# ANNUAL REPORT 2018



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#### **KEY FIGURES**

KSEK	2018	2017
Net sales	54,884	20,692
Operating expenses	-109,089	-77,881
Operating profit/loss*	-54,206	-57,189
Financial items, net	5,913	914
Profit/loss before tax	-48,292	-56,275
Tax on net profit	7,233	7,086
Profit/loss for the year	-41,059	-49,190
Non-current assets	12,407	7,806
Current receivables	15,990	18,256
Cash and cash equivalent	54,678	22,313
Total assets	83,075	48,375
Equity	39,457	37,628
Current liabilities	43,617	10,747
Total equity and liabilities	83,075	48,375
Cash flow from operating activities	-22,920	-57,339
Cash flow for the year	24,738	-30,134
	0040	0017
	2018	2017
Operating margin, %*	Negative	Negative
Equity ratio, %*	47%	78%
Dividend, SEK	0.00	0.00

\* Financial measures marked with \* are not defined under IFRS, so called alternative performance measures. The definition and rationale for presenting can be found in note 31 to the financial statements.

### 2018 in brief

#### SIGNIFICANT EVENTS IN 2018

#### Final step towards commercialization as Medix prepares regulatory filings following successful Phase 3 registration trial

In 2017, Saniona became a Phase 3 company as its partner Productos Medix S.A. (Medix) initiated a Phase 3 trial in Mexico with tesofensine for treatment of obesity.

In December 2018, Medix successfully reported positive top line data from this registration trial. Medix is now preparing to apply for a new drug application in Mexico in 2019 and expects to launch the product in 2020.

Tesofensine will be the first program from Saniona's product portfolio to reach the market. Saniona is entitled to double digit royalties on net sales of tesofensine in Mexico and Argentina. Saniona retains the commercial rights in the rest of world.

### Tesomet obtains proof-of-concept in Prader-Willi syndrome and dose finding is ongoing

Saniona is developing Tesomet, its proprietary fixeddose combination of tesofensine and metoprolol, for two rare eating disorders, Prader-Willi syndrome (PWS) and hypothalamic obesity (HO).

In January 2018, Saniona reported top line results from a Phase 2a clinical study for Tesomet in adult PWS patients. The results showed that Tesomet (tesofensine 0.5 mg + metoprolol 50 mg daily) may provide clinically meaningful weight loss and a significant reduction in hyperphagia in adult patients. The study also revealed that the clearance of tesofensine is slower in the PWS patient group than in the general population, and that the optimal dose in PWS therefore may be a quarter to half the dose used in other indications such as obesity and hypothalamic obesity.

Based on the proof of concept obtained in the first part of our Phase 2a study in adult PWS patients, Saniona initiated a dose-finding Phase 2a study of Tesomet in adolescent patients who initially received Tesomet at a quarter of the tesofensine dose (tesofensine 0.125 mg + metoprolol 25 mg daily). The treatment was well tolerated, and the study confirmed that the halflife of tesofensine in the adolescent patient population is very long as also seen in the adult patient population. The study also revealed that a 0.125 mg daily dose does not result in therapeutically meaningful plasma levels of tesofensine. Saniona has consequently doubled the dose to 0.25 mg daily in an open-label extension of the study. The objective is to obtain a similar plasma level of tesofensine in PWS patients as obtained in previous Phase 2 and Phase 3 studies in obese patients where tesofensine has proven to be well tolerated and highly effective in controlling appetite and reducing weight.

### Phase 2a proof of concept study for treatment of hypothalamic obesity initiated

In parallel with PWS, Saniona initiated in March 2019 a Phase 2a proof of concept study for Tesomet in hypothalamic obesity (HO). This study will include up to 25 patients, who will receive treatment or placebo for 24 weeks followed by an open-label extension in which all patients will receive Tesomet for 24 weeks. We expect to complete the double-blind part of the study in Q4 2019. The objective is to prepare Tesomet for pivotal Phase 2b/3 studies in at least one of the two indications, PWS and HO, during 2019 and start these studies in 2020.

#### Early stage pipeline is moving rapidly into the clinic

The long-term value of Saniona's unique technology platform is demonstrated by an increasing number of programs that enter the clinic. In 2018, Cadent Therapeutics initiated a Phase 1 study for CAD-1883 and a Phase 2a study for treatment of essential tremor. CAD-1883 is the first program from our ion channel research portfolio to enter clinical development. However, three more programs may enter clinical development within the next two years. Saniona successfully completed preclinical development for SAN711, and the compound is now ready for Phase 1 clinical studies for treatment of neuropathic pain and itching. Saniona's partner Boehringer Ingelheim GmbH selected a clinical candidate for treatment of schizophrenia and is now preparing the program for Phase 1 studies. Finally, Saniona's IK program for treatment of Inflammatory bowel disease (IBD), specifically of Crohn's disease and ulcerative colitis, is in the final candidate selection stage following which Saniona will perform IND enabling studies for the start of Phase 1.

#### **Reinforcing the Board of Directors**

In January 2018, Saniona's shareholders elected Anna Ljung and J. Donald deBethizy to the Board of Directors following the recommendation of the Nomination Committee. Anna Ljung currently serves as the CFO of Moberg Pharma where she prepared the company for its initial public offering in 2011. J. Donald deBethizy, who replaced Claus Bræstrup as Chairman of the Board, has more than 30 years of experience in research and development and financial, business and operational management in the biotech and consumer products industry. Both appointments reflect Saniona's continued efforts to attract highly talented and experienced individuals to the company as it develops its later stage programs into potential commercialization opportunities.

### Saniona at a glance

#### VISION AND OBJECTIVE

Saniona aims to be a leading biotech company focusing on treatment of diseases of the central nervous system and eating disorders. Saniona's overall objective is to develop - both in-house and together with partners - new treatments that address significant unmet medical needs. Strategically, the company intends to develop and commercialize treatments for orphan indications on its own and engage in partnerships with larger pharmaceutical companies for development programs aiming at treating large indications such as obesity.

#### **OVERVIEW**

Saniona has five programs in clinical development including three late stage clinical programs focused on the development of treatments to effectively regulate obsessions, cravings and addictions related to food and drugs. In total, the company has a portfolio of nine active drug programs in clinical and pre-clinical development stages, of which four are financed through partnerships or grants.

#### **Clinical programs**

Saniona's most advanced program is tesofensine, which is being developed for obesity in collaboration with Medix. Medix has completed a Phase 3 registration trial for tesofensine in December 2018 and expects to file a new drug application in 2019 for treatment of obesity in Mexico with potential market approval and launch in 2020. Medix holds an exclusive license to commercialize tesofensine in Mexico and Argentina, while Saniona is entitled to milestone payments and royalties on product sales. Saniona retains commercial rights in the rest of the world and rights to use any data generated in the Phase 3 trial.

Tesomet is Saniona's most advanced internal program and is being developed for the treatment of eating disorders. Saniona is currently conducting a dose-finding Phase 2a study in PWS and a Phase 2a proofof-concept study in HO. The objective is to prepare Tesomet for pivotal Phase 2b/3 studies in at least one of the two indications, and start pivotal studies in 2020.

The University of Pennsylvania Treatment Research Center (TRC) is conducting an investigator-initiated Phase 2a proof-ofconcept study with NS2359 for the treatment of cocaine addiction. The study is financed through grants and Saniona retains commercial rights to the compound and the clinical data developed by TRC.

Saniona's partner Cadent Therapeutics has initiated a Phase 2a study for the treatment of essential tremor and expects to start another Phase 2a study in the second half of 2019 for the treatment of Ataxia. Saniona holds an ownership stake in Cadent and will receive royalties on CAD-1883 if it reaches the market.

In February 2019, Saniona completed the preclinical development of SAN711 for the treatment of chronic itching and neuropathic pain. The program is ready for Phase 1 clinical testing either internally or together with a potential partner.

#### **Research programs**

Saniona's early stage pipeline is based on its ion channel platform with well-established targets for drug discovery. Ion channels comprise a unique class of proteins, which, among other things, controls the activity of muscles and nerves and is central to numerous other functions in the body.

Saniona currently has four pre-clinical programs of which one program is financed by its partner Boehringer Ingelheim. Boehringer Ingelheim is currently conducting a preclinical development program in preparation for Phase 1 studies in schizophrenia. Saniona's three internal research programs, which are targeting the IK, Kv7 and Nicotinic α6 ion channels, are focused on the treatment of inflammatory diseases and certain neurological diseases including epilepsy and Parkinson's diseases.

These pre-clinical programs hold immense long-term potential for Saniona while we work to bring our later stage programs to commercialization.

### Market

Saniona's ongoing programs address significant market segments:

Target/Program	Indication	Market estimate
Tesomet	Prader-Willi syndrome Hypothalamic obesity	<ul> <li>Orphan indication &gt; USD 1 billion<sup>1</sup></li> <li>Orphan indication &gt; USD 1 billion<sup>2</sup></li> </ul>
Tesofensine	Obesity	- USD 250 million in Mexico <sup>3</sup>
NS2359	Cocaine addiction	> USD 1.8 billion <sup>4</sup>
SAN711	Neuropathic pain	> USD 6 billion <sup>5</sup>
Boehringer Ingelheim program	Schizophrenia	> USD 4.8 billion <sup>6</sup>
IK program	Inflammatory bowel disease	> USD 5.9 billion <sup>7</sup>
Nic-a6 program	Parkinson's disease	> USD 2.8 billion <sup>8</sup>
Kv7 program	Pain, epilepsy, Urinary	> USD 6 billion <sup>5</sup>
	Incontinence	
Cadent Therapeutic program	Ataxia	- Orphan indication
	Essential tremor	

Apart from orphan indications such as Prader-Willi syndrome and hypothalamic obesity, where Saniona may develop and commercialize Tesomet on its own, Saniona will aim to partner with major pharmaceutical companies for purchasing, developing and commercializing projects from Saniona's pipeline of preclinical and clinical drug candidates.

The pharmaceutical industry is in great need of new and innovative products. For innovative companies such as Saniona this creates an attractive opportunity for out-licensing cutting-edge programs. Importantly, there are relatively few biotech companies within the field of ion channels that can offer major pharmaceutical companies valuable research and development projects. In combination, this should provide Saniona with substantial business opportunities.

1 Financial analysts estimate that there is 20 - 30,000 PWS patients in the US and Europe collectively and that the obtainable average price level is USD 60,000 – 150,000 per patient per year, Nordea Markets, Redeye, Jarl Securities, Leerink, JMP Securities, Canaccord Genuity, SunTrust Robinson Humphrey

2 Financial analysts estimate that the market for hypothalamic obesity is 30-50% of the market for PWS due to fewer patients, see above 3 Estimates of drugs for obesity in Mexico by Medix 2016

4 Estimates by TRC 5 Major markets 2012, Decision Resources

6 Schizophrenia Forecast 7 major market, Datamonitor, 2014 7 Major markets 2014, Datamonitor

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

### Letter from the CEO

Annual results are a natural time to take stock on the events of the past year, and on the many successes that underpin the development of Saniona as a biotech company focused on the treatment of diseases of the central nervous system and eating disorders. We are developing and commercializing treatments for orphan indications such as Prader-Willi syndrome and hypothalamic obesity, and are rapidly advancing programs based on our ion channel technology platform, which can also address larger indications. Our aim is to be as capital-efficient as possible - retaining ownership of orphan disease programs, while seeking partnerships for larger disease areas.

A particular highlight of the year is that our partner Medix successfully completed a Phase 3 registration trial for tesofensine in obesity. The results are deeply impressive: 10% average weight loss in 24 weeks, more than half of patients losing more than 10% in weight, and a statistically significant reduction in key obesity-related risk factors. Medix, which owns commercial rights in Mexico and Argentina, will now prepare regulatory filings in those countries, which we expect to be filed in H1 2019 with launch in 2020. As Saniona holds all rights to these data and all other commercial rights to tesofensine in the rest of the world, we believe this program has significant upside.

Seven out of 10 Mexicans are categorized as overweight or obese, more than twice the worldwide average, and eight in 10 deaths are caused by chronic, non-communicable diseases that to a large degree are linked to the overweight and obese population. This trial provides validation of tesofensine as a potentially highly efficacious treatment for obesity and may bring a significant double-digit royalty stream in both Mexico and Argentina to help fund our broad pipeline.

#### **TESOMET DEVELOPMENT**

The strong Phase 3 results also support development of Saniona's wholly-owned Tesomet, a fix-dosed combination of tesofensine and metoprolol in Phase 2 for rare eating disorders. From this and previous studies, we know that the product reduces appetite and provides a significant and clinically meaningful weight loss. We have obtained proof of concept in the first part of our Phase 2a study of Tesomet in PWS, key opinion leaders strongly support further development, and we are now working to establish the optimal dose. PWS is a significant commercial opportunity, with 20,000 patients in the US and Europe combined, short time to market and potential premium pricing as an orphan drug.

Data showed the clearance of tesofensine is much slower in this patient group than in the general population, and that PWS patients consequently should be given a lower dose to obtain the same blood concentration and effect as seen in normal obese patients. Therefore, in the second part of the study in adolescent PWS patients we initially gave a conservative dose, a quarter of that given to adult PWS patients during the first part of the study. Since this did not result in the required plasma concentration, we are now continuing at a double dose in this dose optimization study (equivalent to half of that given to adult PWS patients).

Based on the strong efficacy on both hyperphagia and weight seen in the first part of the study in adult PWS patients, and the successful Phase 3 trial of tesofensine, the active ingredient in Tesomet, we are confident that Tesomet holds the potential of treating debilitating hyperphagia and significantly reduce weight in this severely underserved population.

#### PHASE 2A IN HYPOTHALAMIC OBESITY (HO)

In parallel with PWS, we are exploring the potential for Tesomet in HO and have initiated a Phase 2a study in March 2019. This study will include up to 25 patients, who will receive treatment or placebo for 24 weeks followed by an open-label extension, where all patients will receive Tesomet for 24 weeks. We expect to complete the double-blind part of the study in Q4 2019.

The two rare eating disorders, PWS and HO, have several factors in common, including clinical symptoms, clinical trial design, regulatory advantages from potential orphan drug designation and premium pricing as well as fast time to market due to relatively short and small clinical studies. There are no valid data about prevalence in HO, which most often occurs following surgical removal of craniopharyngioma, a benign brain tumor, with a reported prevalence of 1/50,000. The number of patients is probably half those with PWS, since not all patients with craniopharyngioma develop hyperphagia and associated obesity, but this is still an interesting market due to potential premium pricing under orphan drug status.

The objective is to prepare Tesomet for pivotal Phase 2b/3 studies in at least one of the two indications, PWS and HO, during 2019 and start such pivotal studies in 2020.

We have also completed two Phase 1 studies and an additional preclinical toxicology study for Tesomet. The results from these trials, together with the long-term toxicology studies, provide more flexibility in designing clinical studies (extension of ongoing PWS study and 6-12 months studies in HO) and pave the way for pivotal Phase 2b/3 trials.

#### PROGRESS IN EARLY PIPELINE

The early-stage pipeline is progressing rapidly into the clinic and our partnerships are proving fruitful, both in the long- and short-term, providing important non-dilutive funding for our own programs.

SAN711, a new and potentially gamechanging treatment of neuropathic pain and itching, which comes from our advanced ion channel platform, has successfully completed preclinical development. Preparations for Phase 1 clinical trials are underway and may start during summer 2019, either internally or together with a potential partner. Preclinical data for SAN711 are very compelling and we believe it has the potential to become a firstline treatment in patients suffering from severe untreatable itching conditions and neuropathic pain disorders. There is a significant unmet medical need and a significant commercial opportunity in rare itching disorders for which we may potentially pursue accelerated development, for example in Brachioradial pruritus.

We received a €4 million milestone payment from Boehringer Ingelheim following selection of a clinical candidate for schizophrenia, bringing the total Saniona has received from this agreement to €9 million. Boehringer Ingelheim is conducting IND-enabling studies to initiate clinical studies. Cadent Therapeutics raised \$40 million to support the development of their lead compound, CAD-1883, which comes from a collaboration with Saniona. Cadent initiated a Phase 1 study in Q1 2018, have already started a Phase 2a



study for in essential tremor, and expects to start another Phase 2a study for Ataxia in H2 2020. Saniona holds an ownership stake in Cadent of 3.4% and will receive royalties on CAD-1883 if it reaches the market.

The IK program has also made significant progress during the year and we hope to soon be able to present a clinical candidate for IND enabling studies. This is a new concept in inflammatory and autoimmune diseases and we have strong data in models for Crohn's disease and ulcerative colitis, the indications in which we are most likely to develop it in collaboration with a partner. The concept may also be developed for rare diseases, potentially internally. Overall, we believe it represents an important asset for Saniona.

Finally, we have been granted SEK 1.4 million by the Danish Innovation Fund (DIF) for the development of our Kv-7 program, which could lead to a potential new treatment within urinary incontinence, pain and epilepsy, including rare types of epilepsy where there is a genetic link to Kv-7 channels and where there are currently no good treatment options.

As you can see from the above, Saniona is developing rapidly. We are at the cusp of the approval of our first major product – tesofensine, and moving a large number of promising products through value inflection points. I am deeply grateful for the efforts and commitment of our team, shareholders and partners who are supporting our efforts. This year has been a very exciting one, and I am very much looking forward to continuing our journey through 2019 and beyond.

Jørgen Drejer, CEO

### **Strategy and business model**

Saniona has a broad product pipeline, which is developed both internally and in collaboration with pharmaceutical companies.

We are developing products internally with the aim of attaining market approval ourselves in the U.S. and Europe for certain orphan indications where the required investments are limited, and the commercial opportunities can be highly attractive. For example, Saniona is currently developing Tesomet for Prader-Willi syndrome and Hypothalamic Obesity in the U.S. and Europe. The required investments for developing Tesomet in these indications are comparatively small, while the required commercial infrastructure for servicing these patients in the U.S. and Europe is manageable.

In addition to this, Saniona has entered into and will engage in research collaborations with pharmaceutical companies or is developing products internally with the aim of entering into a collaboration with a pharmaceutical company at a later stage. The structure of Saniona's collaboration agreements depends on the product, the indication, the investment and the risk, as well as the interest and capabilities of Saniona's partners. Saniona can either grant its partners commercial license to a limited territory or globally. In exchange, the partners typically finance future research and development activities and pay Saniona upfront payments, research funding, milestone payments and royalties on product sales when the product candidates are commercialized.

Saniona's short term strategic priorities are set-out below:

- To develop and attain market approval for Tesomet in the U.S. and Europe in orphan indications by ourselves
- To develop Tesomet in rest of the world through partnerships with pharmaceutical companies for metabolic diseases
- To attain market approval for tesofensine in collaboration with Medix in Mexico and Argentina
- To develop at least one drug candidate internally from our unique ion channel research platform
- To leverage our leading position within ion channel research in partnership with pharmaceutical companies



#### DEVELOPING AND ATTAINING MARKET APPROVAL FOR TESOMET INTERNALLY IN EUROPE AND THE U.S. IN ORPHAN INDICATIONS

Saniona's most advanced internal program is Tesomet. Saniona believes that due to Tesomet's mode of action, it has tremendous potential for the treatment of obsessive eating disorders such as Prader-Willi Syndrome, hypothalamic obesity and binge eating.

Saniona is currently conducting Phase 2a studies to explore the possibility for developing Tesomet for two orphan indications, Prader-Willi syndrome and hypothalamic obesity.

The clinical pathway for the development of Tesomet in eating disorders appears to be faster and less expensive than in metabolic indications in the U.S. and Europe. By pursuing orphan indications such as Prader-Willi syndrome and hypothalamic obesity, we are creating a unique opportunity to develop and bring our own product to the market in the U.S. and Europe.

#### DEVELOPING TESOMET IN THE REST OF THE WORLD THROUGH PARTNERSHIPS WITH PHARMACEUTICAL COMPANIES FOR METABOLIC DISEASES

Tesomet may potentially also be used for the treatment of large pandemic metabolic diseases such as obesity, type 2 diabetes and fatty liver diseases (NASH). For these indications Saniona would partner with pharmaceutical companies, since the required clinical Phase 3 studies tend to be very large, expensive, and long. This is particularly the case in the U.S. and Europe. Initially, Saniona expects to partner for these indications in countries outside the U.S. and Europe.

There is a substantial medical need for effective and safe weight loss products in countries outside the U.S. and Europe, as obesity becomes an increasing global problem. The cost of developing Tesomet for metabolic diseases is often lower in countries outside the U.S. and Europe as large long-term cardiovascular clinical trials typically would not be required for market approval. In these countries, Saniona may out-license the Tesomet program for limited territories.

#### ATTAINING MARKET APPROVAL FOR TESOFENSINE IN COLLABORATION WITH MEDIX IN MEXICO AND ARGENTINA

In December 2018, Saniona's partner Medix completed a Phase 3 registration clinical trial for tesofensine in obesity. Medix expects to file a new drug application in 2019 in Mexico, with potential market approval and launch in 2020.

Medix has an exclusive license to commercialize tesofensine in Mexico and Argentina, and Saniona is entitled to receive double digit royalties on product sales. Saniona retains all rights to tesofensine including the exclusive rights to use the clinical data developed my Medix in the rest of the world.

#### DEVELOPING AT LEAST ONE DRUG CANDIDATE INTERNALLY FROM OUR UNIQUE ION CHANNEL RESEARCH PLATFORM

Saniona intends to develop selected drug candidates internally with the aim of adding value to these programs before out-licensing to third parties. In the short term, it is Saniona's objective to develop at least one drug candidate internally to achieve proofof-concept in a Phase 2 study, and then to out-license the program to a major pharmaceutical company for further development.

Saniona expects to receive upfront payments upon out-licensing of its internally developed programs to partners following completion of Phase 2 clinical studies. In addition to this, Saniona expects to receive clinical milestone payments and royalties on product sales when the product candidates are commercialized.

#### LEVERAGING OUR LEADING POSITION IN ION CHANNEL RESEARCH IN PARTNERSHIP WITH PHARMACEUTICAL COMPANIES

Saniona's research strategy is also based on the establishment of partnerships on early stage drug discovery programs with pharmaceutical companies, by joint ventures or spin-outs. Saniona aims to effectively utilize its key competences in focused research areas, while simultaneously leveraging its partners' expertise in clinical development and marketing of medicines in a wide range of disease areas. This strategy also enables Saniona to manage the risks and upside potential on a relatively large number of pharmaceutical programs.

Saniona's research activities in early stage collaborations will traditionally be fully funded by Saniona's partners. It is Saniona's objective that most of its internal operational costs shall be financed through revenues from collaboration agreements. Therefore, the income from Saniona's research collaborations represents an important contribution to the company's short-term operations. However, the majority of Saniona's income from research collaborations with pharmaceutical companies (e.g. Boehringer Ingelheim) is expected to be clinical milestone payments and royalties on product sales when the product candidates are commercialized.

If a program is developed through spin-outs or joint ventures, the majority of Saniona's income will be payable upon exits, for example the sale of the spin-out or program to a third party. The proceeds from significant exits and income from milestones and royalty payments will be used for the continued development of Saniona or be payable as dividends to Saniona's shareholders.

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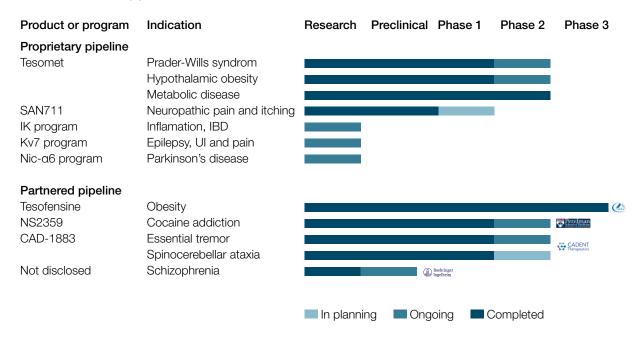
### **Pipeline**

Saniona has a portfolio of nine active drug development programs in clinical and pre-clinical stages, four of which are financed through partnerships or grants.

