



# SAVARA

## Drugrecure ApS

Tuborg Boulevard 12, 4.  
2900 Hellerup  
VAT no. 29154406

## Annual Report 2022

The Annual Report has been presented and adopted at the general meeting 2nd March 2023

*Mathias Stange*

Mathias Harder Stange  
Chairman of the general meeting

# TABLE OF CONTENT

1	Management's Report	3
2	Independent Auditor's Report	4
3	Managements Review	7
4	Profit and Loss Account	9
5	Balance Sheet	10
6	Changes in Equity	12
7	Notes to the Accounts	13



# MANAGEMENT'S REPORT

## **Statement of the Executive Management**

The Executive Management has today considered and adopted the Annual Report of Drugrecure ApS for the period 1 January to 31 December 2022.

The financial statements have been prepared in accordance with The Danish Financial Statement Act.

In my opinion, the financial statements give a true and fair view of the company's assets, liabilities and financial position at 31 December 2022 and of the result of the operations in 2022.

I am of the opinion that the management commentary includes a fair description of the issues dealt with.

The annual report is recommended for approval at the general meeting.

Hellerup, 2nd March 2023



---

David Lee Lowrance  
Executive management of Drugrecure ApS

# INDEPENDENT AUDITOR'S REPORT

## **To the shareholders of Drugrecure ApS**

### **Opinion**

We have audited the financial statements of Drugrecure ApS for the financial year 1 January to 31 December 2022, which comprise income statement, statement of financial position, notes and accounting policies. The financial statements are prepared in accordance with the Danish Financial Statements Act.

In our opinion, the financial statements give a true and fair view of the financial position of the company at 31 December 2022 and of the results of the company's operations for the financial year 1 January to 31 December 2022 in accordance with the Danish Financial Statements Act.

### **Basis for opinion**

We conducted our audit in accordance with International Standards on Auditing (ISAS) and the additional requirements applicable in Denmark. Our responsibilities under those standards and requirements are further described in the section "Auditor's responsibilities for the audit of the financial statements". We are independent of the company in accordance with international ethical requirements for auditors (IESBA's Code of Ethics) and the additional 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.

### **Managements responsibilities for the financial statements**

Management is responsible for the preparation of financial statements that give a true and fair view in accordance with the Danish Financial Statements Act. Management is also responsible for such 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, the 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 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 ISAS 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 ISAS and the additional requirements applicable in Denmark, we exercise professional judgment and maintain professional scepticism throughout the audit.

We also:

- Identify and assess the risks of material misstatement in the financial statements, whether due to fraud or error, design and perform audit procedures in response 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 the 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 management.
- Conclude on the appropriateness of the 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 represents the underlying transactions and events in a manner that presents 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.

#### **Statement on the managements review**

The management is responsible for the management review.

Our opinion on the financial statements does not cover the management 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 the management review, and in doing so, consider whether management review is materially inconsistent with the financial statements or our knowledge obtained during the audit, or whether it otherwise appears to be materially misstated.

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

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

Copenhagen, 2nd March 2023

#### **Grant Thornton**

Statsautoriseret Revisionspartnerselskab  
Company reg. no. 34 20 99 36

Ulrik Bloch-Sørensen  
State Authorised Public Accountant  
mne2913

Martin Bomholtz  
State Authorised Public Accountant  
mne34117

# MANAGEMENT REVIEW

## **Main Activities**

Drugrecure ApS is a 100% subsidiary of Savara ApS and part of the Savara Inc. group. Savara Inc. is a U.S.-based emerging pharmaceutical development company. The company is focused on advancing inhalation therapies for the treatment of patients with rare pulmonary conditions. In Drugrecure ApS, the treatment is centered around Molgramostim, inhaled nebulized GM-CSF to treat Autoimmune Pulmonary Alveolar Proteinosis (a PAP).

## **Extraordinary events**

No extraordinary events have occurred in 2022

## **Estimates and Judgements**

The preparation of the financial statements requires the making of estimates and judgments that affect the reporting of assets, liabilities and expenses. The estimates and judgments are reviewed on an ongoing basis. Estimates and judgments are based on historical results and on various other assumptions, which Savara believes to be reasonable under the circumstances. However, the actual results may differ significantly from the estimates. We believe that the accounting policies relating to development costs and deferred tax involve estimates or judgments by management that could materially affect the reported financial position and results.

