will be reduced to 25%, and the reduced corporate income tax rate will be further reduced to 20% as of assessment year 2021 for financial years starting as of 1 January 2020. Internal transfers to and from the trading portfolio are assimilated to a realisation.

Capital gains realised by Belgian resident companies upon redemption of the Shares or upon liquidation of the Issuer will, in principle, be subject to the same taxation regime as dividends.

(c) Belgian resident organisations for financing pensions

Capital gains on the Shares realised by OFPs within the meaning of article 8 of the Belgian Act of 27 October 2006 are in principle exempt from corporate income tax and capital losses are not tax deductible.

(6) Such capital gains realised by non-small and medium-sized companies in a financial year starting before 1 January 2018 or ending before 31 December 2018 will still be subject to a corporate income tax of 0.412%.

(7) Such capital gains realised in a financial year starting before 1 January 2018 or ending before 31 December 2018 will still be subject to a separate corporate income tax rate of 25.75%.

(8) Such capital gain realised in a financial year starting before 1 January 2018 or ending before 31 December 2018 will still be subject to the standard corporate income tax rate of 33.99%, unless the reduced corporate income tax rates apply.

(d) Other Belgian resident legal entities subject to Belgian legal entities tax

Capital gains realised upon disposal of the Shares by Belgian resident legal entities are in principle not subject to Belgian income tax and capital losses are not tax deductible.

Capital gains realised upon disposal of (part of) a substantial participation in a Belgian company (i.e. a participation representing more than 25% of the share capital of the Issuer at any time during the last five years prior to the disposal) may, however, under certain circumstances be subject to income tax in Belgium at a rate of 16.5% (plus crisis surcharge of 2%; such surcharge will however be abolished as of 1 January 2020).

Capital gains realised by Belgian resident legal entities upon redemption of the Shares or upon liquidation of the Issuer will, in principle, be subject to the same taxation regime as dividends.

(e) Non-resident individuals, non-resident companies or non-resident entities

Non-resident individuals, companies or entities are, in principle, not subject to Belgian income tax on capital gains realised upon disposal of the Shares, unless the Shares are held as part of a business conducted in Belgium through a fixed base in Belgium or a Belgian PE. In such a case, the same principles apply as described with regard to Belgian individuals (holding the Shares for professional purposes), Belgian companies, Belgian resident organisations for financing pensions or other Belgian resident legal entities subject to Belgian legal entities tax.

Non-resident individuals who do not use the Shares for professional purposes and who have their fiscal residence in a country with which Belgium has not concluded a tax treaty or with which Belgium has concluded a tax treaty that confers the authority to tax capital gains on the Shares to Belgium, might⁹ be subject to tax in Belgium if the capital gains are obtained or received in Belgium and arise from transactions which are to be considered speculative or beyond the normal management of one's private estate or in case of disposal of a substantial participation in a Belgian company as mentioned in the tax treatment of the disposal of the shares by Belgian individuals. See subsection (a) (Belgian resident individuals) above. Such non-resident individuals might therefore be obliged to file a tax return and should consult their own tax adviser.

Capital gains realised by non-resident individuals or non-resident companies upon redemption of the Shares or upon liquidation of the Issuer will, in principle, be subject to the same taxation regime as dividends.

18.4 Annual tax on securities accounts

On 9 March 2018, the Law of 7 February 2018 on the introduction of a tax on securities accounts has been published in the Belgian State Gazette with entry into force as of 10 March 2018. Pursuant to this law, Belgian resident and non-resident individuals are taxed at a rate of 0.15 per cent. on their share in the average value of qualifying financial instruments (such as the Shares and other shares, bonds, certain other type of debt instruments, units of undertakings for collective investment, warrants) held on one or more securities accounts during a reference period of 12 consecutive months starting on 1 October and ending on 30 September of the subsequent year.

No Tax on Securities Accounts is due provided the holder's share in the average value of the qualifying financial instruments on those accounts amounts to less than €500,000. If, however, the holder's share in the average value of the qualifying financial instruments on those accounts amounts to €500,000 or more, the Tax on Securities Accounts is due on the entire share of the holder in the average value of the qualifying financial instruments on those accounts (and hence, not only on the part which exceeds the €500,000 threshold).

For the purpose of the Tax on Securities Accounts a financial intermediary is defined as (i) a credit institution or a stockbroking firm as defined by Article 1, §2 and §3 of the Belgian Banking Law and (ii) the investment companies as defined by Article 3, §1 of the Law of 25 October 2016 on access to the activity of investment services and on the legal status and supervision of portfolio management and investment advice companies, which are pursuant to national law admitted to hold financial instruments for the account of customers.

The Tax on Securities Accounts is in principle due by the financial intermediary established or located in Belgium if (i) the holder's share in the average value of the qualifying financial

⁽⁹⁾ Belgium has concluded tax treaties with more than 95 countries which generally provide for a full exemption from Belgian capital gains taxation on such gains realised by residents of those countries. Capital losses are generally not tax deductible.

instruments held on one or more securities accounts with said intermediary amounts to €500,000 or more; or (ii) the holder instructed the financial intermediary to levy the Tax on Securities Accounts due (e.g. in case such holder holds qualifying financial instruments on several securities accounts held with multiple intermediaries of which the average value does not amount to €500,000 or more but of which the holder's share in the total average value of these accounts exceeds €500,000 EUR). Otherwise, the Tax on Securities Accounts has to be declared and is due by the holder itself, unless the holder provides evidence that the Tax on Securities Accounts has already been withheld, declared and paid by an intermediary which is not established or located in Belgium. In that respect, intermediaries located or established outside of Belgium could appoint a Tax on the Securities Accounts representative in Belgium, subject to certain conditions and formalities ("Tax on the Securities Accounts Representative"). Such a Tax on the Securities Accounts Representative will then be liable towards the Belgian Treasury for the Tax on the Securities Accounts due and for complying with certain reporting obligations in that respect.

Belgian resident individuals have to report in their annual income tax return various securities accounts held with one or more financial intermediaries of which they are considered as a holder within the meaning of the Tax on Securities Accounts. Non-resident individuals have to report in their annual Belgian non-resident income tax return various securities accounts held with one or more financial intermediaries established or located in Belgium of which they are considered as a holder within the meaning of the Tax on Securities Accounts.

Investors should consult their own professional advisors in relation to the annual tax on securities accounts.

18.5 Belgian tax on stock exchange transactions

The purchase and the sale and any other acquisition or transfer for consideration of existing Shares (secondary market transactions) is subject to the Belgian tax on stock exchange transactions ("*taks op de beursverrichtingen*" / "*taxe sur les opérations de bourse*") if (i) it is entered into or carried out in Belgium through a professional intermediary, or (ii) deemed to be entered into or carried out in Belgium, which is the case if the order is directly or indirectly made to a professional intermediary established outside of Belgium, either by private individuals with habitual residence in Belgium, or legal entities for the account of their seat or establishment in Belgium (both referred to as a "**Belgian Investor**"). The tax on stock exchange transactions is not due upon the issuance of the New Shares (primary market transactions).

The tax on stock exchange transactions is levied at a rate of 0.35% of the purchase price, capped at €1,600 per transaction and per party.

Such tax is separately due by each party to the transaction, and each of those is collected by the professional intermediary. However, if the order is made directly or indirectly to a professional intermediary established outside of Belgium, the tax will in principle be due by the Belgian Investor, unless that Belgian Investor can demonstrate that the tax has already been paid. In the latter case, the foreign professional intermediary also has to provide each client (which gives such intermediary an order) with a qualifying order statement ("*bordereau*" / "*borderel*"), at the latest on the business day after the day the transaction concerned was realised. The qualifying order statements must be numbered in series and a duplicate must be retained by the financial intermediary. The duplicate can be replaced by a qualifying day-today listing, numbered in series. Alternatively, professional intermediaries established outside of Belgium can, subject to certain conditions and formalities, appoint a Belgian stock exchange tax representative ("**Stock Exchange Tax Representative**"), which will be liable for the tax on stock exchange transactions in respect of the transactions executed through the professional intermediary and for complying with the reporting obligations and the obligations relating to the order statement in that respect. If such a Stock Exchange Tax Representative has paid the tax on stock exchange transactions due, the Belgian Investor will, as per the above, no longer be the debtor of the tax on stock exchange transaction.

No tax on stock exchange transactions is due on transactions entered into by the following parties, provided they are acting for their own account: (i) professional intermediaries described in article 2, 9° and 10° of the Belgian Law of 2 August 2002 on the supervision of the financial sector and financial services; (ii) insurance companies described in article 2, §1 of the Belgian Law of 9 July 1975 on the supervision of insurance companies; (iii) pension institutions referred to in article 2,1° of the Belgian Law of 27 October 2006 concerning the supervision of pension institutions; (iv) undertakings for collective investment; (v) regulated real estate companies; and (vi)

Belgian non-residents provided they deliver a certificate to their financial intermediary in Belgium confirming their non-resident status.

The EU Commission adopted on 14 February 2013 the Draft Directive on a common Financial Transaction Tax. The Draft Directive currently stipulates that, once the FTT enters into force, the Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax). For Belgium, the tax on stock exchange transactions should thus be abolished once the FTT enters into force. The Draft Directive regarding the FTT is still subject to negotiation between the Participating Member States and therefore may be changed at any time.

18.6 Common Reporting Standard

Following recent international developments, the exchange of information will be governed by the Common Reporting Standard (“**CRS**”). More than 90 jurisdictions have signed the multilateral competent authority agreement (“**MCAA**”). The MCAA is a multilateral framework agreement to automatically exchange financial and personal information, with the subsequent bilateral exchanges coming into effect between those signatories that file the subsequent notifications.

More than 45 jurisdictions, including Belgium, have committed to a specific and ambitious timetable leading to the first automatic information exchanges in 2017, relating to income year 2016 (“**early adopters**”). More than 50 jurisdictions have committed to exchange information as from 2018.

Under CRS, financial institutions resident in a CRS country will be required to report, according to a due diligence standard, financial information with respect to reportable accounts, which includes interest, dividends, account balance or value, income from certain insurance products, sales proceeds from financial assets and other income generated with respect to assets held in the account or payments made with respect to the account. Reportable accounts include accounts held by individuals and entities (which includes trusts and foundations) with fiscal residence in another CRS country. The standard includes a requirement to look through passive entities to report on the relevant controlling persons.

On 9 December 2014, EU Member States adopted Directive 2014/107/EU on administrative cooperation in direct taxation (“**DAC2**”), which provides for mandatory automatic exchange of financial information as foreseen in CRS. DAC2 amends the previous Directive on administrative cooperation in direct taxation, Directive 2011/16/EU.

The mandatory automatic exchange of financial information by EU Member States as foreseen in DAC2 started as of 30 September 2017 (as of 30 September 2018 for Austria).

The Belgian government has implemented said Directive 2014/107/EU, respectively the Common Reporting Standard, per the Law of 16 December 2015 regarding the exchange of information on financial accounts by Belgian financial institutions and by the Belgian tax administration, in the context of an automatic exchange of information on an international level and for tax purposes.

As a result of the Law of 16 December 2015, the mandatory automatic exchange of information applies in Belgium (i) as of income year 2016 (first information exchange in 2017) towards the EU Member States, (ii) as of income year 2014 (first information exchange in 2016) towards the US and (iii), with respect to any other non-EU States that have signed the MCAA, as of the respective date as determined by the Royal Decree of 14 June 2017. The Royal Decree provides that (i) for a first list of 18 countries, the mandatory exchange of information applies as of income year 2016 (first information exchange in 2017) and (ii) for a second list of 44 countries, the mandatory automatic exchange of information applies as of income year 2017 (first information exchange in 2018).

Investors who are in any doubt as to their position should consult their professional advisers.

18.7 The proposed Financial Transaction Tax (FTT)

On 14 February 2013 the EU Commission adopted the Draft Directive on a common Financial Transaction Tax. Earlier negotiations for a common transaction tax among all 28 EU Member States had failed. The current negotiations between the Participating Member States (i.e. Austria, Belgium, France, Germany, Greece, Italy, Portugal, Slovakia, Slovenia and Spain) are seeking a

compromise under “enhanced cooperation” rules, which require consensus from at least nine nations. Estonia already left the negotiations by declaring it would not introduce the FTT.

The Draft Directive currently stipulates that once the FTT enters into force, the Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax). For Belgium, the tax on stock exchange transactions should thus be abolished once the FTT enters into force.

Pursuant to the Draft Directive, the FTT would be payable on financial transactions provided at least one party to the financial transaction is established or deemed established in a Participating Member State and there is a financial institution established or deemed established in a Participating Member State which is a party to the financial transaction, or is acting in the name of a party to the transaction. The FTT would, however, not apply to (*inter alia*) primary market transactions referred to in article 5(c) of Regulation (EC) No 1287/2006, including the activity of underwriting and subsequent allocation of financial instruments in the framework of their issue.

The rates of the FTT would be fixed by each Participating Member State but for transactions involving financial instruments other than derivatives shall amount to at least 0.1% of the taxable amount. The taxable amount for such transactions would in general be determined by reference to the consideration paid or owed in return for the transfer or the market price (whichever is higher). The FTT should be payable by each financial institution established or deemed established in a Participating Member State which is either a party to the financial transaction, or acting in the name of a party to the transaction or where the transaction has been carried out on its account. Where the FTT due has not been paid within the applicable time limits, each party to a financial transaction, including persons other than financial institutions, would become jointly and severally liable for the payment of the FTT due.

In case of implementation any sale, purchase or exchange of Shares would become subject to the FTT at a minimum rate of 0.1% provided the above mentioned prerequisites are met. The issuance of New Shares would not be subject to the FTT.

However, the Draft Directive on the FTT remains subject to negotiations between the Participating Member States. It may therefore be altered prior to any implementation, of which the eventual timing and fate remains unclear. Additional EU Member States may decide to participate or drop out of the negotiations. The project will be terminated if the number of Participating Member States falls below nine.

Prospective investors should consult their own professional advisors in relation to the FTT.

18.8 Certain Material U.S. federal income tax considerations

The following is a description of certain material U.S. federal income tax consequences that may be relevant with respect to the acquisition, ownership and disposition of the Offered Shares by a U.S. Holder (as defined below). This summary deals only with purchasers of Offered Shares in the Offering, who will be new shareholders of the Issuer, who use the U.S. Dollar as their functional currency and will hold the Offered Shares as capital assets (within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended (the “Code”)).

This description does not purport to address all material U.S. tax consequences of the acquisition, ownership and disposition of the Offered Shares and does not address aspects of U.S. federal income taxation that may be applicable to investors that are subject to special tax rules, including without limitation:

- banks, financial institutions or insurance companies;
- dealers or certain traders in securities, commodities or currencies;
- real estate investment trusts, regulated investment entities or grantor trusts;
- persons holding Offered Shares as part of a straddle, wash sale, hedging or conversion transaction or integrated transaction or persons entering into a constructive sale with respect to the Offered Shares;
- persons who receive Offered Shares as compensation for the performance of services;
- persons who are resident in or have a permanent establishment in Belgium;
- certain U.S. expatriates;

- tax-exempt entities, including “Section 401” pension plans;
- a partnership (or other entity or arrangement treated as a partnership for U.S. federal income tax purposes) or a partner, member, or owner thereof;
- individual retirement accounts and other tax deferred accounts;
- “dual resident” corporations;
- persons that own or are deemed to own (directly, indirectly, or by attribution) ten per cent. or more of the Issuer’s stock by vote or value; or
- persons holding Offered Shares in connection with a trade or business outside the U.S.

Further, this description does not address state, local, non-U.S. or other tax laws, nor does it address the 3.8 per cent. U.S. federal Medicare tax on net investment income, the alternative minimum tax or the U.S. federal gift and estate tax consequences of the acquisition, ownership and disposition of the Offered Shares.

This description is based on the Code, its legislative history, existing and proposed regulations promulgated thereunder, published rulings and court decisions, as well as on the Convention Between the Government of the United States of America and the Government of the Kingdom of Belgium for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income (the “**Treaty**”), in each case as of the date of this Offering, all of which are subject to change (or to changes in interpretation), possibly with retroactive effect. The Issuer has not requested, and does not intend to request, a ruling from the U.S. Internal Revenue Service (the “**IRS**”) with respect to matters addressed herein.

(a) U.S. Holders

You are a “U.S. Holder” for purposes of this discussion if for U.S. federal income tax purposes you are a beneficial owner of the Issuer’s Offered Shares and are:

- a citizen or individual resident of the U.S.;
- a corporation created or organised in or under the laws of the U.S., any state therein or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) a court within the U.S. is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of the substantial decisions of such trust, or (ii) such trust has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes.

If a partnership (or any other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds Offered Shares, the tax treatment of the partnership and a partner in such partnership will generally depend upon the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax adviser as to the U.S. federal income tax consequences to it and its partners of acquiring, holding, or disposing of the Offered Shares.

THE SUMMARY OF U.S. FEDERAL INCOME TAX CONSEQUENCES SET OUT BELOW IS FOR GENERAL INFORMATION ONLY. ALL PROSPECTIVE PURCHASERS SHOULD CONSULT THEIR TAX ADVISERS AS TO THE PARTICULAR TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING THE OFFERED SHARES, INCLUDING THEIR ELIGIBILITY FOR THE BENEFITS OF THE TREATY. THE APPLICABILITY AND EFFECT OF STATE, LOCAL, NON-U.S. AND OTHER TAX LAWS AND POSSIBLE CHANGES IN TAX LAW.

(b) Taxation of distributions

Subject to the discussion below under subsection (d) (Passive foreign investment company rules), distributions paid on the Offered Shares (including the amount of any Belgian taxes withheld), other than certain *pro rata* distributions of Offered Shares to all shareholders, will be treated as dividends to the extent paid out of the Issuer’s current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will be treated as a non-taxable return of capital to the extent of the U.S. Holder’s basis in the Offered Shares and thereafter as capital gain. Because the Issuer does not maintain calculations of its earnings and profits under U.S. federal income tax

principles, it is expected that distributions with respect to Offered Shares generally will be treated as taxable dividends. You should consult your tax adviser with respect to the appropriate U.S. federal income tax treatment of any distribution received from the Issuer. As discussed above in section 18.2 (Belgian taxation of dividends on Shares), under current law payments of dividends by the Issuer to foreign investors are subject to a 30 per cent. Belgian withholding tax. The rate of withholding tax applicable to U.S. Holders that are eligible for benefits under the Treaty is reduced to a maximum of 15 per cent. For U.S. federal income tax purposes, U.S. Holders will be treated as having received the amount of Belgian taxes withheld by the Issuer, and as then having paid over the withheld taxes to the Belgian taxing authorities. As a result, the amount of dividend income included in gross income for U.S. federal income tax purposes by a U.S. Holder with respect to a payment of dividends may be greater than the amount of cash actually received (or receivable) by the U.S. Holder from the Issuer with respect to the payment. Dividends will not be eligible for the dividends received deduction allowed to U.S. corporate shareholders in respect of dividends received from certain corporations.

Subject to applicable limitations, the U.S. Dollar amount of dividends received on the Offered Shares by certain non-corporate U.S. Holders will be subject to taxation at the lower capital gains rate if the dividends are “qualified dividends”. Dividends will be treated as qualified dividends if (a) certain holding period requirements are satisfied, (b) the Issuer is eligible for the benefits of the Treaty, which the Issuer expects will be the case provided that the Offered Shares are regularly traded on the regulated market of Euronext Brussels, and (c) the Issuer was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a PFIC. The Issuer does not believe it was a PFIC for its most recent taxable year. However, its status in the current year and future years will depend upon its income and assets (which for this purpose depends in part on the market value of the Offered Shares) in those years. See the discussion below under subsection (d) (Passive foreign investment company rules). You should consult your tax adviser regarding the availability of the reduced tax rate on qualified dividends.

