

YEAR-END REPORT FOR SANIONA AB (PUBL) 556962-5345 January - December 2017 <u>Published F</u>ebruary 21, 2018



# THE PHASE 3 TRIAL FOR TESOFENSINE IS SCHEDULED TO BE COMPLETED IN 2018

# **Financial highlights**

# Jan - Dec 2017 (Jan - Dec 2016)

- Net revenues were SEK 20.7 M (74.9 M)
- EBIT was SEK -57.2 M (4.2 M)
- Net profit/loss was SEK -49.2 M (2.2 M)
- Earnings per share were SEK -2.30 (0.11)
- Diluted earnings per share were SEK -2.30 (0.11)

# Q4 2017 (Q4 2016)

- Net revenues were SEK 4.6 M (5.4 M)
- EBIT was SEK -16.6 M (-15.0 M)
- Net profit/loss was SEK -14.8 M (-12.5 M)
- Earnings per share were SEK -0.68 (-0.60)
- Diluted earnings per share were SEK -0.68 (-0.60)

# **Business highlights in Q4 2017**

- Saniona establish equity financing of up to SEK 144 million, sufficient to fund planned activities until 2020
- Saniona decides to perform interim analysis of the Phase 2a study for Tesomet in adult patients with Prader-Willi syndrome
- Saniona selects preclinical candidate in GABAA α2/α3 program for neuropathic pain and chronic itching
- Saniona receives third and final milestone payment under the USD 590,700 (about SEK 5.2 M) grant from the Michael J. Fox Foundation for Parkinson's Research
- Saniona partner and spin-out company Cadent Therapeutics receives milestone from Novartis
- Saniona spin-out, Scandion Oncology, raises DKK 2 million and prepares for a potential public listing

# Significant events after the reporting period

- Saniona reports topline results from the Tesomet Phase 2a interim study in Prader-Willi syndrome, indicating clinical meaningful reduction in weight and hyperphagia
- Saniona's partner, Medix, completes recruitment of Phase 3 obesity study (272 patients) of tesofensine in Mexico
- The extraordinary shareholders' meeting resolved to elect J. Donald deBethizy and Anna Ljung as new ordinary board members and to elect J. Donald deBethizy as new chairman of the board of directors
- Saniona initiates and completes recruitment of the 60 volunteers in Phase 1 study with new Tesomet tablet
- Saniona and Proximagen extend research collaboration

# **Comments from the CEO**

"We achieved encouraging and insightful results in our Phase 2 study in adult patients with Prader-Willi syndrome in 2017 with our lead candidate, Tesomet. The results support further study of Tesomet in Prader-Willi syndrome," 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 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 Boehringer Ingelheim GmbH, Proximagen Ltd., Productos Medix, S.A de S.V and Cadent Therapeutics Inc. Saniona is based in Copenhagen, Denmark, where it has a research center of high international standard. Saniona is listed at Nasdaq Stockholm Small Cap and has about 5,300 shareholders. The company's share is traded under the ticker SANION. Read more at <u>www.saniona.com</u>.



# Letter from the CEO

"As I reflect on the past year, I see many successes that have helped form Saniona into a strong biotech company that is well positioned to continue its development for years to come. But there is one milestone more significant than the others – it is the fact that during this year we can start to call ourselves a Phase 3-company. Our partner Medix is now taking the lead on our programs within the metabolic field as they have made remarkable progress in the Phase 3 trial for tesofensine in Mexico with both the completion of recruitment of all 372 patients in just five short months and the expectation to conclude the trial by the end of 2018, nearly one year ahead of schedule. We are confident that this study will serve to further validate tesofensine as a novel and highly effective treatment for obesity. Not only will it add to our already robust efficacy and safety database; it also holds the potential to provide Saniona with a significant double-digit royalty stream in both Mexico and Argentina, which may be used to fund the development of our wholly owned programs including Tesomet.

I would like to highlight a few other clinical and operational successes that we have made this past year in addition to Medix's rapid progress. Clinically, we are very proud of our positive Phase 2 trial and are excited by our selection of two new development candidates under our research programs. On the operational side, our uplisting to the main market of Nasdaq Stockholm, appointment of two new Board members and solid financing will all help to support our future initiatives. Additionally, our acquisition of NeuroSearch's remaining rights of certain preclinical and clinical programs reinforces our confidence in the potential of our assets. As we move into 2018 we intend to unlock the potential of these achievements as we eagerly await the results for the Phase 3 tesofensine trial as well as continue the clinical development of Tesomet for metabolic indications and eating disorders.

Bringing the focus now onto our lead asset, Tesomet, which led 2017 with a positive Phase 2 trial that demonstrated a statistically significant reduction in weight in type 2 diabetic patients with no increase in heart rate. Tesomet appears to be a cardiovascular neutral and highly effective weight loss drug with a benign safety profile for the treatment of metabolic diseases, which represent one of the largest healthcare challenges worldwide.

Within eating disorders, we initiated an explorative Phase 2a study in adult patients with Prader-Willi syndrome (PWS) in 2017. After having completed nine adult patients in autumn, we decided to perform a full analysis before the potential continuation of the study in adolescent patients. The full analysis revealed both encouraging and insightful data that Tesomet can potentially provide a statistically meaningful reduction in hyperphagia and weight at a lower dose in this difficult patient group, which has no treatment option today. As we confer with experts in the field to determine our next steps, we believe that by pursuing an orphan indication such as PWS we are creating a unique opportunity to develop and bring our own product to the market in the U.S. and Europe.

