



# CBio A/S

Transformervej 8, 2860 Soeborg CVR no. 40 21 66 42

# **Annual report for 2021**

This annual report has been adopted at the annual general meeting on 24.02.22

Ulrik Cordes

Chairman of the meeting



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# The company

CBio A/S
Transformervej 8
2860 Soeborg

CVR no.: 40 21 66 42

Financial year: 01.01 - 31.12

# **Executive Board**

CEO Ulrik Cordes

# **Board of Directors**

Else Beth Trautner Andreea loana Kaiser Christian Henri Leroy Karin Cecilia Hultén CEO Ulrik Cordes

#### **Auditors**

Beierholm

Statsautoriseret Revisionspartnerselskab



CBio A/S

# Statement by the Executive Board and Board of Directors on the annual report

We have on this day presented the annual report for the financial year 01.01.21 - 31.12.21 for CBio A/S.

The annual report is presented in accordance with the Danish Financial Statements Act (Årsregnskabsloven).

In our opinion, the financial statements give a true and fair view of the company's assets, liabilities and financial position as at 31.12.21 and of the results of the company's activities for the financial year 01.01.21 - 31.12.21.

We believe that the management's review includes a fair review of the matters dealt with in the management's review.

The annual report is submitted for adoption by the general meeting.

Soeborg, February 24, 2022

#### **Executive Board**

Ulrik Cordes CEO

#### **Board of Directors**

Else Beth Trautner

Chairman

Andreea loana Kaiser

Christian Henri Leroy

Karin Cecilia Hultén

Ulrik Cordes

CEO



#### To the Shareholders of CBio A/S

# Opinion

We have audited the financial statements of CBio A/S for the financial year 01.01.21 - 31.12.21, which comprise the income statement, balance sheet, statement of changes in equity and notes to the financial statements, including a summary of significant accounting policies. The financial statements are prepared in accordance with the Danish Financial Statements Act (Årsregnskabsloven).

In our opinion the financial statements give a true and fair view of the company's assets, liabilities and financial position at 31.12.21 and of the results of the company's operations for the financial year 01.01.21 - 31.12.21 in accordance with the Danish Financial Statements Act (Årsregnskabsloven).

# **Basis for Opinion**

We conducted our audit in accordance with International Standards on Auditing and the additional requirements applicable in Denmark. Our responsibilities under those standards and requirements are further described in the "Auditor's responsibilities for the audit of the financial statements" section of our report. We are independent of the company in accordance with the International Ethics Standards Board for Accountants' International Code of Ethics for Professional Accountants (IESBA Code) and the additional ethical requirements applicable in Denmark, and we have fulfilled our other ethical responsibilities in accordance with these requirements and the IESBA Code. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

# Statement regarding the management's review

Management is responsible for management's review.

Our opinion on the financial statements does not cover management's review, and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read management's review and, in doing so, consider whether management's review is materially inconsistent with the financial statements or our knowledge obtained during the audit, or otherwise appears to be materially misstated.

Moreover, it is our responsibility to consider whether management's review provides the information required under the Danish Financial Statements Act.



Based on the work we have performed, we conclude that management's review is in accordance with the financial statements and has been prepared in accordance with the requirements of the Danish Financial Statements Acts. We did not identify any material misstatement of management's review.

## Management's responsibility for the financial statements

The Management is responsible for the preparation of financial statements that give a true and fair view in accordance with the Danish Financial Statements Act. Furthermore the Management is responsible for the internal control as the Management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management 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 in preparing the financial statements unless management either intends to liquidate the company or to cease operations, or has no realistic alternative but to do so.

#### Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements 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 International Standards on Auditing and the additional requirements applicable in Denmark 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 financial statements.

As part of an audit conducted in accordance with International Standards on Auditing and the additional requirements applicable in Denmark, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

• Identify and assess the risks of material misstatement of the 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 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 management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting in preparing the financial statements 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 auditor's report to the related disclosures in the 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 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 contents of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that gives a true and fair view.

We communicate with those charged with governance 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.

Soeborg, Copenhagen, February 24, 2022

#### Beierholm

Statsautoriseret Revisionspartnerselskab CVR no. 32 89 54 68

Anders Ladegaard State Authorized Public Accountant MNE-no. mne18830



# **Primary activities**

The company's purpose is to conduct research, development and manufacturing of cell-based therapies for its partners and for own-sponsored programs for the benefit of cancer and other seriously ill patients.

