YEAR-END REPORT FOR SANIONA AB (PUBL)
556962-5345
January - December 2019
Published February 7, 2020

Saniona accelerates transformation into fully-fledged biopharmaceutical company focused on rare CNS diseases

Financial highlights

Jan – Dec 2019 (Jan – Dec 2018)

- Net revenues were SEK 2.7 M (54.9 M)
- EBIT was SEK -103.9 M (-54.2 M)
- Net profit/loss was SEK -75.8 M (-41.1 M)
- Earnings per share were SEK -2.95 (-1.84)
- Diluted earnings per share were SEK -2.95 (-1.84)

Q4 2019 (Q4 2018)

- Net revenues were SEK 0.0 M (2.2 M)
- EBIT was SEK -28.1 M (-34.3 M)
- Net profit/loss was SEK -3.4 M (-23.3 M)
- Earnings per share were SEK -0.12 (-1.02)
- Diluted earnings per share were SEK -0.12 (-1.02)

Business highlights in Q4 2019

- Saniona recruited the last patient in the Phase 2a clinical study for Tesomet in hypothalamic obesity (HO). Patients will receive either Tesomet or placebo for 24 weeks followed by an open-label extension study where all patients will receive Tesomet for 24 weeks resulting in a total treatment period of 48 weeks. Saniona expects to report top line results from double-blind part of the study in Q2 2020.
- Saniona's partner Medix submitted a new drug application to the Mexican food and drug administration (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS) for approval of tesofensine for the treatment of patients with obesity. Medix expects to launch the product in Mexico in 2020, which will lead to double digit royalties on product sales.

Significant events after the reporting period

- 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.
- 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.

Comments from the CEO

"Saniona has reached an important inflection point in its development, poised for the approval and commercialization of Tesomet in the rare CNS disorders Prader-Willi Syndrome (PWS) and Hypothalamic Obesity (HO). We made significant progress towards our strategic targets in 2019, with positive and encouraging Phase 2a results with Tesomet in PWS and a continuing Phase 2 trial in HO. This underpins our commitment to bringing Tesomet to the market and to becoming a leading rare disease company, focusing on diseases of the central nervous system by developing new treatments that address significant unmet medical needs," says Rami Levin, President & CEO of Saniona.

For more information, please contact

Thomas Feldthus, EVP and CFO, Saniona, Mobile: +45 2210 9957, E-mail: tf@saniona.com

Letter from the CEO

“It is with great pleasure that I address my first letter to you as President and Chief Executive Officer of Saniona. I am greatly honored and proud to have been asked to take on this role. I look forward to leveraging my experience in bringing treatments to the market in both rare diseases and diseases of the central nervous system to patients who desperately need them.

Saniona has reached an important point in its development and is rapidly advancing Tesomet towards pivotal clinical trials in the rare eating disorders Prader-Willi Syndrome (PWS) and Hypothalamic Obesity (HO). In addition, Saniona also has a unique ion-channel discovery platform to fuel its future pipeline.

Our objective is 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 ourselves. This will ensure a continuing future revenue stream from commercialization of Saniona’s core products as well as royalties from out-licensing and partnerships.

Our first focus is the U.S., where we intend to build up a full-fledged organization to address key future opportunities. This will be a vital step towards our longer-term aim of becoming a global company.

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 PWS, which will inform the trial design for the Phase 2b and Phase 3 studies. Top-line results from the double-blind part of the ongoing Phase 2a in HO are expected in Q2 2020.

We have successfully completed a full regulatory 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 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. Medix expects to launch in 2020, which would create a new revenue stream as Saniona is entitled to double digit royalties on product sales.

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. Cadent Therapeutics has also informed that they intend to explore a third, undisclosed indication. Our partner Boehringer Ingelheim continues its preclinical development in Schizophrenia.

In January, we completed a private placement of SEK 25 million and proposed a financing of up to SEK 158 million, which provides further funds to pursue development of Tesomet in PWS and HO.

Saniona is a truly exciting company, and I am privileged to be able to rely on the skills and experience in place. In particular, I am grateful to Jørgen Drejer for his excellent work in establishing and steering the company. Jørgen is part of the DNA of the company and has an essential role to play as Chief Scientific Officer in developing our pipeline.

In short, Saniona has highly promising products moving towards commercialization and the right team in place to capitalize on these outstanding opportunities as we transform the company into a fully-fledged biopharmaceutical company focused on rare diseases of the central nervous system.”

Rami Levin

President & CEO, Saniona

About Saniona

Saniona (OMX: SANION) focuses on research and development of drugs to treat rare diseases of the central nervous system. Saniona intends to independently develop and commercialize treatments for orphan indications such as Prader-Willi syndrome and hypothalamic obesity. The company currently has three proprietary programs in clinical development and four clinical development programs in partnership. Saniona's drug discovery platform is focused on ion channel research and the company has a broad portfolio of early stage programs. Saniona's partners include Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and Cadent Therapeutics.

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.

Strategy and business model

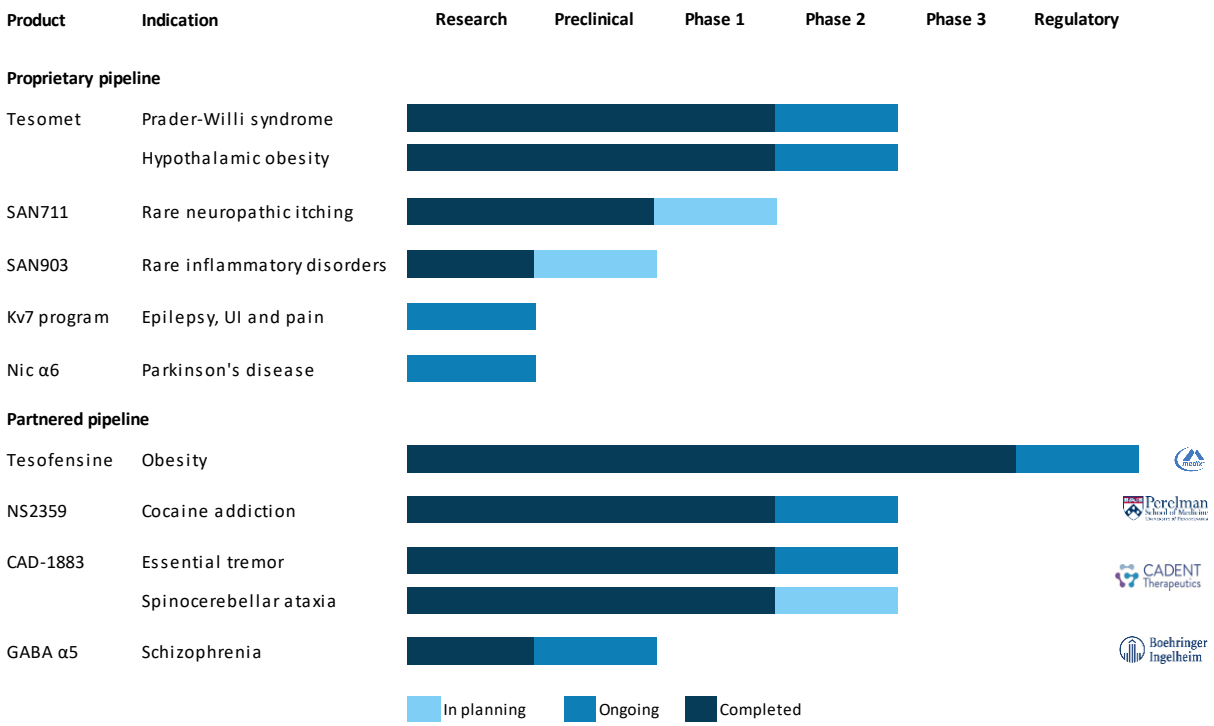
Saniona's focus on the development and commercialization of proprietary products for treatment of rare diseases with high unmet medical need. Saniona is currently developing Tesomet for Prader-Willi syndrome and hypothalamic obesity in the U.S. and Europe. The required investments for developing Tesomet 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 or is developing products internally with the aim of out-licensing the product to a pharmaceutical company at a later stage. The structure of Saniona's partnership agreements depends on the product, the indication, the investment and the 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 and pay Saniona upfront payments, research funding, milestone payments and royalties on product sales when the product candidates are commercialized.