Taking a look at our first-in-class research programs, which may appear to be in their infancy, we are confident that they will add significant long-term value for Saniona as these programs enter the clinic. All of our partnered research programs with Boehringer Ingelheim, Proximagen, Cadent Therapeutics and the Michael J. Fox Foundation have progressed well so far, and we look forward to providing more tangible results from these efforts over the coming year. We are also pleased to make the same claim for our spin-out companies, with the public listing of Initiator Pharma, the seed financing of Scandion Oncology and the recent Novartis milestone payment to Cadent Therapeutics.

In 2017 we significantly increased the upside on tesofensine, Tesomet and NS2359 by acquiring NeuroSearch's remaining interest in them, specifically because we believe these assets hold immense value for the future of the company. To help guide this future, we would like to welcome J. Donald deBethizy and Anna Ljung to our board of directors. Both appointments represent our continued efforts to attract highly talented individuals to Saniona as we develop our later stage programs into potential commercialization opportunities.

As we begin to execute on our initiatives for 2018, we are optimistic that we will be able to continue to build on our past successes and grow the company further. Looking back, I think we can be very proud of the achievements made. I am grateful for all the efforts made by our team, shareholders and partners. As a young company we have just started to unlock the opportunities of our assets. Therefore, looking forward, we have the most exciting part of our journey ahead of us."

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 preclinical and clinical stage. The research is focused on ion channels. Saniona has ongoing collaboration agreements with Boehringer Ingelheim GmbH, Proximagen Ltd., Productos Medix, S.A de S.V and Cadent Therapeutics 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.

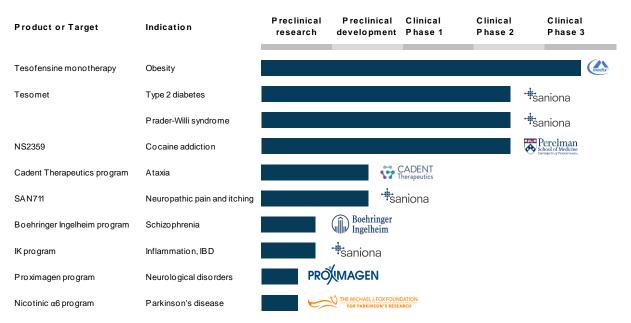
# **Business model**

The company commercializes its research efforts through the following three 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 six 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 positioned for partnering or spin-out.



# Market

Saniona's ongoing programs address significant market segments:

Target/Program	Indication	Market estimate
Tesomet	Type 2 diabetes	> USD 23 billion <sup>1</sup>
Tesomet	Prader-Willi syndrome	- Orphan indication
Tesofensine	Obesity	- USD 250 million in Mexico <sup>2</sup>
NS2359	Cocaine addiction	> USD 1.8 billion <sup>3</sup>
SAN711	Neuropathic pain	> USD 6 billion <sup>4</sup>
Boehringer Ingelheim program	Schizophrenia	> USD 4.8 billion <sup>5</sup>
IK program	Inflammatory bowel disease	> USD 5.9 billion <sup>6</sup>
Nic-α6 program	Parkinson's disease	> USD 2.8 billion <sup>7</sup>
Proximagen program	Neurological diseases	- Not available
Cadent Therapeutics program	Ataxia	- Orphan indication

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

There is a significant need for new and innovative products for the pharmaceutical companies, which often have a limited number of products in their pipelines. Therefore, the market for out-licensing of new, innovative pharmaceutical projects and product programs are considered attractive. Importantly, within the field of ion channels, there are relatively few biotech companies supplying major pharmaceutical companies with research and development projects. Combined, this is creating interesting opportunities for Saniona.

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

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

<sup>&</sup>lt;sup>3</sup> Estimates by TRC

<sup>&</sup>lt;sup>4</sup> Major markets 2012, Decision Resources

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

<sup>&</sup>lt;sup>6</sup> Major markets 2014, Datamonitor

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



# **Financial review**

# Financial key figures

<i>y</i> 0		2017-10-01	2016-10-01	2017-01-01	2016-01-01
		2017-12-31	2016-12-31	2017-12-31	2016-12-31
Net sales, KSEK		4,621	5,411	20,692	74,921
Total operating expenses, KSEK		-21,219	-20,439	-77,881	-70,764
Operating profit/loss, KSEK	*	-16,598	-15,028	-57,189	4,156
Operating margin, %	*	-359%	-278%	-276%	6%
Cash flow from operating activities		-17,482	-9,918	-57,339	7,953
Cash flow per share, SEK	*	-0.79	-0.51	-1.41	0.32
Earnings per share, SEK		-0.68	-0.60	-2.30	0.11
Diluted earnings per share, SEK		-0.68	-0.60	-2.30	0.11
Average shares outstanding		21,762,520	20,841,467	21,416,810	20,841,467
Diluted average shares outstanding		21,864,812	20,905,467	21,519,102	20,905,467
Average number of employees, #		24.7	21.7	24.1	19.7
				2017-12-31	2016-12-31
Cash and cash equivalent, KSEK				22,313	53,261
Equity, KSEK				37,628	54,252
Total equity and liabilities, KSEK				48,375	70,769
Liquidity ratio, %	*			377%	412%
Equity ratio, %	*			78%	77%
Equity per share, SEK	*			1.76	2.60

