



# SAVARA

**Drugrecure ApS**

Slotsmarken 17, 1 th.  
2970 Hørsholm

CVR 29154406

## Annual Report

## 2018

The Annual Report has been presented and adopted at the general meeting 24/5 2019

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Lena Erichsen

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## MANAGEMENT'S STATEMENT

The Executive Management has today considered and adopted the Annual Report of Drugrecure ApS for the period 1 January to 31 December 2018.

The Annual Report is 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 2018 and of the company operations in 2018.

I am of the opinion that the Annual Review includes a fair description of the issues dealt with.

I recommend the Annual Report to be adopted at the Annual General Meeting.

Hørsholm 24 May 2019



Robert Neville  
CEO

## INDEPENDENT AUDITORS REPORT

### To the shareholders of Drugrecure ApS

#### **Opinion**

We have audited the annual accounts of Drugrecure ApS for the financial year 1 January - 31 December 2018, which comprise accounting policies used, profit and loss account, balance sheet and notes. The annual accounts have been prepared in accordance with the Danish Financial Statements Act.

In our opinion, the annual accounts give a true and fair view of the assets and liabilities, and the financial position at 31 December 2018, and of the results of the company's operations for the financial year 1 January - 31 December 2018 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 below section "Auditor's responsibilities for the audit of the annual accounts". We are independent of the company in accordance with international ethics standards for accountants (IESBA's Code of Ethics) and the additional requirements applicable in Denmark, and we have fulfilled our other ethical responsibilities in accordance with these standards and requirements. We believe that the audit evidence obtained is sufficient and appropriate to provide a basis for our opinion.

#### **The management's responsibilities for the annual accounts**

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

In preparing the annual accounts, the management is responsible for evaluating the company's ability to continue as a going concern, and, when relevant, disclosing matters related to going concern and using the going concern basis of accounting when preparing the annual accounts, unless the management either intends to liquidate the company or to cease operations, or if it has no realistic alternative but to do so.

#### **Auditor's responsibilities for the audit of the annual accounts**

Our objectives are to obtain reasonable assurance about whether the annual accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue 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 may arise due to fraud or error and may be considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions made by users on the basis of the annual accounts

As part of an audit conducted in accordance with international standards on auditing and the additional requirements applicable in Denmark, we exercise professional evaluations and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement in the annual accounts, 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 the risk of not detecting a misstatement 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 by the management and the reasonableness of accounting estimates and related disclosures made by the management.
- Conclude on the appropriateness of the management's preparation of the annual accounts being based on the going concern principle and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may raise significant doubt about 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 annual accounts or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our 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 annual accounts, including the disclosures in the notes, and whether the annual accounts reflect 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 the internal control that we identify during our audit.

#### **Statement on the management's review**

The management is responsible for the management's review.

Our opinion on the annual accounts does not cover the management's review, and we do not express any kind of assurance opinion on the management's review.

In connection with our audit of the annual accounts, our responsibility is to read the management's review and in that connection, consider whether the management's review is materially inconsistent with the annual accounts or our knowledge obtained during the audit, or whether it otherwise appears to contain material misstatement.

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


Based on the work we have performed, we believe that the management's review is in accordance with the annual accounts and that it has been prepared in accordance with the requirements of the Danish Financial Statement Acts. We did not find any material misstatement in the management's review.

Copenhagen, 24 May 2019

#### **Grant Thornton**

Statsautoriseret Revisionspartnerselskab


Company reg. no. 34 20 99 36



Ulrik Bloch-Sørensen

State Authorised Public Accountant

MNE-nr.2913



Martin Bomholtz

State Authorised Public Accountant

MNE-nr. 34117

## MANAGEMENT REVIEW

### MAIN ACTIVITY

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 Molgradex, inhaled nebulized GM-CSF to treat Pulmonary Alveolar Proteinosis (PAP).

### EXTRAORDINARY EVENTS

No extraordinary events have occurred in 2018.

### 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 judgements are reviewed on an ongoing basis. Estimates and judgments are based on historical results and on various other assumptions, which Drugrecure 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.

#### **Development costs**

Drugrecure is confident it will obtain approval of its pipeline products, as the products are based on an existing approved drug, and hold the evidence to support this. Drugrecure is confident, that it will acquire the necessary resources to either sell or complete the development. Thus, management judge that the technical feasibility criterion for recognition of development costs as non-current intangible assets is met. Management has reviewed the development cost and has not identified any need for impairment.

#### **Deferred tax**

Due to tax credit reimbursement instalment by the Danish government, Savara Group expects to be reimbursed DKK 5,500k of the tax asset in Q4 2019 - 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 -15.9 million in 2018, and holds total assets of DKK 270.8 million, equity of DKK 51.3 million and liabilities of DKK 219.5 million as of 31 December 2018.

Drugrecure intends to license its products to pharmaceutical companies and thereby derive income from a combination of fixed payments and ongoing royalty income. Until Drugrecure has established such a 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 2021.

Based on a letter of support from the parent company Savara Inc, Drugrecure ApS has a satisfactory funding assurance until the end of 2019 to continue the ongoing clinical trials related to the Molgradex® project hence, the annual report for 2018 has been prepared for on-going business.