Saniona is currently conducting Phase 2 studies for Tesomet for the treatment of eating disorders. In addition, Saniona is preparing to start a Phase 1 study for SAN711 for the treatment of chronic pain and itching. Saniona's three research programs, which are targeting the IK, Kv7 and Nicotinic  $\alpha$ 6 ion channels, are focused on the treatment of inflammatory diseases and certain neurological diseases including epilepsy and Parkinson's diseases.

Saniona's partner Medix has successfully completed a Phase 3 registration trial for tesofensine in December 2018 and expects to file a new drug application in 2019 for treatment of obesity in Mexico. Cadent Therapeutics is conducting Phase 1 and Phase 2 studies for movement disorders, and Boehringer Ingelheim is preparing for Phase 1 studies in schizophrenia. In addition, the University of Pennsylvania is conducting an investigator-initiated clinical Phase 2a proof-of-concept study with NS2359 for the treatment of cocaine addiction.

Saniona's pipeline is set out below.



#### TESOFENSINE MONOTHERAPY FOR TREATMENT OF OBESITY (MEDIX)

Tesofensine is a triple monoamine reuptake inhibitor. It is a new chemical entity and has not been made commercially available previously. Tesofensine will be provided in tablets and the formulation of tesofensine is covered by patent applications and issued patents expiring in 2036. In addition, the company expects to obtain data exclusivity, which provides protection for at least five years in Mexico and the U.S. and ten years in Europe after market approval.

Saniona's partner Medix has completed a Phase 3 registration trial for tesofensine in December 2018. The trial met its primary endpoints and Medix expects to apply for a new drug application in Mexico in H1 2019 and to launch the product in 2020. Tesofensine has demonstrated strong weight reducing effects in Phase 2 and Phase 3 clinical studies in obese patients. In the Phase 3 registration trial, patients reached an average weight loss of 10% over 24 weeks and more than half of the patients lost more than 10% in weight. Tesofensine has been administered to more than 1,700 patients and is well tolerated.

Mexico ranks among the most obese countries in the world. It is estimated that more than 70% of the 128 million Mexicans are overweight or obese. Eight in ten deaths are caused by chronic, non-communicable diseases that are strongly linked to the overweight and obese population. Standardized mortality rates for diabetes, acute myocardial infarction, and hypertension have increased dramatically. As of 2012, diabetes - associated with obesity - was the largest single cause of death in Mexico. According to Medix, the current market for prescription medicine for obesity in Mexico is about USD 250 million of which Medix has about 50 percent by volume and value. The current market for prescription medicine for obesity in Mexico is dominated by old generics. Tesofensine is believed to be more efficacious and better tolerated than the existing products.

In February 2016, Saniona entered into a collaboration with Medix for the development and commercialization of tesofensine and Tesomet in Mexico and Argentina. Medix holds an exclusive license to commercialize tesofensine in Mexico and Argentina, while Saniona is entitled to milestone payments and double-digit royalties on product sales. Saniona retains all rights to tesofensine and Tesomet including the exclusive rights to use the clinical data developed by Medix in the rest of the world.

Medix is a Mexican pharmaceutical company established in 1956 and primarily focused on the treatment of excess weight and obesity. Medix is the market leader for the treatment of excess weight and obesity in Mexico, offering the most comprehensive product and service line. Medix's leading product for treatment of excess weight and obesity is among the top ten pharmaceutical products in Mexico overall. Medix has earned several recognitions for its social responsibility through its participation in philanthropic programs for the benefit of the Mexican population and for its educational efforts involving thousands of doctors in Mexico. Medix has subsidiaries in Argentina and certain other South American countries.

#### TESOMET FOR TREATMENT OF PRADER-WILLI SYNDROME AND HYPOTHALAMIC OBESITY

Tesomet is a fixed-dose combination of tesofensine and metoprolol, which currently is being tested in late-stage clinical trials for treatment of Prader-Willi syndrome, hypothalamic obesity, and metabolic diseases. Tesomet is covered by several patent applications and certain issued patents which together may provide patent protection until 2036.

#### Prader-Willi syndrome

Saniona is conducting a dose-finding Phase 2a study of Tesomet in patients with PWS.

The study was designed as an exploratory randomized, double-blind, placebo-controlled Phase 2a trial. The primary endpoint of the study was to examine the change in bodyweight over 12 weeks of treatment with Tesomet compared to placebo. Secondary objectives included eating behavior and food craving (hyperphagia), body composition, lipids and other metabolic parameters. The study was divided into two parts.

The first part included nine adult PWS patients and was successfully concluded in 2018. The results showed that Tesomet (tesofensine 0.5 mg + metoprolol 50 mg daily) may provide clinically meaningful weight loss and an impressive significant reduction in hyperphagia in adult patients. The study also revealed that the clearance of tesofensine is slower in the PWS patient group than in the general population, and that the optimal dose in PWS therefore may be a quarter to half of the dose used in other indications such as hypothalamic obesity.

The second part included nine adolescent PWS patients who received Tesomet (tesofensine 0.125 mg + metoprolol 25 mg daily) at a quarter of the tesofensine dose given to adult PWS patients during the first part of the study. The treatment was well tolerated, and eight of the nine adolescent patients decided to continue in a threemonth open-label extension study at the same dose. The study also showed that a dose of tesofensine (0.125 mg daily) does not result in therapeutically relevant plasma levels of tesofensine. Saniona has consequently doubled the dose to 0.25 mg daily in another three-month open-label extension of the study. The objective is to obtain a similar plasma level of tesofensine in PWS patients as obtained in previous Phase 2 and Phase 3 studies in obese patients where tesofensine has proven to be well tolerated and highly effective in controlling appetite and reducing weight.

Prader-Willi syndrome is recognized as the most common genetic cause of life-threatening obesity. The disease results from a deletion or loss of function of a cluster of genes on chromosome 15, which among other things leads to dysfunctional signaling in the brain's appetite/satiety center (hypothalamus). Patients suffer from a constant, extreme, ravenous insatiable appetite which persists no matter how much the patients eat. As a result, many of those affected with Prader-Willi syndrome become morbidly obese and suffer significant mortality. Compulsive eating and obsession with food usually begin before the age of six. The hyperphagia affects the quality of life for the patients as well as their families.

Published statistics from e.g. patient organizations indicate that there are about 20,000 known patients in the U.S. and Europe combined, equivalent to a prevalence of known and confirmed PWS patients of 1:40,000. There is no cure for this disease and there is no approved pharmacological treatment for the life-threatening hyperphagia and resulting obesity in these patients. The costs for payors are estimated to be 100–300 KUSD per patient per year in the U.S. (SVB Leerink) comprising assistance to families, residential homes in adulthood, medications as well as breathing devices and hospitalizations due to complications of hyperphagia and obesity.

There is a significant medical need for treatments that can reduce the hyperphagia and provide a weight loss in these patients. PWS is a significant commercial opportunity for Tesomet, with 20,000 patients in the U.S. and Europe combined and potential premium pricing as an orphan drug.

#### Hypothalamic obesity

Saniona is conducting a Phase 2a clinical study of Tesomet to treat hypothalamic obesity. The trial comprises a total of up to 25 patients and is conducted at Rigshospitalet in Copenhagen, Denmark. In this exploratory randomized, double-blind, placebo-controlled study, patients will receive either Tesomet (tesofensine 0.5 mg + metoprolol 50 mg daily) or matching placebo (2:1 randomization) for 24 weeks followed by an open-label extension study where all patients will receive Tesomet for 24 weeks, resulting in a total treatment period of 48 weeks.

Saniona expects to report the results from the double-blind part of the study in Q4 2019 and the full study in H1 2020. It is believed that dose finding will be easier in hypothalamic obesity patients than in PWS patients. Therefore, if this trial is successful Saniona may be able to continue into pivotal Phase 2b/3 studies for hypothalamic obesity.

Like Prader-Willi syndrome, hypothalamic obesity is a rare disease characterized by a constant craving for food with severe consequences for the patients. Hypothalamic obesity can be the result of damage to the hypothalamus e.g. from the growth or surgical removal of a rare brain tumor and from other types of injury to the hypothalamus including stroke, brain trauma or radiation for cancer patients. The hypothalamus is a small nucleus in the brain that controls important biological functions including body temperature, hunger and body weight. A rare brain tumor, craniopharyngioma, or the treatment therefore, is the most common cause of hypothalamic obesity. Hypothalamic obesity is therefore sometimes also referred to as craniopharyngioma associated obesity.

A craniopharyngioma is a benign tumor, which most commonly affects children between 5-10 years old, though onset can sometimes occur during adulthood. Craniopharyngioma is also a rare disease with an estimated prevalence of 1:50,000 in the US. The treatment involves surgical removal of the tumor in almost all patients. The procedure can lead to complications, including damage to the hypothalamus resulting in loss of appetite control, insatiable hunger and morbid obesity. A high frequency of hypothalamic obesity, between 30% and 77%, has been reported following treatment. Due to the Prader-Willi syndrome-like insatiable hunger, hypothalamic obesity is sometimes referred to as "acquired Prader-Willi syndrome".

As in Prader-Willi syndrome, the condition reduces quality of life and there is no effective pharmacological treatment available today for appetite control in these patients.

#### **NS2359 FOR TREATMENT OF COCAINE** ADDICTION (TRC)

NS2359 is a triple monoamine reuptake inhibitor, which may displace the dopamine reuptake inhibitor cocaine. NS2359's pharmacological profile means that it may be able to reduce cocaine withdrawal symptoms, reduce cocaine craving and reduce cocaineinduced euphoria. The salt products of NS2359 are covered by issued patents in the U.S. expiring in 2028. In addition, the company expects to obtain data exclusivity, which provides five-year protection in the U.S. and ten years in Europe after market approval.

The Treatment Research Center (TRC) at the University of Pennsylvania is conducting an investigator-initiated clinical Phase 2a proof-of-concept study with NS2359 for treatment of cocaine addiction. In January 2019, TRC informed Saniona that they plan to continue the cocaine addiction study with NS2359 at a higher dose following an

interim analysis of the still blinded data for the first 50 patients enrolled.

Cocaine dependence is a significant public health problem. In 2012, the National Survey on Drug Use and Health revealed that in the US 1.1 million persons were classified as dependent on or abusing cocaine. Cocaine abuse and dependence leads to significant morbidity and mortality. Other problems associated with cocaine use include increased rates of crime, violence, poverty, and family disruption. The standard treatment for cocaine dependence consists of individual and group psychotherapy and self-help groups. Although progress has been made in developing new psychosocial treatments, psychotherapy alone does not provide substantial benefit for many patients. Dropout rates in outpatient treatment programs are very high. Even among patients who complete treatment, relapse is common. Thus, medications have been sought to augment psychosocial treatment. Currently, there are no medications approved for the treatment of cocaine dependence. According to The Treatment Research Center (TRC) at University of Pennsylvania, the market value for an effective medication for cocaine addiction may exceed USD 1.8 billion in the U.S.

In June 2015 Saniona granted TRC rights to perform a Phase 2 trial for its compound NS2359. The study is funded by non-dilutive grants from the Dana Foundation and the Groff Foundation. Saniona retains the commercial rights to NS2359.

The Treatment Research Center ("TRC") is a clinical outpatient treatment center that is part of the PENN/VA Center for the Studies of Addiction (CSA). TRC has a modern treatment facility with a fully certified clinical laboratory and a state-of-the-art data management unit. The investigators have been leaders in addiction pharmacotherapy research for over 35 years and highly experienced clinicians and research associates staff the center. TRC has an active recruitment process and network in place for cocaine addiction. The center screens about 250 cocaine dependent

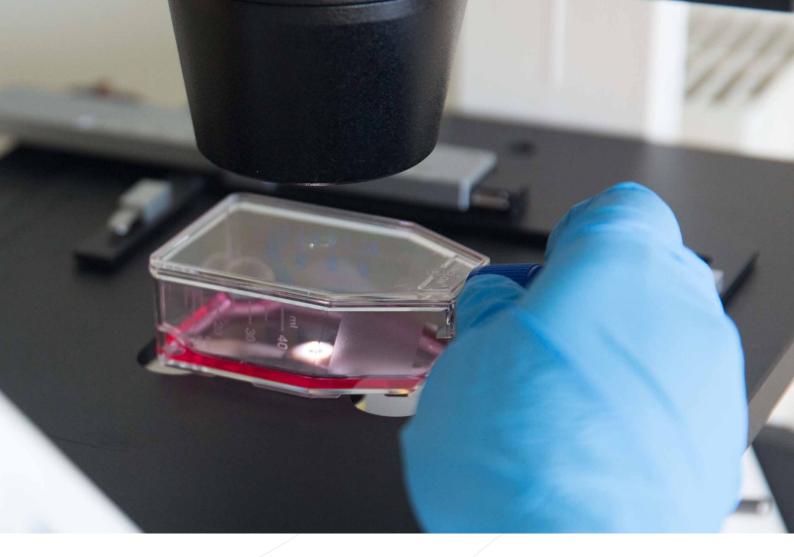
patients per year of which about 100 cocaine dependent patients are randomized into research protocols. TRC offers a comprehensive biopsychosocial evaluation in relation to clinical programs comprising a physical exam and ECG, an outpatient medical detoxification stabilization unit, and daily individual and group therapy sessions that are made available to patients eligible for one of the treatment-research studies.

#### CAD-1883 FOR TREATMENT OF ESSEN-TIAL TREMOR AND SPINOCEREBELLAR ATAXIA (CADENT THERAPEUTICS)

Cadent Therapeutics leverages a unique precision neuroscience approach combining target specificity, patient selection, drug design and optimization, and novel quantitative endpoints to create first-in-class molecules to treat movement and cognitive disorders. Currently in early clinical development, Cadent Therapeutics is rapidly advancing its pipeline of therapies to treat spinocerebellar ataxia, essential tremor and schizophrenia. Investors include Atlas Venture, Cowen, Healthcare Investments, Clal Biotechnology Industries, Slater Technology Fund and Novartis. CAD-1883 is a first-in-class selective positive allosteric modulator of SK channels (small conductance, calcium-activated potassium ion channels) discovered in a research collaboration between Saniona and Cadent Therapeutics. By increasing the calcium sensitivity of the SK channels, CAD-1883 causes the potassium current to flow at lower calcium concentrations, potentially restoring neuronal firing regularity and improving motor function.

Cadent is developing CAD-1883 for the treatment of essential tremor and spinocerebellar ataxia, two neurological movement disorders. Cadent initiated a Phase 2a study in essential tremor, and intends to start a Phase 2a trial in spinocerebellar ataxia in the second half of 2019.

Essential tremor is a neurological disorder characterized by uncontrollable shaking in different parts of the body, including the head, arms, hands, neck, and chin. It is the most common movement disorder, affecting 10 million people in the United States alone. In preclinical disease models, CAD-1883 has demonstrated the ability to improve motor control and reduce tremor. A Phase 2 trial was initiated in the fourth quarter of 2018 for the treatment of essential tremor.



Spinocerebellar ataxia is a genetic, degenerative neurological condition that affects approximately 6,000 people in the United States. Patients are readily identified through genetic testing and most often carry genetic abnormalities called "poly-Q expansions," similar to those found in patients with Huntington's disease. The disease is progressive and over time results in ongoing damage to the cerebellum, a part of the brain that regulates motor control and balance.

In March 2017, Cadent Therapeutics merged with Saniona's Boston based spinout Ataxion Inc. Saniona has a 3.4% ownership in Cadent Therapeutics as of December 31, 2018. In addition to ownership in Cadent Therapeutics, Saniona is eligible to receive royalties on any potential products developed and commercialized from the SK-program including CAD-1883.

#### SAN711 FOR TREATMENT OF NEUROPATHIC PAIN AND CHRONIC ITCHING (SANIONA)

SAN711 is a first-in-class pain and itchrelieving compound, which has the potential to be a first-line treatment option for pain management in patients suffering from untreatable neuropathic pain or itching disorders, either as a standalone treatment or as an add-on medication to existing suboptimal therapies. SAN711 acts on the receptors for GABA, the main inhibitory signaling mediator in the nervous system. SAN711 works selectively on receptors containing the GABA, 3 proteins without acting on the main GABA, receptors. This implies that SAN711 may regulate the body's own pain and itch regulating system in the spinal cord without causing side effects. This concept has been supported by preclinical studies with the compound. SAN711 is a new chemical entity and Saniona has filed a compound patent, which may provide patent protection until 2038.

In February 2019, Saniona successfully completed preclinical development of SAN711, and the program is ready for Phase 1 clinical trials, which may start during the summer 2019, either internally or together with a potential partner.

Pruritus or itch is the most frequent symptom seen in skin disease, including atopic dermatitis, urticaria and psoriasis. Pruritus is often defined as an unpleasant sensation associated with the desire to scratch and significantly reduces the quality of life of the affected individuals. With a lifetime prevalence of up to 22% and a high rate of therapeutic failure due to suboptimal treatment options, chronic itch imposes a significant socio-economic burden. Antihistamines have traditionally been the first-line treatment option for most pruritic conditions despite low efficacy in the substantial number of pruritic diseases characterized by histamineindependent pruritus. Certain systemic diseases have long been known to cause pruritus that ranges in intensity from a mild annovance to an intractable, disabling condition. Generalized pruritus may be classified into the following categories based on the underlying causative disease: renal pruritus, cholestatic pruritus, hematologic pruritus, endocrine pruritus, pruritus related to malignancy, and idiopathic generalized pruritus. The global combined market for treatment of atopic dermatitis and psoriasis amounts to approximately USD10 billion and is expected to double over the next 10 years.

Neuropathic pain is caused by a lesion or dysfunction of the central or peripheral nervous system in diseases such as diabetes, varicella zoster, cancer and HIV, or following mechanical lesion and trauma or the use of drugs such as chemotherapy. Neuropathic pain is often chronic, irreversible and notoriously difficult to manage. According to industry estimates, neuropathic pain is believed to affect about 40 million people in seven major markets. Major indications include chronic lower-back pain, painful diabetic neuropathy, post herpetic neuralgia (following shingles), neuropathic cancer pain and HIV related neuropathic pain. Wellknown painkillers, such as Aspirin®, Panodil®, and ibuprofen have no or little effect on neuropathic pain. Apart from narcotic analgesics (where tolerance development is a further complication), patients are typically treated with drugs developed for other indications including anti-epileptic drugs and antidepressants. Furthermore, the existing drugs typically have significant and dose-limiting side effects such as drowsiness, dizziness and somnolence. The market for neuropathic pain is estimated to be approximately USD6 billion with an anti-epileptic drug being the current market leader. It is estimated that 40-60% of the treated patients do not respond to existing drugs and that those who do only achieve partial pain relief, creating a significant medical need for more effective treatments.

#### BOEHRINGER INGELHEIM PROGRAM FOR TREATMENT OF SCHIZOPHRENIA (BOEHRINGER INGELHEIM)

Saniona and Boehringer Ingelheim GmbH ("Boehringer Ingelheim") have partnered for the discovery and development of new small molecule therapeutics to restore brain network activity in patients with schizophrenia. By combining Saniona's expertise in ion channels and related technology platforms with Boehringer Ingelheim's expertise in research and clinical development and commercialization, we are well positioned to advance new treatment options for schizophrenia.

In July 2018, Boehringer Ingelheim selected the first candidate for preclinical and clinical development, triggering a milestone payment of €4 million to Saniona. The program is in the preclinical development phase and Boehringer Ingelheim is preparing the lead candidate for clinical studies.

Boehringer Ingelheim is responsible for the preclinical and clinical development and has global commercial rights. Saniona is eligible to receive up to €90 million in milestone payments and royalties on worldwide net sales of any resulting products under the collaboration. As of December 2018, Saniona has received a total of €9 million under the collaboration excluding earned income under the research collaboration.

Boehringer Ingelheim, founded in 1885, is one of the world's 20 leading pharmaceutical companies. The focus of the family-owned company is on researching, developing, manufacturing and marketing new medications of high therapeutic value for human and veterinary medicine.

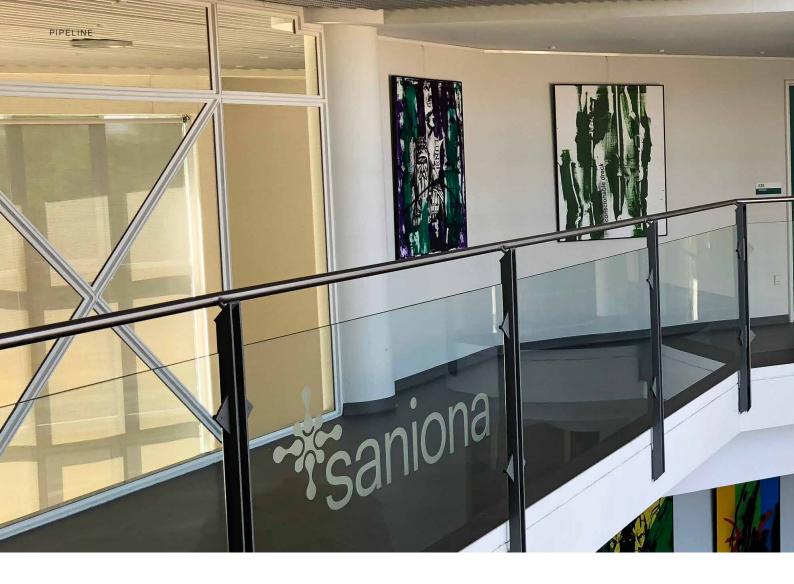


#### IK PROGRAM FOR TREATMENT OF INFLAMMATORY BOWEL DISEASES (SANIONA)

Saniona has identified novel proprietary IK channel inhibitors, which effectively dampen gut inflammation and can be used for the treatment of inflammatory bowel diseases (IBD), like Crohn's disease and ulcerative colitis. Saniona is in the final candidate selection phase for preclinical development. The drug will likely be the first ion channel modulator medicine for IBD (first-in-class).

The prevalence and incidence of IBD is increasing worldwide, especially in countries with an established or newly adopted Western lifestyle. Unfortunately, IBD requires frequent interventions with strong systemic anti-inflammatory treatments (steroids, anti-cancer type medicines, cytokine neutralizing antibodies), which have numerous side-effects. In addition to this, IBD patients often face a gradual worsening of their condition due to chronic fibrotic changes, which may lead to life-threatening obstructions that can only be resolved by acute gut-shortening surgery. There is preclinical evidence that IK inhibition both reduces ongoing intestinal inflammation and may have an independent effect on the chronic complications of the disease without having any of the side effects observed with the traditional IBD medicines.