# Development in activities and financial affairs

The income statement for the period 01.01.21 - 31.12.21 shows a profit/loss of DKK-8,556,249. The balance sheet shows equity of DKK 8,265,410.



#### Letter from the CEO

2021 has been another remarkable year for Cbio in our quest towards enabling cancer cure. With a strong and enthusiastic team in place, a state-of-the-art facility, and a clear focus, we have further advanced our lead candidate, novoleucel, for Tumor Infiltrating Lymphocyte (TIL) therapy creating a new hope for seriously ill cancer patients where all other therapeutic interventions have been exhausted.

Building upon the strong foundation laid out in 2020

From the beginning of 2021, the key focus was to qualify and validate our facility and cleanroom infrastructure to comply with the authority requirements for producing cell-based therapies for human clinical use. The team worked diligently in setting up the monitoring, quality controls, and testing regimens and generated appropriate quality management systems to support the processes. One of the key achievements included a successful meeting with the Danish Medical Agency to secure alignment with their demands.

A scalable, robust, and commercially viable TIL manufacturing process

With the facility and processes in place, we reached a design freeze of a clearly improved novoleucel TIL manufacturing process in the autumn of 2021. One of the key obstacles in cell-based therapies is the long and highly complex manufacturing process. Overall, we managed to decrease processing time from 49 to just 20 days, reduced the number of manual steps by almost 90%, and improved pan-tumor robustness, with production yield reaching close to 100%. We stand with a scalable and commercially viable novoleucel TIL product that is ready for the last verification and validation steps before the clinical trials.

# Unleashing a potential breakthrough therapy

With novoleucel, we add a number of carefully selected checkpoint inhibitors and stimulators to the tumor fragments in the first step of the TIL production protocol. 2021 was when we further characterized and shed light on the key discoveries and started to realize how powerful the technology is.

One of the biggest surprises was that we could start with much less starting material as opposed to IL-2 only TIL products. Where 1-2 grams of tumor material is typically required for making a therapeutic TIL product, novoleucel only requires 2-5 milligrams. This opens the door for a minimally invasive TIL therapy, where the starting material can be acquired from the cancer patients by using fine needle aspirate biopsies instead of surgery. As many patients have inoperable tumors or are too ill to undergo surgery, novoleucel can potentially be offered to many more patients than standard TIL therapy.



In addition, on a more technical level, we see that the novoleucel TIL product contains T-cells that, in popular wording is, simply more 'fit' than the IL-2 only TIL products. They have a higher in-vitro killing capacity, are 'younger' and might have a much broader tumor recognition pattern leaving much fewer opportunities for the cancer cells to escape. These preclinical findings are very exciting and are boding well for a possible improved clinical outcome bringing TIL therapy to new heights.

#### Protecting our inventions

2021 was also when we submitted the first patent application for novoleucel, I with an early priority dating back to December 2019. Protecting our core inventions and limiting workarounds is a cornerstone for Cbio putting us in a unique position as a clear technology leader in the attractive TIL therapy market.

#### Partnering for success

To stay at the forefront of scientific discoveries, Cbio aims to expand our network of key collaboration partners that share the same interest in fighting cancer. In 2021, we established a collaboration with Professor Krister Wennerberg's group at the University of Copenhagen. Krister is a pioneer in high-throughput functional screening for cancer compounds that possibly can be applied to TIL therapy. Also, we established a collaboration with Odense University Hospital headed by Professor Niels Marcussen to develop and pre-clinically optimize TIL products for colorectal, kidney, ovarian and pancreatic cancer patients. These are all indications where standard TIL therapy has had limited clinical success, but we want to explore whether novoleucel could potentially have a play.

#### Annual report and financing

We constantly strive to deliver on our promises and finish the year as expected on the financial side. As we move forward, our ambition is to complete the preclinical work, enabling us to start clinical studies for novoleucel. Starting the clinical trial will be another significant step in Cbio's history and significantly increase the required investments. Therefore, we aim to attract additional funding that eventually will enable us to test novoleucel's clinical potential getting us another step closer to our mission of enabling cancer cure.



