

INTERIM REPORT FOR SANIONA AB (PUBL) 556962-5345 January - June 2016 Published August 23, 2016



FULL SPEED AHEAD DURING THE SECOND QUARTER

Financial highlights

H1 2016 (H1 2015)

- Net revenues were KSEK 18,899 (9,848)
- EBIT was KSEK -14,560 (-11,891)
- Earnings per share were SEK -0.61 (-0.61)
- Diluted earnings per share were SEK -0.61 (-0.61)

Q2 2016 (Q2 2015)

- Net revenues were KSEK 3,046 (5,000)
- EBIT was KSEK -13,502 (-6,787)
- Earnings per share were SEK -0.49 (-0.32)
- Diluted earnings per share were SEK -0.49 (-0.32)

Business highlights in Q2 2016

- 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 early 2017.
- Saniona initiates extended preclinical research studies on backup compounds to AN363, which is discontinued
- Saniona participates in formation of a new company, Initiator Pharma A/S, and spins out three programs to Initiator Pharma, which Saniona does not plan to pursue internally.
- Saniona is listed 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 acquires NeuroSearch's remaining portfolio comprising the two compounds, ACR325 and ACR343.
- Saniona's partner the University of Pennsylvania Treatment Research Center (TRC), initiates recruitment of
 patients in a Phase 2a study on Saniona's compound, NS2359, for treatment of cocaine addiction.
- Saniona receives positive prior consent from the tax authorities in Sweden and in Denmark regarding the distribution of Saniona's shares in Initiator Pharma.

Significant events after the reporting period

- Saniona awarded three grants for research programs totaling SEK 5.3 million.
- Saniona completes recruitment of patients in Phase 2a study for Tesomet in type 2 diabetes.

Comments from the CEO

"Recruitment of patients in two clinical studies in diabetes and cocaine addiction during the second quarter of 2016 documents our commitment to advancing innovative treatment options towards the market to be benefit of patients and shareholders," says Jørgen Drejer, CEO of Saniona.

For more information, please contact

Thomas Feldthus, EVP and CFO, Saniona, Mobile: +45 2210 9957, E-mail: tf@saniona.com

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 preclinical 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 Nasdaq First North Premier and has about 4,300 shareholders. Pareto Securities is Certified Advisor for Saniona. The company's share is traded under the ticker SANION. Read more at www.saniona.com.



Letter from the CEO

"We took a significant step forward and became a phase 2 clinical stage company in the second quarter of 2016. Not only one, but two Phase 2 clinical studies were initiated. First, we started recruitment in a Phase 2 study for Tesomet, which represents a potential new and innovative treatment for type 2 diabetes. Second, with our partners at Penn University we enrolled patients into a Phase 2 study with NS2359, which may be the first drug for the treatment of cocaine addiction.

Initiating two Phase 2 studies in a single quarter would represent a huge achievement for any biotech company. This clearly shows the strength and breadth of our portfolio. And it emphasizes without any questions that we now have become a clinical stage company.

Importantly, the two studies may lead to development of new breakthrough therapies, which we hope will demonstrate substantial improvement over existing therapies and may have a significant impact of the lives of patients.

Tesomet represents a new treatment for type 2 diabetes which may not only improve the quality of life of large patient populations but even bring certain groups of patients in complete remission. After the end of the quarter, we completed the recruitment of patients in this Phase 2 study and we hope that we are able to report top line results from this study already in the beginning of 2017.

Likewise, the study together with Penn University may represent a breakthrough in the treatment of cocaine addiction. There is no medical treatment today. Patients may be offered psychosocial treatment but it is not effective and relapse rate is very high. The objective of the study is to demonstrate the effect of NS2359 as potentially the first medical treatment in this field. Obviously, it will have a fundamental impact on the life of cocaine addicts and their families if this trial proves to be successful. For shareholders it comes as an extra bonus, that this trial is conducted by some of the leading scientists in this field and funded by public and private grants.