Dividends will generally be included in your income on the date of actual or constructive receipt. The amount of any dividend income paid in euro will be the U.S. Dollar amount calculated by reference to the spot rate in effect on the date of receipt, regardless of whether the payment is in fact converted into U.S. Dollars. U.S. Holders will have a tax basis in the currency received equal to its U.S. Dollar value on the date of receipt. If the dividend is converted into U.S. Dollars on the date of receipt, you should not be required to recognise foreign currency gain or loss in respect of the amount received. You may have foreign currency gain or loss if the dividend is converted into U.S. Dollars after the date of receipt, and any such gain or loss will be U.S.-source ordinary income or loss.

The amount of a dividend will include any amounts withheld by the Issuer in respect of Belgian withholding taxes. Dividends paid by the Issuer generally will constitute income from sources outside the U.S. for U.S. foreign tax credit limitation purposes and will be categorised as “passive income” or, in the case of certain U.S. Holders, as “general category income,” for U.S. foreign tax credit purposes. Subject to applicable limitations, some of which vary depending upon your circumstances, Belgian income taxes withheld from dividend payments on the Offered Shares at a rate not exceeding the applicable Treaty rate will be creditable against your U.S. federal income tax liability. Belgian income taxes withheld in excess of the applicable Treaty rate and with respect to which the holder is entitled to obtain a refund from the Belgian taxing authorities will not be eligible for credit against such holder’s U.S. federal income tax liability. If dividends with respect to the Offered Shares are qualified dividend income (as discussed above), the amount of the dividends taken into account for purposes of calculating the foreign tax credit limitation will in general be limited to the gross amount of the dividend, multiplied by a fraction, the numerator of which is the reduced rate on qualified dividends, and the denominator of which is the highest rate of tax normally applicable to dividends. In lieu of claiming a foreign tax credit, you may elect to deduct foreign taxes, including any Belgian taxes, in computing your taxable income, subject to applicable limitations. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the relevant taxable year. You will not be entitled to a credit or deduction for any Belgian taxes that are not income taxes. The rules governing foreign tax credits are complex and involve the application of rules that depend on your particular circumstances. Accordingly, you should consult your tax adviser regarding the creditability of foreign taxes in your particular circumstances.

(c) Sale or other taxable disposition of Offered Shares

Subject to the discussion below under subsection (d) (Passive foreign investment company rules), you generally will recognise taxable gain or loss on a sale or other taxable disposition of the Offered Shares equal to the difference between the amount realised on the sale or disposition and your adjusted tax basis in the Offered Shares, each as determined in U.S. Dollars. This gain or loss will generally be capital gain or loss, and will be long-term capital gain or loss if at the time of sale or disposition the Offered Shares have been held for more than one year. For non-corporate U.S. Holders, such capital gain will be eligible for a preferential rate of taxation applicable to long-term capital gains if the U.S. Holder's holding period determined at the time of such sale or other taxable disposition for the Offered Shares exceeds one year. Any gain or loss will generally be U.S.-source for foreign tax credit purposes. The deductibility of capital losses is subject to limitations. U.S. Holders should consult their tax advisers regarding whether they will recognize any foreign currency gain or loss in acquiring or disposing of the Offered Shares.

As discussed above in section 18.3 (Belgian taxation of capital gains and losses on Shares), subsection (e) (Non-resident individuals or non-resident companies), capital gains realised by non-resident individuals or non-resident companies upon redemption of the Offered Shares or upon liquidation of the Issuer may be subject to the same Belgian taxation regime as dividends. A U.S. Holder generally will be entitled, subject to certain limitations, to a credit against its U.S. federal income tax liability, or a deduction in computing its U.S. federal taxable income, for Belgian income taxes withheld by the Issuer. For U.S. federal income tax purposes, depending on the facts and circumstances at the time of redemption, U.S. Holders generally will either be treated as receiving a distribution from the Issuer, as described in subsection (b) (Taxation of distributions) above, or as recognizing gain or loss from the disposition of the Offered Shares, as described in the paragraph above. Since, for U.S. federal income tax purposes, the gain from the sale or other disposition of the Offered Shares will generally constitute U.S.-source income, a U.S. Holder may have insufficient foreign source income to utilize foreign tax credits attributable to any Belgian withholding tax imposed on a sale or disposition as a result of a redemption or liquidation. If Belgium imposed Belgian withholding tax on such income, the Treaty contains rules to permit U.S. Holders that are eligible for the benefits of the Treaty to treat such income as income from Belgian sources for U.S. foreign tax credit purposes. U.S. Holders should consult their own tax advisors regarding the tax consequences if Belgian withholding tax is imposed on the disposition of Offered Shares, including the appropriate U.S. federal income tax treatment of any redemption, the application of the foreign tax credit rules and the Treaty in their particular circumstances.

If you receive euros (or other currency other than U.S. Dollars) upon a sale, exchange or other disposition of the Offered Shares, the amount realised generally will be the U.S. Dollar value of the payment received determined on (a) the date of receipt of payment in the case of a cash basis U.S. Holder and (b) the trade date in the case of an accrual basis U.S. Holder. On the settlement date, an accrual basis U.S. Holder generally will recognise U.S.-source foreign currency gain or loss (taxable as ordinary income or loss) equal to any difference between the U.S. Dollar value of the amount received based on the exchange rates in effect on the trade date and the settlement date. If the Offered Shares are traded on an "established securities market", an accrual basis taxpayer, may elect to determine the U.S. Dollar value of the amount realised by translating the amount received at the spot rate of exchange on the settlement date of the sale. A U.S. Holder will have a tax basis in the foreign currency received equal to the U.S. Dollar amount realised on the settlement date. Any currency exchange gain or loss realised on a subsequent conversion of the foreign currency into U.S. Dollars for a different amount generally will be treated as ordinary income or loss from sources within the U.S. However, if such foreign currency is converted into U.S. Dollars on the date received by the U.S. Holder, a cash basis or electing accrual basis U.S. Holder should not recognise any gain or loss on such conversion.

(d) Passive foreign investment company rules

A non-U.S. corporation will be classified as a "passive foreign investment company", or a PFIC, for U.S. federal income tax purposes in any taxable year in which, after applying certain look-through rules, either:

- at least 75.0 per cent. of its gross income is "passive income"; or
- at least 50.0 per cent. of the quarterly average value of its gross assets is attributable to assets that produce "passive income" or are held for the production of passive income.

Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. However, rents and gains derived in the active conduct of a trade or business in certain circumstances are considered active income. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25.0 per cent. interest (by value) is taken into account.

The Issuer does not believe that it was a PFIC for its most recent taxable year. However, as the determination of PFIC status is a factual determination that must be made annually at the close of each taxable year, therefore, there can be no certainty as to its status in this regard until the close of the current or any future taxable year. The Issuer's status could change depending, among other things, upon the sources of its income, the manner and rate at which the Issuer utilises the proceeds of the Offering, a decrease in the trading price of the Offered Shares, or changes in the composition and relative values of its assets (including goodwill and other intangible assets). In particular, with respect to the Issuer's income, although it is engaged in active business, and while it does not generate substantial amounts of passive income, its ability to generate revenue from its active business is uncertain and it may generate passive income during the current and future taxable years which could cause it to be treated as a PFIC in such years.

If the Issuer were a PFIC in any year during a U.S. Holder's holding period for the Offered Shares, the Issuer would ordinarily continue to be treated as a PFIC for each subsequent year during which the U.S. Holder owned the Offered Shares. If the Issuer were a PFIC for a taxable year during a U.S. Holder's holding period for the Offered Shares, the U.S. Holder generally would be subject to additional taxes (including taxation at ordinary income rates and an interest charge) on any "excess distributions" received from the Issuer and on any gain realised from a sale or other disposition of the Offered Shares. A U.S. Holder would have an excess distribution to the extent that distributions on the Offered Shares during a taxable year exceed 125.0 per cent. of the average amount received during the three preceding taxable years (or, if shorter, the U.S. Holder's holding period). To compute the tax on excess distributions or any gain, (i) the excess distribution or gain would be allocated rateably over the U.S. Holder's holding period, (ii) amounts allocated to the current taxable year and any year before the Issuer became a PFIC would be taxed as ordinary income in the current year and (iii) amounts allocated to other taxable years would be taxed at the highest applicable marginal tax rate in effect for each such year (i.e. at ordinary income tax rates) and (iv) an interest charge would be imposed to recover the deemed benefit from the deferred payment of the tax attributable to each year described in (iii). Gain on the disposition of the Offered Shares will be subject to taxation in the same manner as an excess distribution, described immediately above. Additionally, if the Issuer were a PFIC with respect to a U.S. Holder for any taxable year in which the Issuer pays a dividend or for the prior taxable year, the preferential rates discussed above with respect to qualified dividends paid to certain U.S. Holders would not apply.

You would not be able to avoid the tax consequences described above by electing to treat the Issuer as a qualified electing fund ("QEF"), because the Issuer does not intend to provide U.S. Holders with the information that would be necessary to make a QEF election with respect to the Offered Shares. However, a U.S. Holder may be able to avoid some of the adverse impacts of the PFIC rules described above with respect to the Offered Shares by electing to mark the Offered Shares to market annually. In order for the Offered Shares to qualify for the mark-to-market election, the Offered Shares must be listed on a foreign securities exchange regulated by a governmental authority of the country in which the market is located and which meets certain requirements, including that the rules of the exchange effectively promote active trading of listed stocks. If such stock is traded on such a qualified exchange or other market, such stock generally will be "regularly traded" for any calendar year during which such stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. The Offered Shares will be traded on Euronext Brussels which may qualify as an eligible foreign securities exchange for this purpose, but no assurances can be given in this regard. Any gain from marking the Offered Shares to market or from disposing of them would be ordinary income. Any losses from marking the Offered Shares to market would be recognised only to the extent of unreversed gains previously included in income. Losses from marking the Offered Shares to market would be ordinary, but losses on disposing of them would be capital losses except to the extent of mark to market gains previously included in income. Because a mark-to-market election cannot be made for equity

interests in any lower-tier PFICs that the Issuer may own, a U.S. Holder may continue to be subject to the PFIC rules with respect to its indirect interest in any investments held by the Issuer that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. Each U.S. Holder should ask its own tax adviser whether a mark-to-market election is available or desirable. A valid mark-to-market election cannot be revoked without the consent of the IRS unless the Offered Shares cease to be marketable.

If the Issuer were regarded as a PFIC, a U.S. Holder of Offered Shares generally would be required to file an information return on IRS Form 8621 for any year in which such U.S. Holder receives a direct or indirect distribution with respect to the Offered Shares, or recognizes gain on a direct or indirect disposition of the Offered Shares. In addition, if the Issuer were regarded as a PFIC, a U.S. Holder of the Offered Shares would be required to file an annual information return (also on IRS Form 8621) relating to the U.S. Holder's ownership of the Offered Shares. This requirement would be in addition to other reporting requirements applicable to ownership in a PFIC. U.S. Holders should consult their tax advisers concerning the U.S. federal income tax consequences of holding the Offered Shares if the Issuer were considered to be a PFIC.

(e) Backup withholding and information reporting

Payments of dividends and sales proceeds that are made within the U.S. or through U.S. or certain U.S.-related financial intermediaries will generally be reported to the IRS and to you as may be required under applicable regulations and subject to backup withholding, unless (i) you are an exempt recipient or (ii) in the case of backup withholding, you provide a correct taxpayer identification number and certify that you are not subject to backup withholding. Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against your U.S. federal income tax liability, provided that the required information is timely furnished to the IRS.

Under U.S. federal income tax law, certain U.S. Holders with interests in "specified foreign financial assets" with an aggregate value in excess of certain threshold amounts are, subject to certain exceptions, required to report certain information with respect to the Offered Shares to the IRS by attaching a complete IRS Form 8938 (Statement of Specified Foreign Financial Assets) to their tax return for each year in which they hold the Offered Shares. U.S. Holders should consult their own tax advisers regarding information reporting requirements relating to their ownership of the Offered Shares, including the requirement to file IRS Form 8938.

Annex A – Sources

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102. Estimate based on market research conducted by Sequana Medical.

Annex B – Glossary

SF-36	A patient-reported 36-Item short form survey consisting of 36 quality-of-life questions. The SF-36 consists of eight scales scores (i.e. vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, mental health) which are weighted sums of the questions in their sections.
AIMD	Active implantable medical device.
AIMD Directive	The European Active Implantable Medical Devices Directive 90/385/EEC and subsequent amendments, which have been repealed and replaced on 5 April 2017 by the Medical Devices Regulation.
AKI	Acute kidney injury (a sudden episode of kidney failure or kidney damage that happens within a few hours or a few days, causing a build-up of waste products in the blood and making it difficult for the kidneys to maintain the correct balance of fluid in the body).
Albumin Replacement Study	European study on the impact of albumin replacement therapy on clinical outcomes in 10-15 patients implanted with the alfapump [®] .
alfapump [®]	A fully-implantable, wirelessly charged system that automatically and continuously pumps ascites from the abdominal cavity into the bladder, where the body eliminates the ascites naturally through urination, providing a treatment solution for the long-term management of liver refractory ascites and malignant ascites.
alfapump [®] DSR	A fully implantable, wirelessly charged system for DSR therapy.
ARIA Pump Study	Randomised, open-label health economic study in France in 90 liver refractory ascites patients to evaluate the cost utility of the alfapump [®] vs. standard of care (60 patients not waiting for liver transplant and 30 patients as bridge to transplant) over 12 months to support French reimbursement
ascites	The accumulation of fluid in the abdomen.
CE-Mark	A mandatory conformance mark on active implantable medical devices placed on the market in the EEA (and Switzerland based on mutual recognition). With the CE-Marking on a product, the manufacturer certifies (i) compliance of the design of the product with the applicable harmonised standards and essential requirements of the AIMD Directive and (ii) the QMS (including that of critical suppliers) is in conformity with the requirements under the AIMD Directive.
CLDQ	The Chronic Liver Disease Questionnaire, which was developed to evaluate the impact of chronic liver diseases on patient's quality of life.
CMO	A third party contract manufacturing organisation.
CRO	A third party contract research organisation.
DSR	Direct Sodium Removal, a proprietary approach to the treatment of volume overload in heart failure, which involves removing sodium from the body using diffusion via the peritoneal cavity with the use of a low or no sodium infusate. Once the sodium has been removed, the body eliminates excess fluid via urination and osmotic ultrafiltration.
EASL	European Association for the Study of the Liver.
EU5	The U.K., France, Germany, Italy and Spain

European RCT	A six-month European randomised controlled trial on the alfapump [®] versus LVP for the treatment of liver refractory ascites (completed in 2016).
FDA	The U.S. Food and Drug Administration.
Fitbit[®] Study	Quality of life study in 20 patients to measure the impact of the alfapump [®] versus standard of care on patient activity. Fitbit [®] is not affiliated or associated with Sequana Medical, and Fitbit [®] is not affiliated with, and has not otherwise endorsed, the Fitbit [®] Study.
FSCA	A field service correction action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device.
G-DRG	In Germany, medical devices are reimbursed according to 'German Diagnosis Related Group' codes, the receipt of which requires the submission of data collected through usage of the device.
GCP	Good Clinical Practices against which clinical trials in the U.S. will be examined against by the FDA at the time that marketing authorisation is assessed in order to ensure that data and reported results are credible and accurate and that the rights, safety and welfare of trial participants are protected
Gines Study	Prospective, single-centre, uncontrolled study to evaluate the effects of the alfapump [®] on kidney and circulatory function in 10 patients with liver cirrhosis and refractory ascites.
GPO	A group purchasing organisation created to leverage the combined purchasing power of its members to get maximum discounts from suppliers, for all of its members
Health Canada	The department of the government of Canada with responsibility for national public health.
Healthy pig DSR proof of concept study	Single dose, single arm proof of concept study to assess impact of direct sodium removal therapy in healthy pigs.
Heart failure pig DSR proof of concept study	Single dose, single arm proof of concept study to assess impact of direct sodium removal therapy in pigs with experimentally induced heart failure via tamponade.
HTA	A health technology assessment, which is the systematic evaluation of properties, effects, and/or impacts of health technology used in Canada. It is a multidisciplinary process to evaluate the social, economic, organisational and ethical issues of a health intervention or health technology.
infusate	A "sodium-free" fluid administered into the peritoneal cavity.
IDE	An investigational device exemption provided by the FDA, which allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data.
IMOC	The Israel Ministry of Communications.
IMOH	The Israel Ministry of Health.
Investigator	A physician engaged at a clinical study centre to maintain overall responsibility for conduct of the clinical study.
KOL	Key opinion leader.
LVP	Paracentesis where at least 5 litres of fluid is removed.

liver recurrent ascites	Liver recurrent ascites, also known as recidivant ascites, is a condition whereby a patient experiences ascites which recurs on at least 3 occasions within a 12-month period despite prescription of dietary sodium restriction and adequate diuretic dosage.
liver refractory ascites	Ascites that is unresponsive to a sodium-restricted diet and high-dose diuretic treatment or that recurs rapidly after paracentesis.
malignant ascites	Ascites caused by certain late-stage cancers.
Malignant Ascites CT	Controlled study in Europe to evaluate the efficacy and clinical impact of the alfapump [®] versus standard of care in 25-30 malignant ascites patients.
Medical Devices Regulation	The European Medical Devices Regulation (Regulation 2017/745).
Medical Devices Vigilance System	An E.U. vigilance reporting system, to improve the protection of health and safety of patients, healthcare professionals, and other users by reducing the likelihood of reoccurrence of incidents related to the use of a medical device.
MDSAP	Medical Devices Single Audit Program, which allows manufacturer's quality management system that satisfies the requirements of up to five regulatory jurisdictions (Australia, Brazil, Canada, Japan and the U.S.).
MOSAIC (North American IDE feasibility) Study	12-month open-label, single-arm study in North America to assess the safety and efficacy of the alfapump [®] in patients with liver recurrent or refractory ascites (completed in 2018).
NAFLD	Non-alcoholic fatty liver disease, which is caused by a build-up of fat in the liver of people who drink little or no alcohol.
NASH	Non-alcoholic steatohepatitis, which is a type of NAFLD whereby there is inflammation and liver cell damage, along with fat in the liver.
NHC	The U.K. National Health Service
NICE	The National Institute for Health and Clinical Excellence, which is a public body of the Department of Health in the U.K. that publishes guidelines for the use of health technologies within the National Health System, including the use of new and existing medicines, treatments and procedures, and clinical practice, including guidance on the appropriate treatment and care of people with specific diseases and conditions.
North America	The U.S. and Canada
Notified Bodies	Organisations designated to assess whether manufacturers (and their subcontractors) and their medical devices meet applicable regulatory requirements in the EEA.
NUB	The Neue Untersuchungs- und Behandlungsmethoden (New Research and Treatment Methods), a short-term, intermediate reimbursement mechanism that provides hospitals with financial incentives to use a new medical device before it is reimbursed under the G-DRG system.
paracentesis	A procedure in which a needle or catheter is inserted into the peritoneal cavity to obtain ascitic fluid.
PAS	A post-approval study (or studies) that may be required by the FDA following the grant of a PMA.
PCS	Physical component score, which is one of eight components of the SF-36.