Support from stakeholders

With a state-of-the-art factory for cell-based therapies, a pharmaceutical quality system, a world-class TIL manufacturing process, groundbreaking preclinical data, and a growing IP portfolio, Cbio has reached very far in what is only three years since its inception. I want to personally express my gratitude to all the great people who have supported us in making this happen. It accounts for our dedicated and enthusiastic team, investors, board of directors, collaborators, financial partners, and other stakeholders.

Thank you for all your support.

#### **Ulrik Cordes**

Founder, CEO



	2021	2020
	DKK	DKF
Gross loss	-1,913,052	-1,813,621
Staff costs	-7,609,434	-3,077,064
Loss before depreciation, amortisation, write-downs and impairment losses	-9,522,486	-4,890,685
Depreciation and impairments losses of property, plant and equipment	-1,636,187	-250,803
Operating loss	-11,158,673	-5,141,488
Financial income Financial expenses	1,151 -400,534	21,146 -67,288
Loss before tax	-11,558,056	-5,187,630
Tax on loss for the year	3,001,807	1,286,239
Loss for the year	-8,556,249	-3,901,391
Proposed appropriation account		
Retained earnings	-8,556,249	-3,901,391
Total	-8,556,249	-3,901,391



# **ASSETS**

	31.12.21	31.12.20
	DKK	DKK
Leasehold improvements	3,237,319	4,519,724
Other fixtures and fittings, tools and equipment	3,684,786	537,977
Total property, plant and equipment	6,922,105	5,057,701
Deposits	854,777	462,863
Total investments	854,777	462,863
Total non-current assets	7,776,882	5,520,564
Income tax receivable	4,357,131	1,355,324
Other receivables	1,484,313	2,389,684
Prepayments	411,757	305,616
Total receivables	6,253,201	4,050,624
Cash	4,745,074	6,305,649
Total current assets	10,998,275	10,356,273
Total assets	18,775,157	15,876,837



# **EQUITY AND LIABILITIES**

	Total equity and liabilities	18,775,157	15,876,837
	Total payables	10,509,747	9,055,178
	Total short-term payables	2,780,853	3,105,178
	Deferred income	371,602	537,778
	Other payables	1,506,294	1,146,755
	Trade payables	570,614	1,401,392
	Payables to other credit institutions	345	19,253
3	Short-term part of long-term payables	331,998	0
	Total long-term payables	7,728,894	5,950,000
3	Lease commitments	1,419,390	0
3	Subordinate loan capital	6,309,504	5,950,000
	Total equity	8,265,410	6,821,659
	Retained earnings	6,681,613	5,502,818
	Share capital	1,583,797	1,318,841
е			
е		DKK	DKK
		31.12.21	31.12.20

<sup>4</sup> Contingent liabilities



# Statement of changes in equity

Figures in DKK	Share capital	Retained earnings	Total equity
Statement of changes in equity for 01.01.21 - 31.12.21			
Balance as at 01.01.21 Capital increase Net profit/loss for the year	1,318,841 264,956 0	5,502,818 9,735,044 -8,556,249	6,821,659 10,000,000 -8,556,249
Balance as at 31.12.21	1,583,797	6,681,613	8,265,410



	2021 DKK	2020 DKK
1. Staff costs		
Wages and salaries Other social security costs Other staff costs	7,220,349 80,501 308,584	2,912,581 9,025 155,458
Total	7,609,434	3,077,064
Average number of employees during the year	11	4

# 2. Property, plant and equipment

Figures in DKK	Leasehold improvements	Other fixtures and fittings, tools and equipment
Cost as at 01.01.21	4,765,961	542,543
Additions during the year	707,131	2,793,460
Transfers during the year to/from other items	-1,294,706	1,294,706
Cost as at 31.12.21	4,178,386	4,630,709
Depreciation and impairment losses as at 01.01.21	-246,237	-4,566
Depreciation during the year	-761,722	-874,465
Transfers during the year to/from other items	66,892	-66,892
Depreciation and impairment losses as at 31.12.21	-941,067	-945,923
Carrying amount as at 31.12.21	3,237,319	3,684,786
Carrying amount of assets held under finance leases		
as at 31.12.21	0	1,705,481



# 3. Long-term payables

Figures in DKK		Outstanding debt after 5 years	Total payables at 31.12.21	Total payables at 31.12.20
Subordinate loan capital Lease commitments	0 331,998	0 62,334	6,309,504 1,751,388	5,950,000 0
Total	331,998	62,334	8,060,892	5,950,000

## 4. Contingent liabilities

#### Lease commitments

The company has concluded lease agreements with terms to maturity of 36 - 60 months and average lease payments of t.DKK 18, a total of t.DKK 831. The company has a residual obligation of t.DKK 486.

