Saniona A/S
Smedeland 26B
2600 Glostrup
Central Business Registration No 34049610

Annual Report 2020

The Annual General Meeting adopted the annual report on June 2, 2021

Chairman of the General Meeting

____

Name: Søren Skjærbæk

Contents

Entity details

Saniona A/S

Smedeland 26B

2600 Glostrup

Central Business Registration No: 34049610

Registered in: Albertslund

Financial year: 01.01.2020 – 31.12.2020

Board of Directors

Joseph Donald deBethizy, Chairman

Karl Johan Bertil Sundberg

Anna Helena Constance Ljung

Edward Saltzman

Jørgen Drejer

Executive Board

Rami Levin, CEO

Auditors

Deloitte Statsautoriseret Revisionspartnerselskab

Weidekampsgade 6

2300 Copenhagen S

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 01.01.2020 - 31.12.2020.

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 31.12.2020 and of the results of its operations for the financial year 01.01.2020 - 31.12.2020.

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.

Glostrup, 02.07.2021

Executive Board

Rami Levin

President & CEO

Board of Directors

Joseph Donald deBethizy	Karl Johan Bertil Sundberg	
Chairman		
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 01.01.2020 - 31.12.2020, 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 31.12.2020 and of the results of its operations for the financial year 01.01.2020 - 31.12.2020 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.

Emphasis of matter in the financial statements

As discussed in Accounting policies, the comparative 2019 financial statements have been restated to correct certain misstatements. Our conclusion is not modified as a result of this matter.

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, 02.07.2021

Deloitte

Statsautoriseret Revisionspartnerselskab

Central Business Registration No: 33963556

Lars Hansen

State Authorised Public Accountant

Identification number (MNE) mne24828

Management commentary

Letter from the CEO

2020 was an unprecedented year on many fronts. First and foremost, the entire world spent much of the year battling the COVID-19 pandemic, which wreaked havoc on the healthcare system and families across the globe. I am incredibly proud of how the Saniona team adapted to efficiently continue our work under ever-changing public health guidelines across our global locations, prioritizing the safety of our employees and the patients and physicians who participate in our clinical studies. We were able to complete our Phase 2 clinical trial of Tesomet for hypothalamic obesity despite the pandemic, and we continued to have productive discussions with the FDA to align on plans for future clinical trials.

The past year has been unprecedented for Saniona as well. One of my first areas of focus after I joined the company as President and CEO in January was to define the business strategy moving forward. I knew that in order to optimize value, Saniona needed to become a fully-integrated biopharmaceutical company with the ability to discover, develop and commercialize our own innovative treatments for rare diseases. Thus, shifting our business model became one of my highest priorities. We needed to transition from focusing on external collaborations to the internal development of our own proprietary compounds. To execute on this strategy, we required a significant amount of funding to conduct mid-stage clinical trials of Tesomet for hypothalamic obesity (HO) and Prader-Willi syndrome (PWS), and it was critical that we increase our presence in the U.S. to facilitate our access to its established regulatory pathways, well-developed rare disease market, and extensive healthcare investor base.

I am proud to say that we achieved these goals in 2020. First, Saniona AB raised USD $65 million (approximately DKK 412 million) through a direct issue of shares with syndicate of U.S. and international institutional investors including RA Capital Management, Pontifax Venture Capital, New Leaf Venture Partners, multiple Swedish National Pension Funds, and others. The majority of these investors have proven to be long-term, committed shareholders who continue to have confidence in Saniona's prospects. We are currently well-funded to execute on our current strategy into the second half of 2022. Second, we hired a very experienced U.S.-based executive team and several additional key positions to provide us with the clinical, financial, legal and other expertise we need to succeed.

