

Saniona marks breakthrough 2018 with first Phase 3 trial completion

- Sets stage for lead program Tesomet in rare eating disorders and metabolic diseases
- Large number of promising products moving through clinical trials

Financial highlights

Jan - Dec 2018 (Jan - Dec 2017)

- Net revenues were SEK 54.9 M (20.7 M)
- EBIT was SEK -54.2 M (-57.2 M)
- Net profit/loss was SEK -41.1 M (-49.2)
- Earnings per share were SEK -1.84 (-2.30)
- Diluted earnings per share were SEK -1.84 (-2.30)

Q4 2018 (Q4 2017)

- Net revenues were SEK 2.2 M (4.6 M)
- EBIT was SEK -34.3 M (-16.6 M)
- Net profit/loss was SEK -23.3 M (-14.8)
- Earnings per share were SEK -1.02 (-0.68)
- Diluted earnings per share were SEK -1.02 (-0.68)

Business highlights in Q4 2018

- Saniona completed recruitment of adolescents for the second part of its Phase 2a study of Tesomet in patients with Prader Willi Syndrome (PWS). The trial is expected to be completed in early 2019.
- Saniona's partner Medix successfully completed a Phase 3 registration trial for tesofensine in obesity. The trial met its primary endpoints with a statically and clinically significant weight loss for both doses of tesofensine compared to placebo. Patients achieved an average weight loss of ten percent in the highest dose group and more than half of the patients lost more than ten percent in weight. The trial also met other secondary endpoints with statistically significant reduction in key obesity-related risk factors.
- Saniona's partner Cadent Therapeutics secured USD 40 million financing anchored by Atlas Ventures, a leading US-based investor, and initiated a Phase 2 study for its lead compound, CAD-1883, in essential tremor, which was discovered under the collaboration with Saniona.
- Saniona's spin-out company Scandion Oncology was listed on the Spotlight Stock Market on November 8, 2018 and received total proceeds of SEK 26 million before issuance costs through an Initial Public Offering.
- Saniona entered into a 1-year option agreement with Initiator Pharma A/S, where Initiator Pharma obtains the right to acquire the AN788 program under certain conditions.

Significant events after the reporting period

- 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 studies. Saniona has now filed and received approval to increase the dose to 0.25 mg/day in the Czech Republic; approval in Hungary is pending. The first patients are expected to be switched to the 0.25 mg dose in March and the study is scheduled to continue until the end of June.
- 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 following their interim analysis.
- 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.

Comments from the CEO

"Our partner Medix successfully completed a Phase 3 registration trial of tesofensine, paving the way for a regulatory filing in Mexico and supporting our fully-owned program with Tesomet. We made significant progress at Saniona in the fourth quarter with our pipeline in rare eating disorders, moving towards the market to provide help to patients with these debilitating diseases," says Jørgen Drejer, CEO of Saniona.

For more information, please contact

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Letter from the CEO

Annual results are a natural time to take stock on the events of the past year, and on the many successes that are underpinning the development of Saniona as a biotech company. In particular, the successful completion, by our partner Medix, of a Phase 3 registration trial for tesofensine in obesity really stands out. The results are deeply impressive: 10% average weight loss in 24 weeks, more than half of patients losing more than 10% in weight, and a statistically significant reduction in key obesity-related risk factors. Medix, which owns commercial rights in Mexico and Argentina, will now prepare regulatory filings in those countries, which we expect in H1 2019 with launch in 2020. As Saniona holds all rights to these data and all other commercial rights to tesofensine in the rest of the world, we believe this program has significant upside.

Seven out of 10 Mexicans are categorized as overweight or obese, more than twice the worldwide average, and eight in 10 deaths are caused by chronic, non-transmitted diseases that are linked to the overweight and obese population. This trial provides validation of tesofensine as a potentially highly efficacious treatment for obesity and may bring a significant double-digit royalty stream in both Mexico and Argentina, to help fund our broad pipeline.

Tesomet development

These results support development of Saniona's wholly-owned Tesomet, a fix-dosed combination of tesofensine and metoprolol in Phase 2 for rare eating disorders. From this and previous studies, we know that the product reduces appetite and provides a significant and clinically relevant weight loss.

We have obtained proof of concept in the first part of our Phase 2a study of Tesomet in Prader-Willi Syndrome (PWS), key opinion leaders strongly support further development and we are now working to establish the optimal dose. PWS is a significant commercial opportunity, with 20,000 patients in the US and Europe combined and potential premium pricing as an orphan drug.

