

## SANIONA INCREASINGLY EMERGES AS A ROBUST COMPANY WITH BOTH DEPTH AND BREADTH

### Financial highlights

#### Jan - Dec 2016 (Jan - Dec 2015)

- Net revenues were SEK 74.9 M (13.6 M)
- EBIT was SEK 4.2 M (-28.1 M)
- Earnings per share were SEK 0.11 (-1.29)
- Diluted earnings per share were SEK 0.11 (-1.29)

#### Q4 2016 (Q4 2015)

- Net revenues were SEK 5.4 M (1.8 M)
- EBIT was SEK -15.0 M (-5.3 M)
- Earnings per share were SEK -0.60 (-0.23)
- Diluted earnings per share were SEK -0.60 (-0.23)

### Business highlights in Q4 2016

- Distribution of all Saniona's shares held in Initiator Pharma to Saniona's shareholders decided at an extra ordinary general meeting.
- Saniona postponed list change to Nasdaq Stockholm following advanced ruling from the listing committee.
- Research milestone of about SEK 1.5 million obtained from The Michael J. Fox Foundation for Parkinson's Research.
- Saniona and Upsher Smith extended research collaboration under the drug discovery and development collaboration for neurological diseases, which the parties signed in the beginning of 2016.
- Saniona filed a clinical trial application in Czech Republic and Hungary for the performance of a Phase 2a study for Tesomet in patients with Prader-Willi Syndrome during the first half of 2017.
- Saniona's tesofensine partner, Medix, files application for Phase 3 clinical trials in obesity.

### Significant events after the reporting period

- Saniona reports positive top line results from the Tesomet Phase 2a study in type 2 diabetes.

### Comments from the CEO

"We have in effect moved the company from a being a discover company to a company with several programs in late stage clinical development in 2016. With the flying start this year, we are setting a pace, which makes me confident for 2017," says Jørgen Drejer, CEO of Saniona.

### For more information, please contact

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### About Saniona

*Saniona is a research and development company focused on drugs for diseases of the central nervous system, autoimmune diseases, metabolic diseases and treatment of pain. The company has a significant portfolio of potential drug candidates at pre-clinical and clinical stage. The research is focused on ion channels, which makes up a unique protein class that enables and controls the passage of charged ions across cell membranes. Saniona has ongoing collaboration agreements with Boehringer Ingelheim GmbH, Upsher-Smith Laboratories, Inc., Productos Medix, S.A de S.V and Saniona's Boston based spinout Ataxion Inc. Saniona is based in Copenhagen, Denmark, where it has a research center of high international standard. Saniona is listed at Nasdaq First North Premier and has about 4,500 shareholders. Pareto Securities is Certified Advisor for Saniona. The company's share is traded under the ticker SANION. Read more at [www.saniona.com](http://www.saniona.com).*

## Letter from the CEO

"At the year-end, we were waiting in suspense for the results from the important Phase 2 trial for Tesomet. The redemption came just three days into the new year. The trial was successful. The conclusion is that Tesomet can be used as a safe and effective weight loss drug in patients with metabolic disorders like diabetes and obesity. In addition, it may potentially also be used for patients with eating disorders like binge eating and Prader-Willi syndrome. Obviously, there was good mood in the office on that day!

We are confirmed in the view that intelligent plans and hard work will provide a solution to the challenges we are facing. What makes me confident about the prospect of Saniona is that Saniona increasingly emerges as a robust company with both depth and breadth.

The depth comprises the substantial amount of supporting data and the numerous of opportunities within each of our programs. As an example, Tesomet may be used for many indications of which we have already developed the product to an advanced stage in several. The breadth comprises our broad portfolio of programs, which we are pursuing on our own or in collaboration with partners, as well as the many opportunities we have identified but not yet been able to pursue. Some of them, we have so far not even defined.

We now know that Tesomet can be used as a safe and effective treatment of patients with type 2 diabetes. Based on the results, we strongly believe that Tesomet will provide double digit weight loss in this patient group. Recent research suggests that a weight loss of this magnitude can bring certain groups of patients in complete remission.

We are now investigating the possibility of using Tesomet in other indications where a significant weight loss will provide substantial benefit for patients. We have already taken the decisions to start a Phase 2a clinical trial in patients with Prader-Willi Syndrome - a serious hereditary disease for which there is no treatment today. Due to the mode of action, we believe Tesomet could provide substantial benefits to the patients as well as their families. We are in parallel to this analysing the feasibility of using Tesomet for other indications such as binge eating and NASH (non-alcoholic steatohepatitis, a liver inflammation caused by fat in the liver). Both indications represent significant markets. It is estimated that 2 percent of men and 3.5 percent of women in the US suffer from binge eating. NASH is in general believed to be the next common illnesses in the wake of obesity and type 2 diabetes which have spread rapidly across the world and now are considered epidemic.