PIONEER Study	Prospective, multi-centre, open-label, uncontrolled study to assess the safety and performance of the alfapump [®] in patients with liver refractory ascites and diuretic resistance (completed in 2013).
PMA	Pre-market approval from the FDA to market a medical device in the U.S.
PMSR	Multi-centre, open-label observational study in Europe designed to follow patients implanted with an alfapump [®] for up to 24 months (completed in 2018).
POSEIDON (North American pivotal) Study	North American pivotal study in up to 100 patients with liver refractory and recurrent ascites to demonstrate the efficacy and cost-effectiveness of the alfapump [®] vs. standard of care (LVP).
QALY	Quality-adjusted life years, a way to measure the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health.
QMS	Quality management system
QSR	Quality System Regulations applicable to manufacturers of medical devices in the U.S. prior to and/or after the granting of a pre-market approval.
RED	The European Radio Equipment Directive 2014/53/EU.
Repeated Dose DSR Proof of Concept	Study expected to be conducted in clinical centres in Europe in approximately 5-10 patients with volume overload in heart failure to demonstrate the safety, tolerability and efficacy (sodium and fluid removal) of the alfapump [®] DSR in connection with multiple dose DSR therapy over a 90-day period.
Retrospective Study at Hannover Medical School	Retrospective, single-centre study at Hannover Medical School to investigate the alfapump [®] as an alternative for LVP in a real-world setting (published in 2018).
Single Dose DSR Proof of Concept	First-in-human clinical study in approximately 20 patients in the U.S. at Yale University to demonstrate the safety, tolerability and dynamics of a single dose of DSR therapy (no alfapump [®]).
TIPS	Transjugular intrahepatic portosystemic shunt, which is an artificial channel within the liver that establishes a connection between the inflow portal vein and the outflow hepatic vein.
TOPMOST	European registry study in cirrhosis patients that have been implanted with the alfapump [®] .
USPTO	The U.S. Patent and Trademark Office.

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**Sequana Medical NV
(former Sequana Medical AG, Zug)
Ghent**

**Review Report to the
Board of Directors on the
Interim consolidated financial statements
*as of 30 September 2018***





Report on the Review
of Interim consolidated financial statements
to the Board of Directors of Sequana Medical NV
(former Sequana Medical AG, Zug)
Ghent

Introduction

We have reviewed the accompanying interim consolidated financial statements (condensed consolidated statement of profit or loss, condensed consolidated statement of comprehensive income, condensed consolidated balance sheet, condensed consolidated statement of changes in equity, condensed consolidated statement of cash flows and notes) of Sequana Medical NV (former Sequana Medical AG) for the period ended 30 September 2018. The Board of Directors is responsible for the preparation and presentation of these interim consolidated financial statements in accordance with International Accounting Standard 34 “Interim Financial Reporting”. Our responsibility is to express a conclusion on this interim consolidated financial statements based on our review.

Scope of Review

We conducted our review in accordance with Swiss Auditing Standard 910 and International Standard on Review Engagements 2410, “Review of interim financial information performed by the independent auditor of the entity”. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Swiss Auditing Standards and International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the accompanying interim consolidated financial statements have not been prepared, in all material respects, in accordance with International Accounting Standard 34 “Interim Financial Reporting”.

Emphasis of Matter

We draw attention to note 4 in the financial statements which states that the company’s ability to continue operations depends on its ability to raise additional capital in order to fund operations and assure the solvency of the company until revenues reach a level to sustain positive cash flows. This, along with other matters as described in note 4, indicates the existence of a material uncertainty, which may cast significant doubt about the ability of the company to continue as a going concern. Our conclusion is not qualified in respect of this matter.

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PricewaterhouseCoopers AG

Thomas Brüderlin

Susanne Halimi

Basel, 21 November 2018

Enclosure:

- Interim consolidated financial statements (condensed consolidated statement of profit or loss, condensed consolidated statement of comprehensive income, condensed consolidated balance sheet, condensed consolidated statement of changes in equity, condensed consolidated statement of cash flows and notes)

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**INTERIM FINANCIAL REPORT
FOR THE PERIOD ENDED
SEPTEMBER 30, 2018**

**Condensed consolidated statement of profit or loss
For the three months ending 30 September**

In EUR	Notes	01.07.18 to 30.09.18	01.07.17 to 30.09.17
Revenues	5	239,111.01	215,765.38
Costs of goods sold		(10,870.49)	(27,389.93)
Gross Margin		228,240.52	188,375.45
Sales & marketing		(534,516.53)	(428,114.01)
Clinical affairs		(297,941.31)	(480,281.08)
Quality & regulatory		(290,012.21)	(300,883.90)
Supply chain		(224,513.96)	(193,303.68)
Engineering		(368,706.93)	(245,257.23)
General & administration	6	(2,075,374.26)	(534,757.31)
Other income		—	—
Total Operating Expenses		(3,791,065.20)	(2,182,597.21)
Earnings before interests and taxes (EBIT)		(3,562,824.68)	(1,994,221.76)
Financial result		(435,652.38)	(160,940.88)
Taxes		(245.38)	4,345.45
Net loss for the period		(3,998,722.44)	(2,150,817.19)
Attributable to Sequana shareholders		(3,998,722.44)	(2,150,817.19)
Earnings per share (basic and diluted)		(0.40)	(0.23)

**Condensed consolidated statement of profit or loss
For the nine months ending 30 September**

In EUR	Notes	01.01.18 to 30.09.18	01.01.17 to 30.09.17
Revenues	5	686,370.00	957,467.00
Costs of goods sold		(106,577.00)	(197,843.55)
Gross Margin		579,793.00	759,623.45
Sales & marketing		(1,478,754.71)	(1,090,499.53)
Clinical affairs		(1,040,164.31)	(1,310,317.02)
Quality & regulatory		(815,637.04)	(973,605.10)
Supply chain		(729,094.14)	(861,964.43)
Engineering		(885,119.89)	(743,352.68)
General & administration	6	(3,547,327.00)	(1,708,785.16)
Other income		—	—
Total Operating Expenses		(8,496,097.09)	(6,688,523.92)
Earnings before interests and taxes (EBIT)		(7,916,304.09)	(5,928,900.47)
Financial result		(693,269.49)	(494,605.20)
Taxes		(24,531.77)	(12,414.70)
Net loss for the period		(8,634,105.35)	(6,435,920.37)
Attributable to Sequana shareholders		(8,634,105.35)	(6,435,920.37)
Earnings per share (basic and diluted)		(0.87)	(0.70)

**Condensed consolidated statement of comprehensive income
For the three months ending 30 September**

In EUR	Notes	01.07.18 to 30.09.18	01.07.17 to 30.09.17
Net loss for the period		(3,998,722.44)	(2,150,817.19)
Components of other comprehensive income (OCI) items that will not be reclassified to profit or loss:			
Remeasurements of defined benefit plans		—	—
Items that may be reclassified subsequently to profit or loss:			
Currency translation adjustments		(182,054.42)	631,257.57
Total other comprehensive income/(loss), net of tax		(182,054.42)	631,257.57
Total comprehensive income for the period		(4,180,776.86)	(1,519,559.62)
Attributable to Sequana shareholders.....		(4,180,776.86)	(1,519,559.62)

**Condensed consolidated statement of comprehensive income
For the nine months ending 30 September**

In EUR	Notes	01.01.18 to 30.09.18	01.01.17 to 30.09.17
Net loss for the period		(8,634,105.35)	(6,435,920.37)
Components of other comprehensive income (OCI) items that will not be reclassified to profit or loss:			
Remeasurements of defined benefit plans		—	—
Items that may be reclassified subsequently to profit or loss:			
Currency translation adjustments		(82,507.00)	452,086.00
Total other comprehensive income/(loss), net of tax		(82,507.00)	452,086.00
Total comprehensive income for the period		(8,716,612.35)	(5,983,834.37)
Attributable to Sequana shareholders.....		(8,716,612.35)	(5,983,834.37)

Condensed consolidated balance sheet

In EUR	Notes	Total September 30, 2018	Total December 31, 2017
Tangible fixed Assets	7	170,439.81	205,954.54
Laboratory.....		7,954.14	9,794.79
Information technology (IT).....		154,238.06	185,830.17
RD tools.....		8,247.61	10,329.58
Financial assets		51,051.56	41,744.85
Financial assets – Rental deposit.....		51,051.56	41,744.85
Total non-current assets		221,491.37	247,699.39
Trade Receivables		119,850.00	164,622.00
Trade Receivables – Third parties.....		119,850.00	164,622.00
Other Receivables		284,143.74	152,256.01
Other Receivables – Third parties.....		169,557.00	129,751.35
Other Receivables – Related parties.....		—	9,147.14
Other Receivables – prepaid expenses		114,586.74	13,357.52
Inventory		1,453,176.00	1,270,802.89
Inventory.....		1,453,176.00	1,270,802.89
Cash and cash equivalents		541,005.00	1,683,827.80
Cash and cash equivalents		541,005.00	1,683,827.80
Total current assets		2,398,174.74	3,271,508.70
TOTAL ASSETS		2,619,666.11	3,519,208.09
Total Equity		(13,348,594.21)	(4,610,672.42)
Share capital.....	9	956,168.83	954,577.23
Other equity.....	10	184,477.97	—
Own shares		(193,274.93)	(193,274.93)
Share premium		65,156,558.95	65,156,558.95
Reserves		(389,888.88)	(182,509.86)
Loss brought forward.....		(79,716,077.28)	(71,081,971.94)
Cumulative translation adjustment.....		653,441.13	735,948.13
Long term financial debts		—	1,757,266.67
Long term financial debts		—	1,757,266.67
Retirement benefit obligation		874,898.84	818,583.09
Retirement benefit obligation		874,898.84	818,583.09
Total non-current liabilities		874,898.84	2,575,849.76
Short term financial debts		10,923,152.84	2,820,494.02
Short term financial debts.....	10	10,923,152.84	2,820,494.02
Trade Payables		2,190,335.81	2,012,130.73
Trade Payables – Third parties		1,175,145.00	908,910.85
Contract liabilities.....	8	1,015,190.81	1,103,219.88
Other payables		17,605.83	270,486.58
Other payables – Third parties		17,605.83	270,486.58
Accrued liabilities		1,962,267.00	450,919.42
Accrued liabilities – Provision warranty		61,763.00	29,227.02
Accrued liabilities – Third parties.....	6	1,900,504.00	421,692.40
Total current liabilities		15,093,361.48	5,554,030.75
TOTAL EQUITY AND LIABILITIES		2,619,666.11	3,519,208.09

Condensed consolidated statement of changes in equity

In EUR	Notes	Share capital	Other Equity	Own shares	Share premium	Reserves	Loss brought forward	Currency translation differences	Total shareholder equity
January 1, 2017		859,984.93			55,437,784.33	(334,682.99)	(62,856,783.38)	226,144.02	(6,667,553.08)
Net loss							(6,435,920.37)		(6,435,920.37)
Other comprehensive income						1,453.78		452,086.00	452,086.00
Capital increase (net of costs)		94,592.30			9,717,320.81	17,210.86			9,813,366.89
Share-based compensation						(316,018.35)	(69,292,703.75)	678,230.02	17,210.86
September 30, 2017		954,577.23			65,155,105.14	(316,018.35)	(69,292,703.75)	678,230.02	(2,820,809.72)
January 1, 2018		954,577.23		(193,274.93)	65,156,558.95	(182,509.86)	(71,081,971.93)	735,948.13	(4,610,672.41)
Net loss							(8,634,105.35)	(82,507.00)	(8,634,105.35)
Other comprehensive income									(82,507.00)
Capital increase (net of costs)	9	1,591.60				(225,711.59)			1,591.60
Transaction costs for equity instruments	6		184,477.97						(225,711.59)
Conversion rights on convertible notes	9								184,477.97
Share-based compensation						18,332.57			18,332.57
September 30, 2018		956,168.83	184,477.97	(193,274.93)	65,156,558.95	(389,888.88)	(79,716,077.28)	653,441.13	(13,348,594.21)

Condensed consolidated statement of cash flows

In EUR	Notes	01.01.18 to 30.09.18	01.01.17 to 30.09.17
Net loss for the period		(8,634,105.35)	(6,435,920.37)
Income taxes		24,531.77	12,414.70
Financial result		693,269.49	494,605.20
Depreciation		53,920.87	58,433.35
Change in defined benefit plan		—	—
Share-based compensation		18,112.21	17,210.87
Changes in trade and other receivables		(87,115.73)	(58,385.04)
Changes in inventories		(182,373.11)	453,148.34
Changes in trade and other payables/provisions		1,436,671.89	(1,658,488.95)
Taxes paid		(8,610.53)	(12,414.70)
Cash flow from operating activities		(6,685,698.49)	(7,129,396.60)
Investments in tangible fixed assets		(3,239.24)	(6,516.19)
Investments in financial assets		(10,609.00)	(3,787.84)
Cash flow used for investing activities		(13,848.24)	(10,304.03)
Proceeds from capital increase		—	9,813,366.89
Exercise of employee options		1,592.09	—
Proceeds from financial debts	10	5,711,310.28	—
Other finance expenses paid		—	—
Transaction costs deducted from equity	6	(225,711.59)	—
Interest paid		(6,706.05)	(250,328.90)
Cash flow from financing activities		5,480,484.73	9,563,037.99
Net change in cash and cash equivalents		(1,219,062.00)	2,423,337.36
Cash and cash equivalents at the beginning of the year (1 January)		1,683,827.80	797,456.82
Net effect of currency translation on cash and cash equivalents		76,239.20	(145,235.66)
Cash and cash equivalents at the end of the period (30 September)		541,005.00	3,075,558.52

Notes to the condensed interim financial statements

1. Corporate Information

The condensed interim financial statements incorporate the financial statements of Sequana Medical AG, a company domiciled and incorporated in Switzerland, and its subsidiaries (together referred to as “Sequana” or “Sequana Group” or “Group”).

Sequana’s principal executive office is at Technoparkstrasse 1, 8005 Zurich, Switzerland.

Sequana is a commercial stage medical device company and an innovator in the management of liver disease. The first and up to date only product, alfapump[®], is a fully implantable, programmable, transcutaneously charged, battery-powered pump for the management of refractory ascites (chronic fluid build-up in the abdomen). Through the experience from the design, development, manufacture and commercialization of the alfapump[®], together with the extensive intellectual property portfolio, Sequana is developing an enabling platform for the management of heart failure and other fluid-imbalance disorders.

2. Basis of preparation of the interim financial statements

This condensed consolidated interim financial report for the three and nine-month period ending 30 September 2018 has been prepared in accordance with Accounting Standard IAS 34 Interim Financial Reporting.

The interim report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 31 December 2017 and any public announcements made by the Group during the interim reporting period (see note 11).

The accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period.

The Group’s annual consolidated financial statements for the year ended 31 December 2017 were prepared in compliance with International Financial Reporting Standards as endorsed by the EU.

a. Impact of standards issued but not yet applied by the entity – IFRS 16 Leases

IFRS 16 was issued in January 2016. It will result in almost all leases being recognized on the balance sheet, as the distinction between operating and finance leases is removed. Under the new standard, an asset (the right to use the leased item) and a financial liability to pay rentals are recognized. The only exceptions are short-term and low-value leases.

The accounting for lessors will not significantly change and the standard will affect primarily the accounting for the group’s operating leases.

Some of the commitments may be covered by the exception for short-term and low-value leases and some commitments may relate to arrangements that will not qualify as leases under IFRS 16.

The standard is mandatory for first interim periods within annual reporting periods beginning on or after 1 January 2019. The group does not intend to adopt the standard before its effective date and will adopt the standard as from next accounting year.

3. Significant accounting judgments, estimates and assumptions

For the preparation of the consolidated financial statements, it is necessary to make judgments, estimates and assumptions to form the basis of presentation, recognition and measurement of the Group’s assets, liabilities, items of income statements, accompanying disclosures and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

In the process of applying Sequana’s accounting policies, management has made various judgments. Those which management has assessed to have the most significant effect on the amounts recognized in the consolidated financial statements have been discussed in the individual notes of the related financial statement line items.

The Group based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that

are beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

Sequana is subject to risks and uncertainties, which may lead to actual results differing from these estimates, both positively and negatively. Sequana's specific estimates including tax, pension liabilities or provisions are discussed in the relevant sections of the management's review and in the notes.

Significant estimates and judgments of the Group include:

a. Pensions (IAS 19) – key assumptions for measuring defined benefit obligation for post-employment expense for the period and the defined benefit obligation at the period end.

The company's measurement of defined benefit plan assets and liabilities requires the use of statistical data and other parameters used to anticipate future changes. The key assumptions have not changed compared to the 2017 year-end reporting. Therefore, we refer to the 2017 consolidated financial statements for the detailed assumptions.

b. Going concern – key assumptions on the company's ability to continue as a going concern

We refer to note 4 for the update regarding the going concern

c. Fair value of financial instruments (convertible loans)

The fair value of financial instruments that are not traded in an active market is determined by using valuation techniques. The group uses its judgment to select a variety of methods and make assumptions that are mainly based on market conditions existing at the end of each reporting period.

Valuation of the convertible loans denominated originally in CHF:

The initial fair value of the liability component of the bond was determined using a market interest rate of 12%, which represents the market interest rate for similar bonds having no conversion rights at the issue date. One of the conversion options represents a fixed amount of the entity's shares for a fixed amount of cash. We refer to note 10 for further information on the accounting treatment.

Valuation of the convertible loans denominated originally in EUR:

The initial fair value of the liability portion of the bond was determined using a market interest rate of 12%, which represents the market interest rate for similar bonds having no conversion rights at the issue date. The corresponding fair value of the conversion option was determined using the expected share price range multiplied by the number of shares capable to be converted. The share price range is based on the expected gross amount of proceeds of EUR 35 million, whereas probability weighted scenarios between EUR 9.3 and EUR 11 per share have been applied. Based on the entity's assumption regarding the estimates described, the resulting fair value of the conversion option is insignificant to these financial statements. We refer to note 10 for further information on the accounting treatment.

4. Significant changes in the current reporting period

a. Financial position and performance

The financial position and performance of the Group was particularly affected by the following events and transactions during the nine months to 30 September 2018:

- Signing of a convertible loan of EUR 1.7 million (CHF 2.0 million) with existing investors. The conversion options are disclosed in note 10.
- Signing of three convertible loans with three new investors for a total amount of EUR 4.2 million. The conversion options are disclosed in note 10.
- Authorized share capital: The right of the Board of Directors to increase the share capital has expired by 24 April 2018

b. Update on going concern assumption:

- The Company is still in its start-up phase and subject to various risks and uncertainties, including but not limited to the timing of achieving profitability and the substantial uncertainty of the development process. The Company's ability to continue operations

also depends on its ability to raise additional capital in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows. These conditions indicate the existence of material uncertainties, which may also cast significant doubt about the Company's ability to continue as a going concern.

- The consolidated balance sheet as at 30 September 2018 shows a negative equity in the amount of EUR 13.3 million. Throughout the year, the company successfully gathered external funds to finance its business. In October, additional funds amounting to EUR 2.6 million have been raised. The Company continues to evaluate equity financing options, including discussions with existing investors and the possibility of an initial public offering (IPO) (see note 11). On the basis of these discussions, the Board of Directors remains confident that the liquidity requirements for next 12 months, estimated to be EUR 14 million can be secured. In case the financing is endangered, the going concern of the Company can most probably no longer be ensured. However, the Management and the Board of Directors remain confident that the strategic direction, comprising financing measures such as additional financing rounds or capital market transactions, will be successful and therefore considers the preparation of the present financial statements on a going concern basis as appropriate.

