INTERIM REPORT FOR SANIONA AB (PUBL)
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# SANIONA WELL POSITIONED TO START PHASE 2 CLINICAL STUDIES

## Financial highlights

### Jan-Sep 2015 (Jan-Sep 2014)

- Net revenues were KSEK 11,803 (17,998)
- EBIT was KSEK -22,748 (2,016)
- Earnings per share were SEK -1.05 (-0.11)
- Diluted earnings per share were SEK -1.04 (-0.11)

### Q3 2015 (Q3 2014)

- Net revenues were KSEK 1,955 (5,247)
- EBIT was KSEK -10,857 (-2,322)
- Earnings per share were SEK -0.46 (-0.13)
- Diluted earnings per share were SEK -0.46 (-0.13)

## Business highlights in Q3 2015

- Saniona expects to initiate a confirmatory Phase 2a study with Tesomet in the first half of 2016.
- FDA accepts the University of Pennsylvania Treatment Research Center's IND for conducting a Phase 2 clinical trial for NS2359 for cocaine addiction. Saniona retains all commercial rights.
- The Board decides to perform a rights issue of SEK 60.7 million with a subscription price of SEK 14.00 per share. The rights issue is secured up to approximately 80 per cent equivalent to SEK 48.8 million.
- Saniona and Pfizer terminate the research collaboration within neurological diseases. Saniona maintains the rights to continue the program.
- Preliminary preclinical toxicology data published for AN363 and announces that it will perform additional studies on a finding seen at higher doses in rats. Subject to a positive outcome of these investigations, Saniona can initiate the clinical Phase 1 trial at the Centre for Human Drug Research in Holland, CHDR.
- New clinical data published which strongly supports the concept for the use of Tesomet for treatment of type 2 diabetes.
- Professor Carl Johan Sundberg is appointed as new member of the Board of Directors at the extraordinary general meeting on September 4, 2015.
- IFRS implemented from the Q2 interim report 2015 in preparation for the planned listing on Nasdaq Stockholm Small Cap in 2016.

## Significant events after the reporting period

- Saniona and Ataxion extend their on-going drug discovery and development collaboration on a three month rolling basis with the aim of identifying a development candidate.
- Rights issue is subscribed to 80.4% and the company raises about SEK 48.8 Million before issue expenses, amounting to around SEK 5.3 million.
- New pre-clinical efficacy data for AN363 published at the Society for Neurosciences 2015 Conference in Chicago along with new scientific data in relation to the AN346 program.

## Comments from the CEO

"With the recent completion of the rights issue we are ready for a new era. Within a short period we have gone from being an early stage company to a clinical stage company with the lead compound entering Phase 2 in first half of 2016. I am thrilled by the development in the company," 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 an ongoing collaboration agreement with Saniona's Boston based spinout Ataxion Inc., which is financed by Atlas Venture Inc. and Biogen Idec Inc. Saniona is based in Copenhagen, Denmark, where it has a research center of high international standard and 18 employees. Saniona is listed at AktieTorget since April 2014 and has about 2,000 shareholders. The company's share is traded under the ticker SANION. Read more at www.saniona.com

## Letter from the CEO

”With the completion of the recent rights issue in November, Saniona is now positioned to enter into a completely new era. We are leaving the early stage with only preclinical programs behind us. We are entering a stage where several programs can enter the clinical phase, two programs in Phase 2 and potentially one program in Phase 1. Still we have retained our broad portfolio comprising a number of exciting programs and opportunities.

We are primarily focusing on the three programs, which can enter clinical phase:

- Tesomet is planned to initiate Phase 2a studies in the first half of 2016 for type 2 diabetes. Tesomet is a combination of a weight-loss drug candidate, tesofensine, and a beta blocker, metoprolol.
- NS2359 obtained an IND by the FDA in August to start Phase 2 clinical trials in the US for cocaine addiction. These studies can bet started without significant investments by Saniona. Researchers at the University of Pennsylvania are currently applying for public funds to support this study. Saniona retains all rights.
- Regarding AN363, provided that the results of the additional toxicological studies in rats are positive, we can initiate Phase 1 clinical studies in 2016 for neuropathic pain.

With respect to Tesomet, we are looking very much forward to initiate our Phase 2a clinical study in the first half of 2016. It represents to a large extent a confirmatory study of the results we have seen in pre-diabetes patients. A retrospective analysis of existing data from a previous clinical Phase 2 trial in humans shows that tesofensine reduces the glycemic parameters in individuals with pre-diabetes. In addition, a retrospective analysis of a Phase 1 study with tesofensine and metoprolol shows that metoprolol prevents the increase in heart rate caused by tesofensine in human volunteers.

