

# STATUTORY AUDITOR'S REPORT TO THE GENERAL SHAREHOLDERS' MEETING OF SEQUANA MEDICAL NV ON THE CONSOLIDATED ACCOUNTS FOR THE YEAR ENDED 31 DECEMBER 2022

We present to you our statutory auditor's report in the context of our statutory audit of the consolidated accounts of Sequana Medical NV (the "Company") and its subsidiaries (jointly "the Group"). This report includes our report on the consolidated accounts, as well as the other legal and regulatory requirements. This forms part of an integrated whole and is indivisible.

We have been appointed as statutory auditor by the general meeting *d.d.* 27 May 2021, following the proposal formulated by the board of directors and following the recommendation by the audit committee. Our mandate will expire on the date of the general meeting which will deliberate on the annual accounts for the year ended 31 December 2023. We have performed the statutory audit of the Group's consolidated accounts for 5 consecutive years.

#### Report on the consolidated accounts

## Unqualified opinion

We have performed the statutory audit of the Group's consolidated accounts, which comprise the consolidated statement of financial position as at 31 December 2022, the consolidated income statement, consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies and other explanatory information, and which is characterised by a consolidated statement of financial position total of EUR 26.025.232 and a loss for the year of EUR 30.763.083.

In our opinion, the consolidated accounts give a true and fair view of the Group's net equity and consolidated financial position as at 31 December 2022, and of its consolidated financial performance and its consolidated cash flows for the year then ended, in accordance with International Financial Reporting Standards as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium.

# Basis for unqualified opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs) as applicable in Belgium. Furthermore, we have applied the International Standards on Auditing as approved by the IAASB which are applicable to the year-end and which are not yet approved at the national level. Our responsibilities under those standards are further described in the "Statutory auditor's responsibilities for the audit of the consolidated accounts" section of our report. We have fulfilled our ethical responsibilities in accordance with the ethical requirements that are relevant to our audit of the consolidated accounts in Belgium, including the requirements related to independence.

We have obtained from the board of directors and Company officials the explanations and information necessary for performing our audit.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

PwC Bedrijfsrevisoren BV - PwC Reviseurs d'Entreprises SRL - Financial Assurance Services
Maatschappelijke zetel/Siège social: Culliganlaan 5, B-1831 Diegem
Vestigingseenheid/Unité d'établissement: Generaal Lemanstraat 67, B-2018 Antwerpen
T: +32 (0)3 259 3011, F: +32 (0)3 259 3099, www.pwc.com
BTW/TVA BE 0429.501.944 / RPR Brussel - RPM Bruxelles / ING BE43 3101 3811 9501 - BIC BBRUBEBB /
BELFIUS BE92 0689 0408 8123 - BIC GKCC BEBB



## Material Uncertainty Related to Going Concern

We draw attention to Note 4 in the consolidated accounts, which indicates that the Company is still in its development phase conducting clinical trials in order to achieve regulatory marketing approvals and is subject to various risks and uncertainties, including but not limited to the uncertainty of the development process and the timing of achieving profitability. The Company's ability to continue operations also depends on its ability to raise additional capital and to refinance existing debt, in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows. The impact of macroeconomic conditions and the geopolitical situation in Ukraine on the Company's ability to secure additional financing rounds or undertake capital market transactions remains unclear at this point in time. The Consolidated Statement of Financial Position as at 31 December 2022 shows negative equity in the amount of EUR 2.2 million and ending cash balance of EUR 18.9 million.

These events or conditions as set forth in Note 4 indicate that a material uncertainty exists that may cast significant doubt on the Group's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

# Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the consolidated accounts of the current period. These matters were addressed in the context of our audit of the consolidated accounts as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. In addition to the matter described in the "Material Uncertainty Related to Going Concern" section, we have determined the matter described below to be the key audit matters to be communicated in our report.

Accounting for the Kreos Loan Agreement and related Kreos Subscription Rights Agreement Refer to notes 8.7.2 and 8.8.2 in the Group financial statements

### Description of the Key Audit Matter

Sequana has entered into a secured loan facility agreement with Kreos (the "Kreos Loan Agreement") in the amount of EUR 10 million. In the framework of the Kreos Loan Agreement, the Company and Kreos Capital VII Aggregator SCSp entered into a subscription rights agreement in July 2022 (the "Kreos Subscription Rights Agreement").

Sequana has assessed that the loan facility classifies as a financial debt, to be recognized at fair value at its inception in accordance with IFRS 9 and subsequently accounted for at amortised cost. The amortised cost per fiscal year end 2022 amounts to 8.919 KEUR.

The subscription rights qualify as a financial instrument and are measured at fair value through profit & loss. The fair value amounts to 466 KEUR per financial year end 2022.

This is an area of focus for our audit due to the complexity of the accounting for this transaction.