The tesofensine program for treatment of obesity represents an addition to the depth of our "Tesomet-world". At the end of 2016, our partner Medix filed a clinical trial application in Mexico for initiation of a Phase 3 study for tesofensine in obesity. This important milestone may potentially lead to a stable income stream through royalties in the foreseeable future. It is certainly a unique and fortunate position to be in for a biotech company.

Combining the depth of the Tesomet program with the breadth of our product pipeline, I think that it is fair to characterize Saniona as a robust company. We currently have a total of nine active programs which are developed for 10 indications either on our own or through collaboration with partners.

Tesomet and tesofensine are the most advanced programs and are in Phase 2 and Phase 3 clinical studies for three indications within the metabolic field. In addition to this, we have a program for treatment of cocaine addiction, which is in Phase 2. The other programs are in the early stage and represent innovative and potential first in class therapies within their respective fields. As an example, the collaboration with Boehringer-Ingelheim which we hope will provide a new treatment for schizophrenia is truly exciting.

In addition to the published pipeline, we have a platform and several additional assets. In 2016, we could build further value into some of these assets through new collaborations and spin-outs to the benefit of our shareholders. At an extraordinary general meeting in October, it was decided to distribute all Saniona's shares in Initiator Pharma A/S to Saniona's shareholders. Initiator Pharma has completed a rights issue in February and the company is expected to be listed on AktieTorget in March. In Saniona, we will continue to look for opportunities for developing our platform and additional assets through new collaboration or spin-outs.

Saniona enjoyed a tremendous development in 2016. We have in effect moved the company from a discovery company to a company with several programs in late stage clinical development. We are at the same time able to report a profit for the total year due to several new collaboration agreements. With the flying start this year, we are setting the pace for the future, which makes us confident for 2017. I am certain that all our dedicated employees will continue to work hard for Saniona to succeed to the benefit of our partners and shareholders."

Jørgen Drejer

CEO, Saniona AB

## About Saniona

Saniona is a research and development company focused on drugs for diseases of the central nervous system, autoimmune diseases, metabolic diseases and treatment of pain. The company has a significant portfolio of potential drug candidates at pre-clinical and clinical stage. The research is focused on ion channels. Saniona has ongoing collaboration agreements with Boehringer Ingelheim GmbH, Upsher-Smith Laboratories, Inc., Productos Medix, S.A de S.V and Saniona's Boston based spinout Ataxion Inc. Saniona is based in Copenhagen, Denmark, where it has a research center of high international standard.

## Vision

Saniona will be a leading biotech company within the field of ion channel-dependent diseases.

## Business idea

Saniona will discover and develop better medical treatments in areas with significant unmet medical needs through modulation of ion channels.

## Overall objective

Saniona's overall objective is by itself and together with partners to develop and provide new medicines for severe diseases, more specifically diseases of the central nervous system, auto-immune diseases, metabolic diseases and treatment of pain.











## Business model

The company commercializes its research efforts through the following 3 business models:

- By internal development of selected programs through the early phases of drug development before out-licensing to pharmaceutical companies who will take over the further development of Saniona's programs and typical pay upfront, milestone and royalty payments on product sales to Saniona;
- Through early stage research and development collaboration with pharmaceutical companies who will fund the research and development activities and pay upfront, milestones and royalty payments on product sales to Saniona; and
- Through joint ventures or spin-outs, where Saniona's financial partner will obtain a share of the upside by financing the development of one of Saniona's programs.

## Project portfolio

Saniona currently has nine active programs of which six are financed through grants, by collaborations with partners, or in joint ventures/spin-outs. Saniona's pipeline is set out below.

Product or program	Indication	Preclinical research	Preclinical development	Clinical Phase 1	Clinical Phase 2	Clinical Phase 3
Tesofensine monotherapy	Obesity					
Tesomet	Type 2 diabetes					
	Prader-Willi syndrome					
NS2359	Cocaine addiction					
GABAA $\alpha 2/\alpha 3$ program	Neuropathic pain					
Boehringer Ingelheim program	Schizophrenia					
IK program	Inflammation, IBD					
Ataxion program	Ataxia					
Upsher-Smith program	Neurological disorders					
Nicotinic $\alpha 6$ program	Parkinson's disease					

In addition to the active pipeline shown above, Saniona has a range of validated drug discovery assets as well as clinical stage assets positioned for partnering or spin-out.