A part of our strategy is to develop selected programs internally through the early phases of drug development in order to build further value into these programs before out-licensing to third parties. The largest value increase is often generated during or upon completion of Phase 2a clinical studies. We believe that we can create significant value in the above-mentioned programs. They have a very large market potential with sales of existing products in the single or double digit billion dollar range, they are addressing indications with significant unmet medical need and importantly, Saniona will subject to sufficient funding be able to complete Phase 2a clinical trials.

Despite the focus on the above three programs, we shall not forget Saniona’s platform and broad portfolio of other programs. Especially our collaboration with Ataxion, which was extended recently. Furthermore, although that Pfizer and Saniona recently have terminated their collaboration due to strategic decisions at Pfizer, we do see significant opportunities for developing this program with another partner. We are continuing working on business development activities in respect to various programs and we see good opportunities to enter into new agreements on our platform where we have several programs in early stages.

Therefore, we are convinced that Saniona has an exciting future.

I want to take this opportunity to thank all the shareholders and not least the guarantors and presubscribes who supported us in the last rights issue. Thank you."

Jørgen Drejer

CEO, Saniona AB

## 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 drug candidates at pre-clinical and clinical stage. The research is focused on ion channels. Saniona has ongoing collaboration agreements with Saniona's Boston based spinout Ataxion Inc., which is financed by Atlas Venture Inc. and Biogen Idec Inc. Saniona is based in Copenhagen, Denmark, where it has a research center of high international standard and 18 employees.