In addition to the Phase 2 studies, we succeeded in taking several other crucial steps during the second quarter:

- We transferred our listing from AktieTorget to Nasdaq First North Premier. We see this a logical and important step towards a listing Nasdaq Stockholm Small Cap later this year
- We participated in the formation of a new company, Initiator Pharma, together with a group of scientists.
 Saniona owns 60% of Initiator Pharma, which has acquired three noncore programs from Saniona. Initiator Pharma plans to apply for a public listing at AktieTorget in Sweden. The board of directors of Saniona intends to propose at an extra ordinary general meeting that Saniona's shareholding in Initiator Pharma shall be distributed to Saniona's shareholders as a specific dividend payment before the listing of Initiator Pharma.
- We moved our internal and partnered programs forward towards our goals and were able to vitalize new as well as non-active innovative research programs in our pipeline after receiving three prestigious public grants.

We continue to deliver in accordance to Saniona's three strategic business models: 1) internal development of selected programs; 2) early stage research collaborations; and 3) joint ventures and spin-outs.

We have moved our clinical stage Tesomet program forward with full speed during the second quarter. We have retained a high pace in partnered programs and continue to deliver to the benefits 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 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.

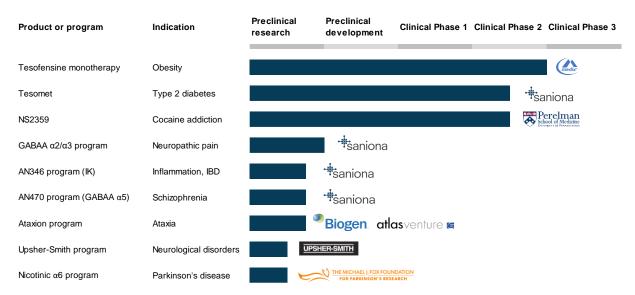
Business model

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 outlicensing 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.



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 ¹
Tesofensine	Obesity	- USD 250 million in Mexico ²
NS2359	Cocaine addiction	> USD 1.8 billion ³
AN363 Program (GABA _A α2α3)	Neuropathic pain	> USD 6 billion ⁴
AN470 program (GABA _A α5)	Schizophrenia	> USD4.8 billion ⁵
AN346 program (IK)	Inflammatory bowel disease	> USD 5.9 billion ⁶
Nic-α6	Parkinson's disease	> USD 2.8 billion ⁷

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.

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

² Estimates of drugs for obesity in Mexico by Medix 2016

³ Estimates by TRC

⁴ Major markets 2012, Decision Resources

⁵ Schizophrenia Forecast 7 major market, Datamonitor, 2014

⁶ Major markets 2014, Datamonitor

⁷ 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

	2016-04-01 2016-06-30	2015-04-01 2015-06-30	2016-01-01 2016-06-30	2015-01-01 2015-06-30	2015-01-01 2015-12-31
Net sales, KSEK	3,046	5,000	18,899	9,848	13,630
Total operating expenses, KSEK	-16,549	-11,787	-33,459	-21,738	-41,705
Operating profit/loss, KSEK	-13,502	-6,787	-14,560	-11,891	-28,075
Cash flow from operating activities	-12,320	-4,546	-9,869	-5,425	-27,637
Operating margin, %	-443%	-136%	-77%	-121%	-206%
Average number of employees, #	18.9	16.3	18.5	16.6	16.8
	2016-06-30		2015-06-30		2015-12-31
Cash and cash equivalent, KSEK	34,002		22,973		47,004
Equity, KSEK	39,649		21,141		52,943
Total equity and liabilities, KSEK	47,832		33,806		57,673
Equity ratio, %	83%		63%		92%

Revenues and result of the operation

Revenue

Saniona generated total revenues of KSEK 18,899 (9,848) for the first 6 months of 2016, an increase of 92%. In 2016 revenues comprised upfront payments from Medix and Upsher-Smith as well as services under the agreement with Ataxion and Upsher-Smith. In 2015, revenues comprised primarily services under the agreements with Ataxion and Pfizer.

