

## SANIONA MADE A FLYING START IN Q1 WITH THREE NEW COLLABORATIONS AND AN INCREASE IN REVENUES OF 227%

### Financial highlights

#### Q1 2016 (Q1 2015)

- Net revenues were KSEK 15,853 (4,848)
- EBIT was KSEK -1,058 (-5,103)
- Earnings per share were SEK -0.12 (-0.30)
- Diluted earnings per share were SEK -0,12 (-0.30)

### Business highlights in Q1 2016

- Saniona and Upsher-Smith, through its wholly-owned UK subsidiary Proximagen, sign collaboration agreement for the research and development of therapeutics for neurological disorders. Proximagen is granted exclusive worldwide rights to develop, manufacture and commercialize medicines identified through the collaboration. Saniona is entitled to pre-commercial milestone payments of up to US\$30 million (about SEK 250 million) and tiered royalties on product sales.
- Saniona and Medix sign a drug development and commercialization collaboration. Medix is granted exclusive rights to develop and commercialize tesofensine and Tesomet in Mexico and Argentina. Medix will finance the clinical development in the two countries. Medix intends to initiate Phase 3 clinical studies for tesofensine for obesity later this year. Saniona retains all rights to tesofensine and Tesomet in the rest of the world including clinical data developed by Medix. Medix will pay Saniona an upfront payment of US\$ 1.25 million (about SEK 10.5 million), regulatory milestone payments, and double-digit royalties on product sales.
- Saniona is awarded a grant of up to USD 590,700 (approximately SEK 5.1 million) by The Michael J. Fox Foundation for Parkinson's Research to develop drug candidates for the treatment of Parkinson's disease.
- Saniona obtains patent in the United States until 2033 for the combination of tesofensine and metoprolol.
- Saniona appoints Laika Consulting for IR and PR support and issue the first newsletter.
- Saniona obtains approval by BfArM to initiate Phase 2a clinical study for Tesomet in type 2 diabetes patients.

### Significant events after the reporting period

- Saniona initiates recruitment of patients in the Phase 2a clinical studies for Tesomet in type 2 diabetes. The trial comprises a total of 60 patients. Saniona expects to report the results from the trial within one year.
- Saniona submits an application for trading on Nasdaq First North Premier as a step in company's plans to list its shares on Nasdaq Stockholm Small Cap later in 2016.
- Saniona initiates extended preclinical research studies on backup compound to AN363; AN363 is put on hold
- Saniona invests in a new company, Initiator Pharma A/S, and spins out three programs, which Saniona does not plan to pursue internally.

### Comments from the CEO

"Saniona made a flying start in Q1 2016 where we signed three new collaboration agreements. This had direct impact on revenues, which increased by 227% compared to Q1 2015. After the end of the quarter we have started a Phase 2 study for Tesomet and announced our intention to be listed on Nasdaq First North Premier in May, a step on the road to Nasdaq Stockholm. I see great opportunities for the company in the future," 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 Upsher-Smith Laboratories, Inc., Productos Medix, S.A de S.V and Saniona's Boston based spinout Ataxion Inc., which is financed by Atlas Venture Inc. and Biogen Inc. Saniona is based in Copenhagen, Denmark, where it has a research center of high international standard. Saniona is listed at AktieTorget since April 2014 and has about 3,700 shareholders. The company's share is traded under the ticker SANION. Read more at [www.saniona.com](http://www.saniona.com).*

## Letter from the CEO

“We have had a fantastic start in 2016 with three new collaboration agreements during the first quarter. All agreements are important to us and enable us to report significantly higher sales compared to first quarter last year.

- The agreement with Upsher-Smith relates to one of our early stage discovery programs which we have not discussed in public previously. It illustrates that we are able to create significant value for our shareholders by entering into early stage collaborations on assets belonging to our broad pipeline of discovery programs. In the long term, Saniona may receive up to USD 30 million (about SEK 250 million) in milestone payments plus royalties on net sales of products coming of this collaboration.
- The agreement with Medix is highly interesting and illustrates how Saniona may finance late stage clinical development of specific programs. Furthermore, the collaboration takes the company a significant step forward towards the market and potential royalty income since Medix intends to start Phase 3 trials this year.
- The agreement with Michael J. Fox Foundation for Parkinson’s Research relates also to one of our early stage discovery programs which we have not discussed in public previously. We are very proud that The Michael J. Fox Foundation for Parkinson’s Research supports the development of our technology and we are pleased to be collaborating with such a prestigious organization. Moreover, the grant illustrates how Saniona may finance early stage programs and still retain the commercial rights.

