INTERIM REPORT FOR SANIONA AB (PUBL)
556962-5345
January - September 2019
Published November 13, 2019

Significant progress on Tesomet in PWS orphan indication

Financial highlights

Jan – Sep 2019 (Jan – Sep 2018)

- Net revenues were SEK 2.7 M (52.7 M)
- EBIT was SEK -75.8 M (-19.9 M)
- Net profit/loss was SEK -72.3 M (-17.7)
- Earnings per share were SEK -2.89 (-0.80)
- Diluted earnings per share were SEK -2.89 (-0.80)

Q3 2019 (Q3 2018)

- Net revenues were SEK 0.3 M (44.6 M)
- EBIT was SEK -26.0 M (19.9 M)
- Net profit/loss was SEK -27.7 (15.3 M)
- Earnings per share were SEK -1.00 (0.68)
- Diluted earnings per share were SEK -1.00 (0.68)

Business highlights in Q3 2019

- Saniona reported positive Tesomet Phase 2a clinical results in adolescent patients with Prader-Willi syndrome. Tesomet was safe and well tolerated in growing adolescent patients with PWS at both tested doses. Reduction in body weight and improvement of BMI observed at the high dose with hyperphagia score reduced to low single digits. Data provides additional guidance for the Phase 2b and Phase 3 studies now in planning.
- Saniona selected a development candidate, SAN903, in the IK program. Based on work done to date, Saniona has elected to focus SAN903 initially on the treatment of Crohn's disease and colitis.
- In July Saniona received the gross proceeds of SEK 66.5 million (SEK 53.7 million after transaction costs) from the Rights Issue, which was completed in June.

Significant events after the reporting period

- Saniona recruited the last patient in the Phase 2a clinical study for Tesomet in hypothalamic obesity. Patients will receive either Tesomet or matching placebo for 24 weeks followed by an open-label extension study where all patients will receive Tesomet for 24 weeks resulting in a total treatment period of 48 weeks. Saniona expects to report top line results from double-blind part of the study in Q2 2020

Comments from the CEO

"The results from our Phase 2a study in PWS provide strong de-risking and guidance for the pivotal Phase 2b/3 studies that we are now planning in PWS and other rare eating disorders, including hypothalamic obesity. Tesomet has the potential to significantly reduce weight and body mass index (BMI), and treat debilitating hyperphagia in these severe, rare and highly underserved eating disorders. By pursuing such orphan indications, we are creating a unique opportunity to develop and bring our own product to the market," says Jørgen Drejer, CEO of Saniona.

For more information, please contact

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Letter from the CEO

“Saniona made significant progress on its top strategic priority in Q3 reporting positive Phase 2a results for Tesomet in the rare eating disorder Prader-Willi syndrome (PWS). These data contribute to the overall aim of developing products internally with the intention to attaining market approval in the U.S. and Europe for certain orphan indications, which require limited investments, while representing attractive commercial opportunities.

Our priority is to develop and gain market approval for Tesomet in the U.S. and Europe ourselves for two orphan indications, PWS and hypothalamic obesity (HO). Tesomet has the potential to significantly reduce weight and body mass index (BMI), and treat debilitating hyperphagia in these severe, rare and highly underserved eating disorders. By pursuing such orphan indications, we are creating a unique opportunity to develop and bring our own product to the market.

We have reported results from the open-label extension studies in patients with PWS, performed during H1 and completed over the summer. The studies demonstrate that Tesomet is well tolerated at doses of 0.125 mg and 0.25 mg per day and that patients obtain significant benefit, with low single digit hyperphagia score and significant improvement in BMI. We will present the data at the International Prader-Willi Syndrome Organization conference (IPWSO) in Havana, Cuba, on November 13-17, 2019.

In the explorative Phase 2a study, we tested Tesomet in three different doses in nine adults and nine adolescents with PWS, with treatment lasting up to nine months. Our conclusion is that these studies provide proof of concept for Tesomet. We see a good correlation between efficacy, dose and plasma level and predict that a 0.25mg daily dose will be safe and efficacious in adolescent and adult patients with PWS. Furthermore, the length of the studies we have conducted with patients receiving treatment up to 9 months, supports the conclusion that Tesomet is feasible for long term treatment of PWS.

Based on this encouraging proof of concept data, we are preparing for meetings with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), with the aim of filing an Investigational New Drug (IND) application to initiate a pivotal Phase 2b/Phase 3 program. In parallel to this, we are exploring a number of financing options of the Phase 2b/3 program, including grants, private placements and collaborations.

