

## Continued positive development on Saniona's clinical programs

### Financial highlights

#### Q1 2019 (Q1 2018)

- Net revenues were SEK 1.7 M (4.3 M)
- EBIT was SEK -29.1 M (-15.7 M)
- Net profit/loss was SEK -24.8 M (-13.5)
- Earnings per share were SEK -1.06 (-0.62)
- Diluted earnings per share were SEK -1.06 (-0.62)

### Business highlights in Q1 2019

- In January, Saniona initiated an open label extension study in the second part of its Phase 2a study of Tesomet comprising nine adolescent patients with PWS. The treatment with a dose of 0.125 mg/day appeared to be well tolerated but did not achieve sufficient plasma levels known to be efficacious in previous Phase 2 and Phase 3 obesity studies. Saniona has increased the dose to 0.25 mg/day in March and the final open label study is scheduled to continue until July.
- In March, Saniona recruited the first patient in a Phase 2a clinical study of Tesomet to treat the rare eating disorder hypothalamic obesity. The trial comprises a total of up to 25 patients and is conducted at Rigshospitalet in Copenhagen, Denmark.
- Following the interim analysis, Saniona's partner University of Pennsylvania Treatment Research Center plans to continue the investigator-initiated study with NS2359 for cocaine addiction at a higher dose.
- Saniona successfully completed a full regulatory toxicological program for its first in class compound, SAN711, which offers a new treatment paradigm for itching and neuropathic pain. Saniona has scaled-up the manufacturing process, produced the material for clinical studies and the program is now ready for Phase 1 studies.
- Selection of ABG Sundal Collier As a financial advisor.

### Significant events after the reporting period

- Saniona announced a Rights Issue of SEK 78 MSEK. The intention with this Rights Issue is to secure Saniona's financing requirement and thereby replace potential future tranches under the existing funding agreement with Nice & Green.
- Saniona established a Scientific Advisory Board for the development of Tesomet in PWS.

### Comments from the CEO

"Saniona continued development of its promising portfolio of new drugs in the first quarter, making further progress as a leading biotech company focusing on treatment of eating disorders and diseases of the central nervous system. In particular, we advanced the clinical trials of our lead product Tesomet. In further positive news for Saniona, our partner Medix remain confident about launching tesofensine in Mexico in 2020, which would be the first program from our portfolio to reach the market. At the same time, we continue the development of our business and have engaged with several leading biopharmaceutical companies regarding partnering of assets", says Jørgen Drejer, CEO of Saniona.

### For more information, please contact

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## Letter from the CEO

Saniona continued development of its promising portfolio of new drugs in the first quarter, making further progress towards its objective of being a leading biotech company focusing on treatment of eating disorders and diseases of the central nervous system. In particular, we made significant progress in the clinical trials of our lead product, Tesomet, a proprietary fixed-dose combination of tesofensine and metoprolol for two rare eating disorders, Prader-Willi syndrome (PWS) and hypothalamic obesity (HO). The objective is to prepare Tesomet for pivotal Phase 2b/3 studies in at least one of these indications during 2019 and start these studies in 2020.

Based on the proof-of-concept obtained in adult PWS patients, we initiated a dose-finding Phase 2a study of Tesomet in adolescent patients in Q4, 2018. These young patients initially received Tesomet at a quarter of the tesofensine dose (tesofensine 0.125 mg + metoprolol 25 mg daily) given to adult patients. The placebo-controlled study was completed in January and eight of the nine adolescent patients agreed to continue in a 24-week open label extension study at the same dose, which was completed in March. The treatment was well tolerated but did not yet result in therapeutically meaningful plasma levels of tesofensine.

In the dose-finding, we have doubled the dose to 0.25 mg daily in another 24-week open-label extension, in which four adolescent patients have agreed to participate. This study was initiated at the end of March and three out of the four patients have now been treated with Tesomet at this dose level for one month. While the sample size is small and it is still early, we can already see that Tesomet appears to be well tolerated at this dose level, and the first data suggest that the patients have stabilized in weight with a small weight loss recorded in two patients. Therefore, we are very much looking forward to seeing the results once the study has been completed in July.

In March we also initiated a Phase 2a proof of concept study for Tesomet in HO patients. This study will include up to 25 patients, who will receive treatment or placebo for 24 weeks followed by an open-label extension in which all patients will receive Tesomet for additional 24 weeks.

In December 2018, Medix successfully reported positive top line data from a registration trial. Medix is on track with the preparation of the significant documentation dossier for a new drug application for tesofensine in Mexico and they remain confident about launching the product in 2020. This is particularly exciting news for us at Saniona, as tesofensine would be the first program from our product portfolio to reach the market. Saniona is entitled to double digit royalties on net sales of tesofensine in Mexico and Argentina. Saniona retains the commercial rights in the rest of world

We are advancing a number of preclinical programs to the clinical stage. In February we reported completion of the preclinical development for SAN711, and that the compound is ready for Phase 1 clinical studies for treatment of neuropathic pain and itching.

In addition, we are successfully progressing the IK program for treatment of inflammatory bowel disease (IBD), specifically of Crohn's disease and ulcerative colitis, towards the final candidate selection.