Data showed the clearance of tesofensine is much slower in this patient group than in the general population, and that PWS patients consequently should be given a lower dose to obtain the same blood concentration and effect as seen on normal obese patients. Therefore, in the second part of the study in adolescent PWS patients we initially gave a conservative dose, a quarter of the dose given to adult PWS patients during the first part of the study. Since this did not result in the required plasma concentration, we are now continuing at a double dose in this dose optimization study.

Based on the strong efficacy on both hyperphagia and weight seen in the first part of the study in adult PWS patients, and the successful Phase 3 trial of tesofensine, the active ingredient in Tesomet, we are confident that Tesomet holds the potential of treating debilitating hyperphagia and significantly reduce weight in this severely underserved population.

Phase 2a in hypothalamic obesity

In parallel with PWS, we are exploring the potential for Tesomet in hypothalamic obesity (HO) and expect to initiate a Phase 2a study in Q1 2019. This study will include up to 25 patients, who will receive treatment for 24 weeks followed by an open-label extension, where all patients will receive Tesomet for 24 weeks, resulting in a total treatment period of 48 weeks. We expect results from the double-blind part of the study in Q4 2019 and the full data in H1 2020.

The two rare eating disorders, PWS and HO, have several factors in common, including clinical symptoms, clinical trial design, regulatory advantages from potential orphan drug designation and premium pricing as well as fast time to market due to relative short and small clinical studies.

There are no valid data about prevalence in HO, which most often occurs following surgical removal of a benign brain tumor with a reported incidence of 1/50,000. The number of patients is probably half those with PWS, since not all HO patients develop hyperphagia and associated obesity, but this is still an interesting market due to potential premium pricing under orphan drug status.

The objective is to prepare Tesomet for pivotal Phase 2b/3 studies in at least one of the two indications, PWS and HO, during 2019 and start such pivotal studies in 2020.

We have also successfully completed two Phase 1 studies and an additional preclinical toxicology study for Tesomet. The results from these trials, together with the long-term toxicology studies, provide more flexibility in

designing clinical studies (extension of ongoing PWS study and 6-12 months studies in HO) and pave the way for pivotal Phase 2b/3 trials.

Progress in early pipeline

The early-stage pipeline is progressing rapidly into the clinic and our partnerships are proving fruitful, both in the long- and short-term, providing important non-diluting funding for our own programs.

We received a €4 million milestone payment from Boehringer Ingelheim following selection of a clinical candidate for schizophrenia, bringing the total Saniona has received from this agreement to €9 million. Boehringer Ingelheim is conducting IND-enabling studies to initiate clinical studies.

Cadent Therapeutics raised \$40 million to support the development of their lead compound, CAD-1883, which comes from a collaboration with Saniona. Cadent initiated a Phase 1 study in Q1 2018, have already started a Phase 2a study for in essential tremor, and expect to start another Phase 2a study for Ataxia in H2 2020. Saniona holds an ownership stake in Cadent and will receive royalties on CAD-1883 if it reaches the market.

Saniona has completed the IND-enabling studies for SAN711 as a new and potentially game-changing treatment of neuropathic pain and itching. The compound also has potential in rare itching disorders, which Saniona potentially could pursue itself. The compound is expected to be ready to start Phase 1 studies in summer 2019.

The IK program has also made significant progress during the year and we hope to soon be able to present a clinical candidate for IND enabling studies. This is a new concept in inflammatory and autoimmune diseases and we have strong data in models for Crohn's disease and colitis, the indications in which we are most likely to develop it in collaboration with a partner. The concept may also be developed for rare diseases, potentially internally. Overall, we believe it represents an important asset for Saniona.

In addition, we have been granted SEK 1.4 million by the Danish Innovation Fund (DIF) for the development of our Kv-7 program, which could lead to a potential new treatment within urinary incontinence, pain and epilepsy, including rare types of epilepsy where there is a genetic link to Kv-7 channels and where there are currently no good treatment options.

As you can see from the above, Saniona is developing rapidly as a biotech company and we are moving a large number of promising products through value inflection points. I am deeply grateful for the efforts and commitment of our team, shareholders and partners who are supporting our efforts to combat these diseases. This year has been a very exciting one, and I am very much looking forward to continuing our journey through 2019 and beyond.

