Cbio A/S

ANNUAL REPORT 2022

CBio A/S

Transformervej 8, 2860 Soeborg

CVR no. 40 21 66 42

Annual report for 2022

Årsrapporten er godkendt på den
ordinære generalforsamling, d. 28.06.23

Ulrik Cordes
Dirigent

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Company information etc.

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 Ioana Kaiser
Christian Henri Leroy
Karin Cecilia Hultén
CEO Ulrik Cordes

Auditors

Beierholm
Statsautoriseret Revisionspartnerselskab

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 01.01.22 - 31.12.22 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 31.12.22 and of the results of the company's activities for the financial year 01.01.22 - 31.12.22.

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, June 28, 2023

Executive Board

Ulrik Cordes
CEO

Board of Directors

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

Independent auditor's report

To the Shareholders of CBio A/S

Opinion

We have audited the financial statements of CBio A/S for the financial year 01.01.22 - 31.12.22, 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 31.12.22 and of the results of the company's operations for the financial year 01.01.22 - 31.12.22 in accordance with the 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, June 28, 2023

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 seriousley ill patients.

Development in activities and financial affairs

The income statement for the period 01.01.22 - 31.12.22 shows a profit/loss of DKK -8,975,691 against DKK -8,556,249 for the period 01.01.21 - 31.12.21. The balance sheet shows equity of DKK -710,280.

Letter From the CEO

2022 was a breakthrough year for TIL therapy with the announcement of the clinical data from an academic phase III clinical study led by Professor John Haanen from the Netherland's Cancer Institute. With a 50% overall response rate, including 20% complete responders in metastatic melanoma patients, there is no doubt that TIL therapy will become mainstream in treating late-stage cancer patients thereby giving new hope of survival and possible cure to thousands of patients worldwide.

However, this academic approach has clear obstacles, including the long production time of 6-7 weeks and the labor-intensive process involving more than 3,000 manual steps per patient. It is, therefore, challenging to scale this academically developed product to meet demand why there is a need for the industry to ensure that patients in need can access this life-prolonging therapy.

With our focus on advancing TIL therapy and our steep progress towards this goal, Cbio A/S is at the forefront of taking this disruptive new therapeutic approach to the market, bringing us closer to our mission to enable cancer cure.

Discoveries paving the way for clinical breakthroughs

2022 was also the year where we further gained insights on the underlying mechanism of action for our novoleucel TIL therapy product. As opposed to first-generation TIL products, we selectively expand T-cells that have a more stemness-like phenotype, thereby creating a pool of T-cells that when encountering tumor cells, not only will kill them – but also can divide to generate even more T-cells – thereby making the immune system rise to the occasion and combat cancer.

It is remarkable how significant an improvement to the final TIL product that the novoleucel process is creating. Cancer cells evolving in the body for years develop strategies to evade the immune system turning tumor-killing T-cells off. Otherwise, they would not be there. The T-cells are popularly speaking 'lured to sleep', and the process we have discovered is reinvigorating these cells, thereby turning them back 'on' again, boding well for the clinical outcome of the planned clinical trials.

Manufacturing Authorization from the Danish Medicines Agency

Cell-based therapy is a novel approach to combat diseases and will revolutionize how we treat patients with serious illnesses such as cancer. TIL therapy is the most promising first step in this endeavor, but one should not underestimate the competencies and skills that are required to make this a success. In August 2022, Cbio A/S received manufacturing authorization from the Danish Medicines Agency as an ultimate recognition of the diligent work of the whole team to reach this critical milestone. It brings Cbio A/S up in the super league of cell-based companies, one of the few companies in the industry with full control over its cell manufacturing capabilities. The importance of having manufacturing know-how and skills in-house is critical – especially in an emerging field such as cell-based therapies. While developing novoleucel, this has allowed us to design in essential criteria such as production success rate, high yield/dose, manufacturability, and robustness, securing that novoleucel is a scalable and commercially viable product. Despite good underlying science, many other cell-based therapy companies have failed their clinical development programs, as their products were not robust enough. As an example, a close peer had to give up their clinical development program recently as their production success rate was too low, failing to produce products for too many of the recruited patients in their trial.