\* = Alternative performance measures

# Definitions and relevance of alternative performance measures

Saniona presents certain financial measures in the year-end report that are not defined according to IFRS, so called alternative performance measures. These have been noted with an "\*" in the table above. The company considers that these measures provide valuable supplementary information for investors and company management as they enable an assessment of relevant trends of the company's performance. These financial measures should not be regarded as substitutes for measures defined per IFRS. Since not all companies calculate financial measures in the same way, these are not always comparable to measures used by other companies. The definition and relevance of key figures not calculated according to IFRS are set-out in the table below.

Key figure	Definition	Relevance
Operating profit/loss	Profit/loss before financial items and tax.	The operating profit/loss is used to measure the profit/loss generated by the operating activities.
Operating margin	Operating profit/loss as a proportion of revenue.	The operating margin shows the proportion of revenue that remains as profit before financial items and taxes, and has been included to allow investors to get an impression of the company's profitability.
Liquidity ratio	Current assets divided by current liabilities.	Liquidity ratio has been included to show the Company's short-term payment ability.
Equity ratio	Shareholders' equity as a proportion of total assets.	The equity ratio shows the proportion of total assets covered by equity and provides an indication of the company's financial stability and ability to survive in the long term.
Average number of employees	Average number of employees employed during the period.	This key figure may explain part of the development in personnel expenses and has been included to provide an impression of how the number of employees at the company has developed.
Equity per share	Equity divided by the number of outstanding shares at the end of the period.	Equity per share has been included to provide investors with information about the equity reported in the balance sheet as represented by one share.
Cash flow per share	Cash flow for the period divided by number of shares for the period.	Cash flow per share has been included to provide investors with information about the cash flow represented by one share during the period.



37,628

1.76

21,416,810

54,252

2.60

20,841,467

#### Derivation of alternative performance measurers

	2017-10-01	2016-10-01	2017-01-01	2016-01-01
	2017-12-31	2016-12-31	2017-12-31	2016-12-31
Operation profit/loss, KSEK	-16,598	-15,028	-57,189	4,156
Net sales, KSEK	4,621	5,411	20,692	74,921
Operating margin, %	-359%	-278%	-276%	6%
Cash flow for the period, KSEK	-17,267	-10,665	-30,134	6,735
Number of shares	21,762,520	20,841,467	21,416,810	20,841,467
Cash flow per share, SEK	-0.79	-0.51	-1.41	0.32
			2017-12-31	2016-12-31
Current assets, KSEK			40,569	68,066
Current assets, KSEK Current liabilities, KSEK			40,569 10,747	,
			,	68,066 16,517 <b>412%</b>
Current liabilities, KSEK			10,747	16,517
Current liabilities, KSEK Liquidity ratio, %			10,747 <b>377%</b>	16,517 <b>412%</b>

# Equity, KSEK Number of shares Equity per share, SEK

#### Revenues and result of the operation

#### Revenue

Total revenues during the fourth quarter of 2017 was SEK 4.6 million (5.4). In 2017 revenues comprised research funding under the agreements with Boehringer Ingelheim and Proximagen whereas in the fourth quarter of 2016 revenues comprised research funding under the agreement with Boehringer Ingelheim, Proximagen and Cadent Therapeutics.

Saniona generated total revenues of SEK 20.7 million (74.9) for the full year of 2017. In 2017 revenues comprised research funding under the agreement with Boehringer Ingelheim, Proximagen and Cadent Therapeutics. In 2016 revenues comprised upfront payments from Boehringer Ingelheim, Medix and Proximagen totalling SEK 60.4 million whereas the balance of SEK 14.5 million comprised research funding under the agreements with Boehringer Ingelheim, Proximagen and Cadent Therapeutics.

#### **Operating profit/loss**

The operating loss for the fourth quarter was SEK 16.6 million (15.0).

The company recognized operating expenses of SEK 21.2 million (20.4) for the fourth quarter of 2017.

External expenses amounted to SEK 13.7 million (14.7). In the fourth quarter of 2017, external expenses comprised primarily research and development costs in relation to Tesomet followed research and development costs in relation to the IK program and the GABAA  $\alpha 2\alpha 3$  program. In the fourth quarter of 2016, external expenses comprised primarily research and development costs in relation to Tesomet followed by costs in relation to the listings on Nasdaq and research and development costs in relation to the IK Program and the GABAA  $\alpha 2\alpha 3$  program. Personnel costs amounted to SEK 6.3 million (5.0). The increase is in personal costs is in part explained by the increase in the average employee employed.