Saniona's short term strategic priorities are set-out below:

- To build internal capabilities in the organization to support late stage clinical development for rare diseases
- To develop and attain market approval for Tesomet in the U.S. and Europe for treatment of the rare eating disorders Prader-Willi syndrome and hypothalamic obesity
- To strengthen the company's position and presence in the U.S.
- To develop at least one drug candidate internally from our unique ion channel research platform
- To leverage our leading position within ion channel research through out-licensing and partnerships with other pharmaceutical companies

Project portfolio



Proprietary pipeline

Saniona's most advanced proprietary clinical program is Tesomet for the treatment of eating disorders. Saniona has completed a dose-finding Phase 2a study proof-of-concept study in PWS and is currently planning for pivotal Phase 2b/3 studies. In parallel Saniona is currently conducting a Phase 2a proof-of-concept study in HO with the aim of preparing for Phase 2b/3 studies in this indication. The goal is to initiate pivotal Phase 2b/3 studies in at least one of the two indications in 2020.

Saniona's early stage pipeline is based on its ion channel platform. Ion channels comprise a unique class of proteins, which, among other things, controls the activity of muscles and nerves and is central to numerous other functions in the body. Saniona has completed the preclinical development of SAN711 for the treatment of chronic itching and neuropathic pain. The program is ready for Phase 1 in rare itching disorders. Saniona has initiated preclinical development for SAN903 in preparation for Phase 1 studies in rare inflammatory disorders or for out-licensing for common inflammatory indications such as IBD. Finally, Saniona has two internal research programs, which are targeting the Kv7 and Nicotinic α6 ion channels and are focused on the treatment of certain neurological diseases including rare and untreatable epilepsy and Parkinson's diseases.

Out-licensing and partnerships

Saniona's most advanced out-licensed program is tesofensine, which is being developed for obesity by Medix. Medix has submitted a new drug application to the Mexican food and drug administration in December 2019 for approval of tesofensine for the treatment of patients with obesity. Medix expects to launch the product in Mexico in 2020. Medix holds an exclusive license to commercialize tesofensine in Mexico and Argentina, while Saniona is entitled to milestone payments and royalties on product sales. Saniona retains commercial rights in the rest of the world and rights to use any data generated from the Phase 3 trial.

Saniona's partner Cadent Therapeutics has completed a Phase 2a study for the treatment of essential tremor and expects to start another Phase 2a study in the first half of 2020 for the treatment of Ataxia. Saniona holds an ownership stake in Cadent and will receive royalties on product sales. The University of Pennsylvania Treatment Research Center (TRC) is conducting an investigator-initiated Phase 2a proof-of-concept study with NS2359 for the treatment of cocaine addiction. The study is financed through grants and Saniona retains commercial rights to the compound and the clinical data developed by TRC. Saniona's partner Boehringer Ingelheim is currently conducting a preclinical development program in preparation for Phase 1 studies in schizophrenia. Saniona has received a total of € 9 million in upfront and milestone payments and is entitled to receive additional € 81 million in milestone payment plus royalties on product sales.

Financial review

Financial key figures

		2019-10-01 2019-12-31	2018-10-01 2018-12-31	2019-01-01 2019-12-31	2018-01-01 2018-12-31
Net sales, KSEK		-	2,216	2,658	54,884
Total operating expenses, KSEK		-28,123	-36,478	-106,563	-109,089
Operating profit/loss, KSEK	*	-28,123	-34,263	-103,906	-54,206
Operating margin, %	*	-	-1546%	-3909%	-99%
Cash flow from operating activities, KSEK		-28.218	-7,579	-98,469	-22,920
Cash flow per share, SEK	*	-1.02	0.44	-0.87	1.11
Earnings per share, SEK		-0.12	-1.02	-2.95	-1.84
Diluted earnings per share, SEK		-0.12	-1.02	-2.95	-1.84
Average shares outstanding		28,410,347	22,850,645	25,719,586	22,288,524
Diluted average shares outstanding		28,427,119	22,877,327	25,732,676	22,314,283
Shares outstanding at the end of the period		28,412,519	23,324,413	28,412,519	23,324,413
Average number of employees, #		22.2	23.4	22.4	23.5
				2019-12-31	2018-12-31
Cash and cash equivalent, KSEK				40,248	54,678
Equity, KSEK				58,428	39,457
Total equity and liabilities, KSEK				95,991	83,075
Liquidity ratio, %	*			152%	162%
Equity ratio, %	*			61%	47%
Equity per share, SEK	*			2.10	1.69

* = *Alternative performance measures*
#= *Average number of employees employed during the period*

Definitions and relevance of alternative performance measures
Saniona presents certain financial measures in the year-end report that are not defined according to IFRS, so called alternative performance measures. These have been noted with an "*" in the table above. The company considers that these measures provide valuable supplementary information for investors and company management as they enable an assessment of relevant trends of the company's performance. These financial measures should not be regarded as substitutes for measures defined per IFRS. Since not all companies calculate financial measures in the same way, these are not always comparable to measures used by other companies. The definition and relevance of key figures not calculated according to IFRS are set-out in the table below.

Key figure	Definition	Relevance
Operating profit/loss	Profit/loss before financial items and tax.	The operating profit/loss is used to measure the profit/loss generated by the operating activities.
Liquidity ratio	Current assets divided by current liabilities.	Liquidity ratio has been included to show the Company's short-term payment ability.
Equity ratio	Shareholders' equity as a proportion of total assets.	The equity ratio shows the proportion of total assets covered by equity and provides an indication of the company's financial stability and ability to survive in the long term.
Equity per share	Equity divided by the shares outstanding at the end of the period.	Equity per share has been included to provide investors with information about the equity reported in the balance sheet as represented by one share.
Cash flow per share	Cash flow for the period divided by the average shares outstanding for the period.	Cash flow per share has been included to provide investors with information about the cash flow represented by one share during the period.

Derivation of alternative performance measurers

	2019-10-01 2019-12-31	2018-10-01 2018-12-31	2019-01-01 2019-12-31	2018-01-01 2018-12-31
Operation profit/loss, KSEK	-28,123	-34,263	-103,906	-54,206
Net sales, KSEK	0	2,216	2,658	54,884
Operating margin, %	**-**	**-1546%**	**-3909%**	**-99%**
Cash flow for the period, KSEK	-29,036	9,987	-22,482	24,738
Average shares outstanding	28,410,347	22,850,645	25,719,586	22,288,524
Cash flow per share, SEK	**-1.02**	**0.44**	**-0.87**	**1.11**

	2019-12-31	2018-12-31
Current assets, KSEK	53,883	70,668
Current liabilities, KSEK	35,416	43,617
Liquidity ratio, %	**152%**	**162%**
Equity, KSEK	58,428	39,457
Total equity and liabilities, KSEK	95,991	83,075
Equity ratio, %	**61%**	**47%**
Equity, KSEK	58,428	39,457
Shares outstanding at the end of the period	27,763,347	23,324,413
Equity per share, SEK	**2.10**	**1.69**

Revenues and result of the operation

Revenue

Total revenues during the fourth quarter of 2019 was SEK 0.0 million (2.2).