We have completed enrolment in a Phase 2a study of Tesomet for HO, in which patients are receiving Tesomet at the optimal dose for obese patients (tesofensine 0.5 mg + metoprolol 50 mg daily) or matching placebo (2:1 randomization) for 24 weeks, followed by an open-label extension study where all receive Tesomet for 24 weeks. We expect to report results from the double-blind part of the study in Q2 2020 and from the full study in Q4 2020, with the aim of preparing Tesomet for pivotal Phase 2b/3 studies.

Looking at our other programs, Medix intends to file a new drug application (NDA) for tesofensine for treatment of obesity in Mexico. We have now forwarded a “drug master file” on the drug substance, compiled and validated by our contract manufacturer, to Medix. This is an important part of the application, and we are thus looking forward to reporting that Medix has filed the complete NDA application soon.

Cadent Therapeutics has completed a Phase 2a study of CAD-1883 in essential tremor, demonstrating an improvement in the “Essential Tremor Rating Assessment Scale Performance Score”. Cadent intends to file an IND for a Phase 2a study of CAD-1883 in ataxia in Q4 2019 and to explore a third and undisclosed indication.

Boehringer Ingelheim’s preparations for Phase 1 in schizophrenia are progressing according to plan. We have selected a clinical candidate, SAN903, in the IK program and there is significant interest from pharmaceutical and biotech companies, as it may be used in many indications beyond inflammatory bowel disease (IBD). We also continue preparations for a Phase 1 trial of SAN711, either internally or with a partner.

Progressing Tesomet to U.S. and European approval is the Saniona’s first priority, and this is where we are focusing our resources. The clinical data are compelling, and we are looking forward to bringing this treatment to patients.”

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 n launch the product in Mexico in 2020. Medix holds an exclusive license to commercialize tesofensine in Mexico and Argentina, while Saniona is entitled to milestone payments and royalties on product sales. Saniona retains commercial rights in the rest of the world and rights to use any data generated 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.

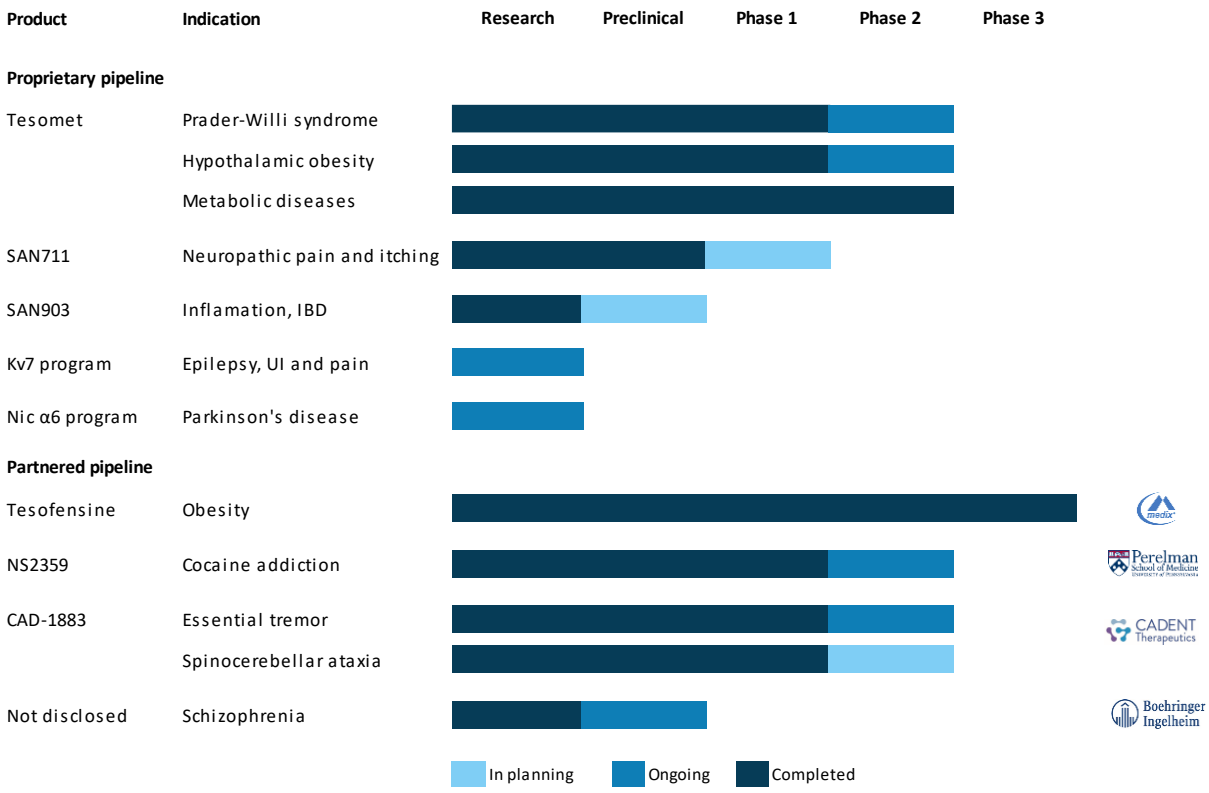
Saniona has completed the preclinical development of SAN711 for the treatment of chronic itching and neuropathic pain. The program is ready for Phase 1 either internally or together with a potential partner.