## **Change in the accounting policies**

The company has effective from 1 January 2021 changed its accounting policy for development projects, with the effect that no development projects are recognized in the balance sheet effective from 1 January 2021. Additional information on the changes to the accounting policy is reflected in the accounting policies on page 13.

## **Deferred tax**

Due to tax credit reimbursement instalment by the Danish government, Savara expects to be reimbursed DKK 5,500k of the tax asset in 2023 - hence the tax receivable has been recognized in the balance sheet. The long-term deferred tax asset has been evaluated against the future income within the next three fiscal years and will not be recognised in the balance sheet.

**Development and expectations**

Drugrecure ApS reached a net loss of DKK -84.4 million in 2022, and holds total assets of DKK 37.7 million, equity of DKK -669.6 million and liabilities of DKK 707.3 million as of 31 December 2022.

The Molgramostim Autoimmune Pulmonary Alveolar Proteinosis (aPAP) Phase 3 study with data read in June 2019 failed to meet the primary endpoint. A second Phase 3 study is now underway and topline data from this study should be available in mid-2024. With positive data, the company will submit a BLA for approval and if approved, the company would begin selling commercial product.

Drugrecure intends to sell its products Molgramostim directly on license to pharmaceutical companies and thereby derive income from a combination of fixed payments and ongoing royalty income. Until Drugrecure has established such a sales on license agreement, Drugrecure will be a capital-consuming company due to investments in drug development and in further strengthening of the pipeline. Therefore, it is vital that the company always has sufficient financial resources. Drugrecure does not expect commercial revenue until the fiscal year of 2026 or later.

Based on a letter of support from the parent company Savara Inc, Drugrecure ApS has a satisfactory funding assurance until the end of 2023 to continue the ongoing clinical trials related to the Molgramostim project hence, the annual report for 2022 has been prepared for on-going business.



## PROFIT & LOSS ACCOUNT

<b>DKK '000</b>	<b>Notes</b>	<b>2022</b>	<b>2021</b>
<b>Gross deficit</b>		<b>(66.145)</b>	<b>(88.638)</b>
Net financials	3	(27.801)	(24.493)
<b>Deficit before tax</b>		<b>(93.946)</b>	<b>(113.131)</b>
Tax	4	9.591	5.500
<b>Net deficit</b>		<b>(84.355)</b>	<b>(107.631)</b>
<b>Distribution of net result</b>			
<b>Net deficit</b>		<b>(84.355)</b>	<b>(107.631)</b>
Transferred to retained earnings		(84.355)	(107.631)
		<b>(84.355)</b>	<b>(107.631)</b>

## BALANCE SHEET, ASSETS

<b>DKK '000</b>	<b>Notes</b>	<b>2022</b>	<b>2021</b>
CURRENT ASSETS			
Tax receivables	5	5.500	5.500
Group receivables		26.072	19.616
Group tax receivables		4.091	0
Prepayments		2.042	3.066
<b>Total current assets</b>		<b>37.705</b>	<b>28.182</b>
<b>Total assets</b>		<b>37.705</b>	<b>28.182</b>

## BALANCE SHEET, EQUITY AND LIABILITIES

<b>DKK '000</b>	<b>Notes</b>	<b>2022</b>	<b>2021</b>
EQUITY			
Share capital		162	162
Retained earnings		(669.749)	(585.394)
<b>Total equity</b>		<b>(669.587)</b>	<b>(585.232)</b>
CURRENT LIABILITIES			
Group payables	5	702.884	605.002
Other debts		4.408	8.412
<b>Total current liabilities</b>		<b>707.292</b>	<b>613.414</b>
<b>Total liabilities</b>		<b>707.292</b>	<b>613.414</b>
<b>Total equity and liabilities</b>		<b>37.705</b>	<b>28.182</b>
Important matters	1		