In addition to these two key achievements, Saniona met several important milestones in 2020. We reported positive results from both the double-blind and the open label extension portions of the Phase 2 study of Tesomet in HO. We engaged with the FDA in multiple productive discussions clarifying our regulatory path forward in both HO and PWS. We aligned with the FDA on conducting Phase 2b trials of Tesomet in PWS and HO, and we started to prepare for our Phase 1 trial of SAN711 in rare neuropathic disorders; all three studies are expected to start this year. We also saw value realized in early 2021 from some of our out-licensing agreements, as evidenced by the USD $2.9 million (DKK 17.8 million) upfront payment we received due to Cadent Therapeutics' acquisition by Novartis, and the royalty we will begin to receive pending Medix's approval of tesofensine for chronic weight management in Mexico.

I said in an interview earlier this year that Saniona is currently in the strongest position the company has ever been in. Saniona Group has a strong cash runway to last us into the second half of 2022, and we have the financial and operational support as well as the necessary expertise to advance our strategic activities. We are poised to begin three new clinical trials, and our ion channel drug discovery engine continues to generate proprietary compounds to fill our pipeline. Saniona AB also continue to assess our opportunity to access the U.S. capital market through a U.S. Nasdaq listing – and the interest from potential institutional investors on this front is encouraging. `

Overall, I am incredibly proud of the progress Saniona has made in 2020, and I am excited about the potential I see ahead to achieve milestones and create value in 2021 and beyond. We appreciate the continued support from all our shareholders during the past year. We remain confident in the potential of Tesomet and our ion-channel discovery engine, and I look forward to providing continued updates in 2021 as we execute on our strategic initiatives and identify opportunities to increase value for patients and for shareholders.

Rami Levin

President & CEO, Saniona

Our core values

Put People First
Treat all people with kindness, respect and equity. Support people on their journey and enable a sense of belonging.

Innovation with Impact
Push boundaries with courage. Embrace empowerment. And deliver excellence.

Integrity, Always
Maintain the highest ethical standards in all that we do as we deliver with urgency for patients in need.

Our strategy
Discovering, developing and delivering innovative rare disease treatments
Saniona's focus is on the discovery, development and delivery of proprietary product candidates for the treatment of rare diseases with high unmet medical need. We believe our research, clinical development, and commercial expertise, and our ability to leverage our ion channel research engine, will enable us to advance Tesomet and generate a robust pipeline of clinical candidates with preferred pharmacological properties that we believe will make a meaningful difference in the lives of patients.

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.

Saniona A/S established Saniona Inc in January 2020 and owns 100% of the shares in the company.

About Saniona
Saniona is a biopharmaceutical company focused on discovering, developing, and delivering innovative treatments for rare disease patients around the world. The company's lead product candidate, Tesomet, is in mid-stage clinical trials for hypothalamic obesity and Prader-Willi syndrome, severe rare disorders characterized by uncontrollable hunger and intractable weight gain. Saniona's robust drug discovery engine has generated a library now consisting of more than 20,000 proprietary modulators of ion channels, a significantly untapped drug class that is scientifically validated. Lead candidate SAN711 is entering Phase 1 for rare neuropathic disorders, with SAN903 for rare inflammatory and fibrotic disorders advancing through preclinical studies. Led by an experienced scientific and operational team, Saniona has an established research organization in Copenhagen, Denmark and is building its corporate office in the Boston, Massachusetts area, U.S. Saniona AB's shares are listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at www.saniona.com.

Development in activities and finances
In 2020, the company reported revenues and other operating income of DKK 6,664 thousand in total and net loss before tax of DKK 94,032 thousand. The company had positive equity of DKK 458,250 thousand at the end of 2020. The company is financed through loans from the parent company and collaboration agreements. The loan has been converted to equity end of 2020.