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. Furthermore, Saniona has initiated preclinical development for SAN903 in preparation for Phase 1 studies in IBD. Finally, Saniona's two internal research programs, which are targeting the Kv7 and Nicotinic α6 ion channels, are focused on the treatment of 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
Tesomet	Prader-Willi syndrome Hypothalamic obesity	- Orphan indication > USD 1 billion[1] - 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]
SAN903	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 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.

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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

		2019-07-01 2019-09-30	2018-07-01 2018-09-30	2019-01-01 2019-09-30	2018-01-01 2018-09-30	2018-01-01 2018-12-31
Net sales, KSEK		256	44,559	2,658	52,668	54,884
Total operating expenses, KSEK		-26,300	-24,638	-78,440	-72,611	-109,089
Operating profit/loss, KSEK	*	-26,045	19,921	-75,782	-19,943	-54,206
Cash flow from operating activities, KSEK		25,376	19,119	-81,590	-15,342	-22,920
Cash flow per share, SEK	*	0.92	0.86	-0.14	0.67	1.11
Earnings per share, SEK		-1.00	0.68	-2.89	-0.80	-1.84
Diluted earnings per share, SEK		-1.00	0.68	-2.89	-0.80	-1.84
Average shares outstanding		27,869,681	22,459,010	25,050,865	22,099,091	22,288,524
Diluted average shares outstanding		27,878,190	22,487,555	25,060,912	22,131,162	22,314,283
Shares outstanding at the end of the period		28,408,441	22,834,675	28,408,441	22,834,675	23,324,413
Average number of employees, #		22.2	23.4	22.4	23.5	23.5
		2019-09-30	**2018-09-30**			**2018-12-31**
Cash and cash equivalent, KSEK		59,126	37,292			54,678
Equity, KSEK		51,544	50,061			39,457
Total equity and liabilities, KSEK		90,348	61,588			83,075
Liquidity ratio, %	*	196%	457%			162%
Equity ratio, %	*	57%	81%			47%
Equity per share, SEK	*	1.86	2.19			1.69

** = 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
Operating profit/loss	Profit/loss before financial items and tax.	The operating profit/loss is used to measure the profit/loss generated by the operating activities.
Liquidity ratio	Current assets divided by current liabilities.	Liquidity ratio has been included to show the Company's short-term payment ability.
Equity ratio	Shareholders' equity as a proportion of total assets.	The equity ratio shows the proportion of total assets covered by equity and provides an indication of the company's financial stability and ability to survive in the long term.
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

	2019-07-01 2019-09-30	2018-07-01 2018-09-30	2019-01-01 2019-09-30	2018-01-01 2018-09-30	2018-01-01 2018-12-31
Operation profit/loss, KSEK	-26,045	19,921	-75,782	-19,943	-54,206
Net sales, KSEK	256	44,559	2,658	52,668	54,884
Operating margin, %	**-10190%**	**45%**	**-2851%**	**-38%**	**-99%**
Cash flow for the period, KSEK	25,567	19,414	-3,614	14,751	24,738
Average shares outstanding	27,869,681	22,459,010	25,050,865	22,099,091	22,288,524
Cash flow per share, SEK	**0.92**	**0.86**	**-0.14**	**0.67**	**1.11**

	2019-09-30	2018-09-30			2018-12-31
Current assets, KSEK	72,324	52,627			70,668
Current liabilities, KSEK	36,991	11,528			43,617
Liquidity ratio, %	**196%**	**457%**			**162%**
Equity, KSEK	51,544	50,061			39,457
Total equity and liabilities, KSEK	90,348	61,588			83,075
Equity ratio, %	**57%**	**81%**			**47%**
Equity, KSEK	51,544	50,061			39,457
Shares outstanding at the end of the period	27,763,347	22,834,675			23,324,413
Equity per share, SEK	**1.86**	**2.19**			**1.69**

Revenues and result of the operation

Revenue

Total revenues during the third quarter of 2019 was SEK 0.3 million (44.6).

