Saniona A/S

Baltorpvej 154

2750 Ballerup

Central Business Registration No 34049610

Annual Report 2019

The Annual General Meeting adopted the annual report on 06.05.2020

Chairman of the General Meeting

Name: Søren Skjærbæk

Contents

Entity details

Saniona A/S

Baltorpvej 154

2750 Ballerup

Central Business Registration No: 34049610

Registered in: Ballerup

Financial year: 01.01.2019 – 31.12.2019

Board of Directors

Joseph Donald deBethizy, Chairman

Claus Tycho Bræstrup

Karl Johan Bertil Sundberg

Anna Helena Constance Ljung

Edward Saltzman

Jørgen Drejer

Executive Board

Rami Levin, CEO

Auditors

Deloitte Statsautoriseret Revisionspartnerselskab

Weidekampsgade 6

P.O. Box 1600

0900 Copenhagen C

Statement by Management on the annual report

The Board of Directors and the Executive Board have today considered and approved the annual report of Saniona A/S for the financial year 01.01.2019 - 31.12.2019.

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

In our opinion, the financial statements give a true and fair view of the Entity's financial position at 31.12.2019 and of the results of its operations for the financial year 01.01.2019 - 31.12.2019.

We believe that the management commentary contains a fair review of the affairs and conditions referred to therein.

We recommend the annual report for adoption at the Annual General Meeting.

Ballerup, 15.04.2020

Executive Board

Rami Levin

CEO

Board of Directors

Joseph Donald deBethizy Chairman	Claus Tycho Bræstrup	Karl Johan Bertil Sundberg
Jørgen Drejer	Anna Helena Constance Ljung	Edward Saltzman

Independent auditor's report

To the shareholders of Saniona A/S

Opinion

We have audited the financial statements of Saniona A/S for the financial year 01.01.2019 - 31.12.2019, which comprise the income statement, balance sheet, statement of changes in equity and notes, including a summary of significant 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 Entity's financial position at 31.12.2019 and of the results of its operations for the financial year 01.01.2019 - 31.12.2019 in accordance with the Danish Financial statements Act.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs) and 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 this auditor's report. We are independent of the Entity in accordance with the International Ethics Standards Board of Accountants' Code of Ethics for Professional Accountants (IESBA Code) 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.

Management's 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, and for such internal control as 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 Entity's ability to continue as a going concern, for disclosing, as applicable, matters related to going concern, and for using the going concern basis of accounting in preparing the financial statements unless Management either intends to liquidate the Entity 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 exits. 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 judgement and maintain professional scepticism 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 Entity'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 Entity'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 Entity to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures in the notes, 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.

Statement on the management commentary

Management is responsible for the management commentary.

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

Moreover, 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 conclude that the management commentary is in accordance with the financial statements and has been prepared in accordance with the requirements of the Danish Financial statements Act. We did not identify any material misstatement of the management commentary.

Copenhagen, 15.04.2020

Deloitte

Statsautoriseret Revisionspartnerselskab

Central Business Registration No: 33963556

Thomas Hermann

State Authorised Public Accountant

Identification number (MNE) mne26740

Management commentary

Letter from the CEO

It is an honor to assume the role as President and Chief Executive Officer of Saniona, and thus to introduce the Annual Report for the first time.

I am thrilled to accept the challenge of leading the company through a transformative and exciting time in its development as we move Tesomet towards pivotal clinical trials in rare eating disorders Prader Willi Syndrome (PWS) and Hypothalamic Obesity (HO), and ultimately advance towards market approval and commercialization.

In 2019, we updated and refocused our global strategy with the overall aim of transforming Saniona from a research-focused to a clinical development organization. Our objective was to build a combined drug development and commercial organization focused on rare diseases of the central nervous system, while capitalizing on opportunities to partner with companies on programs in larger therapeutic areas, which we do not intend to develop internally. This strategy ensures a continuing future revenue stream from the commercialization of Saniona’s core products as well as non-dilutive funding in the form of royalties from out-licensing and partnerships.

Our first focus is building a U.S-based, fully integrated organization to address key future opportunities. This will be a vital step towards our longer-term aim of becoming a global company. As part of these efforts, we are currently preparing and planning for commercialization, with an initial focus on the U.S. which is the largest market in the world. Being Boston-based, I will leverage my presence in the U.S. while also working to expand our management presence in the U.S. with an ongoing CFO search.