### Vision and objective

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

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

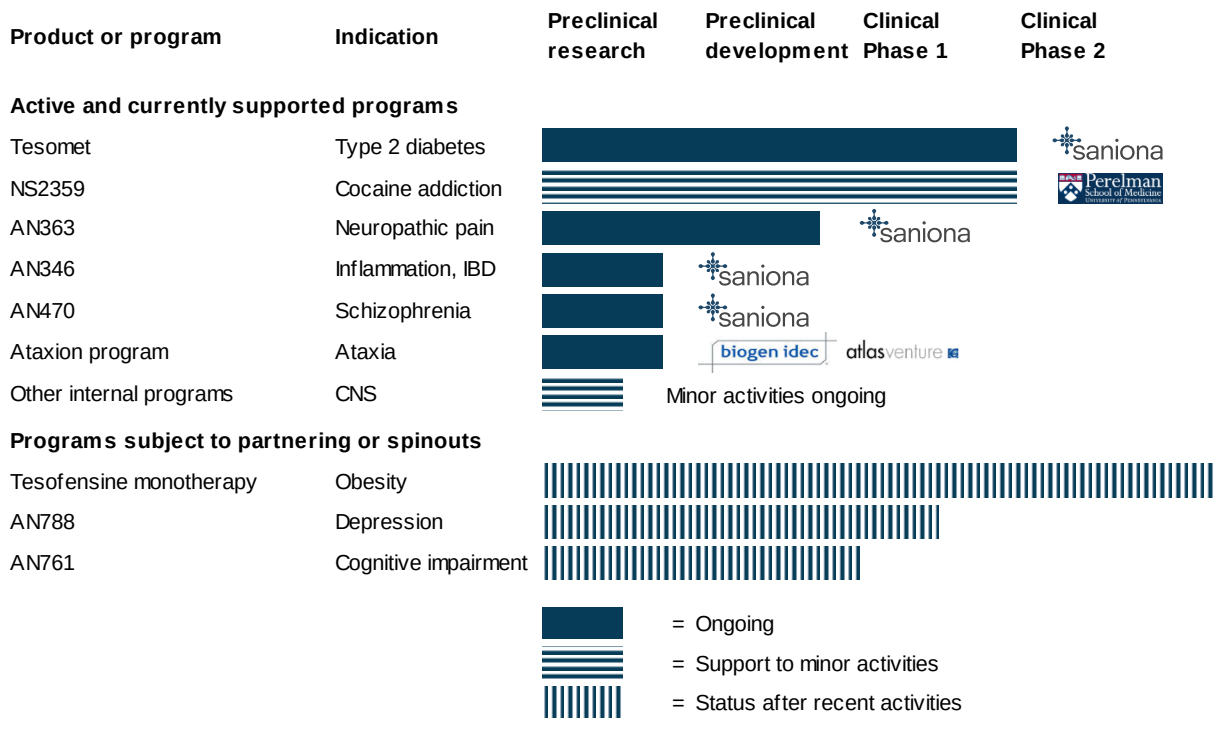
### Business model

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 has a significant portfolio of potential drug candidates at pre-clinical and clinical stage. The clinical stage programs include Tesomet, where the active ingredient tesofensine has demonstrated strong weight reducing effects in Phase 2 clinical studies in obese patients, and NS2359, which is a promising drug candidate for the treatment of cocaine dependence. The company is currently preparing a Phase 2a trial for Tesomet in type 2 diabetes and is allocating limited resources to prepare a potential Phase 2a trial for NS2359 in cocaine addiction in collaboration with the University of Pennsylvania's Treatment Research Center (TRC). Saniona currently has four active research programs. The company is developing three internal research programs and one research program in collaboration with Saniona's spin-out Ataxion Inc. Ataxion is financed by Atlas Venture Inc. and Biogen Inc. The company's project portfolio is set-out below.



## Market

Sanionas research is focused in the field of ion channels, which is an established concept in pharmaceutical development. According to a recent global strategic business report, the global market for ion channel-modulators is expected to exceed $21 billion in 2018[1].

Sanionas ongoing programs address significant market segments:

| Product | Indication | Market estimate |
|---|---|---|
| Tesomet | Type 2 diabetes | > USD 23 billion[2] |
| NS2359 | Cocaine addiction | > USD 1.8 billion[3] |
| AN363 | Neuropathic pain | > USD 6 billion[4] |
| AN470 | Schizophrenia | > USD4.8 billion[5] |
| AN346 | Inflammatory bowel disease | > USD 5.9 billion[6] |

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.

1 *http://www.prweb.com/releases/ion_channel_modulators/electrophysiology/prweb10579822.htm. Further details may be found in the annual report for 2014 page 6.*
2 *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*
3 *Estimates by TRC, University of Penn*
4 *Major markets 2012, Decision Resources*
5 *Schizophrenia Forecast 7 major market, Datamonitor, 2014*
6 *Major markets 2014, Datamonitor*

## Financial review

| | 2015-07-01<br>2015-09-30<br>3 months | 2014-07-01<br>2014-09-30<br>3 months | 2015-01-01<br>2015-09-30<br>9 months | 2014-01-01<br>2014-09-30<br>9 months | 2014-01-01<br>2014-12-31<br>12 months |
|---|---|---|---|---|---|
| Net sales, KSEK | 1,955 | 5,247 | 11,803 | 17,998 | 21,718 |
| Total operating expenses, KSEK | -12,812 | -7,569 | -34,550 | -20,014 | -29,977 |
| Operating profit/loss, KSEK | -10,857 | -2,322 | -22,748 | -2,016 | -8,258 |
| | | | | | |
| Cash flow from operating activities | -8,223 | -4,321 | -13,648 | -3,993 | -8,478 |
| Operating margin, % | -555 | -44 | -193 | -11 | -38 |
| Average number of employees, # | 16.6 | 15.4 | 16.6 | 14.3 | 14.8 |
| | | | 2015-09-30 | 2014-09-30 | 2014-12-31 |
| Cash and cash equivalent, KSEK | | | 12,456 | 14,170 | 9,689 |
| Equity, KSEK | | | 13,161 | 13,200 | 8,780 |
| Total equity and liabilities, KSEK | | | 26,401 | 20,606 | 15,461 |
| Equity ratio, % | | | 50 | 64 | 57 |

### Revenues and result of the operation

**Revenue**
Saniona generated total revenues of SEK 11,803,000 (17,998,000) for the first 9 months of 2015, a decrease of 34%. In 2015 revenues comprised primarily services under the agreement with Pfizer and Ataxion. In 2014 revenues comprised an upfront payment from Pfizer plus fees for services under the agreement with Pfizer and Ataxion.

**Operating profit/loss**
The company recognized an operating loss of SEK 22,748,000 (2,016,000) for the first 9 months of 2015. The development is primarily due to the decrease in revenues and an increase in external expenses, which amounted to SEK 21,146,000 (9,398,000), and in personnel costs, which amounted to SEK 11,042,000 (8,916,000). The increase in external expenses relates primarily to the preclinical development of the company's internal program, AN363, followed by external costs in relation to AN346 and Tesomet. The loss for the first 9 months of 2015 was SEK 18,156,000 (1,467,000). The company recognized a tax credit of SEK 5,066,000 (326,000) in the first 9 months of 2015 under the Danish R&D tax credit scheme (please see note 5).