5. Segment information

Operating segments requiring to be reported are determined on the basis of the management approach. Accordingly, external segment reporting reflects the internal organizational and management structure used within the Group as well as the internal financial reporting to the Chief Operating Decision Maker (CODM), which has been identified as the Executive Management Board (EMB). The EMB is responsible for the operational management of the Group, in line with the instructions issued by the Board of Directors.

Based on the Group's structure Sequana's only entity, which performs production and procurement of its only product, alfapump[®] is located in Switzerland. All other entities are both administration or distribution entities and are not able to operate on a stand-alone basis. Therefore, Sequana constitutes only one reportable segment represented by the whole group.

Nevertheless, the EMB monitors all revenues on a country basis.

An overview of revenue by primary geographic market for the Group's reportable segment is included below:

Geographical market:	YTD Q3 2018	YTD Q3 2017
<i>Switzerland</i>	55,551	106,066
<i>Germany</i>	426,675	455,620
<i>UK</i>	67,966	68,755
<i>Rest of the world</i>	136,178	327,026
Total revenue	686,370	957,467

Given the nature of the business, there is no significant seasonality of interim operations.

6. Profit and loss information (significant items)

The result for the first 9 months includes the following items that are unusual because of their nature, size or incidence:

Expenses in EUR	30 sep 2018	30 sep 2017
IPO related expenses	1,012,954.14	—

The total amount of known and accrued IPO related expenses is 1,238,665.73 EUR, of which 1,012,954.14 EUR has been recognized in the Profit and Loss statement as G&A expenses and 225,711.59 EUR has been reported under equity. The IPO expenses accounted for in equity relate to an anticipated issuance of equity instruments and represent the incremental costs attributable to new shares.

The total amount of Accrued Liabilities-Third parties in the Balance Sheet amounts to 1,900,504 EUR of which 990,224 EUR for the IPO related expenses. Other accruals included are salary- and liability related.

7. Property, plant and equipment

Reconciliation of beginning and ending balance by classes of assets:

Cost (in EUR)	Laboratory	IT	RD Tools	Total
At December 31, 2017	23,399.14	356,819.42	17,437.19	397,655.75
Additions	—	13,289.82	—	13,289.82
Currency translation effects	797.14	12,502.15	594.03	13,893.32
At September 30, 2018	24,196.28	382,611.39	18,031.22	424,838.89
Accumulated depreciation (in EUR)	Laboratory	IT	RD Tools	Total
At December 31, 2017	13,604.35	170,989.25	7,107.61	191,701.21
Additions	2,824.65	49,449.95	2,372.04	54,646.64
Currency translation effects	(186.86)	7,934.13	303.96	8,051.23
At September 30, 2018	16,242.14	228,373.33	9,783.61	254,399.08
Net book value December 31, 2017	9,794.79	185,830.17	10,329.58	205,954.54
Net book value September 30, 2018	7,954.14	154,238.06	8,247.61	170,439.81

8. Current provisions & contract liabilities

Contract liabilities refer to advances received from customers, for which revenue is recognized only upon implant to the final customer. An overview of the changes in the contract liabilities from contracts with customers is as follows

	EUR
Contract liabilities per 31 December 2017	1,103,220
Revenue recognized in the period (included in contract liability at the beginning of the period)	(122,421)
Increases due to cash received as advance payment	—
Effect of currency translation	34,392
Contract liabilities per 30 September 2018	1,015,191

In the period, there was no revenue recognized from performance obligations satisfied or partially satisfied in the previous period.

The Group applies the practical expedient of IFRS 15 (paragraph 121), and does not disclose information about the aggregate transaction price of remaining performance obligations that have original expected durations of one year or less. The Group also applies the practical expedient in paragraph 94 of IFRS 15, whereby the incremental costs of obtaining contracts are expensed as incurred if the amortization period of the assets that the Group would otherwise have recognized is one year or less.

9. Equity securities issued

Issues of ordinary shares during the nine months	Shares	EUR
December 31, 2017	10,029,885	954,577
Exercise of options issued under the ESOP	18,468	1,592
September 30, 2018	10,048,353	956,169

Three employees have exercised their options in the reporting period for a total value of 1,592 EUR.

10. Borrowings (financial debts)

a. Loan agreement with Bootstrap

In 2016, the Group has entered into a loan agreement with Bootstrap Europe S.C.Sp to grant a loan facility of max. CHF 10 million. A first drawdown of CHF 5 million (EUR 4.7 million) was made in 2016. The loan has to be fully repaid within 36 months from the drawdown date, i.e. is due in 2019. However, the Company may repay on any repayment date any outstanding advance. The interest is 12% per annum and is payable over the period as agreed between both parties.

In 2017, the loan agreement was amended and both parties agreed that the second advance of CHF 5 million would be cancelled.

As a security for the fulfilment of the financial obligation, the Company has pledged Intellectual Property as well as the related assets to the venture debt provider Bootstrap Europe S.C.Sp. The Intellectual Property has not been capitalized.

In 2018, the loan agreement was amended again and we refer to note 11 Events after the reporting period for further details.

b. Convertible loan denominated in CHF

The Company signed a Convertible Loan Agreement with existing Shareholders in February 2018, which guarantees liquid funds of EUR 1.7 million (CHF 2 million) in total.

The following conversion options are foreseen in the Agreement:

- In the event of an IPO, Mandatory conversion: the entire outstanding Convertible Loan Amounts shall automatically be converted into shares of the Company in the event of, and simultaneously with the initial closing of, the next increase of the Company's share capital ("next financing round"). The number of shares to be issued upon such conversion shall be equal to the entire outstanding Convertible Loan Amounts divided by the price per share paid by the investor/s at the occasion of such Next Financing Round. Otherwise, the issuance of the shares shall be upon the terms and subject to the conditions applicable to such Next Financing Round. The "fixed-for-fixed" criteria fails for this option, and thus this component of the instrument together with the loan itself represents a liability.
- Voluntary conversion: The lenders' majority may at any time prior the maturity date (including without limitation, prior to an IPO, Liquidity Event or a Next Financing Round) decide to convert the entire outstanding Convertible Loan Amounts into the most senior class of preferred shares at CHF 10.48 per share. This conversion option qualifies as "fixed-for-fixed", and thus represents an equity component.

The convertible loans denominated in CHF are initially recognized at fair value. The liability is subsequently recognized on an amortized cost basis until extinguished on conversion or maturity of the bonds. The remainder of the proceeds is allocated to the conversion option, recognized in shareholders' equity, and not subsequently re-measured. The mandatory conversion option is not material and therefore has not been accounted for separately.

Transaction costs incurred are not material and thus expensed as incurred.

c. Convertible loans denominated in EUR

An additional Convertible Loan Agreement with funds of EUR 1.7 million has been signed in June 2018 with a new investor, Participatiemaatschappij Vlaanderen NV ("PMV").

The following conversion options are foreseen in the Agreement:

PMV is entitled to convert the loan and the accrued interest at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share.

In August and September 2018, two additional Convertible Loan Agreements with funds of EUR 2.5 million have been signed with two new investors, Federale Participatie- en Investeringsmaatschappij NV ("FPIM") and Cofipalux Invest SA ("Vlerick").

The following conversion options are foreseen in the Agreement:

- In the event of an IPO, Mandatory conversion: the entire outstanding Convertible Loan Amounts shall automatically be converted into shares of the Company in the event of, and simultaneously with the initial closing of, the next increase of the Company's share capital ("next financing round"). The number of shares to be issued upon such conversion shall be equal to the entire outstanding Convertible Loan Amounts divided by CHF 10.48 per share.
- Voluntary conversion: The lenders' majority may at any time prior the maturity date (including without limitation, prior to an IPO, Liquidity Event or a Next Financing Round) decide to convert the entire outstanding Convertible Loan Amounts into the most senior class of preferred shares at CHF 10.48 per share.

The convertible debentures denominated in EUR, are classified entirely as liabilities as they were issued in a currency other than the functional currency of the company. As the instrument contains an embedded derivative, the entire instrument has been designated at fair value through profit or loss on initial recognition and as such, the embedded conversion feature is not separated.

Management has calculated the fair value of the options and based on this calculation, the fair value of these options is considered as not significant and hence, the options are not presented separately.

Transaction costs incurred are not material and thus expensed as incurred.

The table below contains an analysis of the net debt and the relevant movements for the periods presented. The amounts disclosed in the table are not substantially different to the undiscounted contractual cash flows.

Net debt reconciliation 30 September 2018 in EUR	30 Sep 2018	1 Jan 2018
Cash and cash equivalents	541,005.00	1,683,827.80
Borrowings – repayable within one year.....	(10,923,152.84)	(2,820,494.02)
Borrowings – repayable after one year.....	—	(1,757,266.67)
Net debt	(10,382,147.84)	(2,893,932.89)

in EUR	Cash and cash equivalents	Borrowings due within 1 year	Borrowings due after 1 year	Total
Net debt as per 1 January 2018	1,683,827.80	(2,820,494.02)	(1,757,266.67)	(2,893,932.89)
Cash flows	(1,219,062.00)	(5,711,310.28)	—	(6,930,372.28)
Accrued interest (non-cash)	—	(670,112.51)	—	(670,112.51)
Transfer (non-cash)	—	(1,757,266.67)	1,757,266.67	—
Foreign exchange impact (non-cash)	76,239.20	36,030.64	—	112,269.84
Net debt as per 30 September 2018	541,005.00	(10,923,152.84)	—	(10,382,147.84)

As per 30 September 2018, an amount of 2,117,526.70 EUR is overdue under the Bootstrap loan agreement amendment signed in 2017. We refer for more information about the Bootstrap loan agreement to Note 11.

The convertible loans are presented in the balance sheet as follows:

In EUR	30 Sep 2018	31 Dec 2017
Face value of convertible loans issued in CHF	1,764,529.87	—
Interest expense accrued on convertible loans issued in CHF ⁽¹⁾	(184,477.97)	—
Face value of convertible loans issued in EUR	4,180,000.00	—
Other loans	5,163,100.94	4,577,760.69
Total short term and long term debt	10,923,152.84	4,577,760.69

(1) Interest expense calculation based on the effective interest rate of 12.0% to the liability component.

11. Fair value measurement of financial instruments

a. Fair value hierarchy

This note presents the judgements and estimates made by the group in determining fair values of the financial instruments recognized and measured at fair value in the financial statements. To provide an indication about the reliability of the inputs used in determining fair value, the group has classified its financial instruments into the three levels prescribed under the accounting standards.

Recognized fair value measurements:

Level 1: The fair value of financial instruments traded in active markets is based on quoted market prices at the end of the reporting period.

Level 2: The fair value of financial instruments that are not traded in an active market is determined using valuation techniques, which maximize the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.

Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3. This is the case for unlisted debt securities.

There were no transfers between levels for recurring fair value measurements during the year.

The group's financial instruments measured at fair value on a recurring basis are classified as level 3. This is due to the market interest rate, on which basis the valuation of the financial liabilities was performed, being based on the most current loans with non-related parties (see significant judgements in note 3).

The following table presents the group's financial liabilities measured and recognized at fair value at 30 September 2018 and 31 December 2017:

Description	Note	Level	At 30 September 2018 in EUR	At 31 December 2017 in EUR
Liability component of convertible loan EUR including conversion option.....	10 c	3	4,180,000.00	0

The carrying amounts of other financial instruments that are not measured subsequently at fair value are not materially different from their fair values due to their nature.

b. Valuation techniques used to determine fair values

The fair value of the company's convertible loans is determined using discounted cash flow analysis, based on interest rate of 12% in the most recent loan with non-related parties, which is deemed to be the best indicator of the market interest rate for loans without conversion features for the company. Refer to note 3 for further information.

c. Valuation inputs and relationships to fair value

The following table summarizes the quantitative information about the significant unobservable inputs used in level 3 fair value measurements.

Description / Financial statement item	Liability component of convertible bond denominated in EUR including the conversion option
Class of subsequent measurement.....	Fair value through profit or loss
Fair value at 30 Sep 2018.....	EUR 4,180,000.00
Unobservable inputs.....	Discount rate / market interest rate
Input range (probability-weighted average)	10% – 14% (12%)
Relationship of unobservable inputs to fair value.....	An increase/decrease of the market interest rate of +2%/-2% would change the fair value of the liability by EUR -38k / EUR +38k

As the discount rate / market interest rate represents the only unobservable input, there are no inter-relationships between any unobservable inputs that affect fair values.

d. Valuation processes

The only level 3 inputs used by the group in measuring the fair value of financial liabilities are market interest rates. These inputs are derived and evaluated by recent comparable bonds having no conversion rights at the issue date.

12. Principal currency translation rates

Period-end rates used for the consolidated balance sheets at 30 September and 31 December, to translate the following currencies into EUR, are:

Per EUR	30.09.2018	31.12.2017
Swiss Franc (CHF).....	1.1316	1.1702
US Dollar (USD).....	1.1576	1.2008

Average rates during the periods ended 30 September, used for the consolidated income and cash flow statements, to translate the following currencies into EUR, are:

Per EUR	2018	2017
Swiss Franc (CHF).....	1.1611	1.1116
US Dollar (USD).....	1.1950	1.1289

13. Expenses by nature

In EUR	2018	2017
Personnel costs.....	3,455,831	2,883,448
External consultancy	1,381,202	713,328
IPO Costs.....	1,012,954	—
Clinical Studies.....	552,246	871,118
Travel & Lodging.....	403,598	341,133
Rent & infrastructure expenses.....	329,006	290,842
External accounting & legal services	241,329	194,773
Marketing	210,232	50,994
Intellectual Property	165,428	146,827
Insurance & IT	142,522	116,142
Depreciation and amortization 1)	53,921	58,433
Other	547,827	1,021,486
Total operating expenses.....	8,496,097	6,688,524

14. Events after the reporting period

a. Transfer of domicile

The Company continues to evaluate equity financing options, including discussions with existing investors and the possibility of an Initial Public Offering (IPO) on Euronext Brussels, Belgium. In view of these possible financing scenarios, the registered office was transferred, effective October 1, from Switzerland to Belgium.

As from October 1, the registered office's address is:

Sequana Medical NV
Technologiepark 19
9052 Ghent – BELGIUM

b. New employee's option plan signed early October

Early October, Sequana implemented a new option plan for a certain group of employees and granted 111,177 share options, which each entitle the holder for a subscription of one share.

c. Bootstrap loan agreement amendment signed 1 October 2018

On October 1, 2018, the agreement for the Bootstrap Loan was further amended to provide that 5% of the proceeds of an Initial Public Offering must be used for a partial repayment of the principal outstanding under the facility, which would lead to cash outflows ranging from a minimum of €0.75 million and a maximum of €1.5 million.

In addition, Sequana Medical granted Bootstrap additional rights to subscribe for new shares in the Issuer by further amending the Bootstrap Warrant. The New Shares in the Offering can also be subscribed for through a contribution in kind by Bootstrap of the payable due by the Company upon the closing of the Offering as "Exit Fee" pursuant to the Bootstrap Loan. As provided for by the Bootstrap Loan, the Exit Fee Amount shall not exceed a maximum of CHF 750,000. The exit fee mentioned above shall be settled by issuance of common shares of Sequana Medical at the time of the Offering and does not result in an increase of the contractually agreed cash flows.

With the exception of the event described above, no repayments of the principal amount are due until 31 December 2020. After that period, the entire outstanding principal amount shall be repaid in four equal monthly instalments starting on 31 December 2020.

Interest remains at the contractually agreed 12% per annum, with payments due on a monthly basis beginning in October 2018 through March 2021. In accordance with the revised contract, the unpaid interest from 1 January 2018 through 31 October 2018 amounting to €0.44 million (CHF 0.50 million) will be due at the time of the Offering, including the balance of unpaid interest from 1 May 2017 to 31 December 2017 in the amount of €0.42 million (CHF 0.48 million) to be paid in equal monthly instalments over the six-month period following the completion of the Offering.

d. Newton Biocapital Convertible Loan signed 11 October 2018

The Issuer and Newton Biocapital I Pricav Privée SA ("Newton") have entered into a convertible loan agreement, dated 11 October 2018, pursuant to which Newton granted a loan to the Issuer in a principal amount of €2,000,000 (the "Newton Convertible Loan" and, together with the February 2018 Convertible Loan, the PMV Convertible Loan, the FPIM Convertible Loan, and the Cofipalux Convertible Loan the "Convertible Loans").

The loan was granted until 31 December 2018. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment.

In the event of an IPO, shortly before the final pricing of an Initial Public Offering, there will be a mandatory conversion whereby the loan and the accrued and unpaid interest will be converted into share capital of the Issuer in consideration of new series E preferred Shares (most senior class of preferred shares) at the lowest of CHF 10.48 per Share and the subscription price of the latest Financing Round, excluding any Financing Round primarily related to the grant or exercise of equity-related incentive plans for employees or board members, and the capital increase to effect the IPO.

The Newton Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.

e. PMV Convertible Loan addendum signed 23 October 2018

PMV agreed via an addendum to the original contract signed on 6 June 2018, to increase their maximum amount to €2 Million, with no further changes to the initial conditions.

There have been no other events occurring after the reporting period, which would have a material effect on the Group financials as of 30 September 2018.

f. Three additional convertible loan agreements signed 25 October 2018, 30 October 2018 and 2 November 2018

The Issuer entered into three additional convertible loan agreements, dated 25 October 2018, 30 October 2018 and 2 November 2018, respectively, with two individuals and BioMedInvest II LP pursuant to which BioMedInvest II LP granted a loan to the Issuer in a principal amount of CHF 198,000 and the two individuals granted a loan to the Issuer in a principal amount of respectively CHF 100,000 and CHF 52,400 (respectively, the “BioMed Convertible Loan” and the “Individual Convertible Loans”, and together with the February 2018 Convertible Loan, the PMV Convertible Loan, the FPIM Convertible Loan, and the Cofipalux Convertible Loan and the Newton Convertible Loan, the “Convertible Loans”). The loans were granted until 31 December 2018. The loans do not bear an interest. The loans can be converted at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. In the event of a capital increase, such as the Offering, the loans are also subject to a mandatory conversion into share capital of the Issuer.

15. Related party transactions

As part of its business, Sequana Medical has entered into several transactions with related parties, including its principal shareholders. The following is a summary of Sequana Medical’s most significant transactions with related parties for the nine months ending 30 September 2018.

a. Relations with the shareholders

Currently, most of the existing shareholders have entered into the Shareholders’ Agreement, containing, amongst others, terms regarding the Issuer’s business and governance, as well as pre-emptive rights and transfer restrictions regarding the Shares. The Shareholders’ Agreement was entered into on 1 October 2018, and is an amendment and restatement of a previous shareholders’ agreement that had been entered into prior to the Belgian Seat Transfer. The Shareholders’ Agreement will be terminated effective as of the closing of the Offering.

The Company and certain of its shareholders have entered into a convertible loan agreement, dated 16 February 2018, pursuant to which these shareholders granted a non-interest-bearing loan to the Issuer in a principal amount of CHF 2 million (the “February 2018 Convertible Loan”). The loan was granted until 31 December 2018, but can be extended if lenders representing more than 50% of the principal amount of the loan agree with the extension. The loan must be converted in a number of circumstances, including at the time of an initial public offering. The loan can be converted at any time prior to maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share if lenders representing more than 50% of the principal amount of the loan agree with the conversion.