We will also build our capabilities to support late-stage clinical development for rare diseases, first with a U.S.-based Chief Medical Officer and Head of Clinical Development, which will then be followed with a comprehensive clinical team in the U.S. In 2019, Saniona made significant progress towards our strategic targets. On our proprietary drugs in development, we reported positive Phase 2a results with Tesomet in patients with Prader Willi Syndrome (PWS), which will inform the trial design for the Phase 2b and Phase 3 studies. In addition, Saniona initiated a double-blind placebo-controlled phase 2 study in Hypothalamic obesity (HO) for 24 weeks followed by an additional 24 weeks of an open label phase, where all patients were offered the opportunity to switch to active treatment. Top-line results from the double-blind part of the ongoing Phase 2 in HO are expected in Q2 2020.

We have successfully completed a full regulatory preclinical toxicological program for our first in class compound, SAN711, which offers a new treatment paradigm for rare neuropathic itching disorders such as brachioradial pruritus; and we selected a development candidate, SAN903, in the IK potassium channel program for treatment of rare inflammatory and fibrotic disorders such as idiopathic pulmonary fibrosis.

On our out-licensing and partnerships, our partner Medix has submitted a New Drug Application to the Mexican regulatory authority for approval of tesofensine for the treatment of patients with obesity. With an expected 2020 launch, Saniona would be entitled to double digit royalties on product sales, creating an important source or revenue for the Company.

Saniona has a unique ion channel discovery platform that fuels its future internal proprietary pipeline and also creates partnership and out licensing opportunities. I am proud of our leading ion channel drug discovery team which has delivered numerous first in class drug candidates addressing significant medical needs in the rare disease space and also in broader indications developed with partners. Our partner Cadent Therapeutics has completed a Phase 2a study of CAD-1883 in essential tremor with positive results and received acceptance of an Investigational New Drug (IND) application for a Phase 2a study in ataxia, which is a lack of voluntary coordination of muscle movements. Cadent Therapeutics also intends to explore a third, undisclosed indication. Our partner Boehringer Ingelheim continues its preclinical development program of Saniona candidates in Schizophrenia.

The opportunity at Saniona is truly exciting and I am privileged to take the helm at an emerging leader in ion channel drug discovery, development and eventually commercialization. I look forward to collaborating with the team who have unparalleled experience and skill in this domain.

As you can see, we have built a strong foundation for the transformation of Saniona into the next phase of its history. We have highly promising products moving towards commercialization and are expanding our incredible team to capitalize on these outstanding opportunities.

I look forward to speaking with you regularly and keeping you up to date as Saniona becomes a fully integrated biopharmaceutical company focused on rare diseases of the central nervous system.

Rami Levin

President & CEO, Saniona

Primary activities
Saniona is a rare disease biopharmaceutical company focused on research, development and commercialization of treatments for the central nervous system. The company has four programs in clinical development. Saniona intends to develop and commercialize treatments for rare disease indications such as Prader-Willi syndrome and hypothalamic obesity on its own. The research is focused on ion channels and the company has a broad portfolio of research programs.

Our vision
To become a leading global rare disease biopharmaceutical company focused on treatments for the central nervous system.

Our mission
To deliver innovative therapies to patients with rare diseases including Prader-Willi syndrome and hypothalamic obesity.

Saniona's focus is on the development and commercialization of proprietary products for the treatment of rare diseases with high unmet medical need. Saniona is currently developing Tesomet for Prader-Willi syndrome and hypothalamic obesity in the U.S. and Europe. The required investments for developing Tesomet in these indications are comparatively small, while the required commercial infrastructure for servicing these patients in the U.S. and Europe is manageable.

Saniona also has research partnerships with other pharmaceutical companies and is developing products internally with the aim of out licensing the products to pharmaceutical companies for later stage development or commercialization. The structure of Saniona's partnership and out licensing agreements vary by product, indication, the investment and risk, as well as the interest and capabilities of Saniona's partners. Saniona can either grant its partners commercial license to a limited territory or globally. In exchange, the partners typically finance future research and development activities along with upfront payments, research funding, milestone payments and royalties on future product sales when the product candidates are commercialized.

Group relations
The company became part of a group on 30 January 2014, where the parent company, Saniona AB, acquired 100 % of the shares in the company. Saniona AB does not have any business other than owning shares in the company. The group is listed on Nasdaq Stockholm First North Premier. The group's share is traded under the ISIN code SE0005794617.The group is a research and development company focused on drugs for diseases of the central nervous system, autoimmune diseases, metabolic diseases and treatment of pain.

Development in activities and finances
In 2019, the company reported revenues and other operating income of DKK 2,952 thousand in total and net loss before tax of DKK 71,344 thousand. The company had positive equity of DKK 7,774 thousand at the end of 2019. The company is financed through loans from the parent company and collaboration agreements.

Saniona is in an expansion phase where the company will continue to invest significant resources in research and development aiming at generating future income. Saniona intends to finance its operations for the next 12 months through available cash and other assets, as well as revenues from current collaboration agreements. Should the opportunity rise for faster growth, Saniona may raise additional capital through issuing new shares. Also, warrants such as in the financing agreement with Formue Nord entered in January 2020 can be used.