Events after the balance sheet date

- On January 25, 2021: Saniona received approximately USD $2.9 million (DKK 17.8 million) in an upfront payment resulting from the completed acquisition of Cadent Therapeutics by Novartis.
- On March 3, 2021: Saniona received U.S. FDA Orphan Drug Designation for Tesomet in Prader-Willi syndrome.
- On March 8, 2021: Saniona received feedback from the U.S. FDA providing a regulatory path forward for Tesomet in hypothalamic obesity.
- On April 14, 2021: Saniona presented preclinical data on SAN903 in a model of idiopathic pulmonary fibrosis at the American Society of Pharmacology and Experimental Therapeutics (ASPET) Annual Meeting at Experimental Biology (EB) 2021.
- On April 19, 2021: Saniona announced a partnership with the Foundation for Prader-Willi Research (FPWR) to increase awareness about Saniona's upcoming Phase 2b clinical trial of Tesomet for the treatment of PWS.
- On April 21, 2021: Saniona announced the receipt of manufacturing feedback from the FDA that will delay the start of the Tesomet Phase 2b trials into the second half of 2021.
- On May 20, 2021: Saniona hosted a research and development (R&D) day featuring presentations highlighting its ion channel drug discovery engine, including its IONBASE™ database now consisting of more than 20,000 proprietary molecules targeting various ion channels, and data from ion channel modulators SAN711 and SAN903.
- Saniona received a 33.3% ownership stake in Cephagenix, as per the terms of the previously announced February 2020 collaboration agreement through which the company was formed to explore ion channel modulators for the treatment of migraine.
- On June 8, 2021: Saniona present Preclinical Data on SAN711 at the 7th Congress of the European Academy of Neurology.
- On June 25, 2021: Saniona provides update on ongoing review of tesofensine in Mexico.

Income statement for 2020

DKK	Notes	2020	2019
Revenue		5,818,910	5,030,891
Other operating income		845,330	1,061,640
Costs of raw materials and consumables		-6,277,705	-10,598,690
Other external expenses		-48,232,834	-36,117,208
Gross profit/loss		-47,846,300	-40,623,367
Staff costs	1	-28,969,621	-18,104,960
Depreciation, amortization and impairment losses		-2,617,513	-1,550,694
Operating profit/loss		**-79,433,433**	**-60,279,021**
Other financial income	2	24,015,289	1,719,525
Income from other investments		9,718,510	12,544,168
Other financial expenses	3	-48,332,549	-6,247,506
Profit/loss before tax		**-94,032,183**	**-52,262,834**
Tax on profit/loss for the year	4	5,451,897	5,503,294
Profit/loss for the year		**-88,580,286**	**-46,759,540**
Proposed distribution of profit/loss			
Retained earnings		-88,580,286	-46,759,540
		-88,580,286	-46,759,540

Balance sheet

DKK	Notes	2020	2019
Acquired intangible assets		4,500,000	5,500,000
Intangible assets	5	**4,500,000**	**5,500,000**
Other fixtures and fittings, tools and equipment		6,309,209	2,444,538
Leasehold improvements		2,101,550	-
Land and buildings		9,560,777	-
Tangible assets	6	**17,971,536**	**2,444,538**
Investment in subsidiaries	7	356,181,212	-
Other financial assets		1,278,284	28,283
Other investments	8	27,658,985	17,940,476
Financial assets		385,118,481	17,968,759
Other assets	9	379,751	186,086
Deferred tax		-	48,103
Non-current assets		**407,969,767**	**26,147,486**
Trade receivables		3,737,746	666,080
Current tax assets		5,500,000	5,500,000
Other assets		3,890,715	2,089,931
Current receivables		**13,128,461**	**8,256,011**
Cash		**71,509,869**	**21,727,483**
Current assets		**84,638,331**	**29,983,494**
Total assets		**492,608,098**	**56,130,980**