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

Strategy and business model

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 appear to be very large. Saniona is currently developing Tesomet for Prader Willi syndrome and hypothalamic obesity with emphasis on the U.S. and Europe. Patients with these rare eating disorders suffer from extreme hyperphagia which can lead to severe obesity. There is a major medical need for a product, which can provide weight loss and reduce hyperphagia in these patients. The market for such a product may be significant despite a relatively small number of patients. Furthermore, the required investments for developing Tesomet in these indications are comparatively small and the required commercial infrastructure for servicing these patients in the U.S. and Europe is manageable.

In general, the majority of Saniona's internal development programs may potentially be developed and commercialised for both orphan indications by Saniona and for larger indications in collaboration with partners. One of Saniona's short term objectives is to develop at least one of its preclinical programs to Phase 2, with the aim of positioning the product for a potential orphan indication itself or to out-license it to a pharmaceutical company to treat a more common disease.

The structure of Saniona's collaboration agreements depend on the product, the indication, the investment and the risk as well as the interest and capabilities of Saniona's partners. In general, when it decides to develop a product in collaboration with pharmaceutical company, Saniona grants its partners commercial license to a limited territory or on a world-wide basis. In exchange, Saniona's 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.

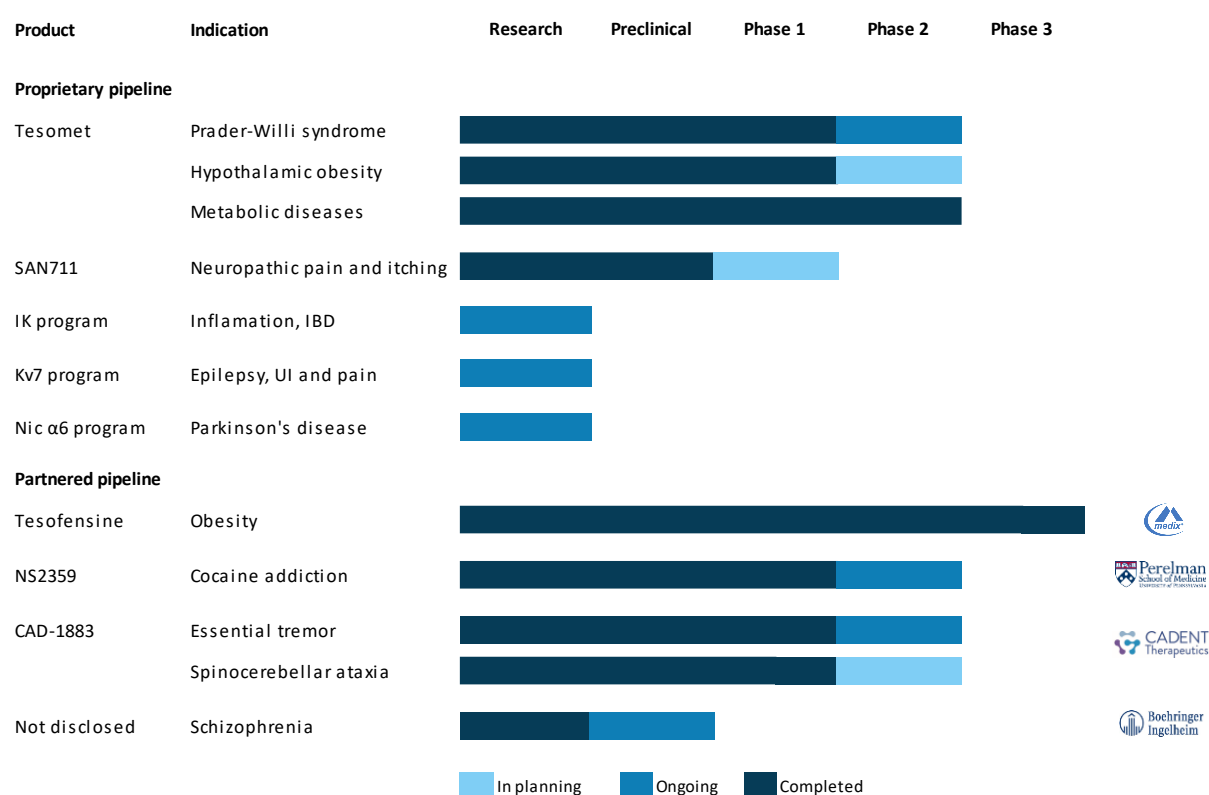
Project portfolio

Saniona has a portfolio of nine active drug development programs in clinical and pre-clinical stages, of which four are financed through partnerships or grants.