**Financial position**
The equity/assets ratio was 50 (64) % as of September 30, 2015, and equity was SEK 13,161,000 (13,200,000). Cash and cash equivalents amounted to SEK 12,456,000 (14,170,000) as of September 30, 2015, an increase of SEK 2,767,000 from the beginning of the year. Total assets as of September 30, 2015, were SEK 26,401,000 (20,606,000). Saniona has raised approximately SEK 48.8 million in equity capital before issue expenses, amounting to around SEK 5.3 million, through a right issue in October 2015. The company expects to have sufficient capital to initiate and finance the planned Phase 2a study for Tesomet in 2016.

**Cash flow**
Operating cash flow for the first 9 months of 2015 was an outflow of SEK 13,648,000 (3,993,000). Consolidated cash flow for the first 9 months of 2015 was an inflow of SEK 2,831,000 (inflow 13,241,000). The positive inflow in 2015 is explained by the right issue in the first quarter this year and the positive inflow in 2014 by the initial public offering in the second quarter last year.

### The share, share capital and ownership structure
At September 30, 2015, the number of shares outstanding amounted to 17,352,750 (13,882,200). In February 2015, Saniona raised about SEK 24.3 million before finance cost through a right issue comprising 3,470,550 shares at SEK 7 per share. The company has established a warrant program on July 1, 2015, totaling 64,000 warrants.

At September 30, 2015 the company had 2,094 (791) shareholders, excluding holdings in life insurance and foreign custody account holders. The following shareholders own more than 5% of the number of shares in Saniona AB:

| Name | Number of shares | | Share of capital and votes | |
|---|---|---|---|---|
| | 2015-09-30 | 2014-09-30 | 2015-09-30 | 2014-09-30 |
| Jørgen Drejer | 2,329,571 | 2,301,000 | 13.4% | 16.6% |
| Thomas Feldthus | 1,822,857 | 1,801,000 | 10.5% | 13.0% |
| Försäkringsaktiebolaget, Avanza Pension | 1,244,493 | 570,000 | 7.2% | 4.1% |
| Other | 11,955,829 | 9,210,200 | 68.9% | 66.3% |
| Total | 17,352,750 | 13,882,200 | 100.0% | 100.0% |

## Personnel

As of June, the number of employees was 18 (18) of which 9 (9) are women. Of these employees, 3 (4) are part-time employees and 15 (14) are full-time employees, and a total of 16 (16) 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 5 (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.

A more detailed description of the Group's risk exposure and risk management is included in Saniona's 2014 Annual Report and in the prospectus published in September 2015. There are no major changes in the Group's risk exposure and risk management in 2015.

## Audit review

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

## Financial calendar

| | |
|---|---|
| Year-End Report | February 19, 2016 |
| Interim Report Q1 | May 10, 2016 |
| Annual General Meeting | May 10, 2016 |
| Interim Report Q2 | August 23, 2016 |
| Interim Report Q3 | November 15, 2016 |
| Year-End Report | February 21, 2017 |

