



FREE TRANSLATION

SEQUANA MEDICAL NV

Statutory auditor's report to the general shareholders' meeting on  
the consolidated accounts for the year ended 31 December 2019

23 April 2020



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STATUTORY AUDITOR'S REPORT TO THE GENERAL SHAREHOLDERS' MEETING OF  
SEQUANA MEDICAL NV ON THE CONSOLIDATED ACCOUNTS FOR THE YEAR ENDED  
31 DECEMBER 2019

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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.* 1 October 2018, following the proposal formulated by the board of directors. Our mandate will expire on the date of the general meeting which will deliberate on the annual accounts for the year ended 31 December 2020. We have performed the statutory audit of the Company's consolidated accounts for 2 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 2019, the consolidated statement of profit or loss and other 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 9.350.142 and a loss for the year of EUR 14.977.445.

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 2019, 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.

***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 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 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 COVID-19 on the Company's ability to secure additional financing rounds or undertake capital market transactions is unclear at this point in time and will remain under review by the executive management and the board of directors. 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 2019 shows a positive equity in the amount of EUR 8,4 million. The Company will continue to require additional financing in the near future and in that respect already successfully raised EUR 19 million in January 2020 in a private equity placement via an accelerated book building offering. Together with existing cash resources, the net proceeds from this private placement are expected to extend the current cash runway of the Company from Q2 2020 into H1 2021. The Company continues to evaluate equity and non-dilutive financing options, including discussions with existing and/or new investors including the refinancing of Bootstrap (of which an amount in principal of EUR 3.17 million is still outstanding). 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 judgment, were of most significance in our audit of the annual accounts of the current period. These matters were addressed in the context of our audit of the annual accounts as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. We have determined there were no other matters to be considered as key audit matters to be communicated in our report, in addition to the matter described in the "Material Uncertainty Related to Going Concern" section.

***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 the financial-reporting framework 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 intend 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 board of directors' current or future business management at Group level.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism 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 director's report and the other information included in the annual report on the consolidated accounts.

#### ***Statutory auditor's responsibilities***

In the context of our mandate 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 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.

***Other statements***

- This report is consistent with the additional report to the audit committee referred to in article 11 of the Regulation (EU) N° 537/2014.

Antwerp, 23 April 2020

The statutory auditor  
PwC Bedrijfsrevisoren BV  
Represented by

Roel Boons  
Réviseur d'Entreprises / Bedrijfsrevisor