Events after the balance sheet date
An outbreak of an infectious disease, a pandemic or a similar public health threat, such as the recent outbreak of the novel coronavirus known as COVID-19, could adversely impact the company by causing operating, clinical trial and project development delays and disruptions, labour shortages, travel and shipping disruption and shutdowns (including as a result of government regulation and prevention measures). The Company may incur expenses or delays relating to such events outside of its control, which could have a material adverse impact on its business, operating results and the company's ability to raise capital.

To date, Saniona's clinical trials have not been impacted by COVID-19. The hypothalamic obesity phase 2 clinical trial, the last active clinical trial we currently have, was able to conclude and close in March 2020 despite COVID-19 Pandemic.

- On January 7, 2020, Saniona appointed Rami Levin as President and Chief Executive Officer. Rami Levin will oversee the transition of Saniona to a fully-fledged biopharmaceutical company. He has extensive commercial experience in CNS and rare diseases, both in U.S and globally. Jørgen Drejer, previous CEO, will continue in the role of Chief Scientific Officer.
- In January 2020 Saniona, Inc. was registered in the commonwealth of Massachusetts, U.S.A.
- On January 10, 2020, Saniona completed a private placement of SEK 25 million and proposed a financing of up to SEK 158 million comprising a combination of the directed issue and rights issue of warrants totaling SEK 111 million – 133 million at a strike price of SEK 25 – 30 per share as well as a loan facility of SEK 25 million.
- On February 7, 2020, the extraordinary shareholders' meeting resolved on approval of the board of directors' proposed financing comprising a combination of the directed issue and rights issue of warrants. Furthermore, the extraordinary shareholders meeting resolved to adopt an employee option program for the CEO, Rami Levin, involving the allotment of a maximum of 710,313 employee options.
- On February 14, 2020, Saniona published prospectus relating to the rights issue of units.
- On February 18, 2020, Saniona co-founds new migraine therapy company Cephagenix.
- On February 18, 2020, Saniona announced CFO Thomas Feldthus will be departing the company and Saniona initiated search for new, U.S.-based CFO.
- On February 19, 2020, Saniona publishes supplementary prospectus.
- On March 4, 2020, Saniona publishes that the rights issue of free-of-payment units is oversubscribed.
- On March 24, 2020, Saniona announced that Anita Milland, VP of Finance & Administration is appointed as interim CFO and Head of IR, and Jørgen Drejer is appointed deputy CEO.
- On March 26, 2020, Saniona enters into second collaboration agreement with Boehringer Ingelheim in schizophrenia.

Income statement for 2019

DKK	Notes	2019	2018
Revenue		1,890,378	39,537,696
Other operating income		1,061,640	1,060,830
Costs of raw materials and consumables		(2,322,935)	(2,773,928)
Other external expenses		(48,490,076)	(54,538,910)
Gross profit/loss		(47,860,993)	(16,714,312)
Staff costs	1	(17,397,484)	(17,014,894)
Depreciation, amortization and impairment losses		(1,550,695)	(461,162)
Operating profit/loss		**(66,809,172)**	**(34,190,368)**
Other financial income	2	1,712,892	2,318,678
Other financial expenses	3	(6,247,506)	(1,469,947)
Profit/loss before tax		**(71,343,786)**	**(33,341,637)**
Tax on profit/loss for the year	4	5,503,294	5,366,810
Profit/loss for the year		**(65,840,492)**	**(27,974,827)**
Proposed distribution of profit/loss			
Retained earnings		(65,840,492)	(27,974,827)
		(65,840,492)	(27,974,827)

Balance sheet at 31.12.2019

DKK	Notes	2019	2018
Land and buildings		-	-
Other fixtures and fittings, tools and equipment		2,444,538	1,313,300
Leasehold improvements		-	24,589
Property, plant and equipment	5	**2,444,538**	**1,337,889**
Other receivables		901,869	2,906,072
Deferred tax		48,103	44,809
Fixed asset investments	6	**949,972**	**2,950,881**
Fixed assets		**3,394,510**	**4,288,770**
Trade receivables		-	1,521,282
Other receivables		2,966,889	3,195,157
Income tax receivable		5,500,000	5,500,000
Prepayments		544,006	507,669
Receivables		**9,010,895**	**10,724,108**
Cash		**21,727,483**	**29,973,070**
Current assets		**30,738,378**	**40,697,178**
Assets		**34,132,888**	**44,985,948**