Saniona is currently conducting Phase 2 studies for Tesomet for treatment of eating disorders. In addition, Saniona is preparing to start a Phase 1 study for SAN711 for treatment of chronic pain and itching. Saniona's three research programs, which are targeting the IK, Kv7 and Nicotinic $\alpha 6$ ion channels, are focused on treatment of inflammatory diseases and various neurological diseases including epilepsy and Parkinson's diseases.

Saniona's partner 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. Cadent Therapeutics is conducting Phase 1 and Phase 2 studies for movement disorders and Boehringer Ingelheim is preparing for Phase 1 studies in schizophrenia. In addition to this the University of Pennsylvania is conducting an investigator-initiated clinical Phase 2a proof-of-concept study with NS2359 for treatment of cocaine addiction.

Saniona's pipeline is set out below.



Market

Saniona's ongoing programs address significant market segments:

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

Apart from orphan indications such as Prader-Willi syndrome and hypothalamic obesity, where Saniona may develop and commercialise 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.

¹ 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

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

³ Estimates of drugs for obesity in Mexico by Medix 2016

⁴ Estimates by TRC

⁵ Major markets 2012, Decision Resources

⁶ Schizophrenia Forecast 7 major market, Datamonitor, 2014

⁷ Major markets 2014, Datamonitor

⁸ 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

	2018-10-01	2017-10-01	2018-01-01	2017-01-01
	2018-12-31	2017-12-31	2018-12-31	2017-12-31
Net sales, KSEK	2,216	4,621	54,884	20,692
Total operating expenses, KSEK	-36,478	-21,219	-109,089	-77,881
Operating profit/loss, KSEK	*	-34,263	-16,598	-54,206
Operating margin, %	*	-1546%	-359%	-99%
Cash flow from operating activities, KSEK		-7,579	-17,482	-22,920
Cash flow per share, SEK	*	0.44	-0.79	1.11
Earnings per share, SEK		-1.02	-0.68	-1.84
Diluted earnings per share, SEK		-1.02	-0.68	-1.84
Average shares outstanding	22,850,645	21,762,520	22,288,524	21,416,810
Diluted average shares outstanding	22,877,327	21,789,512	22,314,283	21,452,001
Shares outstanding at the end of the period	23,324,413	21,762,520	23,324,413	21,762,520
Average number of employees, #	23.4	24.7	23.5	24.1
Cash and cash equivalent, KSEK			54,678	22,313
Equity, KSEK			39,457	37,628
Total equity and liabilities, KSEK			83,075	48,375
Liquidity ratio, %	*		162%	377%
Equity ratio, %	*		47%	78%
Equity per share, SEK	*		1.69	1.73

* = Alternative performance measures

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.
Operating margin	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.
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.
Average number of employees	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.
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

	2018-10-01 2018-12-31	2017-10-01 2017-12-31	2018-01-01 2018-12-31	2017-01-01 2017-12-31
Operation profit/loss, KSEK	-34,263	-16,598	-54,206	-57,189
Net sales, KSEK	2,216	4,621	54,884	20,692
Operating margin, %	-1546%	-359%	-99%	-276%
Cash flow for the period, KSEK	9,987	-17,267	24,738	-30,134
Average shares outstanding	22,850,645	21,762,520	22,288,524	21,416,810
Cash flow per share, SEK	0.44	-0.79	1.11	-1.41

	2018-12-31	2017-12-31
Current assets, KSEK	70,668	40,569
Current liabilities, KSEK	43,617	10,747
Liquidity ratio, %	162%	377%
Equity, KSEK	39,457	37,628
Total equity and liabilities, KSEK	83,075	48,375
Equity ratio, %	47%	78%
Equity, KSEK	39,457	37,628
Shares outstanding at the end of the period	23,324,413	21,762,520
Equity per share, SEK	1.69	1.73

Revenues and result of the operation

Revenue

Total revenues during the fourth quarter of 2018 was SEK 2.2 million (4.6). In 2018, revenues comprised research funding under the agreements with Boehringer Ingelheim. In 2017, revenues comprised research funding under the agreements with Boehringer Ingelheim and BenevolentAI.

Saniona generated total revenues of SEK 54.9 million (20.7) for the full year of 2018. 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 totalling SEK 13.1 million under the agreements with Boehringer Ingelheim and BenevolentAI. In 2017, revenues comprised research funding under the agreements with Boehringer Ingelheim, BenevolentAI and Cadent Therapeutics.

Operating profit/loss

The operating loss for the fourth quarter was SEK 34.3 million (16.6).