The Company and Participatiemaatschappij Vlaanderen NV (“PMV”) have entered into a convertible loan agreement, dated 6 June 2018, pursuant to which PMV granted a loan to the Issuer in a principal amount of €1,680,000 (the “PMV Convertible Loan”). The loan was granted until 31 December 2018. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. PMV is entitled to convert the loan and the accrued interest at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. The PMV Convertible Loan furthermore contains a negative pledge on the Company and its subsidiaries.

The Company and Federale Participatie- en Investeringsmaatschappij NV (“FPIM”) have entered into a convertible loan agreement, dated 27 July 2018, pursuant to which FPIM granted a loan to the Issuer in a principal amount of €2,000,000 (the “FPIM Convertible Loan” and, together with the February 2018 Convertible Loan and the PMV Convertible Loan, the “Convertible Loans”). The loan was granted until 31 December 2018. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. Shortly before the final pricing of the Offering, the loan and the accrued and unpaid interest will be converted into share capital of the Issuer in

consideration of new series E preferred Shares at CHF 10.48 per Share. The FPIM Convertible Loan furthermore contains a negative pledge on the Company and its subsidiaries.

The Company and Cofipalux Invest SA (“Vlerick”) have entered into a convertible loan agreement, dated 30 August 2018, pursuant to which Vlerick granted a loan to the Issuer in a principal amount of €500,000 (the “Vlerick Convertible Loan” and, together with the February 2018 Convertible Loan, the PMV Convertible Loan, and the FPIM Convertible Loan the “Convertible Loans”). The loan was granted until 31 December 2018. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. Shortly before the final pricing of the Offering, the loan and the accrued and unpaid interest will be converted into share capital of the Issuer in consideration of new series E preferred Shares at CHF 10.48 per Share. The Vlerick Convertible Loan furthermore contains a negative pledge on the Company and its subsidiaries.

The Issuer and Newton Biocapital I Pricav Privée SA (“Newton”) have entered into a convertible loan agreement, dated 11 October 2018, pursuant to which Newton granted a loan to the Issuer in a principal amount of EUR 2,000,000 (the “Newton Convertible Loan” and, together with the February 2018 Convertible Loan, the PMV Convertible Loan, the FPIM Convertible Loan, and the Cofipalux Convertible Loan the “Convertible Loans”). The loan was granted until 31 December 2018. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. Shortly before the final pricing of the Offering, the loan and the accrued and unpaid interest will be converted into share capital of the Issuer in consideration of new series E preferred Shares at CHF 10.48 per Share. The Newton Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.

The Issuer entered into three additional convertible loan agreements, dated 25 October 2018, 30 October 2018 and 2 November 2018, respectively, with two individuals and BioMedInvest II LP pursuant to which BioMedInvest II LP granted a loan to the Issuer in a principal amount of CHF 198,000 and the two individuals granted a loan to the Issuer in a principal amount of respectively CHF 100,000 and CHF 52,400 (respectively, the “BioMed Convertible Loan” and the “Individual Convertible Loans”, and together with the February 2018 Convertible Loan, the PMV Convertible Loan, the FPIM Convertible Loan, and the Cofipalux Convertible Loan and the Newton Convertible Loan, the “Convertible Loans”). The loans were granted until 31 December 2018. The loans do not bear an interest. The loans can be converted at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. In the event of a capital increase, such as the Offering, the loans are also subject to a mandatory conversion into share capital of the Issuer.

b. Relations with key management

In 2017, due to the passing of the former CEO, the Company signed a settlement agreement with the wife of the former CEO, in relation to among others the outstanding payment of wages, severance and bonuses for a total amount of USD 308,446. In addition, the Company signed a stock option and share purchase agreement with the wife of the former CEO to acquire his 117,569 common Shares and 90,845 Share options by offsetting outstanding payables by the Issuer in the amount of CHF 226,161 (€211,000 as of December 31, 2016).

Other than these agreements, Sequana Medical has not undertaken any related party transactions except the compensation paid to its board of directors and executive management.

**Sequana Medical NV
(former Sequana Medical AG, Zug)
Ghent**

**Independent auditor's report
to the Board of Directors on the
consolidated financial statements 2017, 2016 and 2015**



**Independent auditor's report
to the Board of Directors of Sequana Medical NV
(former Sequana Medical AG, Zug)
Ghent**

Opinion

On your instructions, we have audited the consolidated financial statements of Sequana Medical NV (former Sequana Medical AG) "the Group", which comprise the consolidated balance sheet as at 31 December 2017, 2016 and 2015, the consolidated statement of profit or loss, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the years then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies.

In our opinion, the accompanying consolidated financial statements give a true and fair view of the financial position of the Group as at 31 December 2017, 2016 and 2015, and its financial performance and its cash flows for the years then ended in accordance with the International Financial Reporting Standards (IFRS) as endorsed by the EU.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs) and Swiss Auditing Standards. Our responsibilities under those provisions and standards are further described in the "Auditor's responsibilities for the audit of the consolidated financial statements" section of our report.

We are independent of the Group in accordance with the requirements of the Swiss audit profession and the IESBA Code of Ethics for Professional Accountants, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Emphasis of matter

We draw your attention to note 2.5 to these financial statements, which states that the company's ability to continue operations depends on its ability to raise additional capital in order to fund operations and assure the solvency of the company until revenues reach a level to sustain positive cash flows. This, along with other matters as described in note 2.5, indicates the existence of a material uncertainty, which may cast significant doubt about the ability of the company to continue as a going concern. Our opinion is not qualified in respect of this matter.

Responsibilities of Management and the Board of Directors for the consolidated financial statements

Management is responsible for the preparation of the consolidated financial statements that give a true and fair view in accordance with IFRS as endorsed by the EU, and for such internal control as Management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, Management is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless Management either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

The Board of Directors is responsible for overseeing the Group's financial reporting process.

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Auditor's responsibilities for the audit of the consolidated financial statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and Swiss Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As part of an audit in accordance with ISAs and Swiss Auditing Standards, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by Management.
- Conclude on the appropriateness of the Management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the Group audit. We remain solely responsible for our audit opinion.

We communicate with the Board of Directors or its relevant committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.



PricewaterhouseCoopers AG

Thomas Brüderlin

Audit expert

Basel, 21 November 2018

Enclosure:

- Consolidated financial statements
(the consolidated balance sheet as at 31 December 2017, 2016 and 2015, the consolidated statement of profit or loss, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the years then ended and notes)

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**CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEARS ENDED
DECEMBER 31, 2017, 2016 AND 2015**

Consolidated statement of profit or loss

In EUR	Notes	2017	2016	2015
Revenues	4.1 / 4.2	1,303,975.15	1,488,799.15	1,684,918.24
Costs of goods sold		(212,426.67)	(320,406.57)	(359,237.66)
Gross Margin		1,091,548.48	1,168,392.57	1,325,680.58
Sales & marketing		(1,506,395.53)	(3,336,687.85)	(2,987,972.97)
Clinical affairs		(1,749,034.76)	(3,325,455.47)	(2,790,224.32)
Quality & regulatory		(1,225,318.62)	(1,492,082.53)	(1,090,819.82)
Supply chain		(1,040,671.83)	(1,774,534.48)	(1,795,309.70)
Engineering		(1,004,311.81)	(1,146,354.61)	(994,974.22)
General & administration		(1,987,812.66)	(4,058,923.17)	(3,285,821.35)
Other income		3,562.98	20,740.03	263,754.83
Total Operating Expenses		(8,509,982.24)	(15,113,298.09)	(12,681,367.55)
Earnings before interests and taxes (EBIT)		(7,418,433.76)	(13,944,905.51)	(11,355,686.97)
Financial income	5.3	10.80	3,076.81	4,219.66
Financial expense	5.3	(635,511.85)	(190,109.20)	(88,513.36)
Foreign exchange gains/ (losses), net	5.3	(152,903.51)	197,712.69	(72,157.53)
Taxes	5.1	(18,350.23)	(40,611.97)	(44,486.48)
Net loss for the period		(8,225,188.56)	(13,974,837.19)	(11,556,624.66)
Attributable to Sequana shareholders		(8,225,188.56)	(13,974,837.19)	(11,556,624.66)
Earnings per share (basic and diluted)	5.2	(0.88)	(2.10)	(2.47)

Consolidated statement of comprehensive income

In EUR	Notes	2017	2016	2015
Net loss for the period		(8,225,188.56)	(13,974,836.87)	(11,556,624.66)
Components of other comprehensive income (OCI) items that will not be reclassified to profit or loss:				
Remeasurements of defined benefit plans.....	6.7	129,225.31	(37,417.91)	(318,317.09)
		129,225.31	(37,417.91)	(318,317.09)
Items that may be reclassified subsequently to profit or loss:				
Currency translation adjustments....		509,804.11	(263,533.87)	489,677.89
		509,804.11	(263,533.87)	489,677.89
Total other comprehensive income/(loss)		639,029.42	(300,951.78)	171,360.80
Total comprehensive income		(7,586,159.13)	(14,275,788.65)	(11,385,263.86)
Attributable to Sequana shareholders.....		(7,586,159.13)	(14,275,788.65)	(11,385,263.86)

Consolidated balance sheet

In EUR	Notes	Total December 31, 2017	Total December 31, 2016	Total December 31, 2015	Total January 1, 2015
Tangible fixed Assets		205,954.54	298,785.13	160,111.13	107,442.07
Laboratory	6.4	9,794.79	16,165.10	16,826.84	15,955.85
Information Technology (IT)	6.4	185,830.17	267,919.12	136,409.25	84,138.83
RD Tools	6.4	10,329.58	14,700.91	6,875.04	7,347.39
Financial assets		41,744.85	103,843.26	101,505.24	82,232.09
Financial assets – Rental deposit		41,744.85	45,532.70	44,870.01	31,768.41
Loans to related parties		—	58,310.57	56,635.23	50,463.68
Total non-current assets		247,699.39	402,628.39	261,616.37	189,674.16
Trade Receivables		164,622.00	225,116.86	258,309.14	138,073.19
Trade Receivables – Third Parties	6.2	164,622.00	225,116.86	258,309.14	138,073.19
Other Receivables		152,256.01	418,686.30	590,845.20	237,462.07
Other Receivables – Third parties		129,751.35	193,213.67	244,860.97	69,387.69
Other Receivables – Related Parties		9,147.14	152,660.20	102,795.71	107,478.01
Other Receivables – prepaid expenses		13,357.52	72,812.43	243,188.52	60,596.36
Inventory		1,270,802.89	1,963,639.55	2,143,996.23	1,386,206.18
Inventory	6.3	1,270,802.89	1,963,639.55	2,143,996.23	1,386,206.18
Cash and cash equivalents		1,683,827.80	797,456.82	1,426,964.03	4,090,895.77
Cash and cash equivalents	6.1	1,683,827.80	797,456.82	1,426,964.03	4,090,895.77
Total current assets		3,271,508.70	3,404,899.53	4,420,114.60	5,852,637.21
TOTAL ASSETS		3,519,208.09	3,807,527.92	4,681,730.97	6,042,311.37

Consolidated balance sheet (continued)

In EUR	Notes	Total December 31, 2017	Total December 31, 2016	Total December 31, 2015	Total January 1, 2015
Total Equity		(4,610,672.41)	(6,667,553.08)	(284,656.92)	2,848,845.81
Share capital.....	6.5	954,577.23	859,984.93	4,410,792.24	3,806,033.19
Own shares	9.0	(193,274.93)	—	—	—
Share premium		65,156,558.95	55,437,784.35	48,622,802.03	40,987,298.22
Reserves		(182,509.86)	(334,683.00)	(306,818.86)	—
Loss brought forward.....		(71,081,971.93)	(62,856,783.38)	(53,501,110.22)	(41,944,485.60)
Cumulative translation adjustment		735,948.13	226,144.02	489,677.89	—
Long term financial debts		1,757,266.67	4,664,179.10	—	—
Long term financial debts	6.6	1,757,266.67	4,664,179.10	—	—
Provisions		—	—	—	269,949.10
Provisions – legal case.....		—	—	—	269,949.10
Retirement benefit obligation		818,583.09	968,277.05	846,120.10	468,213.91
Retirement benefit obligation	6.7	818,583.09	968,277.05	846,120.10	468,213.91
Total non-current liabilities		2,575,849.76	5,632,456.16	846,120.10	738,163.01
Short term financial debts		2,820,494.02	—	—	—
Short term financial debts	6.6	2,820,494.02	—	—	—
Trade Payables		2,012,130.73	3,224,108.68	2,766,171.72	1,859,883.47
Trade payables – Third parties.....	6.2	908,910.85	1,803,405.90	1,304,182.39	1,268,183.22
Contract liabilities		1,103,219.88	1,420,702.78	1,461,989.33	591,700.25
Other payables		270,486.58	182,466.75	570,712.11	149,870.30
Other payables – Third parties.....	8.0	270,486.58	182,466.75	570,712.11	149,870.30
Accrued liabilities		450,919.43	1,436,049.41	783,383.95	445,548.77
Accrued liabilities – Provision warranty		29,227.02	53,544.78	49,016.00	27,279.91
Accrued liabilities – Third parties.....	8.0	421,692.40	1,382,504.63	734,367.95	418,268.86
Total current liabilities		5,554,030.75	4,842,624.84	4,120,267.79	2,455,302.55
TOTAL EQUITY AND LIABILITIES		3,519,208.09	3,807,527.92	4,681,730.97	6,042,311.37

Consolidated statement of changes in equity

In EUR	Notes	Share capital	Own shares	Share premium	Reserves	Loss brought forward	Currency translation differences	Total shareholder equity
January 1, 2015		3,806,033.19	—	40,987,298.22	—	(41,944,485.60)	—	2,848,845.81
Net loss						(11,556,624.66)		(11,556,624.66)
Other comprehensive income							489,677.89	171,360.80
Capital increase (net of costs)	6.5	570,824.90		7,635,503.79	(318,317.09)			8,206,328.69
Exercise of employee options	6.5	33,934.15			11,498.25			33,934.15
Share-based compensation	7.0							11,498.25
December 31, 2015		4,410,792.24	—	48,622,802.01	(306,818.84)	(53,501,110.26)	489,677.89	(284,656.95)
Net loss						(13,974,836.87)		(13,974,836.87)
Other comprehensive income							(263,533.87)	(300,951.78)
Capital increase (net of costs)	6.5	997,624.16		6,814,982.32	(37,417.9)			7,812,606.48
Capital decrease	6.5	(4,619,163.75)				4,619,163.75		—
Exercise of employee options	6.5	70,732.28						70,732.28
Share-based compensation	7.0				9,553.75			9,553.75
December 31, 2016		859,984.93	—	55,437,784.33	(334,682.99)	(62,856,783.38)	226,144.02	(6,667,553.09)
Net loss						(8,225,188.56)		(8,225,188.56)
Other comprehensive income							509,804.11	639,029.42
Capital increase (net of costs)	6.5	94,592.30		9,718,774.62	129,225.31			9,842,592.23
Acquisition of own shares (non-cash transaction)	9.0		(193,274.93)					(193,274.93)
Share-based compensation	7.0				22,947.82			22,947.82
December 31, 2017		954,577.23	(193,274.93)	65,156,558.95	(182,509.86)	(71,081,971.93)	735,948.13	(4,610,672.41)

Consolidated statement of cash flows

In EUR	Notes	2017	2016	2015
Net loss for the period		(8,225,188.56)	(13,974,837.19)	(11,556,624.66)
Income taxes	5.1	18,350.23	40,611.97	44,486.48
Financial result	5.3	788,404.57	(10,680.29)	156,451.22
Depreciation	6.4	77,911.13	80,104.00	46,539.82
Change in defined benefit plan		63,950.12	71,379.43	10,276.10
Share-based compensation.....		22,947.82	9,553.75	11,498.25
Changes in trade and other receivables		145,576.24	212,968.35	(451,965.33)
Changes in inventories		555,963.10	207,652.49	(622,289.48)
Changes in trade and other payables/provisions		(1,807,494.82)	656,013.22	1,146,655.13
Taxes paid		(18,350.23)	(40,611.97)	(44,486.48)
Cash flow from operating activities ..		(8,377,930.39)	(12,747,846.24)	(11,259,458.95)
Investments in tangible fixed assets	6.4	(6,516.19)	(214,689.97)	(88,810.44)
Investments in financial assets		(3,787.84)	(2,338.02)	(19,273.15)
Cash flow used for investing activities		(10,304.04)	(217,027.99)	(108,083.59)
Proceeds from capital increase.....		9,814,515.72	7,812,606.48	8,206,328.71
Exercise of employee options		—	70,732.28	33,934.15
Proceeds from financial debts.....	6.6	—	4,545,454.55	—
Interest paid		(314,328.90)	(190,109.20)	(21,765.13)
Cash flow from financing activities ..		9,500,186.81	12,238,684.10	8,218,497.74
Net change in cash and cash equivalents		1,111,952.38	(726,190.13)	(3,149,044.80)
Cash and cash equivalents at the beginning of the year (1 January)		797,456.82	1,426,964.03	4,090,895.77
Net effect of currency translation on cash and cash equivalents.....		(225,581.41)	96,682.93	485,113.06
Cash and cash equivalents at the end of the year (31 December)		1,683,827.80	797,456.82	1,426,964.03

In 2017, the non cash transactions include the settlement with the former CEO to acquire his shares/options by offsetting the corresponding loan/other receivable.

Notes to the financial statements

1. Corporate Information

The consolidated financial statements incorporate the financial statements of Sequana Medical AG, a company domiciled and incorporated in Switzerland, and its subsidiaries (together referred to as “Sequana” or “Sequana Group” or “Group”).

Sequana’s principal executive office is at Technoparkstrasse 1, 8005 Zurich, Switzerland.

Sequana is a commercial stage medical device company and an innovator in the management of liver disease. The first and up to date only product, alfapump[®], is a fully implantable, programmable, transcutaneous-charged, battery-powered pump for the management of refractory ascites (chronic fluid build-up in the abdomen). Through the experience from the design, development, manufacture and commercialisation of the alfapump, together with the extensive intellectual property portfolio, Sequana is developing an enabling platform for the management of heart failure and other fluid-imbalance disorders.

Group information

Information about the subsidiaries

The consolidated financial statements of Sequana Group include:

Company	Purpose	Share capital	Investment 2017	Investment 2016	Investment 2015
Sequana Medical AG (Switzerland)	Holding / Production and research Company	CHF 1,002,988.5	n/a	n/a	n/a
Sequana Medical GmbH (Germany)	Distribution	EUR 25,000	100%	100%	100%
Sequana Medical Inc. (USA)	Administration	USD 0	100%	100%	100%

There are no non-controlling interests or structured entities. All entities have been newly established by the Group, and included in the consolidated financial statement as from their respective date of incorporation.

The holding company

The ultimate parent of the Group is Sequana Medical AG (the “Company”). The Group has no associated companies nor joint arrangements to which the Group is a party.

Shareholders with influence over the Group:

Shareholders’ interest (%)	2017
NeoMed IV Extension / Innovation V.....	35.5%
LSP Health Economics Fund Management.....	10.7%
Venture Incubator	9.9%
Entrepreneurs Fund.....	8.7%
BioMedInvest	8.1%
Capricorn Health-tech Fund.....	8.0%
Others (each below 3%).....	19.1%
Total.....	100%

2. Basis of preparation of the consolidated financial statements

2.1 Basis of preparation

These consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as endorsed by the EU. The consolidated financial statements have been prepared on an historical cost basis, except for items measured at fair value. These consolidated financial statements are the first IFRS financial statements of the Group prepared in accordance with IFRSs, based on the principles of IFRS 1 “First-time adoption”. Refer to note 2.3 for additional information on how the Group adopted IFRS.