During the quarter, two other important achievements should be noted. First, we obtained a patent in the United States covering the combination of tesofensine and metoprolol, which are the active ingredients in our internal lead candidate, Tesomet. Second, we obtained approval by the German authorities, BfArM, to initiate Phase 2a clinical study for Tesomet in type 2 diabetes.

We have continued in high pace after the end of the quarter.

First, we started a Phase 2 clinical study for Tesomet. This is in every way an important milestone for the company. Our vision for Tesomet is to develop a new type of treatment for type 2 diabetes which can bring certain groups of patients in complete remission. The market is huge and the clinical need significant. Therefore, Tesomet has the potential to become a blockbuster if developed successfully.

Second, we submitted an application for trading on Nasdaq First North Premier in May as a step in company’s plans to list its shares on Nasdaq Stockholm Small Cap later this year. The aim of the Nasdaq Stockholm listing is to make the company more visible for foreign investors and not least institutional investors, who in most cases do not have a mandate to invest in companies listed at AktieTorget and First North.

Third, we decided to initiate extended non GLP preclinical studies on a backup compound to AN363. We remain highly enthusiastic about the concept of using GABAA  $\alpha 2$ ,  $\alpha 3$  subtype specific compounds for chronic pain. However, we are still concerned about using AN363 for chronic pain still not having a clear understanding of the observed toxicological finding in the rat. Rather than continuing an expensive and time consuming investigation of this finding without any guarantee for success, we have concluded that a more constructive path forward is to focus on a backup compound from the broad preclinical program.

Finally, we participated in the formation of a new company, Initiator Pharma A/S, which subsequently acquired three Saniona programs, which we do not intend to pursue internally. Saniona commercializes its research efforts through three different business models including internal development in early phases of drug development, through early stage research collaborations, and through spin-outs. The formation of Initiator Pharma represents a variant of the third model. The intention is that Initiator Pharma applies for listing at AktieTorget in Sweden and that Saniona’s shareholding in Initiator Pharma is distributed to Saniona’s shareholders before the listing. We have applied for Lex ASEA in Sweden with the aim of distributing our shareholding in Initiator Pharma as a specific dividend to our shareholders. By pursuing this opportunity, we hope to create a new interesting company to the benefit of patients and Saniona’s shareholders.

If I should summarize the first quarter in one word it would be “fantastic”. However, we know that superlatives of the past do not help us in the future. We have retained a high pace after the quarter and we intend to continue to do so in the future. We have still a lot to do, the opportunities are significant and the future looks bright.”

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 Upsher-Smith Laboratories, Inc., Productos Medix, S.A de S.V and Saniona's Boston based spinout Ataxion Inc., which is financed by Atlas Venture Inc. and Biogen 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 five 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	[Progress bar]				
Tesomet	Type 2 diabetes	[Progress bar]				
NS2359	Cocaine addiction	[Progress bar]				
AN363 program (GABA $\alpha 2\alpha 3$ )	Neuropathic pain	[Progress bar]				
AN346 program (IK)	Inflammation, IBD	[Progress bar]				
AN470 program (GABA $\alpha 5$ )	Schizophrenia	[Progress bar]				
Ataxion program	Ataxia	[Progress bar]				
Upsher-Smith program	Neurological disorders	[Progress bar]				
Nic- $\alpha 6$	Parkinsons	[Progress bar]				

In addition to the active pipeline shown above, Saniona has a range of validated drug discovery assets as well as clinical stage assets (e.g. AN788 and AN761) positioned for partnering or spin-out.