The company recognized an operating loss of SEK 57.2 million (profit 4.2) for the full year of 2017. The company recognized operating expenses of SEK 77.9 million (70.8) for the full year of 2017. External expenses amounted to SEK 51.4 million (51.1) and personnel costs amounted to SEK 22.7 million (17.8). In 2017, external expenses comprised primarily research and development costs in relation to Tesomet followed by research and development costs in relation to Tesomet followed by research and development costs in relation to Tesomet followed by research and development costs in relation to the IK program and the GABAA  $\alpha 2\alpha 3$  program and costs in relation to the listing on Nasdaq Stockholm Small Cap. In 2016, external expenses comprised primarily research and development



costs in relation to Tesomet followed by costs in relation to the listing on Nasdaq Stockholm Small Cap and research and development costs in relation to the IK program and the GABAA α2α3 program.

#### Cash flow

Operating cash flow for the fourth quarter of 2017 was an outflow of SEK 17.7 million (9.6). Consolidated cash flow for the fourth quarter of 2017 was an outflow of SEK 17.3 million (10.7).

Operating cash flow for the full year of 2017 was an outflow of SEK 56.6 million (inflow of 7.2). Consolidated cash flow for the full year of 2017 was an outflow of SEK 30.1 million (inflow of 6.7).

The consolidated cash flow in 2017 is explained by an inflow from the private placement in the second quarter of 2017 of SEK 33.2 million after finance expenses and an outflow from the one-time payment to NeuroSearch for the remaining rights in Saniona's preclinical and clinical assets (see note 10) and the operating loss during the period. The consolidated inflow in 2016 is explained by the operating income during the period.

#### **Financial position**

The equity ratio was 78 (77) % as of December 31, 2017, and equity was SEK 37.6 million (54.3). Cash and cash equivalents amounted to SEK 22.3 million (53.3) as of December 31, 2017. Total assets as of December 31, 2017, were SEK 48.4 million (70.8).

Saniona entered into a convertible notes funding agreement with Nice & Green S.A on December 29, 2017. Under the terms of the agreement, Nice & Green has committed to subscribe up to SEK 72 million in convertible notes in individual tranches of SEK 6 million each over a 12-month period subject to prolongation by Saniona. Saniona has the right to extend the convertible notes funding agreement with Nice & Green for an additional SEK 72 million with the same terms, totalling SEK 144 million over a two-year period. If Saniona were to extend the agreement for an additional 12-month period and utilize the program in full, Saniona may have sufficient financing to fund the planned activities until 2020 excluding potential financing from upfront and milestone payments under existing and potential future collaboration agreements.

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

At December 31, 2017, the number of shares outstanding amounted to 21,762,520 (20,841,467). The company established a warrant program on July 1, 2015, totalling 64,000 warrants, and on July 1, 2017, totalling 38,750 warrants. At December 31, 2017, the company had 5,195 (4,491) shareholders excluding holdings in life insurance and foreign custody account holders.

#### Personnel

As of December 31, 2017, the number of employees was 26 (26) of which 14 (14) are women. Of these employees, 3 (8) are part-time employees and 23 (18) are full-time employees, and a total of 21 (21) work in the company's research and development operations. 12 (12) of Saniona's employees hold PhDs, 3 (4) hold university degrees, 8 (7) have laboratory training and the remaining 3 (3) have other degrees.

#### **Operational risks and uncertainties**

All business operations involve risk. Managed risk-taking is necessary to maintain good profitability. Risk may be due to events in the external environment and may affect a certain industry or market. Risk may also be specific to a certain company. The main risks and uncertainties which Saniona is exposed to are related to drug development, the company's collaboration agreements, competition, technology development, patent, regulatory requirements, capital requirements and currencies.

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

Currency risks is the risk that the fair value of future cash flows fluctuate because of changed exchange rates. Exposure to currency risk is primarily sourced from payment flows in foreign currency and from the translation of balance sheet items in foreign currency, as well as upon the translation of foreign subsidiaries' income statements and balance sheets to the Group's reporting currency, which is SEK.

A more detailed description of the Group's risk exposure and risk management is included in Saniona's 2016 Annual Report. There are no major changes in the Group's risk exposure and risk management in 2017.

#### **Audit review**

This year-end report has not been subject to review by the company's auditors.



# **Financial calendar**

Interim Report Q1	May 24, 2018
Annual General Meeting	May 24, 2018
Interim Report Q2	August 22, 2018
Interim Report Q3	November 14, 2018
Year-End Report 2018	February 21, 2019

#### **Annual General Meeting 2018**

Saniona's Annual General Meeting will be held at Setterwalls Advokatbyrå AB's office at Stortorget 23, Malmö, Sweden on May 24, 2018 at 4 pm CET.

The Board of Directors proposes that no dividend will be paid for the 2017 financial year.

The Annual Report for 2017 will be published on www.saniona.com no later than May 3, 2018. It will also be available at Saniona's head office at Baltorpvej 154, 2750 Ballerup, Denmark.

Shareholders who wish to have a matter addressed at the Annual General Meeting should, to ensure that the proposal may be considered, send such proposal to the Board of Directors no later than April 5, 2018. The Board of Directors can be contacted by email to tf@saniona.com marked "Annual General Meeting" or through regular mail to: Saniona AB, Att.: Thomas Feldthus, Baltorpvej 154, DK-2750 Ballerup, Denmark.