Balance sheet at 31.12.2019

DKK	Notes	2019	2018
Contributed capital		502,000	501,000
Other reserves		2,743,613	1,623,265
Retained earnings		4,528,228	(65,731,740)
Equity		**7,773,841**	**(63,607,475)**
Payables to group enterprises		-	81,702,997
Lease liabilities		1,016,934	-
Other payables	8	520,178	-
Non-current liabilities	7	**1,537,112**	**81,702,997**
Current portion of non-current liabilities other than provisions	7	464,617	-
Trade payables		21,424,245	5,263,829
Other payables		2,165,100	2,772,397
Deferred income		767,973	18,854,200
Current liabilities other than provisions		**24,821,935**	**26,890,426**
Liabilities other than provisions		**26,359,047**	**108,593,423**
Equity and liabilities		**34,132,888**	**44,985,948**
Unrecognized rental and lease commitments	9		
Related parties with controlling interest	10		

Statement of changes in equity for 2019

DKK	Contributed capital	Other reserves	Retained earnings	Total
Equity beginning of year	501,000	1,623,264	(65,731,739)	(63,607,475)
Increase of capital	1,000	-	136,100,459	136,101,459
Other equity postings	-	1,120,349	-	1,120,349
Profit/loss of the year	-	-	(65,840,492)	(65,840,492)
Equity end of year	**502,000**	**2,743,613**	**4,528,228**	**7,773,841**

Notes

1. Staff costs

DKK	2019	2018
Wages and salaries	15,915,369	15,345,206
Pension costs	1,208,718	1,247,276
Other social security costs	-110,372	44,507
Other staff costs	383,769	377,905
	17,397,484	**17,014,894**
Average number of employees	**23**	**24**

Share based payments

A detailed description of the warrant program for 2017 and 2018 can be found in the annual report for 2018.

2019:1 The 2019 Annual General Meeting voted in favor of establishing an employee incentive program involving the allotment of a maximum of 34,500 options free of charge to certain employees and consultants of the Group. Allotment of 34,500 options took place in September 2019. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 17.86. The options are earned gradually over a period of 48 months. Holders can take advantage of assigned and earned stock options during 30 days from the day following the publication of the Group's quarterly reports, or in the case of full-year, full-year report, for the first time after publication of the quarterly report for the first quarter of 2023 and last time after publication of the quarterly report for the third quarter of 2024.

2019:2 The 2019 Annual General Meeting voted in favor of establishing an employee incentive program involving the allotment of a maximum of 12,000 options free of charge to certain members of the board of directors of the Group. Allotment of 12,000 options took place in September 2019. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 17.86. 1/3 of the options are vested when the annual shareholders' meeting takes place in 2020. Additional 1/3 of the options are vested when the annual shareholders' meeting takes place in 2021 and the last 1/3 of the options are vested when the annual shareholders' meeting takes place in 2022. The holder can take advantage of assigned and earned stock options during 30 days from the day following the publication of the Group's quarterly reports, or in for full-year, the year-end report, the first time after publication of the quarterly report for the first quarter of 2022 and last time after publication of the quarterly report for the first quarter of 2023. In order to enable the Parent Company's delivery of shares under the option program and to secure social security charges which may arise in connection with the Option Program, the extraordinary shareholders' meeting resolved to issue a maximum of 15,770 warrants to a wholly owned subsidiary in the Group.

<u>General terms</u>

In case the Option Holder terminates the employment without the company being in material breach of the employment agreement or in case the Subsidiary terminates or expels the Option Holder due to the Option Holder's breach of the employment agreement, all rights to allotted unexercised Options expire at the time the employment terminates/ceases, without separate notice or consideration and irrespective of whether or not the Options are vested.

No program is subject to any profit or market conditions.

The fair value of the options was determined using the Black-Scholes pricing model. The data below has been used for the calculation.

Incentive program	2017	2018:1	2018:2	2018:3	2019:1	2019:2
Allotted options	38,750	286,003	34,500	10,513	34,500	15,770
Fair value per option (SEK)	29.48	12.67	18.89	18.89	7.55	6.69
Share price for underlying shares (SEK)	45.50	26.95	33.85	33.85	17.76	17.76
Subscription price (SEK)	41.13	33.60	30.08	30.08	17.86	17.86
Vesting period	4 years	3 years	4 years	3 years	4 years	3 years
Estimated life of the option	5.50 years	6.25 years	5.5 years	4 years	5.5 years	4 years
Risk-free interest rate during the life of the option	-0.0584%	0.2389%	-0.0713%	-0.0356%	-0.6929%	-0.6995%
Assumed volatility*	76.75%	57.41%	63.58%	63.58%	51.03%	51.03%
Expected dividends	0	0	0	0	0	0

** In 2017, the volatility equals the historical volatility for the longest period where trading activity is available (for the period since listing at the Spotlight Stock Market on April 22, 2014 to date of grant). In 2018 and 2019, the volatility equals a twelve-month period.*

Share-based compensation expenses for the full year of 2019 totaled DKK 1,120 (1,099) thousand. The Group accounts for share-based compensation by recognizing compensation expenses related to share-based instruments granted to the board, management, employees and consultants in the income statement. Such compensation expenses represent the fair market values of warrants granted and do not represent actual cash expenditures.