## Market

Saniona's research is focused in the field of ion channels, which is an established concept in pharmaceutical development. 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>
AN363 Program (GABA <sub>A</sub> α2α3)	Neuropathic pain	> USD 6 billion <sup>4</sup>
AN470 program (GABA <sub>A</sub> α5)	Schizophrenia	> USD4.8 billion <sup>5</sup>
AN346 program (IK)	Inflammatory bowel disease	> USD 5.9 billion <sup>6</sup>
Nic-α6	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.

Many of the large pharmaceutical companies have in recent years undergone considerable restructuring, which has resulted in fewer research projects and a close-down of research sites. Furthermore, the number of dedicated biotech firms that can provide new innovative products to the pharmaceutical industry has decreased as a result of the global financial crisis. However, there is still 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

	2016-01-01 2016-03-31 3 months	2015-01-01 2015-03-31 3 months	2015-01-01 2015-12-31 12 months
Net sales, KSEK	15,853	4,848	13,630
Total operating expenses, KSEK	-16,910	-9,951	-41,705
Operating profit/loss, KSEK	-1,058	-5,103	-28,075
Cash flow from operating activities	2,307	-878	-27,637
Operating margin, %	-7%	-105%	-206%
Average number of employees, #	17.2	16.9	16.8
	2016-03-31	2013-12-31	2015-12-31
Cash and cash equivalent, KSEK	48,876	29,320	47,004
Equity, KSEK	50,380	26,575	52,943
Total equity and liabilities, KSEK	59,812	34,954	57,673
Equity ratio, %	84%	76%	92%

## Revenues and result of the operation

### Revenue

Saniona generated total revenues of KSEK 15,853 (4,848) for the first quarter of 2016, an increase of 227%. In the first quarter of 2016 revenues comprised upfront payments from Medix and Upsher-Smith as well as services under the agreement with Ataxion and Upsher-Smith. In the first quarter of 2015, revenues comprised primarily services under the agreements with Ataxion and Pfizer.

### Operating profit/loss

The company recognized an operating loss of KSEK 1,058 (5,103) for the first quarter of 2016. The reduction in operating loss is primarily due to an increase in revenues of KSEK 11,004. The company recognized operating expenses of KSEK 16,910 (9,995) for the first quarter of 2016, an increase of 70%. External expenses amounted to KSEK 12,250 (5,263) and personnel costs amounted to KSEK 4,067 (3,878). In the first quarter of 2016, external expenses comprised primarily research and development costs in relation to Tesomet followed by AN346 and AN363. In the first quarter of 2015, the external expenses comprised primarily research and development costs in relation to AN363 followed by AN346.

### Financial position

The equity ratio was 84 (76) % as of March 31, 2016, and equity was KSEK 50,380 (26,575). Cash and cash equivalents amounted to KSEK 48,876 (29,320) as of March 31, 2015. Total assets as of March 31, 2015, were KSEK 59,812 (34,954). The company expects to have sufficient capital to initiate and finance the planned Phase 2a study for Tesomet in 2016 and 2017.

### Cash flow

Operating cash flow for the first quarter of 2016 was an inflow of KSEK 2,307 (outflow of 878). Consolidated cash flow for the first quarter of 2016 was an inflow of KSEK 1,991 (inflow 19,712). The inflow in 2016 is explained by an increase in current liabilities whereas the inflow in 2015 is explained by the right issue in the first quarter last year.

## The share, share capital and ownership structure

At March 31, 2016, the number of shares outstanding amounted to 20,841,467 (17,352,750). The company has established a warrant program on July 1, 2015, totaling 64,000 warrants.

At March 31, 2016 the company had 3,705 (1,489) shareholders, excluding holdings in life insurance and foreign custody account holders.

### Personnel

As of March 31, the number of employees was 19 (19) of which 10 (10) are women. Of these employees, 4 (4) are part-time employees and 15 (15) are full-time employees, and a total of 17 (17) work in the company's research and development operations. 11 (11) of Saniona's employees hold PhDs, 2 (2) hold university degrees and the remaining 6 (6) have laboratory training.

### 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.

Exchange rate risks arise because the Group's expenses and income in different currencies do not match and because the Group's assets and liabilities denominated in foreign currency do not balance. The management of these risks is focused on risk mitigation, which is somewhat mitigated by income and cost incurred in USD.