Operating profit/loss

The company recognized an operating loss of KSEK 14,560 (11,891) for the first 6 months of 2016. The company recognized operating expenses of KSEK 33,459 (21,738) for the first 6 months of 2016, an increase of 54%. External expenses amounted to KSEK 24,228 (12,368) and personnel costs amounted to KSEK 8,679 (7,593). In 2016, external expenses comprised primarily research and development costs in relation to Tesomet followed by the IK program and the GABAA α 2,3 program. In 2015, the external expenses comprised primarily research and development costs in relation to AN363 followed by the IK program.

Financial position

The equity ratio was 83 (63) % as of June 30, 2016, and equity was KSEK 39,649 (21,141). Cash and cash equivalents amounted to KSEK 34,002 (22,973) as of June 30, 2016. Total assets as of June 30, 2016, were KSEK 47,832 (33,806). 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 6 months of 2016 was an outflow of KSEK 9,869 (outflow of 5,425). Consolidated cash flow for the first 6 months of 2016 was an outflow of 12,423 (inflow 13,327). The inflow in 2015 is explained by the rights issue in the first guarter last year.

The share, share capital and ownership structure

At June 30, 2016, the number of shares outstanding amounted to 20,841,467 (17,352,750). The company established a warrant program on July 1, 2015, totaling 64,000 warrants.

At June 30, 2016 the company had 4,304 (2,073) shareholders, excluding holdings in life insurance and foreign custody account holders.

Personnel

As of June 30, the number of employees was 22 (18) of which 12 (9) are women. Of these employees, 6 (3) are part-time employees and 16 (15) are full-time employees, and a total of 19 (16) work in the company's research and development operations. 11 (11) of Saniona's employees hold PhDs, 4 (2) hold university degrees and the remaining 7 (5) 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 been subject to review by the company's auditors in accordance with the Standard on Review Engagements (ISRE) 2410, Review of Interim Financial Information Performed by the Independent Auditor of the Entity.

Financial calendar

Ballerup, August 23, 2016

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

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.

Saliiolia Ab	
Claus Bræstrup – Chairman	Jørgen Drejer – CEO and board member
Anker Lundemose – Board member	Leif Andersson – Board member
Carl Johan Sundberg – Board member	



Auditors' Review Report

Introduction

We have reviewed the interim report for Saniona AB (publ) for the period January 1 - June 30, 2016. The Board of Directors and the President are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

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

Conclusion

Deloitte AB

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

Taront Company in accordance with the Attinual Accounts Act.
Malmö, August 23, 2016

Elna Lembrér Åström

Authorized Public Accountant



Consolidated statement of comprehensive income - Group

KSEK	2016-04-01	2015-04-01	2016-01-01	2015-01-01	2015-01-01
Note	2016-06-30	2015-06-30	2016-06-30	2015-06-30	2015-12-31
1-3					
Net sales	3,046	5,000	18,899	9,848	13,630
Total operating income	3,046	5,000	18,899	9,848	13,630
Raw materials and consumables	121	-708	-378	-1,339	-2,050
Other external costs	-11,978	-7,105	-24,228	-12,368	-23,926
Personnel costs 4	-4,612	-3,715	-8,679	-7,593	-14,966
Depreciation and write-downs	-81	-260	-174	-439	-763
Total operating expenses	-16,549	-11,787	-33,459	-21,738	-41,705
Operating profit/loss	-13,502	-6,787	-14,560	-11,891	-28,075
Other financial income	10	-25	13	1	-3
Other financial expenses	846	-214	300	-991	-1,180
Total financial items	856	-239	313	-990	-1,183
Profit/loss after financial items	-12,646	-7,026	-14,247	-12,881	-29,258
Tax on net profit 5	2,375	1,556	1,531	2,683	6,311
Profit/loss for the period	-10,271	-5,470	-12,715	-10,198	-22,947
Other comprehensive income for the period	-513	37	-683	-44	314
Total comprehensive income for the period	-10,784	-5,433	-13,398	-10,241	-22,633
Earnings per share, SEK	-0.49	-0.32	-0.61	-0.61	-1.29
Diluted earnings per share, SEK	-0.49	-0.32	-0.61	-0.61	-1.29