Total revenues during the first nine months of 2019 was SEK 2.7 million (52.7).

In 2019, revenues comprised research funding under the agreement 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 third quarter was SEK 26.0 million (profit 19.9). The company recognized operating expenses of SEK 26.3 million (24.6) for the third quarter of 2019. External expenses amounted to SEK 19.1 million (17.5) and personnel costs amounted to SEK 5.9 million (5.7). In the third quarter of 2019, as well as the third quarter 2018, external expenses comprised primarily development costs in relation to Tesomet followed by preclinical development costs in relation to SAN711 and research and development costs in relation to the IK program.

The company recognized an operating loss of SEK 75.8 million (19.9) for the first 9 months of 2019. The company recognized operating expenses of SEK 78.4 million (72.6) whereof external expenses amounted to SEK 54.7 million (50.8) and personnel costs amounted to SEK 19.6 million (18.2). In both 2019 and 2018, external expenses comprised primarily development costs in relation to Tesomet followed by development costs in relation to SAN711 and development costs in relation to the IK program.

Cash flow

Operating cash flow for the third quarter of 2019 was an inflow of SEK 25.4 million (inflow of 19.1). Consolidated cash flow for the third quarter of 2019 was an inflow of SEK 25.6 million (inflow of 19.4).

In 2019, the operating cash flow for the third quarter is primarily explained by the operating loss of SEK 27.7 million and a decrease in working capital of SEK 54.9 million corresponding to the net proceeds from rights issue, which was declared as “Other receivable” on June 30, 3019, and paid-in in July 2019. In 2018, the operating cash flow for the third quarter is explained by the operating income. The consolidated cash flows for the third quarter in 2018 and 2019 are primarily explained by the operating cash flows in the respective periods.

The consolidated cash flow during the first nine months of 2018 is explained by an inflow from finance activities of SEK 29.1 million through the issue of convertible loan notes to Nice & Green totaling SEK 30 million of which SEK 1 million has not been converted at the balance sheet date. The balance of SEK 29 million was converted into equity during the first nine months and is recorded under new share issues after deduction of issuing expenses.

Operating cash flow for the first 9 months of 2019 was an outflow of SEK 81.0 million (outflow of 15.2). Consolidated cash flow for the first 9 months of 2019 was an outflow of SEK 3.6 million (inflow 14.8).

In 2019, the operating cash flow for the first nine months is explained by the operating loss. The consolidated cash flow in 2019 is further explained by an inflow from finance activities of SEK 76.7 million through a rights issue providing net proceeds of SEK 53.6 million and the issue of convertible loan notes to Nice & Green totaling SEK 24 million. During the first nine months of 2019, the convertible loan notes of SEK 24 million together with the outstanding loan notes at year-end 2018 totaling SEK 6 million have been converted into equity and the net proceeds of SEK 29 million is recorded under new share issues after deduction of issuing expenses.

In 2018, the operating cash flow for the first nine months is explained by the operating loss during the period and the improvement in working capital primarily due to an increase in trade payables and accrued expenses following increased development activities in 2018. The consolidated cash flow during the first nine months is explained by an inflow from finance activities of SEK 29.1 million through the issue of convertible loan notes to Nice & Green totaling SEK 30 million of which SEK 1 million has not been converted at the balance sheet date. The balance of SEK 29 million was converted into equity during the first nine months and is recorded under new share issues after deduction of issuing expenses.

Financial position
The equity ratio was 57 (81) % as of September 30, 2019, and equity was SEK 51.5 million (50.1). Cash and cash equivalents amounted to SEK 59.1 million (37.3) as of September 30, 2019. Total assets as of September 30, 2019, were SEK 90.3 million (61.6).

The share, share capital and ownership structure

At September 30, 2019, the number of shares outstanding amounted to 28,408,441 (22,834,675). During the first nine months of 2019, the total capital increased by SEK 254,137.40 and the total number of shares increased by 5,084,028. Through the rights issue in June 2019, the Company's share capital increased by SEK 184,855.45 and the number of shares increased by 3,697,109. Through the conversion of convertible loan notes totaling SEK 30 million during the first nine months of 2019, the Company's share capital increased by SEK 69,281.95 and the number of shares by 1,386,919.