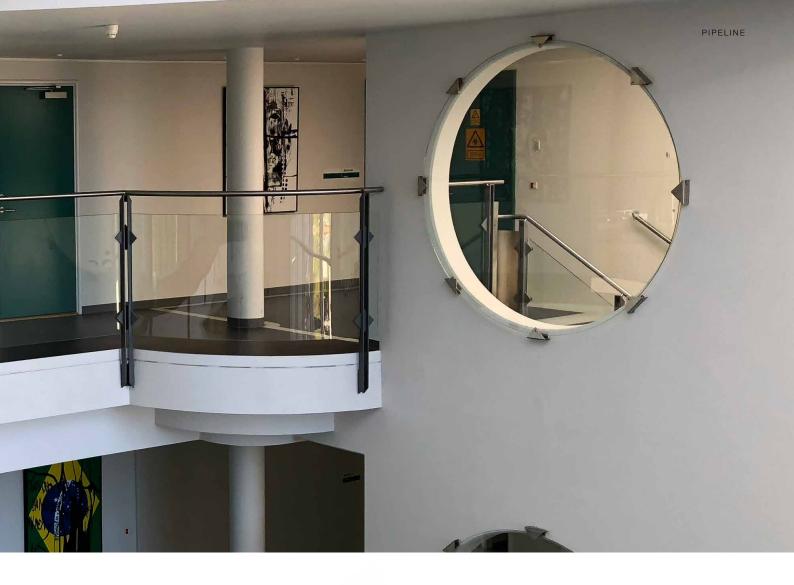
The IK potassium channel (also known as KCa3.1 and encoded by the gene KCNN4) is very important for controlling immune cell functions in both peripheral tissues and the brain. A precise pharmacological modulation of the IK channel can thus be used for treatment of multiple diseases which involve overactive or mistimed immunological reactions, such as autoimmune diseases like rheumatic arthritis and multiple sclerosis, the prevention of organ rejection after transplantation, and reducing brain damage after a stroke.



#### KV7 PROGRAM FOR TREATMENT OF EPILEPSY, PAIN, AND URINARY INCON-TINENCE (SANIONA)

Saniona's Kv7 channel activator programs are in the late stage drug discovery. The programs focus on developing effective new treatments for neurological diseases, such as treatment-resistant partial epilepsy, and various pain disorders. Furthermore, Saniona has demonstrated that Kv7 channel activators are also highly efficacious for relaxation of overactive bladder smooth muscle cells, a characteristic of urinary incontinence (UI). Therefore, one of our Kv7 channel activator programs aims at finding new treatment options for patients suffering from UI, which currently is not optimally treated, and Painful Bladder Syndrome (PBS), which is without any dedicated treatment options.

The Kv7 family of potassium channels is composed of five members (Kv7.1-5). Kv7.2-5 are expressed in many neurons where they give rise to voltage-dependent potassium currents with slow activation kinetics, no inactivation upon depolarization, and a complex modulation by various neurotransmitters, including acetylcholine via muscarinic receptors, which is why these channels are called M-currents. The M-current contributes to setting the neuronal resting membrane potential and has a strong influence on membrane excitability by acting as a brake and limiting neuronal firing frequency. Known mutations in the Kv7 subunits are involved in human pathologies, such as long QT syndrome (Kv7.1), epilepsy (Kv7.2 and Kv7.3), and deafness (Kv7.4), which highlight the involvement of these channels in a variety of physiological functions. Lately, Kv7.4 and Kv7.5 channels have also been implicated in regulation of smooth muscle function, where they contribute to setting the contractile state of these cells. Thus, the Kv7 family offers a unique target for the treatment of a broad range of severe pathologies.



### NIC a6 PROGRAM FOR TREATMENT OF PARKINSON'S DISEASE (SANIONA)

Saniona's Nic α6 Program for treatment of Parkinson's disease is in the drug discovery phase.

Nicotinic acetylcholine (nAChRs) receptors are ligand-gated ion channels that are activated by acetylcholine under physiological conditions. The α6 subtype exhibits an extremely localized expression mainly confined to dopaminergic neurons in the area of the brain affected in Parkinson's disease patients where they act as important regulators of dopamine signaling.

As a result of a focused screening campaign, Saniona has identified selective positive allosteric modulators (PAMs) of a6 containing receptors and furthermore demonstrated that these PAMs increase the affinity for acetylcholine. Given the restricted expression pattern of a6-containing nA-ChRs, selective PAMs could provide a novel therapy to increase dopaminergic signaling in Parkinson's disease patients. In addition, a6 selective PAMs have the potential to slow or stop neurodegeneration seen in Parkinson's disease that could result in stabilization of symptoms and disease progression. The identified PAMs offer a novel approach to counteract degeneration of dopaminergic neurons in patients and could optimally be used as a disease modifying therapy in Parkinson's disease.

Parkinson's disease is a chronic and progressive neurological disorder that is characterized by well-known motor symptoms including tremors, stiffness of limbs, slowness of movements, and difficulties with posture and balance. In addition to motor symptoms, many Parkinson's disease patients experience non-motor symptoms, including sleep disorders, sensory symptoms, depression and gastrointestinal symptoms. It is the second most common neurological disorder and it is estimated to affect seven to 10 million people worldwide.

The Michael J. Fox Foundation for Parkinson's Research awarded Saniona a research grant of USD 0.6 million to perform chemical optimization of its nicotinic a6 modulators to identify compounds suitable to demonstrate activity in relevant animal models and to assess their potential neuroprotective effects. Saniona retains all rights to any potential products developed and commercialized from the program.

### The Saniona share

Saniona is listed at Nasdaq Stockholm main market. Saniona's share is traded under the ticker SANION and the ISIN code SE0005794617.

### SHARE PRICE PERFORMANCE AND TURNOVER

The market price of Saniona's share was SEK 32.0 at the end of the year representing an increase of 4% compared to the previous year. In 2018, the highest price paid during the year was SEK 40.90 on June 12 and the lowest price was SEK 24.75 on April 24. In 2017, the highest price paid during the year was SEK 55.00 on July 26 and the lowest price paid was SEK 25.90 on December 28.

The average volume and trading values were 50,291 (61,748) shares and SEK 1,618,508 (2,669,583). Market capitalization was 746 MSEK at the end of the year, compared to 668 MSEK at the end of the previous year.

#### SHARE CAPITAL

At December 31, 2018, the number of shares outstanding was 23,324,413 (21,762,520).

All shares have equal entitlement to dividends and each share has equal voting rights. Each share has one vote at the General Meeting. At year-end, the share capital was SEK 1,166,221 (1,088,126) equal to a par value per share of SEK 0.05.

Saniona established a warrant program on July 1, 2015, totaling 64,000 warrants, on July 1, 2017, totaling 38,500 warrants, on January 19, 2018 totaling 286,003 warrants and on July 1, 2018, totaling 45,013 warrants. For further details, please see note 9.

#### SHAREHOLDERS

At December 31, 2018, Saniona had 5,569 (5,195) shareholders, excluding holdings in life insurance and foreign custody account holders.

#### **DEVELOPMENT IN PRICE AND VOLUME IN 2018**



#### LARGEST SHAREHOLDERS AS OF DECEMBER 31, 2018

Shareholder	Number of shares	Ownership and votes
Bny Mellon Sa/Nv (Former Bny), W8IMY*	2,633,751	11.3%
Försäkringsaktiebolaget, Avanza Pension	1,358,981	5.8%
Feldthus, Thomas**	1,220,000	5.2%
Leif Andersson Consulting Aps	1,003,437	4.3%
Christophersen, Palle	820,000	3.5%
Bræstrup, Claus	735,700	3.2%
Nordnet Pensionsförsäkring AB	662,235	2.8%
Credit Suisse (Switzerland) Ltd	559,552	2.4%
Nordea Livförsäkring Sverige AB	520,852	2.2%
Six Sis Ag, W8IMY	480,012	2.1%
Other shareholders	13,329,893	57.1%
Total	23,324,413	100.0%

\* Includes CEO Jørgen Drejer's shareholding of 2,344,711 shares

\*\* Excluding 650,000 shares lent to Nice & Green under convertible note agreement dated December 31, 2017

The shareholders are presented as they appear in the shareholder register held by Euroclear Sweden AB. The list may therefore not show shareholders whose shares have been registered in the name of a nominee, through trust of bank or similar.

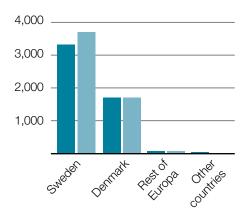
#### INSIDERS

All members of the Board and management have insider status.

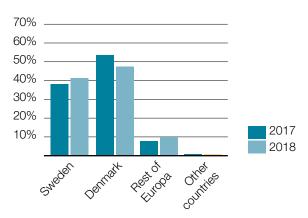
### SHAREHOLDERS AND OWNERSHIP DISTRIBUTION BY SIZE AT THE END OF YEAR IN 2017 AND 2018

	Number of shareholders		Shareholding and vo	
Shareholding	2017	2018	2017	2018
1 - 500	2,810	3,068	2.5%	2.4%
501 - 1,000	856	882	3.2%	3.1%
1,001 - 5,000	1,192	1,249	12.3%	12.0%
5,001 - 10,000	170	186	5.5%	5.6%
10,001 - 15,000	54	62	3.0%	3.3%
15,001 - 20,000	33	30	2.6%	2.3%
20,001 -	80	92	70.9%	71.4%
Total	5,195	5,569	100.0%	100.0%

#### SHAREHOLDERS BY COUNTRY



#### **OWNERSHIP BY COUNTRY**



### **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.

#### 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. For further details, please see description about Cadent Therapeutics under CAD-1883 in the Pipeline section.

#### **BENEVOLENTAI**

BenevolentAl acquired Proximagen Ltd. in Q1 2017.

#### BOEHRINGER INGELHEIM

Boehringer Ingelheim GmbH. For further details, please see the Boehringer Program in the Pipeline section.

#### CADENT THERAPEUTICS

Cadent Therapeutics was established in March 2017 through a merger between Saniona's spin-out company, Ataxion, and Luc Therapeutics. For further details, please see CAD-1883 in the Pipeline section.

#### **CHRONIC ITCHING**

Chronic itching (also known as pruritus) is defined as an unpleasant sensation that provokes the desire to scratch. Prolonged itching and scratching may increase the intensity of the itch and lead to skin injury, infection and scarring. The possible causes are numerous and include dry skin, skin disorders such as eczema and psoriasis, infections such as chicken pox and scabies, underlying illness such liver disease, kidney failure and cancers, nerve disorders such as multiple sclerosis and diabetes mellitus, and allergic diseases including allergic reactions to medications such as antibiotics and chemotherapy. For some patients, there's no known cause. Chronic itching ranges in intensity from a mild annoyance to a disabling condition. The constant need to scratch can be as debilitating as chronic pain. Depending on the underlying cause, the current treatment options include moisturizing cream, antihistamines, corticosteroids, local anesthetics, calcineurin inhibitors and antidepressants. Many patients experience only a partial relief whereas others have no relief from existing treatment options.

#### 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.

#### COLITIS

An inflammation of the inner lining of the colon. There are numerous causes of colitis including infection, inflammatory bowel disease (Crohn's disease, ulcerative colitis), ischemic colitis, allergic reactions, and microscopic colitis. Symptoms depend upon the cause and may include abdominal pain, cramping and diarrhea.

#### **CROHN'S DISEASE**

An IBD which causes inflammation of the digestive tract, which can lead to abdominal pain, severe diarrhea, fatigue, weight loss and malnutrition. Inflammation caused by Crohn's disease can involve different areas of the digestive tract in different people.

#### CTA

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

#### EMA

European Medicines Agency

#### EPILEPSY

Epilepsy is a central nervous system (neurological) disorder in which brain activity becomes abnormal, causing seizures or periods of unusual behavior, sensations, and sometimes loss of awareness. Treatment with medications or sometimes surgery can control seizures for the majority of people with epilepsy. Some people require lifelong treatment to control seizures, but for others, the seizures eventually go away.

#### **ESSENTIAL TREMOR**

Essential tremor is the most common movement disorder with a prevalence of 4% in persons age 40 and older and considerably higher among persons in their 60s, 70s, 80s and 90s. It typically involves a tremor of the arms, hands or fingers but sometimes involving the head, vocal cords or other body parts during voluntary movements such as eating and writing. Although essential tremor is often mild, people with severe tremor have difficulty performing many of their routine activities of daily living.

#### FATTY LIVER DISEASE (NASH)

Nonalcoholic steatohepatitis (NASH), or fatty liver disease, is a form of nonalcoholic fatty liver disease (NAFLD) in which a patient has hepatitis - inflammation of the liver - and liver cell damage, in addition to fat in the liver. Inflammation and liver cell damage can cause fibrosis, or scarring, of the liver. NASH may lead to cirrhosis or liver cancer.

#### FDA

US Food and Drug Administration

#### GABA, a2/a3 PROGRAM

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

#### HYPOTHALAMIC OBESITY

A common sequel to tumors of the hypothalamic region and their treatment with surgery and radiotherapy. Weight gain results from damage to the ventromedial hypothalamus which leads, variously, to hyperphagia, a low metabolic rate, autonomic imbalance, growth hormone deficiency and various other problems that contribute to weight gain.

#### **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 U.S. before a marketing application for the drug has been approved. In Europe, the application is called a Clinical Trial Application (CTA).

#### INFLAMMATORY BOWEL DISEASE (IBD)

IBD is an umbrella term used to describe disorders that involve chronic inflammation of the digestive tract. Types of IBD include ulcerative colitis and Crohn's disease.

#### 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.

#### **KV7 PROGRAMS**

Saniona's Kv7 programs focus on developing effective new treatments for neurological diseases, such as treatment-resistant partial epilepsy, and various pain disorders. Furthermore, we have demonstrated that activators of the Kv7 family of potassium channels are also highly efficacious for relaxation of overactive bladder smooth muscle cells, a characteristic of urinary incontinence (UI).

#### 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. For further details, please see under tesofensine in the Pipeline section.

#### METOPROLOL

Metoprolol is a medication of the selective  $\beta$ 1 receptor blocker type, which work by blocking the neurotransmitter norepinephrine and epinephrine from binding to receptors. It is used to treat high blood pressure, chest pain due to poor blood flow to the heart, and a number of conditions involving an abnormally fast heart rate. It is also used to prevent further heart problems after myocardial infarction and to prevent headaches in those with migraines.

#### MULTIPLE SCLEROSIS

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

#### NEUROPATHIC PAIN

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

#### NIC a6 PROGRAM

The Nic α6 program is a small molecule program designed to positively modulate (PAM) the α6 ion channels. The α6 subtype exhibits an extremely localized expression mainly confined to dopaminergic neurons in the area of the brain affected in Parkinson's disease patients, where they act as important regulators of dopamine signaling.

#### 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.

#### OBESITY

A medical condition in which body fat has accumulated to an extent that it may have a negative effect on health. Obesity is most commonly caused by a combination of excessive food intake, lack of physical activity and genetic susceptibility. A few cases are caused primarily by genes, endocrine disorders, medications or mental disorder.

#### PARKINSON'S DISEASE

Parkinson's disease (PD) is a neurodegenerative disorder that affects predominately dopamine-producing neurons in a specific area of the brain called substantia nigra. Symptoms generally develop slowly over years and may include tremors, bradykinesia, limb rigidity and gait and balance problems. The cause remains largely unknown and there is still no cure.

#### PHARMACODYNAMICS (PD)

Pharmacodynamics is the study of the biochemical and physiologic effects of a drug in the body including the relationship between the drug concentration and the desirable effects as well as the undesirable effects.

#### PHARMACOKINETICS (PK)

Pharmacokinetics is the study of how the body affects a drug including the relationship between the dosed amount of a drug and the obtained blood concentration of the drug.

#### PRADER-WILLI SYNDROME

Prader-Willi syndrome is a complex genetic condition that affects many parts of the body. In infancy, this condition is characterized by weak muscle tone (hypotonia), feeding difficulties, poor growth, and delayed development. Affected individuals develop an insatiable appetite, which leads to chronic overeating (hyperphagia) and obesity. Some people with Prader-Willi syndrome, particularly those with obesity, also develop type 2 diabetes.

#### SAN711

SAN711 is a selective GABA<sub>A</sub>  $\alpha$ 3 modulator (PAM), which increases the activity of the GABA<sub>A</sub> receptor protein in the vertebrate central nervous system. It is derived from Saniona's advanced ion channel platform and has demonstrated strong efficacy in rodent itching and pain models. SAN711 is ready for Phase 1 clinical testing.

#### **SCHIZOPHRENIA**

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

#### TESOFENSINE

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

#### TRC

The University of Pennsylvania Treatment Research Center. For further details, please see under NS2359 in the Pipeline section.

#### **TYPE 2 DIABETES**

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

#### **URINARY INCONTINENCE (UI)**

UI, or the loss of bladder control, is a common and often embarrassing problem. It is not a disease, but rather a symptom of many conditions. Many factors increase risk, for example aging, pregnancy, prostate problems and obesity.

# **Board of Directors report**

### **Five-year summary**

Income statement, KSEK	2018	2017	2016	2015	2014
Net sales	54,884	20,692	74,921	13,630	21,718
Operating expenses	-109,089	-77,881	-70,764	-41,705	-29,977
Operating profit/loss*	-54,206	-57,189	4,156	-28,075	-8,258
Financial items, net	5,913	914	757	-1,183	520
Profit/loss before tax	-48,292	-56,275	4,913	-29,258	-7,739
Tax on net profit	7,233	7,086	-2,696	6,311	1,831
Profit/loss for the year	-41,059	-49,190	2,217	-22,947	-5,908
Balance sheet, KSEK	2018	2017	2016	2015	2014
Non-current assets	12,407	7,806	2,703	2,300	2,088
Financial assets	10,504	6,439	1,519	1,547	815
Current receivables	15,990	18,256	14,804	8,369	3,684
Cash and cash equivalent	54,678	22,313	53,261	47,004	9,689
Total assets	83,075	48,375	70,769	57,673	15,461
Equity	39,457	37,628	54,252	52,943	8,780
Current liabilities	43,617	10,747	16,517	4,730	6,681
Total equity and liabilities	83,075	48,375	70,769	57,673	15,461
Cash flow, KSEK	2018	2017	2016	2015	2014
Cash flow from operating activities	-22,920	-57,339	7,953	-28,820	-7,958
Cash flow from investing activities	914	-5,970	-816	-975	-856
Cash flow from financing activities	46,745	33,175	-403	66,693	17,553
Cash flow for the year	24,738	-30,134	6,735	36,898	8,739
Key figures, %	2018	2017	2016	2015	2014
Operating margin*	Negative	Negative	6%	Negative	Negative
Liquidity ratio*	162%	377%	412%	1171%	200%
Equity ratio*	47%	78%	77%	92%	57%
Share data, SEK	2018	2017	2016	2015	2014
Earnings per share	-1.84	-2.30	0.11	-1.29	-0.45
Diluted earnings per share	-1.84	-2.30	0.11	-1.29	-0.45
Equity per share*	1.69	1.73	2.60	2.54	0.63
Dividend	0.00	0.00	0.02	0.00	0.00
Cash flow per share*	1.11	-1.41	0.32	2.08	0.66
Share data, #	2018	2017	2016	2015	2014
Average shares outstanding	22,288,524	21,416,810	20,841,467	17,775,099	13,231,668
Diluted average shares outstanding	22,314,283	21,452,001	20,905,467	17,839,099	13,231,668
Shares outstanding at the end of the period	23,324,413	21,762,520	20,841,467	20,841,467	13,882,200

\* Financial measures marked with \* are not defined under IFRS, so called alternative performance measures. The definition and rational for presenting them can be found in note 31 to the financial statements.

### **Board of Directors report**

The Board of Directors and the Chief Executive Officer of Saniona AB (publ), corporate identity number 556962-5345, hereby present the Annual Accounts and Consolidated accounts for the financial year January 1, 2018 – December 31, 2018.

The Group comprises the Parent Company Saniona AB and its subsidiary Saniona A/S, which is registered in the municipality of Ballerup, Denmark. The subsidiary, Saniona A/S, was registered in November 2011 and began operations in September 2012. The Group was formed in a transaction on January 30, 2014, in which the Parent Company acquired 100 % of the shares in Saniona A/S by an issue in kind. Before that transaction, the owners of Saniona A/S had established the Parent Company. Under Swedish GAAP the issue in kind was performed at the book-values in Saniona A/S, hence no assets or liabilities was revalued, and no new goodwill was recorded.

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 is listed at Nasdaq Stockholm Small Cap.

#### ABOUT SANIONA

Saniona is a research and development company focused on drugs for diseases of the central nervous system and eating disorders. The company has five programs in clinical development. The research is focused on ion channels and the company has a broad portfolio of preclinical programs. Saniona has partnerships with Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and Cadent Therapeutics.

Saniona is developing products internally with the aim of attaining market approval itself in the U.S. and Europe for certain orphan indications where the required investments are limited, and the commercial opportunities substantial. Saniona is currently developing Tesomet for Prader-Willi syndrome and hypothalamic obesity with emphasis on the U.S. and Europe. The market for such a product may be significant despite a relatively small number of patients. Furthermore, the required investments for developing Tesomet in these indications are comparatively small and the required commercial infrastructure for servicing these patients in the U.S. and Europe is manageable.

In general, the majority of Saniona's internal development programs may potentially be developed and commercialized for both orphan indications by Saniona and for larger indications in collaboration with partners. One of Saniona's short term objectives is to develop at least one of its preclinical programs to Phase 2, with the aim of positioning the product for a potential orphan indication itself or to out-license it to a pharmaceutical company to treat a more common disease.

Saniona has not commercialized any products but has generated income through its partnerships. The structure of Saniona's collaboration agreements depend on the product, the indication, the investment and the risk as well as the interest and capabilities of Saniona's partners. In general, when Saniona decides to develop a product in collaboration with pharmaceutical company, Saniona grants its partners commercial license to a limited territory or on a worldwide basis. In exchange, Saniona's partners typically finance future research and development activities and pay Saniona upfront payments, research funding, milestone payments and royalties on product sales when the product candidates are commercialized. Saniona's research and development programs as well as the company's collaborations are described in the pipeline section of this annual report (page 14-23).

#### BUSINESS REVIEW FOR 2018 Successful Phase 3 registration trial paves the way for tesofensine as a new treatment in obesity

In December 2018, Saniona's partner Medix successfully completed a Phase 3 trial for tesofensine in obesity. The Phase 3 study comprised 372 patients who were randomized into three arms with 124 patients in each arm receiving either 0.25 mg tesofensine, 0.5 mg tesofensine or placebo tablets once daily for 24 weeks. The primary endpoint was absolute and percent change in body weight. The trial met the primary endpoints with an impressive 10% average weight loss in 24 weeks and with more than half of patients losing more than 10% in weight. There was also seen a statistically significant reduction in key obesity-related risk factors. Medix, which owns commercial rights in Mexico and Argentina, expects to submit a regulatory filing in 2019 and launch the product in 2020. Under the agreement, Medix will pay Saniona regulatory milestones and doubledigit royalties on product sales in Mexico and Argentina. Saniona retains all rights to tesofensine in the rest of the world including the exclusive rights to use the clinical data generated by Medix. These results also support development of Saniona's whollyowned Tesomet, a fix-dosed combination of tesofensine and metoprolol in Phase 2 for rare eating disorders.

#### Phase 2a study in adult patients with Prader-Willi syndrome provides proof of concept and supports further studies of Tesomet in this patient group

In January 2018, Saniona reported top line results from a Phase 2a clinical study for Tesomet in adult patients with Prader-Willi syndrome (PWS). The study included nine adult patients where six patients received Tesomet (tesofensine 0.5 mg + metoprolol 50 mg daily) and three patients received a matching placebo (3:2 randomization) for a total of 12 weeks. The primary endpoint showed a clinically meaningful reduction in weight for patients treated with Tesomet compared to placebo. The study also showed a remarkable reduction in the craving for food in patients treated with Tesomet compared to placebo. There were no reports of serious adverse events in the trial, but all patients participating in the trial did report certain adverse events. In the treatment group, the adverse events included an exacerbation of already occurring behavioral problems and CNS disorders, which were

reversed after the completion of the study or in two cases where patients were offered a temporary reduction in dose during the study. In addition to this, the Phase 2 study revealed that patients with Prader-Willi syndrome have a significantly slower clearance of tesofensine than other patient groups. The slower clearance led over the course of the study to a two to four times higher plasma concentration of tesofensine when compared to other patient groups given the same dose. The high plasma concentration may contribute to the observed adverse events in patients treated with Tesomet and it provides a clear rationale for further studies.