Total revenues for the full year of 2019 was SEK 2.7 million (54.9). In 2019, revenues comprised research funding under the agreement with Boehringer Ingelheim. In 2018, revenues comprised a research milestone payment of SEK 41.8 million (€ 4 million) as a result of the candidate selection by Boehringer Ingelheim and research funding totaling SEK 13.1 million under the agreements with Boehringer Ingelheim and BenevolentAI.

Operating profit/loss

The operating loss for the fourth quarter was SEK 28.1 million (34.3). The company recognized operating expenses of SEK 28.1 million (36.5) for the fourth quarter of 2019. External expenses amounted to SEK 20.3 million (29.4) and personnel costs amounted to SEK 6.3 million (6.0). In the fourth quarter of 2019, external expenses comprised primarily development costs in relation to Tesomet. In the fourth quarter 2018, external expenses comprised primarily development costs in relation to Tesomet followed by preclinical development costs in relation to SAN711 and research and development costs in relation to the Kv7 program and the IK program.

The company recognized an operating loss of SEK 103.9 million (54.2) for the full year of 2019. The company recognized operating expenses of SEK 106.6 million (109.1) whereof external expenses amounted to SEK 75.0 million (80.1) and personnel costs amounted to SEK 25.9 million (24.2). In 2019, external expenses comprised primarily development costs in relation to Tesomet followed by research and development costs in relation to SAN903 and research and development costs in relation to other research programs. In 2018, external expenses comprised primarily development costs in relation to Tesomet followed by preclinical development costs in relation to SAN711 and research and development costs in relation to the SAN903 program.

Cash flow

Operating cash flow for the fourth quarter of 2019 was an outflow of SEK 28.2 million (outflow of 7.6). Consolidated cash flow for the fourth quarter of 2019 was an outflow of SEK 29.0 million (inflow of 10.0).

In 2019, the operating cash flow for the fourth quarter is primarily explained by the loss before tax of SEK 3.5 million and adjustment for non-cash transaction of 24.3 million where reclassification of the company ownership in Scandion Oncology accounts for SEK 23.9 million. The consolidated cash flow for the fourth quarter 2019 is primarily explained by the operating cash flow. In 2018, the operating cash flow for the fourth quarter is explained by the loss before tax of SEK 27.8 million and an improvement in working capital of SEK 26.4 million primarily due to an increase in prepayments from customers and a reduction in trade receivables

Operating cash flow for the full year of 2019 was an outflow of SEK 98.5 million (outflow 22.9). Consolidated cash flow for the full year of 2019 was outflow of SEK 20.5 million (inflow 24.7)

In 2019, the operating cash flow is explained by the loss before tax of SEK 83.5 million and adjustment for non-cash transaction of 18.1 million where reclassification of the company ownership in Scandion Oncology accounts for SEK 21.3 million which is partly offset by non-cash transacting relating to depreciation and share based payments. The consolidated cash flow in 2019 is further explained by an inflow from finance activities of SEK 76.7 million through a rights issue providing net proceeds of SEK 53.6 million and the issue of convertible loan notes to Nice & Green totaling SEK 24 million. In 2019, the convertible loan notes of SEK 24 million together with the outstanding loan notes at year-end 2018 totaling SEK 6 million have been converted into equity and the net proceeds of SEK 29 million is recorded under new share issues after deduction of issuing expenses.

In 2018, the operating cash flow is explained by the loss before tax of SEK 48.3 million and an improvement in working capital of SEK 29.4 million primarily due to an increase in prepayments from customers and a reduction in trade receivables. The consolidated cash flow in 2018 is further explained by an inflow from finance activities of SEK 46.7 million through the issue of convertible loan notes to Nice & Green totaling SEK 48 million of which SEK 6 million has not been converted at the balance sheet date. The balance of SEK 42 million was converted into equity during 2018 and the net proceeds of SEK 40.7 million is recorded under new share issues after deduction of issuing expenses.

Financial position
The equity ratio was 62 (48) % as of December 31, 2019, and equity was SEK 58.4 million (39.5). Cash and cash equivalents amounted to SEK 40.2 million (54.7) as of December 31, 2019. Total assets as of December 31, 2019, were SEK 96.0 million (83.1).

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. The financing replaces the financing agreement with Nice & Green dated 28 December 2017, which has been terminated as of January 10, 2020.

The share, share capital and ownership structure

At December 31, 2019, the number of shares outstanding amounted to 28,412,519 (23,324,413). During the full year of 2019, the total capital increased by SEK 254,405.53 and the total number of shares increased by 5,088,106. Through the rights issue in June 2019, the Company's share capital increased by SEK 184,855.45 and the number of shares increased by 3,697,109. Through the conversion of convertible loan notes totaling SEK 30 million during the full year of 2019, the Company's share capital increased by SEK 69,345.95 and the number of shares by 1,386,919. Through exercise of warrants under the employee option program 2015, the Company's share capital increased by SEK 203.90 and the number of shares increased by 4,078.

The company established a warrant program on July 1, 2017, totaling 38,750 warrants, on January 19, 2018 totaling 286,003 warrants, on July 1, 2018, totaling 45,013 warrants and on September 15, 2019, totaling 50,270 warrants. See note 4 for further information about share based payments after the rights issue.

At December 31, 2019, the company had 6,108 (5,569) shareholders excluding holdings in life insurance and foreign custody account holders.

Personnel

As of December 31, the number of employees was 24 (25) of which 13 (13) are women. Of these employees, 3 (3) are part-time employees and 21 (22) are full-time employees, and a total of 19 (20) work in the company's research and development operations. 11 (12) of Saniona's employees hold PhDs, 2 (2) hold university degrees, 8 (8) have laboratory training and the remaining 3 (3) have other degrees.

Operational risks and uncertainties

All business operations involve risk. Managed risk-taking is necessary to maintain good profitability. Risk may be due to events in the external environment and may affect a certain industry or market. Risk may also be company specific.

The main risks and uncertainties which Saniona is exposed to are related to drug development, the company's collaboration agreements, competition, technology development, patent, regulatory requirements, capital requirements and currencies.

The Group's programs are sold primarily to pharmaceutical companies and spin-outs funded by pharmaceutical companies and venture capital firms. Historically, the Group has not sustained any losses on trade receivables and other receivables.

Currency risks is the risk that the fair value of future cash flows fluctuate because of changed exchange rates. Exposure to currency risk is primarily sourced from payment flows in foreign currency and from the translation of balance sheet items in foreign currency, as well as upon the translation of foreign subsidiaries' income statements and balance sheets to the Group's reporting currency, which is SEK.

A more detailed description of the Group's risk exposure and risk management is included in Saniona's 2018 Annual Report. There are no major changes in the Group's risk exposure and risk management in 2019.

Audit review

The year-end report has not been audited or reviewed by the company's independent auditor.