Balance sheet

DKK	Notes	2020	2019
Share capital		503,000	502,000
Other reserves		4,024,318	3,119,474
Retained earnings		453,722,794	23,787,702
Equity		**458,250,112**	**27,409,176**
Other financial liabilities		11,206,922	1,016,934
Other liabilities		1,540,683	520,178
Non-current liabilities	10	**12,747,606**	**1,537,112**
Current portion of non-current liabilities other than provisions	10	3,689,827	464,617
Payables to group enterprises		4,195,781	-
Trade payables		11,109,571	24,315,682
Other financial liabilities		2,003,876	1,331,688
Other liabilities		611,324	1,072,704
Current liabilities		**21,610,380**	**27,184,691**
Total liabilities		**34,357,986**	**28,721,803**
Total equity and liabilities		**492,608,098**	**56,130,980**
Related parties with controlling interest	11		

Statement of changes in equity for 2020

DKK	Share capital	Other reserves	Retained earnings	Shareholders' equity
Equity beginning of year (previously reported)	502,000	2,743,613	4,528,228	7,773,841
Correction of material misstatements		375,861	19,259,474	19,635,335
Equity beginning of year	502,000	3,119,474	23,787,702	27,409,176
Profit/loss of the year			-88,580,286	-88,580,286
Increase of capital	1,000		518,515,379	518,516,379
Share-based compensation expenses		904,844		904,843
Equity end of year	**503,000**	**4,024,318**	**453,722,794**	**458,250,112**

Notes

1. Staff costs

DKK	2020	2019
Wages and salaries	26,747,995	14,795,021
Pension costs	1,209,825	1,208,718
Share-based payment	904,844	1,827,825
Other social security costs	-251,007	-110,372
Other staff costs	357,963	383,769
	28,969,621	**18,104,960**
Average number of employees	**22**	**23**

Share based payments

A detailed description of the warrant program for 2017, 2018 and 2019 can be found in the annual report for 2019.

2020:2 On October 23, 2020, the extraordinary shareholders' meeting in the parent company Saniona AB voted in favor of establishing an employee incentive program involving the allotment of a maximum of 7,976,690 options free of charge (the 'Options Program 2020'). A total of 777,200 options were allotted at various points in time in the fourth quarter of 2020. Each option entitles the holder a right to acquire one new share in Saniona for a subscription price equal to the closing price of our common stock on the day before the allotment. The options are subject to a service condition, 25% vest on the 12-month anniversary, and the remaining 75% vest gradually on a quarterly basis at a rate of 6.25% over the following 36 months, resulting in a total vesting period of 48 months. The holder can exercise vested options from the time of vesting until the date that falls 10 years after the allotment date. However, for a participant that ceases to be employed or in a service relationship in Saniona, vested options have to be exercised within 90 days from the date when the participant ceased to be employed or in a service relationship in Saniona (or, in the case such cessation is due to the participant's death or disability, 12 months from such date).

Share-based compensation expenses for the years ended December 31, 2020 and 2019 totaled DKK 0.9 million and DKK 1.8 million, respectively. The fair value of the service that entitles an employee to allotment of options under the Option Programs is recognized as a personnel cost with a corresponding increase in equity. Such compensation expenses represent the fair market values of options granted and do not represent actual cash expenditures.

Saniona uses the Black-Scholes-Merton model to determine the grant date fair value of its options granted. The estimated life has been based on the average of the end of the vesting period and the contractual life of the respective instruments, absent sufficient Saniona-specific information about employees exercising options. Expected volatility has been based on an evaluation of the historical volatility of the Parent Company's share price, particularly over the historical period commensurate with the estimated life.