Finally, the preclinical development by our partner Boehringer Ingelheim GmbH progress in accordance to the plan with the aim of initiating Phase 1 studies next year for schizophrenia.

Over the past six months, we have been actively engaged in discussions with a number of pharmaceutical companies regarding the potential of our research and clinical assets., which may generate important non-dilutive funding to the company.

Yesterday, we announced a Rights Issue of SEK 78 MSEK. The intention with this Rights Issue is to secure Saniona's financing requirement and thereby replace potential future tranches under the existing funding agreement with Nice & Green, which together with non-dilutive income from our partnerships have financed the company's activities since the beginning of 2018. During this period, we have drawn 12 tranches of 6 MSEK totaling 72 MSEK under the agreement with Nice & Green and received 57 MSEK in non-dilutive income through milestone payments and research funding from our partners.

The above financing has enabled us to make a tremendous progress on our pipeline. We have obtained proof of concept for Tesomet in PWS and are now in the dose finding phase. We have started another proof of concept study in HO. We have finalized the Phase 1 enabling studies for SAN711 and moved the IK program to the candidate selection phase. Our partner Medix has successfully completed a Phase 3 registration trial for tesofensine in obesity. Boehringer Ingelheim has selected a candidate and is now preparing for Phase 1 for

schizophrenia and Cadent Therapeutics has moved CAD-1883 from preclinical development phase to Phase 2 for essential tremor.

Based on this remarkable progress, we trust that our shareholders will find the announced Rights Issue very attractive and take advantages of this opportunity.

I look forward to the rest of the year with excitement and to share with you the continued progress of our clinical pipeline. I would like to take this opportunity to thank colleagues, board members and shareholders for their strong belief in and commitment to Saniona.

Jørgen Drejer

CEO, Saniona AB

## About Saniona

Saniona is a research and development company focused on drugs for diseases of the central nervous system and eating disorders with five programs in clinical development. Saniona intends to develop and commercialize treatments for orphan indications such as Prader-Willi syndrome and hypothalamic obesity on its own. The research is focused on ion channels and the company has a broad portfolio of research programs. Saniona has partnerships with Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and Cadent Therapeutics. Saniona is based in Copenhagen, Denmark, and the company's shares are listed at Nasdaq Stockholm Small Cap (OMX: SANION).

## Vision and objective

Saniona aims to be a leading biotech company focusing on treatment of eating disorders and diseases of the central nervous system. Saniona's overall objective is to develop - both in-house and together with partners - new treatments that address significant unmet medical needs.

## Strategy and business model

Saniona has a broad product pipeline, which is developed both internally and in collaboration with pharmaceutical companies.

Strategically, the company intends to develop and commercialize treatments for orphan indications on its own and engage in partnerships with larger pharmaceutical companies for development programs aiming at treating large indications such as obesity.

Saniona is developing products internally with the aim of attaining market approval itself in the U.S. and Europe for certain orphan indications where the required investments are limited, and the commercial opportunities can be highly attractive. For example, 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.

In addition to this, Saniona has entered into and will engage in research collaborations with pharmaceutical companies or is developing products internally with the aim of entering into a collaboration with a pharmaceutical company at a later stage. The structure of Saniona's collaboration 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 develop and attain market approval for Tesomet in the U.S. and Europe in orphan diseases by ourselves
- To develop Tesomet in rest of the world through partnerships for metabolic diseases
- To attain market approval for tesofensine in collaboration with Medix in Mexico and Argentina
- To develop at least one drug candidate internally from our unique ion channel research platform
- To leverage our leading position within ion channel research in partnership with pharmaceutical companies

## Project portfolio

Saniona has five programs in clinical development including three late stage clinical programs focused on the development of treatments to effectively regulate obsessions, cravings and addictions related to food and drugs. In total, the company has a portfolio of nine active drug programs in clinical and pre-clinical development stages, of which four are financed through partnerships or grants.

## Clinical programs

Saniona's most advanced program is tesofensine, which is being developed for obesity in collaboration with Medix. Medix has completed a Phase 3 registration trial for tesofensine in December 2018 and expects to file a new drug application in 2019 for treatment of obesity in Mexico with potential market approval and launch 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 in the Phase 3 trial.

Tesomet is Saniona's most advanced internal program and is being developed for the treatment of eating disorders. Saniona is currently conducting a dose-finding Phase 2a study in PWS and a Phase 2a proof-of-

concept study in HO. The objective is to prepare Tesomet for pivotal Phase 2b/3 studies in at least one of the two indications and start pivotal studies in 2020.

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 Cadent Therapeutics has initiated a Phase 2a study for the treatment of essential tremor and expects to start another Phase 2a study in the second half of 2019 for the treatment of Ataxia. Saniona holds an ownership stake in Cadent and will receive royalties on CAD-1883 if and when it reaches the market.