Financial calendar

Interim Report Q1	May 7, 2020
Annual General Meeting	May 27, 2020
Interim Report Q2	August 27, 2020
Interim Report Q3	November 26, 2020
Year-End Report 2020	February 25, 2021

Annual General Meeting 2020

Saniona's Annual General Meeting will be held at Setterwalls Advokatbyrå AB's office at Stortorget 23, Malmö, Sweden on May 27, 2020 at 10 am CET.

The Board of Directors proposes that no dividend will be paid for the 2019 financial year.

The Annual Report for 2019 will be published on www.saniona.com no later than April 30, 2020. It will also be available at Saniona's head office at Baltorpvej 154, 2750 Ballerup, Denmark.

Shareholders who wish to have a matter addressed at the Annual General Meeting should, to ensure that the proposal may be considered, send such proposal at least seven weeks prior to the meeting or at least in such time that the item, if necessary, can be included in the notice to attend the meeting. The Board of Directors can be contacted by email to tf@saniona.com marked "Annual General Meeting" or through regular mail to: Saniona AB, Att.: Thomas Feldthus, Baltorpvej 154, DK-2750 Ballerup, Denmark.

The Nomination Committee's member are: Søren Skjærbæk, owner of Ursus law, Vejle, Denmark, appointed by Jørgen Drejer; John Haurum, professional board member for life science companies and former CEO of F-star Biotechnology Limited, Cambridge, UK, appointed by Thomas Feldthus; and J. Donald deBethizy, Chairman of Saniona AB's Board of Directors.

Shareholders who would like to submit proposals to the Nomination Committee can do so via e-mail to tf@saniona.com marked "Recommendation to the Nomination Committee" or by ordinary mail to the address: Saniona AB, Att. Thomas Feldthus, Baltorpvej 157, DK-2750 Ballerup, Denmark.

The Board of Directors and the CEO of Saniona AB (publ) provide their assurance that the year-end report provides a fair and true overview of the Parent Company's and the Group's operations, financial position and results, and describes material risks and uncertainties faced by the parent Company and the companies in the Group.

Ballerup, 7 February 2020
Saniona AB

J. Donald deBethizy - Chairman	Rami Levin, CEO
Claus Bræstrup – Board member	Jørgen Drejer – Board member
Anna Ljung - Board member	Carl Johan Sundberg - Board member
Edward Salzman – Board member	

Condensed consolidated statement of comprehensive income – Group

KSEK	Note	2019-10-01 2019-12-31	2018-10-01 2018-12-31	2019-01-01 2019-12-31	2018-01-01 2018-12-31
	1-2				
Net sales	3	0	2,216	2,658	54,884
Total operating income		0	2,216	2,658	54,884
Raw materials and consumables		-910	-925	-3,517	-4,089
Other external costs		-20,291	-29,386	-74,984	-80,149
Personnel costs	4	-6,309	-5,979	-25,860	-24,219
Depreciation and write-downs		-614	-189	-2,202	-632
Total operating expenses		-28,123	-36,478	-106,563	-109,089
Operating profit/loss		**-28,123**	**-34,263**	**-103,906**	**-54,206**
Share of result of associates	8	23,936	6,505	20,214	6,174
Financial income		673	-	674	-
Financial expenses		64	-88	-483	-261
Total financial items		24,673	6,417	20,404	5,913
Profit/loss after financial items		**-3,450**	**-27,846**	**-83,501**	**-48,292**
Tax on net profit	5	5	4,505	7,713	7,233
Profit/loss for the period		**-3,445**	**-23,341**	**-75,788**	**-41,059**
Other comprehensive income					
Item that may be reclassified to profit and loss					
Translation differences		-504	-74	-187	625
Item that will not be reclassified to profit and loss					
Fair value financial assets	8	10,657	-	10,657	-
Total other comprehensive income net after tax		**10.153**	**-74**	**10,470**	**625**
Total comprehensive income		**6,708**	**-23,415**	**-65,319**	**-40,434**
Earnings per share, SEK		-0.12	-1.02	-2.95	-1.84
Diluted earnings per share, SEK		-0.12	-1.02	-2.95	-1.84

The recognized loss and total comprehensive income are all attributable to the shareholders of the Parent Company, since there is no non-controlling interest in the subsidiaries of the Group.

Condensed consolidated statement of financial position – Group

KSEK	Note	2019-12-31	2018-12-31
	1-2		
ASSETS			
Fixtures, fittings, tools and equipment		3,415	1,841
Tangible assets		3,415	1,841
Other financial assets	8	37,376	-
Investments in associated companies	8	-	6,505
Other long-term receivables	9	1,260	3,999
Financial assets		38,635	10,504
Deferred tax		67	62
Non-current assets		**42,117**	**12,407**
Trade receivables		-	2,093
Current tax assets	5	7,682	7,568
Other receivables		4,430	4,654
Prepayments and accrued income		1,523	1,675
Current receivables		13,636	15,990
Cash and cash equivalent		40,248	54,678
Current assets		**53,883**	**70,668**
Total assets		**96,000**	**83,075**
EQUITY AND LIABILITIES			
Share capital	10	1,421	1,166
Additional paid in capital	10	239,592	157,118
Retained earnings		-192,268	-118,051
Reserves		9,693	-777
Equity		**58,437**	**39,457**
Lease liabilities		1,420	-
Other payables		727	-
Non-current liabilities		2,147	0
Trade payables		29,248	7,243
Convertible loan	10	-	6,000
Other payables		745	616
Accrued expenses and deferred income		5,423	29,759
Current liabilities		35,416	43,617
Total liabilities		**37,563**	**43,617**
Total equity and liabilities		**96,000**	**83,075**

Condensed consolidated statement of changes in equity – Group

	Share capital	Additional paid in capital	Translation reserves	Fair value reserve	Retained earnings	Shareholders' equity
January 1, 2018	**1,088**	**116,452**	**-1,402**	**0**	**-78,511**	**37,628**
Comprehensive income						
Profit/loss for the year					-41,059	-17,718
Other comprehensive income:						
Translation differences			625			699
Total comprehensive income			**625**		**-41,059**	**-40,434**
Transactions with owners						
Shares issued for cash	78	41,922				42,000
Expenses related to capital increase		-1,255				-1,255
Share-based compensation expenses					1,519	1,519
Total transactions with owners	**78**	**40,666**			**1,519**	**42,263**
December 31, 2018	**1,166**	**157,118**	**-777**	**0**	**-118,051**	**39,457**
January 1, 2019	**1,166**	**157,118**	**-777**	**0**	**-118,051**	**39,457**
Comprehensive income						
Profit/loss for the year					-75,788	-75,788
Other comprehensive income:						
Fair value reserve				10,657		10,657
Translation differences			-187			-187
Total comprehensive income			**-187**	**10,657**	**-75,788**	**-65,319**
Transactions with owners						
Shares issued for cash	254	96,347				96,601
Expenses related to capital increase		-13,874				-13,874
Share-based compensation expenses					1,571	1,571
Total transactions with owners	**254**	**82,473**			**1,571**	**84,299**
December 31, 2019	**1,421**	**239,592**	**-964**	**10,657**	**-192,268**	**58,437**