Ballerup, November 19, 2015
Saniona AB

Claus Bræstrup – Chairman

Jørgen Drejer – CEO and board member

Anker Lundemose – Board member

Leif Andersson – Board member

Carl Johan Sundberg – Board member

# Financial statements

## Consolidated statement of comprehensive income – Group

| (KSEK) | 2015-07-01<br>2015-09-30<br>3 months | 2014-07-01<br>2014-09-30<br>3 months | 2015-01-01<br>2015-09-30<br>9 months | 2014-01-01<br>2014-09-30<br>9 months | 2014-01-01<br>2014-12-31<br>12 months |
|---|---|---|---|---|---|
| Net sales | 1,955 | 5,247 | 11,803 | 17,998 | 21,718 |
| Total operating income | 1,955 | 5,247 | 11,803 | 17,998 | 21,718 |
| Raw materials and consumables | -357 | -151 | -1,696 | -1,154 | -1,729 |
| Other external costs | -8,778 | -3,520 | -21,146 | -9,398 | -15,022 |
| Personnel costs | -3,448 | -3,661 | -11,042 | -8,916 | -12,465 |
| Depreciation and write-downs | -228 | -237 | -667 | -546 | -760 |
| Total operating expenses | -12,812 | -7,569 | -34,550 | -20,014 | -29,977 |
| **Operating profit/loss** | **-10,857** | **-2,322** | **-22,748** | **-2,016** | **-8,258** |
| Other financial income | 0 | 168 | 1 | 262 | 559 |
| Other financial expenses | 516 | -31 | -476 | -39 | -39 |
| Total financial items | 516 | 138 | -475 | 223 | 520 |
| **Profit/loss after financial items** | **-10,341** | **-2,184** | **-23,223** | **-1,793** | **-7,739** |
| Tax on net profit | 2,383 | 326 | 5,066 | 326 | 1,831 |
| **Profit/loss for the period** | **-7,959** | **-1,858** | **-18,156** | **-1,467** | **-5,908** |
| Other comprehensive income for the period | -73 | -22 | -117 | 15 | 37 |
| **Total comprehensive income for the period** | **-8,032** | **-1,880** | **-18,273** | **-1,452** | **-5,871** |
| Earnings per share, SEK | -0.46 | -0.13 | -1.05 | -0.11 | -0.43 |
| Diluted earnings per share, SEK | -0.46 | -0.13 | -1.04 | -0.11 | -0.43 |

## Consolidated statement of financial position – Group

| (KSEK) | 2015-09-30 | 2014-09-30 | 2014-12-31 |
|---|---|---|---|
| **ASSETS** | | | |
| Fixtures, fittings, tools and equipment | 873 | 1,201 | 1,273 |
| Tangible assets | 873 | 1,201 | 1,273 |
| Non-current tax assets | 5,098 | 0 | 0 |
| Other long-term receivables | 1,098 | 787 | 815 |
| Financial assets | 6,196 | 787 | 815 |
| **Non-current assets** | **7,069** | **1,987** | **2,088** |
| Trade receivables | 1,994 | 1,854 | 3 |
| Current tax assets | 1,800 | 1,471 | 1,893 |
| Other receivables | 2,050 | 1,093 | 1,205 |
| Prepayments and accrued income | 1,033 | 31 | 583 |
| Current receivables | 6,876 | 4,449 | 3,684 |
| Cash and cash equivalent | 12,456 | 14,170 | 9,689 |
| **Current assets** | **19,332** | **18,619** | **13,373** |
| **Total assets** | **26,401** | **20,606** | **15,461** |
| **EQUITY AND LIABILITIES** | | | |
| Share capital | 868 | 694 | 694 |
| Share premium account | 39,407 | 16,978 | 16,978 |
| Retained earnings | -8,860 | -2,952 | -2,952 |
| Currency translation reserve | -97 | -53 | -32 |
| Profit for the period | -18,156 | -1,467 | -5,908 |
| **Equity** | **13,161** | **13,200** | **8,780** |
| Prepayments from customers | 1,732 | 2,013 | 0 |
| Trade payables | 678 | 949 | 2,229 |
| Other payables | 9,400 | 4,443 | 2,962 |
| Accrued expenses and deferred income | 1,430 | 0 | 1,489 |
| Current liabilities | 13,240 | 7,406 | 6,681 |
| **Total liabilities** | **13,240** | **7,406** | **6,681** |
| **Total equity and liabilities** | **26,401** | **20,606** | **15,461** |
| **Pledged assets** | **0** | **247** | **256** |
| **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 |
|---|---|---|---|---|---|---|
| **December 31, 2014** | **13,882,200** | **694** | **16,978** | **-32** | **-8,860** | **8,780** |
| Total comprehensive income | | | | -117 | -18,156 | -18,273 |
| **Transactions with owners** | | | | | | |
| Shares issued for cash | 3,470,550 | 174 | 24,120 | | | 24,294 |
| Expenses related to capital increase | | | -1,692 | | | -1,692 |
| Share-based compensation expenses | | | | | 52 | 52 |
| **September 30, 2015** | **17,352,750** | **868** | **39,407** | **-149** | **-26,965** | **13,161** |
| | | | | | | |
| **December 31, 2013** | **10,000,000** | **120** | **0** | **-68** | **-2,952** | -2,901 |
| Total comprehensive income | | | | 15 | -1,467 | -1,452 |
| Transactions with owners | | | | | | |
| Shares issued for cash | 3,882,200 | 574 | 18,341 | | | 18,916 |
| Expenses related to capital increase | | | -1,363 | | | -1,363 |
| **September 30, 2014** | **13,882,200** | **694** | **16,978** | **-53** | **-4,419** | **13,200** |