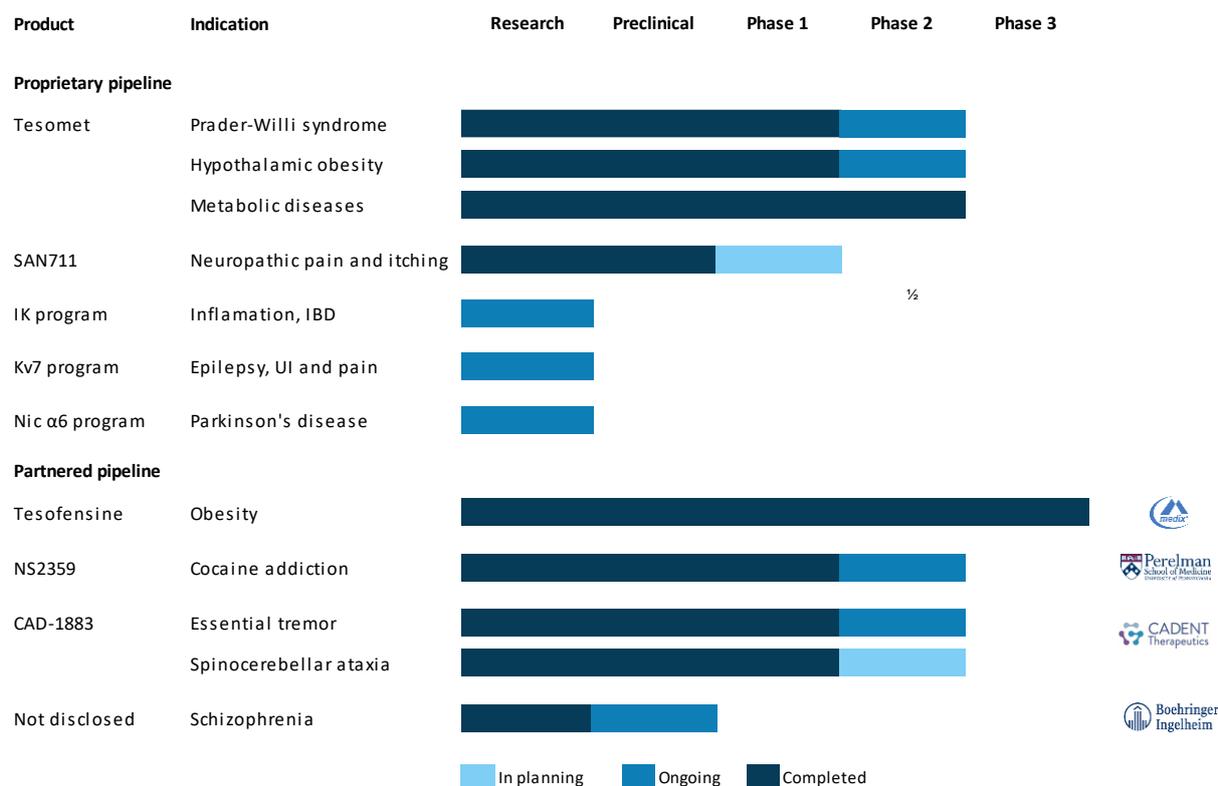
Saniona has completed the preclinical development of SAN711 for the treatment of chronic itching and neuropathic pain. The program is ready for Phase 1 either internally or together with a potential partner.

### Research programs

Saniona's early stage pipeline is based on its ion channel platform with well-established targets for drug discovery. 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 currently has four pre-clinical programs of which one program is financed by its partner Boehringer Ingelheim. Boehringer Ingelheim is currently conducting a preclinical development program in preparation for Phase 1 studies in schizophrenia. Saniona's three internal research programs, which are targeting the IK, Kv7 and Nicotinic α6 ion channels, are focused on the treatment of inflammatory diseases and certain neurological diseases including epilepsy and Parkinson's diseases.

Saniona's pipeline is set out below.



## Market

Saniona's ongoing programs address significant market segments:

Target/Program	Indication	Market estimate
<b>Tesomet</b>	Prader-Willi syndrome Hypothalamic obesity	- Orphan indication > USD 1 billion <sup>1</sup> - Orphan indication > USD 1 billion <sup>2</sup>
<b>Tesofensine</b>	Obesity	- USD 250 million in Mexico <sup>3</sup>
<b>NS2359</b>	Cocaine addiction	> USD 1.8 billion <sup>4</sup>
<b>SAN711</b>	Neuropathic pain	> USD 6 billion <sup>5</sup>
<b>Boehringer Ingelheim program</b>	Schizophrenia	> USD 4.8 billion <sup>6</sup>
<b>IK program</b>	Inflammatory bowel disease	> USD 5.9 billion <sup>7</sup>
<b>Nic-α6 program</b>	Parkinson's disease	> USD 2.8 billion <sup>8</sup>
<b>Kv7 program</b>	Pain, epilepsy, Urinary Incontinence	> USD 6 billion <sup>5</sup>
<b>Cadent Therapeutic program</b>	Ataxia Essential tremor	- Orphan indication NA

Apart from orphan indications such as Prader-Willi syndrome and hypothalamic obesity, where Saniona may develop and commercialize Tesomet on its own, Saniona will aim to partner with major pharmaceutical companies for purchasing, developing and commercializing projects from Saniona's pipeline of preclinical and clinical drug candidates.