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 Q2	August 23, 2016
Interim Report Q3	November 15, 2016
Year-End Report	February 21, 2017

Ballerup, May 10, 2016  
Saniona AB

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Claus Bræstrup – Chairman

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Jørgen Drejer – CEO and board member

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Anker Lundemose – Board member

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Leif Andersson – Board member

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Carl Johan Sundberg – Board member

**Consolidated statement of comprehensive income – Group**

KSEK	Note	2016-01-01	2015-01-01	2015-01-01
		2016-03-31	2015-03-31	2015-12-31
		3 months	3 months	12 months
	1-3			
Net sales		15,853	4,848	13,630
Total operating income		15,853	4,848	13,630
Raw materials and consumables		-499	-631	-2,050
Other external costs		-12,250	-5,263	-23,926
Personnel costs	4	-4,067	-3,878	-14,966
Depreciation and write-downs		-94	-179	-763
Total operating expenses		-16,910	-9,951	-41,705
<b>Operating profit/loss</b>		<b>-1,058</b>	<b>-5,103</b>	<b>-28,075</b>
Other financial income		3	26	-3
Other financial expenses		-546	-777	-1,180
Total financial items		-543	-752	-1,183
<b>Profit/loss after financial items</b>		<b>-1,601</b>	<b>-5,855</b>	<b>-29,258</b>
Tax on net profit	5	-844	1,128	6,311
<b>Profit/loss for the period</b>		<b>-2,445</b>	<b>-4,727</b>	<b>-22,947</b>
Other comprehensive income for the period		-171	-81	315
<b>Total comprehensive income for the period</b>		<b>-2,616</b>	<b>-4,808</b>	<b>-22,632</b>
Earnings per share, SEK		-0.12	-0.30	-1.29
Diluted earnings per share, SEK		-0.12	-0.30	-1.29

**Consolidated statement of financial position – Group**

KSEK	Note	2016-03-31	2013-12-31	2015-12-31
	1-3			
<b>ASSETS</b>				
Fixtures, fittings, tools and equipment		680	1,249	753
Tangible assets		680	1,249	753
Non-current tax assets	5	222	1,128	0
Other long-term receivables		1,078	793	1,405
Deferred tax		144	0	142
Financial assets		1,300	1,920	1,547
<b>Non-current assets</b>		<b>1,980</b>	<b>3,169</b>	<b>2,300</b>
Trade receivables		20	124	0
Current tax assets	5	6,182	1,774	6,109
Other receivables		2,393	525	1,983
Prepayments and accrued income		361	41	277
Current receivables		8,956	2,464	8,369
Cash and cash equivalent		48,876	29,320	47,004
<b>Current assets</b>		<b>57,832</b>	<b>31,784</b>	<b>55,373</b>
<b>Total assets</b>		<b>59,812</b>	<b>34,954</b>	<b>57,673</b>
<b>EQUITY AND LIABILITIES</b>				
Share capital		1,042	868	1,042
Share premium account		83,323	39,407	83,323
Retained earnings		-31,807	-8,860	-8,860
Currency translation reserve		266	-113	385
Profit for the period		-2,445	-4,727	-22,947
<b>Equity</b>		<b>50,380</b>	<b>26,575</b>	<b>52,943</b>
Prepayments from customers		0	2,611	0
Trade payables		7,954	2,162	2,868
Other payables		-140	2,040	0
Accrued expenses and deferred income		1,619	1,566	1,862
Current liabilities		9,432	8,379	4,730
<b>Total liabilities</b>		<b>9,432</b>	<b>8,379</b>	<b>4,730</b>
<b>Total equity and liabilities</b>		<b>59,812</b>	<b>34,954</b>	<b>57,673</b>
<b>Pledged assets</b>		<b>0</b>	<b>0</b>	<b>0</b>
<b>Contingent liabilities</b>		<b>50</b>	<b>50</b>	<b>50</b>