#### Phase 2a dose finding study in adolescent patients with Prader-Willi syndrome is ongoing

Based on the obtained proof of concept in the first part of the Phase 2a study of Tesomet in adult patients with PWS, Saniona continued into a second part of the exploratory dose finding study. The second part in adolescent patients started with a 3-month placebo-controlled study including nine adolescent PWS patients who initially received Tesomet (tesofensine 0.125 mg + metoprolol 25 mg daily) at a guarter of the tesofensine dose given to adult PWS patients during the first part of the study. The treatment was well tolerated, and eight of the nine adolescent patients decided to continue into a three-month open-label extension study at the same dose. The half-life of tesofensine in the adolescent patient population was confirmed to be very long as also seen in the adult patient population. The study also revealed that a dose of tesofensine 0.125 mg daily was not providing therapeutically relevant plasma levels of tesofensine. Saniona has consequently doubled the dose to 0.25 mg daily in another three-month open-label extension of the study. The objective is to obtain a similar plasma level of tesofensine in PWS patients as obtained in previous Phase 2 and Phase 3 studies in obese patients where tesofensine has proven to be well tolerated and highly effective in controlling appetite and reduce weight.

# Phase 2a proof of concept study for treatment of hypothalamic obesity initiated

In parallel with PWS, Saniona initiated in February 2019 a Phase 2a proof of concept study for Tesomet in hypothalamic obesity (HO). This study will include up to 25 patients, who will receive treatment for 24



weeks followed by an open-label extension, where all patients will receive Tesomet for additional 24 weeks, resulting in a total treatment period of 48 weeks. We expect results from the double-blind part of the study in Q4 2019 and the full data in H1 2020.

#### Pre-clinical studies for Tesomet enable long-term studies in metabolic diseases and eating disorders

Saniona has previously only been able to perform clinical studies with Tesomet for a three-month period. In June 2018, Saniona successful completed preclinical toxicology studies, which confirms that Tesomet is well tolerated and may be safely dosed in longterm clinical studies. These studies provide more flexibility in designing clinical studies (extension of ongoing PWS study and 6-12 months studies in HO) and pave the way for pivotal Phase 2b/3 trials for Tesomet in eating disorders and metabolic diseases.

#### Completion of two Phase 1 studies enables the use of proprietary Tesomet tablets in future studies

In 2018, Saniona conducted two additional Phase 1 clinical studies in preparation for long term dose range finding and pivotal studies with Tesomet. The first study was a Phase 1 pharmacokinetic study, where the objective was to determine the release of the two compounds in the new tablet. The second study was a Phase 1 pharmacodynamic study, where the objective was to establish the optimal ratio between tesofensine and metoprolol at various doses of tesofensine. The Phase 1 pharmacokinetic study demonstrated that is possible to obtain clinically relevant and stable plasma levels of tesofensine and metoprolol in a wide dose range using Saniona's novel proprietary fixed-dose combination tablet. The Phase 1 pharmacodynamic study provided clear guidelines and documentations for establishing the optimal ratio between tesofensine and metoprolol at various doses of tesofensine.

### Investigator-initiated Phase 2a study with NS2359 for cocaine addiction

In January 2019, The University of Pennsylvania Treatment Research Center (TRC) informed Saniona that they plan to continue their investigator-initiated Phase 2a study with NS2359 for cocaine addiction at a higher dose following an interim analysis of the blinded data for the first 50 patients enrolled. The study comprises a total of up to 80 patients, where 40 patients will receive NS2359 and 40 patients will receive matching placebo for a total of 8 weeks. The primary objective of the Phase 2a study is to examine whether NS2359 leads to abstinence from cocaine during the last 2 weeks of treatment. If successful, NS2359 could become the first treatment for cocaine addiction. The clinical trial is financed through grants and Saniona has retained the commercial rights to the compound and the clinical data developed by TRC.

#### Saniona's partner, Cadent Therapeutics, initiates Phase 2a for the Saniona collaboration compound, CAD-1883

Saniona's partner, Cadent Therapeutics, has made significant progress on the collaboration compound, CAD-1883, in 2018. Cadent Therapeutics is developing CAD-1883 for the serious movement disorders, essential tremor and spinocerebellar ataxia. The company initiated a Phase 1 study in March and a Phase 2a study in November for the treatment of essential tremor. Furthermore, the company has informed Saniona that they plan to start a second Phase 2a study for Ataxia during the second half of 2019. CAD-1883 was the first program from Saniona's large portfolio of unique first in class research programs to enter clinical development. Apart from being a shareholder of Cadent Therapeutics, Saniona has rights to royalties on CAD-1883.

# SAN711 is ready for Phase 1 clinical studies for treatment of chronic itching and neuropathic pain

In 2018, Saniona scaled-up the manufacturing process, produced tablets for clinical use and performed IND enabling studies for its clinical candidate, SAN711, for the treatment of neuropathic pain and chronic itching. Saniona successfully completed the preclinical program in February 2019 and the product is now ready for Phase 1 human studies, performed either internally or together with a potential partner. SAN711 is a first in class compound, which offers a new treatment paradigm for itching and neuropathic pain

# Boehringer Ingelheim selected clinical candidate triggering a €4 million milestone payment to Saniona

Saniona received a €4 million milestone payment from Boehringer Ingelheim in July 2018 following selection of a clinical candidate for schizophrenia. Saniona has now received €9 million in upfront and milestone payments under the agreement with Boehringer Ingelheim. Boehringer Ingelheim has exclusive worldwide rights to research, develop, manufacture and commercialize therapeutics identified through the collaboration. Saniona may receive up to € 90 million in upfront and milestone payments and royalties on worldwide net sales of any resulting products under the collaboration. Boehringer Ingelheim is currently conducting IND-enabling studies to initiate clinical studies.

### Progress in research programs provides opportunities for long term value creation

Saniona is currently working on three active research programs, which are targeting the IK, Kv7 and Nicotinic a6 ion channels. The IK program has made significant progress during the year and the program is in the final candidate selection stage. This is a new concept in inflammatory and autoimmune diseases and Saniona has strong data in models for Crohn's disease and colitis. The concept may also be developed for rare diseases, potentially internally. The Kv-7 program has progressed well during the year. The program could lead to a potential new treatment within urinary incontinence, pain and epilepsy, including rare types of epilepsy where there is a genetic link to Kv-7 channels and where there are currently no good treatment options. The program is in the lead optimization stage. The Nicotinic a6 program for Parkinson's disease is in early stage. In 2018, the focus has been on broadening the chemistry series.

#### Spin-out company Scandion Oncology IPO on Spotlight secures financing for non-core assets

Saniona participated in the formation of Scandion Oncology A/S, a company focused on developing cancer drugs. Scandion Oncology acquired from Saniona a development compound, SCO-101, and a platform comprising a large series of chemical analogues. Saniona had no intention to develop these assets internally. In 2015, Saniona granted scientists at the University of Copenhagen, Denmark, rights to test some of the compounds in their screening systems leading to the discovery that the compounds could re-sensitize resistant cancer cells to standard chemotherapy. In 2018, Scandion Oncology raised 26 MSEK in an initial public offering prior to the listing on Spotlight stock

market. Saniona owned 29.2% of the shares in Scandion Oncology as of December 31, 2018.

#### J. Donald deBethizy elected as Chairman of the Board of Directors and Anna Ljung elected as new member of the Board of Directors and chairman of the Audit Committee

At an extraordinary shareholders meeting in January 2018, Saniona's shareholders elected Anna Ljung and J. Donald deBethizy to the Board of Directors in accordance to the recommendation of the Nomination Committee. Anna Ljung currently serves as the CFO of Moberg Pharma where she prepared the company for its initial public offering in 2011. J. Donald deBethizy who replaced Claus Bræstrup as Chairman of the Board has more than 30 years of experience in research and development and financial, business and operational management in the biotech and consumer products industry.

#### FINANCIAL REVIEW FOR 2018 Revenue and results of operation

Saniona generated total revenues of 54.9 MSEK (20.7) for the full year of 2018. In 2018, revenues comprised a research milestone payment of 41.8 MSEK (€ 4 million) because of the candidate selection by Boehringer Ingelheim and research funding totaling 13.1 MSEK, under the agreements with Boehringer Ingelheim and BenevolentAI. In 2017, revenues comprised research funding under the agreements with Boehringer Ingelheim, BenevolentAI and Cadent Therapeutics.

The company recognized operating expenses of 109.1 MSEK (77.9), an increase of 40%. External expenses amounted to 80.1 MSEK (51.4), an increase of 51%. In 2018, external expenses comprised primarily development costs in relation to Tesomet totaling 35.7 MSEK followed by preclinical development costs in relation to SAN711 with 13.0 MSEK and research and development costs in relation to the IK program with 4.0 MSEK. In 2017, external expenses comprised primarily development costs in relation to the Phase 2 study for Tesomet totaling 18.9 MSEK followed by research cost in relation to the IK program with 4.5 MSEK and the GABA  $\alpha 2/\alpha 3$  program with 3.5 MSEK. Personnel costs amounted to 24.2 MSEK (22.7), an increase of 7%. This is mainly explained by a weakening of the SEK in 2018. The average exchange rate of SEK against DKK decreased with 6% in 2018 compared to 2017 leading to an increase in Saniona personnel costs of a similar amount when presented in SEK.

The operating loss for the full year of 2018 was 54.2 MSEK (57.2). Net financial items amounted to SEK 5.9 MSEK (0.9). The loss for the full year of 2018 was 41.1 MSEK (49.2). Saniona recognize a tax credit for the full year of 2018 of 7.2 MSEK (7.1) under the Danish R&D tax credit scheme (please see note 12, Income tax and deferred tax subsidiaries in Denmark).

#### Financial position

Total assets as of December 31, 2018, were 83.1 MSEK (48.4). Cash and cash equivalents amounted to 54.7 MSEK (22.3) as of December 31, 2018. The equity ratio was 47 (78) % as of December 31, 2018, and equity was 39.5 MSEK (37.6).

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 72 MSEK in convertible notes in individual tranches of 6 MSEK each over a 12-month period subject to prolongation by Saniona. Saniona called 8 tranches of 6 MSEK in 2018 equal to 48 MSEK. The remaining four tranches are available for 2019 under the prolongation by Saniona. Saniona has the right to extend the convertible notes funding agreement with Nice & Green for an additional 72 MSEK with the same terms. If Saniona were to extend the agreement for an additional 12-month period and utilize the program in full, Saniona may have enough financing to fund the planned activities until 2020 excluding potential financing from upfront and milestone payments under existing and potential future collaboration agreements. The convertible notes will bear no interest and will mature 12 months from the date issued. The convertible notes may be converted into shares at an 8% discount to the lowest daily volume-weighted average share price of the five trading days prior to the date on which Nice & Green has sent a conversion notice to Saniona.

#### Cash flow

Operating cash flow for the full year of 2018 was an outflow of 22.7 MSEK (outflow of 56.6). Consolidated cash flow for the full year of 2018 was an inflow of 24.7 MSEK (outflow of 30.1).

In 2018, the operating cash flow is explained by the operating loss and an improvement in working capital primarily due to an increase in prepayments from customers and a reduction in trade receivables. The consolidated cash flow in 2018 is further explained by an inflow from finance activities of 46.7 MSEK through the issue of convertible loan notes to Nice & Green totaling 48 MSEK of which 6 MSEK has not been converted at the balance sheet date. The balance of 42 MSEK was converted into equity during 2018 and the net proceeds of 40.7 MSEK is recorded under new share issues after deduction of issuing expenses.

The consolidated cash flow in 2017 is explained by an inflow from the private placement in the second quarter of 2017 of 33.2 MSEK 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 28) and the operating loss during the period.

#### Parent Company

The majority of the Group's operations takes place in the subsidiary Saniona A/S. The Parent Company, Saniona AB recognized revenues of SEK 0 (0). Operating expenses amounted to 7.9 MSEK (8.5), a decrease of 8%. The Parent Company recognized a profit on net financial items of 7.9 MSEK (0.8). The increase in net financial items is primarily due to recognition of Saniona's share of the equity in Scandion Oncology totaling 6.2 MSEK (0). The profit for the full year of 2018 was 19 KSEK as opposed to a loss of 7.7 MSEK in 2017.

#### **Risks management**

Saniona is exposed to various kinds of risks that may impact the Group's results and financial position. The risks can be divided into operational risks and financial risks.

### Risk related to the company and industry

#### Brief business history

Saniona A/S was formed in 2011 and became operational in 2012. In January 2014, the Parent Company Saniona AB was founded whereby the current group structure arose. Hence, the company's contacts with customers, suppliers and partners are relatively newly established. For this reason, the relationships can be difficult to assess and may therefore affect the prospects that the company has. There is for example a risk that the company's partners terminate existing agreements, which might have a material adverse effect on Saniona's business, earnings and financial position.

#### Financing needs and capital

Saniona's research and development efforts require significant investments. Saniona is thus dependent on its ability to raise capital in the future to finance its planned activities. Any delays in clinical trials or product development, or prematurely interrupted collaborations with the company's partners, could affect the cash flow negatively. There is a risk that the company is unable to raise additional capital, maintain or achieve additional partnerships or to be supplied with other financing. This may lead to the development temporarily being stopped or that Saniona is forced to operate at a lower rate than wanted, which may affect the company's operations negatively. In case Saniona cannot raise additional capital, obtain additional partnerships or other financing, there is a risk that the company cannot finance further studies and development of its business. Lack of financing can hence have a material adverse effect on Saniona's business, earnings and financial position.

#### **Clinical studies**

Saniona has five programs in clinical phase and four programs in pre-clinical research phase. All the programs require continued clinical studies to prove acceptable safety, risk and efficiency profile before they can be launched in the market as finished products. If Saniona or its partners cannot obtain, or are unable to maintain, required permits for such pre-clinical and clinical studies, or if the studies will not demonstrate the required efficiency or safety, it will not be possible to achieve commercialization.

Clinical studies are extensive and time and cost consuming and associated with great

uncertainty and risks related to delays and to results in the studies. Results from early pre-clinical studies and clinical studies are not always consistent with the results obtained in more extensive studies. In addition, thereto, the time and costs aspects may be hard to determine accurately in advance and can hence lead to delays and increased costs.

To perform clinical studies, Saniona and its partners are dependent on participation from patients. In case such participation cannot be obtained on satisfactory conditions, this can delay or complicate the performance of clinical studies.

The above risks related to pre-clinical and clinical studies might have a material adverse effect on Saniona's business, earnings and financial position.

Dependency on external parties for studies and pharmaceutical development Saniona's need of pharmaceutical development is partly covered by internal competence, but the company also engages external parties. Saniona has entered into agreements with the Indian service providers, Syngene International Limited and Aurigen, regarding chemical synthesis, Klifo A/S and Parexel regarding clinical trials and Cambrex Karlskoga AB regarding the manufacture of drug substance for clinical and commercial use. The company also has less comprehensive agreements with other operations related to studies including drug absorption and efficiency in specific disease models. If present or future external parties do not fulfil their undertakings or the quality requirements requested by Saniona, or chose to terminate their cooperation with the company, this might have a material adverse effect on Saniona's business, earnings and financial position. Engagement of new external suppliers, or change of existing suppliers, can also be costlier and/or take longer time than the company estimates, which might have a material adverse effect on Saniona's business, earnings and financial position.

#### Legislation and regulatory approvals

To conduct pre-clinical and clinical studies and/or to market and sell pharmaceutical products, registration must take place with and permits must be obtained from the relevant authority in the respective market, such as FDA in the US and EMA in EU. It is time and cost consuming to obtain required permits and this may increase costs, delay or hinder the development of the company's programs, for example in case the company or its partners are not considered to fulfil applicable requirements for clinical studies or pharmaceutical manufacturing or if authorities make other judgements than Saniona and its partners in relation to the evaluation of data from trials. Future changes in applicable legislation may also lead to delays and increased costs. In case Saniona and its partners do not obtain required regulatory approvals for one or more product candidates, the product candidates cannot be commercialized, which might have a material adverse effect on Saniona's business, earnings and financial position.

Saniona and its partners will be obliged to meet certain regulatory requirements also after a product has been approved for marketing, including requirements for supervision of the marketing of the products and safety reporting. In addition, Saniona and its partners will be obliged to comply with rules pharmaceutical production including rules for trials, quality control and documentation of the company's products. Production facilities must be approved through inspection from authorities and will be subject to regular inspections by the authorities, which might lead to remarks and new production requirements. In case Saniona or its partners, including external manufacturers, do not meet the applicable regulatory requirements, the company may be subject to fines, withdrawals or seizure of products, withdrawal of regulatory approvals or permits, other operational restrictions and criminal sanctions, that might have a material adverse effect on Saniona's business, earnings and financial position.

#### Product liability and insurance

Since Saniona conducts research and development of pharmaceuticals, risks of product liability arise. Saniona may be held liable for side effects, diseases, death or other injuries on patients in connection with clinical studies, even if clinical studies are carried out by an external party. If Saniona would be held responsible for incidents in a clinical study, there is the risk that the company's insurance coverage is not enough to cover any future legal claims, which might negatively affect Saniona both in terms of reputation and financially. Claims related to product liability might have a material adverse effect on Saniona's business, earnings and financial position.

#### Key individuals and employees

Saniona's key individuals and employees have high competence and long experience within the company's field of business. In accordance with practice in the Danish labor market, the notice period for several senior executives and key employees, with the exception of the CEO and CFO, for the employee to terminate the employment is only one month. Several key individuals can therefore terminate their employment with only one month's notice, which means that Saniona may need to replace key individuals at short notice. If one or more key individuals or employees terminate their employment with the company or if the company fails to recruit new persons with relevant skills and expertise this may delay or hinder the development of the company's programs, which might have a material adverse effect on Saniona's business, earnings and financial position.

Patents and other intellectual property rights Patents and other intellectual property rights are key assets in Saniona's business and the company's potential future success is dependent on that the company can obtain and maintain necessary patent protection for individual projects, technology and production methods. Even if Saniona obtains patent protection there is a risk that an approved patent will not provide satisfactory commercial protection in the future, for example if competitors develop products or technologies that lead to Saniona's intellectual property rights being circumvented or replaced. If Saniona is forced to defend future patent rights against a competitor, this might involve considerable costs for the company.

Furthermore, in the industry in which Saniona operates, there is always the risk that the company may, or is alleged to infringe patents held by third parties. Other actors' patents may also limit the ability of one or more of the company's future partners to freely use the product or production method concerned. The risk associated with patent protection implies that the outcome of such disputes is difficult to predict. Negative outcomes of disputes relating to intellectual property rights may lead to loss of protection, prohibition to continue to use the right or obligation to pay damages. In addition, the costs of a dispute, even in case of a favorable outcome for Saniona,

may be substantial. The above risks might have a material adverse effect on Saniona's business, earnings and financial position.

Protection of trade secrets and know-how Saniona is dependent on trade secrets and know-how which cannot be protected by registration in the same way as other intellectual property rights. Saniona uses confidentiality agreements to protect trade secrets and know-how but it is not possible to provide complete protection against unauthorized disclosure of information, which entails risks that competitors might obtain and benefit from the company's trade secrets and know-how developed by Saniona, which might be of damage to the company. Such disclosure of information might have a material adverse effect on Saniona's business, earnings and financial position.

#### **Competitors**

Saniona operates in a competitive industry characterized by rapid technological development. The company's competitors may be major multinational companies as well as minor research companies active within the field of ion channels. These competitors may have greater resources than Saniona and its partners in areas such as research and development, contacts with approval authorities, marketing and product launching. There is hence a risk that competitors may achieve commercialization of products earlier than Saniona and its partners. Competitors may also develop and market products that are more efficient, safer and are more affordable than Saniona's potential products. Such competing products can limit Saniona's ability to generate revenue, which might have a material adverse effect on the company's business, earnings and financial position.

#### Partners

Saniona has chosen to enter into partnerships for certain projects in early phase to reduce the ongoing capital need through financing via collaborations. The company's partners include Boehringer Ingelheim International GmbH, Productos Medix S.A. de S.V. and Cadent Therapeutics Inc. A substantial part of Saniona's activities has been financed through partners and the partners are hence crucial for the conduct of certain projects. In case any of the company's partners would chose to terminate the cooperation with Saniona there is a risk that projects are delayed or cannot be continued. Saniona may not have the financial resources necessary to continue the project on its own or may fail to enter into new collaborations with new partners for the continuation of the project. In addition, a change of partner might also lead to increased costs which may further complicate the continuation of the project. Terminated or delayed collaboration projects might have a material adverse effect on the company's business, earnings and financial position.

Dependency on future commercialization Saniona is entitled to royalty for successfully developed and marketed products and milestone payments within the framework of several cooperation projects. The company is hence to a large extent dependent on future commercialization to generate revenues. Even if marketing approval is received, there is a risk that the sales do not correspond to the expectations and that commercial success will not be achieved. The potential revenues depend on several factors such as the product's characteristics, competing products, distribution opportunities, marketing, price, and availability. Absence of commercial success might have a material adverse effect on Saniona's operations, earnings and financial position.

#### **Financial risks**

Financial risks relate to a potential negative impact on the financial position resulting from changes in the financial risk factors. The Board of Directors is ultimately responsible for the exposure, management and monitoring of the group's financial risks. The Board of Directors sets the framework that applies to the exposure, management and monitoring of the financial risks and this framework is evaluated and revised yearly. The Board of Directors can decide on temporary departures from its predetermined framework. For a more detailed description see note 4.

### ORGANIZATION

The average number of employees in the Group during the year amounted to 23.5 (24.1), of whom 12.2 (13.7) were women. As of December 31, 2018, the number of employees was 25 (26) of which 13 (14) were women. Of these employees, 3 (3) were part-time employees and 22 (23) were full-time employees, and a total of 20 (21) worked in the company's research and development operations. 12 (12) of Saniona's

employees hold PhDs, 2 (3) hold university degrees, 8 (8) have laboratory training and the remaining 3 (3) have other degrees. In addition to its employees Saniona has several consultants, who work with the Group on an ongoing basis.

#### **GUIDELINES FOR REMUNERATION**

The Annual General Meeting held on May 24, 2018 resolved, in accordance with the proposal from the Board of Directors, on the below principles for remuneration to management to apply until the annual General Meeting 2019. The management is defined as the CEO and the senior executives who report to the CEO, which for the time being comprise the CFO and CSO.

#### **Fundamental principles**

Saniona's principle is that remuneration shall be payable on terms that enables senior executives to be recruited and retained. Remuneration to senior executives may consist of basic salary and other customary benefits which can be considered reasonable in relation to market practice (such as home internet connection, newspaper subscriptions, etc.).

The remuneration shall not be discriminating on grounds of gender, ethnic background, national origin, age, disability or other irrelevant factors.

#### **Fixed Salary**

The management shall be offered a fixed salary based on the individual's work duties, expertise, position, responsibilities, performances and other considerations. Salary shall be determined per calendar year with salary revision on January 1 each year.

#### Variable remuneration

Saniona does not offer any variable remuneration to the management and the management does not participate in the employee warrant program.

#### Pensions

Saniona does not offer any separate pension benefits to the management. Certain part of the management's fixed salary is however allocated to pension payments. The proportion of such pension payments can be selected by the senior executives.

#### Termination and severance payment

Upon termination by the company, the notice period for the CEO and other senior executives shall not exceed six months.