Note 2 Financial income

DKK	2020	2019
Foreign exchange gains	-	1,719,523
Financial income from group enterprises	22,108,931	-
Other financial income	1,906,358	-
Total	**24,015,289**	**1,719,523**

Note 3 Financial expenses

DKK	2020	2019
Financial expenses from group enterprises	30,032,135	6,095,205
Interest expense	188,503	55,598
Other financial expenses	340,632	96,696
Foreign exchange losses	17,771,278	-
Total	**48,332,548**	**6,247,506**

4. Tax on profit/loss for the year

DKK	2020	2019
Tax on current year taxable income	5,500,000	5,500,000
Change in deferred tax for the year	48,103	3,294
Total	**5,451,897**	**5,503,294**

5. Intangible assets

DKK	Acquired intangible assets
Cost on January 1	5,500,000
Additions	-
Cost on December 31	**5,500,000**
Depreciation on January 1	-
Depreciation	1,000,000
Depreciation on December 31	**1,000,000**
Carrying amount December 31	**4,500,000**

6. Property, plan and equipment

DKK	Other fixtures and fittings, tools and equipment	Leasehold improve-ments	Land & building	Total
Cost on January 1	5,509,243	250,276	-	5,759,519
Additions	4,517,728	2,203,988	10,429,938	17,151,654
Disposals	-1,007,656	-250,276	-	-1,257,932
Cost on December 31	**9,019,315**	**2,203,988**	**10,429,938**	**21,653,241**
Depreciation on January 1	3,064,705	250,276	-	3,314,981
Depreciation	645,913	102,438	869,162	1,617,513
Disposals	-1,000,513	-250,276	-	-1,250,789
Depreciation on December 31	**2,710,105**	**102,438**	**869,162**	**3,681,705**
Carrying amount December 31	**6,309,210**	**2,101,550**	**9,560,776**	**17,971,536**
Recognised assets not owned by the entity	**5,327,239**		**9,560,776**	

7. Investments in subsidiaries

Direct subsidiary	Share of equity	Share of voting power	Carrying amount in Parent Company DKK
Saniona Inc, 500 Totten Pond Road, Suite 620, Waltham, MA 02451, USA	100%	100%	356,181,212

DKK	2020
Cost on January 1	-
Additions	356,181,212
Disposals	-
Carrying amount December 31	**356,181,212**

8. Other investments

DKK	Other financial assets
Cost of January 1	17,940,475
Additions	9,718,510
Carrying amount December 31	**27,658,985**

9. Other assets

DKK	Other receivables (Restated)	Deferred tax
Cost on January 1	186,086	48,103
Additions	193,665	-
Disposals	-	-48,103
Carrying amount December 31	**379,751**	**0**

10. Non-current liabilities

DKK	Lease liabilities	Other payables*	Total
Less than one year	3,689,827		3,689,827
Between one and five years	11,206,922	1,540,683	12,747,605
More than five years	-		

*As of December 31, 2020, Saniona had other payables of DKK 1.5 million (0.5), 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”.

11. 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

Other investments are measured at fair value at the balance sheet date. Other investments were previously measured at the lower of cost and net realisable value. The comparative figures have been restated to reflect the changed accounting policies.

The change in accounting policies has increased the profit for 2019 by DKK 12.5 million, other investments have increased by DKK 17.9 million, and equity at 1 January 2019 has increased by DKK 5.4 million. The change has not had any tax effect.

Correction of material misstatements

Certain comparative amounts in the income statement and the statement of financial position have been restated, reclassified or re-presented, as a result of a correction of prior-period errors. These restatements have also resulted in changes to the statement of changes in equity.

The total impact of the restatements on selected key performance measures for the year ended December 31, 2019 is as follows:

DKK	2019-01-01 2019-12-31 (Restated)	Adjustments	2019-01-01 2019-12-31 (Previously Reported)
Revenue	5,030,891	3,410,513	1,890,378
Operating loss	(60,279,021)	6,530,151	(66,809,172)
Profit/loss for the period	(46,759,540)	19,080,952	(65,840,492)
Total Assets	56,130,980	21,998,092	34,132,888
Equity	27,409,176	19,635,335	7,773,841

Intangible assets: Saniona purchased certain intellectual property from NeuroSearch between 2012 and 2017. In the third quarter of 2017, we had made a one-time cash payment of DKK 5.5 million to NeuroSearch in connection with the purchased intellectual property. In our Previously Issued Financial Statements, we had recorded the payment as a prepaid asset and presented it within current prepayments. We had amortized it to other external costs over a period of 4 years, resulting in an accumulated amortization of DKK 2.1 million as of January 1, 2019, and an expense of approximately DKK 1.4 million in 2019. Refer to Note 5 Intangible assets for details.