# Profit and Loss Account

1 January 2018 - 31 December 2018

<b>DKK thousand</b>	<b>Notes</b>	<b>2018</b>	<b>2017</b>
Gross profit		(15.871)	(9.821)
Operating profit/loss (-)		<b>(15.871)</b>	<b>(9.821)</b>
Net financials		(5.495)	(1.311)
Profit/loss (-) before tax		<b>(21.366)</b>	<b>(11.132)</b>
Tax expenses	3	5.500	5.500
Net profit/loss (-) □		<b>(15.866)</b>	<b>(5.632)</b>
<b>DISTRIBUTION OF NET RESULT</b>			
Net profit/loss (-) □		<b>(15.866)</b>	<b>(5.632)</b>
Suggestion of distribution			
Transferred to retained earnings		<b>(15.866)</b>	<b>(5.632)</b>
		<b>(15.866)</b>	<b>(5.632)</b>

# Balance Sheet

31 December 2018

## ASSETS

<b>DKK thousand</b>	<b>Notes</b>	<b>2018</b>	<b>2017</b>
<b>FIXED ASSETS</b>			
<b>Fixed intangible assets</b>			
Development projects		253.342	148.822
Plant & Equipment		1.823	2.690
Total fixed assets	4	255.165	151.513
<b>CURRENT ASSETS</b>			
Inventories		-	382
<b>Receivables</b>			
Tax receivables	3	5.500	5.500
Receivables from group companies		8.124	2.515
Prepayments		2.018	10.504
Total receivables		15.642	18.519
Total current assets		15.642	18.901
<b>Total assets</b>		<b>270.807</b>	<b>170.413</b>



# Balance Sheet

31 December 2018

## EQUITY AND LIABILITIES

<b>DKKthousand</b>	<b>Notes</b>	<b>2018</b>	<b>2017</b>
<b>Equity</b>			
Share capital		162	162
Statutory Reserves		198.908	94.388
Retained earnings		(147.746)	(27.361)
<b>Total equity</b>		<b>51.323</b>	<b>67.188</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Payables to group companies		206.171	99.106
Other debts		13.313	4.118
<b>Total current liabilities</b>		<b>219.485</b>	<b>103.225</b>
<b>Total liabilities</b>		<b>219.485</b>	<b>103.225</b>
<b>Total equity and liabilities</b>		<b>270.807</b>	<b>170.413</b>

## Changes in equity

<u>DKK thousand</u>	<u>Share Capital</u>	<u>Retained Earnings</u>	<u>Statutory Reserves</u>	<u>Total</u>
Equity at 1 January 2018	162	(27.361)	94.388	67.189
Profit/loss (-)	-	(15.866)	-	(15.866)
Statutory transfer of retained earnings	-	(104.520)	104.520	-
<u>Equity at 31 December 2018</u>	<u>162</u>	<u>(147.746)</u>	<u>198.908</u>	<u>51.323</u>

# Notes

DKK thousand

## 1. IMPORTANT MATTERS

Drugrecure intends to license its products to pharmaceutical companies and thereby derive income from a combination of fixed payments and ongoing royalty income. Until Drugrecure has established such a 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 2021.

Based on a letter of support from the parent company Savara Inc, Drugrecure ApS has a satisfactory funding assurance until the end of 2019 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 projects as assets in the balance sheet.

## 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. Drugrecure has a satisfactory funding assurance for 2019 - thus, the annual report for 2018 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.

# Notes

DKK thousand

## INCOME STATEMENT

### Net revenue

As of 31 December 2018, 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 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.

## BALANCE SHEET ITEMS

### Fixed assets

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

# Notes

DKK thousand

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, patents, and licenses 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 intangible 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.

## **Inventories**

Inventories are measured at cost on basis of measured average prices. In case the net realizable value is lower than the cost, write-down takes place at this lower value.

The inventory includes:

Acquisition of pharmaceutical ingredients, which include the cost for raw materials and the initial processing  
The cost for manufactured goods and works in progress

The net realizable value for inventories is recognised as the market price with the deduction of completion costs and selling costs, and it is determined by taking negotiability, obsolescence, and the development of the expected market price into consideration. All logistic costs related to the inventories are recognised in the profit and loss account.

## **Tax**

Corporate tax (less than 12 months) are recognised in the balance sheet reflecting the tax credit reimbursement installment by the Danish government - receivable in November 2019.

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.

# Notes

DKK thousand

The current tax rate is 22%.

## **Other Debts**

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

# Notes

DKK thousand

## 3. Tax expenses

	<b>2018</b>	<b>2017</b>
Deferred tax for the year	(5.500)	(5.500)
<b>Total tax expense</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 2019.

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 until 15 July 2016, has not been recognised.

## 4. Fixed Assets

	<b>R&amp;D equipment</b>	<b>R&amp;D projects</b>	<b>Total</b>
Cost 1. January 2018	2.690	156.951	159.641
Additions in the period	45	104.520	104.564
Cost 31. December 2018	2.735	261.471	264.205
Depreciation and writedown 1. January 2018	-	8.129	8.129
Depreciation and writedown in period	912	-	912
Depreciation and writedown 31. December 2018	912	8.129	9.041
<b>Book value 31. December 2018</b>	<b>1.823</b>	<b>253.342</b>	<b>255.165</b>

All capitalised development costs are related to development work in progress.

## 5. Contingent liabilities

Drugrecure ApS has no contingent liabilities as of 31st December 2018.

## 6. Contractual obligations and pending litigations

Drugrecure ApS has no contractual obligations nor pending litigations as of 31 December 2018.

# Notes

DKK thousand

## **7. Related parties and ownership**

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.

## **8. 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 2018