The company has concluded lease agreements for rental of premises. The company has a rent obligation of t.DKK 3.151.

# Other contingent liabilities

The company is taxed jointly with the other Danish companies in the group and is liable for income taxes on a pro rata basis and must comply with any obligations to withhold tax at source on interest, royalties and dividends for the jointly taxed companies. The maximum liability totals an amount corresponding to the share of the capital in the company which is owned directly or indirectly by the ultimate parent. The maximum liability is stated in the parent company's annual repport for 2021. The liability also includes any subsequent corrections to the calculated tax liability as a consequence of changes made to the jointly taxable income etc.



# 5. Accounting policies

#### **GENERAL**

The annual report is presented in accordance with the provisions of the Danish Financial Statements Act (*Årsregnskabsloven*) for enterprises in reporting class B with application of provisions for a higher reporting class.

The accounting policies have been applied consistently with previous years.

#### Basis of recognition and measurement

Income is recognised in the income statement as earned, including value adjustments of financial assets and liabilities. All expenses, including depreciation, amortisation, impairment losses and write-downs, are also recognised in the income statement.

Assets are recognised in the balance sheet when it is probable that future economic benefits will flow to the company, and the value of such assets can be measured reliably. Liabilities are recognised in the balance sheet when it is probable that future economic benefits will flow from the company, and the value of such liabilities can be measured reliably. On initial recognition, assets and liabilities are measured at cost. Subsequently, assets and liabilities are measured as described for each item below.

On recognition and measurement, account is taken of foreseeable losses and risks arising before the date at which the annual report is presented and proving or disproving matters arising on or before the balance sheet date.

#### **LEASES**

Leases relating to assets where the company has substantially all the risks and benefits incidental to the ownership of the asset (finance leases) are recognised in the balance sheet. On initial recognition, assets held under finance leases and related lease commitments are measured at the lower of the fair value of the leased asset and the present value of future lease payments. Subsequently, assets held under finance leases are treated like other similar assets.

Lease commitments relating to assets held under finance leases are recognised in the balance sheet as payables. Subsequent to initial recognition, lease commitments are measured at amortised cost according to which the interest element of the lease payment is recognised in the income statement over the lease term.

Lease payments relating to operating leases are recognised in the income statement on a straight-line basis over the lease term.



#### **GRANTS**

Grants are recognised when there is reasonable certainty that the grant conditions have been met and that the grant will be received.

Grants to cover expenses incurred are recognised on a proportionate basis in the income statement over the period in which the expenses eligible for grants are expensed. Grants are recognised under other operating income.

#### INCOME STATEMENT

#### **Gross loss**

Gross loss comprises revenue and other operating income and other external expenses.

#### Revenue

Income from the sale of services is recognised in the income statement as delivery takes place (delivery method). Revenue is measured at the selling value of the agreed consideration exclusive of VAT and other taxes collected on behalf of third parties and less discounts.

#### Other operating income

Other operating income comprises income of a secondary nature in relation to the enterprise's activities, including rental income, negative goodwill and gains on the sale of intangible assets and property, plant and equipment.

#### Other external expenses

Other external expenses comprise costs relating to distribution, sales and advertising and administration, premises and bad debts to the extent that these do not exceed normal writedowns.

#### Staff costs

Staff costs comprise wages and salaries as well as other staff-related costs.



#### Depreciation and impairment losses

The depreciation of property, plant and equipment aim at systematic depreciation over the expected useful lives of the assets. Assets are depreciated according to the straight-line method based on the following expected useful lives and residual values:

	Useful	Residual
	lives,	value
	years	DKK
Leasehold improvements	6	0
Other plant, fixtures and fittings, tools and equipment	6	0

The basis of depreciation is the cost of the asset less the expected residual value at the end of the useful life. Moreover, the basis of depreciation is reduced by any impairment losses. The useful life and residual value are determined when the asset is ready for use and reassessed annually.