## Consolidated statement of cash flows - Group

| (KSEK) | 2015-07-01 2015-09-30 3 months | 2014-07-01 2014-09-30 3 months | 2015-01-01 2015-09-30 9 months | 2014-01-01 2014-09-30 9 months | 2014-01-01 2014-12-31 12 months |
|---|---|---|---|---|---|
| Operating loss before financial items | -10,857 | -2,322 | -22,748 | -2,016 | -8,258 |
| Depreciation | 228 | 237 | 667 | 546 | 760 |
| Changes in working capital | 2,405 | -2,237 | 8,433 | -2,524 | -980 |
| **Cash flow from operating activities before financial items** | **-8,223** | **-4,321** | **-13,648** | **-3,993** | **-8,478** |
| Interest income received | 0 | 168 | 1 | 262 | 559 |
| Interest expenses paid | 516 | -31 | -476 | -39 | -39 |
| **Cash flow from operating activities** | **-7,708** | **-4,184** | **-14,123** | **-3,771** | **-7,958** |
| **Investing activities** | | | | | |
| Investment in tangible assets | -43 | -491 | -267 | -519 | -805 |
| Investment in other financial assets | -2,745 | 0 | -5,381 | -22 | -51 |
| **Cash flow from investing activities** | **-2,788** | **-491** | **-5,648** | **-541** | **-856** |
| **Financing activities** | | | | | |
| New share issue | 0 | 0 | 22,602 | 17,553 | 17,553 |
| **Cash flow from financing activities** | **0** | **0** | **22,602** | **17,553** | **17,553** |
| **Cash flow for the period** | **-10,495** | **-4,675** | **2,831** | **13,241** | **8,739** |
| **Cash and cash equivalents at beginning of period** | **22,973** | **18,867** | **61,982** | **37,879** | **914** |
| Exchange rate adjustments | -21 | -22 | -65 | 15 | 37 |
| **Cash and cash equivalents at end of period** | **12,456** | **14,170** | **64,749** | **51,135** | **9,689** |

## Statement of comprehensive income – Parent Company

| (KSEK) | 2015-07-01 2015-09-30 3 months | 2014-07-01 2014-09-30 3 months | 2015-01-01 2015-09-30 9 months | 2014-01-30 2014-09-30 8 months | 2014-01-01 2014-12-31 11 months |
|---|---|---|---|---|---|
| Total operating income | 0 | 0 | 0 | 0 | 0 |
| Other external costs | -729 | -77 | -1,272 | -327 | -576 |
| Personnel costs | -38 | 0 | -38 | 0 | 0 |
| Total operating expenses | -767 | -77 | -1,309 | -327 | -576 |
| **Operating profit/loss** | **-767** | **-77** | **-1,309** | **-327** | **-576** |
| Other financial income | 60 | 51 | 73 | 140 | 404 |
| Other financial expenses | 484 | -29 | -448 | -29 | -29 |
| Total financial items | 544 | 22 | -375 | 111 | 375 |
| **Profit/loss after financial items** | **-222** | **-55** | **-1,684** | **-217** | **-202** |
| Tax on net profit | 0 | 0 | 0 | 0 | 0 |
| **Profit/loss for the period** | **-222** | **-55** | **-1,684** | **-217** | **-202** |
| **Total comprehensive income for the period** | **-222** | **-55** | **-1,684** | **-217** | **-202** |

## Statement of financial position – Parent Company

| (KSEK) | 2015-06-30 | 2014-06-30 | 2014-12-31 |
|---|---|---|---|
| **ASSETS** | | | |
| Investment in subsidiaries | 11,832 | 524 | 11,832 |
| **Non-current assets** | **11,832** | **524** | **11,832** |
| Receivables from group companies | 8,633 | 0 | 0 |
| Other receivables | 1,007 | 385 | 570 |
| Prepayments and accrued income | 146 | 0 | 131 |
| Current receivables | 9,786 | 385 | 701 |
| Cash and cash equivalent | 15,725 | 17,248 | 8,742 |
| **Current assets** | **25,510** | **17,634** | **9,442** |
| **Total assets** | **37,342** | **18,158** | **21,274** |
| **EQUITY AND LIABILITIES** | | | |
| Share capital | 868 | 694 | 694 |
| Share premium account | 37,896 | 15,467 | 15,467 |
| Retained earnings | -202 | 0 | 0 |
| Profit for the period | -1,462 | -162 | -202 |
| **Equity** | **37,100** | **15,999** | **15,960** |
| Trade payables | 242 | 0 | 172 |
| Liabilities to companies in the Group | 0 | 2,158 | 5,142 |
| Current liabilities | 242 | 2,158 | 5,314 |
| **Total liabilities** | **242** | **2,158** | **5,314** |
| **Total equity and liabilities** | **37,342** | **18,158** | **21,274** |
| **Pledged assets** | **0** | **0** | **0** |
| **Contingent liabilities** | **50** | **286** | **297** |