The Nomination Committee's member are: Søren Skjærbæk, Partner at Saxo lawyers, Vejle, Denmark, appointed by Jørgen Drejer; John Haurum, CEO of F-star Biotechnology Limited, Cambridge, UK, appointed by Thomas Feldthus; and Claus Bræstrup, Chairman of Saniona AB's Board of Directors.

Shareholders who would like to submit proposals to the Nomination Committee can do so via e-mail to tf@saniona.com marked "Recommendation to the Nomination Committee" or by ordinary mail to the address: Saniona AB, Att. Thomas Feldthus, Baltorpvej 157, DK-2750 Ballerup, Denmark.

The Board of Directors and the CEO of Saniona AB (publ) provide their assurance that the year-end report provides a fair and true overview of the Parent Company's and the Group's operations, financial position and results, and describes material risks and uncertainties faced by the parent Company and the companies in the Group.

Ballerup, February 21, 2018 Saniona AB

J. Donald deBethizy - Chairman

Jørgen Drejer – CEO and board member

Claus Bræstrup – Board member

Anna Ljung - Board member

Carl Johan Sundberg - Board member

Leif Andersson - Board member



# Condensed consolidated statement of comprehensive income - Group

KSEK		2017-10-01	2016-10-01	2017-01-01	2016-01-01
	Note	2017-12-31	2016-12-31	2017-12-31	2016-12-31
	1-3				
Net sales	4	4,621	5,411	20,692	74,921
Total operating income		4,621	5,411	20,692	74,921
Raw materials and consumables		-1,071	-631	-3,263	-1,476
Other external costs		-13,712	-14,675	-51,387	-51,098
Personnel costs	5	-6,277	-5,021	-22,671	-17,805
Depreciation and write-downs		-157	-112	-561	-384
Total operating expenses		-21,219	-20,439	-77,881	-70,764
Operating profit/loss		-16,598	-15,028	-57,189	4,156
Other financial income		1,289	-218	1,289	991
Other financial expenses		564	-89	-376	-234
Total financial items		1,853	-307	914	757
Profit/loss after financial items		-14,745	-15,335	-56,275	4,913
Tax on net profit	6	-14	2,859	7,086	-2,696
Profit/loss for the period		-14,758	-12,476	-49,190	2,217
Other comprehensive income					
Item that may be reclassified to profit and loss		-	-	-	-
Translation differences		-1,076	178	-968	-715
Total other comprehensive income net after tax		-1.076	178	-968	-715
Total comprehensive income		-15,835	-12,298	-50,157	1,501
Earnings per share, SEK		-0.68	-0.60	-2.30	0.11
Diluted earnings per share, SEK		-0.68	-0.60	-2.30	0.11

The recognized loss and total comprehensive income are all attributable to the shareholders of the Parent Company, since there is no non-controlling interest in the subsidiaries of the Group.



# Condensed consolidated statement of financial position - Group

KSEK	Note	2017-12-31	2016-12-31
	1-3		
ASSETS			
Fixtures, fittings, tools and equipment		1,366	1,184
Tangible assets		1,366	1,18
5		.,000	.,
Investments in associated companies	9	331	
Other long-term receivables	10	6,019	1,41
Deferred tax		89	10
Financial assets		6,439	1,519
Non-current assets	_	7,806	2,703
Trade receivables		7,180	12,26
Current tax assets	6	7,276	
Other receivables	10	3,261	1,88
Prepayments and accrued income		540	66
Current receivables		18,256	14,80
Cash and cash equivalent		22,313	53,26
Current assets		40,569	68,06
Total assets		48,375	70,76
EQUITY AND LIABILITIES			
Share capital		1,088	1,04
Additional paid in capital		116,452	83,32
Retained earnings		-29,321	-31,89
Currency translation reserve		-1,402	-43
Profit/loss for the period		-49,190	2,21
Equity		37,628	54,25
Prepayments from customers		604	3,00
Trade payables		5,209	6,22
Current tax liabilities		0	1,60
Other payables		511	43
Accrued expenses and deferred income		4,423	5,25
Current liabilities		10,747	16,51
Total liabilities		10,747	16,51
Total equity and liabilities		48,375	70,76



# Condensed consolidated statement of changes in equity - Group

	Number of shares	Share capital	Additional paid in capital	Translation reserves	Retained earnings	Share- holders' equity
January 1, 2016	20,841,467	1,042	83,323	282	-31,704	52,943
Comprehensive income						
Profit/loss for the year					2,217	2,217
Other comprehensive income:						
Translation differences				-715		-715
Total comprehensive income				-715	2,217	1,501
Transactions with owners Share-based compensation						
expenses					211	211
Dividends paid					-403	-403
Total transactions with owners	0	0	0	0	-192	-192
December 31, 2016	20,841,467	1,042	83,323	-434	-29,680	54,252
January 1, 2017	20,841,467	1,042	83,323	-434	-29,680	54,252
Comprehensive income						
Profit/loss for the year					-49,190	-49,190
Other comprehensive income:						
Translation differences				-968		-968
Total comprehensive income				-968	-49,190	-50,157
Transactions with owners						
Shares issued for cash	921,053	46	34,954			35,000
Expenses related to capital increase			-1,825			-1,825
Share-based compensation			,			,
expenses					359	359
Total transactions with owners	921,053	46	33,129	0	359	33,534
December 31, 2017	21,762,520	1,088	116,452	-1,402	-78,511	37,628