However, an adjusted notice period may be applied for the CEO and the CFO during an initial period of six months after a transaction with the outcome that a majority shareholding in Saniona AB or Saniona A/S has been acquired by one or more persons. The adjustment shall mean that the notice period, upon termination by Saniona, may be extended to twelve months immediately after the relevant change in ownership. The notice period shall thereafter be reduced by one month for every month that passes after the change in ownership until the notice period is consistent with the normal notice period of the employment agreements.

Severance payment, apart from salary during the notice period, shall not occur.

#### Deviation from the guidelines

The Board of Directors shall be entitled to deviate from these guidelines in individual cases if there are special reasons for doing so.

The Board of Directors has proposed that the Annual General Meeting to be held on May 29, 2019, should resolve on essentially unchanged guidelines for remuneration to apply until the Annual General Meeting in 2020.

#### ENVIRONMENTAL INFORMATION

Saniona does not yet have any actual industrial production, so its discharge into the air, soil and water is exceedingly limited. Saniona believes that it follows current environmental laws and regulations.

Saniona conducts its operations in accordance with the permits issued for the company by the authorities. The company has, for example, permit for the handling of radioactive materials, permit for handling gene modified organisms and permit for conducting animal experiments. Saniona uses small quantities of radioactive trace elements in certain laboratory experiments. This radioactive material is stored and disposed of in compliance with the guidelines and instructions issued by the Danish National Institute of Radiation Hygiene. When new drugs are developed, regulatory authorities require that animal experiments are conducted. These experiments are necessary to evaluate the effect and mode of action of new drugs and to maximize safety for participants in the clinical studies. At Saniona all animal experiments are conducted with the approval of the Danish Animal Experiments Inspectorate and complies with all regulatory requirements regarding animal studies. Saniona considers the

three R's guideline principles (i.e. Replace, Reduce and Refine) for the use of animals in research highly important and conducts studies according to those principles. External contract research organizations are carefully selected when safety experiments are to be made in animals before clinical studies are conducted with the company's drug candidates. Saniona only uses organizations with a good international reputation which comply with all European standards on animal welfare and receive relevant inspections by the authorities.

Saniona considers it highly important to maintain a good working environment and at any time wishes to meet regulatory requirements regarding the way the workplace is designed. This also includes the psychological and physical working environment, including exhaust and air change, ventilation, heating, furniture and in-house safety regulations in general. Saniona is from time to time screened by the Danish Working Environment Authority for compliance with the Danish Working Environment Act. Saniona is continuing its efforts to improve the working environment through an active working environment organization based on workplace assessments (physical, chemical, biological, ergonomic, accident-related and psychological working environment conditions) as well as based on analyses of developments in the number of days lost due to sickness. Saniona believes that a good working environment is very important to employee wellbeing and thus also to our staff's ability to always perform at best for the company.

### OWNERSHIP STRUCTURE SHARE CAPITAL AND VOTING RIGHTS

At December 31, 2018, the company had 5,569 (5,195) shareholders excluding holdings in life insurance and foreign custody account holders. The company's CEO, Jørgen Drejer, was the largest shareholder with 10.1 percent (10.8) of the share capital and voting rights. The ten largest shareholders jointly accounted for 42.9 percent (46.3) of the share capital and voting rights. Apart from Jørgen Drejer, there were no other shareholders with a holding of more than one-tenth of the total number of shares and votes in the company at year-end.

Saniona's share capital totaled SEK 1,166,221 divided between 23,324,413 shares as of December 31, 2018. In 2017, Saniona's share capital totaled SEK 1,088,126 divided between 21,762,520 shares. All shares have a quotient value of SEK 0.05 and one vote and confer equal entitlement to the Company's assets and profits. Saniona's Articles of Association have no limitations regarding the number of votes each shareholder may cast at the Annual General Meeting.

# AUTHORIZATION FOR THE BOARD OF DIRECTORS REGARDING NEW ISSUES

At the Annual General Meeting held on May 24, 2018, it was resolved to authorize the board of directors to, at one or several occasions, during the time up until the next annual shareholders' meeting, with or without deviation from the shareholders' preferential rights, resolve to issue shares and/or convertibles. A new issue should be able to be made with or without provisions regarding contribution in kind, set-off or other conditions.

In case the authorization is used for a new issue of shares, the total number of shares that may be issued shall not exceed 4,411,467 shares, corresponding to 20% of the total number of existing shares in the Company at the time of the annual shareholders' meeting and the subscription price shall be on market terms (subject to customary new issue discount, as applicable). The purpose of the authorization as regards new issues of shares is to be able to source working capital, to be able to execute and finance acquisitions of companies as well as to enable new issues to industrial partners within the framework of partnerships and alliances.

In case the authorization is used for issues of convertibles, such issue must only be made within the financing agreement that the Company on 29 December 2017 entered into with Nice & Green S.A. ("N&G") and the total number of shares that may be issued upon conversion of convertibles issued thereunder shall not exceed 12,000,000 shares. The conversion rate shall be determined in accordance with the provisions in the financing agreement with N&G which stipulate that the conversion rate for convertibles issued to N&G shall amount to the higher of SEK 6 and 92% of the lowest daily volume weighted average price for the Company's share during the 5 trading days preceding the day for the request for conversion. Due to issue technical reasons, each issue resolution regarding convertibles must stipulate a minimum conversion rate which pursuant to the financing agreement

with N&G is stipulated to be SEK 6. At each issue resolution. this minimum conversion rate forms the basis for the maximum numbers of shares that may be issued upon conversion of issued convertibles. Each tranche of convertibles under the financing agreement amounts to SEK 6,000,000 and the stipulated maximum number of shares of 12,000,000 thereby enables the Company to draw 12 tranches under the financing agreement with N&G prior to the next annual shareholders' meeting. It should however be noted that as long as 92% of the lowest daily volume weighted average price for the Company's share during the 5 trading days preceding the day for the request for conversion exceeds SEK 6, the conversion rate so calculated will be applied and the number of shares issued at conversion will then be lower than the maximum number as per the above. For further information regarding the financing agreement with N&G, please refer to the Company's press release issued on 29 December 2017. The purpose of the authorization about issue of convertibles is to be able to draw tranches under the financing agreement with N&G. Upon full utilization of the authorization, a maximum of 16,411,467 shares will be issued or alternatively be issued upon conversion, which corresponds to a total dilution effect of approximately 42.7%. However, please see above for a description regarding the number of shares that can be issued pursuant to the financing agreement with N&G.

#### OTHER INFORMATION

For additional information, please see the Corporate Governance Report on page 80-89.

# EVENTS AFTER THE BALANCE SHEET DATE

In January, Saniona initiated an open label extension study in the second part of its Phase 2a study of Tesomet comprising nine adolescent patients with PWS. The treatment with a dose of 0.125 mg/day appeared to be well tolerated but did not achieve sufficient plasma levels known to be efficacious in previous Phase 2 and Phase 3 studies. Saniona has received approval to increase the dose to 0.25 mg/day and the f patients was switched to the 0.25 mg dose in March. The study is scheduled to continue until the end of June.

- Saniona's partner University of Pennsylvania Treatment Research Center continues the investigator-initiated study with NS2359 for cocaine addiction at a higher dose following their interim analysis.
- Saniona successfully completed a full regulatory toxicological program for its first in class compound, SAN711, which offers a new treatment paradigm for itching and neuropathic pain. Saniona has scaled-up the manufacturing process, produced the material for clinical studies and the program is now ready for Phase 1 studies.
- Saniona recruited the first patient in a Phase 2a clinical study of Tesomet to treat the rare eating disorder hypothalamic obesity. The trial comprises a total of up to 25 patients and is conducted at Rigshospitalet in Copenhagen, Denmark.

#### FINANCIAL CALENDAR

Interim Report Q1	May 29, 2019
Annual General Meeting	May 29, 2019
Interim Report Q2	August 21, 2019
Interim Report Q3	November 13, 2019
Year-End Report 2019	February 20, 2020

#### PROPOSED APPROPRIATION OF FUNDS

The following funds are at the disposal of the Annual General Meeting:

#### SEK

Share premium reserve	155,606,895
Profit/loss carried forward	-17,978,771
Profit/loss for the year	19,049
Total	137,647,173

The Board of Directors propose that the funds at their disposal, SEK 137,647,173, be carried forward.

The results and position of the Group and the Parent Company in other respects are presented in the following income statements, balance sheets, cash flow statements and statements of equity with related notes and supplementary information, which form an integral part of this annual report. All amounts are stated in SEK 000s unless otherwise indicated.

# **Financial Statements**

# **Consolidated statement of comprehensive income – Group**

1-5       1-5       54,884       20,692         Total operating income       54,884       20,692         Raw materials and consumables       -4,089       -3,263         Other external costs       8       80,149       -51,387         Personnel costs       9       -24,219       -22,671         Depreciation and write-downs       -632       -561         Total operating expenses       -109,089       -77,881         Operating profit/loss       -54,206       -57,189         Share of result of associates       27       6,174         Financial income       10       -261         Financial expenses       11       -261         Total financial items       5,913       914         Profit/loss after financial items       -48,292       -56,275         Tax on net profit       12       7,233       7,086         Profit/loss for the year       -41,059       -49,190         Other comprehensive income for the period       -       -         Item that may be reclassified to profit and loss       -       -         Translation differences       625       -968         Total other comprehensive income for the year, net after tax       625       -968	KSEK	Note	2018	2017
Total operating income       54,884       20,692         Raw materials and consumables       -4,089       -3,263         Other external costs       8       -80,149       -51,387         Personnel costs       9       -24,219       -22,671         Depreciation and write-downs       -632       -561         Total operating expenses       -109,089       -77,881         Operating profit/loss       -54,206       -57,189         Share of result of associates       27       6,174         Financial income       10       -         Profit/loss after financial items       5,913       914         Profit/loss for the year       -48,292       -56,275         Tax on net profit       12       7,233       7,086         Profit/loss for the year       -48,292       -56,275         Tax on net profit       12       7,233       7,086         Profit/loss for the year       -41,059       -49,190         Other comprehensive income for the period       -       -         Item that may be reclassified to profit and loss       -       -         Total other comprehensive income for the year, net after tax       625       -968         Total other comprehensive income for the year, net after tax		1-5		
Raw materials and consumables       -4,089       -3,263         Other external costs       8       -80,149       -51,387         Personnel costs       9       -24,219       -22,671         Depreciation and write-downs       -692       -561         Total operating expenses       -109,089       -77,881         Operating profit/loss       -54,206       -57,189         Share of result of associates       27       6,174         Financial income       10       -       1,289         Financial expenses       11       -261       -376         Total financial items       10       -       1,289         Financial expenses       11       -261       -376         Total financial items       12       7,233       7,086         Profit/loss after financial items       -48,292       -56,275         Tax on net profit       12       7,233       7,086         Profit/loss for the year       -41,059       -49,190         Other comprehensive income for the period       -       -         Item that may be reclassified to profit and loss       -       -         Total other comprehensive income for the year, net after tax       625       -968         Total other c	Net sales	6-7	54,884	20,692
Other external costs       8       -80,149       -51,387         Personnel costs       9       -24,219       -22,671         Depreciation and write-downs       -632       -632         Total operating expenses       -109,089       -77,881         Operating profit/loss       -54,206       -57,189         Share of result of associates       27       6,174         Financial income       10       -         11       -261       -376         Total financial items       5,913       914         Profit/loss after financial items       -48,292       -56,275         Tax on net profit       12       7,233       7,086         Profit/loss for the year       12       7,233       7,086         Item that may be reclassified to profit and loss       -       -       -         Tatal other comprehensive income for the year, net after tax       625       -968         Total other comprehensive income for the year, net after tax       6265       -968         Total other comprehensive income for the year       -40,434       -50,157         Earnings per share, SEK       13       -1.84       -2.30	Total operating income		54,884	20,692
Other external costs       8       -80,149       -51,387         Personnel costs       9       -24,219       -22,671         Depreciation and write-downs       -632       -632       -561         Total operating expenses       -109,089       -77,881         Operating profit/loss       -54,206       -57,189         Share of result of associates       27       6,174       -         Financial income       10       -       1,289         Financial expenses       11       -261       -376         Total financial items       5,913       914       -         Profit/loss after financial items       -48,292       -56,275         Tax on net profit       12       7,233       7,086         Profit/loss for the year       -41,059       -49,190         Other comprehensive income for the period       -       -         Item that may be reclassified to profit and loss       -       -         Translation differences       -968       -968         Total other comprehensive income for the year, net after tax       6225       -968         Total other comprehensive income for the year       -40,434       -50,157         Earnings per share, SEK       13       -1.84       -2.30 </td <td></td> <td></td> <td></td> <td></td>				
Personnel costs       9       -24,219       -22,671         Depreciation and write-downs       -632       -632         Total operating expenses       -109,089       -77,881         Operating profit/loss       -54,206       -57,189         Share of result of associates       27       6,174         Financial income       10       -12         Prinancial expenses       11       -261         Total financial items       5,913       914         Profit/loss after financial items       -48,292       -56,275         Tax on net profit       12       7,233       7,086         Profit/loss for the year       -41,059       -49,190         Other comprehensive income for the period       -41,059       -49,190         Item that may be reclassified to profit and loss       -       -         Translation differences       -968       -968       -968         Total other comprehensive income for the year, net after tax       6225       -968         Total comprehensive income for the year       -40,434       -50,157         Earnings per share, SEK       13       -1.84       -2.30	Raw materials and consumables		-4,089	-3,263
Depreciation and write-downs         -632         -561           Total operating expenses         -109,089         -77,881           Operating profit/loss         -54,206         -57,189           Share of result of associates         27         6,174         -           Financial income         10         -         1,289           Financial expenses         11         -261         -376           Total financial items         5,913         914           Profit/loss after financial items         -48,292         -56,275           Tax on net profit         12         7,233         7,086           Profit/loss for the year         -41,059         -49,190           Other comprehensive income for the period         -         -           Item that may be reclassified to profit and loss         -         625         -968           Total other comprehensive income for the year, net after tax         625         -968           Total comprehensive income for the year         -40,434         -50,157           Earnings per share, SEK         13         -1.84         -2.30	Other external costs	8	-80,149	-51,387
Total operating expenses-109,089-77,881Operating profit/loss-54,206-57,189Share of result of associates276,174Financial income10-11-261-376Total financial expenses11-261Total financial items5,913914Profit/loss after financial items-48,292-56,275Tax on net profit127,2337,086Profit/loss for the year127,2337,086Profit/loss for the year-41,059-49,190Other comprehensive income for the period Item that may be reclassified to profit and lossTotal other comprehensive income for the year, net after tax625-968Total other comprehensive income for the year, net after tax625-968Total comprehensive income for the year-40,434-50,157Earnings per share, SEK13-1.84-2.30	Personnel costs	9	-24,219	-22,671
Operating profit/loss-54,206-57,189Share of result of associates276,174-Financial income101,289Financial expenses11-261-376Total financial items5,913914Profit/loss after financial items-48,292-56,275Tax on net profit127,2337,086Profit/loss for the year-41,059-49,190Other comprehensive income for the period Item that may be reclassified to profit and lossTotal other comprehensive income for the year, net after tax625-968Total other comprehensive income for the year-40,434-50,157Earnings per share, SEK13-1.84-2.30	Depreciation and write-downs		-632	-561
Share of result of associates276,174-Financial income101,289Financial expenses11-261-376Total financial items5,913914Profit/loss after financial items-48,292-56,275Tax on net profit127,2337,086Profit/loss for the year-41,059-49,190Other comprehensive income for the periodItem that may be reclassified to profit and lossTotal other comprehensive income for the year, net after tax625-968Total comprehensive income for the year-40,434-50,157Earnings per share, SEK13-1.84-2.30	Total operating expenses		-109,089	-77,881
Share of result of associates276,174Financial income101,289Financial expenses11-261Total financial items5,913914Profit/loss after financial items-48,292-56,275Tax on net profit127,2337,086Profit/loss for the year-41,059-49,190Other comprehensive income for the period-41,059-49,190Item that may be reclassified to profit and lossTotal other comprehensive income for the year, net after tax625-968Total comprehensive income for the year-40,434-50,157Earnings per share, SEK13-1.84-2.30				
Financial income       10       -       1,289         Financial expenses       11       -261       -376         Total financial items       5,913       914         Profit/loss after financial items       -48,292       -56,275         Tax on net profit       12       7,233       7,086         Profit/loss for the year       -41,059       -49,190         Other comprehensive income for the period           Item that may be reclassified to profit and loss           Translation differences       625       -968         Total other comprehensive income for the year, net after tax       625       -968         Total comprehensive income for the year       -40,434       -50,157         Earnings per share, SEK       73       -1.84       -2.30	Operating profit/loss		-54,206	-57,189
Financial income       10       -       1,289         Financial expenses       11       -261       -376         Total financial items       5,913       914         Profit/loss after financial items       -48,292       -56,275         Tax on net profit       12       7,233       7,086         Profit/loss for the year       -41,059       -49,190         Other comprehensive income for the period           Item that may be reclassified to profit and loss           Translation differences       625       -968         Total other comprehensive income for the year, net after tax       625       -968         Total comprehensive income for the year       -40,434       -50,157         Earnings per share, SEK       73       -1.84       -2.30				
Financial expenses       11       -261       -376         Total financial items       5,913       914         Profit/loss after financial items       -48,292       -56,275         Tax on net profit       12       7,233       7,086         Profit/loss for the year       -41,059       -49,190         Other comprehensive income for the period	Share of result of associates	27	6,174	-
Total financial items5,913914Profit/loss after financial items-48,292-56,275Tax on net profit127,2337,086Profit/loss for the year-41,059-49,190Other comprehensive income for the period Item that may be reclassified to profit and lossTranslation differences625-968Total other comprehensive income for the year, net after tax625-968Total comprehensive income for the year-40,434-50,157Earnings per share, SEK13-1.84-2.30	Financial income	10	-	1,289
Profit/loss after financial items-48,292-56,275Tax on net profit127,2337,086Profit/loss for the year127,2337,086Other comprehensive income for the period Item that may be reclassified to profit and loss-41,059-49,190Other comprehensive income for the period Item that may be reclassified to profit and loss-625-968Total other comprehensive income for the year, net after tax625-968Total comprehensive income for the year-40,434-50,157Earnings per share, SEK13-1.84-2.30	Financial expenses	11	-261	-376
Tax on net profit127,2337,086Profit/loss for the year-41,059-49,190Other comprehensive income for the period Item that may be reclassified to profit and lossTranslation differences625-968Total other comprehensive income for the year, net after tax625-968Total comprehensive income for the year13-1.84-2.30	Total financial items		5,913	914
Tax on net profit127,2337,086Profit/loss for the year-41,059-49,190Other comprehensive income for the period Item that may be reclassified to profit and lossTranslation differences625-968Total other comprehensive income for the year, net after tax625-968Total comprehensive income for the year13-1.84-2.30				
Profit/loss for the year-41,059-49,190Other comprehensive income for the period Item that may be reclassified to profit and lossTranslation differences625-968Total other comprehensive income for the year, net after tax625-968Total comprehensive income for the year-40,434-50,157Earnings per share, SEK13-1.84-2.30	Profit/loss after financial items		-48,292	-56,275
Profit/loss for the year-41,059-49,190Other comprehensive income for the period Item that may be reclassified to profit and lossTranslation differences625-968Total other comprehensive income for the year, net after tax625-968Total comprehensive income for the year-40,434-50,157Earnings per share, SEK13-1.84-2.30				
Other comprehensive income for the period Item that may be reclassified to profit and loss	Tax on net profit	12	7,233	7,086
Other comprehensive income for the period Item that may be reclassified to profit and loss				
Item that may be reclassified to profit and lossTranslation differences625Total other comprehensive income for the year, net after tax625Total comprehensive income for the year-40,434Earnings per share, SEK1313-1.84	Profit/loss for the year		-41,059	-49,190
Item that may be reclassified to profit and lossTranslation differences625Total other comprehensive income for the year, net after tax625Total comprehensive income for the year-40,434Earnings per share, SEK1313-1.84				
Translation differences625-968Total other comprehensive income for the year, net after tax625-968Total comprehensive income for the year-40,434-50,157Earnings per share, SEK13-1.84-2.30				
Total other comprehensive income for the year, net after tax625Total comprehensive income for the year-40,434Earnings per share, SEK131.84-2.30			- 625	-
Total comprehensive income for the year-40,434-50,157Earnings per share, SEK13-1.84-2.30				
Earnings per share, SEK 13 -1.84 -2.30			025	-500
Earnings per share, SEK 13 -1.84 -2.30	Total comprehensive income for the year		-40.434	-50,157
			10,104	00,101
	Earnings per share, SEK	13	-1.84	-2.30
	Diluted earnings per share, SEK			

The recognized loss and total comprehensive income for 2017 and 2018 are all attributable to the shareholders of the Parent Company, since there is no non-controlling interest in the subsidiaries of the Group.