## Consolidated statement of changes in equity – Group

	Number of shares	Share capital	Share premium	Translation reserves	Retained earnings	Shareholders' equity
<b>January 1, 2016</b>	<b>20,841,467</b>	<b>1,042</b>	<b>83,323</b>	<b>283</b>	<b>-31,704</b>	<b>52,944</b>
<b>Comprehensive income</b>						
Profit/loss for the year					-2,445	-2,445
Other comprehensive income:						0
Translation differences				-171		-171
<b>Total comprehensive income</b>				<b>-171</b>	<b>-2,445</b>	<b>-2,616</b>
<b>Transactions with owners</b>						0
Share-based compensation expenses					51	51
<b>Total transactions with owners</b>					<b>51</b>	<b>51</b>
<b>March 31, 2016</b>	<b>20,841,467</b>	<b>1,042</b>	<b>83,323</b>	<b>112</b>	<b>-34,097</b>	<b>50,380</b>
<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					-4,727	-4,727
Other comprehensive income:						0
Translation differences				-81		-81
<b>Total comprehensive income</b>				<b>-81</b>	<b>-4,727</b>	<b>-4,808</b>
<b>Transactions with owners</b>						
Shares issued for cash	3,470,550	174	24,120			24,294
Expenses related to capital increase			-1,692			-1,692
<b>Total transactions with owners</b>	<b>3,470,550</b>	<b>174</b>	<b>22,429</b>			<b>22,602</b>
<b>March 31, 2015</b>	<b>17,352,750</b>	<b>868</b>	<b>39,407</b>	<b>-113</b>	<b>-13,587</b>	<b>26,575</b>
<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				315		315
<b>Total comprehensive income</b>				<b>315</b>	<b>-22,947</b>	<b>-22,632</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>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>283</b>	<b>-31,704</b>	<b>52,944</b>

**Consolidated statement of cash flows – Group**

KSEK	Note	2016-01-01	2015-01-01	2015-01-01
		2016-03-31	2015-03-31	2015-12-31
		3 months	3 months	12 months
Operating loss before financial items		-1,058	-5,103	-28,075
Depreciation		94	179	763
Changes in working capital		3,271	4,046	-325
<b>Cash flow from operating activities before financial items</b>		<b>2,307</b>	<b>-878</b>	<b>-27,637</b>
Interest income received		3	26	-3
Interest expenses paid		-546	-777	-1,180
<b>Cash flow from operating activities</b>		<b>1,764</b>	<b>-1,630</b>	<b>-28,820</b>
<b>Investing activities</b>				
Investment in tangible assets		-21	-155	-242
Investment in other financial assets		247	-1,105	-732
<b>Cash flow from investing activities</b>		<b>227</b>	<b>-1,260</b>	<b>-975</b>
<b>Financing activities</b>				
New share issue		0	22,602	66,693
<b>Cash flow from financing activities</b>		<b>0</b>	<b>22,602</b>	<b>66,693</b>
<b>Cash flow for the period</b>		<b>1,991</b>	<b>19,712</b>	<b>36,898</b>
<b>Cash and cash equivalents at beginning of period</b>		<b>47,004</b>	<b>9,689</b>	<b>9,689</b>
Exchange rate adjustments		-118	-81	417
<b>Cash and cash equivalents at end of period</b>		<b>48,876</b>	<b>29,320</b>	<b>47,004</b>

### Statement of income – Parent Company

KSEK	Note	2016-01-01	2015-01-01	2015-01-01
		2016-03-31	2015-03-31	2015-12-31
		3 months	3 months	12 months
	1-3			
Net sales		0	0	0
Total operating income		0	0	0
Other external costs		-425	-306	-1,957
Personnel costs		-254	0	-38
Total operating expenses		-679	-306	-1,994
<b>Operating profit/loss</b>		<b>-679</b>	<b>-306</b>	<b>-1,994</b>
Other financial income		155	0	172
Other financial expenses		-59	-777	-548
Total financial items		96	-777	-376
<b>Profit/loss after financial items</b>		<b>-583</b>	<b>-1,083</b>	<b>-2,370</b>
Tax on net profit		0	0	0
<b>Profit/loss for the period</b>		<b>-583</b>	<b>-1,083</b>	<b>-2,370</b>