According to the table below, the Group had 417,870 (433,308) options outstanding as of December 31, 2019. If all issued warrants are exercised for subscription of new shares, the Parent Company's will issue a total of 417,870 new shares corresponding to a dilution of approximately 1.47%.

	Options allotted in 2015	Options allotted in 2017	Options allotted in 2018	Options allotted in 2019	Total
Share-based payment					
Outstanding at 1 January 2019	64,000	38,292	331,016	-	433,308
Granted during the period	-	-	-	50,270	50,270
Exercise during the period	-3,998*	-	-	-	-3,998
Expired	60,002	-	-	-	-60,002
Forfeited during the period	-	-	-1,708	-	-1,708
Outstanding at 31 December 2019	**0**	**38,292**	**329,308**	**50,270**	**417,870**
Exercisable options at 31 December 2019					**0**

** The subscription price for the options and the number of shares that each option entitles to subscription of, have been recalculated as a result of the rights issue. The 3,998 options granted in 2015 equal to 4,078 shares, which have been exercised in November 2019.*

The weighted average share price at the date of exercise for share options, exercised during the period was SEK 28.67 per share option (no options were exercised in 2018). The number of exercisable options at the end of the year is 0 (64,000). Outstanding options have a weighted average remaining contractual life of 2.67 (3.00) years.

Incentive program after rights issue**	2017	2018:1	2018:2	2018:3	2019:1	2019:2
Allotted options	38,750	286,003	34,500	10,513	34,500	15,770
Subscriptions price after rights issue (SEK)	40.71	33.26	29.77	29.77		
Equal to no of shares	39,525	291,723	35,190	10,723	34,500	15,770

*** The subscription price for the options and the number of shares that each option entitles to subscription of have been recalculated as a result of the rights issue.*

During 2019, the Group re-priced certain of its outstanding options. The strike price was, due to result of a right issue increased in accordance to above table.

The Board of Directors and Executive Management options in the Company as of December 31, 2019.

	Beginning	Granted	Total
Share-based payment			
Joseph Donald deBethizy, chairman of the board	217,625	-	217,625
Anna Helena Constance Ljung, board member	4,000	4,000	8,000
Edward Saltzman, board member	-	4,000	4,000
Karl Johan Bertil Sundberg, board member	4,000	4,000	8,000
Social security charges	70,891	3,770	74,661
Outstanding at 31 December 2019	**296,516**	**15,770**	**312,286**

Note 2 Financial income

DKK	2019	2018
Foreign exchange gains	1,712,891	2,318,678
Total	**1,712,892**	**2,318,678**

Note 3 Financial expenses

DKK	2019	2018
Interest expense associates	6,095,205	1,384,702
Interest expense	152,301	57,208
Foreign exchange losses	-	28,037
Total	**6,247,506**	**1,469,947**

4. Tax on profit/loss for the year

DKK	2019	2018
Tax on current year taxable income	(5,500,000)	(5,500,000)
Correction joined taxation	-	110,584
Change in deferred tax for the year	(3,294)	22,606
	(5,503,294)	**(5,366,810)**

5. Property, plant and equipment

DKK	Other fixtures and fittings, tools and equipment	Land & buildings	Leasehold improve-ments
Cost beginning of year	3,894,778	-	250,276
Additions	1,632,558	3,031,458	-
Disposals	(18,093)	3,031,458	-
Cost end of year	**5,509,243**	**0**	**250,276**
Depreciation and impairment losses beginning of the year	(2,581,478)	-	(225,687)
Depreciation for the year	(497,727)	(1,028,379)	(24,589)
Disposals	14,500	1,028,379	-
Depreciation and impairment losses end of the year	**3,064,705**	**0**	**250,276**
Carrying amount end of year	**2,444,538**	**0**	**0**
Recognised assets not owned by the entity	**1,555,143**	**0**	**0**

6. Fixed asset investments

DKK	Other receivables	Deferred tax
Cost beginning of year	2,906,072	44,809
Additions	186,086	3,294
Disposals	(2,190,289)	-
Cost end of year	**901,869**	**48,103**

7. Non-current liabilities

DKK	Lease liabilities	Other payables
Due within 1 year (2019)	464,617	-
Due within 1 year (2018)	-	-
Due between 1 and 5 years	1,016,934	520,178
More than 5 years	-	-
Total	**1,481,551**	**520,178**

8. Other payables

As of December 31, 2019, Saniona had other payables of DKK 0.5 million (0), which is holiday funds. In Denmark a new Holiday Act come in effect from 1 September 2020. The employee will in the transition year from 1 September 2019 to 21 August 2020 earn holiday funds, which will be frozen until 2021. The holiday funds will be deposit in a new fund “Lønmodtagernes Feriemidler”. Saniona expect to deposit the frozen funds to the fund in 2021.