The company recognized operating expenses of SEK 36.5 million (21.2) for the fourth quarter of 2018.

External costs amounted to SEK 29.4 million (13.7) and personnel costs amounted to SEK 6.0 million (6.3). In the fourth quarter of 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. In the fourth quarter of 2017, external expenses comprised primarily development costs in relation to Tesomet followed by research and development costs in relation to the IK program and SAN711.

The company recognized an operating loss of SEK 54.2 million (loss 57.2) for the full year of 2018. The company recognized operating expenses of SEK 109.1 million (77.9) whereof external expenses amounted to SEK 80.1 million (51.4) and personnel costs amounted to SEK 24.2 million (22.7). 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 IK program. In 2017, external expenses comprised primarily development costs in relation to Tesomet followed by research and development costs in relation to the IK program and SAN711, and costs in relation to the listing on Nasdaq Stockholm Small Cap.

Cash flow

Operating cash flow for the fourth quarter of 2018 was an outflow of SEK 7.5 million (outflow of 17.7).

Consolidated cash flow for the fourth quarter of 2018 was an inflow of SEK 10.0 million (outflow of 17.3).

Operating cash flow for the full year of 2018 was an outflow of SEK 22.7 million (outflow of 56.6). Consolidated cash flow for the full year of 2018 was an inflow of SEK 24.7 million (outflow of 30.1).

In 2018, the operating cash flow is explained by the operating loss and an improvement in working capital 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 totalling 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. The consolidated cash flow in 2017 is explained by an inflow from the private placement in the second quarter of 2017 of SEK 33.2 million after finance expenses and an outflow from the one-time payment to NeuroSearch for the remaining rights in Saniona's preclinical and clinical assets (see note 9) and the operating loss during the period.

Financial position

The equity ratio was 48 (78) % as of December 31, 2018, and equity was SEK 39.5 million (37.6). Cash and cash equivalents amounted to SEK 54.7 million (22.3) as of December 31, 2018. Total assets as of December 31, 2018, were SEK 83.1 million (48.4).

The share, share capital and ownership structure

At December 31, 2018, the number of shares outstanding amounted to 23,324,413 (21,762,520). The company established a warrant program on July 1, 2015, totalling 64,000 warrants, on July 1, 2017, totalling 38,500 warrants, on January 19, 2018 totalling 286,003 warrants and on July 1, 2018, totalling 45,013 warrants. At December 31, 2018, the company had 5,569 (5,195) shareholders excluding holdings in life insurance and foreign custody account holders.

Personnel

As of December 31, the number of employees was 25 (26) of which 13 (14) are women. Of these employees, 3 (3) are part-time employees and 22 (23) are full-time employees, and a total of 20 (21) work in the company's research and development operations. 12 (12) of Saniona's employees hold PhDs, 2 (3) 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 2017 Annual Report. There are no major changes in the Group's risk exposure and risk management in 2018.

Audit review

This year-end report has not been subject to review by the company's auditors.

Financial calendar

Interim Report Q1	May 29, 2019
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

Annual General Meeting 2019

Saniona's Annual General Meeting will be held at Setterwalls Advokatbyrå AB's office at Stortorget 23, Malmö, Sweden on May 29, 2019 at 4 pm CET.

The Board of Directors proposes that no dividend will be paid for the 2018 financial year.

The Annual Report for 2018 will be published on www.saniona.com no later than April 30, 2019. It will also be available at Saniona's head office at Baltorpevej 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 to the Board of Directors no later than April 2, 2019. 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, Baltorpevej 154, DK-2750 Ballerup, Denmark.

The Nomination Committee's member are: Søren Skjæræk, owner of Ursuslaw, 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, Baltorpevej 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.