## Market

Saniona's ongoing programs address significant market segments:

Product	Indication	Market estimate
Tesomet	Type 2 diabetes	> USD 23 billion <sup>1</sup>
Tesofensine	Obesity	- USD 250 million in Mexico <sup>2</sup>
NS2359	Cocaine addiction	> USD 1.8 billion <sup>3</sup>
GABA <sub>A</sub> α2α3 program	Neuropathic pain	> USD 6 billion <sup>4</sup>
Boehringer Ingelheim program	Schizophrenia	> USD4.8 billion <sup>5</sup>
IK program	Inflammatory bowel disease	> USD 5.9 billion <sup>6</sup>
Nic-α6 program	Parkinson's disease	> USD 2.8 billion <sup>7</sup>

For a significant time to come, Saniona will be dependent on major pharmaceutical companies' interest in purchasing, developing and commercializing projects from Saniona's pipeline of preclinical and clinical drug candidates. According to the Board's assessment, there is a well-developed market for licensing, sale, and establishment of research and development collaboration between smaller, research-intensive businesses and large pharmaceutical companies.

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 opportunities for Saniona.

<sup>1</sup> The market for type 2 diabetes is estimated to be USD 23.3 billion in the 7 major markets in 2014. Diabetes Type 2 Forecast, 7 major Markets, Datamonitor 2015

<sup>2</sup> Estimates of drugs for obesity in Mexico by Medix 2016

<sup>3</sup> Estimates by TRC

<sup>4</sup> Major markets 2012, Decision Resources

<sup>5</sup> Schizophrenia Forecast 7 major market, Datamonitor, 2014

<sup>6</sup> Major markets 2014, Datamonitor

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

## Financial review

	2016-10-01	2015-10-01	2016-01-01	2015-01-01
	2016-12-31	2015-12-31	2016-12-31	2015-12-31
Net sales, KSEK	5,411	1,827	74,921	13,630
Total operating expenses, KSEK	-20,439	-7,155	-70,764	-41,705
Operating profit/loss, KSEK	*	-5,327	4,156	-28,075
Operating margin, %	*	-292%	6%	-206%
Cash flow from operating activities	-9,611	-13,989	7,196	-27,637
Earnings per share, SEK	-0.60	-0.23	0.11	-1.29
Diluted earnings per share, SEK	-0.60	-0.23	0.11	-1.29
Average shares outstanding	20,841,467	20,386,417	20,841,467	17,775,099
Diluted average shares outstanding	20,905,467	20,450,417	20,905,467	17,839,099
Average number of employees, #	21.7	17.5	19.7	16.8
			2016-12-31	2015-12-31
Cash and cash equivalent, KSEK			53,261	47,004
Equity, KSEK			54,252	52,943
Total equity and liabilities, KSEK			70,769	57,673
Equity ratio, %	*		77%	92%
Liquidity ratio, %	*		412%	1171%

\* 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 in the table above. Further information and why these are considered important can be found in Financial key ratios and definitions at the end of this report.

## Revenues and result of the operation

### Revenue

Total revenues during the fourth quarter of 2016 was SEK 5.4 million (1.8). In 2016 revenues comprised research funding under the agreements with Boehringer Ingelheim, Ataxion and Upsher Smith whereas in 2015 revenues primarily comprised research funding under the agreement with Ataxion.

Saniona generated total revenues of SEK 74.9 million (13.6) for the full year of 2016. In 2016 revenues comprised upfront payments from Boehringer Ingelheim, Medix and Upsher-Smith totalling SEK 60.4 million whereas the balance comprised research funding under the agreement with Boehringer Ingelheim, Ataxion and Upsher-Smith. In 2015, revenues comprised primarily research funding under the agreements with Ataxion and Pfizer.

### Operating profit/loss

The operating loss for the fourth quarter was SEK 15.0 million (5.3). The operating profit for the full year was SEK 4.2 million (loss of 28.1).

The company recognized operating expenses of SEK 20.4 million (7.2) for fourth quarter of 2016.

The company recognized operating expenses of SEK 70.8 million (41.7) for the full year of 2016, an increase of 70%. External expenses amounted to SEK 51.1 million (23.9) and personnel costs amounted to SEK 17.8 million (15.0). In 2016, external expenses comprised primarily development costs in relation to Tesomet totalling SEK 24.3 million followed by the IK program with SEK 2.8 million and the GABA<sub>A</sub> α2,3 program with SEK 2.7 million. In 2015, the external expenses comprised primarily research and development costs in relation to AN363 with SEK 7.3 million followed by the IK program SEK 3.1 million and the Tesomet program SEK 2.6 million.