Condensed consolidated statement of cash flows – Group

KSEK	Note	2019-10-01 2019-12-31	2018-10-01 2018-12-31	2019-01-01 2019-12-31	2018-01-01 2018-12-31
Profit/loss before tax		-3,450	-27,846	-83,501	-48,292
Adjustments for non-cash transactions		-24,327	-6,054	-18,088	-3,795
Other provisions		334	-	2,147	-
Changes in working capital		-1,513	26,410	783	29,428
Cash flow from operating activities before financial items		**-28,956**	**-7,491**	**-98,660**	**-22,659**
Interest income received		673	-	674	-
Interest expenses paid		64	-88	-483	-261
Cash flow from operating activities		**-28,218**	**-7,579**	**-98,469**	**-22,920**
Investing activities					
Investment in tangible assets		-2,315	-552	-3,488	-1,107
Repayment of financial assets		1,435	479	2,739	2,021
Cash flow from investing activities		**-880**	**-73**	**-749**	**914**
Financing activities					
Convertible loan	10	-	5,000	-6,000	6,000
New share issue	10	53	12,639	82,728	40,745
Cash flow from financing activities		**53**	**17,639**	**76,728**	**46,745**
Cash flow for the period		**-29,045**	**9,987**	**-22,491**	**24,738**
Cash and cash equivalents at beginning of period		**59,126**	**37,292**	**54,678**	**22,313**
Exchange rate adjustments		10,166	7,399	8,061	7,626
Cash and cash equivalents at end of period		**40,248**	**54,678**	**40,248**	**54,678**

Statement of income – Parent Company

KSEK	Note	2019-10-01 2019-12-31	2018-10-01 2018-12-31	2019-01-01 2019-12-31	2018-01-01 2018-12-31
	1-2				
Other operating income		338	-	1,354	-
Total operating income		338	0	1,354	0
Raw materials and consumables		-6	-2	-13	-10
Other external costs		-1,745	-1,848	-6,416	-5,524
Personnel costs		-1,079	-596	-4,046	-2,379
Total operating expenses		-2,830	-2,447	-10,475	-7,912
Operating profit/loss		**-2,492**	**-2,447**	**-9,121**	**-7,912**
Share of result of associates	8	2,630	6,505	-1,092	6,174
Financial income		2,331	544	8,657	1,900
Financial expenses		-38	-10	-269	-144
Total financial items		4,923	7,038	7,295	7,931
Profit/loss after financial items		**2,432**	**4,592**	**-1,826**	**19**
Tax on net profit		0	0	0	0
Profit/loss		**2,432**	**4,592**	**-1,826**	**19**

Balance Sheet – Parent Company

KSEK	Note	2019-12-31	2018-12-31
	1-2		
ASSETS			
Investment in subsidiaries		204,100	11,832
Other financial assets	8	5,413	-
Investments in associated companies	8	-	6,505
Financial assets		209,512	18,337
Non-current assets		**209,512**	**18,337**
Receivables from group companies		-	112,424
Other receivables		286	257
Prepayments and accrued income		763	977
Current receivables		1,049	113,658
Cash and cash equivalent		9,899	13,435
Current assets		**10,948**	**127,093**
Total assets		**220,460**	**145,429**
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	10	1,421	1,166
Unrestricted equity			
Additional paid in capital	10	238,080	155,607
Retained earnings		-17,960	-17,979
Profit for the period		-1,826	19
Equity		**219,715**	**138,813**
Convertible loan	10	-	6,000
Other payables		745	616
Current liabilities		745	6,616
Total liabilities		**745**	**6,616**
Total equity and liabilities		**220,460**	**145,429**

Notes

Note 1 General Information

Saniona AB (publ), Corporate Registration Number 556962-5345, the Parent Company and its subsidiaries, collectively the Group, is a publicly listed research and development company focused on drugs for diseases of the central nervous system, autoimmune diseases, metabolic diseases and treatment of pain. The Parent Company is a limited liability company registered in the municipality of Malmö in the county of Skåne, Sweden. The address of the head office is Baltorpvej 154, DK-2750 Ballerup, Denmark. Saniona is listed at Nasdaq Stockholm Small Cap. The Parent Company's share is traded under the ticker SANION and the ISIN code SE0005794617.

Note 2 Significant accounting policies

The year-end report has been prepared in accordance with IAS 34 Interim reporting. The Group applies the International Financial Reporting Standards (IFRS) and interpretations of IFRS IC as adopted by the EU, the Annual Accounts Act and the Financial Reporting Board's recommendation RFR 1, Supplementary Accounting Rules for Groups.

The condensed consolidated financial statements have been prepared under the historical cost convention, except in the case of certain financial assets and liabilities, which are measured at fair value. The condensed consolidated financial statements are presented in Swedish kronor (SEK) which is also the accounting currency of the Parent Company.

The applied accounting principles are in accordance with those described in the Annual Report for 2018. More detailed information about the Group's and the Parent Company's accounting and valuation principles can be found in the Annual Report for 2018, which is available on www.saniona.com.

Disclosures in accordance with IAS 34 Interim Financial Reporting are presented either in the notes or elsewhere in the year-end report.

Effects of new accounting policies

IFRS 16 Leasing

IFRS 16 Leasing entered into force on January 1, 2019. Saniona has used the modified retrospective method allowed under IFRS 16, valuing the lease liability at the net present value of the future payments under the lease term. The corresponding right of use asset has been valued at an amount equal to the lease liability as allowed under IFRS 16 transition rules. At the balance sheet date Saniona had no active lease agreement which required adjustments following the implementation of IFRS 16. As of January 1, 2019, Saniona had a leasehold agreement for its premises in Ballerup, Denmark, which was subject to adjustment following the implementation of IFRS 16. This agreement has not been taken to the balance sheet under IFRS 16 as of December 31, 2019 since it has been terminated by the landlord in 2019. The company plans to move to new facilities in Q3 2020.

In Q4 2019, Saniona entered into a 3-year lease agreement on a fixed asset, which has been value to SEK 2.1 million in accordance to IFRS 16 as described above resulting in a recorded short and long-term lease liability of SEK 0.7 and 1.4 million respectively.

Note 3 Segment reporting

The Group is managed as a single business unit. The basis for identifying reportable segments is the internal reporting as reported to and followed up by the highest executive decision maker. The Group has identified the highest executive decision maker as the CEO. The internal management and reporting structure comprise only one business unit, and the Group therefore has only one operating segment, for which reason no segment information is provided.

Note 4 Share based payments

Share-based compensation expenses for the full year of 2019 totaled SEK 1,571 (1,518) 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.

	Options granted in 2017	Options granted in 2018	Options granted in 2019	Total
Share-based payment				
Outstanding at 1 January 2019	38,292	331,016	-	369,308
Granted during the period	-	-	50,270	50,270
Forfeited during the period	-	1,708	-	1,708
Outstanding at 31 December 2019	**38,292**	**329,308**	**50,270**	**421,286**

If all issued warrants are exercised for subscription of new shares, the Parent Company's will issue a total of 421,286 new shares corresponding to a dilution of approximately 1,46%. 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	16.75	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

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

** 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.*

*** 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.*

A detailed description of the warrant program in 2017, 2018:1, 2018:2 and 2018:3 can be found in the annual report 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.

On January 10, 2020 the board of directs proposed an employee option program for the CEO. The Employee Option Program 2020/2025 shall be comprised by a maximum of 710,313 employee options. Allotment shall take place no later than as of 31 March 2020. Each employee option entitles the holder a right to acquire one new share in the Company against cash consideration at a subscription price amounting to 100 per cent of the average closing price of the Company's share on Nasdaq Stockholm during ten trading days prior to the extraordinary general meeting on 7 February 2020. The allotted employee options will be vested with 1/4 each at the dates falling 12, 24, 36 and 48 months after allotment. The employee options shall be allotted without consideration. The holder can exercise allotted and vested employee options during 30 days from the day following after the announcement of the Company's quarterly reports, or for full year, the year-end re-port, the first time after the announcement of the quarterly report for the fourth quarter of 2022 and the last time after the announcement of the quarterly report for the third quarter of 2025

Note 5 Income tax and deferred tax subsidiaries in Denmark

Tax on income for the year, consisting of the year's current tax and deferred tax, is recognized in the income statement to the extent that it relates to the income or loss for the period and in other comprehensive income or equity to the extent that it relates thereto.