Revenue Boehringer Ingelheim: In August 2016, Saniona had received an upfront payment of DKK 37.2 million from Boehringer Ingelheim (“BI”) as consideration for a license and research collaboration agreement that included options for BI to extend the research collaboration term. The payment had been recognized as revenue in full in 2016 upon receipt. Accordingly, we have derecognized DKK 2.7 million of previously recognized revenue by adjusting our December 31, 2018 retained earnings and recorded it as revenue in the first quarter of 2019. We also derecognized DKK 5.2 million or previously recognized revenue and recorded it as revenue on a straight-line basis over the second and the third quarters of 2019.

***Revenue Medix*:** In 2016, we entered into a license and collaboration agreement with Productos Medix, S.A de S.V. (Medix). Under that agreement, Saniona received an upfront payment and is entitled to receive certain variable consideration when certain events occur. In February 2019, uncertainties pertaining to contingent payments from Medix in the amount of DKK 0.7 million were resolved. In our Previously Issued Consolidated Financial Statements, we had not recognized revenue for these payments. We should have recorded revenue and corresponding trade receivables of DKK 0.7 million in 2019.

***Operating expenses*:** We have adjusted for the allocation of certain costs between prior reporting periods. In addition, we have performed new grant-date valuations of existing share-based payment grants.

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

i. General

Saniona generates revenue from out-licensing of intellectual property and from providing research and development services, either in combination with an out-licensing arrangement, or standalone. For all contracts with customers, Saniona (1) identifies the performance obligations in the contract, (2) determines the transaction price, (3) allocates the transaction price to the performance obligations in the contract, and (4) recognizes revenue when or as Saniona satisfies a performance obligation.

ii. Out-licensing arrangements

For out-licensing arrangements that include promises in addition to the promised license, Saniona determines if the license is ‘distinct’ by assessing whether the customer can benefit from the license on its own or together with other resources that are readily available, and whether the license is separately identifiable from other goods or services in the contract. If the license is not distinct, then Saniona recognizes revenue for the single performance obligation when or as the combined goods or services are transferred to the customer.

If the license is distinct, Saniona determines the nature of the license. If the nature of the promise is to provide the customer with a right to access the Saniona’s intellectual property (‘IP’) throughout the license period, then Saniona recognizes revenue over time, because the customer simultaneously consumes and receives benefit from Saniona’s performance of providing access to its IP as that performance occurs. A promise to provide the customer with a right to use Saniona’s IP is satisfied at a point in time.

iii. Service revenue

Revenue from providing R&D services is recognized when a contractual promise to a customer (performance obligation) has been fulfilled by transferring control over the promised services to the customer.

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

The grant-date fair value of equity-settled share-based payment arrangements granted to employees is generally recognized as an expense, with a corresponding increase in equity, over the vesting period of the awards. The amount recognized as an expense is adjusted to reflect the number of awards for which the related service and non-market performance conditions are expected to be met, such that the amount ultimately recognized is based on the number of awards that meet the related service and non-market performance conditions at the vesting date.

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.

Income from investments in group enterprises

Income from investments in group enterprises includes dividends etc. received from the individual businesses in the financial year

Income from other investments

Income from other financial assets includes returns by way of fair value adjustments etc. of financial assets that are not investments in group enterprises or associates.

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.

Expected useful lives and residual values are reassessed annually.

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.

Investments in group enterprises

Investments in subsidiaries are measured at cost. The investment is written down to the lower of the recoverable amount and the carrying amount.

Other investments

Other securities and investments include unlisted securities, which are measured at fair value at the balance sheet date.

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.