### Financial position

The equity ratio was 77 (92) % as of December 31, 2016, and equity was SEK 54.3 million (52.9). Cash and cash equivalents amounted to SEK 53.3 million (47.0) as of December 31, 2016. Total assets as of December 31, 2016, were SEK 70.8 million (57.7). The company expects to have sufficient capital to finance planned and communicated activities in 2017.

### **Cash flow**

Operating cash flow for the fourth quarter of 2016 was an outflow of SEK 9.6 million (outflow of 14.0). Consolidated cash flow for the fourth quarter of 2016 was an outflow of SEK 10.3 million (inflow 34.1).

Operating cash flow for the full year of 2016 was an inflow of SEK 7.2 million (outflow of 27.6). Consolidated cash flow for the full year of 2016 was an inflow of 7.2 million (inflow 36.9). The inflow in 2016 is explained by the operating income during 2016. The inflow in 2015 is explained by the rights issues in the first and fourth quarter last year.

### **Segment information**

Financial information reported to the CEO as the basis for allocating resources and judging the Group's profit or loss is not divided into different operating segments. Accordingly, the Group consists of a single operating segment.

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

At December 31, 2016, the number of shares outstanding amounted to 20,841,467 (20,841,467). The company established a warrant program on July 1, 2015, totalling 64,000 warrants.

At December 31, 2016, the company had 4,491 (3,212) shareholders excluding holdings in life insurance and foreign custody account holders.

### **Personnel**

As of December 31, the number of employees was 26 (19) of which 14 (10) are women. Of these employees, 8 (3) are part-time employees and 18 (16) are full-time employees, and a total of 21 (17) work in the company's research and development operations. 12 (11) of Saniona's employees hold PhDs, 4 (2) hold university degrees, 7 (6) have laboratory training and the remaining 3 (0) 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 specific to a certain company.

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 2015 Annual Report. There are no major changes in the Group's risk exposure and risk management in 2016.

### **Audit review**

This Interim Report has not been subject to review by the company's auditors.

### **Financial calendar**

Interim Report Q1	May 23, 2017
Annual General Meeting	May 23, 2017
Interim Report Q2	August 23, 2017
Interim Report Q3	November 15, 2017
Year-End Report 2017	February 21, 2018

### **Annual General Meeting 2017**

Saniona's Annual General Meeting will be held at Setterwalls Advokatbyrå AB's office at Stortorget 23, Malmö, Sweden on May 23, 2017 at 4 pm CET.

The Board of Directors proposes that no dividend will be paid for the 2016 financial year.

The Annual Report for 2016 will be published on [www.saniona.com](http://www.saniona.com) three weeks before the AGM. It will also be available at Saniona's head office at Baltorpvej 154, 2750 Ballerup, Denmark.

Shareholders who wish to have a matter addressed at the Annual General Meeting should, to ensure that the proposal may be considered, send such proposal to the Board of Directors no later than April 4, 2017. The Board of Directors can be contacted by email to [tf@saniona.com](mailto:tf@saniona.com) marked "Annual General Meeting" or through regular mail to: Saniona AB, Att.: Thomas Feldthus, Baltorpvej 154, DK-2750 Ballerup, Denmark.

The Nomination Committee's member are: Søren Skjærbæk, Partner at Saxo lawyers, Vejle, Denmark, appointed by Jørgen Drejer; John Haurum, CEO of F-star Biotechnology Limited, Cambridge, UK, appointed by Thomas Feldthus; and Claus Bræstrup, 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](mailto:tf@saniona.com) marked "Recommendation to the Nomination Committee" or by ordinary mail to the address: Saniona AB, Att. Thomas Feldthus, Baltorpvej 157, DK-2750 Ballerup, Denmark.

The Board of Directors and the CEO of Saniona AB (publ) provide their assurance that the 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, February 21, 2017  
Saniona AB

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Claus Bræstrup – Chairman

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Jørgen Drejer – CEO and board member

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Carl Johan Sundberg – Board member

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Leif Andersson – Board member