Malmö, February 21, 2019
Saniona AB

J. Donald deBethizy - Chairman

Jørgen Drejer – CEO and board member

Claus Bræstrup – Board member

Anna Ljung - Board member

Carl Johan Sundberg - Board member

Condensed consolidated statement of comprehensive income – Group

KSEK	Note	2018-10-01	2017-10-01	2018-01-01	2017-01-01
		2018-12-31	2017-12-31	2018-12-31	2017-12-31
	1-2				
Net sales	3	2,216	4,621	54,884	20,692
Total operating income		2,216	4,621	54,884	20,692
Raw materials and consumables		-925	-1,071	-4,089	-3,263
Other external costs		-29,386	-13,712	-80,149	-51,387
Personnel costs	4	-5,979	-6,277	-24,219	-22,671
Depreciation and write-downs		-189	-157	-632	-561
Total operating expenses		-36,478	-21,219	-109,089	-77,881
Operating profit/loss		-34,263	-16,598	-54,206	-57,189
Share of result of associates	8	6,505	-	6,174	-
Other financial income		-	1,853	-	1,289
Other financial expenses		-88	-	-261	-376
Total financial items		6,417	1,853	5,913	914
Profit/loss after financial items		-27,846	-14,745	-48,292	-56,275
Tax on net profit	5	4,505	-14	7,233	7,086
Profit/loss for the period		-23,341	-14,758	-41,059	-49,190
Other comprehensive income					
Item that may be reclassified to profit and loss		-	-	-	-
Translation differences		-74	-1,076	625	-968
Total other comprehensive income net after tax		-74	-1,076	625	-968
Total comprehensive income		-23,415	-15,835	-40,434	-50,157
Earnings per share, SEK		-1.02	-0.68	-1.84	-2.30
Diluted earnings per share, SEK		-1.02	-0.68	-1.84	-2.30

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	2018-12-31	2017-12-31
	1-2		
ASSETS			
Fixtures, fittings, tools and equipment		1,841	1,366
Tangible assets		1,841	1,366
Investments in associated companies	8	6,505	331
Other long-term receivables	9	3,999	6,019
Financial assets		10,504	6,350
Deferred tax		62	89
Non-current assets		12,407	7,806
Trade receivables		2,093	7,180
Current tax assets	5	7,568	7,276
Other receivables		4,654	3,261
Prepayments and accrued income		1,675	540
Current receivables		15,990	18,256
Cash and cash equivalent		54,678	22,313
Current assets		70,668	40,569
Total assets		83,075	48,375
EQUITY AND LIABILITIES			
Share capital	10	1,166	1,088
Additional paid in capital	10	157,118	116,452
Retained earnings		-76,992	-29,321
Currency translation reserve		-777	-1,402
Profit/loss for the period		-41,059	-49,190
Equity		39,457	37,628
Prepayments from customers		25,944	604
Trade payables		7,243	5,209
Convertible loan	10	6,000	0
Other payables		616	511
Accrued expenses and deferred income		3,815	4,423
Current liabilities		43,617	10,747
Total liabilities		43,617	10,747
Total equity and liabilities		83,075	48,375

Condensed consolidated statement of changes in equity – Group

	Number of shares	Share capital	Additional paid in capital	Translation reserves	Retained earnings	Shareholders' equity
January 1, 2017	20,841,467	1,042	83,323	-434	-29,680	54,252
Comprehensive income						
Profit/loss for the year					-49,190	-49,190
Other comprehensive income:						
Translation differences				-968		-968
Total comprehensive income				-968	-49,190	-50,157
Transactions with owners						
Shares issued for cash	921,053	46	34,954			35,000
Expenses related to capital increase			-1,825			-1,825
Share-based compensation expenses					359	359
Total transactions with owners	921,053	46	33,129	0	359	33,534
December 31, 2017	21,762,520	1,088	116,452	-1,402	-78,511	37,628
January 1, 2018	21,762,520	1,088	116,452	-1,402	-78,511	37,628
Comprehensive income						
Profit/loss for the year					-41,059	-41,059
Other comprehensive income:						
Translation differences				625		625
Total comprehensive income				625	-41,059	-40,434
Transactions with owners						
Shares issued for cash	1,561,893	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	1,561,893	78	40,666	0	1,519	42,263
December 31, 2018	23,324,413	1,166	157,118	-777	-118,051	39,457

Condensed consolidated statement of cash flows – Group

KSEK	Note	2018-10-01	2017-10-01	2018-01-01	2017-01-01
		2018-12-31	2017-12-31	2018-12-31	2017-12-31
Operating loss before financial items		-34,263	-16,598	-54,206	-57,189
Adjustments for non-cash transactions		363	284	2,118	918
Changes in working capital		26,410	-1,387	29,428	-347
Cash flow from operating activities before financial items		-7,491	-17,701	-22,659	-56,617
Interest income received		-	1,853	-	1,289
Interest expenses paid		-88	-	-261	-376
Tax paid		0	-1,635	-	-1,635
Cash flow from operating activities		-7,579	-17,482	-22,920	-57,339
Investing activities					
Investment in tangible assets		-552	-43	-1,107	-708
Investments in associated companies	8	-	-	-	-331
Investment in other financial assets		479	258	2,021	-4,931
Cash flow from investing activities		-73	215	914	-5,970
Financing activities					
Convertible loan	10	5,000	-	6,000	-
New share issue	10	12,639	-	40,745	33,175
Cash flow from financing activities		17,639	0	46,745	33,175
Cash flow for the period		9,987	-17,267	24,738	-30,134
Cash and cash equivalents at beginning of period		37,292	40,869	22,313	53,261
Exchange rate adjustments		7,399	-1,288	7,626	-815
Cash and cash equivalents at end of period		54,678	22,313	54,678	22,313