# Condensed consolidated statement of cash flows - Group

		2017 10 01	2016 10 01	2017-01-01	2016 01 01
KSEK		2017-10-01	2016-10-01		2016-01-01
	Note	2017-12-31	2016-12-31	2017-12-31	2016-12-31
Operating loss before financial items		-16,598	-15,028	-57,189	4,156
Adjustments for non-cash transactions		284	112	918	384
Other provisions		0	0	0	0
Changes in working capital		-1,387	5,304	-347	2,656
Cash flow from operating activities before financial items		-17,701	-9,611	-56,617	7,196
Interest income received		1,289	-218	1,289	991
Interest expenses paid		564	-89	-376	-234
Tax paid		-1,635	0	-1,635	0
Cash flow from operating activities		-17,482	-9,918	-57,339	7,953
Investing activities					
Investment in tangible assets		-43	-502	-708	-816
Investments in subsidiaries/associated companies		0	403	-331	0
Investment in other financial assets		258	-245	-4,931	0
Cash flow from investing activities		215	-344	-5,970	-816
Financing activities					
New share issue		0	0	33,175	0
Dividends paid		0	-403	0	-403
Cash flow from financing activities		0	-403	33,175	-403
Cash flow for the period		-17,267	-10,665	-30,134	6,735
Cash and cash equivalents at beginning of period		40,869	63,695	53,261	47,004
Exchange rate adjustments		-1,288	231	-815	-477
Cash and cash equivalents at end of period		22,313	53,261	22,313	53,261



# Statement of income – Parent Company

KSEK		2017-10-01	2016-10-01	2017-01-01	2016-01-01
	Note	2017-12-31	2016-12-31	2017-12-31	2016-12-31
	1-3				
Net sales		0	0	0	0
Total operating income		0	0	0	0
Raw materials and consumables		-4	-3	-20	-3
Other external costs		-1,529	-2,119	-7,218	-6,758
Personnel costs		-322	-289	-1,249	-1,033
Total operating expenses		-1,854	-2,410	-8,487	-7,794
Operating profit/loss		-1,854	-2,410	-8,487	-7,794
Other financial income		343	225	1,085	749
Other financial expenses		-50	-47	-259	-298
Total financial items		293	178	826	450
Profit/loss after financial items		-1,561	-2,232	-7,660	-7,344
Tax on net profit		0	0	0	0
Profit/loss		-1,561	-2,232	-7,660	-7,344



# **Balance Sheet – Parent Company**

KSEK	Note	2017-12-31	2016-12-31
ASSETS			
Investment in subsidiaries		11,832	11,832
Investments in associated companies		331	0
Financial assets		12,162	11,832
Non-current assets		12,162	11,832
Receivables from group companies		69,062	45,076
Other receivables		122	437
Prepayments and accrued income		95	270
Current receivables		69,279	45,783
Cash and cash equivalent		17,120	15,355
Current assets		86,399	61,138
Total assets		98,561	72,969
EQUITY AND LIABILITIES			
Restricted equity			
Share capital		1,088	1,042
Unrestricted equity			
Additional paid in capital		114,941	81,812
Retained earnings		-10,318	-2,975
Profit for the period		-7,660	-7,344
Equity		98,050	72,535
Other payables		511	434
Current liabilities		511	434
Total liabilities		511	434
Total equity and liabilities		98,561	72,969



# Notes

# **Note 1 General Information**

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

# Note 2 Significant accounting policies

The year-end report has been prepared in accordance with IAS 34 Interim reporting. The Group applies the International Financial Reporting Standards (IFRS) and interpretations of IFRS IC as adopted by the EU, the Annual Accounts Act and the Financial Reporting Board's recommendation RFR 1, Supplementary Accounting Rules for Groups.

The condensed consolidated financial statements have been prepared under the historical cost convention, except in the case of certain financial assets and liabilities, which are measured at fair value. The condensed consolidated financial statements are presented in Swedish kronor (SEK) which is also the functional currency of the Parent Company.

The applied accounting principles are in accordance with those described in the Annual Report for 2016. More detailed information about the Group's and the Parent Company's accounting and valuation principles can be found in the Annual Report for 2016, which is available on www.saniona.com. New and amended standards and interpretations implemented as of January 1, 2017, 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.

# Effects of new accounting policies

#### **IFRS 9 Financial Instruments**

This is a new standard for financial instruments that will replace IAS 39. The standard came into effect on January 1, 2018. The new standard will not have any material impact on the classifications and valuations of the Group's financial statements since the Group has had no derived financial instruments and do not expect to achieve losses on trade receivables as well the company's cash position at bank accounts as of December 31, 2017.

# IFRS 15 Revenue from Contracts with Customers

The standard came into effect on January 1, 2018. The standard will replace all earlier released standards and interpretations related to revenue recognition. The standard regulates revenue recognitions and disclosure requirements relating to all contracts with customers. The commercial agreements that Saniona enters often includes the delivery of services that is divided up into separate identifiable performance obligations that are recognised when each performance obligation is satisfied. Unlike the previous standards on revenue recognition IFRS 15 provides much more specific guidance on how these and other revenue recognition issues should be evaluated. The initial assessment is that IFRS 15 will not have any material impact on the financial statements since the company has recognised revenues based on industry practise and interpretation similar to the principles now described in IFRS 15.