# **Consolidated statement of financial position – Group**

KSEK	Note	2018-12-31	2017-12-3
ASSETS	1-5		
Fixtures, fittings, tools and equipment	14-15	1,841	1,36
Tangible assets		1,841	1,36
Investment in associated companies	27	6,505	33
Other long-term receivables	28	3,999	6,01
Financial assets		10,504	6,35
Deferred tax	22	62	8
Non-current assets		12,407	7,80
Trade receivables	16	2,093	7,18
Current tax assets	17	7,568	7,27
Other receivables	18	4,654	3,26
Prepayments and accrued income	18	1,675	54
Current receivables		15,990	18,25
Cash and cash equivalent	19	54,678	22,31
Current assets		70,668	40,56
Total assets		83,075	48,37
EQUITY AND LIABILITIES			
Share capital	26	1,166	1,08
Additional paid in capital		157,118	116,45
Retained earnings		-118,051	-78,51
Currency translation reserve		-777	-1,40
Equity		39,457	37,62
Prepayments from customers	7	-	60
Trade payables		7,243	5,20
Convertible loan	25	6,000	
Other payables		616	51
Accrued expenses and deferred income	22	29,759	4,42
Current liabilities		43,617	10,74
Total liabilities		43,617	10,74
		83,075	48,37

# **Consolidated statement of changes in equity - Group**

	Share capital	Additional paid in capital	Trans- lation reserves	Retained earnings	Share- holders' equity
January 1, 2017	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	0	0	-968	-49,190	-50,157
Transactions with owners					
Shares issued for cash	46	34,954			35,000
Expenses related to capital increase		-1,825			-1,825
Share-based compensation expenses				359	359
Total transactions with owners	46	33,129	0	359	33,534
December 31, 2017	1,088	116,452	-1,402	-78,511	37,628
January 1, 2018	1,088	116,452	-1,402	-78,511	37,628
Comprehensive income					
Profit/loss for the year				-41,059	-41,059
Other comprehensive income:					
Translation differences			625		625
Total comprehensive income			625	-41,059	-40,434
Transactions with owners					
Shares issued for cash	78	41,922			42,000
Expenses related to capital increase		-1,255			-1,255
Share-based compensation expenses				1,519	1,519
Total transactions with owners	78	40,666	0	1,519	42,263
December 31, 2018	1,166	157,118	-777	-118,051	39,457

# **Consolidated statement** of cash flows - Group

KSEK	Note	2018	201
Profit/loss before tax		-48,292	-56,27
Adjustments for non-cash transactions	29	-3,795	Ę
Changes in working capital	29	29,428	-347
Cash flow from operating activities before financial items		-22,659	-56,61
Interest income received		-	1,28
Interest expenses paid		-261	-37
Tax paid	12	-	-1,63
Cash flow from operating activities		-22,920	-57,33
Investing activities			
Investment in tangible assets		-1,107	-70
Investment in associated companies	27	-	-33
Investment in other financial assets		2,021	-4,93
Cash flow from investing activities		914	-5,97
Financing activities			
Convertible Ioan	25	6,000	
New share issue	26	40,745	33,17
Cash flow from financing activities		46,745	33,17
Cash flow for the year		24,738	-30,13
Cash and cash equivalents at beginning of year		22,313	53,26
Exchange rate adjustments		7,626	-81
Cash and cash equivalents at end of year		54,678	22,31

# Statement of income – Parent Company

KSEK	Note	2018	2017
Total operating income	1-5	-	-
Raw materials and consumables		-10	-20
Other external costs	8	-5,524	-7,218
Personnel costs	9	-2,379	-1,249
Total operating expenses		-7,912	-8,487
	_		
Operating profit/loss		-7,912	-8,487
Share of result of associates	27	6,174	-
Financial income	10	1,900	1,085
Financial expenses	11	-144	-259
Total financial items		7,931	826
Profit/loss after financial items		19	-7,660
Tax on net profit	12	-	-
Profit/loss for the year		19	-7,660

# Statement of comprehensive income – Parent Company

KSEK	Note	2018	2017
Profit/loss for the year	1-5	19	-7,660
Other comprehensive income for the period			
Item that may be reclassified to profit and loss			
Other comprehensive income for the year		-	-
Total other comprehensive income for the year, net after tax		0	0
Total comprehensive income for the year		19	-7,660

# Statement of financial position – Parent Company

KSEK	Note	2018-12-31	2017-12-3
ASSETS			
Investment in subsidiaries	23	11,832	11,83
Investment in associated companies	27	6,505	33
Financial assets		18,337	12,16
Non-current assets		18,337	12,16
Receivables from group companies		112,424	69,06
Other receivables	18	257	12
Prepayments and accrued income	18	977	S
Current receivables		113,658	69,27
Cash and cash equivalent	19	13,435	17,12
Current assets		127,093	86,39
Total assets		145,429	98,56
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	26	1,166	1,08
Unrestricted equity			
Additional paid in capital	25	155,607	114,94
Retained earnings		-17,979	-10,31
Profit/loss for the period		19	-7,66
Equity		138,813	98,05
Convertible loan	25	6,000	
Other payables		616	51
Current liabilities		6,616	51
Total liabilities		6,616	51
Total equity and liabilities		145,429	98,56

# Statement of changes in equity – Parent Company

	Share capital	Additional paid in capital	Retained earnings	Shareholders' equity
	Restricted capital	Unrestricted	Unrestricted capital	
January 1, 2017	1,042	81,812	-10,318	72,535
Total comprehensive income			-7,660	-7,660
Transactions with owners				
Shares issued for cash	46	34,954		35,000
Expenses related to capital increase		-1,825		-1,825
December 31, 2017	1,088	114,941	-17,979	98,050
January 1, 2018	1,088	114,941	-17,979	98,050
Total comprehensive income			19	19
Transactions with owners				
Shares issued for cash	78	41,922		42,000
Expenses related to capital increase		-1,255		-1,255
December 31, 2018	1,166	155,607	-17,960	138,813

# Statement of cash flows – Parent Company

KSEK	Note	2018	2017
Profit/loss before tax		19	-7,660
Adjustments for non-cash transactions	29	-7,931	-826
Changes in working capital	29	-44,274	-23,419
Cash flow from operating activities before financial items	_	-52,186	-31,906
Interest income received		1,900	1,085
Interest expenses paid		-144	-259
Cash flow from operating activities		-50,430	-31,080
Investments in subsidiaries/associated companies		-	-331
Cash flow from investing activities		0	-331
Financing activities			
Convertible loan	25	6,000	-
New share issue	26	40,745	33,175
Cash flow from financing activities		46,745	33,175
Cash flow for the period		-3,685	1,765
Cash and cash equivalents at beginning of period		17,120	15,355
Cash and cash equivalents at end of period		13,435	17,120

# Notes to the consolidated and Parent Company's financial statements

### NOTE 1 GENERAL INFORMATION

The Annual Report for Saniona AB 2018 was approved for publication by decision of the Board on April 30, 2019. The Annual Report will be submitted to the Annual General Meeting (AGM) for adoption on May 29, 2019. 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 and eating disorders. 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 is listed on 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 BASIS OF PREPARATION

The consolidated financial statements have been prepared in accordance 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.

# NEW STANDARDS AND INTERPRETA-TIONS FROM 2018 AND LATER

International Accounting Standards Board (IASB) has issued several new and amended standards of which two came into effect in 2018 and one in 2019. The standard which came into effect in 2019 has not been early adopted. The new standard and the relevance for the Group's financial statements are set-out below.

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

This is a new standard for financial instruments that replaced IAS 39. The standard came into effect on January 1, 2018. The new standard has not have any material impact on the classifications and valuations of the Group's financial statements since the Group has had no derivative instruments, the Groups receivables are non-material and the Group's cash position at bank accounts as of December 31, 2018, is hold at a bank with a high credit rating (Moody's: P-1 and Aa3 short-term and long-term, see note 19).

# IFRS 15 Revenue from contracts with customers

The standard came into effect on January 1, 2018. The standard replaced 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 recognized 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. IFRS 15 did not have any material impact on the financial statements since the company has recognized revenues based on industry practice and interpretation similar to the principles now described in IFRS 15.

#### **IFRS 16 Leases**

IFRS 16 Leasing will enter into force on January 1, 2019. Apart from rental agreements in relation to the company's premises, the company has no other lease commitments as of December 31, 2018. Therefore, the new standard will only impact the financial statements insofar as rental contracts for premises. This means that Saniona will recognize the value of its rental contract in relation to the company's premises as a lease asset and a lease liability in the balance sheet from January 1, 2019. Saniona has recognize the value of the rental contract, which will increase assets and liabilities with KSEK 4,171. Cash flow from operation activities will increase as a portion of lease payments will be classified as financing cash outflows.

#### BASIS OF CONSOLIDATION

The consolidated accounts include the Parent Company and companies in which the Parent Company directly or indirectly has control. Control is achieved when Saniona is exposed, or has rights, to variable returns from its involvement with an entity and has the ability to affect those returns through its power over the entity. The consolidated financial statements are prepared based on uniform accounting policies in all group entities. Consolidation of group entities is performed after elimination of all intra-group transactions, balances, income and expenses. Apart from the Parent Company, the current group enterprises comprise Saniona A/S.

#### FOREIGN CURRENCY TRANSLATION

For each of the reporting companies in the Group, a functional currency is determined. The functional currency is the currency used in the primary economic environment in which the individual reporting entity operates. Transactions in currencies other than the functional currency are transactions denominated in foreign currencies.

Transactions denominated in foreign currencies are translated into the functional currency at the exchange rate at the dates of the respective transactions. Exchange differences arising be¬tween the exchange rate at the transaction date and the exchange rate at the date of actual payment are recognized in the income statement under financial income or financial expense.

Receivables, payables and other monetary items denominated in foreign currencies that have not been settled at the balance sheet date are translated by applying the exchange rates at the balance sheet date. The difference between the exchange rate at the balance sheet date and the exchange rate at the date of the arising of the receivable or payable, or the exchange rate applied in the most recent financial report, is recognized in the income statement under financial income or financial expense.

For the purposes of presenting these consolidated financial statements, the assets and liabilities of the Group's foreign operations with functional currencies other than SEK are translated into SEK using exchange rates prevailing at the end of each reporting period. Income and expense items are translated at the average exchange rates for the period. Exchange differences arising, if any, are recognized in other comprehensive income and accumulated in currency translation reserve.

Foreign exchange adjustment of balances that are considered as part of the overall net investment in subsidiaries with functional currencies other than SEK are recognized directly in equity in the Consolidated Financial Statements in a separate reserve for currency translation.

#### INCOME STATEMENT Revenue recognition

The Group recognizes revenue from the research agreements, development and license agreements, biotech alliances, and other biotech business models. Revenue is measured based on the consideration to which the Group expects to be entitled in a contract with a customer and excludes amounts collected on behalf of third parties. Revenue consists of up-front payments, milestone payments, royalties and other income from research, development and license agreements.

The Group may receive up-front payments upon entering research and development agreements. Up-front payments that are attributable to subsequent research and/ or development activities are considered as prepayments and are recognized as contract liabilities and will subsequently be recognized as revenue over the expected contract period, that is revenue recognition over time. Revenue recognition is made linearly over the contract period as there is currently no other better method available to measure progress for the delivery of services under the applicable contract.

Non-refundable up-front payments that are not attributable to subsequent research and/or development activities or other delivery obligations are recognized as revenue when the contracts are signed.

Milestone payments that are attributable to specific milestone events as a consequence of previous research and/or development activities are recognized as revenues at a point in time when it is certain that the milestone criteria have been met, as this is considered to being equivalent with transfer of control.

Any future royalty revenues are recognized as revenue in accordance with the economic substance of agreements.

#### **Employee benefits**

Remuneration of employees in the form of salaries, bonuses, share-based payments, paid vacation, paid sickness absence, etc. and pensions are recognized in line with the remuneration being earned.

# Retirement benefit costs and termination benefits

Post-employment pensions and other remuneration are classified as defined-contribution or defined-benefit pension plans. The Group has only defined-contribution pension plans. For defined-contribution plans, the Group pays fixed contributions to a separate, independent legal entity and does not have any obligation to pay additional contributions. The Group's earnings are charged with expenses in line with the benefits being earned, which normally coincides with the time when the premium is paid.

#### Share-based payments

Saniona has established share-based incentive programs comprising equity-settled programs (warrant programs) to board members, employees and consultants providing similar services. The equity-settled sharebased payments are measured at the fair value of the equity instruments at the grant date. Details regarding the determination of the fair value of equity-settled share-based transactions are set out in note 3 and note 9. The fair value determined at the grant date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the Group's estimate of equity instruments that will eventually vest, with a corresponding increase in equity. At the end of each reporting period, the Group revises its estimate of the number of equity instruments expected to vest. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the equity-settled employee benefits reserve.

#### Net financials

Financial items comprise interest realized and unrealized currency translation adjustments and fair value adjustments of securities. Financial income and financial expenses are recognized in the income statement with the amounts related to the financial year.

# 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 2017 and 2018 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.

#### SEGMENT REPORTING

Operating segments are presented from the management's perspective, which means presented on the same basis that is used for internal reporting. 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. In internal reporting to the CEO, only one segment is used. For more information, see note 6.

### PROPERTY, PLANT AND EQUIPMENT

Plant and machinery, IT equipment, other fixtures and fittings, tools and equipment and leasehold improvements are measured at cost less accumulated depreciation. Cost comprises acquisition price and costs directly related to acquisition until the time when the Group starts using the asset. The basis for depreciation is cost less estimated residual value after the end of useful life. Assets are depreciated under the straight-line method over the expected useful lives of the assets. The depreciation periods are as follows:

Leasehold improvements	5 years
Plant and machinery	5 years
IT equipment	3 years
Other fixtures and fittings,	
tools and equipment	2-3 years

Profits and losses arising from disposal of plant and equipment are stated as the difference between the selling price less the selling costs and the carrying amount of the asset at the time of the disposal. Profits and losses are recognized in the income statement under research and development expenses and administrative expenses.

# IMPAIRMENT OF NON-CURRENT ASSETS

The carrying amount of property, plant and equipment as well as non-current asset investments is reviewed for impairment when events or changed conditions indicate that the carrying amount may not be recoverable. If there is such an indication, an impairment test is made. An impairment loss is recognized in the amount with which the carrying amount exceeds the recoverable amount of the asset, which is the higher of the net present value and the net selling price. In order to assess the impairment, the assets are grouped on the least identifiable group of assets that generates cash flows (cash flow generating units). Impairments are recognized in the income statement under the same items as the related depreciation and amortization.

#### FINANCIAL INSTRUMENTS

Financial assets and financial liabilities are recognized in the Group's statement of financial position when the Group becomes a party to the contractual provisions of the instrument. Financial assets and financial liabilities are initially measured at fair value. Transaction costs that are directly attributable to the acquisition or issue of financial assets and financial liabilities (other than financial assets and financial liabilities at fair value through profit or loss) are added to or deducted from the fair value of the financial assets or financial liabilities, as appropriate, on initial recognition. Transaction costs directly attributable to the acquisition of financial assets or financial liabilities at fair value through profit or loss are recognized immediately in profit or loss.

#### FINANCIAL ASSETS

All regular way purchases or sales of financial assets are recognized and derecognized on a trade date basis. All recognized financial assets are measured subsequently in their entirety at either amortized cost or fair value, depending on the classification of the financial assets.

#### Classification of financial assets

Debt instruments that meet the following conditions are measured subsequently at amortized cost:

- the financial asset is held within a business model whose objective is to hold financial assets in order to collect contractual cash flows; and
- the contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Debt instruments that meet the following conditions are measured subsequently at fair value through other comprehensive income (FVTOCI):

- the financial asset is held within a business model whose objective is achieved by both collecting contractual cash flows and selling the financial assets; and
- the contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

By default, all other financial assets are measured subsequently at fair value through profit or loss (FVTPL).

The Group has only financial assets in the form of debt instruments subsequently measured at amortized cost being loans and receivables and cash and cash equivalents.

# Amortized cost and effective interest method

The effective interest method is a method of calculating the amortized cost of a debt instrument and of allocating interest income over the relevant period. The amortized cost of a financial asset is the amount at which the financial asset is measured at initial recognition minus the principal repayments, plus the cumulative amortization using the effective interest method of any difference between that initial amount and the maturity amount, adjusted for any loss allowance. Interest income is recognized using the effective interest method for debt instruments measured subsequently at amortized cost.

#### Impairment of financial assets

The Group recognizes a loss allowance for expected credit losses (ECL) on investments in trade receivables. The amount of expected credit losses is updated at each reporting date to reflect changes in credit risk since initial recognition of the respective financial instrument. The Group always recognizes lifetime ECL for trade receivables. The expected credit losses on these financial assets are estimated using a provision matrix based on the Group's historical credit loss experience, adjusted for factors that are specific to the debtors, general economic conditions and an assessment of both the current as well as the forecast direction of conditions at the reporting date, including time value of money where appropriate.

Cash and cash equivalents are subject to impairment under the requirements for ECL, but for cash and cash equivalents the low credit risk exemption is used. The Group measures the loss allowance at an amount equal to lifetime ECL at the current reporting date using the simplified approach.

#### Definition of default

The Group considers the following as constituting an event of default for internal credit risk management purposes as historical experience indicates that financial assets that meet either of the following criteria are generally not recoverable:

- when there is a breach of financial covenants by the debtor; or
- information developed internally or obtained from external sources indicates that the debtor is unlikely to pay its creditors, including the Group, in full (without taking into account any collateral held by the Group).

Irrespective of the above analysis, the Group considers that default has occurred when a financial asset is more than 90 days past due unless the Group has reasonable and supportable information to demonstrate that a more lagging default criterion is more appropriate.

#### Write-off policy

The Group writes off a financial asset when there is information indicating that the debtor is in severe financial difficulty and there is no realistic prospect of recovery, e.g. when the debtor has been placed under liquidation or has entered into bankruptcy proceedings, or in the case of trade receivables, when the amounts are over two years past due, whichever occurs sooner.

#### Derecognition of financial assets

The Group derecognizes a financial asset only when the contractual rights to the cash flows from the asset expire, or when it transfers the financial asset and substantially all the risks and rewards of ownership of the asset to another entity. If the Group retains substantially all the risks and rewards of ownership of a transferred financial asset, the Group continues to recognize the financial asset and also recognizes a collateralized borrowing for the proceeds received. On derecognition of a financial asset measured at amortized cost, the difference between the asset's carrying amount and the sum of the consideration received and receivable is recognized in profit or loss.

### FINANCIAL LIABILITIES AND EQUITY Classification as debt or equity

Debt and equity instruments are classified as either financial liabilities or as equity in accordance with the substance of the contractual arrangements and the definitions of a financial liability and an equity instrument.

#### FINANCIAL LIABILITIES

All financial liabilities are measured subsequently at amortized cost using the effective interest method or at FVTPL. The Group have only financial liabilities subsequently measured at amortized cost in the form of trade payables.

# Financial liabilities measured subsequently at amortized cost

Financial liabilities that are not held-for-trading, or designated as at FVTPL, are measured subsequently at amortized cost using the effective interest method. The effective interest method is a method of calculating the amortized cost of a financial liability and of allocating interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) through the expected life of the financial liability, or (where appropriate) a shorter period, to the amortized cost of a financial liability.

#### Derecognition of financial liabilities

The Group derecognizes financial liabilities when, and only when, the Group's obligations are discharged, cancelled or have expired. The difference between the carrying amount of the financial liability derecognized and the consideration paid and payable is recognized in profit or loss.

# Foreign exchange gains and losses on financial assets and liabilities

The carrying amount of financial assets that are denominated in a foreign currency is determined in that foreign currency and translated at the spot rate at the end of each reporting period. For financial assets measured at amortized cost that are not part of a designated hedging relationship, exchange differences are recognized in profit or loss (note 11).

For financial liabilities that are denominated in a foreign currency and are measured at amortized cost at the end of each reporting period, the foreign exchange gains and losses are determined based on the amortized cost of the instruments. These foreign exchange gains and losses are recognized in profit or loss (note 11).

#### EQUITY INSTRUMENTS

The Group entered into a convertible notes funding agreement with Nice & Green. Please see note 25 for further information.

#### PREPAID EXPENSES

Prepaid expenses comprise incurred expenses related to the following financial year.

# TAX ASSETS, TAX PAYABLE AND DEFERRED TAX

Current tax liabilities and current tax receivables are recognized in the statement of financial position as tax calculated on the taxable income for the year adjusted for tax on previous years' taxable income and taxes paid on account/prepaid. 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.

Deferred tax is calculated on all temporary differences between accounting and tax values. Deferred taxes are measured according to current tax rules and at the tax rates expected to be in force on the elimination of the temporary differences. Any changes in deferred tax because of amendments to tax rates are recognized in the income statement. Deferred tax arising on tax-deductible temporary differences (tax assets) is included in the balance sheet only if there is reasonable certainty that the tax assets can be set off by Saniona A/S against future taxable income. The amounts of tax-deductible temporary differences which are not capitalized are disclosed in a note to the Financial Statements of the annual report.

#### PREPAYMENTS FROM CUSTOMERS

Prepayments from customers comprise payments for future research services under the Group's research collaborations.

#### STATEMENT OF CASH FLOWS

The statement of cash flows shows the cash flow for the year together with the cash and cash equivalents at the beginning and end of the period. The statement of cash flows is prepared according to the indirect method. For the consolidated cash flow statement, cash flows from foreign subsidiaries are translated at average exchange rates for the respective quarters as presented in the quarterly reports.

#### Cash flow from operating activities

Cash flows from operating activities represent the net result adjusted for non-cash transactions, other provisions, changes in working capital, net financial items and income taxes paid.

#### Cash flow from investment activities

Cash flows from investing activities include cash flows from the purchase and sale of intangible assets, property, plant and equipment, long-term financial assets and marketable securities with original maturities of more than three months.

#### Cash flow from financing activities

Cash flows from financing activities include cash flows from capital increases, the raising and repayment of long-term debt and financial items.

#### Cash and cash equivalents

Cash and cash equivalents comprise cash and deposits held at the Groups monetary market accounts, short-term investments with original maturities of three months or less and bank overdrafts.

### ACCOUNTING POLICIES FOR THE PARENT COMPANY

The Parent Company applies the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2, Accounting for Legal Entities. The application of RFR 2 means that as far as possible, the Parent Company applies all IFRS as endorsed by the EU within the auspices of the Swedish Annual Accounts Act and the Swedish Pension Obligations Vesting Act and considering the relationship between accounting and taxation. The differences between the Parent Company's and the Group's accounting policies are reviewed below:

#### Classification and presentation

The Parent Company presents a separate Statement of Comprehensive Income, separately from the Income Statement.

# Investments in subsidiaries and associates

Investments in subsidiaries are recognized at cost in the Parent Company's financial statements. Dividends are recognized in the income statement.

Investments in associates is recognized in the balance sheet in accordance with the equity method and taken to the profit and loss statement as a financial income or expense.

# NOTE 3 CRITICAL ACCOUNTING JUDGEMENTS AND KEY SOURCES OF ESTIMATION UNCERTAINTY

In the statement of the carrying amounts of certain assets and liabilities estimates are required on how future events will affect the carrying amounts of these assets and liabilities at the balance sheet date.

The used estimates are based on assumptions assessed reasonable by management, however, estimates are inherently uncertain and unpredictable. The assumptions can be incomplete or inaccurate and unexpected events or circumstances might occur. Furthermore, the enterprise is subject to risks and uncertainties that might result in deviations in actual results compared to estimates.

#### REVENUE

Evaluating the criteria for revenue recognition with respect to the Group's research and development and collaboration agreements requires management's judgment to ensure that all criteria have been fulfilled prior to recognizing any amount of revenue. Such judgments are made with respect to determination of the nature of transactions, whether simultaneous transactions shall be considered as one or more revenue-generating transactions, allocation of the contractual price (upfront and milestone payments subscribed in connection with a collaboration agreement) to several elements included in an agreement, and the determination of the control has been transferred to the buyer. Collaboration agreements are reviewed carefully to understand the nature of risks and rewards of the arrangement.

All the Group's revenue-generating transactions, including those with Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and Cadent Therapeutics Inc. have been subject to such evaluation by management.

The Group did not receive any upfront payments in 2017 and 2018. Upfront payments under the agreements mentioned above were recognized as revenue when the contracts were signed since these upfront payments were non-refundable and not attributable to subsequent research and/ or development activities or other delivery obligations when the contracts were signed.

### SHARE-BASED PAYMENTS

In accordance with IFRS 2 "Share-based Payment", the fair value of the warrants, classified as equity settled, are measured at grant date and is recognized as an expense in the income statement over the vesting period and the period of delivery of work. Subsequently, the fair value is not re-measured. The fair value of each warrant granted during the year is calculated using the Black Scholes pricing model. This pricing model requires the input of subjective assumptions such as:

- The expected stock price volatility, which is estimated using the historical volatility of Saniona's stock price;
- The risk-free interest rate, which is determined as the interest rate on Swedish zero-coupon government bond with a maturity of 4-5 years equivalent to the expected life of the granted warrants;
- The expected life of warrants, which is based on vesting terms, expected rate of exercise and life terms in current warrant program.

These assumptions can vary over time and can change the fair value of future warrants granted. For more information, see note 9.

#### DEFERRED TAX

The Group has unused tax losses. The Group recognizes deferred tax assets, including the tax base of tax loss carry-forwards, if management assesses that these tax assets can be offset against positive taxable income within a foreseeable future. This judgment is made on an ongoing basis and is based on budgets and business plans for the coming years, including planned commercial initiatives. The creation and development of therapeutic products within the biotechnology and pharmaceutical industry is subject to considerable risks and uncertainties.

#### INTANGIBLE ASSETS Research and Development

According to the IAS 38, "Intangible Assets," intangible assets arising from development projects should be recognized in the statement of financial position. The criteria that must be met for capitalization are that:

- The development project is clearly defined and identifiable and the attributable costs can be measured reliably during the development period;
- The technological feasibility, adequate resources to complete and a market for the product or an internal use of the product can be documented; and
- Management has the intent to produce and market the product or to use it internally.