# How our audit addressed the key audit matter

We verified the contractual basis and documentation of the transaction by reading the board minutes, the Loan Agreement and the Subscription Rights Agreement.

We have discussed with management on the nature of the Kreos Loan Agreement (including the Subscription Rights Agreement) and the substance of the transactions.



We have assessed whether the accounting policies used by the Group are in accordance with IFRS and are appropriate and challenged management on its applied methodology and its compliance with IAS 32 and IFRS 9.

In performing the procedures outlined above, we involved our IFRS specialists for a review over the accounting method as applied by management.

We also considered the appropriateness and sufficiency of related disclosures in the consolidated financial statements.

# Responsibilities of the board of directors for the preparation of the consolidated accounts

The board of directors is responsible for the preparation of consolidated accounts that give a true and fair view in accordance with International Financial Reporting Standards as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium, and for such internal control as the board of directors determine is necessary to enable the preparation of consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated accounts, the board of directors 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 the board of directors either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

# Statutory auditor's responsibilities for the audit of the consolidated accounts

Our objectives are to obtain reasonable assurance about whether the consolidated accounts 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 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 accounts.

In performing our audit, we comply with the legal, regulatory and normative framework applicable to the audit of the consolidated accounts in Belgium. A statutory audit does not provide any assurance as to the Group's future viability nor as to the efficiency or effectiveness of the directors' current or future business management at Group level. Our responsibilities in respect of the use of the going concern basis of accounting by the board of directors are described below.

As part of an audit in accordance with ISAs, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated accounts, 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 the board of directors;
- Conclude on the appropriateness of the board of directors' 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 statutory auditor's report to the related disclosures in the consolidated accounts 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 statutory 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 accounts, including the disclosures, and whether the consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation;
- Obtain sufficient and 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 audit 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.

We also provide the audit committee with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the audit committee, we determine those matters that were of most significance in the audit of the consolidated accounts of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter.

## Other legal and regulatory requirements

# Responsibilities of the board of directors

The board of directors is responsible for the preparation and the content of the directors' report on the consolidated accounts and the other information included in the annual report on the consolidated accounts.

#### Statutory auditor's responsibilities

In the context of our engagement and in accordance with the Belgian standard which is complementary to the International Standards on Auditing (ISAs) as applicable in Belgium, our responsibility is to verify, in all material respects, the directors' report on the consolidated accounts and the other information included in the annual report on the consolidated accounts and to report on these matters.



# Aspects related to the directors' report on the consolidated accounts

In our opinion, after having performed specific procedures in relation to the directors' report on the consolidated accounts, this directors' report is consistent with the consolidated accounts for the year under audit and is prepared in accordance with article 3:32 of the Companies' and Associations' Code.

In the context of our audit of the consolidated accounts, we are also responsible for considering, in particular based on the knowledge acquired resulting from the audit, whether the directors' report on the consolidated accounts is materially misstated or contains information which is inadequately disclosed or otherwise misleading. In light of the procedures we have performed, there are no material misstatements we have to report to you.

## Statement related to independence

- Our registered audit firm and our network did not provide services which are incompatible with the statutory audit of the consolidated accounts, and our registered audit firm remained independent of the Group in the course of our mandate.
- The fees for additional services which are compatible with the statutory audit of the consolidated accounts referred to in article 3:65 of the Companies' and Associations' Code are correctly disclosed and itemized in the notes to the consolidated accounts.

# European Uniform Electronic Format (ESEF)

We have also verified, in accordance with the draft standard on the verification of the compliance of the financial statements with the European Uniform Electronic Format (hereinafter "ESEF"), the compliance of the ESEF format with the regulatory technical standards established by the European Delegate Regulation No. 2019/815 of 17 December 2018 (hereinafter: "Delegated Regulation").

The board of directors is responsible for the preparation, in accordance with ESEF requirements, of the consolidated financial statements in the form of an electronic file in ESEF format (hereinafter "digital consolidated financial statements") included in the annual financial report.

Our responsibility is to obtain sufficient appropriate evidence to conclude that the format and marking language of the digital consolidated financial statements comply in all material respects with the ESEF requirements under the Delegated Regulation.

Since Sequana Medical NV does not prepare digital consolidated financial statements in English we are unable to express an opinion on these. However, we refer to our report on the consolidated financial statements for the year ended 31 December 2022 in Dutch. This contains our opinion on the official Dutch version of the digital consolidated financial statements of Sequana Medical NV which have been prepared in accordance with the ESEF requirements under the Delegated Regulation.



# Other statements

This report is consistent with the additional report to the audit committee referred to in article 11 of the Regulation (EU)  $N^{\circ}$  537/2014.

Antwerp, 24 April 2023

The statutory auditor PwC Reviseurs d'Entreprises SRL/PwC Bedrijfsrevisoren BV Represented by

Peter D'hondt Réviseur d'Entreprises / Bedrijfsrevisor