With a grant from the Innovation Fund and collaboration with Karolinska Institute, we target cervical cancer
In a highly competitive field, Cbio A/S secured DKK 26.9 million in a grant from the Innovation Fund Denmark to test novoleucel in 20 patients with advanced cervical cancer over the next three years at the Karolinska Hospital in Stockholm. By all standards, it is a significant contribution from the Fund recognizing the potential of the breakthrough discoveries we have uncovered during the last years of research.

Advanced cervical cancer is a devastating disease with a 5-year survival rate of only 17%, hitting relatively young women (the incidence rate is highest in the 30-34 years of age), and where there are few and ineffective treatment options. In the Stockholm region alone, there are 30 women every year that reach this advanced stage of disease, and we are sprinting as fast as we can to bring novoleucel's hope of survival and possible cure to these women aiming to start the clinical trial in the first half of 2024. In the broader context, more than 30,000 women are dying from cervical cancer annually in Europe and North America – so the commercial potential for novoleucel in this indication is in the billions of DKK.

We are grateful to the Danish Innovation Fund, and our collaboration partners at Karolinska. Not only is Karolinska, for good reasons, one of the most recognized academic institutions in Europe, but also very competent and skilled in the art of cell therapies, including TILs. We are working with the research group headed by Professor MD Rolf Kiessling, globally known for his contributions to the field of immunology and immuno-oncology. So, novoleucel is in safe hands when going to the next level from pre-clinical to clinical development, bringing us an important step closer to making an impact.

Strong support from our shareholders and perspectives
2022 has been a challenging year for biotechnology, with the global crisis hitting longer-term investment opportunities. The stock market valuations have plummeted, and Venture Capital funding, even for solid investment cases, has dried out. Despite this turmoil, our shareholders have stayed with us and support our further advancement, which we are grateful for. Fortunately, unlike many other biotech companies, we run at a very modest burn rate. On the financial side, we are very conscious of securing a high level of capital efficiency, securing that we meet the critical value inflection points, including bringing novoleucel to the clinic, putting us in a good position when capital markets reopen in the

coming years. Together with the recent grant from Innovation Fund Denmark amounting to DKK 27 million and a capital raise in excess of DKK 7 million, we have secured sufficient cashflow for the remainder of 2023 and well into 2024 to advance our business.

We stay committed to securing a solid return to our shareholders for their trust in us, thereby also securing that we can further advance towards our mission to enable cancer cure.

Ulrik Cordes
Founder, CEO

Income statement

Note		2022 DKK	2021 DKK
	Gross loss	**-1,104,139**	**-1,913,052**
1	Staff costs	-8,212,934	-7,609,434
	Loss before depreciation, amortisation, write-downs and impairment losses	**-9,317,073**	**-9,522,486**
	Depreciation and impairments losses of property, plant and equipment	-1,868,021	-1,636,187
	Operating loss	**-11,185,094**	**-11,158,673**
	Financial income	129	1,151
	Financial expenses	-592,583	-400,534
	Loss before tax	**-11,777,548**	**-11,558,056**
	Tax on loss for the year	2,801,857	3,001,807
	Loss for the year	**-8,975,691**	**-8,556,249**

Proposed appropriation account

Retained earnings	-8,975,691	-8,556,249
Total	**-8,975,691**	**-8,556,249**

Balance sheet

ASSETS

Note		31.12.22 DKK	31.12.21 DKK
	Leasehold improvements	2,531,973	3,237,319
	Other fixtures and fittings, tools and equipment	4,483,326	3,684,786
2	**Total property, plant and equipment**	**7,015,299**	**6,922,105**
3	Deposits	780,827	854,777
	Total investments	**780,827**	**854,777**
	Total non-current assets	**7,796,126**	**7,776,882**
	Income tax receivable	5,803,663	4,357,131
	Other receivables	259,473	1,484,313
	Prepayments	190,283	411,757
	Total receivables	**6,253,419**	**6,253,201**
	Cash	**700,587**	**4,745,074**
	Total current assets	**6,954,006**	**10,998,275**
	Total assets	**14,750,132**	**18,775,157**