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, on July 1, 2018, totaling 45,013 warrants and on September 15, totaling 50,270 warrants. See note 4 for further information about share based payments after the rights issue.

At September 30, 2019, the company had 6,219 (5,516) shareholders excluding holdings in life insurance and foreign custody account holders.

Personnel

As of September 30, the number of employees was 24 (25) of which 13 (13) are women. Of these employees, 3 (3) are part-time employees and 21 (22) are full-time employees, and a total of 19 (20) work in the company's research and development operations. 11 (12) of Saniona's employees hold PhDs, 2 (2) hold university degrees, 8 (8) have laboratory training and the remaining 3 (3) have other degrees.

Operational risks and uncertainties

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

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

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

Currency risks is the risk that the fair value of future cash flows fluctuate because of changed exchange rates. Exposure to currency risk is primarily sourced from payment flows in foreign currency and from the translation of

balance sheet items in foreign currency, as well as upon the translation of foreign subsidiaries' income statements and balance sheets to the Group's reporting currency, which is SEK.

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

Financial calendar

Year-End Report 2019	February 20, 2020
Interim Report Q1	May 27, 2020
Annual General Meeting	May 27, 2020
Interim Report Q2	August 27, 2020
Interim Report Q3	November 26, 2020
Year-End Report 2020	February 25, 2021

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, 13 November 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

Edward Salzman – Board member

Condensed consolidated statement of comprehensive income – Group

Consolidated statement of comprehensive income - Group

KSEK	Note	2019-07-01 2019-09-30	2018-07-01 2018-09-30	2019-01-01 2019-09-30	2018-01-01 2018-09-30	2018-01-01 2018-12-31
	1-2					
Net sales	3	256	44,559	2,658	52,668	54,884
Total operating income		256	44,559	2,658	52,668	54,884
Raw materials and consumables		-798	-1,272	-2,607	-3,164	-4,089
Other external costs		-19,085	-17,473	-54,694	-50,764	-80,149
Personnel costs	4	-5,856	-5,735	-19,552	-18,240	-24,219
Depreciation and write-downs		-561	-158	-1,588	-443	-632
Total operating expenses		-26,300	-24,638	-78,440	-72,611	-109,089
Operating profit/loss		**-26,045**	**19,921**	**-75,782**	**-19,943**	**-54,206**
Share of result of associates	8	-1,543	-331	-3,722	-331	6,174
Financial income		-	-	-	6	-
Financial expenses		-153	-2	-547	-179	-261
Total financial items		-1,696	-333	-4,269	-504	5,913
Profit/loss after financial items		**-27,741**	**19,589**	**-80,052**	**-20,447**	**-48,292**
Tax on net profit	5	0	-4,293	7,708	2,728	7,233
Profit/loss for the period		**-27,741**	**15,296**	**-72,343**	**-17,718**	**-41,059**
Other comprehensive income						
Item that may be reclassified to profit and loss		-	-	-	-	-
Translation differences		-161	-530	316	699	625
Total other comprehensive income net after tax		**-161**	**-530**	**316**	**699**	**625**
Total comprehensive income		**-27,902**	**14,765**	**-72,027**	**-17,019**	**-40,434**
Earnings per share, SEK		-1.00	0.68	-2.89	-0.80	-1.84
Diluted earnings per share, SEK		-1.00	0.68	-2.89	-0.80	-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	2019-09-30	2018-09-30	2018-12-31
	1-2			
ASSETS				
Fixtures, fittings, tools and equipment		4,578	1,478	1,841
Tangible assets		4,578	1,478	1,841
Non-current tax assets	5	7,904	2,914	-
Investments in associated companies	8	2,783	-	6,505
Other long-term receivables	9	2,694	4,477	3,999
Financial assets		13,381	7,391	10,504
Deferred tax		64	93	62
Non-current assets		**18,024**	**8,962**	**12,407**
Trade receivables		256	2,759	2,093
Current tax assets	5	7,904	7,592	7,568
Other receivables		2,794	3,419	4,654
Prepayments and accrued income		2,244	1,564	1,675
Current receivables		13,198	15,334	15,990
Cash and cash equivalent		59,126	37,292	54,678
Current assets		**72,324**	**52,627**	**70,668**
Total assets		**90,348**	**61,588**	**83,075**
EQUITY AND LIABILITIES				
Share capital	10	1,420	1,142	1,166
Additional paid in capital	10	239,538	144,504	157,118
Retained earnings		-188,954	-94,883	-118,051
Currency translation reserve		-460	-702	-777
Equity		**51,544**	**50,061**	**39,457**
Lease liabilities		1,813	-	-
Non-current liabilities		1,813	0	0
Prepayments from customers		-	111	-
Trade payables		4,201	6,225	7,243
Convertible loan	10	-	1,000	6,000
Other payables		531	384	616
Lease liabilities		1,370	-	-
Accrued expenses and deferred income		30,890	3,808	29,759
Current liabilities		36,991	11,528	43,617
Total liabilities		**38,804**	**11,528**	**43,617**
Total equity and liabilities		**90,348**	**61,588**	**83,075**