# **IFRS 16 Leasing**

The new standard will be applied as of January 1, 2019. Saniona has commenced preparations for transition to the new standard on January 1, 2019 and intends to implement system support to comply with the new requirements. Apart from rental agreements in relation to the company's premises, the company has no other lease commitments as of December 31, 2017. Therefore, the initial assessment is that the new standard will only impact the financial statements insofar as rental contracts for premises. This means that Saniona is required to recognize all leases as a lease asset and a lease liability in the balance sheet.

# Note 3 Financial assets and liabilities

All financial asset and financial liabilities, except for the investment in Cadent Therapeutics 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 2016 and 2017.



The Group owns 7% of the share capital of Cadent Therapeutics. Cadent Therapeutics merged in March 2017 with Ataxion, which 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. The merged company Cadent Therapeutics is today developing the Ataxia-program. 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 Cadent Therapeutics is sold or public listed or the project has been finalized and the necessary regulatory final approval of the product has been obtained. Accordingly, the value of Cadent Therapeutics is measured at costs since the fair value cannot be determined reliable.

# Note 4 Segment reporting

The Group is managed as a single business unit. The basis for identifying reportable segments is the internal reporting as reported to and followed up by the highest executive decision maker. The Group has identified the highest executive decision maker as the CEO. The internal management and reporting structure comprises only one business unit, and the Group therefore has only one operating segment, for which reason no segment information is provided.

# Note 5: Share based payments

Share-based compensation expenses for the full year of 2017 totalled SEK 359 (211) 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.

	Options granted in 2015	Options granted in 2017	Total
Share-based payment			
Outstanding at 1 January 2017	64,000	-	64,000
Granted during the period	-	38,750	38,750
Forfeited during the period	-	- 458	- 458
Outstanding at 31 December 2017	64,000	38,292	102,292

If all issued warrants are exercised for subscription of new shares, the Parent Company's will issue a total of 102,292 new shares corresponding to a dilution of approximately 0.47%. The fair value of the options was determined to be SEK 13.13 per option for the 2015 program and SEK 29.48 per option for the 2017 using the Black-Scholes model. The data below has been used for the calculation.

Employee incentive program	2015	2017
Allotted options	64,000	38,750
Fair value per option (SEK)	13.13	29.48
Share price for underlying shares (SEK)	19.90	45.50
Subscription price (SEK)	20.72	41.13
Vesting period	4 years	4 years
Estimated life of the option	4.50 years	5.50 years
Risk-free interest rate during the life of the option	0.2257%	-0.0584%
Assumed volatility*	91.29%	76.75%
Expected dividends	0	0

\* The volatility equals the historical volatility for the longest period where trading activity is available (for the period since listing at AktieTorget on April 22, 2014 to date of grant).

Option granted in 2015 entitle the holder to acquire one new share in Saniona for a subscription price of SEK 20.72. The options are earned gradually over a period of 48 months. Holders can take advantage of assigned and earned stock options during 30 days from the day following the publication of the Group's quarterly reports, or in the case of full-year, full-year report, for the first time after publication of the quarterly report for the first quarter of 2018 and last time after publication of the quarter of 2019. A more detailed description can be found in the annual report for 2016.



Allotment of 38,750 options took place in July 2017. Option granted in 2017 entitle the holder to acquire one new share in Saniona for a subscription price of SEK 41.13. The options are earned gradually over a period of 48 months. Holders can take advantage of assigned and earned stock options during 30 days from the day following the publication of the Group's quarterly reports, or in the case of full-year, full-year report, for the first time after publication of the quarterly report for the first quarter of 2021 and last time after publication of the quarterly report for the first quarter of 2021 and last time after publication of the quarterly report for the first quarter of 2021 and last time after publication of the quarterly report for the first quarter of 2021 and last time after publication of the quarterly report for the first quarter of 2021 and last time after publication of the quarterly report for the first quarter of 2021 and last time after publication of the quarterly report for the first quarter of 2021 and last time after publication of the quarterly report for the first quarter of 2021 and last time after publication of the quarterly report for the third quarter of 2022.

#### Note 6 Income tax and deferred tax subsidiaries in Denmark

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

The Group recognized a tax income of KSEK 7,086 (-2,696) during the full year of 2017. This amount has been recognized under non-current tax assets in accordance to the accounting policies described below.

Under the Danish R&D tax credit scheme (Skattekreditordningen), loss-making R&D entities can obtain a tax credit which is equal to the tax value of the incurred research and development expenses. The tax credit is payable in November in the following financial year. In 2016 and 2017, the R&D expense tax-base is capped to DKK 25 million equal to a tax credit of DKK 5.5 million at a tax rate of 22%. Research and development tax-credits under the Danish R&D tax credit scheme is recognized in the income statement to the extent that it relates to the research and development expenses for the period and Saniona expects to fulfil the requirement for tax credit for the year. The tax credit under the Danish R&D tax credit scheme is recognized in the balance sheet under current tax assets if payable within 12 months and under non-current tax assets if payable after 12 months. As of December 31, 2017, the Group had no non-current tax asset and KSEK 7,276 in current tax asset, which will be payable in November 2018. As of December 31, 2016, the Group had no tax asset.