**Condensed consolidated statement of comprehensive income – Group**

KSEK		2016-10-01	2015-10-01	2016-01-01	2015-01-01
	Note	2016-12-31	2015-12-31	2016-12-31	2015-12-31
	1-3				
Net sales	4	5,411	1,827	74,921	13,630
Total operating income		5,411	1,827	74,921	13,630
Raw materials and consumables		-631	-355	-1,476	-2,050
Other external costs		-14,675	-2,780	-51,098	-23,926
Personnel costs	5	-5,021	-3,925	-17,805	-14,966
Depreciation and write-downs		-112	-96	-384	-763
Total operating expenses		-20,439	-7,155	-70,764	-41,705
<b>Operating profit/loss</b>		<b>-15,028</b>	<b>-5,327</b>	<b>4,156</b>	<b>-28,075</b>
Other financial income		0	0	1,114	0
Other financial expenses		-307	-708	-357	-1,183
Total financial items		-307	-708	757	-1,183
<b>Profit/loss after financial items</b>		<b>-15,335</b>	<b>-6,036</b>	<b>4,913</b>	<b>-29,258</b>
Tax on net profit	6	2,859	1,245	-2,696	6,311
<b>Profit/loss for the period</b>		<b>-12,476</b>	<b>-4,790</b>	<b>2,217</b>	<b>-22,947</b>
<b>Other comprehensive income for the period</b>					
Item that may be reclassified to profit and loss		-	-	-	-
Translation differences		-225	431	-1,118	314
<b>Total other comprehensive income for the period, net after tax</b>		<b>-225</b>	<b>431</b>	<b>-1,118</b>	<b>314</b>
				-	-
<b>Total comprehensive income for the period</b>		<b>-12,701</b>	<b>-4,360</b>	<b>1,098</b>	<b>-22,633</b>
Earnings per share, SEK		-0.60	-0.23	0.11	-1.29
Diluted earnings per share, SEK		-0.60	-0.23	0.11	-1.29

**Condensed consolidated statement of financial position – Group**

KSEK	Note	2016-12-31	2015-12-31
	1-3		
<b>ASSETS</b>			
Fixtures, fittings, tools and equipment		1,184	753
Tangible assets		1,184	753
Other long-term receivables		1,419	1,405
Deferred tax		100	142
Financial assets		1,519	1,547
<b>Non-current assets</b>		<b>2,703</b>	<b>2,300</b>
Trade receivables	8	12,260	0
Current tax assets	6	0	6,109
Other receivables		1,880	1,983
Prepayments and accrued income		665	277
Current receivables		14,804	8,369
Cash and cash equivalent		53,261	47,004
<b>Current assets</b>		<b>68,066</b>	<b>55,373</b>
<b>Total assets</b>		<b>70,769</b>	<b>57,673</b>
<b>EQUITY AND LIABILITIES</b>			
Share capital		1,042	1,042
Additional paid in capital		83,323	83,323
Retained earnings		-31,807	-8,860
Currency translation reserve		-523	385
Profit for the period		2,217	-22,947
<b>Equity</b>		<b>54,252</b>	<b>52,943</b>
Trade payables		6,225	2,868
Current tax liabilities		1,600	0
Other payables		5,686	0
Accrued expenses and deferred income		3,006	1,862
Current liabilities		16,517	4,730
<b>Total liabilities</b>		<b>16,517</b>	<b>4,730</b>
<b>Total equity and liabilities</b>		<b>70,769</b>	<b>57,673</b>

## Condensed consolidated statement of changes in equity – Group

	Number of shares	Share capital	Additional paid in capital	Translation reserves	Retained earnings	Shareholders' equity
<b>January 1, 2015</b>	<b>13,882,200</b>	<b>694</b>	<b>16,978</b>	<b>-32</b>	<b>-8,860</b>	<b>8,780</b>
<b>Comprehensive income</b>						
Profit/loss for the year					-22,947	-22,947
Other comprehensive income:						0
Translation differences				314		314
<b>Total comprehensive income</b>				<b>314</b>	<b>-22,947</b>	<b>-22,633</b>
<b>Transactions with owners</b>						
Shares issued for cash	6,959,267	348	72,788			73,136
Expenses related to capital increase			-6,443			-6,443
Share-based compensation expenses					103	103
<b>Total transactions with owners</b>	<b>6,959,267</b>	<b>348</b>	<b>66,345</b>	<b>0</b>	<b>103</b>	<b>66,796</b>
<b>December 31, 2015</b>	<b>20,841,467</b>	<b>1,042</b>	<b>83,323</b>	<b>282</b>	<b>-31,704</b>	<b>52,943</b>
<b>January 1, 2016</b>	<b>20,841,467</b>	<b>1,042</b>	<b>83,323</b>	<b>282</b>	<b>-31,704</b>	<b>52,943</b>
<b>Comprehensive income</b>						
Profit/loss for the year					2,217	2,217
Other comprehensive income:						0
Translation differences				-1,118		-1,118
<b>Total comprehensive income</b>				<b>-1,118</b>	<b>2,217</b>	<b>1,098</b>
<b>Transactions with owners</b>						
Share-based compensation expenses					211	211
<b>Total transactions with owners</b>					<b>211</b>	<b>211</b>
<b>December 31, 2016</b>	<b>20,841,467</b>	<b>1,042</b>	<b>83,323</b>	<b>-837</b>	<b>-29,277</b>	<b>54,252</b>

