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Biocartis Group NV

Statutory auditor's report to the shareholders' meeting for the year ended 31 December 2021 – Consolidated financial statements

The original text of this report is in Dutch

Statutory auditor's report to the shareholders' meeting of Biocartis Group NV for the year ended 31 December 2021 – Consolidated financial statements

In the context of the statutory audit of the consolidated financial statements of Biocartis Group NV ("the company") and its subsidiaries (jointly "the group"), we hereby submit our statutory audit report. This report includes our report on the consolidated financial statements and the other legal and regulatory requirements. These parts should be considered as integral to the report.

We were appointed in our capacity as statutory auditor by the shareholders' meeting of 14 May 2021, in accordance with the proposal of the board of directors ("bestuursorgaan" / "organe d'administration") issued upon recommendation of the audit committee. Our mandate will expire on the date of the shareholders' meeting deliberating on the financial statements for the year ending 31 December 2023. We have performed the statutory audit of the consolidated financial statements of Biocartis Group NV for 7 consecutive periods.

Report on the consolidated financial statements

Unqualified opinion

We have audited the consolidated financial statements of the group, which comprise the consolidated statement of financial position as at 31 December 2021, the consolidated income statement and consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated cash flow statement for the year then ended, as well as the summary of significant accounting policies and other explanatory notes. The consolidated statement of financial position shows total assets of 142 480 (000) EUR and the consolidated income shows a loss for the year then ended of 71 472 (000) EUR.

In our opinion, the consolidated financial statements give a true and fair view of the group's net equity and financial position as of 31 December 2021 and of its consolidated results and its consolidated cash flow for the year then ended, in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium.

Basis for the unqualified opinion

We conducted our audit in accordance with International Standards on Auditing (ISA), as applicable in Belgium. In addition, we have applied the International Standards on Auditing approved by the IAASB applicable to the current financial year, but not yet approved at national level. Our responsibilities under those standards are further described in the "Responsibilities of the statutory auditor for the audit of the consolidated financial statements" section of our report. We have complied with all ethical requirements relevant to the statutory audit of consolidated financial statements in Belgium, including those regarding independence.

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

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

Key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of our audit of the consolidated financial statements as a whole and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Key audit matters

How our audit addressed the key audit matters

Revenue recognition

Revenue for the year 2021 amounts to 48 269 (000) EUR and includes:

- Product related revenues (40 486 (000) EUR) including various combinations of instruments and cartridges in stand-alone and multiple element sales agreements, operational reagent rental agreements and rental agreements; and
- Collaboration revenues (6 053 (000) EUR) for research and development (R&D) collaboration agreements including simultaneous transactions and multiple element arrangements such as licenses and R&D services which are remunerated via combinations of upfront payments, milestone payments and royalties.

The determination of revenue recognition for some of these contracts is complex and requires significant management judgment to determine the nature of the contractual obligations, identify the performance obligations and allocate the transaction price to the performance obligations in accordance with the transfer of the instruments, cartridges, licenses and/or R&D service activities identified in the contract. Furthermore, revenue transactions may be subject to manual adjustments.

The company's disclosures about revenue are included in part 5, note 1.2.2.15 Revenue recognition and part 5 note 1.2.4 Revenue of the consolidated financial statements.

We considered the appropriateness of the Group's revenue recognition principles in accordance with the applicable IFRS standard.

We obtained an understanding of the underlying processes and preventive and detective internal controls.

We read the relevant agreements to assess whether the company correctly applied the Group's revenue recognition principles and we challenged the reasonableness of the judgements made by management in determining the relevant assumptions utilized in calculating recognized revenue.

We tested a sample of transactions of revenue recognized in the income statement for accuracy and appropriate recognition based on the agreements, recognition principles and managements estimates and judgements.

We inquired with management and read relevant meeting minutes to ensure completeness of the reported collaboration agreements.

We have tested a sample of revenue transactions related to product sales.

We have reviewed the manual entries to revenue for accuracy and validity.

Going concern

In the current period, the group has continued to incur losses that have affected its financial position. The directors of the group need to make a judgment as to whether the group will be able to continue to operate for a period of 12 months after the approval of the current consolidated accounts and assess whether there are material uncertainties related to drafting the consolidated financial statements undergoing concern.

