

# Drugrecure ApS Slotsmarken 17, 1. th.

2970 Hørsholm

VAT no. 29154406

**Annual Report** 2020

The Annual Report has been presented and adopted at the general meeting 27th May 2021

Mathias Harder Stange

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# 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 2020.

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 2020 and of the result of the operations in 2020.

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.

Hørsholm, 27th May 2021

David Lee Lowrance

**CFO** 

# 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 2020, which comprise accounting policies, income statement, statement of financial position and notes. The financial statements have been prepared in accordance with the Danish Financial Statements Act.

In our opinion, the financial statements present and fair view of the company's assets, equity and liabilities, and financial position at 31 December 2020 and of the results of the company's activities for the financial year 1 January to 31 December 2020 in accordance with the Danish Financial Statements Act.

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

# Responsibilities of management and those charged with governance for the financial statements

Management is responsible for the preparation of financial statements that provide a 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 including an 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 due to 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 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 preparation of the financial statements using the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists arising from 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 in the notes, and whether the financial statements reflect the underlying transactions and events in a manner that presents a 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 the internal control that we identify during our audit.

# Statement on the management commentary

The management is responsible for the management commentary.

Our opinion on the financial statements does not cover the management commentary, and we express no assurance opinion thereon.

In connection with our audit of the financial statements, it is our responsibility is to read the management commentary and to consider whether the management commentary is materially inconsistent with the financial statements or the evidence obtained during the audit, or whether it otherwise appears to contain material misstatement.

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

Based on the work we have performed, we believe that the management commentary is consistent with the financial statements and that it has been prepared in accordance with the provisions of the Danish Financial Statement Act. We did not discover any material misstatement in the management commentary.

Copenhagen, 27th May 2021

**Grant Thornton** 

Statsautoriseret Revisionspartnerselskab Company reg. no. 34 20 99,36

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Ulrik Bloch-Sørensen

State Authorised Public Accountant

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Martin Bomholtz

**State Authorised Public Accountant** 

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# MANAGEMENT COMMENTARY

#### **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 (aPAP).

#### **Extraordinary events**

No extraordinary events have occurred in 2020

# **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.

#### 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 2021 - 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 -143.0 million in 2020, and holds total assets of DKK 354.0 million, equity of DKK -151.8 million and liabilities of DKK 505.8 million as of 31 December 2020.

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 planned after discussions with U.S. Food and Drug Administration (FDA).

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 2025 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 2021 to continue the ongoing clinical trials related to the Molgramostim project hence, the annual report for 2020 has been prepared for on-going business.

# **PROFIT & LOSS ACCOUNT**

DKK '000	Notes	2020	2019
Gross profit		(121.735)	(33.801)
Depreciaitions and write-downs	5	(15.832)	(21.317)
Operating deficit	e e	(137.567)	(55.118)
Net financials	3	(15.241)	(10.466)
Deficit before tax		(152.808)	(65.585)
Tax	4	9.812	5.500
Net deficit		(142.996)	(60.085)
Distribution of net result			
Net deficit		(142.996)	(60.085)
Transferred to retained earnings		(142.996)	(60.085)
		(142.996)	(60.085)

# **BALANCE SHEET, ASSETS**

DKK '000	Notes	2020	2019
FIXED ASSETS			
Projects under development		325.841	340.763
R&D Equipment		0	911
Total Fixed assets	5	325.841	341.674
CURRENT ASSETS			
Tax receivables	4	5.500	5.500
Group receivables		19.209	8.468
Prepayments		3.474	305
Total current assets	_	28.183	14.273
Total assets	_	354.024	355.947

# **BALANCE SHEET, EQUITY AND LIABILITIES**

DKK '000	Notes	2020	2019
EQUITY			
Share capital		162	162
Reserve for development costs		210.193	221.831
Retained earnings		(362.112)	(230.754)
Total equity	-	(151.757)	(8.761)
	•		
CURRENT LIABILITIES	-	492 341	355 682
CURRENT LIABILITIES  Group payables	-	492.341 13.441	355.682 9.026
CURRENT LIABILITIES  Group payables Other debts		492.341 13.441 <b>505.782</b>	355.682 9.026 <b>364.708</b>
CURRENT LIABILITIES  Group payables Other debts  Total current liabilites  Total liabilities		13.441	9.026

# **CHANGES IN EQUITY**

DKK '000	Share Capital		Reserve for de- velopment cost	Total
Equity at 1 January 2020	162	(230.754)	221.831	(8.761)
Reserve for development cost	~	11.638	(11.638)	0
Net deficit	±	(142.996)	<b>≨</b>	(142.996)
Equity at 31 December 2020	162	(362.112)	210.193	(151.757)



#### 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 2025 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 2021 to continue the operation of the company as planned.