The Group recognized a tax income of SEK 7.7 (7.2) million during the full year of 2019. This amount has been recognized under non-current tax assets in accordance to the accounting policies described below.

Under the Danish R&D tax credit scheme (Skattekreditordningen), loss-making R&D entities can obtain a tax credit which is equal to the tax value of the incurred research and development expenses. The tax credit is payable in November in the following financial year. In 2018 and 2019 the R&D expense tax-base is capped to DKK 25 million equal to a tax credit of DKK 5.5 million at a tax rate of 22%. Research and development tax-credits under the Danish R&D tax credit scheme is recognized in the income statement to the extent that it relates to the research and development expenses for the period and Saniona expects to fulfil the requirement for tax credit for the year. The tax credit under the Danish R&D tax credit scheme is recognized in the balance sheet under current tax assets if payable within 12 months and under non-current tax assets if payable after 12 months. As of December 31, 2019, the Group had SEK 7.7 million (DKK 5.5 million) in current tax assets which will be paid to Saniona in November 2020. As of December 31, 2018, the Group had SEK 7.6 million (DKK 5.5 million) in current tax asset, which was paid to Saniona in November 2019.

Note 6 Pledged assets and contingent liabilities

The Parent Company has provided a guarantee to the subsidiary Saniona A/S to ensure that Saniona A/S will be able to pay its creditors as the obligations fall due for the period until June 30, 2020. Saniona A/S had no external net debt as of December 31, 2019.

Note 7 Related parties

Related parties comprise the Group's Executive Management, Board of Directors and companies within the Group. Apart from intercompany transaction and board fees as well as remuneration of management in accordance to the remuneration policy as resolved at the annual general meeting, there has been no transaction with related parties during 2018 and 2019.

Note 8 Reclassification of investment in Scandion Oncology

On May 3, 2017, Saniona participated in formation of a new company, Scandion Oncology A/S. Scandion Oncology was listed on the Spotlight Stock Market on November 8, 2018.

In previous financial reports, Saniona has classified the investment in Scandion Oncology as an Investment in associates since the criteria for significant influence was met. The value of Saniona's investment has been recognized in the balance sheet in accordance with the equity method and taken to the profit and loss statement as a financial income or expense. When recognizing the value, Saniona has used the published financial statements by Scandion Oncology in the previous quarter as Scandion Oncology's financial reports from the actual quarter had not been published at the time of publication of Saniona's financial report.

In July 2019, Scandion Oncology completed a rights issue, which lead to a decrease of Saniona's holdings of shares and votes from 29.17 % to 18.23 %. Saniona has concluded that the requirement for significant influence is not met after this transaction due to the dilution of Saniona's shareholding in Scandion Oncology. However, in the Q3 report 2019, Saniona recognized the value of its investment in accordance to the equity method since this calculation was based on the published financial statements by Scandion Oncology for Q2 in accordance to the principles described above.

Therefore, Saniona's holding in Scandion Oncology has been reclassified from Investment in associate to Financial assets as of October 1, 2019.

Effect of reclassification in the Parent Company

For the Parent Company, the effect of the reclassification is that the investment in Scandion Oncology is recognized at cost subject to potential impairments.

As of October 1, 2019, the recognized value of Saniona's investment in Scandion Oncology is SEK 5.4 million, which has been calculated in accordance with the equity method by using the reported equity in Scandion Oncology's interim report Q3 2019. The effect of the reclassification is that the Parent Company recognizes a financial income of SEK 2.6 million in Q4 2019 and a financial expense of SEK 1.1 million for the full year 2019. The calculation for the parent company is set-out in the table below.

Saniona report date	Valuation method	Value	Derivation P/L effect Q4 2019	Derivation P/L effect 2019
		SEK	SEK	SEK
January 1, 2019	Equity method OB	6,505,164*		-6,505,164
September 30, 2019	Equity method CB	2,783,064**	-2,783,064	
October 1, 2019	Equity method CB	5,412,674***	5,412,674	5,412,674
Amounts recognized in P/L			2,629,610	-1,092,490

** Valuation is based on the reported equity Scandion Oncology's interim report Q3 2018 and the capital increase in Q4 2018*
*** Valuation is based on reported equity in Scandion Oncology's interim report Q2 2019*
**** Valuation is based on reported equity in Scandion Oncology's interim report Q3 2019*

Effect of reclassification in the Group

Saniona has concluded that its holding of share in Scandion Oncology meets the requirements under IFRS 9.

For the Group, the effect of the reclassification is that the investment is Scandion Oncology is recognized in the balance sheet in accordance to the fair value and that changes in fair value is recognized under Other comprehensive income. The initial value of Saniona's investment has been recognized in the balance sheet in accordance with the fair value method as of October 1, 2019, and differences to the value in accordance to the equity method has been taken to the profit and loss statement as a financial income or expense.

As of October 1, 2019, the recognized value of Saniona's investment in Scandion Oncology is SEK 26.7 million, which has been calculated in accordance with the fair value method by using the market quotation of the shares in Scandion Oncology as of October 1, 2019. The effect of the reclassification is that the Group recognizes a financial income of SEK 23.9 million in Q4 2019 and a financial income of SEK 20,2 million for the full year 2019. Furthermore, the Group recognizes a gain of SEK 10.7 million under Other comprehensive income for Q4 2019 as well as for the full year of 2019 due to an increase in fair value in Q4 2019. The calculation for the Group is set-out in the table below.

Saniona reporting date	Valuation method	Value	Derivation P/L effect Q4	Derivation P/L effect 2019	Derivation FV change Q4 recognized in OCI
		SEK	SEK	SEK	SEK
January 1, 2019	Equity method	6,505,164*		-6,505,164	
September 30, 2019	Equity method	2,783,064**	-2,783,064		
October 1, 2019	Fair value OB	26,718,754***	26,718,754	26,718,754	-26,718,754
December 31, 2019	Fair value CB	37,375,689***			37,375,689
Amounts recognized in P/L or OCI			23,935,690****	20,213,590	10,656,934

** Valuation is based on the reported equity Scandion Oncology's interim report Q3 2018 and the capital increase in Q4 2018.*
*** Valuation is based on reported equity in Scandion Oncology's interim report Q2 2019.*
****Valuation is based on market value of Saniona's shareholding in Scandion Oncology as of Oct 1, 2019 and Dec 31, 2019.*
***** Whereas the total amount consists of a positive change in Result from Shares in Associates of 2,629,610 and gain on reclassification of 21,306,080, totaling 23,935,690.*

Note 9 Other long-term receivables

On July 4, 2017, Saniona acquired NeuroSearch's remaining interest in the preclinical and clinical assets, which Saniona acquired from NeuroSearch during the period 2012-2016. According to the previous agreements, Saniona was obliged to pay NeuroSearch a milestone payment of EUR 400,000 when the first preclinical program was tested in humans. In addition, Saniona was obliged to pay royalties on its product sales or a percentage of its licensing income in relation to the acquired clinical assets including the clinical development compounds, tesofensine and NS2359. According to the new agreement, Saniona has paid NeuroSearch a onetime cash payment of DKK 5.5 million. Following this, Saniona has no additional payment obligations to NeuroSearch. Saniona estimates that the onetime cash payment of DKK 5.5 million would have been payable to NeuroSearch within a four-year period under the previous agreements. Therefore, the amount will be expensed over a four-year period starting July 1, 2017. In 2019 the onetime cash payment has been expensed with SEK 2.0 million (SEK 1.9 million) and as December 31, 2019, the recorded value of the total asset is SEK 2.9 (SEK 4.9 million). SEK 1.0 million of the recorded value is long term and SEK 1.9 million is short term.