Consolidated statement of financial position - Group

KSEK Note	2016-06-30	2015-06-30	2015-12-31
1-3			
ASSETS			
Fixtures, fittings, tools and equipment	716	1,058	753
Tangible assets	716	1,058	753
Non-current tax assets 5	2,639	2,664	C
Investments in subsidiaries 6	391	0	C
Other long-term receivables	1,248	788	1,547
Financial assets	4,277	3,452	1,547
Non-current assets	4,993	4,510	2,300
Trade receivables	204	1,905	O
Current tax assets 5	6,317	1,762	6,109
Other receivables	2,067	2,089	1,983
Prepayments and accrued income	248	568	277
Current receivables	8,837	6,324	8,369
Cash and cash equivalent	34,002	22,973	47,004
Current assets	42,839	29,296	55,373
Total assets	47,832	33,806	57,673
EQUITY AND LIABILITIES			
Share capital	1,042	868	1,042
Share premium account	83,323	39,407	83,323
Retained earnings	-34,252	-8,860	-8,860
Currency translation reserve			
Profit for the period	-194	-76	385
<u> </u>	-10,271	-10,198	-22,947
Equity	39,649	21,141	52,943
Prepayments from customers	0	1,733	O
Trade payables	6,215	5,828	2,868
Other payables	2	3,414	0
Accrued expenses and deferred	4.000	4.000	4.000
income Current liabilities	1,966 8,183	1,690 12,665	1,862 4,730
Total liabilities	8,183	12,665	4,730
Total equity and liabilities	47,832	33,806	57,673
Pledged assets	0	0	0
r ieuyeu assets	U	U	U
Contingent liabilities	50	50	50



Consolidated statement of changes in equity - Group

	Number of shares	Share capital	Share premium	Translation reserves	Retained earnings	Shareholders' equity
January 1, 2015	13,882,200	694	16,978	-32	-8,860	8,780
Comprehensive income						
Profit/loss for the year					-10,198	-10,198
Other comprehensive income:						0
Translation differences				-44		-44
Total comprehensive income				-44	-10,198	-10,241
Transactions with owners						
Shares issued for cash	3,470,550	174	24,120			24,294
Expenses related to capital increase			-1,692			-1,692
Total transactions with owners	3,470,550	174	22,429	0	0	22,602
June 30, 2015	17,352,750	868	39,407	-76	-19,058	21,141
July 1, 2015	17,352,750	868	39,407	-76	-19,058	21,141
Comprehensive income						
Profit/loss for the year					-12,749	-12,749
Other comprehensive income:						
Translation differences				357		357
Total comprehensive income				357	-12,749	-12,392
Transactions with owners						
Shares issued for cash	3,488,717	174	48,668			48,842
Expenses related to capital increase			-4,752			-4,752
Share-based compensation expenses					103	103
Total transactions with owners	3,488,717	174	43,916		103	44,193
December 31, 2015	20,841,467	1,042	83,323	282	-31,704	52,943
January 1, 2016	20,841,467	1,042	83,323	282	-31,704	52,943
	-,- , -	,-			,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Comprehensive income					40.745	40.745
Profit/loss for the year					-12,715	-12,715
Other comprehensive income: Translation differences				-683		-683
Total comprehensive income				-683	-12,715	-13,398
Transactions with owners						
Share-based compensation expenses					104	104
Total transactions with owners					104	104
June 30, 2016	20,841,467	1,042	83,323	-401	-44,316	39,649