The valuation of the assets are based on the expected regulatory approval to market the products under development. Given GM-CSF is already approved for other indications, management believes it is highly likely that the regulatory approval will be obtained, provided the studies result in positive outcomes, and has consequently recognized the development project as an asset in the balance sheet.

In the event that the products under development in Drugrecure ApS against management expectations should fail to be marketed, the US parent company, Savara Pharmaceuticals Inc., which are financing the activities in Drugrecure ApS, will forgive all receivables with the Danish group entities.

# 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 2021 - thus, the annual report for 2020 has been prepared for on-going business. The financial statements are presented in DKK, reflecting the company's functional currency.

### 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, Drugrecure 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.

Up-front payments that are attributable to subsequent research and development activities are recognised as deferred revenue and will subsequently be recognised as revenue over the expected contract period. Non-refundable up-front payments and milestone payments that are not attributable to subsequent research and/or development activities or other delivery obligations are recognised as revenue when the contracts are signed or when the milestone criteria are met respectively.

# 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).

#### **BALANCE SHEET ITEMS**

#### Fixed assets

Intangible fixed assets comprise development projects. Development costs comprise costs directly and indirectly attributable to development of new products from which the Company expects a future economic benefit.

All other development costs are recognised as costs in the profit and loss accounts.

Capitalised development costs are measured at cost with deduction of accrued amortisations or at the recoverable value, if this is lower.

The carrying amounts of intangible assets carried at cost or amortized cost are tested annually to determine whether there are indications of any impairment in excess of that expressed in normal amortisation. If that is the case, the asset is written down to the recoverable amount, which is the higher value of the net sales price and the capitalised value. Impairment losses on intangible assets are recognised under the same line item as amortisation of the assets.

For development projects in progress, the recoverable amount is assessed annually, regardless of whether any indications of impairment have been found.

After completion of the development work, capitalised development costs are amortized on a straight line basis over the estimated financial useful life.

Profit and loss from the realization of development projects are measured as the difference between the sales price with deduction of sales costs and the book value at the time of the sale.

### Write-down of assets

The book values of financial as well as tangible fixed assets are subject to annual write-down assessment in order to disclose any indications of impairment beyond those expressed by amortisation and depreciation respectively.

If indications of impairment are disclosed, impairment tests are carried out for each individual asset or group of assets respectively. Write-down takes place to the recoverable amount, if this value is lower than the book value. The recoverable value is equal to the value of the net selling price or the value in use, whichever is higher. The value in use is determined as the present value of the expected net income deriving from the use of the asset or the group of assets. Any loss based on the write-down test is recognised in the profit and loss account under depreciation.

## 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 2021.

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

	2020	2019
Financial expenses to Group companies	(15.241)	(10.466)
Total net financials	(15.241)	(10.466)

# 4. Tax expenses

2020	2019
5.500	5.500
4.312	:■:
9.812	5.500
	5.500 4.312

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 June 2021.

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. Fixed assets

Net booked value 31 December 2020		325.841	325.841
Depreciation and write-down at 31 December 2020	2.735	43.455	46.190
Depreciation and write-down in the period	911	14.921	15.832
Depreciation and write-down at 1 January 2020	1.824	28.534	30.358
Cost at 31 December 2020	2.735	369.296	372.031
Additions during the year			
Cost at 1 January 2020	2.735	369.296	372.031
	R&D Equipment	Projects under development	Total

The company's capitalized development costs are attributable to the Impala 2 study of Molgramostim for the treatment of aPAP, a rare lung disease.

Due to an increased duration of the planned Impala 2 Phase III study of Molgramostim for the treatment of aPAP, based on CM-CSF, the management has performed an impairment test to determine whether the expected recoverable amount of the Impala 2 project exceeds the amount of capitalized development costs. The recoverable amount is determined as a calculated value in use based on budgets and forecasts for the period until patent expiration of the orphan drug as approved by the Board of Directors.

The managements calculation of the recoverable amount is significantly impacted by management's expectations for qualitative factors such as price/dose, expected number of users (prevalence of the targeted disease), likelihood of approval, and the discount factor applied to discount the expected future net cash flows. Although these factors reflect management's best estimates and are based on extensive analysis performed by the management, each factor is naturally subject to significant uncertainty and actual results may, naturally, deviate from the estimates made.

Based on the review of the qualitative factors and the calculation of the recoverable amount, the management concluded that the recognized book value of the Impala 2 study is not impaired as of 31 December 2020.

# 6. Contingent liabilities

Drugrecure ApS has no contingent liabilities as of 31 December 2020.

# 7. Contractual obligations and pending litigations

Drugrecure ApS has no contractual obligations nor pending litigations as of 31 December 2020.

# 8. Related-party transactions

Parent company is Savara ApS, Slotsmarken 17 1 th, DK-2970 Hørsholm.

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 Australia Pty Ltd.

# 9. Significant events occurring after the balance sheet date

After the balance sheet date no major events have accurred which significantly affect the evaluation of the financial statements for 2020.