## CHANGES IN EQUITY

<b>DKK '000</b>	Share Capital	Retained Earnings	Total
Equity at 1 January 2022	162	(585.393)	(585.232)
Net deficit	-	(84.355)	(84.355)
<b>Equity at 31 December 2022</b>	<b>162</b>	<b>(669.749)</b>	<b>(669.587)</b>

# NOTES

DKK '000

## 1. Important matters

Drugrecure intends to sell its products directly on license to pharmaceutical companies and thereby derive income from a combination of fixed payments and ongoing royalty income. Until Drugrecure has established such a sales on license agreement, Drugrecure will be a capital-consuming company due to investments in drug development and in further strengthening of the pipeline. Therefore, it is vital that the company always has sufficient financial resources. Drugrecure does not expect commercial revenue until the fiscal year of 2026 or later.

Based on a letter of support from the parent company Savara Inc, Drugrecure ApS has a satisfactory funding assurance until the end of 2023 to continue the operation of the company as planned.

Given GM-CSF is already approved for other indications, management believes it is highly likely that a regulatory approval will be obtained, provided the Phase III studies result in positive outcomes.

## 2. Accounting Policies

Accounting policies applied in the preparation of the financial statements are set out below.

### Basis of preparation

The Annual Report has been prepared in accordance with The Danish Financial Statements Act. for class B companies. Furthermore the company has chosen to comply with some of the rules applying to class C companies. Drugrecure has a satisfactory funding assurance for 2023 - thus, the annual report for 2022 has been prepared for on-going business. The financial statements are presented in DKK, reflecting the company's functional currency.

### Change in the accounting policies

The company has effective from 1 January 2021 changed its accounting policy for development projects, with the effect that no development projects are recognized in the balance sheet effective from 1 January 2021. Up to 31 December 2019 external development cost were recognized in the balance sheet under development projects and up to 31 December 2021 the development projects were amortized. The effect on total assets and equity amounts to t.DKK 293.257. The result for 2021 and 2022 is being improved by the change with t.DKK 32.584 due to a reversal of amortizations recognized in 2021 and no amortizations recognized in 2022. The change has no tax effect.

### **Recognition and measurement in general**

The net revenue is recognised in the profit and loss account if delivery and risk transfer to the buyer have taken place before the end of the year, and if the income can be determined reliably and is expected to be received. The net revenue is recognised exclusive of VAT and taxes and with the deduction of any discounts granted in connection with the sale. Recognition of value adjustments of assets and liabilities are recognised in the profit and loss account upon financial assessment.

All costs – including depreciation, amortisation, write-down, provisions, and reversals, which are due to changes in estimated amounts previously recognised in the profit and loss account – are recognised in the profit and loss account.

Assets are recognised in the balance sheet when the company is liable to achieve future, financial benefits and the value of the asset can be measured reliably.

Liabilities are recognised in the balance sheet when the company is liable to lose future, financial benefits and the value of the liability can be measured reliably.

### **Translation of foreign currency**

Operational transactions in foreign currency are translated by using the exchange rate at cost basis upon bank transaction. Differences in the rate of exchange arising between the rate at the date of transaction and the rate at the date of payment are recognised in the profit and loss account as an item under net financials. Debtors, creditors, and other monetary items in foreign currency – not settled at the date of the balance sheet – are translated by using the period closing rate held by The Danish Central Bank.

The difference between the closing rate and the rate at the time of establishment of the receivable or the payable is recognised in the profit and loss account under financial income and financial costs. Fixed assets and other non-monetary assets acquired in foreign currency and which are not considered to be investment assets purchased in foreign currencies are measured at the exchange rate on the transaction date.

## **INCOME STATEMENT**

### **Net revenue**

As of 31 December 2020, Drugrecore has only one sales segment. Revenue represents amounts receivable for products or services delivered in the normal course of business of the company. Revenue is reduced for estimated customer returns and other similar allowances whenever applicable based on historical data and expectations of future sales. Revenue is recognised upon invoiced sale and when risks and rewards of ownership is transferred to the customer. The risks and rewards of ownership are generally transferred at the time the product is shipped and delivered to the customer.

Revenue is recognised in the profit and loss account when management has established that all aforementioned conditions for revenue recognition have been met.