Such an intangible asset should be recognized if sufficient certainty can be documented that the future income from the development project will exceed the aggregate cost of production, development and the sale and administration of the product. A development project involves a single product candidate undergoing a high number of tests to illustrate its safety profile and the effect on human beings prior to obtaining the necessary final approval of the product from the appropriate authorities. The future economic benefits associated with the individual development projects are dependent on obtaining such approval. 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 associated with the individual projects cannot be estimated with sufficient certainty until the project has been finalized and the necessary regulatory final approval of the product has been obtained. Accordingly, Saniona has not recognized such assets at this time and therefore all research and development costs are recognized in the income statement when incurred.

#### Acquired intangible assets

Saniona purchased 15 research and development programs and technical platforms from NeuroSearch A/S in 2012, two additional clinical programs from NeuroSearch A/S in 2014 and two programs from NeuroSearch A/S in 2016. According to the Saniona Board's assessment, NeuroSearch A/S and its partners had invested SEK 2-3 billion in these projects and technical platforms prior to the buy-out taking place. Saniona did not capitalize any amount attributable to these buyouts in its accounts since the agreement was that no purchase consideration was to be paid for the buyouts and instead the future sales revenues that may arise are to be distributed between Saniona and NeuroSearch A/S.

# NOTE 4 FINANCIAL RISK MANAGEMENT

The Group is exposed to various kinds of risks that may impact the Group's results and financial position. The risks can be divided into operational risks and financial risks. Operational risks are described in a separate section in the Directors' report. Financial risks relate to a potential negative impact on the financial position resulting from changes in the financial risk factors. The Board of Directors is ultimately responsible for the exposure, management and monitoring of the Group's financial risks. The Board of Directors sets the framework that applies to the exposure, management and monitoring of the financial risks and this framework is evaluated and revised yearly. The Board of

Directors can decide on temporary departures from its predetermined framework. Below is a description of the financial risk factors that are deemed the most significant for Saniona, and the management of them.

#### MARKET RISKS

Market risks primarily consist of interest risk and currency risk.

#### Currency risks

Currency risks means 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, termed transaction exposure, 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, called balance exposure.

The currency exposure is mainly attributable to the net investment in Saniona since the majority of the Group's operations takes place in the Danish subsidiary, which functional currency is DKK. Income from the Group's partnerships mainly consist of USD and EUR. Internal operational costs mainly consist of DKK and some in SEK whereas external development costs mainly consist of EUR and USD. Consequently, the Group's outflows mainly consist of DKK, EUR and USD and some in SEK, whereas the Group's inflows from operation mainly consist of EUR and USD. The Group's inflows from financing activities consist of SEK.

The Group does not hedge its transaction exposure. The Group's transaction exposure to currency risk between EUR and DKK is limited and between DKK and SEK moderate. The management of the risks in relation to USD is focused on risk mitigation, which is somewhat mitigated by income and cost incurred in USD. The Danish subsidiary represents a significant share of the Group's total assets, and accordingly, the Group is subject to some balance exposure resulting from the translation of DKK to SEK.

#### Interest risks

Interest risk means the risk that fair value or future cash flows fluctuates as a result of changed market interest rates. The group has no loans, and accordingly, any exposure to interest risk is limited.

#### LIQUIDITY AND FINANCING RISK

Liquidity risk means the risk that the Group encounters difficulties in satisfying commitments related to the Group's financial liabilities. Financing risk means the risk that the Group is unable to arrange sufficient finance for a reasonable cost. The Group is financed through equity and has no financial borrowings. Current liabilities amount to KSEK 43,617 (2017: 10,747) and mature within one year. Trade payables mature within three months. The Group's current receivables that become due within one-year amount to KSEK 15,990 (18,256). The Group has cash and cash equivalents of KSEK 54,678 (22,313).

#### **CREDIT AND COUNTERPART RISK**

Credit risk means the risk that a counterpart in a transaction generates a loss for the Group by being unable to satisfy its contracted obligations. 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 2018.

Credit risk may also arise if the Group's surplus liquidity is invested in various types of financial instrument. The Board of Directors' predetermined framework stipulates that surplus liquidity shall be hold at the Group's monetary market accounts at the Group's bank, Nordea A/S.

The credit risk is judged to be limited.

#### MEASUREMENTS OF FINANCIAL INSTRUMENTS

All financial asset and financial liabilities, except for the investment in Cadent Therapeutics as described below, are classified as 'Loans and receivables' and 'Other financial liabilities' respectively. 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 2017 and 2018.

The Group owns 3.4% 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 Ataxiaprogram. 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.

#### CAPITAL

The Group's aim for managing its capital is to ensure the Group's capacity to continue its operations to generate a reasonable return to shareholders and benefit other stakeholders. The Group is funded through equity, which amounts to KSEK 39,457 (37,628). The Group's current policy is not to pay any dividend. A proposal on dividend to shareholders will not be possible until the Group achieves long-term profitability.

# NOTE 5 INTERCOMPANY TRANSACTION

Purchases between the Parent Company and subsidiaries amounted to KSEK 1,452 (1,260) and sales between the Parent Company and subsidiaries to KSEK 1,354 (1,269). The Parent Company recognized an interest income of KSEK 1,900 (1,085) pertaining to loans from the subsidiary. The Parent Company has receivables of KSEK 112,424 (69,062) in subsidiaries.

# NOTE 6 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 comprise only one business unit, and the Group therefore has only one operating segment, for which reason no segment information is provided.

Revenue consists of up-front payments, milestone payments, royalties and other income from research, development and license agreements

In 2018 Saniona's largest customers were Boehringer Ingelheim and BenevolentAl with combined sales of KSEK 54,884 (20,602 Boehringer Ingelheim, BenevolentAl and Cadent Therapeutics) corresponding to 100 percent (100) of the Group's revenues. See note 7 regarding the distribution of revenues by geographic territory.

# NOTE 7 NET SALES

	G	Group		Company
KSEK	2018	2017	2018	2017
Sweden	-	-	-	-
Other European countries	54,884	18,832	-	-
USA	-	1,860	-	-
Total	54,884	20,692	0	0

#### Prepayments from customers

	Group		Parent Compa	
KSEK	2018	2017	2018	2017
Contract liabilities:				
Prepayment from customers	-	604	-	-
Total	0	604	0	0
Whereof:				
Non-current liabilities	-	-	-	-
Current liabilities	-	604	-	-
Total	0	604	0	0
Contract liability at January 1	604	3,006	-	-
Additions	-	604	-	-
Revenue recognized	604	3,006	-	-
Carrying amount December 31	0	604	0	0

# NOTE 8 AUDITORS FEES AND REMUNERATION

	Gr	Group		Company
KSEK	2018	2017	2018	2017
Deloitte				
Audit assignment	474	433	290	245
Audit activities other than audit assignment	335	897	239	733
Tax consultancy services	28	76	18	18
Other assignments	89	-	<u> </u>	-
Total	829	1,406	547	996

# NOTE 9 NUMBER OF EMPLOYEES, SALARIES, OTHER REMUNERATION AND SOCIAL SECURITY EXPENSES

The average number of employees in the Group during the year amounted to 23.5 (24.1), of whom 12.2 (13.7) were women.

As of December 31, the number of employees including the CEO was 25 (26) of which 13 (14) were women. The CEO and all the employees are based in Denmark. Of these employees, 22 (23) were full-time employees 3 (3) were part-time employees, and a total of 20 (21) work in the Group's research and development operations. The level of education among the personnel is high, 12 employees (12) hold PhDs, 2 (3) have university degrees, 8 (8) have laboratory training and 3 (3) have other degrees. In addition to its employees Saniona has several consultants who work with the Group on an ongoing basis.

#### Salaries and remuneration for the year 2018 Group and Parent Company

		•					
KSEK	Board fee	Basic salary	Pension costs	Share based payment	Social security expenses	Other staff expenses	Total
J. Donald deBethizy, Chairman*	275	\ -	-	878	-	-	1,153
Claus Bræstrup, Board member	-	-	-	-	-	-	-
Carl Johan Sundberg, Board member*	110	-	-	-	35	-	145
Anna Ljung, Board member*	140	÷	-	-	44	-	184
Jørgen Drejer, CEO and Board member*	-	1,656	-	-	5	26	1,687
Thomas Feldthus, CFO	-	1,973	197	-	5	26	2,201
Palle Christophersen, CSO	-	1,316	-	-	5	26	1,347
Total CEO, CFO and CSO	0	4,945	197	0	15	78	5,235
Other Employees	-	14,756	1,512	608	99	527	17,502
Total	525	19,701	1,709	1,486	193	605	24,219

\*The board fee to J. Donald deBethizy, Carl Johan Sundberg, Anna Ljung and the salary to Jørgen Drejer relates to fee and salaries in the Parent Company

#### Salaries and remuneration for the year 2017 Group and Parent Company

Board Basic Pension based secu		-	-					
Leif Andersson, Board memberCarl Johan Sundberg, Board member*133Jørgen Drejer, CEO and Board member-1,125-Thomas Feldthus, CFO-1,696170Palle Christophersen, CSO-1,161-Total CEO, CFO and CSO03,9821700Other employees-15,4661,408359	SEK				based	Social security expenses	Other staff expenses	Total
Carl Johan Sundberg, Board member*       133       -       -         Jørgen Drejer, CEO and Board member       -       1,125       -         Thomas Feldthus, CFO       -       1,696       170       -         Palle Christophersen, CSO       -       1,161       -       -         Total CEO, CFO and CSO       0       3,982       170       0         Other employees       -       15,466       1,408       359	aus Bræstrup, Chairman	-	-	-	-	-	-	<u> </u>
Jørgen Drejer, CEO and Board member       -       1,125       -       -         Thomas Feldthus, CFO       -       1,696       170       -         Palle Christophersen, CSO       -       1,161       -       -         Total CEO, CFO and CSO       0       3,982       170       0         Other employees       -       15,466       1,408       359	if Andersson, Board membe	r -	-	-	-	-	-	-
Thomas Feldthus, CFO       -       1,696       170       -         Palle Christophersen, CSO       -       1,161       -       -         Total CEO, CFO and CSO       0       3,982       170       0         Other employees       -       15,466       1,408       359	arl Johan Sundberg, Board m	ember* 133	-	-	-	-	-	133
Palle Christophersen, CSO         -         1,161         -         -           Total CEO, CFO and CSO         0         3,982         170         0           Other employees         -         15,466         1,408         359	rgen Drejer, CEO and Board	member -	1,125	-	-	3	45	1,173
Total CEO, CFO and CSO         0         3,982         170         0           Other employees         -         15,466         1,408         359	iomas Feldthus, CFO	-	1,696	170	-	3	45	1,914
Other employees         -         15,466         1,408         359	alle Christophersen, CSO	_	1,161	-	-	3	45	1,209
	tal CEO, CFO and CSO	0	3,982	170	0	9	135	4,296
Total 133 19,448 1,578 359	her employees	-	15,466	1,408	359	65	944	18,242
	tal	133	19,448	1,578	359	74	1,079	22,671

\*The board fee to Carl Johan Sundberg relates to fee in the Parent Company.

#### SHARE BASED PAYMENTS

The company had five options programs as of December 31, 2018.

### 2015

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 Parent 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 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 quarterly report for the third quarter of 2019.

# 2017

The 2017 Annual General Meeting voted in favor of establishing an employee incentive program involving the allotment of a maximum of 38,750 options free of charge to certain employees and consultants of the Group. Allotment of 38,750 employee options took place in July 2017. Each employee option will entitle the holder to acquire one new share in Saniona for a subscription price of SEK 41.13 corresponding to 100% of the average closing price of the Parent Company's share during the ten trading days after the annual meeting 2017. 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 third quarter of 2022.

### 2018:1

On January 19, 2018, the extraordinary shareholders' meeting voted in favor of establishing an incentive program involving the allotment of a maximum of 217,625 options free of charge to the chairman of the board of directors, J. Donald deBethizy. Allotment of 217,625 options took place in March 2018. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 33.60. 25% of the options vested on January 19, 2018, when the holder was elected as chairman of the Board of Directors. The balance of the options is earned with 25% on each anniversary of the election as chairman of the Board of Directors over a period of 3 years. The holder 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, the year-end report, the first time after publication of the quarterly report for the first guarter of 2021 and last time after publication of the quarterly report for the first quarter of 2024. In order to enable the Parent Company's delivery of shares under the option program and to secure social security charges which may arise in connection with the Option Program, the extraordinary shareholders' meeting resolved to issue a maximum of 286,003 warrants to a wholly owned subsidiary in the Group.

#### 2018:2

The 2018 Annual General Meeting voted in favor of establishing an employee incentive program involving the allotment of a maximum of 34,500 options free of charge to certain employees and consultants of the Group. Allotment of 34,500 options took place in July 2018. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 30.08. 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, the yearend report, the first time after publication of the quarterly report for the first quarter of 2022 and last time after publication of the quarterly report for the third quarter of 2023.

#### 2018:3

The 2018 Annual General Meeting voted in favor of establishing an employee incentive program involving the allotment of a maximum of 8,000 options free of charge to certain members of the board of directors of the Group. Allotment of 8,000 options took place in July 2018. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 30.08. 1/3 of the options are vested when the annual shareholders' meeting takes place in 2019. Additional 1/3 of the options are vested when the annual shareholders' meeting takes place in 2020 and the last 1/3 of the options are vested when the annual shareholders' meeting takes place in 2021. The holder 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, the year-end report, the first time after publication of the quarterly report for the first quarter of 2021 and last time after publication of the guarterly report for the first quarter of 2022. To enable the Parent Company's delivery of shares under the option program and to secure social security charges which may arise in connection with the Option Program, the extraordinary shareholders' meeting resolved to issue a maximum of 10,513 warrants to a wholly owned subsidiary in the Group.

The fair value of the options was determined using the Black-Scholes pricing model. The data below has been used for the calculation.



Incentive program	2015	2017	2018:1	2018:2	2018:3
Allotted options	64,000	38,750	286,003	34,500	10,513
Fair value per option (SEK)	13.13	29.48	12.67	18.89	18.89
Share price for underlying shares (SEK)	19.90	45.50	26.95	33.85	33.85
Subscription price (SEK)	20.72	41.13	33.60	30.08	30.08
Vesting period	4 years	4 years	3 years	4 years	3 years
Estimated life of the option	4.50 years	5.50 years	6.25 years	5.5 years	4 years
Risk-free interest rate during the life of the option	0.2257%	-0.0584%	0.2389%	-0.0713%	-0.0713%
Assumed volatility*	91.29%	76.75%	57.41%	63.58%	63.58%
Expected dividends	0	0	0	0	0

\* In 2015 and 2017, the volatility equals the historical volatility for the longest period where trading activity is available (for the period since listing at the Spotlight Stock Market on April 22, 2014 to date of grant). In 2018, the volatility equals a twelve-month period.

Share-based compensation expenses for the full year of 2018 totaled SEK 1,518 (359) thousand. The Group accounts for sharebased 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. According to the table below, the Group had 433,308 (102,292) options outstanding as of December 31, 2018. If all issued warrants are exercised for subscription of new shares, the Parent Company's will issue a total of 433,308 new shares corresponding to a dilution of approximately 1.82%.

	Options granted in 2015	Options granted in 2017	Options granted in 2018	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	0	102,292
Outstanding at 1 January 2018	64,000	38,292	-	102,292
Granted during the period	-	-	331,016	331,016
Forfeited during the period	-	-	-	-
Outstanding at 31 December 2018	64,000	38,292	331,016	433,308

# NOTE 10 FINANCIAL INCOME

	G	Group		ompany
KSEK	2018	2017	2018	2017
Interest income	-	-	1,900	1,085
Foreign exchange gains	-	1,289	-	-
Total	0	1,289	1,900	1,085

# NOTE 11 FINANCIAL EXPENSES

		Group		Company
KSEK	2018	2017	2018	2107
Interest expense	159	376	81	141
Foreign exchange losses	102	-	63	118
Total	261	376	144	259

# NOTE 12 TAX

### TAX FOR THE YEAR

	Group		Parent C	ompany
KSEK	2018	2017	2018	2107
Current tax on net profit for the year	-7,568	-7,276	-	-
Deferred taxes attributable to temporary differences	-62	-89	-	-
Adjustments tax previous year	151	-	-	-
Exchange rate adjustments	246	279	-	-
Recognized tax on net profit for the year	-7,233	-7,086	0	0

Income tax in Sweden is calculated at 22% (22%) and in Denmark 22% (22%) of taxable profit for the year.

# RECONCILIATION OF EFFECTIVE TAX

A reconciliation of recognized profit and the tax expense for the year is presented below.

	Group		Parent	Company
KSEK	2018	2017	2018	2107
Recognized profit/loss before tax	-48,292	-56,275	19	-7,660
Tax according to the applicable tax rate	-10,624	-12,381	4	-1,685
Tax effect of non-deductible income	-	-	-	-
Tax effect of non-deductible expenses	-11	-9	-	-
Tax effect on deductible costs in relation to share issues taken to equity	-1,256	-402	1,256	-402
Not utilized tax losses carry forward	3,776	5,653	-1,251	2,087
Exchange rate adjustments	1,005	42	-	-
Current Tax	-7,110	-7,096	0	0
Change in deferred tax	28	10	-	-
Adjustments tax previous year	-151	-	-	-
Recognized tax on net profit for the year	-7,233	-7,086	0	0
Applicable tax rates	22%	22%	22%	22%

## TAX LOSS CARRIED FORWARD

The Group has generated an accumulated loss since inception. However, the company management cannot assess when it will be possible to utilize the tax loss carry forwards. Accordingly, deferred tax assets attributable to loss carry forwards have been recognized to the extent that they can be offset against deferred tax liabilities. There is no time limit for the use of the loss carry forwards.

	Group		Parent (	Company
KSEK	2018	2017	2018	2107
Loss carried forward January 1 for which no deferred tax assets were recognized	43,385	17,688	27,174	17,688
Loss carried forward for which no deferred tax assets were recognized	17,854	25,696	5,688	9,485
Loss carried forward December 31 for which no deferred tax assets were recognized	61,238	43,385	32,862	27,174

The Group has an accumulated unrecognized deferred tax asset of KSEK 13,472 (9,545). Deferred tax assets are not recognized since the tax assets are currently not deemed to meet the criteria for recognition as management is not able to provide any convincing positive evidence that deferred tax assets should be recognized.

# NOTE 13 EARNINGS PER SHARE

	Group	
KSEK	2018	2017
Net profit/(loss) (KSEK)	-41,059	-49,190
Average number of outstanding shares (in thousands)	22,289	21,417
Earnings per share for the year (SEK)	-1.84	-2.30
Diluted earnings per share for the year (SEK)	-1.84	-2.30

Earnings/loss per share after dilution is the same as before dilution in 2018, since the result is negative in 2018. This is because dilution effect is only recognized when a potential conversion to ordinary shares would mean that earnings per share will be lower.

# NOTE 14 TANGIBLE ASSETS

	G	iroup	Parent Co	mpany
KSEK	2018	2017	2018	2107
Cost at January 1	4,469	3,513	÷	-
Additions	1,107	708	-	-
Foreign exchange adjustment	128	248	-	- \
Cost at December 31	5,704	4,469	0	0
Depreciation at January 1	3,103	2,328	-	-
Depreciation	632	561	-	-
Foreign exchange adjustment	128	214	-	-
Depreciation at December 31	3,863	3,103	0	0
Carrying amount December 31	1,841	1,366	0	0

# NOTE 15 DEPRECIATION

		Group		Company
KSEK	2018	2017	2018	2107
Depreciation	632	561	-	-
Total	632	561	0	0

## NOTE 16 TRADE RECEIVABLES

As of December 31, 2018, the Group had KSEK 2,093 (7,180) in trade receivables. In 2018, trade receivables comprised FTE payment from Boehringer Ingelheim (Q4). In 2017, trade receivables comprised primarily FTE payment from Boehringer Ingelheim (Q4) and reimbursement of costs from Medix.

### NOTE 17 CURRENT TAX ASSETS

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. As of December 31, 2018, the Group had recorded current tax assets under the Danish R&D tax credit scheme of KSEK 7,568 (7,276).

# NOTE 18 OTHER RECEIVABLES, PREPAYMENTS AND ACCRUED INCOME

	Group		Parent C	ompany
KSEK	2018	2017	2018	2017
VAT reimbursement	2,241	2,207	257	122
Other receivables	2,413	1,054	-	-
Total other receivables	4,654	3,261	257	122
Prepaid costs*	1,675	540	977	95
Total prepaid expenses and accrued income	1,675	540	977	95

\*Prepaid costs concern research activities, insurance, subscriptions, etc.

The carrying amount of other receivables largely corresponds to the fair value. Other receivables are not subject to any material credit risk as they primarily concern prepaid costs and VAT.

# NOTE 19 CASH AND CASH EQUIVALENT

	G	iroup	Parent	Company
KSEK	2018	2017	2018	2017
Money market accounts	54,678	22,313	13,435	17,120
Total	54,678	22,313	13,435	17,120

The credit risk involved in cash is handled by only collaborating with financial institutions with satisfactory creditworthiness. No significant credit risk is considered to exist in relation to cash as the counterparty is Nordea, which has Moody's rating of P-1 and Aa3 short-term and long-term, respectively.

### NOTE 20 RELATED PARTIES

#### SANIONA RELATED PARTIES

Related parties comprise the Group's Executive Management, Board of Directors and companies within the Group.

### TRANSACTION WITH RELATED PARTIES

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 2017 and 2018, please see note 5 and note 9.

During the year, there were no transactions with Scandion Oncology A/S in 2017 and 2018.



# NOTE 21 CONTINGENT ASSETS, PLEDGED ASSETS, CONTINGENT LIABILITIES AND COMMITMENTS

### Pledged assets and contingent liabilities

The Group has KSEK 50 in contingent liabilities towards Euroclear.

	Gro	oup	Parent Co	ompany
KSEK	2018	2017	2018	2017
Pledged assets				
Bank balances	-	-	-	-
Contingent liabilities				
Guarantees	50	50	-	-
Guarantees for Group companies	-	-	-	-

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, 2020. Saniona A/S had no external net debt as of December 31, 2018.

#### CONTRACTUAL OBLIGATIONS

The Group has entered into a Research Collaboration with Boehringer Ingelheim, and Cadent Therapeutics where the Group provides research activities on fee for service arm's length basis. The Group has no material contractual obligations as of December 31, 2018. There is no material change of control clauses in the Group's partnership agreement.

### Unrecognized rental and lease commitments

	Group		Parent Company	
KSEK	2018	2017	2018	2017
Commitments under rental agreements or leases until expiry	1,142	1,179	-	-
Total	1,142	1,179	0	0

The above amounts relate to rental of the Group's domicile in Ballerup Denmark and cover the notice period, which is 9 months.

# NOTE 22 ACCRUED EXPENSES AND DEFERRED INCOME

	Group		Parent	Company
KSEK	2018	2017	2018	2017
Accrued social security expenses	29	28	-	-
Accrued vacation pay liability	2,603	3,463	-	-
Other accrued expenses	1,183	932	-	-
Reimbursement of costs	25,944	-	-	-
Total	29,759	4,423	0	0

### NOTE 23 INVESTMENTS IN SUBSIDIARIES

Specification of Parent Company's holding of shares and participations in Group Companies

Subsidiary / Corp. Reg. No. / Domicile	Share of equity	Share of voting power	Carrying amount KSEK
Saniona A/S / DK34049610 / Ballerup, Denmark	100%	100%	11,832

## Cost

KSEK	2018	2017
Opening cost	11,832	11,832
Acquisitions for the year	-	-
Closing cost	11,832	11,832
Carrying amount at year-end	11,832	11,832

As of December 31, 2018, equity in Saniona A/S equals KSEK -87,525 (-48,590).