9. Unrecognised rental and lease commitments

DKK	2019	2018
Hereof liabilities under rental or lease agreements until maturity in total	**745,803**	**830,286**

The above amounts relate to rental of the Group’s domicile in Ballerup Denmark of 8 months, until end of August 2020. The company plans to move to new facilities in Q3 2020.

10. Related parties with controlling interest

The Company has registered the following shareholder to have the controlling interest of the company:
Saniona AB, Sverige, 100 %.

Accounting policies

Reporting class

This annual report has been presented in accordance with the provisions of the Danish Financial Statements Act governing reporting class B enterprises with addition of certain provisions for reporting class C.

Changes in accounting policies

The Entity has decided to change its accounting policy on recognition of leases.

To better achieve a fair presentation of the Entity's financial position and results, leases are recognised in accordance with the accounting principles of the International Financial Reporting Standard IFRS 16 Leases, effective 1 January 2019. IFRS 16 does not distinguish between operating leases and finance leases but requires the recognition of a lease asset (right-of-use asset) and a lease liability when entering into leases, except for leases with a lease term ending within 12 months (short-term leases) and contracts to lease assets of low value.

The effect of the new lease definition

IFRS 16 has changed the definition of a lease, mainly concerning the right to control. According to IFRS 16, the assessment of whether a contract is a lease shall be made in light of the client's right to control the use of an identified asset for a period of time in exchange for consideration. Previously, the assessment was made on the basis of whether the Entity bears all material risks and also has all benefits associated with the ownership of an identified asset.

Application of transition requirements

According to the transition requirements of the Danish Financial Statements Act, the comparative figures are not restated. The change only includes leases stretching into the current financial year.

Moreover, the following transition requirements of IFRS 16 have been applied:

- For leases previously classified as an operating lease, the following is applicable:
  - Lease liabilities are measured at the present value of the remaining lease payments, discounted using the Entity's incremental borrowing rate at the date of initial application on 1 January 2019.
  - Lease assets are measured at an amount equal to the lease liabilities, adjusted by the amount of any prepaid or accrued lease payments.
  - Lease assets are written down to the lower of recoverable amount and carrying amount.
  - Leases for which the lease term ends within 12 months on 1 January 2019 are accounted for in the same way as short-term leases, despite the original lease term, thus not recognised as a lease asset or a lease liability.
  - Direct costs paid at the inception of a lease are excluded from the measurement of the lease assets.

Interpretation of changes in accounting policies due to the application of IFRS 16

Leases previously classified as operating leases

The application of IFRS 16 changes the treatment of leases previously classified as operating leases, thus not recognised in the balance sheet. Lease payments from operating leases were previously recognised on a straight-line basis in the income statement as "Other external expenses" over the lease term.

Lease payments from short-term leases (with a maximum lease term of 12 months and with no option to extend) and contracts to lease assets of low value (e.g. computers and office furniture) are still recognised on a straight-line basis over the term of the contract. The lease payments are recognised as "Other external expenses" in the income statement.

For all other leases:

A. Lease assets and lease liabilities are recognised in the balance sheet, initially measured at the present value of future lease payments.
B. Depreciation and impairment losses on lease assets and interest on lease liabilities are recognised in the income statement.

If the lease contains non-lease components (e.g. a service agreement on the lease assets), such components are recognised separately from the lease payment based on the stand-alone price of the non-lease component.

Lease incentives (e.g. a rent-free period) are recognised as part of the measurement of lease assets and lease liabilities. They were previously recognised on a straight-line basis over the lease term as a reduction in rental expenses.

Lease assets are written down to the lower of recoverable amount and carrying amount, replacing the former requirement of recognising a provision for onerous leases.

Leases previously classified as finance leases

The biggest difference between IFRS 16 and the former practice of recognising assets held under a finance lease is the measurement of any residual value guarantees provided to the lessor by the lessee. In future, only the amount expected to be paid in connection with a residual value guarantee will be recognised. Previously, the maximum guarantee amount was recognised. This change does not have any material impact on the Entity's financial statements.