Balance sheet

EQUITY AND LIABILITIES

Note		31.12.22 DKK	31.12.21 DKK
	Share capital	1,583,797	1,583,797
	Retained earnings	-2,294,077	6,681,614
	Total equity	**-710,280**	**8,265,411**
4	Subordinate loan capital	6,727,200	6,309,504
4	Lease commitments	2,306,762	1,419,390
4	Other payables	18,956	0
	Total long-term payables	**9,052,918**	**7,728,894**
4	Short-term part of long-term payables	599,855	331,998
	Payables to other credit institutions	343	345
	Trade payables	600,155	570,614
	Other payables	4,871,195	1,506,293
	Deferred income	335,946	371,602
	Total short-term payables	**6,407,494**	**2,780,852**
	Total payables	**15,460,412**	**10,509,746**
	Total equity and liabilities	**14,750,132**	**18,775,157**

5 Contingent liabilities

Statement of changes in equity

Figures in DKK	Share capital	Retained earnings	Total equity
Statement of changes in equity for 01.01.22 - 31.12.22			
Balance as at 01.01.22	1,583,797	6,681,614	8,265,411
Net profit/loss for the year	0	-8,975,691	-8,975,691
Balance as at 31.12.22	1,583,797	-2,294,077	-710,280

	2022 DKK	2021 DKK

1. Staff costs

	2022 DKK	2021 DKK
Wages and salaries	7,781,288	7,220,349
Other social security costs	67,608	80,501
Other staff costs	364,038	308,584
Total	8,212,934	7,609,434
Average number of employees during the year	11	11

2. Property, plant and equipment

Figures in DKK	Leasehold improvements	Other fixtures and fittings, tools and equipment
Cost as at 01.01.22	4,178,386	4,630,709
Additions during the year	73,722	1,887,493
Cost as at 31.12.22	4,252,108	6,518,202
Depreciation and impairment losses as at 01.01.22	-941,067	-945,923
Depreciation during the year	-779,068	-1,088,953
Depreciation and impairment losses as at 31.12.22	-1,720,135	-2,034,876
Carrying amount as at 31.12.22	2,531,973	4,483,326
Carrying amount of assets held under finance leases as at 31.12.22	0	3,090,759

3. Non-current financial assets

Figures in DKK	Deposits
Cost as at 01.01.22	854,777
Additions during the year	26,050
Disposals during the year	-100,000
Cost as at 31.12.22	780,827
Carrying amount as at 31.12.22	780,827

4. Long-term payables

Figures in DKK	Repayment first year	Outstanding debt after 5 years	Total payables at 31.12.22	Total payables at 31.12.21
Subordinate loan capital	0	0	6,727,200	6,309,504
Lease commitments	599,855	133,853	2,906,617	1,751,388
Other payables	0	0	18,956	0
Total	599,855	133,853	9,652,773	8,060,892

5. 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 29, a total of t.DKK 1.169. The Company has a residual obligation of t.DKK 486.

The company has consluded lease agreements for rental of premises. The company has a rent obligation of t.DKK 2.641.

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 2022. The liability also includes any subsequent corrections to the calculated tax liability as a consequence of changes made to the jointly taxable income etc.

6. 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.

6. Accounting policies - continued -

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 write-downs.

Staff costs

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

6. Accounting policies - continued -

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 lives, years	Residual value DKK
Leasehold improvements	5	0
Other plant, fixtures and fittings, tools and equipment	5	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.

6. Accounting policies - continued -

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.

6. Accounting policies - continued -

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 account.

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.

6. Accounting policies - continued -

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.