Note 10 Convertible loan

Saniona entered into a convertible notes funding agreement with Nice & Green S.A on December 29, 2017. Under the terms of the agreement, Nice & Green committed to subscribe up to SEK 72 million in convertible notes in 12 individual tranches of SEK 6 million each over a 12-month period subject to prolongation by Saniona.

The convertible notes did not bear any interest. Nice & Green had the right to request conversion of the convertible notes at any time during a period of 12 months following the issue of the respective tranche. The pricing of the shares was determined as 92% of the lowest daily volume-weighted average share price (VWAP) of the five trading days prior to the date on which Nice & Green had sent a conversion notice to Saniona. For further details, please see Saniona's press release dated December 29, 2017.

In 2019, Saniona has drawn four tranches totaling SEK 24 million (SEK 48 million) and Nice & Green has converted SEK 30 million (SEK 42 million) of which SEK 6 million (0) was outstanding as of December 31, 2018. The converted amount of SEK 30 million (SEK 42 million) is taken to equity after deducting expenses relating to capital increase totaling KSEK 949 (SEK 1.3 million). Therefore, Saniona has drawn all tranches (SEK 72 million) under the convertible notes funding agreement with Nice & Green and all outstanding loan notes (SEK 72 million) have been converted into shares during 2018 and 2019.

In 2019, Saniona extended the convertible notes funding agreement with Nice & Green for an additional SEK 72 million with the same terms. In January 2020, Saniona terminated the convertible notes funding agreement without having drawn any tranches under the extended agreement.

Note 11 Subsequent Events to the Balance Sheet Date

- 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.
- 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.

Business terms - glossary

Alzheimer's disease
A chronic neurodegenerative disease that usually starts slowly and gets worse over time and accounts for 60% to 70% of cases of dementia. As the disease advances, symptoms can include problems with language, disorientation (including easily getting lost), mood swings, loss of motivation, not managing self-care, and behavioral issues. Gradually, body functions are lost, ultimately leading to death. The cause for most Alzheimer's cases is still mostly unknown except for 1% to 5% of cases where genetic differences have been identified. Several competing hypotheses exist trying to explain the cause of the disease.

Ataxia
A neurological sign consisting of lack of voluntary coordination of muscle movements. Ataxia is a non-specific clinical manifestation implying dysfunction of the parts of the nervous system that coordinate movement, such as the cerebellum. Several possible causes exist for these patterns of neurological dysfunction and they can be mild and short term or be symptoms of sever chronic diseases such as Friedreich's ataxia, which is an autosomal recessive inherited disease that causes progressive damage to the nervous system which manifests in initial symptoms of poor coordination that progresses until a wheelchair is required for mobility.

Atlas Venture
Atlas Venture Inc. For further details, please see description about Cadent Therapeutics under CAD-1883 in the Pipeline section.

BenevolentAI
BenevolentAI acquired Proximagen Ltd. in Q1 2017.

Boehringer Ingelheim
Boehringer Ingelheim GmbH. For further details, please see the Boehringer Program in the Pipeline section.

Cadent Therapeutics
Cadent Therapeutics was established in March 2017 through a merger between Saniona's spin-out company, Ataxion, and Luc Therapeutics.

Chronic itching
Chronic itching (also known as pruritus) is defined as an unpleasant sensation that provokes the desire to scratch. Prolonged itching and scratching may increase the intensity of the itch and lead to skin injury, infection and scarring. The possible causes are numerous and include dry skin, skin disorders such as eczema and psoriasis, infections such as chicken pox and scabies, underlying illness such liver disease, kidney failure and cancers, nerve disorders such as multiple sclerosis and diabetes mellitus, and allergic diseases including allergic reactions to medications such as antibiotics and chemotherapy. For some patients, there's no known cause. Chronic itching ranges in intensity from a mild annoyance to a disabling condition. The constant need to scratch can be as debilitating as chronic pain. Depending on the underlying cause, the current treatment options include moisturizing cream, antihistamines, corticosteroids, local anesthetics, calcineurin inhibitors and antidepressants. Many patients experience only a partial relief whereas others have no relief from existing treatment options.

CNS
Central Nervous System, a part of the nervous system consisting of the brain and spinal cord.

Cocaine addiction
The compulsive craving for use of cocaine despite adverse consequences.

Colitis
An inflammation of the inner lining of the colon. There are numerous causes of colitis including infection, inflammatory bowel disease (Crohn's disease, ulcerative colitis), ischemic colitis, allergic reactions, and microscopic colitis. Symptoms depend upon the cause and may include abdominal pain, cramping and diarrhea.

Crohn's disease
An IBD which causes inflammation of the digestive tract, which can lead to abdominal pain, severe diarrhea, fatigue, weight loss and malnutrition. Inflammation caused by Crohn's disease can involve different areas of the digestive tract in different people.

CTA
Clinical Trial Application which a pharmaceutical company file to EMA to obtain permission to ship and test an experimental drug in Europe before a marketing application for the drug has been approved. The approved application is called an Investigational New Drug (IND) in the US.

EMA
European Medicines Agency

Epilepsy
Epilepsy is a central nervous system (neurological) disorder in which brain activity becomes abnormal, causing seizures or periods of unusual behavior, sensations, and sometimes loss of awareness. Treatment with medications or sometimes surgery can control seizures for most people with epilepsy. Some people require lifelong treatment to control seizures, but for others, the seizures eventually go away.

Essential tremor
Essential tremor is the most common movement disorder with a prevalence of 4% in persons age 40 and older and considerably higher among persons in their 60s, 70s, 80s and 90s. It typically involves a tremor of the arms, hands or fingers but sometimes involving the head, vocal cords or other body parts during voluntary movements such as eating and writing. Although essential tremor is often mild, people with severe tremor have difficulty performing many of their routine activities of daily living.

Fatty liver disease (NASH)
Nonalcoholic steatohepatitis (NASH), or fatty liver disease, is a form of nonalcoholic fatty liver disease (NAFLD) in which a patient has hepatitis - inflammation of the liver - and liver cell damage, in addition to fat in the liver. Inflammation and liver cell damage can cause fibrosis, or scarring, of the liver. NASH may lead to cirrhosis or liver cancer.

FDA
US Food and Drug Administration

GABA-A α2/α3 program
A small molecule program which is designed to positively modulate (PAM) GABA-A α2 and GABA-A α3 ion channels, which are expressed in various central and peripheral neurons and are believed to be key mediator in the control of pain signaling and the control of anxiety.

Hypothalamic obesity (HO)
A common sequel to tumors of the hypothalamic region and their treatment with surgery and radiotherapy. Weight gain results from damage to the ventromedial hypothalamus which leads, variously, to hyperphagia, a low metabolic rate, autonomic imbalance, growth hormone deficiency and various other problems that contribute to weight gain.

IK program
A small molecule program which is designed to inhibit IK channels, which are expressed by immune cells and believed to be key mediator of inflammation in auto inflammatory diseases such as inflammatory bowel diseases.