### Statement of comprehensive income – Parent Company

KSEK	Note	2016-01-01	2015-01-01	2015-01-01
		2016-03-31	2015-03-31	2015-12-31
		3 months	3 months	12 months
<b>Profit/loss for the period</b>		<b>-583</b>	<b>-1,083</b>	<b>-2,370</b>
Other comprehensive income for the period		0	0	0
<b>Total comprehensive income for the period</b>		<b>-583</b>	<b>-1,083</b>	<b>-2,370</b>

## Statement of financial position – Parent Company

KSEK	Note	2016-03-31	2015-03-31	2015-12-31
	1-3			
<b>ASSETS</b>				
Investment in subsidiaries		11,832	11,832	11,832
Financial assets		11,832	11,832	11,832
<b>Non-current assets</b>		<b>6,719</b>	<b>11,832</b>	<b>11,832</b>
Receivables from group companies		33,477	0	23,278
Other receivables		1,424	924	1,319
Prepayments and accrued income		162	0	170
Current receivables		35,063	924	24,767
Cash and cash equivalent		33,122	24,974	43,956
<b>Current assets</b>		<b>68,185</b>	<b>25,897</b>	<b>68,723</b>
<b>Total assets</b>		<b>80,016</b>	<b>37,729</b>	<b>80,555</b>
<b>EQUITY AND LIABILITIES</b>				
Share capital		1,042	868	1,042
Share premium account		81,812	37,896	81,812
Retained earnings		-2,572	-202	-202
Profit for the period		-583	-1,083	-2,370
<b>Equity</b>		<b>79,699</b>	<b>37,479</b>	<b>80,282</b>
Trade payables		314	220	273
Liabilities to companies in the Group		0	30	0
Current liabilities		318	250	273
<b>Total liabilities</b>		<b>318</b>	<b>250</b>	<b>273</b>
<b>Total equity and liabilities</b>		<b>80,016</b>	<b>37,729</b>	<b>80,555</b>
<b>Pledged assets</b>		<b>0</b>	<b>0</b>	<b>0</b>
<b>Contingent liabilities</b>		<b>0</b>	<b>0</b>	<b>0</b>

## Statement of changes in equity – Parent Company

	Number of shares	Share capital	Share premium	Retained earnings	Shareholders' equity
<b>January 1, 2016</b>	<b>20,841,467</b>	<b>1,042</b>	<b>81,812</b>	<b>-2,572</b>	<b>80,282</b>
Total comprehensive income				-583	-583
<b>March 31, 2015</b>	<b>20,841,467</b>	<b>1,042</b>	<b>81,812</b>	<b>-3,155</b>	<b>79,699</b>
<b>Januair 1, 2015</b>	<b>13,882,200</b>	<b>694</b>	<b>15,467</b>	<b>-202</b>	<b>15,960</b>
Total comprehensive income				-1,083	-1,083
<b>Transactions with owners</b>					
Shares issued for cash	3,470,550	174	24,120		24,294
Expenses related to capital increase			-1,692		-1,692
<b>March 31, 2015</b>	<b>17,352,750</b>	<b>868</b>	<b>37,896</b>	<b>-1,284</b>	<b>37,479</b>
<b>Janaury 1, 2015</b>	<b>13,882,200</b>	<b>694</b>	<b>15,467</b>	<b>-202</b>	<b>15,960</b>
Total comprehensive income				-2,370	-2,370
<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
<b>December 31, 2015</b>	<b>20,841,467</b>	<b>1,042</b>	<b>81,812</b>	<b>-2,572</b>	<b>80,282</b>