## Statement of changes in equity – Parent Company

| | Number of shares | Share capital | Share premium | Translation reserves | Retained earnings | Shareholders' equity |
|---|---|---|---|---|---|---|
| **December 31, 2014** | **13,882,200** | **694** | **15,467** | **0** | **-202** | **15,960** |
| Total comprehensive income | | | | 0 | -1,684 | -1,684 |
| **Transactions with owners** | | | | | | |
| Shares issued for cash | 3,470,550 | 174 | 24,120 | | | 24,294 |
| Expenses related to capital increase | | | -1,692 | | | -1,692 |
| **September 30, 2015** | **17,352,750** | **868** | **37,896** | **0** | **-1,886** | **36,878** |
| | | | | | | |
| **January 30, 2014** | **10,482,200** | **524** | **0** | **0** | **0** | **524** |
| Total comprehensive income | | | | 0 | -217 | -217 |
| Transactions with owners | | | | | | |
| Shares issued for cash | 3,400,000 | 170 | 16,830 | | | 17,000 |
| Expenses related to capital increase | | | -1,363 | | | -1,363 |
| **September 30, 2014** | **13,882,200** | **694** | **15,467** | **0** | **-217** | **15,944** |

## Statement of cash flows – Parent Company

| (KSEK) | 2015-04-01<br>2015-06-30<br>3 months | 2014-04-01<br>2014-06-30<br>3 months | 2015-01-01<br>2015-06-30<br>6 months | 2014-01-30<br>2014-06-30<br>5 months | 2014-01-30<br>2014-12-31<br>11 months |
|---|---|---|---|---|---|
| Operating loss before financial items | -237 | -118 | -543 | -251 | -576 |
| Changes in working capital | -8,870 | 1,518 | -14,157 | 1,773 | 4,614 |
| **Cash flow from operating activities** | **-9,107** | **1,400** | **-14,700** | **1,523** | **4,038** |
| Interest income received | 13 | 92 | 13 | 89 | 404 |
| Interest expenses paid | -155 | 0 | -932 | 0 | -29 |
| **Cash flow from operating activities** | **-9,249** | **1,492** | **-15,619** | **1,611** | **4,412** |
| **Investing activities** | | | | | |
| Investments in subsidiaries | 0 | 0 | 0 | 0 | -11,307 |
| **Cash flow from investing activities** | **0** | **0** | **0** | **0** | **-11,307** |
| **Financing activities** | | | | | |
| New share issue | 0 | 15,637 | 22,602 | 15,637 | 15,637 |
| **Cash flow from financing activities** | **0** | **15,637** | **22,602** | **15,637** | **15,637** |
| **Cash flow for the period** | **-9,249** | **17,129** | **6,983** | **17,248** | **8,742** |
| **Cash and cash equivalents at beginning of period** | **24,974** | **120** | **8,742** | **0** | **0** |
| **Cash and cash equivalents at end of period** | **15,725** | **17,248** | **15,725** | **17,248** | **8,742** |

# 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 and headquartered 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 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 with the Annual Accounts Act, the Swedish Financial Reporting Board's recommendation RFR 1, Supplementary Accounting Rules for Groups, International Financial Reporting Standards (IFRS) and IFRIC interpretations 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 2014 apart from the changes made in the Interim Report for January – June 2015 in relation to the transition to IFRS. The new accounting principles under IFRS and the changes made to the Annual Report 2014 have been fully described in the Interim Report for January – June 2015. More detailed information about the Group's and the Parent Company's accounting and valuation principles can be found in the Interim Report for January – June 2015, which is available on www.saniona.com.