Other operating income and costs comprise accounting items of secondary nature in proportion to the principal activities of the enterprise.

#### **Cost of goods sold**

The cost of goods sold comprises costs paid for manufacturing in order to generate net revenue for the year including depreciation, amortisation and write-downs of inventory.

#### **Raw materials and consumables used**

Raw materials and consumables used comprise handling charges, distributions costs and costs paid for manufacturing samples and references.

#### **External expenses**

External expenses compromise all external costs including development costs, which are not directly attributable to the Company's development of new products (capitalised costs). External expenses includes rendering of employees in parent company Savara ApS, depreciation and write-downs.

#### **Net financials**

Net financials include interest income, interest expenses on loans, and realized and unrealized exchange rate gains and losses. Net financials are recognised in the profit and loss account with the amounts concerning the financial year.

#### **Tax**

Tax comprises the current income tax for the year and the changes in deferred tax. Tax costs are recognised in the profit and loss account with the amounts concerning the fiscal year with the share referring to entries in the equity subsequently deferred tax asset.

The company is subject to danish rules on compulsory joint taxation of danish group enterprises.

The current danish income tax is allocated among the jointly taxed companies proportional to their respective taxable income (full reduction with reimbursement of tax losses).

**Receivables**

Receivables are measured at amortised cost which usually corresponds to face value. In order to meet expected losses, write down for impairment are measured at net realisable value.

**Tax**

Corporate tax (less than 12 months) are recognised in the balance sheet reflecting the tax credit reimbursement installment by the Danish government – expected to be received in June 2023.

Deferred tax is measured on the basis of all temporary differences in assets and liabilities with a balance sheet focus. Deferred tax is measured based on the tax rules and tax rates applying under the legislation on the balance sheet date and prevailing when the deferred tax is expected to be released as corporate tax.

The current tax rate is 22%.

**Reserve for development costs**

The reserve for development costs comprises recognised development costs less related deferred tax liabilities. The reserve cannot be used as dividend or coverage losses. The reserve is reduced or dissolved if the recognised development costs are amortised or abandoned. This is done by direct transfer to the distributable reserves of the equity.

**Other Debts**

Current liabilities are measured at amortized costs, which usually corresponds to the nominal value.



### 3. Net financials

	<b>2022</b>	<b>2021</b>
Currency translation	(2.388)	(3.291)
Interest income, Group companies	825	599
Financial expenses, Group Companies	(26.237)	(21.801)
<b>Total net financials</b>	<b>(27.801)</b>	<b>(24.493)</b>

### 4. Tax expenses

	<b>2022</b>	<b>2021</b>
Deferred tax for the year	5.500	5.500
<b>Total tax</b>	<b>5.500</b>	<b>5.500</b>

Due to tax credit reimbursement installment by the Danish government, Savara Group expects to be reimbursed DKK 5.5 million of the tax asset - receivable in November 2023.

The company's tax loss carried forward has not been recognised in the balance sheet.

Potential tax reimbursements deriving from tax loss utilisation by the group joint taxation, which the company has been a member of since 15 July 2016, has not been recognised.

### 5. Group Payables

The company's activities is financed from its Parent company Savara ApS, which ultimately is financed from Savara Inc, based in the US. The company expects to be able to repay the loan once the development of Molgramostim is finalized and the company has commercialized the product's full potential after 2026.

## **6. Contingent liabilities**

Drugrecure ApS has no contingent liabilities as of 31 December 2022.

## **7. Contractual obligations and pending litigations**

Drugrecure ApS has no contractual obligations nor pending litigations as of 31 December 2022.

## **8. Related-party transactions**

Parent company is Savara ApS, Tuborg Boulevard 12 4., DK-2900 Hellerup.

The ultimate parent company is Savara Inc., 6836 Bee Cave Road, Bld 3, Suite 200, Austin, Texas 78746, USA

Other related parties are other affiliated companies in the group Pharmaorigin ApS and Savara ApS.

## **9. Significant events occurring after the balance sheet date**

After the balance sheet date no major events have occurred which significantly affect the evaluation of the financial statements for 2022.