The consolidated financial statements are presented in Euro (“EUR”) and have been rounded to the next EUR.

The preparation of financial statements requires management to exercise judgment when applying accounting policies and to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

Actual results could differ from those estimated. *Section 2.4* below includes further discussion of certain critical accounting estimates.

The consolidated financial statements were approved for issue by the Board of Directors on 20 November 2018.

§ Accounting policies

The overall accounting policies applied to the annual report as a whole are described below. The accounting policies related to specific transactions are embedded in the notes to which they relate.

2.2 Principles of consolidation

The consolidated financial statements of Sequana include all entities that are controlled by the Group. The Group controls another entity when it is exposed, or has rights, to variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Newly acquired companies are consolidated starting from the date of acquisition. The results of companies over which control is lost, are included until the date of sale or actual loss of control.

All intercompany transactions and balances between Group companies are eliminated in full.

The individual financial statements of the Group Companies as of 31 December are prepared using uniform accounting policies.

2.3 First Time adoption

The Group did not previously prepare any consolidated financial statements, but only statutory financial statements for the individual entities. Consequently, a reconciliation of equity and OCI at the date of transition to IFRS is not available.

In adopting IFRS, the Group chose to early adopt IFRS 15 ‘Revenue from contracts with customers’ (note 4.1) and IFRS 9 ‘Financial instruments’ (note 6.6).

2.4 Significant accounting policy changes, judgments and estimates

This note describes the impact on Sequana’s consolidated financial statements of significant accounting judgments made when applying IFRSs and critical assumptions and accounting estimates.

Application of critical accounting policies

Revenue recognition

Sequana recognizes revenue at the amount it expects to be entitled as it satisfies promises towards its customers, regardless of when the payment is received. The performance obligation is considered to be satisfied, once the device has been implanted into the patient, as no significant obligations are considered to exist for the company after such time.

The performance obligation is generally realized once the device has been implanted into the patient. Revenue is measured at the fair value of the consideration received or receivable, taking into account contractually defined terms of payment and excluding taxes or duty. The Group has concluded that it is the principal in all of its revenue arrangements, including in its sales to distributors, since it is the primary obligor in all the revenue arrangements, has pricing latitude, and carries inventory risk.

The Group reduces revenue by the amount of expected returns, and records it as part of trade and other payables. No cash refunds are offered for returns, but rather replacement products. The Group estimates returns on the basis of historical data, adjusted for any additional relevant information about the customer or delay in implant.

Refer to note 4.1 for detailed information concerning revenue recognition for the period.

Sales tax

Expenses and assets are recognized net of the amount of sales tax, except:

- When the sales tax incurred on a purchase of assets or services is not recoverable from the taxation authority, in which case, the sales tax is recognized as part of the cost of acquisition of the asset or as part of the expense item, as applicable
- When receivables and payables are stated with the amount of sales tax included

The net amount of sales tax recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the balance sheet.

Current versus non-current classification

In the Group consolidated financial statements assets and liabilities are classified as current or non-current.

An **asset** is current when it is:

- expected to be realized or intended to be sold or consumed in the normal operating cycle
- held primarily for the purpose of trading
- expected to be realized within twelve months after the reporting period

Or

- cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period

All other assets are classified as non-current.

A **liability** is current when:

- it is expected to be settled in the normal operating cycle
- it is held primarily for the purpose of trading
- it is due to be settled within twelve months after the reporting period

Or

- there is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period

The Group classifies all other liabilities as non-current.

Foreign currency translation

The Group's consolidated financial statements are presented in EUR. For each entity, the Group determines the functional currency and items included in the financial statements of each entity are measured using that functional currency. Consequently, the functional currency of the subsidiaries does not necessarily correspond to the functional currency of the parent.

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

Items of income and cash flow statements are measured by entities at the date of transaction. For practical reasons for translation of income statement and cash flow statement the average exchange rate of the period is applied.

Differences arising on settlement or translation of monetary items are recognized in profit or loss.

The results and financial position of foreign operations that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet
- income and expenses for each statement of profit or loss and statement of comprehensive income are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions), and
- all resulting exchange differences are recognised in other comprehensive income.

On consolidation, exchange differences arising from the translation of any net investment in foreign entities are recognised in other comprehensive income. When a foreign operation is sold, the associated exchange differences are reclassified to profit or loss, as part of the gain or loss on sale.

For foreign exchange rates, which were applied for the consolidated financial statements at 31 December 2017 and the comparative periods please refer to Note 9.

Employee benefits

The Group has both defined contribution plans and defined benefit plans.

In the case of defined contribution plans, contributions are paid to publicly or privately administered pension plans on a statutory, contractual, or voluntary basis. The Group has no further payment obligations once the contributions have been paid. The contributions are recognized as personnel expenses.

Defined benefit plans require the Group to contribute to individual plans, for which the ultimate benefit to the employee is based on a defined benefit, e.g., based on a final salary level, defined performance of the plan, etc. For defined benefit plans, the Group obtains actuarial valuations to determine the required defined benefit pension obligation.

General

Wages, salaries, social security contributions, paid annual leave and sick leave, bonuses, and non-monetary benefits are accrued in the year in which the associated services are rendered by employees of the Company.

Pension obligations

The cost of providing benefits under the defined benefit plan is determined using the projected unit credit method.

Re-measurements, comprising of actuarial gains and losses, the effect of the asset ceiling, excluding net interest and the return on plan assets (excluding net interest), are recognized immediately in the balance sheet with a corresponding debit or credit to retained earnings through OCI in the period in which they occur. Re-measurements are not reclassified to profit or loss in subsequent periods.

Past service costs are recognized in profit or loss on the earlier of:

- the date of the plan amendment or curtailment, and
- the date that the Company recognizes restructuring-related costs

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset and is disclosed in the respective expense by function.

The Group recognizes the service costs comprising current service costs, past-service costs, gains and losses on curtailments and non-routine settlements in the net defined benefit obligation under the respective expenses by function.

2.5 Significant accounting judgments, estimates and assumptions

For the preparation of the consolidated financial statements it is necessary to make judgments, estimates and assumptions to form the basis of presentation, recognition and measurement of the Group's assets, liabilities, items of income statements, accompanying disclosures and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

In the process of applying Sequana's accounting policies, management has made various judgments. Those which management has assessed to have the most significant effect on the amounts recognized in the consolidated financial statements have been discussed in the individual notes of the related financial statement line items.

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial years, are also described in the individual notes of the related financial statement line items in section 6.

The Group based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

Sequana is subject to risks and uncertainties, which may lead to actual results differing from these estimates, both positively and negatively. Sequana's specific estimates including tax, pension liabilities or provisions are discussed in the relevant sections of the management's review and in the notes.

Significant estimates and judgments of the Group include:

- **Pensions (IAS 19)** – key assumptions for measuring defined benefit for measuring post-employment benefit expense for a period and the **defined benefit obligation** at the period end
- **Going concern** – key assumptions on the company's ability to continue as a going concern

Post-employment benefits

The aggregate of the present value of the defined benefit obligation and the fair value of plan assets for each plan is recognized in the balance sheet as a net defined benefit liability or net defined benefit asset. The defined benefit obligation is determined annually by independent actuaries using the projected unit credit method. Employee contributions are recognized in the period in which the related service is rendered. Plan assets are not available to the creditors of the Group.

Pension costs consist of three elements: service costs, net interest, and re-measurements of employee benefits.

- Service costs are part of personnel expenses and consist of current service costs, past service costs (gains/losses from plan amendments or curtailments), and gains/losses from plan settlements.
- Net interest is recorded in the financial result and is determined by applying the discount rate to the net defined benefit liability or net defined benefit asset that exists at the beginning of the year.
- Gains and losses resulting from the actuarial valuation are recorded in other comprehensive income (OCI) as re-measurements of employee benefits. The return on plan assets (excluding interest based on the discount rate) and any change in the effect of an asset ceiling are also recorded in OCI.

Significant other non-current employee benefits (mainly jubilee benefits) are also measured using the projected unit credit method, however re-measurements are recorded in the consolidated income statement.

Detailed information about the assumptions and measurement of post-employment benefits are included in note 6.7.

Termination benefits are recognized on the date on which the Group can no longer withdraw the offer of this type of benefit or on which restructuring provisions are recorded.

Going concern

The Company is still in its start-up phase and subject to various risks and uncertainties, including but not limited to the timing of achieving profitability and the substantial uncertainty of the development process. The Company's ability to continue operations also depends on its ability to raise additional capital in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows. These conditions indicate the existence of material uncertainties, which may also cast significant doubt about the Company's ability to continue as a going concern.

The consolidated balance sheet as at 31 December 2017 shows a negative equity in the amount of EUR 4.6 million. The Company signed a Convertible Loan Agreement with existing Shareholders in February 2018, which guarantees liquid funds of EUR 1.7 million (CHF 2 million) in total. Three additional convertible loan agreements have been signed in June 2018 (EUR 1.7 million), July 2018 (EUR 2 million) and August 2018 (EUR 0.5 million) with new investors. The Company continues to evaluate equity financing options, including discussions with existing investors. Based on these discussions, the Board of Directors remains confident that the liquidity requirements for 2018, estimated to be EUR 8 million (CHF 9.5 Million) can be secured. In case the financing is endangered, the going concern of the Company can most probably no longer be ensured. However, the Management and the Board of Directors remain confident that the strategic direction, comprising financing measures such as additional financing rounds or capital market transactions, will be successful and therefore considers the preparation of the present financial statements on a going concern basis as appropriate.

2.6 Issued standards, amendments or interpretations not yet adopted

The following new and revised standards and interpretations were issued by the IASB. These standards were not effective for the reporting period and have not been early adopted in the present consolidated financial statements.

		Effective for annual periods on or after	Planned adoption by Sequana
IFRS 16	Leases	1 January 2019	Financial Year 2019
IFRIC 22	Foreign currency transactions and advance consideration	1 January 2018	Financial Year 2018

IFRS 16 Leasing

The new standard was issued on January 13, 2016, and will replace IAS 17 Leases. The biggest change introduced by the new standard is that leases will be brought onto companies' balance sheets, increasing the visibility of their assets and liabilities. IFRS 16 removes the classification of leases as either operating leases or finance leases, treating all leases as finance leases. Short-term leases (less than 12 months) and leases of low-value assets (such as e.g. personal computers) are exempt from the requirements. The Group is in the process to assess the impact of the new standard.

IFRIC 22 – Foreign currency transactions and advance consideration

This interpretation considers how to determine the date of the transaction when applying the standard on foreign currency transactions, IAS 21. The Interpretation applies where an entity either pays or receives consideration in advance for foreign currency-denominated contracts.

The date of the transaction determines the exchange rate to be used on initial recognition of the related asset, expense or income. The issue arises because IAS 21 requires an entity to use the exchange rate at the 'date of the transaction', which is defined as the date when the transaction first qualifies for recognition. The question therefore is whether the date of the transaction is the date when the asset, expense or income is initially recognised, or the earlier date on which the advance consideration is paid or received, resulting in recognition of a prepayment or deferred income.

The Interpretation provides guidance for when a single payment/receipt is made, as well as for situations where multiple payments/receipts are made. The guidance aims to reduce diversity in practice.

The Group is in the process to assess the impact of the interpretation, however the impact will not be material to the consolidated financial statements. This interpretation is not yet endorsed by the EU:

There were no other standards, interpretations or amendments that are not yet effective and that would be expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

3. Financial Instruments risk management objectives and policies

The nature of Sequana's business and its global presence exposes the Group to market risks and liquidity risks. The Board of Directors is responsible for overseeing the Group's internal control system, which addresses risks to which the Group is exposed. These systems provide appropriate security against significant inaccuracies and material losses. Management is responsible for identifying and assessing risks that are of significance for the respective country.

Market risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. The market risks consist primarily of foreign currency risks and, to a lesser degree, interest rate risks. Main currency exposures are the Swiss franc and the Euro. The Group is not hedging any of these risks.

- **Foreign currency translation risks**

Translation exposure arises from the consolidation of foreign currency denominated financial statements of Sequana's subsidiaries. This is reported as currency translation effects in OCI. Translation risk can be significant to its equity base. Currency translation risks are not hedged.

The following table shows the sensitivity to foreign exchange rate changes (CHF / EUR and USD / EUR), with all other variables held constant, of the Group's income statement and equity:

As at 31 December 2017 (EUR)	Impact on income statement and equity
5% decrease of average foreign exchange rate.....	-395,000
5% increase of average foreign exchange rate.....	380,000
As at 31 December 2016 (EUR)	Impact on income statement and equity
5% decrease of average foreign exchange rate.....	-760,000
5% increase of average foreign exchange rate.....	690,000
As at 31 December 2015 (EUR)	Impact on income statement and equity
5% decrease of average foreign exchange rate.....	-610,000
5% increase of average foreign exchange rate.....	550,000

- **Interest rate risks**

Interest rate risks arise from changes in interest rates, which have negative repercussions on the Group's asset and earnings situation. Interest rate fluctuations lead to changes in interest income and interest expense on interest-bearing assets and liabilities.

The following table shows the sensitivity to interest rate changes, with all other variables held constant, of the Group's income statement and equity:

As at 31 December 2017 (EUR)	Impact on income statement and equity
50 basis points increase / decrease	-/+ 21,500

As at 31 December 2016 (EUR)	Impact on income statement and equity
50 basis points increase / decrease	-/+ 13,700

Liquidity risk

The Group's objective is to maintain sufficient cash and the availability of funding through an adequate amount of committed credit facilities to meet obligations when due. Sequana defines Liquidity risk, a risk of being unable to raise funds to meet payment obligations when they fall due.

Cash outflows

(EUR)	Carrying amount 31.12.2017	Total	Up to 1 year	1 to 3 years	More than 3 years
Trade payable	2,012,131	2,012,131	2,012,131		
Other payables	270,486	270,486	270,486		
Financial debt at amortized costs	4,577,161	4,577,161	2,820,494	1,757,267	
Interest payment on financial debt	0	605,000	500,000	105,000	
Total	6,859,778	7,464,778	5,603,111	1,862,267	—

Cash outflows

(EUR)	Carrying amount 31.12.2016	Total	Up to 1 year	1 to 3 years	More than 3 years
Trade payable	3,224,109	3,224,109	3,224,109		
Other payables	182,467	182,467	182,467		
Financial debt at amortized costs	4,664,179	4,664,179		4,664,179	
Interest payment on financial debt	0	725,500	120,500	605,000	
Total	8,070,755	8,796,255	3,527,076	5,269,179	—

Capital Management

Management presently monitors its capital structure based on its legal, statutory requirements for stand-alone entities and, in particular, for the holding company. The Group's policy is to maintain sufficient capital to continue as a going concern, and sustain the future development of the business (see note 2.5 regarding the assessment of the going concern).

Management monitors rolling forecasts of the group's liquidity reserve and cash and cash equivalents on the basis of expected cash flows for the next 6 months. This is carried out in accordance with practice and limits set by management and in accordance with the statutory capital requirements of the holding company. Consistent with these principles, Sequana monitors capital using equity ratios, and initiates further financing rounds if the equity is below EUR 1 million

In addition, the group's liquidity management policy involves projecting cash flows in EUR, CHF and GBP and considering the level of liquid assets necessary to meet these, monitoring balance sheet liquidity ratios against internal requirements and maintaining debt-financing plans.

Sequana has complied with the financial covenant of the borrowing facility during the reporting period 2017 and 2016. Under the term of the borrowing facility as shown in the table above as "financial debt", the Company is required to comply with the following financial covenant:

- No over-indebtedness of the stand-alone statutory financial statements within the meaning of article 725 para. 2 of the Swiss Code of Obligations (CO), without remediation plan of the over-indebtedness

No changes were made in the objectives, policies or processes for managing capital during the years ended 31 December 2017, 2016 and 2015.

3.1 Fair value measurement (IFRS 13)

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market or in the most advantageous market, if a principal market doesn't exist. The principal or the most advantageous market must be accessible by the Group.

The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant's ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs. All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 – Quoted (unadjusted) market prices in active markets for identical assets or liabilities
- Level 2 – Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable
- Level 3 – Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

At each reporting date, the responsible management analyses the movements in the values of assets and liabilities, which are required to be re-measured or re-assessed as per the Group's accounting policies. For this analysis, the responsible management verifies the major inputs applied in the latest valuation by agreeing the information in the valuation computation to contracts and other relevant documents.

The responsible management, in conjunction with the Group's external valuation agents, also compares the change in the fair value of each asset and liability with relevant external sources to determine whether the change is reasonable.

For the purpose of fair value disclosures, the Group has determined classes of assets and liabilities on the basis of the nature, characteristics and risks of the asset or liability and the level of the fair value hierarchy, as explained above.

The Group has only financial assets and financial liabilities, which are measured at amortised costs, and therefore the financial assets and financial liabilities have not been listed separately.

The fair value of financial assets and financial liabilities are not materially different to their carrying amount, given their short-term maturity, i.e. the loan granted by Bootstrap would have a fair value of EUR 4.64 million compared to the nominal value (carrying amount) of EUR 4.60 million, applying a market interest rate of 11%.

4.1 Revenue

The Group generates sales solely from the sale of Alfapump, with the revenue recognized at a point in time, coinciding with the time the device is implanted in a patient. In case an advance payment is received prior to implant, a contract liability is booked, which is reversed only at the time revenue is recognized.

An overview of the receivables and contract liabilities from contracts with customers is as follows:

In EUR	2017	2016	2015
Trade receivables	164,622	225,117	258,309
Contract liabilities (relating to customers' advance payments)	1,103,220	1,420,703	1,461,989

No significant financing component is included in the amount of advance payment received from customers.

Contract liabilities refer to advances received from customers, for which revenue is recognized only upon implant to the final customer. An overview of the changes in the contract liabilities from contracts with customers is as follows:

In EUR	2017	2016	2015
Revenue recognized in the period (included in contract liability at the beginning of the period)	(394,947)	(296,077)	(326,460)
Increases due to cash received as advance payment	117,865	252,223	897,713
Effect of currency translation	(40,401)	2,567	299,036

In the period, there was no revenue recognized from performance obligations satisfied or partially satisfied in the previous period.

The Group applies the practical expedient of IFRS 15 (paragraph 121), and does not disclose information about the aggregate transaction price of remaining performance obligations that have original expected durations of one year or less. The Group also applies the practical expedient in paragraph 94 of IFRS 15, whereby the incremental costs of obtaining contracts are expensed as incurred if the amortization period of the assets that the Group would otherwise have recognized is one year or less.

4.2 Segmental breakdown of key figures

Operating segments requiring to be reported are determined on the basis of the management approach. Accordingly, external segment reporting reflects the internal organizational and management structure used within the Group as well as the internal financial reporting to the Chief Operating Decision Maker (CODM), which has been identified as the Executive Management Board (EMB). The EMB is responsible for the operational management of the Group, in line with the instructions issued by the Board of Directors.

Based on the Group's structure Sequana's only entity, which performs production and procurement of its only product, alfapump[®] is located in Switzerland. All other entities are either administration or distribution entities and are not able to operate on a stand-alone basis. Therefore, Sequana constitutes only one reportable segment, which is represented by the whole group.

Nevertheless, the EMB monitors all revenues on a country basis.