Condensed consolidated statement of changes in equity – Group

	Share capital	Additional paid in capital	Translation reserves	Retained earnings	Shareholders' equity
January 1, 2018	**1,088**	**116,452**	**-1,402**	**-78,511**	**37,628**
Comprehensive income					
Profit/loss for the year				-17,718	-17,718
Other comprehensive income:					
Translation differences			699		699
Total comprehensive income			**699**	**-17,718**	**-17,019**
Transactions with owners					
Shares issued for cash	54	28,946			29,000
Expenses related to capital increase		-894			-894
Share-based compensation expenses				1,346	1,346
Total transactions with owners	**54**	**28,052**	**0**	**1,346**	**29,452**
September 30, 2018	**1,142**	**144,504**	**-702**	**-94,883**	**50,061**
October 1, 2018	**1,142**	**144,504**	**-702**	**-94,883**	**50,061**
Comprehensive income					
Profit/loss for the year				-23,341	-23,341
Other comprehensive income:					
Translation differences			-74		-74
Total comprehensive income			**-74**	**-23,341**	**-23,415**
Transactions with owners					
Shares issued for cash	24	12,976			13,000
Expenses related to capital increase		-361			-361
Share-based compensation expenses				173	173
Total transactions with owners	**24**	**12,614**	**0**	**173**	**12,812**
December 31, 2018	**1,166**	**157,118**	**-777**	**-118,051**	**39,457**
January 1, 2019	**1,166**	**157,118**	**-777**	**-118,051**	**39,457**
Comprehensive income					
Profit/loss for the year				-72,343	-72,343
Other comprehensive income:					
Translation differences			316		316
Total comprehensive income			**316**	**-72,343**	**-72,027**
Transactions with owners					
Shares issued for cash	254	96,294			96,548
Expenses related to capital increase		-13,874			-13,874
Share-based compensation expenses				1,438	1,438
Total transactions with owners	**254**	**82,420**	**0**	**1,438**	**84,112**
September 30, 2019	**1,420**	**239,538**	**-460**	**-188,956**	**51,542**

Condensed consolidated statement of cash flows – Group

KSEK	Note	2019-07-01 2019-09-30	2018-07-01 2018-09-30	2019-01-01 2019-09-30	2018-01-01 2018-09-30	2018-01-01 2018-12-31
Profit/loss before tax		-27,741	19,589	-80,052	-20,447	-48,292
Adjustments for non-cash transactions		1,311	666	5,233	2,259	-3,795
Other provisions		-2,939	-	-5,841	-	-
Changes in working capital		54,898	-1,133	-384	3,019	29,428
Cash flow from operating activities before financial items		**25,529**	**19,121**	**-81,043**	**-15,169**	**-22,659**
Interest income received		-	-	-	6	-
Interest expenses paid		-153	-2	-547	-179	-261
Cash flow from operating activities		**25,376**	**19,119**	**-81,590**	**-15,342**	**-22,920**
Investing activities						
Investment in tangible assets		-	-251	-3	-555	-1,107
Investment in other financial assets		444	821	1,304	1,542	2,021
Cash flow from investing activities		**444**	**569**	**1,302**	**987**	**914**
Financing activities						
Convertible loan	10	-10,500	-11,000	-6,000	1,000	6,000
New share issue	10	10,247	10,725	82,674	28,106	40,745
Cash flow from financing activities		**-253**	**-275**	**76,674**	**29,106**	**46,745**
Cash flow for the period		**25,567**	**19,414**	**-3,614**	**14,751**	**24,738**
Cash and cash equivalents at beginning of period		**30,203**	**18,264**	**54,678**	**22,313**	**22,313**
Exchange rate adjustments		3,357	-386	8,063	228	7,626
Cash and cash equivalents at end of period		**59,126**	**37,292**	**59,126**	**37,292**	**54,678**