There is a significant need for new and innovative products for the pharmaceutical companies, which often have a limited number of products in their pipelines. Therefore, the market for out-licensing of new, innovative pharmaceutical projects and product programs are considered attractive. Importantly, within the field of ion channels, there are relatively few biotech companies supplying major pharmaceutical companies with research and development projects. Combined, this is creating interesting business opportunities for Saniona.

<sup>1</sup> Financial analysts estimate that there is 20 - 30,000 PWS patients in the US and Europe collectively and that the obtainable average price level is USD 60,000 – 150,000 per patient per year, Nordea Markets, Redeye, Jarl Securities, Leerink, JMP Securities, Canaccord Genuity, SunTrust Robinson Humphrey

<sup>2</sup> Financial analysts estimate that the market for hypothalamic obesity is 30-50% of the market for PWS due to fewer patients, see above

<sup>3</sup> Estimates of drugs for obesity in Mexico by Medix 2016

<sup>4</sup> Estimates by TRC

<sup>5</sup> Major markets 2012, Decision Resources

<sup>6</sup> Schizophrenia Forecast 7 major market, Datamonitor, 2014

<sup>7</sup> Major markets 2014, Datamonitor

<sup>8</sup> The market for Parkinson's disease is estimated to be USD 2.8 billion in the 7 major markets in 2014, Datamonitor 2016

## Financial review

### Financial key figures

	2019-01-01 2019-03-31	2018-01-01 2018-03-31	2018-01-01 2018-12-31
Net sales, KSEK	1,715	4,340	54,884
Total operating expenses, KSEK	-30,864	-20,070	-109,089
Operating profit/loss, KSEK	*	-29,149	-15,730
Operating margin, %	*	-1700%	-362%
Cash flow from operating activities, KSEK	-25,753	-15,393	-22,920
Cash flow per share, SEK	*	-0.34	0.11
Earnings per share, SEK	-1.06	-0.62	-1.84
Diluted earnings per share, SEK	-1.06	-0.62	-1.84
Average shares outstanding	23,350,994	21,769,071	22,288,524
Diluted average shares outstanding	23,370,773	21,791,016	22,314,283
Shares outstanding at the end of the period	23,922,480	22,057,335	23,324,413
Average number of employees, #	22.7	23.6	23.5
	2019-03-31	2018-03-31	2018-12-31
Cash and cash equivalent, KSEK	46,881	25,449	54,678
Equity, KSEK	31,413	33,971	39,457
Total equity and liabilities, KSEK	82,238	53,313	83,075
Liquidity ratio, %	*	129%	224%
Equity ratio, %	*	38%	64%
Equity per share, SEK	*	1.31	1.54

\* = Alternative performance measures

### Definitions and relevance of alternative performance measures

Saniona presents certain financial measures in the interim 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
<b>Operating profit/loss</b>	Profit/loss before financial items and tax.	The operating profit/loss is used to measure the profit/loss generated by the operating activities.
<b>Operating margin</b>	Operating profit/loss as a proportion of revenue.	The operating margin shows the proportion of revenue that remains as profit before financial items and taxes and has been included to allow investors to get an impression of the company's profitability.
<b>Liquidity ratio</b>	Current assets divided by current liabilities.	Liquidity ratio has been included to show the Company's short-term payment ability.
<b>Equity ratio</b>	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.
<b>Average number of employees</b>	Average number of employees employed during the period.	This key figure may explain part of the development in personnel expenses and has been included to provide an impression of how the number of employees at the company has developed.
<b>Equity per share</b>	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.
<b>Cash flow per share</b>	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

	2019-01-01 2019-03-31	2018-01-01 2018-03-31	2018-01-01 2018-12-31
Operation profit/loss, KSEK	-29,149	-15,730	-54,206
Net sales, KSEK	1,715	4,340	54,884
<b>Operating margin, %</b>	<b>-1700%</b>	<b>-362%</b>	<b>-99%</b>
Cash flow for the period, KSEK	-8,009	2,343	24,786
Average shares outstanding	23,350,994	21,769,071	22,288,524
<b>Cash flow per share, SEK</b>	<b>-0.34</b>	<b>0.11</b>	<b>1.11</b>

	2019-03-31	2018-03-31	2018-12-31
Current assets, KSEK	61,628	43,304	70,668
Current liabilities, KSEK	50,825	19,342	43,617
<b>Liquidity ratio, %</b>	<b>129%</b>	<b>224%</b>	<b>162%</b>
Equity, KSEK	31,413	33,971	39,457
Total equity and liabilities, KSEK	82,238	53,313	83,075
<b>Equity ratio, %</b>	<b>38%</b>	<b>64%</b>	<b>47%</b>
Equity, KSEK	31,413	33,971	39,457
Shares outstanding at the end of the period	23,922,480	22,057,335	23,324,413
<b>Equity per share, SEK</b>	<b>1.31</b>	<b>1.54</b>	<b>1.69</b>

## Revenues and result of the operation

### Revenue

Total revenues during the first quarter of 2019 was SEK 1.7 million (4.3). In 2019 revenues comprised research funding under the agreements with Boehringer Ingelheim. In 2018, revenues comprised research funding under the agreements with Boehringer Ingelheim and BenevolentAI.