An overview of revenue by primary geographic market for the Group's reportable segment is included below:

Geographical market:	2017	2016	2015
<i>Switzerland</i>	125,228	164,404	383,364
<i>Germany</i>	764,175	1,107,827	1,020,596
<i>UK</i>	68,448	73,251	185,898
<i>Rest of the world</i>	346,124	143,440	95,067
Total revenue	1,303,975	1,488,922	1,684,925

All revenue is recognized at a point in time, being when the device has been implanted into the patient.

As the Swiss parent Company is the sole operating Company within the Group, the majority of the assets (94%) are located in Switzerland. There are no significant concentrations of credit risk through exposure to individual customers.

4.3 Related party disclosures

Information about the Group, including details of the subsidiaries and holding company are provided in Note 1.

For detailed information relating to related parties, please refer to Note 8.

4.4 Events after the reporting period

The Issuer and certain of its shareholders have entered into a convertible loan agreement, dated 16 February 2018, pursuant to which shareholders granted a non-interest-bearing loan to the Issuer in an aggregate principal amount of CHF 1,996,742.00 (the "February 2018 Convertible Loan"). The loan was granted until 31 December 2018, but can be extended if lenders representing more than 50% of the principal amount of the loan, agree with the extension. The loan must be converted in a number of circumstances, including at the time of an initial public offering. The loan can be converted at any time prior to maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share if lenders representing more than 50% of the principal amount of the loan agree with the conversion.

The Issuer and PMV have entered into a convertible loan agreement, dated 6 June 2018, pursuant to which PMV granted a loan to the Issuer in a principal amount of €1,680,000, which loan was extended to a principal amount of €2,000,000 pursuant to an addendum dated 23 October 2018 (the "PMV Convertible Loan"). The loan was granted until 31 December 2018. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. PMV is entitled to convert the loan and the accrued interest at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. The PMV Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.

The Issuer and Federale Participatie- en Investeringsmaatschappij NV ("FPIM") have entered into a convertible loan agreement, dated 27 July 2018, pursuant to which FPIM granted a loan to the Issuer in a principal amount of €2,000,000 (the "FPIM Convertible Loan"). The loan was granted until 31 December 2018. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. FPIM is entitled to convert the loan and the accrued interest at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. In the event of an Offering, the loan and accrued interest are also subject to a mandatory conversion into share capital of the Issuer in consideration of new series E preferred Shares at CHF 10.48 per Share. The FPIM Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.

The Issuer and Cofipalux Invest SA ("Cofipalux") have entered into a convertible loan agreement, dated 30 August 2018, pursuant to which Cofipalux granted a loan to the Issuer in a principal amount of €500,000 (the "Cofipalux Convertible Loan"). The loan was granted until 31 December 2018. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment. Cofipalux is entitled to convert the loan and the accrued interest at any time prior

to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. In the event of an Offering, the loan and accrued interest are also subject to a mandatory conversion into share capital of the Issuer in consideration of new series E preferred Shares at CHF 10.48 per Share. The Cofipalux Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.

Events after 30 September 2018:

a. Transfer of domicile

The Company continues to evaluate equity financing options, including discussions with existing investors and the possibility of an Initial Public Offering (IPO) on Euronext Brussels, Belgium. In view of these possible financing scenarios, the registered office was transferred, effective October 1, from Switzerland to Belgium.

As from October 1, the registered office's address is:

Sequana Medical NV
Technologiepark 19
9052 Ghent – BELGIUM

b. New employee's option plan signed early October

Early October, Sequana implemented a new option plan for a certain group of employees and granted 111,177 share options, which each entitle the holder for a subscription of one share.

c. Bootstrap loan agreement amendment signed 1 October 2018

On October 1, 2018, the agreement for the Bootstrap Loan was further amended to provide that 5% of the proceeds of an Initial Public Offering must be used for a partial repayment of the principal outstanding under the facility, which would lead to cash outflows ranging from a minimum of €0.75 million and a maximum of €1.5 million.

In addition, Sequana Medical granted Bootstrap additional rights to subscribe for new shares in the Issuer by further amending the Bootstrap Warrant. The New Shares in the Offering can also be subscribed for through a contribution in kind by Bootstrap of the payable due by the Company upon the closing of the Offering as "Exit Fee" pursuant to the Bootstrap Loan. As provided for by the Bootstrap Loan, the Exit Fee Amount shall not exceed a maximum of CHF 750,000. The exit fee mentioned above shall be settled by issuance of common shares of Sequana Medical at the time of the Offering and does not result in an increase of the contractually agreed cash flows.

With the exception of the event described above, no repayments of the principal amount are due until 31 December 2020. After that period, the entire outstanding principal amount shall be repaid in four equal monthly instalments starting on 31 December 2020.

Interest remains at the contractually agreed 12% per annum, with payments due on a monthly basis beginning in October 2018 through March 2021. In accordance with the revised contract, the unpaid interest from 1 January 2018 through 31 October 2018 amounting to €0.44 million (CHF 0.50 million) will be due at the time of the Offering, including the balance of unpaid interest from 1 May 2017 to 31 December 2017 in the amount of €0.42 million (CHF 0.48 million) to be paid in equal monthly instalments over the six-month period following the completion of the Offering.

d. Newton Biocapital Convertible Loan signed 11 October 2018

The Issuer and Newton Biocapital I Pricav Privée SA ("Newton") have entered into a convertible loan agreement, dated 11 October 2018, pursuant to which Newton granted a loan to the Issuer in a principal amount of €2,000,000 (the "Newton Convertible Loan" and, together with the February 2018 Convertible Loan, the PMV Convertible Loan, the FPIM Convertible Loan, and the Cofipalux Convertible Loan (the "Convertible Loans").

The loan was granted until 31 December 2018. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment.

In the event of an IPO, shortly before the final pricing of an Initial Public Offering, there will be a mandatory conversion whereby the loan and the accrued and unpaid interest will be converted into share capital of the Issuer in consideration of new series E preferred Shares (most senior class of preferred shares) at the lowest of CHF 10.48 per Share and the subscription price

of the latest Financing Round, excluding any Financing Round primarily related to the grant or exercise of equity-related incentive plans for employees or board members, and the capital increase to effect the IPO.

The Newton Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.

e. PMV Convertible Loan addendum signed 23 October 2018

PMV agreed via an addendum to the original contract signed on 6 June 2018, to increase their maximum amount to €2 Million, with no further changes to the initial conditions.

There have been no other events occurring after the reporting period, which would have a material effect on the Group financials as of 30 September 2018.

f. Three additional convertible loan agreements signed 25 October 2018, 30 October 2018 and 2 November 2018

The Issuer entered into three additional convertible loan agreements, dated 25 October 2018, 30 October 2018 and 2 November 2018, respectively, with two individuals and BioMedInvest II LP pursuant to which BioMedInvest II LP granted a loan to the Issuer in a principal amount of CHF 198,000 and the two individuals granted a loan to the Issuer in a principal amount of respectively CHF 100,000 and CHF 52,400 (respectively, the “BioMed Convertible Loan” and the “Individual Convertible Loans”, and together with the February 2018 Convertible Loan, the PMV Convertible Loan, the FPIM Convertible Loan, and the Cofipalux Convertible Loan and the Newton Convertible Loan, the “Convertible Loans”). The loans were granted until 31 December 2018. The loans do not bear an interest. The loans can be converted at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. In the event of a capital increase, such as the Offering, the loans are also subject to a mandatory conversion into share capital of the Issuer.

5.1 Income taxes

Income tax expense

(EUR)	2017	2016	2015
Current income taxes	(18,350)	(40,612)	(44,486)
Deferred income taxes	0	0	
Total income tax expense	(18,350)	(40,612)	(44,486)

The following elements explain the difference between the income tax expense at the applicable Group tax rate and the effective income tax expense:

(EUR)	2017	2016	2015
Loss before tax	(8,206,838)	(13,934,225)	(11,512,138)
Applicable tax rate	20.0%	20.0%	20%
Income tax income at the applicable tax rate	1,641,368	2,786,845	2,302,428
Effect of non-recognition of tax losses in current year	(1,659,718)	(2,827,457)	(2,346,914)
Effective income tax expense	(18,350)	(40,612)	(44,486)

The applicable tax rate is the domestic rate of tax in Switzerland. No income tax was applicable for any items recorded directly in equity or OCI.

Taxes on unremitted earnings

At 31 December 2017, 2016 and 2015, there was no recognized deferred tax liability for taxes that would be payable on the unremitted earnings of certain of the Group’s subsidiaries. The Group does not expect any distribution of retained earnings to the parent company within the next twelve months.

Deferred income taxes

The movement in deferred income tax liabilities is as follows:

Deferred tax liabilities (in EUR)

The balance comprises temporary differences attributable to:

	31.12.2017	31.12.2016	31.12.2015	01.01.2015
Tangible fixed assets	—	9,737.71	—	—
Trade receivables.....	—	125.42	—	—
Inventory	—	156,211.58	112,401.76	93,128.94
Provisions.....	—	26,000.00	26,000.00	—
Total deferred tax liabilities	—	192,074.71	138,401.76	93,128.94
Set-off of deferred tax liabilities ¹⁾	—	(192,074.71)	(138,401.76)	(93,128.94)
Net deferred tax liabilities	—	—	—	—

1) The relevant deferred tax assets available to set-off the deferred tax liabilities mainly relate to temporary differences in connection with contract liabilities recognised in accordance with IFRS 15, whereas for tax purposes a provision of acquisition and production costs have been booked. Deferred tax assets on deductible temporary differences are only recognized up to the amount of deferred tax liability and only as long as they can be set-off in the same tax jurisdiction.

Deductible temporary differences and available tax loss carry – forwards

Deductible temporary differences and unused tax losses for which no deferred tax asset has been recognized:

In EUR	31.12.2017	31.12.2016	31.12.2015	01.01.2015
Deferred tax assets not recognised on deductible temporary differences	(349,108.70)	(314,131.48)	(736,615.10)	(318,527.48)
Deductible temporary differences for which no deferred tax asset has been recognised	1,745,543.50	1,570,657.40	3,683,075.50	1,592,637.40
Switzerland.....	61,374,975.00	58,709,847.86	41,655,706.20	28,808,534.47
USA.....	617,785.50	395,874.58	—	—
Total unused tax losses	61,992,760.50	59,105,722.44	41,655,706.20	28,808,534.47

The unused tax losses were mainly incurred by the holding company. As the Company did not generate any taxable profits in the past and due to the fact that there is an uncertainty about the realization of future taxable profits the Company has decided to not recognize a deferred tax asset on the tax loss carry-forwards. Additionally, the holding company is anticipating moving its legal domicile to Belgium in the course of 2018, which will additionally prevent the company from making use of its tax loss carry-forwards. Given this anticipated change in the legal domicile and the consequent loss of the ability of the company to make use of its tax loss carry-forwards, no information has been disclosed about the expiry of the unused tax losses in Switzerland.

§ Accounting policies

Income tax

Current income tax assets and liabilities are measured at the amount expected to be recovered from or payable to the respective tax authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted at the reporting date in the countries where the Group operates and generates taxable income.

Current income tax relating to items recognized directly in equity is recognized in equity. Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred tax

Deferred tax is provided using the balance-sheet liability method on temporary differences at the reporting date between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes. Deferred tax liabilities are recognized for all temporary differences, except where the deferred tax liability arises from the initial recognition of goodwill or of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither accounting profit nor taxable profit or loss.

Deferred tax assets are recognized for all deductible temporary differences and carry-forwards of unused tax credits and unused tax losses to the extent that it is probable that taxable profit will be available. Deductible temporary differences, carry-forwards of unused tax credits and unused tax losses can be offset against taxable profit except where the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.

Deferred tax positions associated with investments in subsidiaries are only recognized to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available, against which they can be utilized.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year the asset is realized or the liability settled, based on tax rates (and tax laws) enacted or substantively enacted at the reporting date. Deferred tax assets and liabilities are offset if the Group has a legally enforceable right to offset current tax assets against current tax liabilities and the deferred tax relates to the same taxable entity and the same tax authority.

5.2 Earnings per share

Basic earnings per share amounts are calculated by dividing net income for the year attributable to registered shareholders of Sequana by the weighted average number of ordinary shares outstanding during the year.

As Sequana did generate a net loss in each business year, the grants of options did not have a dilution impact. Therefore, the basic and diluted earnings per share are the same.

(EUR, except number of shares)	2017	2016	2015
Net loss attributable to shareholders.....	(8,225,189)	(13,974,837)	(11,556,625)
Weighted average number of shares – basic and diluted.....	9,327,947	6,644,096	4,679,636
Basic and diluted earnings per share	(0.88)	(2.10)	(2.47)

5.3 Financial result

The financial result is split into the following categories:

In EUR	2017	2016	2015
Interest income.....	11	3,077	4,220
Interest costs.....	(635,512)	(190,109)	(88,513)
Foreign exchange gains / (losses).....	(152,904)	197,713	(72,158)
Net financial result	(788,405)	10,680	(156,451)

6. Detailed information on balance sheet items

6.1 Cash and cash equivalents

The Group held cash and cash equivalents of EUR 1,683,823 at 31 December 2017 (2016: EUR 797,457 2015: EUR 1,426,964). The cash is held with bank and financial institutions which are rated AA.

6.2 Trade receivables

The following provides information about the exposure to credit risk and expected credit loss for trade receivables:

The counterparties are in most transactions hospitals in the public sector in Germany, Switzerland or the UK. Therefore, there were no credit losses in the past and the expected credit loss is close to nil.

The ageing of trade receivables at 31 December 2017, 2016 and 2015 past due, but not impaired, are as follows:

	Not past due	Total past due	0-90 days	90-180 days	180-360 days	More than 360 days
2017 (EUR)						
Trade receivables, gross	78,941	85,681	24,075	46,606	15,000	0
Weighted average loss rate....	0%					
2016 (EUR)						
Trade receivables, gross	116,507	108,610	37,075	0	0	71,535
Weighted average loss rate....	0%					
2015 (EUR)						
Trade receivables, gross	103,694	154,616	50,608	49,978	54,030	0
Weighted average loss rate....	0%					

§ Accounting policies

According to IFRS 9, trade receivables are classified and measured at amortised cost. The measurement bases are contractual terms, payment history and other sales evidence. Adjustments for doubtful receivables are only allowed to the extent losses are expected in the future or individually determinable. Any losses caused by amortization of receivables are booked in income statements. For the accounting treatment the simplified approach to determine expected lifetimes losses is applied. The expected credit losses above also incorporate forward-looking information.

6.3 Inventories

Inventories are categorized as follows:

In EUR	December 31, 2017	December 31, 2016	December 31, 2015	January 1, 2015
Finished goods	224,750.67	623,188.51	263,442.16	247,921.15
Subassembly	696,486.78	584,413.20	848,419.62	489,152.08
Components	349,565.44	756,037.85	1,032,134.45	649,132.95
Total	1,270,802.89	1,963,639.55	2,143,996.23	1,386,206.18

§ Accounting policies

Inventories are calculated at the lower of initial cost and net realizable value. The cost of inventories shall comprise all costs of purchase (based on first-in, first-out method), costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

The net realisable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

6.4 Property, plant and equipment

Reconciliation of beginning and ending balance by classes of assets:

Cost (in EUR)	Laboratory	IT	RD Tools	Total
At January 1, 2015	15,955.85	84,138.83	7,347.39	107,442.07
Additions	3,741.18	85,069.26	—	88,810.44
Currency translation effects	1,620.34	7,385.30	776.70	9,782.34
At December 31, 2015	21,317.37	176,593.39	8,124.08	206,034.85
Additions	3,852.89	200,223.28	10,613.80	214,689.97
Currency translation effects	371.26	5,915.65	295.82	6,582.72
At December 31, 2016	25,541.52	382,732.32	19,033.70	427,307.54
Additions	—	6,516.19	—	6,516.19
Currency translation effects	(2,142.37)	(32,429.09)	(1,596.51)	(36,167.98)
At December 31, 2017	23,399.14	356,819.42	17,437.19	397,655.75
Accumulated depreciation (in EUR)	Laboratory	IT	RD Tools	Total
At January 1, 2015	—	—	—	—
Additions	4,571.62	40,696.59	1,271.60	46,539.82
Currency translation effects	(81.10)	(512.45)	(22.56)	(616.11)
At December 31, 2015	4,490.53	40,184.14	1,249.05	45,923.71
Additions	4,433.72	72,655.35	3,014.93	80,104.00
Currency translation effects	452.17	1,973.71	68.82	2,494.70
At December 31, 2016	9,376.42	114,813.20	4,332.80	128,522.41
Additions	5,397.62	69,209.89	3,303.63	77,911.13
Currency translation effects	(1,169.68)	(13,033.84)	(528.81)	(14,732.33)
At December 31, 2017	13,604.35	170,989.25	7,107.61	191,701.21
Net book value January 1, 2015	15,955.85	84,138.83	7,347.39	107,442.07
Net book value December 31, 2015 ..	16,826.84	136,409.25	6,875.04	160,111.14
Net book value December 31, 2016 ..	16,165.10	267,919.12	14,700.91	298,785.13
Net book value December 31, 2017 ..	9,794.79	185,830.17	10,329.58	205,954.54

§ Accounting policies

Property plant and equipment is stated at cost, net of accumulated depreciation and accumulated impairment losses. Cost for repair and maintenance are recognized in profit or loss as incurred.

Each Item of property, plant and equipment with a cost that is significant in relation to the total cost of the item is depreciated over its useful life. Sequana recognizes the depreciation charge in profit or loss unless it is included in the carrying amount of another asset. At least annually, the Group reviews depreciation method, useful life on an asset and residual value, and if appropriate adjusts prospectively.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, as follows:

Asset class	Depreciation method	Useful life
Laboratory	Straight-line	5 – 10 years
IT	Straight line	3 – 10 years
RD Tools	Straight-line	10 years

An item of property, plant and equipment and any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on de-recognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the statement of profit or loss when the asset is derecognised.

6.5 Share capital

The share capital is represented by 6,746,244 preferred shares of nominal CHF 0.10 per share and 3'283'641 common shares of nominal CHF 0.10 per share, each fully paid-in.

	Shares	Nominal value in CHF	Share capital in CHF	Share capital in EUR
1 January 2015	4,576,184	1.00	4,576,184.00	3,806,033.19
Capital increase of preference shares	620,715	1.00	620,715.00	570,824.90
Capital increase through the exercise of options	36,900	1.00	36,900.00	33,934.15
31 December 2015	5,233,799	1.00	5,233,799.00	4,410,792.24
Capital increase of preference shares	780,432	1.00	780,432.00	728,014.93
Capital increase through the exercise of options	75,825	1.00	75,825.00	70,732.28
Capital reduction (reduction in nominal value)	6,090,056	(0.90)	(5,481,050.40)	(4,619,163.75)
Capital increase of preference shares	2,890,211	0.10	289,021.10	269,609.24
31 December 2016	8,980,267	0.10	898,026.70	859,984.93
Capital increase of preference shares	1,049,618	0.10	104,961.80	94,592.30
31 December 2017	10,029,885	0.10	1,002,988.50	954,577.23

The reduction of the nominal value from CHF 1 per share to CHF 0.10 per share has been used to off-set with the available tax losses.