**Condensed consolidated statement of cash flows – Group**

KSEK		2016-10-01	2015-10-01	2016-01-01	2015-01-01
	Note	2016-12-31	2015-12-31	2016-12-31	2015-12-31
Operating loss before financial items		-15,028	-5,327	4,156	-28,075
Depreciation		112	96	384	763
Changes in working capital		5,304	-8,757	2,656	-325
<b>Cash flow from operating activities before financial items</b>		<b>-9,611</b>	<b>-13,989</b>	<b>7,196</b>	<b>-27,637</b>
Interest income received		-218	-4	1,114	-3
Interest expenses paid		-89	-704	-357	-1,180
<b>Cash flow from operating activities</b>		<b>-9,918</b>	<b>-14,698</b>	<b>7,953</b>	<b>-28,820</b>
<b>Investing activities</b>					
Investment in tangible assets		-502	24	-816	-242
Investments in subsidiaries	7	403	0	0	0
Investment in other financial assets		-245	4,649	28	-732
<b>Cash flow from investing activities</b>		<b>-344</b>	<b>4,673</b>	<b>-787</b>	<b>-975</b>
<b>Financing activities</b>					
New share issue		0	44,090	0	66,693
<b>Cash flow from financing activities</b>		<b>0</b>	<b>44,090</b>	<b>0</b>	<b>66,693</b>
<b>Cash flow for the period</b>		<b>-10,262</b>	<b>34,066</b>	<b>7,166</b>	<b>36,898</b>
<b>Cash and cash equivalents at beginning of period</b>		<b>63,695</b>	<b>12,456</b>	<b>47,004</b>	<b>9,689</b>
Exchange rate adjustments		-172	481	-908	417
<b>Cash and cash equivalents at end of period</b>		<b>53,261</b>	<b>47,004</b>	<b>53,261</b>	<b>47,004</b>

## Statement of income – Parent Company

KSEK	Note	2016-10-01 2016-12-31	2015-10-01 2015-12-31	2016-01-01 2016-12-31	2015-01-01 2015-12-31
	1-3				
Net sales		0	0	0	0
Total operating income		0	0	0	0
Raw materials and consumables		-3	0	-3	0
Other external costs		-2,119	-685	-6,758	-1,957
Personnel costs		-289	0	-1,033	-38
Total operating expenses		-2,410	-685	-7,794	-1,994
<b>Operating profit/loss</b>		<b>-2,410</b>	<b>-685</b>	<b>-7,794</b>	<b>-1,994</b>
Other financial income		225	99	749	172
Other financial expenses		-47	-100	-298	-548
Total financial items		178	-1	450	-376
<b>Profit/loss after financial items</b>		<b>-2,232</b>	<b>-686</b>	<b>-7,344</b>	<b>-2,370</b>
Tax on net profit		0	0	0	0
<b>Profit/loss for the period</b>		<b>-2,232</b>	<b>-686</b>	<b>-7,344</b>	<b>-2,370</b>

## Statement of comprehensive income – Parent Company

KSEK	Note	2016-10-01 2016-12-31	2015-10-01 2015-12-31	2016-01-01 2016-12-31	2015-01-01 2015-12-31
	1-3				
<b>Profit/loss for the period</b>		<b>-2,232</b>	<b>-686</b>	<b>-7,344</b>	<b>-2,370</b>
<b>Other comprehensive income for the period</b>					
Item that may be reclassified to profit and loss					
Other comprehensive income for the period		0	0	0	0
<b>Total other comprehensive income for the period, net after tax</b>		<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Total comprehensive income for the period</b>		<b>-2,232</b>	<b>-686</b>	<b>-7,344</b>	<b>-2,370</b>

## Balance Sheet – Parent Company

KSEK	Note	2016-12-31	2015-12-31
<b>ASSETS</b>			
Investment in subsidiaries		11,832	11,832
Financial assets		11,832	11,832
<b>Non-current assets</b>		<b>11,832</b>	<b>11,832</b>
Receivables from group companies		45,076	23,278
Other receivables		437	1,319
Prepayments and accrued income		270	170
Current receivables		45,783	24,767
Cash and cash equivalent		15,355	43,956
<b>Current assets</b>		<b>61,138</b>	<b>68,723</b>
<b>Total assets</b>		<b>72,969</b>	<b>80,555</b>
<b>EQUITY AND LIABILITIES</b>			
Share capital		1,042	1,042
Additional paid in capital		81,812	81,812
Retained earnings		-2,975	-202
Profit/loss for the period		-7,344	-2,370
<b>Equity</b>		<b>72,535</b>	<b>80,282</b>
Trade payables		0	273
Other payables		434	0
Current liabilities		434	273
<b>Total liabilities</b>		<b>434</b>	<b>273</b>
<b>Total equity and liabilities</b>		<b>72,969</b>	<b>80,555</b>