Statement of income – Parent Company

KSEK	Note	2019-07-01 2019-09-30	2018-07-01 2018-09-30	2019-01-01 2019-09-30	2018-01-01 2018-09-30	2018-01-01 2018-12-31
	1-2					
Other operating income		338	-	1,015	-	-
Total operating income		338	0	1,015	0	0
Raw materials and consumables		-3	-2	-7	-7	-10
Other external costs		-1,216	-907	-4,671	-3,676	-5,524
Personnel costs		-1,079	-593	-2,966	-1,782	-2,379
Total operating expenses		-2,297	-1,502	-7,645	-5,465	-7,912
Operating profit/loss		**-1,959**	**-1,502**	**-6,630**	**-5,465**	**-7,912**
Share of result of associates	8	-1,543	-331	-3,722	-331	6,174
Financial income		2,320	567	6,326	1,410	1,900
Financial expenses		-95	-	-232	-187	-144
Total financial items		682	237	2,372	892	7,931
Profit/loss after financial items		**-1,277**	**-1,266**	**-4,258**	**-4,573**	**19**
Tax on net profit		0	0	0	0	0
Profit/loss		**-1,277**	**-1,266**	**-4,258**	**-4,573**	**19**

Balance Sheet – Parent Company

KSEK	Note	2019-09-30	2018-09-30	2018-12-31
	1-2			
ASSETS				
Investment in subsidiaries		11,832	11,832	11,832
Investments in associated companies	8	2,783	-	6,505
Financial assets		14,615	11,832	18,337
Non-current assets		**14,615**	**11,832**	**18,337**
Receivables from group companies		158,786	105,568	112,424
Other receivables		235	157	257
Prepayments and accrued income		1,189	890	977
Current receivables		160,210	106,616	113,658
Cash and cash equivalent		42,936	4,519	13,435
Current assets		**203,146**	**111,135**	**127,093**
Total assets		**217,761**	**122,967**	**145,429**
EQUITY AND LIABILITIES				
Restricted equity				
Share capital	10	1,420	1,142	1,166
Unrestricted equity				
Additional paid in capital	10	238,027	142,993	155,607
Retained earnings		-17,960	-17,979	-17,979
Profit for the period		-4,258	-4,573	19
Equity		**217,230**	**121,583**	**138,813**
Convertible loan	10	-	1,000	6,000
Other payables		531	384	616
Current liabilities		531	1,384	6,616
Total liabilities		**531**	**1,384**	**6,616**
Total equity and liabilities		**217,761**	**122,967**	**145,429**

Notes

Note 1 General Information

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

Note 2 Significant accounting policies

The 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 accounting currency of the Parent Company.

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

Disclosures in accordance with IAS 34 Interim Financial Reporting are presented either in the notes or elsewhere in the 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
Assets			
Tangible assets	-	4,233	4,233
Total	**0**	**4,233**	**4,233**
Liabilities			
Lease liabilities, long-term	-	2,901	2,901
Lease liabilities, short-term	-	1,332	1,332
Total	**0**	**4,233**	**4,233**

Apart from rental agreements in relation to the company's premises as described above, the company has no other lease commitments as of September 30, 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 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 first nine months of 2019 totaled SEK 1,325 (1,346) 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	Options granted in 2019	Total
Share-based payment					
Outstanding at 1 January 2019	64,000	38,292	331,016	-	433,308
Granted during the period	-	-	-	50,270	50,270
Forfeited during the period	-	-	-1,708	-	-1,708
Outstanding at 30 September 2019	**64,000**	**38,292**	**329,308**	**50,270**	**481,870**

If all issued warrants are exercised for subscription of new shares, the Parent Company's will issue a total of 481,870 new shares corresponding to a dilution of approximately 1.67%. The data below has been used for the calculation.

Incentive program	2015	2017	2018:1	2018:2	2018:3	2019:1	2019:2
Allotted options	64,000	38,750	286,003	34,500	10,513	34,500	15,770
Fair value per option (SEK)	13.13	29.48	12.67	18.89	16.75	7.55	6.69
Share price for underlying shares (SEK)	19.90	45.50	26.95	33.85	33.85	17.76	17.76
Subscription price (SEK)	20.72	41.13	33.60	30.08	30.08	17.86	17.86
Vesting period	4 years	4 years	3 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	5.5 years	4 years
Risk-free interest rate during the life of the option	0.2257%	-0.0584%	0.2389%	-0.0713%	-0.0356%	-0.6929%	-0.6995%
Assumed volatility*	91.29%	76.75%	57.41%	63.58%	63.58%	51.03%	51.03%
Expected dividends	0	0	0	0	0	0	0