## Note 3: Share based payments

The 2015 Annual General Meeting voted in favor of establishing an employee incentive program involving the allotment of a maximum of 64,000 options free of charge to certain employees and consultants of the Group. Allotment of 64,000 employee options took place in July 2015.

Each employee option will entitle the holder to acquire one new share in Saniona for a subscription price of SEK 20.72 corresponding to 100% of the average closing price of the company's share during the ten trading days after the annual meeting 2015. Holders can take advantage of assigned and earned stock options during 30 days from the day following the publication of the company's quarterly reports, or in the case of full-year, full-year report, for the first time after publication of the quarterly report for the first quarter of 2018 and last time after publication of the quarterly report for the third quarter of 2019.

Assuming that all issued warrants are exercised for subscription of new shares, the Company's will issue a total of 64,000 new shares corresponding to a dilution of approximately 0.37%. The fair value of the options was determined to be SEK 13.13 per option using the Black-Scholes model. The data below has been used for the calculation.

| Employee incentive program | 2015 |
|---|---|
| Allotted options | 64,000 |
| Fair value per option (SEK) | 13.13 |
| Share price for underlying shares (SEK) | 19.90 |
| Subscription price (SEK) | 20.72 |
| Vesting period | 4 years |
| Estimated life of the option | 4.50 years |
| Risk-free interest rate during the life of the option | 0.2257% |
| Assumed volatility | 91.29% |
| Expected dividends | 0 |
| Personnel costs in 2015 covering the last 2 quarters (SEK thousand) | 105 |

Share-based compensation expenses for the first nine months of 2015 totaled SEK 52.5 (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.

## Note 4 Financial risk

| | 2015-09-30 | | 2014-09-30 | |
|---|---|---|---|---|
| SEK '000 | Fair value | Carrying amount | Fair value | Carrying amount |
| Financial assets | | | | |
| Investment in unlisted life science companies | - | - | - | - |
| Loans and receivables | | | | |
| Trade receivables | 1,994 | 1,994 | 1,854 | 1,854 |
| Other receivables | 2,050 | 2,050 | 1,093 | 1,093 |
| Financial assets and investments at fair value through the income statement | 4,044 | 4,044 | 2,947 | 2,947 |
| Financial liabilities | | | | |
| *Other financial liabilities* | | | | |
| Trade payables | 678 | 678 | 949 | 949 |
| Other payables | 9,400 | 9,400 | 4,443 | 4,443 |
| Financial liabilities, measured at amortized cost through the income statement | 10,078 | 10,078 | 5,393 | 5,393 |

The Group owns 14% of the share capital of Saniona's spin-out Ataxion. Ataxion was formed by Saniona, Atlas Ventures 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 Inc. and Atlas Ventures. 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.

There has been no fair value adjustment of the financial assets in 2014 and 2015.

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. This was also the case in 2014 and 2015.

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.

## 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 year and in other comprehensive income or equity to the extent that it relates thereto.

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 2015 the R&D expense tax-base is capped to DKK 25 million equal to a tax credit of DKK 5.875 million at a tax rate of 23.5%. In 2014 the maximum amount was DKK 25 million equal to a tax credit of DKK 6.25 million at a tax rate of 25%. 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.

## Note 6 Subsequent Events to the Balance Sheet Date

Cash and cash equivalents amounted to SEK 12.5 million (14.2 million) as of September 30, 2015. Saniona closed a right issue on October 12, 2015. Saniona raised approximately SEK 48.8 million in equity capital before issue expenses, amounting to around SEK 5.3 million, of which SEK 2.3 million constitute guarantee fees. Following this transaction, the company expects to have sufficient capital to initiate and finance the planned Phase 2a study for Tesomet in 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 behavioral issues. Gradually, body functions are lost, ultimately leading to death. The cause for most Alzheimer's cases is still mostly unknown except for 1% to 5% of cases where genetic differences have been identified. Several competing hypotheses exist trying to explain the cause of the disease.

**AN363**
A small molecule which is designed to positively modulate (PAM) GABA α2 and GABA α3 ion channels, which are expressed in various central and peripheral neurons and are believed to be key mediator in the control of pain signaling and the control of anxiety.

**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 α5 channels. GABA 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.

**AN788**
An 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.

**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.

**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.

**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.

**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.

**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 pains 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.

## Financial glossary

**Earnings per share**
Profit/loss for the period divided by the average number of shares outstanding at the end of 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 at the end of the period

**Operating margin**
EBIT as a proportion of revenue

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