### Operating profit/loss

The operating loss for the first quarter was SEK 29.1 million (15.7).

The company recognized operating expenses of SEK 30.9 million (20.1) for the first quarter of 2019.

External costs amounted to SEK 22.3 million (13.2) and personnel costs amounted to SEK 7.1 million (5.9). In the first quarter of 2019, 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. In the first quarter of 2018, external expenses comprised primarily development costs in relation to Tesomet followed by research and development costs in relation to the IK program and SAN711.

### Cash flow

Operating cash flow for the first quarter of 2019 was an outflow of SEK 25.8 million (outflow of 15.4). Consolidated cash flow for the first quarter of 2019 was an outflow of SEK 8.0 million (inflow of 2.3).

In 2019, the operating cash flow during the first quarter is explained by the operating loss. The consolidated cash flow in 2019 is further explained by an inflow from finance activities of SEK 17.3 million through the issue of convertible loan notes to Nice & Green totaling SEK 18 million of which SEK 2 million has not been converted at the balance sheet date. The balance of SEK 16 million was converted into equity during Q1 2019 and the net proceeds of SEK 15.3 million is recorded under new share issues after deduction of issuing expenses. In 2018, the consolidated cash flow during the first quarter is explained by the operating loss and an inflow of from convertible loan note from Nice & Green totaling SEK 18 million of which SEK 10 million has not been converted. The balance of SEK 8 million was converted into equity during the first quarter and is recorded under new share issues after deduction of issuing expenses.

### **Financial position**

The equity ratio was 38 (64) % as of March 31, 2019, and equity was SEK 31.2 million (34.0). Cash and cash equivalents amounted to SEK 46.9 million (25.4) as of March 31, 2019. Total assets as of March 31, 2019, were SEK 82.2 million (53.3).

### **The share, share capital and ownership structure**

At March 31, 2019, the number of shares outstanding amounted to 23,922,480 (22,057,335). The company established a warrant program on July 1, 2015, totaling 64,000 warrants, on July 1, 2017, totaling 38,750 warrants, on January 19, 2018 totaling 286,003 warrants and on July 1, 2018, totaling 45,013 warrants.

At March 31, 2019, the company had 5,610 (5,297) shareholders excluding holdings in life insurance and foreign custody account holders.

### **Personnel**

As of March 31, 2019, the number of employees was 24 (25) of which 13 (13) were 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**

This interim report has not been subject to review by the company's auditors.

**Financial calendar**

Annual General Meeting	May 29, 2019
Interim Report Q2	August 21, 2019
Interim Report Q3	November 13, 2019
Year-End Report 2019	February 20, 2020

The Board of Directors and the CEO of Saniona AB (publ) provide their assurance that the interim 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, May 29, 2019  
Saniona AB

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J. Donald deBethizy - Chairman

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Jørgen Drejer – CEO and board member

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Claus Bræstrup – Board member

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Anna Ljung - Board member

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Carl Johan Sundberg - Board member

### Condensed consolidated statement of comprehensive income – Group

KSEK	Note	2019-01-01 2019-03-31	2018-01-01 2018-03-31	2018-01-01 2018-12-31
Net sales	1-2 3	1,715	4,340	54,884
Total operating income		1,715	4,340	54,884
Raw materials and consumables		-978	-830	-4,089
Other external costs		-22,302	-13,163	-80,149
Personnel costs	4	-7,073	-5,927	-24,219
Depreciation and write-downs		-510	-151	-632
Total operating expenses		-30,864	-20,070	-109,089
<b>Operating profit/loss</b>		<b>-29,149</b>	<b>-15,730</b>	<b>-54,206</b>
Share of result of associates	8	-1,460	0	6,174
Financial expenses		-197	-136	-261
Total financial items		-1,657	-136	5,913
<b>Profit/loss after financial items</b>		<b>-30,806</b>	<b>-15,866</b>	<b>-48,292</b>
Tax on net profit	5	5,996	2,414	7,233
<b>Profit/loss for the period</b>		<b>-24,810</b>	<b>-13,452</b>	<b>-41,059</b>
<b>Other comprehensive income</b>				
Item that may be reclassified to profit and loss		-	-	-
Translation differences		354	1,219	625
<b>Total other comprehensive income net after tax</b>		<b>354</b>	<b>1,219</b>	<b>625</b>
<b>Total comprehensive income</b>		<b>-24,455</b>	<b>-12,234</b>	<b>-40,434</b>
Earnings per share, SEK		-1.06	-0.62	-1.84
Diluted earnings per share, SEK		-1.06	-0.62	-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	2019-03-31	2018-03-31	2018-12-31
	1-2			
<b>ASSETS</b>				
Fixtures, fittings, tools and equipment		5,925	1,284	1,841
Tangible assets		5,925	1,284	1,841
Non-current tax assets	5	5,999	2,491	-
Investments in associated companies	8	5,045	331	6,505
Other long-term receivables	9	3,578	5,810	3,999
Financial assets		14,622	8,632	10,504
Deferred tax		63	93	62
<b>Non-current assets</b>		<b>20,609</b>	<b>10,009</b>	<b>12,407</b>
Trade receivables		1,716	4,939	2,093
Current tax assets	5	7,680	7,596	7,568
Other receivables		3,456	3,160	4,654
Prepayments and accrued income		1,895	2,159	1,675
Current receivables		14,747	17,855	15,990
Cash and cash equivalent		46,881	25,449	54,678
<b>Current assets</b>		<b>61,628</b>	<b>43,304</b>	<b>70,668</b>
<b>Total assets</b>		<b>82,238</b>	<b>53,313</b>	<b>83,075</b>
<b>EQUITY AND LIABILITIES</b>				
Share capital	10	1,196	1,103	1,166
Additional paid in capital	10	172,419	123,976	157,118
Retained earnings		-141,781	-90,924	-118,051
Currency translation reserve		-422	-183	-777
<b>Equity</b>		<b>31,413</b>	<b>33,971</b>	<b>39,457</b>
Lease liabilities		2,901	-	-
Non-current liabilities		2,901	0	0
Prepayments from customers		-	201	-
Trade payables		8,331	5,392	7,243
Convertible loan	10	8,000	10,000	6,000
Other payables		588	515	616
Accrued expenses and deferred income		31,005	3,234	29,759
Current liabilities		47,924	19,342	43,617
<b>Total liabilities</b>		<b>50,825</b>	<b>19,342</b>	<b>43,617</b>
<b>Total equity and liabilities</b>		<b>82,238</b>	<b>53,313</b>	<b>83,075</b>