Statement of income – Parent Company

KSEK	Note	2018-10-01	2017-10-01	2018-01-01	2017-01-01
		2018-12-31	2017-12-31	2018-12-31	2017-12-31
	1-2				
Net sales		-	-	-	-
Total operating income		0	0	0	0
Raw materials and consumables		-2	-4	-10	-20
Other external costs		-1,848	-1,529	-5,524	-7,218
Personnel costs		-596	-322	-2,379	-1,249
Total operating expenses		-2,447	-1,854	-7,912	-8,487
Operating profit/loss		-2,447	-1,854	-7,912	-8,487
Share of result of associates		6,505	-	6,174	-
Other financial income		544	343	1,900	1,085
Other financial expenses		-10	-50	-144	-259
Total financial items		7,038	293	7,931	826
Profit/loss after financial items		4,592	-1,561	19	-7,660
Tax on net profit		0	0	0	0
Profit/loss		4,592	-1,561	19	-7,660

Statement of comprehensive income – Parent Company

KSEK	Note	2018-10-01	2017-10-01	2018-01-01	2017-01-01
		2018-12-31	2017-12-31	2018-12-31	2017-12-31
Profit/loss	1-2	4,592	-1,561	19	-7,660
Other comprehensive income					
Item that may be reclassified to profit and loss		-	-	-	-
Other comprehensive income		-	-	-	-
Total other comprehensive income net after tax		0	0	0	0
Total comprehensive income		4,592	-1,561	19	-7,660

Balance Sheet – Parent Company

KSEK	Note	2018-12-31	2017-12-31
ASSETS			
Investment in subsidiaries		11,832	11,832
Investments in associated companies		6,505	331
Financial assets		18,337	12,162
Non-current assets		18,337	12,162
Receivables from group companies		112,424	69,062
Other receivables		257	122
Prepayments and accrued income		977	95
Current receivables		113,658	69,279
Cash and cash equivalent		13,435	17,120
Current assets		127,093	86,399
Total assets		145,429	98,561
EQUITY AND LIABILITIES			
<i>Restricted equity</i>			
Share capital	10	1,166	1,088
<i>Unrestricted equity</i>			
Additional paid in capital	10	155,607	114,941
Retained earnings		-17,979	-10,318
Profit for the period		19	-7,660
Equity		138,813	98,050
Convertible loan	10	6,000	-
Other payables		616	511
Current liabilities		6,616	511
Total liabilities		6,616	511
Total equity and liabilities		145,429	98,561

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 functional currency of the Parent Company.

The applied accounting principles are in accordance with those described in the Annual Report for 2017. More detailed information about the Group's and the Parent Company's accounting and valuation principles can be found in the Annual Report for 2017, which is available on www.saniona.com. New and amended standards and interpretations implemented as of January 1, 2018, such as IFRS 15 on revenue recognition and IFRS 9 for financial instruments, has not had any significant impact on the Group's financial statements and implementation of the new standards does not require restatement of previous periods since the effects are insignificant.

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 will enter into force on January 1, 2019. Apart from rental agreements in relation to the company's premises, the company has no other lease commitments as of December 31, 2018. Therefore, the new standard will only impact the financial statements insofar as rental contracts for premises. This means that Saniona will recognize the value of its rental contract in relation to the company's premises as a lease asset and a lease liability in the balance sheet from January 1, 2019. The company does not expect the new standard to have a material effect on Saniona.

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 comprises 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 2018 totalled SEK 1,518 (359) 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
Share-based payment				
Outstanding at 1 January 2018	64,000	38,292	-	102,292
Granted during the period	-	-	331,016	331,016
Forfeited during the period	-	-	-	-
Outstanding at 31 December 2018	64,000	38,292	331,016	433,308

If all issued warrants are exercised for subscription of new shares, the Parent Company's will issue a total of 433,308 new shares corresponding to a dilution of approximately 1.82%. 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 and 2017 can be found in the annual report 2017.

