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SEQUANA MEDICAL NV

Statutory auditor's report to the general shareholders' meeting  
on the annual accounts for the year ended 31 December 2020

26 April 2021

STATUTORY AUDITOR'S REPORT TO THE GENERAL SHAREHOLDERS' MEETING OF  
SEQUANA MEDICAL NV ON THE ANNUAL ACCOUNTS FOR THE YEAR ENDED  
31 DECEMBER 2020

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We present to you our statutory auditor's report in the context of our statutory audit of the annual accounts of Sequana Medical NV (the "Company"). This report includes our report on the annual accounts, as well as on 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 annual accounts for 3 consecutive years.

**Report on the annual accounts**

***Unqualified opinion***

We have performed the statutory audit of the Company's annual accounts, which comprise the balance sheet as at 31 December 2020, and the profit and loss account for the year then ended, and the notes to the annual accounts, characterised by a balance sheet total of EUR 16.594.940 and a profit and loss account showing a loss for the year of EUR 16.994.508.

In our opinion, the annual accounts give a true and fair view of the Company's net equity and financial position as at 31 December 2020, and of its results for the year then ended, in accordance with the financial-reporting framework 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 "Auditor's responsibilities for the audit of the annual 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 annual 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 VOL-kap 6.19 in the annual accounts, which indicates that the Company is still in its development 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.

These events or conditions as set forth in VOL-kap 6.19 indicate that a material uncertainty exists that may cast significant doubt on the Company'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 annual accounts***

The board of directors is responsible for the preparation of annual 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 determines as necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts, the board of directors is responsible for assessing the Company'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 Company or to cease operations, or has no realistic alternative but to do so.

***Statutory auditor's responsibilities for the audit of the annual accounts***

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

In performing our audit, we comply with the legal, regulatory and normative framework applicable to the audit of the annual accounts in Belgium. A statutory audit does not provide any assurance as to the Company's future viability nor as to the efficiency or effectiveness of the board of directors' current or future business management.

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 annual 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 Company'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 Company'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 annual 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 Company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts, including the disclosures, and whether the annual accounts represent the underlying transactions and events in a manner that achieves fair presentation.

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 annual 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, of the documents required to be deposited by virtue of the legal and regulatory requirements, as well as for the compliance with the legal and regulatory requirements regarding bookkeeping, with the Companies' and Associations' Code and with the Company's articles of association.

### ***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, certain documents required to be deposited by virtue of legal and regulatory requirements, as well as compliance with the articles of association and of certain requirements of the Companies' and Associations' Code and to report on these matters.

### ***Aspects related to the directors' report***

In our opinion, after having performed specific procedures in relation to the directors' report, the directors' report is consistent with the annual accounts for the year under audit, and is prepared in accordance with the articles 3:5 and 3:6 of the Companies' and Associations' Code.

In the context of our audit of the annual 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 the social balance sheet***

The social balance sheet, to be deposited in accordance with article 3:12, §1, 8° of the Companies' and Associations' Code, includes, both in terms of form and content, the information required by virtue of the this Code and does not present any material inconsistencies with the information we have at our disposition in our engagement.

### ***Statement related to independence***

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

***Other statements***

- Without prejudice to formal aspects of minor importance, the accounting records were maintained in accordance with the legal and regulatory requirements applicable in Belgium.
- The appropriation of results proposed to the general meeting complies with the legal provisions and the provisions of the articles of association.
- There are no transactions undertaken or decisions taken in breach of the Company's articles of association or the Companies' and Associations' Code that we have to report to you
- This report is consistent with the additional report to the audit committee referred to in article 11 of the Regulation (EU) N° 537/2014.
- We have evaluated the property effects for the Company resulting from the decision related to the conflict of interest as described in the minutes of the decisions made by the board of directors as of 21 January 2020 and we have no remarks to make in this respect.

Antwerp, 26 April 2021

The statutory auditor  
PwC Bedrijfsrevisoren BV  
Represented by

Peter D'hondt  
Réviseur d'Entreprises / Bedrijfsrevisor