IND
Investigational New Drug is a program by which a pharmaceutical company obtains permission to ship and test an experimental drug in the U.S. before a marketing application for the drug has been approved. In Europe, the application is called a Clinical Trial Application (CTA).

Inflammatory bowel disease (IBD)
IBD is an umbrella term used to describe disorders that involve chronic inflammation of the digestive tract. Types of IBD include ulcerative colitis and Crohn's disease.

Ion channel
Channels or pores in cell membranes which is made up of unique protein classes. Ion channels controls muscles and nerves and are central to the function of the body by governing the passage of charged ions across cell membranes.

Ion channel modulators
A drug which modulates the function of ion channels by blocking or opening ion channels or by decreasing or increasing throughput of ion channels. Agonists opens ion channels, Antagonists blocks ion channels, PAMs

(Positive Allosteric Modulators) increase throughput whereas NAMs (Negative Allosteric Modulators) decrease throughput of ion channels.

Kv7 programs
Saniona's Kv7 programs focus on developing effective new treatments for neurological diseases, such as treatment-resistant partial epilepsy, and various pain disorders. Furthermore, we have demonstrated that activators of the Kv7 family of potassium channels are also highly efficacious for relaxation of overactive bladder smooth muscle cells, a characteristic of urinary incontinence (UI).

Major Depressive Disorders
A mental disorder characterized by a pervasive and persistent low mood that is accompanied by low self-esteem and by a loss of interest or pleasure in normally enjoyable activities.

Medix
Productos Medix, S.A de S.V. For further details, please see under tesofensine in the Pipeline section.

Metoprolol
Metoprolol is a medication of the selective β1 receptor blocker type, which work by blocking the neurotransmitter norepinephrine and epinephrine from binding to receptors. It is used to treat high blood pressure, chest pain due to poor blood flow to the heart, and several conditions involving an abnormally fast heart rate. It is also used to prevent further heart problems after myocardial infarction and to prevent headaches in those with migraines.

Multiple sclerosis
A demyelinating disease in which the insulating covers of nerve cells in the brain and spinal cord are damaged by the immune system. This damage disrupts the ability of parts of the nervous system to communicate, resulting in a wide range of signs and symptoms including physical, mental, and sometimes psychiatric problems.

Neuropathic pain
Pain caused by damage or disease affecting the somatosensory nervous system. Central neuropathic pain is found in spinal cord injury, multiple sclerosis, and some strokes. Aside from diabetes (diabetic neuropathy) and other metabolic conditions, the common causes of painful peripheral neuropathies are herpes zoster infection, HIV-related neuropathies, nutritional deficiencies, toxins, remote manifestations of malignancies, immune mediated disorders and physical trauma to a nerve trunk. Neuropathic pain is also common in cancer as a direct result of cancer on peripheral nerves (*e.g.*, compression by a tumor), or as a side effect of chemotherapy, radiation injury or surgery. Neuropathic pain is often chronic and very difficult to manage with some 40-60% of people achieving only partial relief.

Nic α6 program
The Nic α6 program is a small molecule program designed to positively modulate (PAM) the α6 ion channels. The α6 subtype exhibits an extremely localized expression mainly confined to dopaminergic neurons in the area of the brain affected in Parkinson's disease patients, where they act as important regulators of dopamine signaling.

NS2359
A triple monoamine reuptake inhibitor, which blocks the reuptake of dopamine, norepinephrine, and serotonin in a similar manner to cocaine. However, NS2359 dissociates slowly from these transporters and has a long human half-life (up to 10 days) which makes frequent dosing unnecessary. NS2359's pharmacological profile means that it may be able to reduce cocaine withdrawal symptoms, reduce cocaine craving and reduce cocaine-induced euphoria. In preclinical trials, NS2359 has been shown to reduce the reinforcing effects of cocaine and may have effects on cue induced drug craving. Furthermore, human trials with NS2359 have shown that NS2359 has little or no abuse potential and does not have adverse interactions with cocaine.

Obesity
A medical condition in which body fat has accumulated to an extent that it may have a negative effect on health. Obesity is most commonly caused by a combination of excessive food intake, lack of physical activity and genetic susceptibility. A few cases are caused primarily by genes, endocrine disorders, medications or mental disorder.

Parkinson's disease
Parkinson's disease (PD) is a neurodegenerative disorder that affects predominately dopamine-producing neurons in a specific area of the brain called substantia nigra. Symptoms generally develop slowly over years and may include tremors, bradykinesia, limb rigidity and gait and balance problems. The cause remains largely unknown and there is still no cure.

Pharmacodynamics (PD)

Pharmacodynamics is the study of the biochemical and physiologic effects of a drug in the body including the relationship between the drug concentration and the desirable effects as well as the undesirable effects.

Pharmacokinetics (PK)
Pharmacokinetics is the study of how the body affects a drug including the relationship between the dosed amount of a drug and the obtained blood concentration of the drug.

Prader-Willi syndrome (PWS)
Prader-Willi syndrome is a complex genetic condition that affects many parts of the body. In infancy, this condition is characterized by weak muscle tone (hypotonia), feeding difficulties, poor growth, and delayed development. Affected individuals develop an insatiable appetite, which leads to chronic overeating (hyperphagia) and obesity. Some people with Prader-Willi syndrome, particularly those with obesity, also develop type 2 diabetes.

SAN711
SAN711 is a selective GABAA α3 modulator (PAM), which increases the activity of the GABAA receptor protein in the vertebrate central nervous system. It is derived from Saniona's advanced ion channel platform and has demonstrated strong efficacy in rodent itching and pain models. SAN711 is ready for Phase 1 clinical testing.

SAN903
SAN903 is a selective IK channel modulator, which inhibits the potassium outflux from cells through the IK channels, which are expressed by immune cells and believed to be key mediator of inflammation in auto inflammatory diseases such as inflammatory bowel diseases.

Schizophrenia
A mental disorder often characterized by abnormal social behavior and failure to recognize what is real. Common symptoms include false beliefs, unclear or confused thinking, auditory hallucinations, reduced social engagement and emotional expression, and lack of motivation.

Tesofensine
A triple monoamine reuptake inhibitor, which is positioned for obesity and type 2 diabetes, two of the major global health problems. Tesofensine has been evaluated in Phase 1 and Phase 2 human clinical studies with the aim of investigating treatment potential with regards to obesity, Alzheimer's disease and Parkinson's disease. Tesofensine demonstrated strong weight reducing effects in Phase 2 clinical studies in obese patients.

TRC
The University of Pennsylvania Treatment Research Center. For further details, please see under NS2359 in the Pipeline section.

Type 2 diabetes
A metabolic disorder that is characterized by hyperglycemia (high blood sugar) in the context of insulin resistance and relative lack of insulin. This contrasts with diabetes mellitus type 1, in which there is an absolute lack of insulin due to breakdown of islet cells in the pancreas. The classic symptoms are excess thirst, frequent urination, and constant hunger. Type 2 diabetes makes up about 90% of cases of diabetes, with the other 10% due primarily to diabetes mellitus type 1 and gestational diabetes. Obesity is thought to be the primary cause of type 2 diabetes in people who are genetically predisposed to the disease.

Urinary incontinence (UI)
UI, or the loss of bladder control, is a common and often embarrassing problem. It is not a disease, but rather a symptom of many conditions. Many factors increase risk, for example aging, pregnancy, prostate problems and obesity.

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