## Notes

### Note 1 General Information

Saniona AB (publ), Corporate Registration Number 556962-5345, the Parent Company and its subsidiaries, collectively the Group, is a publicly listed research and development company focused on drugs for diseases of the central nervous system, autoimmune diseases, metabolic diseases and treatment of pain. The Parent Company is a limited liability company registered in the municipality of Malmö in the county of Skåne, Sweden. The address of the head office is Baltorpvej 154, DK-2750 Ballerup, Denmark. Saniona is listed at Nasdaq First North Premier. 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 2015. More detailed information about the Group's and the Parent Company's accounting and valuation principles can be found in the Annual Report for 2015, which is available on [www.saniona.com](http://www.saniona.com). New and amended standards and interpretations implemented as of January 1, 2016, has not had any significant impact on the Group's financial statements.

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

### Note 3 Financial assets and liabilities

**All financial asset and financial liabilities, except for the investment in Ataxion as described below, are classified as 'Loans and receivables' respectively 'Other financial liabilities'. These financial instruments are measured at amortized cost and the carrying amount is a reasonable approximation of fair value. There has been no fair value adjustment of the financial assets in 2015 and 2016.**

The Group owns 14% of the share capital of Saniona's spin-out Ataxion. **Ataxion was formed by Saniona, Atlas Venture and the management of Ataxion in 2013 as a spin-out from Saniona. Saniona received shares in Ataxion in return for certain knowhow and patents in relation to Saniona's ataxia program. The specific assets had a carrying and fair value amount of SEK 0 at the time of formation of Ataxion and the investments made by the other parties were insignificant. Considering the significant risk and duration of the development period related to the development of pharmaceutical products, management has concluded that the future economic benefits cannot be estimated with sufficient certainty until Ataxion is sold or the project has been finalized and the necessary regulatory final approval of the product has been obtained. Accordingly, the value of Ataxion is measured at costs since the fair value cannot be determined reliable.**

### Note 4 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 5: Share based payments

Share-based compensation expenses for the full year of 2016 totalled SEK 211 (103) thousand. The Group accounts for share-based compensation by recognizing compensation expenses related to share-based instruments granted to the 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.

As of December 31, 2016, Saniona had 64,000 options outstanding. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 20.77. The options will be exercisable for the first time after publication of the quarterly report for the first quarter of 2018. There were no outstanding options at the

beginning of 2015. There has not been granted any option in Saniona previously. None of the options granted in 2015 have forfeited, exercised or expired. A more detailed description can be found in the annual report for 2015.

#### **Note 6 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 taxes of SEK 2,696 (-6,311) thousands during the full year of 2016. Saniona's Danish subsidiary received an upfront payment of US 1.25 million during the first quarter of 2016, which is subject to a 10% withhold tax in Mexico equal to KUSD 125 (KSEK 1,108). This amount has been deducted towards tax payable in Denmark during the financial year 2016 in accordance to the tax treaty between Denmark and Mexico. The Group has not recognized any tax credit under the Danish R&D tax credit scheme in 2016. In 2015, the Group recognized tax credit of KSEK -6,311 under the Danish R&S tax credit scheme (skattekredit ordningen). This amount was recognized under current tax assets as of December 31, 2015, 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 2016 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%. In 2015 the amount was DKK 25 million equal to a tax credit of DKK 5.9 million at a tax rate of 23.5%. 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, 2016, the Group had no tax asset. As of December 31, 2015, the Group had SEK 6.1 million in current tax asset, which was paid in November 2016.

#### **Note 7 Investment in Initiator Pharma**

In the beginning of May 2016, Saniona participated in formation of a new company, Initiator Pharma A/S, with the aim of spinning out three programs, which Saniona did not plan to pursue internally. Saniona AB paid KSEK 391 (KDKK 313) for the shares at the formation of Initiator Pharma A/S. The investment has been recorded in the Saniona AB's and the Groups balance sheet under Investment in Subsidiaries in the half year report and the interim report for the third quarter 2016. At an extraordinary general meeting on October 13, 2016, it was decided to distribute all shares held by Saniona in Initiator Pharma A/S to Saniona AB's shareholders as extraordinary dividend. The dividend is recognised at fair value and amounts to SEK 402,751, equal to the carrying amount of the Initiator shares, in accordance with IFRIC 17. This corresponds to a dividend of approximately SEK 0.0193 (DKK 0.015) per outstanding share of Saniona. The record date for the dividend payment was on October 21, 2016. Therefore, Saniona did not held any shares in Initiator Pharma A/S as of December 31, 2016.