**Condensed consolidated statement of changes in equity – Group**

	Share capital	Share premium	Translation reserves	Retained earnings	Shareholders' equity
<b>January 1, 2018</b>	<b>1,088</b>	<b>116,452</b>	<b>-1,402</b>	<b>-78,511</b>	<b>37,628</b>
<b>Comprehensive income</b>					
Profit/loss for the year				-13,452	-13,452
Other comprehensive income:					
Translation differences			1,219		1,038
<b>Total comprehensive income</b>			<b>1,219</b>	<b>-13,452</b>	<b>-12,234</b>
<b>Transactions with owners</b>					
Shares issued for cash	15	7,985			8,000
Expenses related to capital increase		-462			-462
Share-based compensation expenses				1,038	1,038
<b>Total transactions with owners</b>	<b>15</b>	<b>7,523</b>	<b>0</b>	<b>1,038</b>	<b>8,577</b>
<b>March 31, 2018</b>	<b>1,103</b>	<b>123,976</b>	<b>-183</b>	<b>-90,925</b>	<b>33,971</b>
<b>April 1, 2018</b>	<b>1,103</b>	<b>123,976</b>	<b>-183</b>	<b>-90,925</b>	<b>33,971</b>
<b>Comprehensive income</b>					
Profit/loss for the year				-27,606	-27,606
Other comprehensive income:					
Translation differences			-594		-594
<b>Total comprehensive income</b>			<b>-594</b>	<b>-27,606</b>	<b>-28,200</b>
<b>Transactions with owners</b>					
Shares issued for cash	63	33,937			34,000
Expenses related to capital increase		-794			-794
Share-based compensation expenses				480	480
<b>Total transactions with owners</b>	<b>63</b>	<b>33,143</b>	<b>0</b>	<b>480</b>	<b>33,687</b>
<b>December 31, 2018</b>	<b>1,166</b>	<b>157,118</b>	<b>-777</b>	<b>-118,051</b>	<b>39,457</b>
<b>January 1, 2019</b>	<b>1,166</b>	<b>157,118</b>	<b>-777</b>	<b>-118,051</b>	<b>39,457</b>
<b>Comprehensive income</b>					
Profit/loss for the year				-24,810	-24,810
Other comprehensive income:					
Translation differences			354		354
<b>Total comprehensive income</b>			<b>354</b>	<b>-24,810</b>	<b>-24,455</b>
<b>Transactions with owners</b>					
Shares issued for cash	30	15,970			16,000
Expenses related to capital increase		-670			-670
Share-based compensation expenses				1,080	1,080
<b>Total transactions with owners</b>	<b>30</b>	<b>15,301</b>	<b>0</b>	<b>1,080</b>	<b>16,411</b>
<b>March 31, 2019</b>	<b>1,196</b>	<b>172,419</b>	<b>-422</b>	<b>-141,780</b>	<b>31,413</b>