Monetary effect of changes in accounting policies

The change in accounting policies leads to a reduction in other external expenses by DKK1,119 thousand, an increase in depreciation by DKK1,028 thousand, and an increase in interest expenses by DKK 84 thousand. The total effect of the change in accounting policies amounts to a increase in results for the year before tax of DKK 7 thousand. Tax for the year as a result of the change in accounting policies, consisting of an adjustment of deferred tax, amounts to DKK 2 thousand, after which results for the year after tax are increased by DKK 5 thousand. The balance sheet total is not affected while equity is reduced by DKK 5 thousand at 31 December 2019.

Recognition and measurement

Assets are recognized in the balance sheet when it is probable as a result of a prior event that future economic benefits will flow to the Entity, and the value of the asset can be measured reliably.

Liabilities are recognized in the balance sheet when the Entity has a legal or constructive obligation as a result of a prior event, and it is probable that future economic benefits will flow out of the Entity, and the value of the liability can be measured reliably.

On initial recognition, assets and liabilities are measured at cost. Measurement subsequent to initial recognition is effected as described below for each financial statement item.

Anticipated risks and losses that arise before the time of presentation of the annual report and that confirm or invalidate affairs and conditions existing at the balance sheet date are considered at recognition and measurement.

Income is recognized in the income statement when earned, whereas costs are recognized by the amounts attributable to this financial year.

Leases

A lease asset (right-of-use asset) and a similar lease liability are recognised for all leases for which the Entity is a lessee. However, this policy does not apply to short-term leases (i.e. leases with a lease term ending within 12 months) and contracts to lease assets of low value. For such leases, lease payments are recognised as an expense on a straight-line basis over the lease term.

If the lease contains non-lease components (e.g. a service agreement on the lease assets), such components are recognised separately.

Foreign currency translation

On initial recognition, foreign currency transactions are translated applying the exchange rate at the transaction date. Receivables, payables and other monetary items denominated in foreign currencies that have not been settled at the balance sheet date are translated using the exchange rate at the balance sheet date. Exchange differences that arise between the rate at the transaction date and the rate in effect at the payment date, or the rate at the balance sheet date are recognized in the income statement as financial income or financial expenses.

Income statement

Revenue

Saniona recognizes revenue from the research agreements, development and license agreements, biotech alliances, and other biotech business models. Revenue is measured based on the consideration to which the Saniona expects to be entitled in a contract with a customer and excludes amounts collected on behalf of third parties. Revenue consists of up-front payments, milestone payments, royalties and other income from research, development and license agreements.

Saniona may receive up-front payments upon entering research and development agreements. Up-front payments that are attributable to subsequent research and/or development activities are considered as prepayments and are recognized as contract liabilities and will subsequently be recognized as revenue over the expected contract period, that is revenue recognition over time. Revenue recognition is made linearly over the contract period as there is currently no other better method available to measure progress for the delivery of services under the applicable contract.

Non-refundable up-front payments that are not attributable to subsequent research and/or development activities or other delivery obligations are recognized as revenue when the contracts are signed.

Milestone payments that are attributable to specific milestone events as a consequence of previous research and/or development activities are recognized as revenues at a point in time when it is certain that the milestone criteria have been met, as this is considered to being equivalent with transfer of control.

Any future royalty revenues are recognized as revenue in accordance with the economic substance of agreements.

Costs of raw materials and consumables

Costs of raw materials and consumables comprise the consumption of raw materials and consumables for the financial year after adjustment for changes in inventories of these goods from the beginning to the end of the year. This item includes shrinkage, if any, and ordinary write-downs of the relevant inventories.

Other external expenses

Other external expenses include expenses relating to the Entity’s ordinary activities, including expenses for premises, stationery and office supplies, marketing costs, etc.

Staff costs

Staff costs comprise salaries and wages as well as social security contributions, pension contributions, etc. for entity staff.

Share-based incentive programmes

Share-based incentive programmes in which the employees are offered to buy shares in the immediate parent company (equity-settled share-based payment transactions) are measured at the fair value of the equity instruments at the time of granting and are recognized in the income statement under staff costs at the time of granting. The related counter entry is recognized directly in equity.

The fair value of the equity instruments is calculated using the Black-Scholes formula including the parameters defined in note 1.

Depreciation, amortization and impairment losses

Amortization, depreciation and impairment losses relating to intangible assets and property, plant and equipment comprise amortization, depreciation and impairment losses for the financial year, calculated on the basis of the residual values and useful lives of the individual assets and impairment testing as well as gains and losses from the sale of intangible assets as well as property, plant and equipment.

Other financial income

Other financial income comprises dividends etc. received on other investments, interest income, including interest income on receivables from group enterprises, net capital gains on securities, payables and transactions in foreign currencies, amortization of financial assets as well as tax relief under the Danish Tax Prepayment Scheme etc.

Other financial expenses

Other financial expenses comprise interest expenses, including interest expenses on payables to group enterprises, net capital losses on securities, payables and transactions in foreign currencies, amortization of financial liabilities as well as tax surcharge under the Danish Tax Prepayment Scheme etc.