#### **Note 8 Trade receivables**

As of December 31, 2016, the Group had KSEK 12,260 (0) in trade receivables. In 2016, trade receivables comprised primarily part of the upfront payment from Boehringer Ingelheim, which will be released upon completion of administrative procedures under the tax treaty between Denmark and Germany.

#### **Note 9 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 cover and ensure that Saniona A/S will be able to pay its creditors as the obligations fall due for the period until the approval of the annual report for 2016 at the general meeting in Saniona A/S. Saniona A/S had no external net debt as of December 31, 2016.

#### **Note 10 Related parties**

Related parties comprise the Group's Executive Management, Board of Directors and companies within the Group. Apart from intercompany transaction, there has been no transaction with related parties during 2015 and 2016.

## 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.

### **AN363**

A small molecule under the GABAA  $\alpha 2\alpha 3$  program.

### **AN761**

A small molecule which is designed to open (agonize) nicotinic  $\alpha 7$  channels. Nicotinic  $\alpha 7$  channels are expressed in various CNS tissue and are believed to be key mediators of cognitive processes. AN761 is a clinical candidate which may be a fast follower in a breakthrough drug class for treatment of cognition deficits in schizophrenia and Alzheimer's disease.

### **AN788**

A unique dual (serotonin-dopamine) reuptake inhibitor which represents a novel clinical candidate for second line treatment of Major Depressive Disorder. AN788 has been administered to healthy volunteers in a single ascending dose study and in a PET study, demonstrating orderly pharmacokinetics and attaining levels of occupancy at serotonin and dopamine transporters that support its potential as a second line treatment for treating residual symptoms in MDD, such as fatigue, excessive sleepiness and lack of interest.

### **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.

### **Ataxion**

Ataxion Inc. is a spin-out from Saniona based on Saniona's ataxia-program. For further details, please see Partners section.

### **Atlas Venture**

Atlas Venture Inc. For further details, please see description about Ataxion under Partners section.

### **Biogen**

Biogen Inc. For further details, please see description about Ataxion under Partners section.

### **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.

### **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.

### **GABAA $\alpha 2\alpha 3$ program**

A small molecule program which is designed to positively modulate (PAM) GABA<sub>A</sub>  $\alpha 2$  and GABA<sub>A</sub>  $\alpha 3$  ion channels, which are expressed in various central and peripheral neurons and are believed to be key mediator in the control of pain signaling and the control of anxiety.

### **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.

#### **EMA**

European Medicines Agency

#### **FDA**

US Food and Drug Administration

#### **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 US 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.

#### **Medix**

Productos Medix, S.A de S.V. For further details, please see the Partner section.

#### **Proximagen**

Proximagen Ltd. is a wholly-owned subsidiary of Upsher-Smith. For further details, please see the Partner section.

#### **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 hyperglycaemia (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.

#### **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.

### **Upsher-Smith**

Upsher-Smith Laboratories, Inc. For further details, please see the Partners section.

### Financial key ratios and definitions

Saniona presents certain financial measures in the interim report that are not defined per IFRS. 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 following ratios are not defined per IFRS, unless stated otherwise.

#### Average number of employees

Average number of employees employed by the company during the period. This average number of employees provides a trend in the company's research and development capacity and may explain part of the development in personnel expenses.

#### Earnings per share

Profit/loss for the period divided by the average number of shares outstanding during the period.<sup>8</sup>

#### Diluted earnings per share

Profit/loss for the period divided by the average number of shares outstanding after dilution during the period.<sup>9</sup>

#### 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.

#### Liquidity ratio

**Current assets divided by current liabilities.** The liquidity ratio is presented to show the company's short-term payment ability.

#### Operating margin

**EBIT as a proportion of revenue.** Operating margin shows the percentage of revenue left as profit before financial items and taxes and are presented to show the company's profitability.

#### Operating profit/loss or EBIT

**Earnings Before Interest and Taxes (Operating profit/loss).**

*The information in this interim report is information that Saniona (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and Sweden's Securities Market Act. The information was submitted for publication, through the agency of the contact person set out above, at 08:00 CET on February 21, 2017.*

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<sup>8</sup> Defined in accordance to IFRS

<sup>9</sup> Defined in accordance to IFRS