Property, plant and equipment are impaired in accordance with the accounting policies referred to in the 'Impairment losses on fixed assets' section.

#### Other net financials

Interest income and interest expenses, the interest element of finance lease payments etc. are recognised in other net financials.

# Tax on profit/loss for the year

The current and deferred tax for the year is recognised in the income statement as tax on the profit/loss for the year with the portion attributable to the profit/loss for the year, and directly in equity with the portion attributable to amounts recognised directly in equity.

The company is jointly taxed with Danish consolidated enterprises.

In connection with the settlement of joint taxation contributions, the current Danish income tax is allocated between the jointly taxed enterprises in proportion to their taxable incomes. This means that enterprises with a tax loss receive joint taxation contributions from enterprises which have been able to use this loss to reduce their own taxable profit.



#### BALANCE SHEET

# Property, plant and equipment

Property, plant and equipment comprise leasehold improvements as well as other fixtures and fittings, tools and equipment.

Property, plant and equipment are measured in the balance sheet at cost less accumulated depreciation and impairment losses.

Cost comprises the purchase price and expenses resulting directly from the purchase until the asset is ready for use. Interest on loans arranged to finance production is not included in the cost.

Property, plant and equipment are depreciated using the straight-line method based on useful lives and residual values, which are stated in the 'Depreciation and impairment losses' section.

Gains and losses on the disposal of property, plant and equipment are determined as the difference between the selling price, if any, less selling costs and the carrying amount at the date of disposal less any costs of disposal.

#### Impairment losses on fixed assets

The carrying amount of fixed assets which are not measured at fair value is assessed annually for indications of impairment over and above what is reflected in depreciation.

If the company's realised return on an asset or a group of assets is lower than expected, this is considered an indication of impairment.

If there are indications of impairment, an impairment test is conducted of individual assets or groups of assets.

The assets or groups of assets are impaired to the lower of recoverable amount and carrying amount.

The higher of net selling price and value in use is used as the recoverable amount. The value in use is determined as the present value of expected net cash flows from the use of the asset or group of assets as well as expected net cash flows from the sale of the asset or group of assets after the expiry of their useful lives.

Impairment losses are reversed when the reasons for the impairment no longer exist.



#### Receivables

Receivables are measured at amortised cost, which usually corresponds to the nominal value, less write-downs for bad debts.

Write-downs for bad debts are determined based on an individual assessment of each receivable if there is no objective evidence of individual impairment of a receivable.

Deposits recognised under assets comprise deposits paid to the lessor under leases entered into by the company.

#### **Prepayments**

Prepayments recognised under assets comprise costs incurred in respect of subsequent financial years.

#### Cash

Cash includes deposits in bank accounts as well as operating cash.

#### Current and deferred tax

Current tax payable and receivable is recognised in the balance sheet as tax computed on the basis of the taxable income for the year, adjusted for tax paid on account.

Joint taxation contributions payable and receivable are recognised as income tax under receivables or payables in the balance sheet.

Deferred tax liabilities and tax assets are recognised on the basis of all temporary differences between the carrying amounts and tax bases of assets and liabilities. However, deferred tax is not recognised on temporary differences relating to goodwill which is non-amortisable for tax purposes and other items where temporary differences, except for acquisitions, have arisen at the date of acquisition without affecting the net profit or loss for the year or the taxable income. In cases where the tax value can be determined according to different taxation rules, deferred tax is measured on the basis of management's intended use of the asset or settlement of the liability.

Deferred tax assets are recognised, following an assessment, at the expected realisable value through offsetting against deferred tax liabilities or elimination in tax on future earnings.



Deferred tax is measured on the basis of the tax rules and at the tax rates which, according to the legislation in force at the balance sheet date, will be applicable when the deferred tax is expected to crystallise as current tax.

# **Payables**

With subordinate loan capital, the creditor has subordinated its claim to those of all other creditors of the company.

Long-term payables are measured at cost at the time of contracting such liabilities (raising of the loan). The payables are subsequently measured at amortised cost where capital losses and loan expenses are recognised in the income statement as a financial expense over the term of the payable on the basis of the calculated effective interest rate in force at the time of contracting the liability.

Short-term payables are measured at amortised cost, normally corresponding to the nominal value of such payables.

#### Deferred income

Deferred income under liabilities comprises payments received in respect of income in subsequent financial years.