## Statement of cash flows – Parent Company

KSEK	Note	2016-01-01	2015-01-01	2015-01-01
		2016-03-31	2015-03-31	2015-12-31
		3 months	3 months	12 months
Operating loss before financial items		-679	-306	-1,994
Changes in working capital		-10,251	-5,287	-29,108
<b>Cash flow from operating activities before financial items</b>		<b>-10,930</b>	<b>-5,593</b>	<b>-31,102</b>
Interest income received		155	0	172
Interest expenses paid		-59	-777	-548
<b>Cash flow from operating activities</b>		<b>-10,834</b>	<b>-6,370</b>	<b>-31,478</b>
<b>Investing activities</b>				
<b>Cash flow from investing activities</b>		<b>0</b>	<b>0</b>	<b>0</b>
<b>Financing activities</b>				
New share issue		0	22,602	66,693
<b>Cash flow from financing activities</b>		<b>0</b>	<b>22,602</b>	<b>66,693</b>
<b>Cash flow for the period</b>		<b>-10,834</b>	<b>16,232</b>	<b>35,215</b>
<b>Cash and cash equivalents at beginning of period</b>		<b>43,956</b>	<b>8,742</b>	<b>8,742</b>
<b>Cash and cash equivalents at end of period</b>		<b>33,122</b>	<b>24,974</b>	<b>43,956</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 has been listed on AktieTorget since April 22, 2014. The Parent Company's share is traded under the ticker SANION and the ISIN code SE0005794617.

### Note 2 Significant accounting policies

The consolidated financial statements have been prepared in accordance with IAS 34 and the Annual Accounts Act, the Financial Reporting Board's recommendation RFR 1, Supplementary Accounting Rules for Groups, International Financial Reporting Standards (IFRS) and interpretations of IFRS IC as adopted by the EU.

The 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 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.

### 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 of Saniona had a carrying and fair value amount 0 at the time of formation of Ataxion and the investments made by the other parties were insignificant. Ataxion is today developing the Ataxia-program based on financing from Biogen. and Atlas Venture. 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: Share based payments

Share-based compensation expenses for the first quarter of 2016 totaled SEK 51 (0) 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 March 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 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 taxes of SEK 844 thousands during the first quarter 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 1,068). Under the tax treaty between Denmark and Mexico, this amount will be deductible towards tax payable in Denmark during the financial year 2016 if any. This tax asset has not been recognized in the balance sheet since the Group does not anticipate to utilize it for the time being. The balance of KSEK -224 represent the recognized tax credit for the first quarter 2016 under the Danish R&D tax credit scheme (Skattekreditordningen). This amount has been recognized under non-current tax assets in accordance to the accounting policies described below. During the first quarter of 2015, the Group recognized taxed of KSEK -1,128 under the Danish R&S tax credit scheme.

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 maximum amount was DKK 25 million equal to a tax credit of DKK 5.875 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 March 31, 2016, the Group had KSEK 6,182 in current tax asset, which will be payable in November 2016, and KSEK 222 in non-current tax assets which will be payable in November 2017. As of March 31, 2015, the Group had KSEK 1,774 in current tax asset, which was paid November 2015, and KSEK 1,128 in non-current tax assets which will be payable in November 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 which is designed to positively modulate (PAM) GABA<sub>A</sub> α2 and GABA<sub>A</sub> α3 ion channels, which are expressed in various central and peripheral neurons and are believed to be key mediator in the control of pain signalling and the control of anxiety.

### AN346

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.

### AN470

A small molecule which is designed to negatively modulate (NAM) GABA<sub>A</sub> α5 channels. GABA<sub>A</sub> α5 channels are expressed in various CNS tissue and are believed to be a key mediator in the control of cognitive processes. AN470 is a novel candidate for treatment of cognitive and psychiatric disorders such as schizophrenia.

### AN761

A small molecule which is designed to open (agonize) nicotinic α7 channels. Nicotinic α7 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 in order 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.

### **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

### **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 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 the Partners section.

### **Type 2 diabetes**

A metabolic disorder that is characterized by hyperglycemia (high blood sugar) in the context of insulin resistance and relative lack of insulin. This is in contrast to 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 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.

#### **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 glossary

### **Earnings per share**

Profit/loss for the period divided by the average number of shares outstanding during the period

### **EBIT**

Earnings Before Interest and Taxes (Operating profit/loss)

### **Equity ratio**

Shareholders' equity as a proportion of total assets

### **Diluted earnings per share**

Profit/loss for the period divided by the average number of shares after dilution during the period

### **Liquidity ratio**

Current assets (excl. inventories) divided by current liabilities

### **Operating margin**

EBIT as a proportion of revenue

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