Consolidated statement of cash flows - Group

KSEK		2016-04-01	2015-04-01	2016-01-01	2015-01-01	2015-01-01
	Note	2016-06-30	2015-06-30	2016-06-30	2015-06-30	2015-12-31
Operating loss before financial items		-13,502	-6,787	-14,560	-11,891	-28,075
Depreciation		81	260	174	439	763
Changes in working capital		1,102	1,981	4,517	6,027	-325
Cash flow from operating activities before financial items		-12,320	-4,546	-9,869	-5,425	-27,637
Interest income received		10	-25	13	1	-3
Interest expenses paid		846	-214	300	-991	-1,180
Cash flow from operating activities		-11,463	-4,785	-9,556	-6,415	-28,820
Investing activities						
Investment in tangible assets		-116	-69	-137	-223	-242
Investments in subsidiaries	6	-391	0	-391	0	0
Investment in other financial assets		-2,443	-1,531	-2,340	-2,637	-732
Cash flow from investing activities		-2,950	-1,600	-2,867	-2,860	-975
Financing activities						
New share issue		0	0	0	22,602	66,693
Shareholders' contribution received		0	0	0	0	0
Cash flow from financing activities		0	0	0	22,602	66,693
Cash flow for the period		-14,413	-6,385	-12,423	13,327	36,898
Cash and cash equivalents at beginning of period		48,876	29,320	47,004	9,689	9,689
Exchange rate adjustments		-460	37	-579	-44	417
Cash and cash equivalents at end of period	_	34,002	22,973	34,002	22,973	47,004



Statement of income - Parent Company

KSEK Note	2016-04-01 2016-06-30	2015-04-01 2015-06-30	2016-01-01 2016-06-30	2015-01-01 2015-06-30	2015-01-01 2015-12-31
1-3					
Net sales	0	0	0	0	0
Total operating income	0	0	0		
Other external costs	-1,704	-237	-2,129	-543	-1,957
Personnel costs	-266	0	-520	0	-38
Total operating expenses	-1,970	-237	-2,649	-543	-1,994
Operating profit/loss	-1,970	-237	-2,649	-543	-1,994
Other financial income	177	13	332	13	172
Other financial expenses	-57	-155	-116	-932	-548
Total financial items	120	-142	216	-919	-376
Profit/loss after financial items	-1,850	-379	-2,433	-1,462	-2,370
Tax on net profit	0	0	0	0	0
Profit/loss for the period	-1,850	-379	-2,433	-1,462	-2,370

Statement of comprehensive income – Parent Company

KSEK	Note	2016-04-01 2016-06-30	2015-04-01 2015-06-30		2015-01-01 2015-06-30	2015-01-01 2015-12-31
	1-3	2010 00 00	2010 00 00	2010 00 00	2010 00 00	2010 12 01
Profit/loss for the period		-1,850	-379	-2,433	-1,462	-2,370
Other comprehensive income for the period		0	0	0	0	0
Total comprehensive income for the period		-1,850	-379	-2,433	-1,462	-2,370



Statement of financial position - Parent Company

KSEK	Note	2016-06-30	2015-06-30	2015-12-31
	1-3			
ASSETS				
Investment in subsidiaries	6	12,222	11,832	11,832
Financial assets		12,222	11,832	11,832
Non-current assets		12,222	11,832	11,832
Receivables from group companies		33,692	8,633	23,278
Other receivables Prepayments and accrued income		445 24	1,007 146	1,319 170
Current receivables		34,161	9,786	24,767
Cash and cash equivalent		31,898	15,725	43,956
Current assets		66,058	25,510	68,723
Total assets		78,281	37,342	80,555
EQUITY AND LIABILITIES				
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		-2,433	-1,462	-2,370
Equity		77,848	37,100	80,282
Trade payables		430	242	273
Other payables		2	0	0
Current liabilities		432	242	273
Total liabilities		432	242	273
Total equity and liabilities		78,281	37,342	80,555
Pledged assets		0	0	0
Contingent liabilities		0	0	0