### Condensed consolidated statement of cash flows – Group

KSEK	Note	2019-01-01 2019-03-31	2018-01-01 2018-03-31	2018-01-01 2018-12-31
Profit/loss before tax		-30,806	-15,866	-48,292
Adjustments for non-cash transactions		2,921	1,293	-3,795
Changes in working capital		2,330	-683	29,428
<b>Cash flow from operating activities before financial items</b>		<b>-25,555</b>	<b>-15,256</b>	<b>-22,659</b>
Interest income received		-	-	-
Interest expenses paid		-197	-136	-261
<b>Cash flow from operating activities</b>		<b>-25,753</b>	<b>-15,393</b>	<b>-22,920</b>
<b>Investing activities</b>				
Investment in tangible assets		-8	-12	-1,107
Investment in other financial assets		421	209	2,021
<b>Cash flow from investing activities</b>		<b>413</b>	<b>197</b>	<b>914</b>
<b>Financing activities</b>				
Convertible loan	10	2,000	10,000	6,000
New share issue	10	15,330	7,538	40,745
<b>Cash flow from financing activities</b>		<b>17,330</b>	<b>17,538</b>	<b>46,745</b>
<b>Cash flow for the period</b>		<b>-8,009</b>	<b>2,343</b>	<b>24,738</b>
<b>Cash and cash equivalents at beginning of period</b>		<b>54,678</b>	<b>22,313</b>	<b>22,313</b>
Exchange rate adjustments		213	793	7,626
<b>Cash and cash equivalents at end of period</b>		<b>46,881</b>	<b>25,449</b>	<b>54,678</b>

### Statement of income – Parent Company

KSEK	Note	2019-01-01 2019-03-31	2018-01-01 2018-03-31	2018-01-01 2018-12-31
	1-2			
Net sales		-	-	-
Other operating income		338	-	-
<b>Total operating income</b>		<b>338</b>	<b>0</b>	<b>0</b>
Raw materials and consumables		-2	-5	-10
Other external costs		-1,816	-1,102	-5,524
Personnel costs		-897	-467	-2,379
<b>Total operating expenses</b>		<b>-2,715</b>	<b>-1,573</b>	<b>-7,912</b>
<b>Operating profit/loss</b>		<b>-2,377</b>	<b>-1,573</b>	<b>-7,912</b>
Share of result of associates	8	-1,460	-	6,174
Financial income		1,976	394	1,900
Financial expenses		-35	-80	-144
<b>Total financial items</b>		<b>481</b>	<b>314</b>	<b>7,931</b>
<b>Profit/loss after financial items</b>		<b>-1,896</b>	<b>-1,259</b>	<b>19</b>
Tax on net profit		-	-	-
<b>Profit/loss</b>		<b>-1,896</b>	<b>-1,259</b>	<b>19</b>

## Balance Sheet – Parent Company

KSEK	Note	2019-03-31	2018-03-31	2018-12-31
	1-2			
<b>ASSETS</b>				
Investment in subsidiaries		11,832	11,832	11,832
Investments in associated companies	8	5,045	331	6,505
Financial assets		16,877	12,162	18,337
<b>Non-current assets</b>		<b>16,877</b>	<b>12,162</b>	<b>18,337</b>
Receivables from group companies		115,284	88,571	112,424
Other receivables		363	240	257
Prepayments and accrued income		1,250	722	977
Current receivables		116,897	89,533	113,658
Cash and cash equivalent		27,062	13,148	13,435
<b>Current assets</b>		<b>143,959</b>	<b>102,682</b>	<b>127,093</b>
<b>Total assets</b>		<b>160,836</b>	<b>114,844</b>	<b>145,429</b>
<b>EQUITY AND LIABILITIES</b>				
<i>Restricted equity</i>				
Share capital	10	1,196	1,103	1,166
<i>Unrestricted equity</i>				
Additional paid in capital	10	170,908	122,464	155,607
Retained earnings		-17,960	-17,979	-17,979
Profit for the period		-1,896	-1,259	19
<b>Equity</b>		<b>152,248</b>	<b>104,329</b>	<b>138,813</b>
Convertible loan	10	8,000	10,000	6,000
Other payables		588	515	616
Current liabilities		8,588	10,515	6,616
<b>Total liabilities</b>		<b>8,588</b>	<b>10,515</b>	<b>6,616</b>
<b>Total equity and liabilities</b>		<b>160,836</b>	<b>114,844</b>	<b>145,429</b>

## 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 interim 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 functional 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](http://www.saniona.com).

Disclosures in accordance with IAS 34 Interim Financial Reporting are presented either in the notes or elsewhere in the interim 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. Please refer to table below for a specification of the amounts recognized under initial recognition of IFRS 16.

KSEK	Figures before IFRS 16 2019-01-01	IFRS 16 adjustments	Adjusted figures 2019-01-01
<b>Assets</b>			
Tangible assets	-	4,233	4,233
<b>Total</b>	<b>0</b>	<b>4,233</b>	<b>4,233</b>
<b>Liabilities</b>			
Lease liabilities, long-term	-	2,901	2,901
Lease liabilities, short-term	-	1,332	1,332
<b>Total</b>	<b>0</b>	<b>4,233</b>	<b>4,233</b>

Apart from rental agreements in relation to the company's premises as described above, the company has no other lease commitments as of March 31, 2019. Given the insignificance of the effect of IFRS 16, the company will present new accounting principles for leasing in the Financial Statement for 2019.