#### Note 7 Pledged assets and contingent liabilities

The Group has provided a guarantee of KSEK 50 (50) to Euroclear. The Parent Company has provided a guarantee to the subsidiary Saniona A/S to ensure that Saniona A/S will be able to pay its creditors as the obligations fall due for the period until June 30, 2019. Saniona A/S had no external net debt as of December 31, 2017.

# **Note 8 Related parties**

Related parties comprise the Group's Executive Management, Board of Directors and companies within the Group. Apart from intercompany transaction and board fees as well as remuneration of management in accordance to the remuneration policy as resolved at the annual general meeting, there has been no transaction with related parties during 2016 and 2017.

#### Note 9 Investment in Scandion Oncology

On May 3, 2017, Saniona participated in formation of a new company, Scandion Oncology A/S. The investment of KSEK 331 has been recorded in the Saniona AB's and the Groups balance sheet under Investment in associated companies. In December, Saniona announced that Scandion Oncology has raised DKK 2 million in a private placement. As of December 31, 2017, Saniona AB owns 47.3% of Scandion Oncology A/S. The remaining 52.7% of the shares are owned by the three co-founders of Scandion Oncology A/S and a group of investors participating in the private placement. Saniona Group has no further obligations toward Scandion Oncology A/S. The financial statements of Scandion Oncology A/S have not been subject to consolidation in the Group. The reason is that the purchase price of KSEK 331 as well as the financial statements of Scandion Oncology was considered as non-material for the financial statements and financial position of Saniona. As of December 31, 2017, Saniona does not have controlling interest in Scandion Oncology.

#### Note 10 NeuroSearch

On July 4, 2017, Saniona acquired NeuroSearch's remaining interest in the preclinical and clinical assets, which Saniona acquired from NeuroSearch during the period 2012-2016. According to the previous agreements, Saniona was obliged to pay NeuroSearch a milestone payment of EUR 400,000 when the first preclinical program was tested in humans. In addition, Saniona was obliged to pay royalties on its product sales or a percentage of its licensing income in relation to the acquired clinical assets including the clinical development compounds, tesofensine and NS2359. According to the new agreement, Saniona has paid NeuroSearch a onetime cash payment of DKK 5.5 million. Following this, Saniona has no additional payment obligations to NeuroSearch. Saniona estimates that the onetime cash payment of DKK 5.5 million would have been payable to NeuroSearch with a four-year period under the previous agreements. Therefore, the amount will be expensed over a four-year period starting July 1, 2017.



# **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.

#### 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.

#### **Atlas Venture**

Atlas Venture Inc.

# CNS

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

# **Cocaine addiction**

The compulsive craving for use of cocaine despite adverse consequences.

# СТА

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

# GABAA α2α3 program

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

# EMA

**European Medicines Agency** 

# FDA

US Food and Drug Administration

# IK program

A small molecule program which is designed to block (antagonize) IK channels, which are expressed by immune cells and believed to be key mediator of inflammation in auto inflammatory diseases such as inflammatory bowel disease, multiple sclerosis and Alzheimer's' disease.



# IND

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

#### Ion channel

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

#### Ion channel modulators

A drug which modulates the function of ion channels by blocking or opening ion channels or by decreasing or increasing throughput of ion channels. Agonists opens ion channels, Antagonists blocks ion channels, PAMs (Positive Allosteric Modulators) increase throughput whereas NAMs (Negative Allosteric Modulators) decrease throughput of ion channels.

#### Major Depressive Disorders

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

#### Medix

Productos Medix, S.A de S.V.

#### **Multiple sclerosis**

A demyelinating disease in which the insulating covers of nerve cells in the brain and spinal cord are damaged by the immune system. This damage disrupts the ability of parts of the nervous system to communicate, resulting in a wide range of signs and symptoms including physical, mental, and sometimes psychiatric problems.

#### **Neuropathic pain**

Pain caused by damage or disease affecting the somatosensory nervous system. Central neuropathic pain is found in spinal cord injury, multiple sclerosis, and some strokes. Aside from diabetes (diabetic neuropathy) and other metabolic conditions, the common causes of painful peripheral neuropathies are herpes zoster infection, HIV-related neuropathies, nutritional deficiencies, toxins, remote manifestations of malignancies, immune mediated disorders and physical trauma to a nerve trunk. Neuropathic pain is also common in cancer as a direct result of cancer on peripheral nerves (*e.g.*, compression by a tumour), or as a side effect of chemotherapy, radiation injury or surgery. Neuropathic pain is often chronic and very difficult to manage with some 40-60% of people achieving only partial relief.

#### NS2359

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

#### Proximagen

Proximagen Ltd. is wholly-owned by the Evenstad family's holding company, ACOVA.

#### **SAN711**

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

#### Schizophrenia

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



# Tesofensine

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

#### TRC

The University of Pennsylvania Treatment Research Center.

#### Type 2 diabetes

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

This information is such information as Saniona AB (publ) is obliged to make public pursuant to the Swedish Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out on the front page above, at 08:00 CET on February 21, 2018.

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