2018:1 On January 19, 2018, the extraordinary shareholders' meeting voted in favour of establishing an incentive program involving the allotment of a maximum of 217,625 options free of charge to the chairman of the board of directors, J. Donald deBethizy. Allotment of 217,625 options took place in March 2018. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 33.60. 25% of the options vested on January 19, 2018, when the holder was elected as chairman of the Board of Directors. The balance of the options is earned with 25% on each anniversary of the election as chairman of the Board of Directors over a period of 3 years. 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 the case of full-year, the year-end report, the first time after publication of the quarterly report for the first quarter of 2021 and last time after publication of the quarterly report for the first quarter of 2024. 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 286,003 warrants to a wholly owned subsidiary in the Group.

2018:2 The 2018 Annual General Meeting voted in favour 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 July 2018. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 30.08. 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, 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 third quarter of 2023.

2018:3 The 2018 Annual General Meeting voted in favour of establishing an employee incentive program involving the allotment of a maximum of 8,000 options free of charge to certain members of the board of directors of the Group. Allotment of 8,000 options took place in July 2018. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 30.08. 1/3 of the options are vested when the annual shareholders' meeting takes place in 2019. Additional 1/3 of the options are vested when the annual shareholders' meeting takes place in 2020 and the last 1/3 of the options are vested when the annual shareholders' meeting takes place in 2021. 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 the case of full-year, the year-end report, the first time after publication of the quarterly report for the first quarter of 2021 and last time after publication of the quarterly report for the first quarter of 2022. 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 10,513 warrants to a wholly owned subsidiary in the Group.

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 7.2 million (7.1) during the full year of 2018. This amount has been recognized under 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 2017 and 2018, 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, 2018, the Group had SEK 7.6 million (DKK 5.5 million) in current tax asset, which will be payable in November 2019. As of December 31, 2017, the Group had SEK 7.3 million (DKK 5.5 million) in current tax asset, which was paid in November 2018.

Note 6 Pledged assets and contingent liabilities

The Group has provided a guarantee of KSEK 50 (50) to Euroclear. 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, 2018.

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 2017 and 2018.

Note 8 Investment in Scandion Oncology

On May 3, 2017, Saniona participated in formation of a new company, Scandion Oncology A/S. The investment of KSEK 331 has been recorded in the Saniona AB's and the Groups balance sheet under Investment in associated companies. Saniona has written down its investment to zero as of September 30, 2018, in accordance to the equity method because the equity of Scandion Oncology was negative as of June 30, 2018. 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 estimated equity in Scandion Oncology was SEK 22.3 million following the IPO. Saniona owns 29.17% of the shares outstanding in Scandion Oncology as of December 31, 2018. Saniona's share of the equity in Scandion Oncology following the IPO is SEK 6.5 million in accordance to the equity method. The increase in equity has been recorded in the statement of income under Share of result of associates and in the balance sheet under Investment in associated companies.

Note 9 NeuroSearch

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 2018 the onetime cash payment has been expensed with DKK 1.4 million (SEK 1.9 million) and as December 31, 2018, the recorded value of the asset is DKK 3.6 million (SEK 4.9 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.

In the full year of 2018, Saniona has drawn eight tranches totalling SEK 48 million of which SEK 42 million has been converted to shares by Nice & Green as of December 31, 2018. The converted amount of SEK 42 million is taken to equity after deducting expenses relating to capital increase totalling SEK 1.3 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 behavioural 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.

BenevolentAI

BenevolentAI acquired Proximagen Ltd. in Q1 2017.

Boehringer Ingelheim

Boehringer Ingelheim GmbH.

Cadent Therapeutics

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

Cocaine addiction

The compulsive craving for use of cocaine despite adverse consequences.

CNS

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

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 as 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 anaesthetics, calcineurin inhibitors and antidepressants. Many patients experience only a partial relief whereas others have no relief from existing treatment options.

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

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.

FDA

US Food and Drug Administration

GABA-A α 2/ α 3 program

A small molecule program which is designed to positively modulate (PAM) GABA-A α 2 and GABA-A α 3 ion channels, which are expressed in various central and peripheral neurons and are believed to be key mediator in the control of pain signalling and the control of anxiety.

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).

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.

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.

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 tumour), 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.

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. Thus, NS2359 is a promising clinical candidate for the treatment of cocaine dependence.

Schizophrenia

A mental disorder often characterized by abnormal social behaviour 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 the Partners 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.

This information is such information as Saniona AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 08:00 CET on February 21, 2019.

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