



## Biotalys NV

Statutory auditor's report to the shareholders' meeting for the year ended  
31 December 2023 - Annual accounts

## Statutory auditor's report to the shareholders' meeting of Biotalys NV/SA for the year ended 31 December 2023 - Annual accounts

In the context of the statutory audit of the annual accounts of Biotalys NV (the "company"), we hereby submit our statutory audit report. This report includes our report on the annual accounts 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 15 April 2022, in accordance with the proposal of the board of directors ("bestuursorgaan" / "organe d'administration"). Our mandate will expire on the date of the shareholders' meeting deliberating on the annual accounts for the year ending 31 December 2024. We have performed the statutory audit of the annual accounts of Biotalys NV for 11 consecutive periods.

### Report on the annual accounts

#### Unqualified opinion

We have audited the annual accounts of the company, which comprises the balance sheet as at 31 December 2023 and the income statement for the period ended at that date, as well as the explanatory notes. The annual accounts show total assets of 31 720 (000) EUR and the income statement shows a loss for the year ended of 20 015 (000) EUR.

In our opinion, the annual accounts give a true and fair view of the company's net equity and financial position as of 31 December 2023 and of its results for the year then ended, in accordance with the financial reporting framework 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 annual accounts" section of our report. We have complied with all ethical requirements relevant to the statutory audit of the annual accounts 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 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.

#### Key audit matter description

The 2023 statement of profit or loss shows a loss for the year ended 31 December 2023 of 20 015 (000) EUR, and the balance sheet includes a loss carried forward of 41 586 (000) EUR.

The Directors of the company are required to make a rigorous assessment of whether the company will remain a going concern for a period of at least twelve months from the date of approval of the financial statements and assess whether there are any material uncertainties in relation to the going concern basis of preparation.

Management has prepared detailed budgets and cash flow forecasts for the years 2024 and 2025. These forecasts reflect the strategy of the company and include significant expenses and cash outflows in relation to the ongoing research and development activities.

While mitigating actions are not forecasted to be required to support the going concern basis, management and the directors have demonstrated the ability to make organizational changes and cost saving measures to concentrate resources on core research and development capabilities in the event of unforeseen cash constraints.

Management acknowledges that uncertainty remains in these cash flow forecasts (such as delays in development or regulatory approval) but believes that the cash position of the company at year-end 2023 is sufficient to cover the cash needs of the company for at least the 12-month period following the approval of the 2023 annual report.

Significant judgments and estimates from management are required in order to predict future cash flows and the company's potential to meet all its commitments over the 12-month period following the approval of the current annual accounts. Therefore, management's assessment of going concern assumption to apply in the preparation of the current annual accounts are subject to significant judgments and estimates.

The company's disclosure in relation to going concern is in annex F-cap 6.19 of the annual accounts.

### **How our audit addressed the key audit matter**

We performed extensive inquiries of management and the board on the company's assessment of going concern assumption for the purpose of preparation of the annual accounts for the year ended 31 December 2023. These inquiries entailed probing questions in order to: a) challenge the assumptions used in the forecasted cash runway, b) understand updates on regulatory approvals of products, and c) assess the likelihood of success in initiatives around future financing pursued by the company.

We have read relevant meeting minutes to assess completeness of the information and have further corroborated the results of our inquiries through ensuring consistency with publicly available information such as press coverage, analysts' reports, amongst others.

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

We tested the mathematical integrity of the calculations in the going concern model. In addition, we audited the cash and cash equivalents position as of the financial year end utilized in the going concern model.

We evaluated the reasonableness of the company's forecasted operating expenses, including the relevant cost saving measures included therein, by obtaining an understanding of the company's operations and strategy, inquiring about the company's research and development activities and comparing the forecasted operating expenses to historical operating expenses.

We assessed management's ability to forecast operating expenses by comparing prior year forecasts to actual cash outflows. In addition, we assessed management's ability to timely implement cost saving measures through retrospective review of similar measures being implemented in the past.

We inspected the current contractual covenants embedded in the company's financing, procurement and grant arrangements to assess reasonability of management's assessment of the outcome of any breach and its impact on the cash runway and therefore on the going concern assumption.

We assessed the adequacy and understandability of the annual account's disclosure related to the going concern assessment. We further tested the design and implementation of relevant internal control around management's disclosure process on going concern matters.

## **Responsibilities of the board of directors for the preparation of the annual accounts**

The board of directors is responsible for the preparation and fair presentation of the annual accounts in accordance with the financial reporting framework applicable in Belgium and for such internal control as the board of directors determines is necessary to enable the preparation of the 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 to be considered for 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.

## **Responsibilities of the statutory auditor 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 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 annual accounts.

During the performance of our audit, we comply with the legal, regulatory and normative framework as applicable to the audit of annual accounts 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 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 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 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 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 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, 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, 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 annual accounts 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 annual accounts, for the documents to be filed according to the legal and regulatory requirements, for maintaining the company's accounting records in compliance with the legal and regulatory requirements applicable in Belgium, as well as for the company's compliance with the Code of companies and associations and the company's articles of association.

### 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 directors' report on the annual accounts, those documents to be filed according to the legal and regulatory requirements, and compliance with certain obligations referred to in the Code of companies and associations and the articles of association, as well as to report on these matters.

### Aspects regarding the directors' report

In our opinion, after performing the specific procedures on the directors' report on the annual accounts, the directors' report on the annual accounts is consistent with the annual accounts for that same year and has been established in accordance with the requirements of articles 3:5 and 3:6 of the Code of companies and associations.

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

### Statement on the social balance sheet

The social balance sheet, to be filed at the National Bank of Belgium in accordance with article 3:12, § 1, 8° of the Code of companies and associations, includes, both in form and in substance, all of the information required by this Code, including those relating to wages and training, and is free from any material inconsistencies with the information available to us in the context of our mission.

### Statements regarding independence

Our audit firm and our network have not performed any prohibited services and our audit firm has remained independent from the company during the performance of our mandate.

## Other statements

- Without prejudice to certain formal aspects of minor importance, the accounting records are maintained in accordance with the legal and regulatory requirements applicable in Belgium.
- The appropriation of results proposed to the general meeting is in accordance with the relevant legal and regulatory requirements.
- We do not have to report any transactions undertaken or decisions taken which may be in violation of the company's articles of association or the Code of companies and associations. This report is consistent with our additional report to the audit committee referred to in article 11 of Regulation (EU) N°537/2014.
- The board of directors has taken the decisions described in the directors' report, with financial consequences as a result. In accordance with article 7:96 of the Code of companies and associations, the board of directors has informed the shareholders about these decisions.

We have assessed the financial consequences for the company relating to the decisions taken in respect of the conflict of interest as described in the directors' report and we have nothing to report.

Signed at Zaventem.

## The statutory auditor

**Digitally signed by**  
Pieter-Jan Van Durme  
Ondertekend door: Pieter-Jan Van Durme (Signature)  
Ondertekentijd: 18-Mar-2024 | 16:46 CET

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**Deloitte Bedrijfsrevisoren/Réviseurs d'Entreprises BV/SRL**

Represented by Pieter-Jan Van Durme

# Deloitte.

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