The group's financial position is strongly linked to its revenue and gross margin generation, its access to additional liquidity from current or new investors, the continued availability of its credit lines and its ability to reduce operating expenses and cut back on planned investments in case the prior items are not (timely) realized.

Significant judgments and estimates from management are required in order to predict future cash flows and the group's potential to meet all its commitments over the 12-month period following the approval of the current consolidated accounts.

The company's disclosure in relation to going concern is in part 5, note 1.2.3.1 Critical accounting estimates, assumptions and judgments.

We have regularly interacted with management and the board on the various initiatives around financing and liquidity and have read relevant minutes to assess completeness of the information.

We compared the forecast incorporated in the going concern model with the board approved budget to ensure consistency.

We have critically evaluated the assumptions in the going concern model, by comparing projected evolutions to past performance, assessing the year-to-date results and the past forecasting accuracy of management.

We have tested the arithmetic integrity of the calculations in the going concern model and have performed sensitivities on management's forecast model to understand its robustness against adverse deviations.

We critically assessed the adequacy of the company's disclosures on going concern.

Responsibilities of the board of directors for the preparation of the consolidated financial statements

The board of directors is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with International Financial Reporting Standards (IFRS) 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 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, the board of directors is responsible for assessing the group's ability to continue as a going concern, disclosing, as applicable, matters to be considered for 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 other realistic alternative but to do so.

Responsibilities of the statutory auditor 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 a statutory 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 ISA 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.

During the performance of our audit, we comply with the legal, regulatory and normative framework as applicable to the audit of consolidated financial statements in Belgium. The scope of the audit does not comprise any assurance regarding the future viability of the company nor regarding the efficiency or effectiveness demonstrated by the board of directors in the way that the company's business has been conducted or will be conducted.

As part of an audit in accordance with ISA, 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 an 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 use of the going concern basis of accounting by the board of directors 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 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 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 financial statements, 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 and 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, amongst 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 we communicate with them about all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated to the audit committee, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our report unless law or regulation precludes any 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 financial statements and other matters disclosed in the annual report on the consolidated financial statements.

Responsibilities of the statutory auditor

As part of our mandate and in accordance with the Belgian standard complementary to the International Standards on Auditing (ISA) as applicable in Belgium, our responsibility is to verify, in all material respects, the director's report on the consolidated financial statements and other matters disclosed in the annual report on the consolidated financial statements, as well as to report on these matters.

Aspects regarding the directors' report on the consolidated financial statements

In our opinion, after performing the specific procedures on the directors' report on the consolidated financial statements, this report is consistent with the consolidated financial statements for that same year and has been established in accordance with the requirements of article 3:32 of the Code of companies and associations.

In the context of our statutory audit of the consolidated financial statements we are responsible to consider, in particular based on information that we became aware of during the audit, if the directors' report on the consolidated financial statements and other information disclosed in the annual report on the consolidated financial statements, are free of material misstatements, either by information that is incorrectly stated or otherwise misleading. In the context of the procedures performed, we are not aware of such a material misstatement.

Statements regarding independence

- Our audit firm and our network have not performed any prohibited services and our audit firm has remained independent from the group during the performance of our mandate.
- The fees for the additional non-audit services compatible with the statutory audit, as defined in article 3:65 of the Code of companies and associations, have been properly disclosed and disaggregated in the notes to the consolidated financial statements.

Single European Electronic Format (ESEF)

In accordance with the draft standard on the audit of the compliance of the financial statements with the Single European Electronic Format ("ESEF"), we have also performed the audit of the compliance of the ESEF format and of the tagging with the technical regulatory standards as defined by the European Delegated Regulation No. 2019/815 of 17 December 2018 ("Delegated Regulation").

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

Our responsibility is to obtain sufficient and appropriate evidence to conclude that the format and the tagging of the digital consolidated financial statements comply, in all material respects, with the ESEF requirements as stipulated by the Delegated Regulation.

Based on our work, in our opinion, the format and the tagging of information in the English version of the digital consolidated financial statements included in the annual financial report of Biocartis Group NV as of 31 December 2021 are, in all material respects, prepared in accordance with the ESEF requirements as stipulated by the Delegated Regulation.

Other statements

This report is consistent with our additional report to the audit committee referred to in article 11 of Regulation (EU) No 537/2014.

Signed at Zaventem.

The statutory auditor



Deloitte Bedrijfsrevisoren/Réviseurs d'Entreprises BV/SRL

Represented by Nico Houthaeve