	Common shares	Preference A shares	Preference B shares	Preference C shares	Preference D shares	Preference E shares	Total
1 January 2015	233,123	545,851	2,211,003	1,586,207			4,576,184
Capital increase of preference shares.....				620,715			620,715
Capital increase through the exercise of options ..	36,900						36,900
31 December 2015	270,023	545,851	2,211,003	2,206,922	—	—	5,233,799
Capital increase through the exercise of options ..	75,825						75,825
Capital increase of preference shares.....	2,937,793	(2,169)	(34,341)	(11,072)	780,432		3,670,643
31 December 2016	3,283,641	543,682	2,176,662	2,195,850	780,432	—	8,980,267
Capital increase of preference shares.....			(4,774)	(469,913)	(574,931)	2,099,236	1,049,618
31 December 2017	3,283,641	543,682	2,171,888	1,725,937	205,501	2,099,236	10,029,885

The share capital of the Company is EUR 954,577.23 (CHF 1,002,988.50). It is divided into 543,682 registered preferred A-shares, 2,171,888 registered preferred B-shares, 1,725,937 registered preferred C-shares, 205,501 registered preferred D-shares, 2,099,236 registered preferred E-shares and 3,283,641 registered common shares of EUR 0.095 (CHF 0.10) nominal value each. The share capital is fully paid-in.

The preference shares are not redeemable and there is no mandatory dividend attached to the preference shares. Each common and preference share shall entitle one vote.

In the event of (each a “Liquidity Event”)

- a) voluntary or involuntary liquidation, dissolution, winding up or bankruptcy of the Company;
- b) any sale, lease, transfer license or other disposition of all or substantially all of the Company’s assets;
- c) any transformation of the Company, including separation and merger of the Company, except when the shareholders will hold more than 50% of the surviving/acquiring company and their rights provided for hereunder are maintained;
- d) a subscription of shares in the frame-work of an initial public offering with a fully diluted capitalization of less than EUR 127.5 million (CHF 150 million) and/or gross proceeds to the Company of less than EUR 25.5 million (CHF 30 million),

the liquidation, sale and transformation proceeds shall be distributed as follows:

- a) shareholder of preferred E-shares shall each receive an amount equal to three times the issue price paid for the preferred E-shares at the time of subscription, then:
- b) shareholders of preferred D-shares shall each receive an amount equal to the issue price paid for the preferred D-shares at the time of subscription; then
- c) shareholders of preferred C-shares shall each receive an amount equal to the issue price paid for the preferred C-shares at the time of subscription; then
- d) shareholders of preferred B-Shares shall each receive an amount of half of the issue price paid for the preferred B-shares at the time of subscription; then
- e) shareholders of preferred A-Shares shall receive an amount equal to half of the issue price paid for the preferred A-shares at the time of subscription; thereafter
- f) the proceeds shall be distributed pro-rata to all shareholders of common shares and preferred shares.

Dividends, if any, shall be distributed in accordance with the distribution water-fall set out above until the aggregate distributions to holders of a class of shares is equal the amount they would receive in case of a Liquidity Event. Distributions to the next junior ranking class of shares shall be made only thereafter.

In case of an initial public offering in the sense of a “Liquidity Event” as described above, the liquidation preferences will be achieved through a transfer of shares between the existing shareholders considering the dilution principle as described before and upon an IPO each preference share would be converted into one common share.

Authorised capital as per December 31, 2017: CHF 15,481.70 (154,817 common shares at nominal value of CHF 0.10 per share)

The right of the Board of Directors to increase the share capital has expired by 24 April 2018.

Conditional capital as per December 31, 2017:

Conditional capital available for the exercise of options granted to employees and members of the Board of Directors: CHF 111,443.20 (1,114,432 common shares at nominal value of CHF 0.10 per share)

Conditional capital available for the exercise of option rights, that are granted to lenders of Venture Debt Financing: CHF 14,200.00 (142,000 preference E shares at nominal value of CHF 0.10 per share)

Conditional capital available for the exercise of options granted to investors of strategic importance: CHF 8,317.30 (83,173 preference E shares at nominal value of CHF 0.10 per share)

In 2017, 2016 and 2015 Sequana did not pay any dividends to shareholders.

6.6 Financial debts / Net debt

In 2016, the Group has entered into a loan agreement with Bootstrap Europe S.C.Sp to grant a loan facility of max. CHF 10 million. A first drawdown of CHF 5 million (EUR 4.7 million) was made in 2016. The loan has to be fully repaid within 36 months from the drawdown date, i.e. is due in 2019. However, the Company may repay on any repayment date any outstanding advance. The interest is 12% per annum and is payable over the period as agreed between both parties.

In 2017, the loan agreement was amended and both parties agreed that the second advance of CHF 5 million will be cancelled.

As a security for the fulfilment of the financial obligation, the Company has pledged Intellectual Property as well as the related assets to the venture debt provider Bootstrap Europe S.C.Sp. The Intellectual Property has not been capitalized.

Included below is an analysis of the net debt and the movements for the periods presented

in EUR	31.12.2017	31.12.2016	31.12.2015	01.01.2015
Cash and cash equivalents	1,683,828	797,457	1,426,964	4,090,896
Borrowings – repayable within one year	(2,820,494)	—	—	—
Borrowings – repayable after one year	(1,757,267)	(4,664,179)	—	—
Net debt	(2,893,933)	(3,866,722)	1,426,964	4,090,896

in EUR	Cash and cash equivalents	Borrowings due within 1 year	Borrowings due after 1 year	Total
Net debt as per 1 January 2015	4,090,896		—	4,090,896
Cash flows	(3,149,045)		—	(3,149,045)
Foreign exchange impact (non-cash)	485,113		—	485,113
Net debt as per 31 December 2015	1,426,964		—	1,426,964
Cash flows	(726,190)		(4,545,455)	(5,271,644)
Foreign exchange impact (non-cash)	96,683		(118,725)	(22,042)
Net debt as per 31 December 2016	797,457	—	(4,664,179)	(3,866,722)
Cash flows	1,111,952		—	1,111,952
Accrued interest (non-cash)	—	(320,867)		(320,867)
Transfer (non-cash)	—	(2,746,021)	2,746,021	—
Foreign exchange impact (non-cash)	(225,581)	246,394	160,892	181,704
Net debt as per 31 December 2017	1,683,828	(2,820,494)	(1,757,267)	(2,893,933)

§ Accounting policies

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized cost using the effective interest method. Gains and losses are recognized in profit or loss when the liabilities are derecognized as well as through the effective and interest amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective and interest method. The amortization is included as finance costs in the statement of profit or loss. This category generally applies to interest-bearing loans and borrowings.

6.7 Post-employment benefits

The Group operates different employee benefit plans: Whilst the pension plans in Germany and the US are defined contribution plans, Sequana operates a defined benefit plan in Switzerland. The defined benefit obligation is determined applying the projected unit credit method. Related plan assets are measured at fair value.

Reconciliation of the amount recognised in the balance sheet

	2017	2016	2015
Defined benefit obligation at 31.12.....	2,833,898.22	3,348,778.92	3,264,459.26
Fair value of plan assets at 31.12.....	2,015,315.13	2,380,501.87	2,418,339.16
Deficit at 31.12.....	818,583.09	968,277.05	846,120.10
Net defined benefit liability at 31.12.....	818,583.09	968,277.05	846,120.10

Pension plan in Switzerland

This pension plan is governed by the Swiss Federal Law on Occupational Retirement, Survivor's and Disability Pension Plans (BVG), which states that pension plans are to be managed by independent, separate legal entities. It also stipulates that a pension plan's most senior

governing body (Board of Trustees) must be composed of equal numbers of employee and employer representatives.

Plan participants are insured against the financial consequences of old age, disability and death. The insurance benefits are subject to regulations, with the BVG specifying the minimum benefits that are to be provided. The employer and employees pay contributions to the pension plan. If a plan is underfunded, various measures can be taken, such as a reduction in benefits by altering the conversion rates or increasing current contributions. Under the BVG employer has to fund at least 50% of the potential restructuring.

The Sequana Pension Fund has entered into an agreement with AXA Foundation (AXA). AXA is responsible for the governance of the plan; the Board is composed of an equal number of representatives from the employers and employees chosen from all affiliated companies. AXA has set up investment guidelines, defining in particular the strategic allocation with margins. AXA has reinsured its actuarial risks consisting of demographic risks (primarily life expectancy) and the financial risk (primarily the discount rate, future increases in salaries/wages, and the return on plan assets). In addition, an actuarial report is drawn up annually in accordance with BVG requirements.

Components of defined benefit cost in profit or loss	2017	2016	2015
Current service cost (employer)	177,800.85	193,311.56	169,503.34
Interest expense on defined benefit obligation.....	19,194.48	29,571.87	32,030.27
Interest income on plan assets	(13,421.56)	(21,697.29)	(25,688.25)
Administration cost excl. cost for managing plan assets.....	1,614.83	1,628.31	1,140.33
Defined benefit cost recognised in profit or loss	185,188.61	202,814.45	176,985.68
thereof service cost and administration cost.....	179,415.69	194,939.87	170,643.67
thereof net interest on the net defined benefit liability (asset)	5,772.92	7,874.58	6,342.02

There were no plan amendments nor settlements in the years 2017, 2016 resp. 2015.

Components of defined benefit cost in OCI	2017	2016	2015
Actuarial (gain) / loss on defined benefit obligation	(195,727.90)	(53,945.90)	229,203.60
Return on plan assets excl. interest income	66,502.59	91,363.81	89,113.48
Defined benefit cost recognised in OCI.....	(129,225.31)	37,417.91	318,317.09

Components of actuarial gain/losses on obligations	2017	2016	2015
Actuarial (gain) / loss arising from changes in financial assumptions	—	97,663.25	88,549.75
Actuarial (gain) / loss arising from experience adjustments.....	(195,727.90)	(151,609.14)	140,653.85
Actuarial (gain) / loss on defined benefit obligation	(195,727.90)	(53,945.90)	229,203.60

Reconciliation in net defined benefit liability	2017	2016	2015
Net defined benefit liability at 1.1.....	968,277.05	846,120.10	468,213.91
Defined benefit cost recognised in profit or loss ...	185,188.61	202,814.45	176,985.68
Defined benefit cost recognised in OCI	(129,225.31)	37,417.91	318,317.09
Contributions by the employer	(121,238.49)	(131,435.02)	(166,709.63)
Currency translation adjustments.....	(84,418.77)	13,359.61	49,313.05
Net defined benefit liability at 31.12.....	818,583.09	968,277.05	846,120.10

Reconciliation of defined benefit obligation	2017	2016	2015
Defined benefit obligation at 1.1.	3,348,778.92	3,264,459.26	2,026,709.36
Interest expense on defined benefit obligation.....	19,194.48	29,571.87	32,030.27
Current service cost (employer)	177,800.85	193,311.56	169,503.34
Contributions by plan participants	121,238.49	131,435.02	166,709.63
Benefits (paid) / deposited	(360,128.64)	(266,093.63)	439,258.09
Administration cost (excl. cost for managing plan assets).....	1,614.83	1,628.31	1,140.33
Actuarial (gain) / loss on defined benefit obligation	(195,727.90)	(53,945.90)	229,203.60
Currency translation adjustments.....	(278,872.82)	48,412.42	199,904.63
Defined benefit obligation at 31.12.....	2,833,898.22	3,348,778.92	3,264,459.26

Reconciliation of fair value of plan assets	2017	2016	2015
Fair value of plan assets at 1.1.....	2,380,501.87	2,418,339.16	1,558,495.45
Interest income on plan assets	13,421.56	21,697.29	25,688.25
Contributions by the employer	121,238.49	131,435.02	166,709.63
Contributions by plan participants	121,238.49	131,435.02	166,709.63
Benefits (paid) / deposited	(360,128.64)	(266,093.63)	439,258.09
Return on plan assets excl. interest income	(66,502.59)	(91,363.81)	(89,113.48)
Currency translation adjustments.....	(194,454.05)	35,052.81	150,591.58
Fair value of plan assets at 31.12.....	2,015,315.13	2,380,501.87	2,418,339.16

Asset allocation: 100% of the plan assets are held via the insurance contract with AXA.

Contributions are paid regularly to the pension funds. Furthermore, the investment strategy respects the need to guarantee the liquidity of the plan at all times. The Group does not make use of any assets held by the pension plan.

Maturity profile of defined benefit obligation	2017	2016	2015
Weighted average duration of DBO in years	17.6	17.6	17.6

There are no retired plan participants for the years 2017, 2016 and 2015.

For the reporting year 2018 employer contributions of EUR 122,534 are expected.

The contributions paid to the defined contribution plans amounted to EUR 5,098 (2016: EUR 11,166, 2015: EUR 10,891).

Significant actuarial assumptions:

The present value of the defined benefit obligation is determined annually by independent actuaries using the projected unit credit method.

Actuarial assumptions	2017	2016	2015
Discount rate (DR) at 1.1.....	0.60%	0.90%	1.20%
Discount rate (DR) at 31.12.....	0.60%	0.60%	0.90%
Interest rate on retirement savings capital (IR) at 31.12.....	0.60%	0.90%	1.20%
Future salary increases (SI) at 31.12.....	1.00%	1.00%	1.00%
Future pension increases (PI) at 31.12.....	0.00%	0.00%	0.00%
Future inflation at 31.12.....	1.00%	1.00%	1.00%
Mortality tables.....	BVG2015 GT	BVG2015 GT	BVG2015 GT

Sensitivities of significant actuarial assumptions

The following impacts on the defined benefit obligation would result from changes in actuarial assumptions:

Sensitivity	2017	2016	2015
DBO = Defined benefit obligation, SC = Service cost (employer)			
DBO at 31.12. with DR -0.25%.....	2,939,659.87	3,473,755.60	3,707,321.13
DBO at 31.12. with DR +0.25%.....	2,712,667.61	3,205,522.39	3,421,052.05
DBO at 31.12. with IR -0.25%.....	2,789,709.01	3,296,561.57	3,518,212.25
DBO at 31.12. with IR +0.25%.....	2,890,923.39	3,416,165.11	3,645,858.01
DBO at 31.12. with SI -0.25%.....	2,803,868.73	3,313,293.84	3,536,069.52
DBO at 31.12. with SI +0.25%.....	2,863,751.66	3,384,055.97	3,611,590.95
DBO at 31.12. with life expectancy +1 year.....	2,866,938.43	3,387,821.83	3,615,609.71
DBO at 31.12. with life expectancy -1 year.....	2,800,671.71	3,309,515.86	3,532,037.89
SC of next year with DR +0.25%.....	146,389.41	—	—
SC of next year with IR +0.25%.....	166,613.07	—	—

The sensitivity analysis is based on reasonable possible changes as at the end of the reporting year. Each change in a significant actuarial assumption was analysed separately as part of the test. Interdependencies were not taken into account.

7. Share-based payments

The Company has introduced a stock option plan in 2011 to promote the interests of the Company by providing eligible persons with the opportunity to acquire a share of the Company as an incentive to remain in the service of the Company.

Options granted under this plan enables the employees (and in rare circumstances members of the BoD) to acquire a pre-defined number of shares as listed in the respective grant notice. The Board of Directors determines the maximum number of shares. A plan administrator is a person designated by the BoD and is acting within the guidelines of the stock option plan administers the plan.

The options are granted free of charge and the exercise price is fixed by the plan administrator. The exercise price for all options granted has been aligned with the nominal value of the underlying share. The plan is defined as equity settled plan and therefore the fair value is determined at grant date and will not be re-assessed in subsequent periods. For the expense recognised for this plan refer to the statement of changes in equity.

Number of options granted:

	<u>Options</u>
1 January 2015	338,589
Granted.....	120,500
Exercised.....	(36,900)
31 December 2015	422,189
Granted.....	—
Exercised.....	(75,825)
31 December 2016	346,364
Granted.....	556,000
Forfeited.....	(90,845)
Exercised.....	—
31 December 2017	811,519

The options expire after 10 years from its grant date, i.e. the options that were granted in 2011 will expire in 2021.

§ Accounting policies

The cost of equity-settled transactions is determined by the fair value at the date when the grant is made. That cost is recognised in employee benefits expense, together with a corresponding increase in equity (reserves).

The expense or credit in the statement of profit or loss for a period represents the movement in cumulative expense recognised as at the beginning and end of that period.

8. Other Payables – Accrued liabilities

In EUR	<u>31.12.2017</u>	<u>31.12.2016</u>	<u>31.12.2015</u>
Other Payables	270,486.58	182,466.75	570,712.11
Accrued liabilities:	450,919.43	1,436,049.41	783,383.95
Provision Warranty.....	29,227.02	53,544.78	49,016.00
Third Parties.....	421,692.40	1,382,504.63	734,367.95

Other payables relate mainly to VAT, Social Security and Employee Insurances like e.g. Health and Pension plan.

Accrued liabilities include the warranty provision and other accruals like for holiday pay and other salary related accruals, as well as the liability provisions for clinical studies. In 2016, a provision was included for the severance payments due to the closure of the US entity.

9. Transactions with related parties

Related parties primarily comprise members of Group Management, members of the Board of Directors and significant shareholders.

The compensation for the Group Management is as follows:

EUR	Short-term employee benefits	Post- employment benefits	Share-based compensation	Total compensation
2017 (6 members)	1,039,618	113,003	7,777	1,160,398
2016 (7 members)	1,205,992	157,227	5,693	1,368,913
2015 (5 members)	962,295	122,060	6,797	1,091,153

Apart from 113,000 options (fair value of total EUR 10,000) which were granted to one member of the BoD in 2017, the members of the Board of Directors did not get a compensation in the years 2017, 2016 and 2015.

In 2017, the Company signed a settlement agreement with the wife of the former CEO to acquire his shares/options by offsetting the corresponding loan/other receivable for CHF 226,161 (EUR 211,000) as of December 31, 2016). The former CEO had been granted a total of 90,845 Stock Options of the Company, all options were vested as part of the settlement agreement. In addition, the former CEO has owned a total of 117,569 common shares of the Company. As part of the amendment to the settlement agreement, the Company has agreed with the wife of the former CEO that the purchase price for the stock options and the shares amounts to the amount owed to the Company and that the purchase price will be offset with the amount owed.

10. Principal currency translation rates

Year-end rates used for the consolidated balance sheets at 31 December, to translate the following currencies into EUR, are:

	31.12.2017 per EUR	31.12.2016 per EUR	31.12.2015 per EUR	01.01.2015 per EUR
Swiss Franc (CHF)	1.1702	1.0720	1.0874	1.2024
US Dollar (USD)	1.2008	1.0536	1.0863	n/a

Average rates during the years ended 31 December, used for the consolidated income and cash flow statements, to translate the following currencies into EUR, are:

	2017 per EUR	2016 per EUR	2015 per EUR
Swiss Franc (CHF)	1.1116	1.0901	1.0681
US Dollar (USD)	1.12894	1.1066	n/a

11. Operating lease liabilities

The German subsidiary has entered into various lease contracts to lease cars for its employees which are classified as operating leases. The lease liability as per December 31, 2017 amounts to EUR 29,381 and the operating lease charge in 2017 amounts to EUR 20,109.

12. Breakdown of expenses by nature

In EUR	2017	2016	2015
Personnel costs	4,156,440	5,653,762	5,856,424
Clinical Studies	1,173,775	2,676,461	1,562,885
External consultancy.....	548,468	806,876	997,493
External accounting & legal services.....	522,740	990,425	95,821
Travel & Lodging	478,825	670,640	878,830
Rent & infrastructure expenses	377,787	472,255	470,736
Intellectual Property	177,039	275,985	166,387
Insurance & IT	132,212	379,790	269,490
Marketing	99,538	435,436	316,183
Depreciation and amortization ¹⁾	77,911	80,104	46,539
Other.....	765,246	2,671,564	2,020,578
Total operating expenses	8,509,982	15,113,298	12,681,367

1) The amount relating to amortization is not material, therefore depreciation and amortization are presented in a single position in the table above.

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