Statement of changes in equity – Parent Company

	Number of shares	Share capital	Share premium	Retained earnings	Shareholders' equity
January 1, 2015	13,882,200	694	15,467	-202	15,960
Total comprehensive income	10,002,200	00.	.0, .0.	-1,462	-1,462
Transactions with owners				., .==	.,
Shares issued for cash	3,470,550	174	24,120		24,294
Expenses related to capital increase			-1,692		-1,692
June 30, 2016	17,352,750	868	37,896	-1,663	37,100
July 1, 2015	17,352,750	868	37,896	-1,663	37,100
Total comprehensive income				-909	-909
Transactions with owners					
Shares issued for cash	3,488,717	174	48,668		48,842
Expenses related to capital increase			-4,752		-4,752
December 31, 2015	20,841,467	1,042	81,812	-2,572	80,282
January 4, 2046	20.944.467	4.042	94 94 9	2 572	90.292
January 1, 2016	20,841,467	1,042	81,812	-2,572	80,282
Total comprehensive income	00.044.407	4.046	04.046	-2,433	-2,433
June 30, 2016	20,841,467	1,042	81,812	-5,005	77,848

Statement of cash flows - Parent Company

KSEK	2016-04-01	2015-04-01	2016-01-01	2015-01-01	2015-01-01
ROLK	2016-06-30	2015-04-01	2016-06-30	2015-06-30	2015-12-31
1-3		2010 00 00	2010 00 00	2010 00 00	2010 12 01
Operating loss before financial items	-1.970	-237	-2.649	-543	-1.994
Changes in working capital	1,017	-8,870	-9,235	-14,157	-29,108
Cash flow from operating activities before financial items	-953	-9,107	-11,884	-14,700	-31,102
Interest in some resolved	177	13	332	13	172
Interest income received	-57	-155	-116	-932	
Interest expenses paid	-57	-155	-110	-932	-548
Cash flow from operating activities	-834	-9,249	-11,668	-15,619	-31,478
Investing activities					
Investments in subsidiaries 6	-391	0	-391	0	0
Cash flow from investing activities	-391	0	-391	0	0
Financing activities					
New share issue	0	0	0	22,602	66,693
Cash flow from financing activities	0	0	0	22,602	66,693
Cash flow for the period	-1,224	-9,249	-12,059	6,983	35,215
Cash and cash equivalents at beginning of period	33,122	24,974	43,956	8,742	8,742
Cash and cash equivalents at end of period	31,898	15,725	31,898	15,725	43,956



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 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. 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 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 half of 2016 totaled SEK 104 (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 June 30, 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 -1,531 thousands during the first 6 months 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). 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 it is uncertain whether the Group would be able to utilize it for the time being. The balance of KSEK -2,639 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 6 months of 2015, the Group recognized tax credit of KSEK -2,664 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 June 30, 2016, the Group had KSEK 6,317 in current tax asset, which will be payable in November 2016, and KSEK 2,639 in non-current tax assets which will be payable in November 2015, and KSEK 2,264 in non-current tax assets which will be payable in November 2016.

Note 6 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 does not plan to pursue internally. Saniona AB paid KSEK 391 for the shares in connection with 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. As of June 30, Saniona AB owns 60% of Initiator Pharma A/S. Saniona has informed that intends to distribute its shareholding in Initiator Pharma A/S to Saniona AB's shareholders as an extraordinary dividend as soon as possible. The financial statements of Initiator Pharma A/S have not been subject to consolidation in the Group. The reason is that the shares in Initiator Pharma A/S have been acquired exclusively for the purpose of distribution to Saniona AB's shareholders.



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_A α 2 and GABA_A α 3 ion channels, which are expressed in various central and peripheral neurons and are believed to be key mediator in the control of pain signalling and the control of anxiety.

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_A α 5 channels. GABA_A α 5 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 $\alpha 7$ 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 us 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 sever chronic diseases such as Friedreich's ataxia, which is an autosomal recessive inherited disease that causes progressive damage to the nervous system which manifests in initial symptoms of poor coordination that progresses until a wheelchair is required for mobility.

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.

FΜA

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

FRIT

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

Saniona AB

Baltorpvej 154

DK-2750 Ballerup

Denmark

www.saniona.com