Tax on profit/loss for the year

Tax for the year, which consists of current tax for the year and changes in deferred tax, is recognized in the income statement by the portion attributable to the profit for the year and recognized directly in equity by the portion attributable to entries directly in equity.

Balance sheet

Property, plant and equipment

Land and buildings, other fixtures and fittings, tools and equipment are measured at cost less accumulated depreciation and impairment losses.

Cost comprises the acquisition price, costs directly attributable to the acquisition and preparation costs of the asset until the time when it is ready to be put into operation.

The basis of depreciation is cost less estimated residual value after the end of useful life. Straight-line depreciation is made on the basis of the following estimated useful lives of the assets:

Land and buildings (lease assets)	3 years
Other fixtures and fittings, tools and equipment	1-10 years
Leasehold improvements	5 years

For leasehold improvements, the depreciation period cannot exceed the contract period.

Items of plant and equipment are written down to the lower of recoverable amount and carrying amount.

Lease assets

On initial recognition, lease assets are measured at the amount of the initial measurement of the lease liabilities, any lease payments made before the commencement date less any lease incentives received, and any initial direct costs incurred by the lessee.

An estimate of costs to be incurred by the lessee in dismantling and removing the lease as-sets, or restoring the underlying assets, are recognised as a separate provision. The costs are added to the cost of the lease assets. Subsequently, lease assets are measured at cost less accumulated depreciation and impairment losses.

Lease assets are depreciated over the lower of the lease term and the useful life of the under-lying assets. If the lease transfers the ownership of the lease assets by the end of the lease term or if the exercise of a purchase option is expected, the lease assets are depreciated over their useful life. Depreciation begins at the commencement date.

Lease assets are written down to the lower of recoverable amount and carrying amount

Lease assets are adjusted upon remeasurement of the lease liabilities; see below in the lease liability section.

Lease assets are recognised as fixed assets within the asset item in which the underlying as-sets of the lease would be recognised if the Entity owned them.

Receivables

Receivables are measured at amortized cost, usually equaling nominal value less write-downs for bad and doubtful debts.

Deferred tax

Deferred tax is recognized on all temporary differences between the carrying amount and tax-based value of assets and liabilities, for which the tax-based value of assets is calculated based on the planned use of each asset.

Deferred tax assets, including the tax base of tax loss carryforwards, are recognized in the balance sheet at their estimated realizable value, either as a set-off against deferred tax liabilities or as net tax assets.

Income tax payable or receivable

Current tax payable or receivable is recognized in the balance sheet, stated as tax computed on this year's taxable income, adjusted for prepaid tax.

Prepayments

Prepayments comprise incurred costs relating to subsequent financial years. Prepayments are measured at cost.

Cash

Cash comprises cash in hand and bank deposits.

Lease liabilities

On initial recognition, lease liabilities are measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease. If that rate cannot be readily determined, the Entity's incremental borrowing rate shall be used.

Lease payments included in the measurement of the lease liability comprise the following payments:

- Fixed payments less any lease incentives provided by the lessor to the lessee.
- Variable lease payments that depend on an index or a rate, initially measured using the index or rate as at the commencement date.
- Amounts expected to be payable under residual value guarantees.
- The exercise price of a purchase option if it is reasonably certain to exercise that option.
- Payments of penalties for terminating the lease if the lease term reflects the lessee exercising an option to terminate the lease.

Variable lease payments that depend on an index or a rate are recognised in the income statement as "Other external expenses" in the period in which the event or the circumstance triggering the payments in question takes place.

On subsequent measurement, lease liabilities are adjusted for accrued interest and repayments made, calculated by the effective interest rate method.

Lease liabilities are remeasured and the corresponding lease assets are similarly adjusted when:

- There is a change in the lease term, e.g. as a result of a change in the assessment of whether an option to extend or to purchase will be exercised. Remeasurement takes place by discounting the revised lease payments using a discount rate revised at the time of changing the lease.
- There is a change in lease payments resulting from a change in an index or a rate, or in the amounts expected to be payable under a residual value guarantee. Remeasurement takes place by discounting the revised lease payments using the original discount rate. However, a revised discount rate is used if the change reflects a change in the floating interest rate.
- There is a lease modification that is not accounted for as a separate lease. Remeasurement takes place by discounting the revised lease payments using a revised discount rate.

If the remeasurement results in the reduction of a lease liability exceeding the carrying amount of the corresponding lease asset, the excess amount is recognised in the income statement.

Other financial liabilities

Other financial liabilities are measured at amortized cost, which usually corresponds to nominal value.

Deferred income

Deferred income comprises income received for recognition in subsequent financial years. Deferred income is measured at cost.