### 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 Q1 2019 totaled SEK 1,080 (1,038) 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 2015	Options granted in 2017	Options granted in 2018	Total
<b>Share-based payment</b>				
Outstanding at 1 January 2019	64,000	38,292	331,016	433,308
Granted during the period	-	-	-	-
Forfeited during the period	-	-	1,708	1,708
<b>Outstanding at 31 March 2019</b>	<b>64,000</b>	<b>38,292</b>	<b>329,308</b>	<b>431,600</b>

If all issued warrants are exercised for subscription of new shares, the Parent Company's will issue a total of 431,600 new shares corresponding to a dilution of approximately 1.77%. The data below has been used for the calculation.

Incentive program	2015	2017	2018:1	2018:2	2018:3
Allotted options	64,000	38,750	286,003	34,500	10,513
Fair value per option (SEK)	13.13	29.48	12.67	18.89	18.89
Share price for underlying shares (SEK)	19.90	45.50	26.95	33.85	33.85
Subscription price (SEK)	20.72	41.13	33.60	30.08	30.08
Vesting period	4 years	4 years	3 years	4 years	3 years
Estimated life of the option	4.50 years	5.50 years	6.25 years	5.5 years	4 years
Risk-free interest rate during the life of the option	0.2257%	-0.0584%	0.2389%	-0.0713%	-0.0713%
Assumed volatility*	91.29%	76.75%	57.41%	63.58%	63.58%
Expected dividends	0	0	0	0	0

\* In 2015 and 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, the volatility equals a twelve-month period.

A detailed description of the warrant program in 2015, 2017, 2018:1, 2018:2 and 2018:3 can be found in the annual report 2018.

### 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 6.0 million (2.4) during the first quarter 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 March 31, 2019, the Group had SEK 7.7 million (DKK 5.5 million) in current tax asset, which will be payable in November 2019 and SEK 6.0 million in non-current tax assets, which will be payable in November 2020. As of March 31, 2018, the Group had SEK 7.6 million (DKK 5.5 million) in current tax asset, which was paid in November 2018 and SEK 2.5 million in non-current tax assets, which will be payable 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 March 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 Investment in associated companies

On May 3, 2017, Saniona participated in formation of a new company, Scandion Oncology A/S. Scandion Oncology has been listed on the Spotlight Stock Market on November 8, 2018, after having raised SEK 26 million in an IPO at a pre-money valuation of SEK 43.7 million. The decrease in equity for Q1 2019 has been recorded in the statement of income under Share of result of associates with SEK 1.5 million.

Scandion Oncology A/S	Equity*	Saniona's share of net profit/(loss) (ownership 29.17%)
January 1, 2019*	22,300,870	6,505,164
March 31, 2019**	17,296,605	5,045,420
		(1,459,744)

\*The calculation of equity is based on Scandion Oncology's interim report Q3 2018 and the capital increase in Q4 2018.

\*\*The calculation of equity is based on Scandion Oncology's year-end report 2018.

#### 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 0.5 million (SEK 0.4 million) and as March 31, 2019, the recorded value of the asset is SEK 4.3 (SEK 6.2 million).

#### **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 has 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. Saniona has the right to extend the convertible notes funding agreement with Nice & Green for an additional SEK 72 million with the same terms, totalling SEK 144 million over a two-year period.

The convertible notes will bear no interest and will mature 12 months from the date issued. Unless an event of default occurs, the non-converted convertible notes will be converted to shares or reimbursed in cash at Saniona's discretion at the maturity date. Nice & Green will have 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. To the extent Nice & Green has not requested conversion at the end of the respective conversion period, Saniona will have the right to request conversion. The pricing of the shares will be 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 has sent a conversion notice to Saniona. Upon each request for conversion, Saniona has the right to instead of effectuating conversion, pay a cash amount to Nice & Green. The cash amount to be paid in case Saniona utilizes this right, will be calculated as  $V/0.97$  where V is the nominal amount of the convertible note for which Saniona chooses to effect cash payment. For further details, please see Saniona's press release dated December 29, 2017.

The Group had SEK 6 million in convertible loan notes outstanding as of December 31, 2018, and it has drawn three tranches totaling SEK 18 million (SEK 18 million) during the first quarter of 2019. During the first quarter, Nice & Green has converted SEK 16 million (SEK 8 million) to shares, which has been taken to equity after deducting expenses relating to capital increase totaling SEK 0.7 million (SEK 0.5 million). As of March 31, 2019, the Group had SEK 8 million (SEK 10 million) in convertible loan notes outstanding.

## 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 severe 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. For further details, please see CAD-1883 in the Pipeline section.

### **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 the majority of 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 $\alpha 2/\alpha 3$ program**

A small molecule program which is designed to positively modulate (PAM) GABA-A  $\alpha 2$  and GABA-A  $\alpha 3$  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 block (antagonize) IK channels, which are expressed by immune cells and believed to be key mediator of inflammation in auto inflammatory diseases such as inflammatory bowel disease, multiple sclerosis and Alzheimer's' disease.

### **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  $\beta_1$  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 a number of 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 $\alpha_6$ program**

The Nic  $\alpha_6$  program is a small molecule program designed to positively modulate (PAM) the  $\alpha_6$  ion channels. The  $\alpha_6$  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  $\alpha 3$  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.

### **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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