Incentive program after rights issue**	2015	2017	2018:1	2018:2	2018:3	2019:1	2019:2
Allotted options	64,000	38,750	286,003	34,500	10,513	34,500	15,770
Subscriptions price after rights issue (SEK)	20.51	40.71	33.26	29.77	29.77		
Equal to no of shares	65,280	39,525	291,723	35,190	10,723	34,500	15,770

** 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.*

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

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

2019:1 The 2019 Annual General Meeting voted in 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 September 2019. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 17.86. The options are earned gradually over a period of 48 months. Holders can take advantage of assigned and earned stock options during 30 days from the day following the publication of the Group's quarterly reports, or in the case of full-year, full-year report, for the first time after publication of the quarterly report for the first quarter of 2023 and last time after publication of the quarterly report for the third quarter of 2024.

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

Note 5 Income tax and deferred tax subsidiaries in Denmark

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

The Group recognized a tax income of SEK 7.7 (2.7) thousand during the first nine month 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 September 30, 2019, the Group had SEK 7.9 million (SEK 7.6 million) in current tax asset, which will be paid to Saniona in November 2019 and SEK 7.9 million (SEK 7.1 million) in non-current tax assets which will be paid to Saniona in November 2020.

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 September 30, 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 was 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 Q3 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
September 30, 2019**	9,540,843	2,783,065
		(3,722,099)

** 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 Q2 report 2019.*

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 1.5 million (SEK 1.4 million) and as September 30, 2019, the recorded value of the total asset is SEK 3.5 (SEK 5.2 million). SEK 2.7 million of he recorded value is long term and SEK 0.8 million is short term.

Note 10 Convertible loan

Saniona entered into a convertible notes funding agreement with Nice & Green S.A on December 29, 2017. Under the terms of the agreement, Nice & Green 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 extended the convertible notes funding agreement with Nice & Green for an additional SEK 72 million with the same terms, totaling SEK 144 million.

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 choses to effect cash payment. For further details, please see Saniona's press release dated December 29, 2017.

In the first 9 month of 2019, Saniona has drawn four tranches totaling SEK 24 million (SEK 30 million) of which SEK 24 million (SEK 29 million) has been converted to shares by Nice & Green as of September 30, 2019. Nice & Green has converted SEK 30 million (SEK 29 million) during the first nine month of 2019 of which SEK 6 million (0) was outstanding as of December 31, 2018. The converted amount of SEK 30 million is taken to equity after deducting expenses relating to capital increase totaling KSEK 949 (KSEK 894).

Review Report

Introduction

We have reviewed the interim report for Saniona AB (publ) for the period January 1 - September 30, 2019. The Board of Directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, *Review of Interim Financial Information Performed by the Independent Auditor of the Entity*. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review has a different focus and is substantially less in scope than an audit conducted in accordance with ISA and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not, in all material respects, prepared for the Group in accordance with IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Malmö November 13, 2019

Deloitte AB

Jeanette Roosberg
Authorized Public Accountant

Business terms - glossary

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

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

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

BenevolentAI
BenevolentAI acquired Proximagen Ltd. in Q1 2017.

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

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

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

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

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

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

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

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

EMA
European Medicines Agency

Epilepsy
Epilepsy is a central nervous system (neurological) disorder in which brain activity becomes abnormal, causing seizures or periods of unusual behavior, sensations, and sometimes loss of awareness. Treatment with medications or sometimes surgery can control seizures for 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 α2/α3 program
A small molecule program which is designed to positively modulate (PAM) GABA-A α2 and GABA-A α3 ion channels, which are expressed in various central and peripheral neurons and are believed to be key mediator in the control of pain signaling and the control of anxiety.

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

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

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

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

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

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

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

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

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

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

Metoprolol
Metoprolol is a medication of the selective β1 receptor blocker type, which work by blocking the neurotransmitter norepinephrine and epinephrine from binding to receptors. It is used to treat high blood pressure, chest pain due to poor blood flow to the heart, and 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 α6 program
The Nic α6 program is a small molecule program designed to positively modulate (PAM) the α6 ion channels. The α6 subtype exhibits an extremely localized expression mainly confined to dopaminergic neurons in the area of the brain affected in Parkinson's disease patients, where they act as important regulators of dopamine signaling.

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

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

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

Pharmacodynamics (PD)

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

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

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

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

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

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

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

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

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

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

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