## NOTE 24 OTHER SECURITIES HELD AS NON-CURRENT ASSETS

Specification of subsidiary's holding of shares and participations in other companies

Company / domicile	Share of	Share of voting	Carrying amount
	equity	power	KSEK
Cadent Therapeutics, Inc. / Cambridge, MA, USA	3.4%	3.4%	-

The ownerships in Cadent Therapeutics, Inc. is 3.4% following Cadent Therapeutics financing of USD 40 million in 2018.

# NOTE 25 CONVERTIBLE LOAN

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 12 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, totaling SEK 144 million over a two-year period.

The convertible notes bear no interest and will mature 12 months from the date issued. Unless an event of default occurs, the non-converted convertible notes will be converted to shares or reimbursed in cash at Saniona's discretion at the maturity date. Nice & Green will have the right to request conversion of the convertible notes at any time during a period of 12 months following the issue of the respective tranche. To the extent Nice & Green has not requested conversion at the end of the respective conversion period, Saniona will have the right to request conversion. The pricing of the shares will be determined as 92% of the lowest daily volume-weighted average share price (VWAP) of the five trading days prior to the date on which Nice & Green has sent a conversion notice to Saniona. Upon each request for conversion, Saniona has the right to instead of effectuating conversion, pay a cash amount to Nice & Green. The cash amount to be paid in case Saniona utilizes this right, will be calculated as V/0.97 where V is the nominal amount of the convertible note for which Saniona choses to effect cash payment. For further details, please see Saniona's press release dated December 29, 2017.

In the full year of 2018, Saniona has drawn eight tranches totaling SEK 48 million of which SEK 42 million has been converted to shares by Nice & Green as of December 31, 2018. The converted amount of SEK 42 million is taken to equity after deducting expenses relating to capital increase totaling SEK 1.3 million.

The convertible loan note funding agreement with Nice & Green compose a series of compound instruments which are classified as equity instruments since the attached conversion option is settled by paying a fixed amount in cash or a number of shares at the company's discretion.

# NOTE 26 SHARE CAPITAL

	Number of shares	Quotient value, SEK	Share capital, SEK
January 1, 2017	20,841,467	0.05	1,042,073
Shares issued for cash	921,053	-	46,052
December 31, 2017	21,762,520	0.05	1,088,125
January 1, 2018	21,762,520	0.05	1,088,125
Shares issued for cash	1,561,893	-	78,159
December 31, 2018	23,324,413	0.05	1,166,284

As of December 31, 2018, Saniona had 23,324,413 (21,762,520) shares outstanding at SEK 0.05 per share equal to a share capital of SEK 1,166,284 (1,088,125).

### NOTE 27 INVESTMENT IN ASSOCIATED COMPANIES

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. Saniona has written down its investment to zero as of September 30, 2018, in accordance to the equity method because the equity of Scandion Oncology was negative as of June 30, 2018. Scandion Oncology has been listed on the Spotlight Stock Market on November 8, 2018, after having raised SEK 26 million in an IPO at a pre-money valuation of SEK 43.7 million. The estimated equity in Scandion Oncology was SEK 22.3 million following the IPO. Saniona owns 29.17% (3.473.577 shares) of the shares outstanding in Scandion Oncology as of December 31, 2018. Saniona's share of the equity in Scandion Oncology following the IPO is SEK 6.5 million in accordance to the equity method. The increase in equity has been recorded in the statement of income under Share of result of associates and in the balance sheet under Investment in associated companies.

#### Investment in associates 2018

Name	Registered office	Ownership (%)	Equity*	Saniona's share of net profit/(loss)
Scandion Oncology A/S	DK	29.17	22,300,870	6,505,164

\*The calculation of equity is based on interim report Q3 and the capital increase in Q4.

#### NOTE 28 OTHER LONG-TERM RECEIVABLES

On July 4, 2017, Saniona acquired Neuro-Search'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 (SEK 7.1 million). Following this, Saniona has no additional payment obligations to NeuroSearch. Saniona estimates that the onetime cash payment of DKK 5.5 million (SEK 7.1 million) would have been payable to NeuroSearch within a four-year period under the previous agreements. Therefore, the amount will be expensed over a four-year period starting July 1, 2017. In 2018 the onetime cash payment has been expensed with DKK 1.4 million (SEK 1.9 million) and as December 31, 2018, the recorded value of the asset is DKK 3.6 million (SEK 4.9 million).

# NOTE 29 ADJUSTMENTS FOR NON-CASH TRANSACTIONS AND CHANGES IN WORKING CAPITAL

	Group		Parent Company	
KSEK	2018	2017	2018	2017
Adjustments for non-cash transactions:				
Share of result of associates	-6,174	-	-6,174	-
Depreciation	632	561	-	-
Warrants	1,519	357	- \	-
Other financial income and expenses	261	-914	-1,756	-826
Currency adjustment	-33	-	\-	-
Total adjustments for non-cash transactions	-3,795	5	-7,931	-826
Changes in working capital:				
Increase (-)/Decrease (+) in operating receivables	2,558	3,823	-44,379	-23,496
Increase (-)/Decrease (+) in operating liabilities	26,870	-4,170	105	77
Total changes in working capital	29,428	-347	-44,274	-23,419

# NOTE 30 PROPOSED APPROPRIATION OF FUNDS

The following funds are at the disposal of the Annual General Meeting:

SEK	
Share premium reserve	155,606,895
Profit/loss carried forward	-17,978,771
Profit/loss for the year	19,049
Total	137,647,173

The Board of Directors propose that the funds at their disposal, SEK 137,647,173 be carried forward.

# NOTE 31 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. 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 finan- cial 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 as- sets 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 develop- ment in personnel expenses and has been inclu- ded to provide an impression of how the number of employees at the company has developed.
Equity per share	Equity divided by the shares outstanding at the end of the period.	Equity per share has been included to provi- de 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 the average shares outstanding 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.

## DERIVATION OF ALTERNATIVE PERFORMANCE MEASURERS

	2018	2017	2016	2015	2014
Operation profit/loss, KSEK	-54,206	-57,189	4,156	-28,075	-8,258
Net sales, KSEK	54,884	20,692	74,921	13,630	21,718
Operating margin, %	99%	-276%	6%	-206%	-38%
Cash flow for the year, KSEK	24,738	-30,134	6,735	36,898	8,739
Average number of shares outstanding	22,288,524	21,416,810	20,841,467	17,775,099	13,231,668
Cash flow per share, SEK	1.11	-1.41	0.32	2.08	0.66

	2018-12-31	2017-12-31	2016-12-31	2015-12-31	2014-12-31
Current assets, KSEK	70,668	40,569	68,066	55,373	13,373
Current liabilities, KSEK	43,617	10,747	16,517	4,730	6,681
Liquidity ratio, %	162%	377%	412%	1171%	200%
Equity, KSEK	39,457	37,628	54,252	52,943	8,780
Total equity and liabilities, KSEK	83,075	48,375	70,769	57,673	15,461
Equity ratio, %	47%	78%	77%	92%	57%
Equity, KSEK	39,457	37,628	54,252	52,943	8,780
Shares outstanding at the end					
of the period	23,324,413	21,762,520	20,841,467	20,841,467	13,882,200
Equity per share, SEK	1.69	1.73	2.60	2.54	0.63

## NOTE 32 SUBSEQUENT EVENTS TO THE BALANCE SHEET DATE

- In January, Saniona initiated an open label extension study in the second part of its Phase 2a study of Tesomet comprising nine adolescent patients with PWS. The treatment with a dose of 0.125 mg/day appeared to be well tolerated but did not achieve sufficient plasma levels known to be efficacious in previous Phase 2 and Phase 3 studies. Saniona has now filed and received approval to increase the dose to 0.25 mg/day in the Czech Republic; approval in Hungary is pending. The first patients are expected to be switched to the 0.25 mg dose in March and the study is scheduled to continue until the end of June.
- Saniona's partner University of Pennsylvania Treatment Research Center plans to continue the investigator-initiated study with NS2359 for cocaine addiction at a higher dose following their interim analysis.
- Saniona successfully completed a full regulatory toxicological program for its first in class compound, SAN711, which offers a new treatment paradigm for itching and neuropathic pain. Saniona has scaled-up the manufacturing process, produced the material for clinical studies and the program is now ready for Phase 1 studies.
- Saniona recruited the first patients in a Phase 2 clinical study of Tesomet to treat the rare eating disorder hypothalamic obesity. The trial comprises a total of up to 25 patients and is conducted at Rigshospitalet in Copenhagen, Denmark.

# **Board of Directors' declaration**

The Board of Directors and Chief Executive Officer declare that the consolidated accounts have been prepared in accordance with International Financial Reporting Standards (IFRS) as endorsed by the EU and give a true and fair view of the Group's financial position and results of operations. The annual accounts have been prepared in accordance with generally accepted accounting principles and give a true and fair view of the Group's and the Parent Company's financial position and results of operations.

The Directors Report of the Group and Parent Company gives a true and fair view of the progress of the Group's and Parent Company's operations, financial position and results of operations, and states significant risks and uncertainty factors facing the Group and the Parent Company.

The Income Statements and Balance Sheets will be submitted to the Annual General Meeting on May 29, 2019, for adoption.

Ballerup, Denmark, April 30, 2019

J. Donald deBethizy Chairman of the Board Jørgen Drejer CEO and Board member

Claus Bræstrup *Board Member*  Anna Ljung Board Member

Carl Johan Sundberg Board Member

> Our Audit Report was presented on April 30, 2019 Deloitte AB

> > Jeanette Roosberg Authorized Public Accountant

# **Auditor's Report**

To the general meeting of the shareholders of Saniona AB (publ) corporate identity number 556962-5345

## REPORT ON THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS Opinions

We have audited the annual accounts and consolidated accounts of Saniona AB (publ) for the financial year 2018-01-01 - 2018-12-31 except for the corporate governance statement on pages 80-92. The annual accounts and consolidated accounts of the company are included on pages 31-75 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company as of 31 December 2018 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2018 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. Our opinions do not cover the corporate governance statement on pages 80-92. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Our opinions in this report on the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

#### **Basis for Opinions**

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

#### Key Audit Matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

## Revenue recognition in the correct period

The revenues of the group are related to research, development and license agreements and other research funding in accordance with collaboration agreements.

The revenues comprise of upfront payments, milestone payments, royalties and other revenues in accordance with research, development and license agreements.

Every agreement is unique and comprises of different requirements of performance. There could be a risk that the revenue recognition criteria are not fully met and that the financial benefits related to the transaction are not recognized in the correct period which leads to that the revenue is not recognized correctly.

The group accounting principles as regards revenue recognition and judgements and estimations are referred to in note 2 and note 3.

#### Our audit procedures

Our audit procedures concluded, but where not limited to:

- review of the group accounting principles of revenue recognition to verify the compliance of IFRS,
- review and testing of transactions in accordance with agreements to be recognized as revenues in the correct period, and
- review that appropriate accounting principles are applied and that relevant disclosures are presented.

## Going concern

Saniona is a biotech research and development company and the going concern situation is dependent on that enough financing is received to continue the operating business with research and development up to the point of the commercialization phase. The group has signed a financing agreement based upon a convertible loan with Nice & Green S.A. on 29 December, 2018 on totally 144 MSEK. The company cash at year-end was 55 MSEK (22). For further information refers to the group's information in the Board of director's report and note 4 in the annual accounts.

#### Our audit procedures

Our audit procedures concluded, but where not limited to:

- review of the group key controls to identify indications of financial needs for going concern continuance,
- review of the group's assessments and methods for the calculation of budgets and forecasts to assure that the assessments and assumptions are reasonable for the group's cash flow the coming twelve months ahead,
- review of the group's decisions as regards actions and received cash payments,
- review that appropriate accounting principles are applied and that relevant disclosures are presented, and
- valuation of investments in subsidiaries.

#### Valuation of investments in subsidiary

In the Balance Sheet of the Parent company as of 31 December, 2018, the investments in subsidiaries accounts to 12 MSEK (12) and current receivables from group companies accounts to 112 MSEK (69). The valuation of the accounted assets is dependent on the future cash flow from the subsidiary. The subsidiary leads all research and development in the group. Saniona has assessed this impairment test related to the future earnings in the subsidiary. Any changes of the judgements or assumptions could have an effect on the result and financial position of the parent. For further information refers to the accounting principles of the parent company in note 2, judgements and estimations in note 3 and investments in subsidiaries in note 23 in the annual accounts.

#### Our audit procedures

Our audit procedures concluded, but where not limited to:

- review of the group's key controls to identify indications that could result in an impairment, and
- review of the parent company's assessment and methods for the impairment test to assure that the relevant assumptions and routines are consistent, and that integrity is included in the calculations.

## Other information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 4-30. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

## Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

#### Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in the auditor's report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

## REPORT ON OTHER LEGAL AND REGULATORY REQUIREMENTS

**Opinions** In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Saniona AB (publ) for the financial year 2018-

01-01 - 2018-12-31 and the proposed appropriations of the company's profit or loss. We recommend to the general meeting of sharehold-

ers that the profit to be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

#### **Basis for Opinions**

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

## Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

#### Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Deloitte AB was appointed auditor of Saniona AB (publ) the general meeting of the shareholders on the 24 May, 2018 and has been the company's auditor since 19 February, 2014.

Malmö, 30 April, 2019

Deloitte AB

Jeanette Roosberg Authorized Public Accountant



## INTRODUCTION

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 and eating disorders. The Parent Company is a public 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 is listed at Nasdaq Stockholm Small Cap. Saniona applies the Swedish Code of Corporate Governance completely. This Corporate Governance Report has been prepared in accordance with the Annual Accounts Act and the Code and audited by the company's auditor in accordance with RevU16.

## APPLICATION OF AND DEPARTURE FROM THE SWEDISH CODE OF CORPORATE GOVERNANCE

The Swedish Corporate Governance Code (the "Code") applies to all Swedish companies whose shares are listed on a regulated marketplace in Sweden. The company is not obliged to adhere to all the regulations of the Code and is free to adopt alternative solutions deemed more suitable to its circumstances, provided that potential departures are reported, the alternative solution described, and the reasons explained (Comply or Explain principle) in the Corporate Governance Report.

Saniona is today listed on Nasdaq Stockholm Small Cap and follows the applicable rules of the Swedish Companies Act, the regulations and recommendations resulting from the Nasdaq Stockholm's Rule Book for Issuers, the Code, as well as generally accepted practices in the stock market. Saniona did not depart from the Code in 2018.

## COMPLIANCE WITH SWEDISH STOCK MARKET REGULATIONS AND ACCEPTED STOCK MARKET PRACTICE

Saniona has not been subject to any ruling by Nasdaq Stockholm's disciplinary commission or statements by the Swedish Securities Council relating to breaches of Nasdag's regulatory framework for issuers or generally accepted accounting practices on the stock market in the 2018 fiscal year.

## **OWNERSHIP STRUCTURE, SHARE CAPITAL AND** VOTING RIGHTS

At December 31, 2018, Saniona had 5,569 (5,195) shareholders, excluding holdings in life insurance and foreign custody account holders. The company's CEO, Jørgen Drejer, was the largest shareholder with 10.1 percent (10.8) of the share capital and voting rights. The ten largest shareholders jointly accounted for 42.9 percent (46.3) of the share capital and voting rights. Apart from Jørgen Drejer, there were no other shareholders with a holding of more than one-tenth of the total number of shares and votes in the company at year-end.

Saniona's share capital totaled SEK 1,166,284 divided among 23,324,413 shares as of December 31, 2018. In 2017, Saniona's share capital totaled SEK 1,088,126 divided among 21,762,520 shares. There is only a single share class. All shares have a quotient value of SEK 0.05 and confer one vote and equal entitlement to the company's assets and profits. Saniona's Articles of Association have no limitations regarding the number of votes each shareholder may cast at the Annual General Meeting.

## **DIVIDEND POLICY**

Saniona may generate income through upfront payments, milestone payments, royalty payments and upon exits in relation to the sale of spinouts. The Board of Directors has decided upon a residual dividend policy. This means that Saniona will only pay a dividend on net income and internally generated equity after it has reserved capital to finance continued development and expansion of the business, including its product pipeline. The Board of Directors' intention at present is to use any future profits made by Saniona to finance continued development and expansion of the business. Regular dividends will only be paid once the company has a product on the market and the company records annual net income through royalty payments. Consequently, the Board of Directors does not intend to propose any dividend within the foreseeable future.

The Board of Directors proposes that no dividend be distributed for the 2018 fiscal year.

## AUTHORIZATION FOR THE BOARD OF DIRECTORS **REGARDING NEW ISSUES**

At the Annual General Meeting held on May 24, 2018, it was resolved to authorize the Board of Directors, on one or several occasions during the time up until the next Annual General Meeting, with or without deviation from the shareholders' preferential rights, to decide to issue shares and/or convertibles. A new issue should be able to be made with or without provisions regarding contribution in kind, set-off or other conditions. In case the authorization is used for a new issue with deviation from the shareholders' preferential rights, the number of shares that may be issued shall not exceed 20 percent of the total number of existing shares in the company at the time of the Annual General Meeting and the subscription price shall be on market terms (subject to customary new issue discount, as applicable). The purpose of the authorization is to be able to source working capital, to be able to execute and finance acquisitions of companies and to enable new issues to industrial partners within the framework of partnerships and alliances.

In case the authorization is used for issues of convertibles, such issue must only be made within the financing agreement that the company on 29 December 2017 entered with Nice & Green S.A. ("N&G") and

the total number of shares that may be issued upon conversion of convertibles issued thereunder shall not exceed 12,000,000 shares. The conversion rate shall be determined in accordance with the provisions in the financing agreement with N&G, which stipulate that the conversion rate for convertibles issued to N&G shall amount to the higher of SEK 6 and 92 percent of the lowest daily volume weighted average price for the company's share during the five trading days preceding the day of the conversion request. Due to issue-technical reasons, each issue resolution regarding convertibles must stipulate a minimum conversion rate, which pursuant to the financing agreement with N&G is stipulated to be SEK 6. At each issue resolution, this minimum conversion rate forms the basis for the maximum numbers of shares that may be issued upon conversion of issued convertibles. Each tranche of convertibles under the financing agreement amounts to SEK 6,000,000 and the stipulated maximum number of shares of 12,000,000 thereby enables the company to draw 12 tranches under the financing agreement with N&G prior to the next annual shareholders' meeting. It should, however, be noted that as long as 92 percent of the lowest daily volume weighted average price of the company's share during the five trading days preceding the day for the conversion request exceeds SEK 6, the conversion rate so calculated will be applied and the number of shares issued at conversion will then be lower than the maximum number as per the above. For further information regarding the financing agreement with N&G, please refer to the company's press release issued on 29 December 2017.

## CORPORATE GOVERNANCE WITHIN SANIONA

Saniona's internal controls and corporate governance are based on applicable legislation/regulations and on sector-specific parameters considered significant to the company. The control system encompasses all applicable regulatory frameworks as well as the specific demands Saniona places on its operations. The internal control and corporate governance tool provide overall control of all critical stages relating to the company. This provides Saniona's Board and management with the conditions required to control and govern operations so that they satisfy the stringent demands of the company, the market, the stock market, the shareholders and the authorities.

The following legislation/regulations, as well as the company's own constitutional documents, form the basis of Saniona's corporate governance:

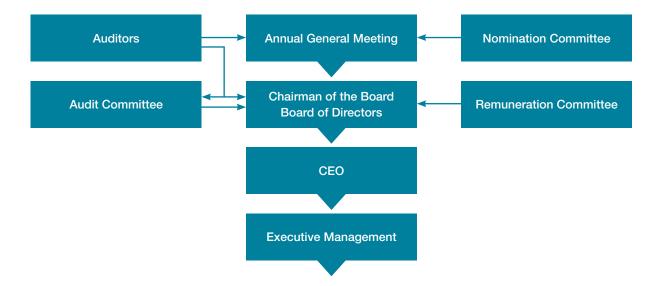
#### External Regulations

- The Swedish Companies Act
- Swedish and international accounting legislation
- The Swedish Corporate Governance Code
- Nasdaq Stockholm's regulatory framework for issuers
- Other applicable rules and recommendations

## Internal constitutional documents

- The Articles of Association
- Rules of procedure for the Board of Directors and Committees
- Instructions for CEO
- Guidelines for remuneration of senior executives
- Code of Conduct
- Information policy
- Financial administration guidelines
- Insider Policy
- Instruction for insider List
- Instructions for financial reporting
- Risk Policy
- Finance Policy
- Finance manual
- Dividend policy
- IT Policy
- GDPR Policy

Saniona's corporate governance structure is presented in the figure below and further described in the following subsections.



## ANNUAL GENERAL MEETING

The shareholders' rights to decide on the company's affairs is exercised at a general meeting of shareholders (Annual General Meeting and Extraordinary General Meeting), which is the highest decision-making body. For example, the general meeting resolves on amendments to the Articles of Association, election of Members of the Board and Auditors, adoption of the income statement and balance sheet, the discharge of the Board of Directors and the CEO from personal responsibility, appropriation of the profit or loss, the principles for the establishment of a Nominating Committee and the guidelines for remuneration of senior executives. Shareholders wishing to raise a matter at the Annual General Meeting must submit a written request to the Board of Directors. Such a request shall normally be received by the Board of Directors no later than seven weeks prior to the general meeting.

The general meeting is to be held in Malmö. Notice of general meetings should be made no earlier than six weeks and not later than four weeks before the meeting if the agenda includes an amendment of the Articles of Association. The notice of other general meetings should be made no earlier than six weeks and not later than three weeks prior to the meeting. Notice of a general meeting is announced in the Swedish Official Gazette (Sw. Post- och Inrikes Tidningar) and on the company's website. An announcement that a meeting has been convened is published in the Swedish daily newspaper Svenska Dagbladet.

To participate in the general meeting, shareholders must be directly registered in the share register maintained by Euroclear Sweden AB five business days prior to the general meeting and notify the company of their intention to attend by no later than the date indicated in the invitation to the general meeting. This day may not be a Sunday, other public holiday, Saturday, midsummer Eve, Christmas Eve or New Year's Eve and may not fall earlier than the fifth weekday prior to the general meeting.

#### Annual General Meeting 2018

The Annual General Meeting for 2018 was held on May 24, 2018 in Malmö. The meeting was attended by 5 (10) shareholders, in person or by proxy, representing about 24 percent (25) of the total voting rights. Lawyer Ola Grahn was elected as Chairman of the meeting. The AGM passed the following resolutions:

- Re-election of J. Donald deBethizy, Claus Bræstrup, Jørgen Drejer, Anna Ljung and Carl Johan Sundberg as ordinary Board members. J. Donald deBethizy was also re-elected as Chairman of the Board. It was noted that Leif Andersson had declined re-election.
- Re-election of Deloitte AB as the auditing firm. It was noted that Deloitte AB had informed that Jeanette Roosberg will be the auditor in charge.
- Remuneration of the Chairman of the Board, the Members of the Board and the auditor.
- Guidelines for remuneration of senior executives.

- Implementation of an employee option program for certain employees and key consultants in accordance with the Board of Directors' proposal.
- Implementation of option program for certain Members of the Board in accordance with the Nomination Committee's proposal.
- Authorization of the Board of Directors on one or several occasions, during the time up until the next annual shareholders' meeting, with or without deviation from the shareholders' preferential rights, to decide to issue shares, convertibles and/or warrants.
- Resolution on discharge from liability in relation to the company for the Members of the Board and the CEO for the 2017 fiscal year.
- Approval of instruction and charter for the Nomination Committee.
- Amendment of the Articles of Association in accordance with the Board of Directors' proposal.

The minutes and information from the Annual General Meeting 2018 are available on www.saniona.com.

#### Annual General Meeting 2019

The Annual General Meeting for 2019 will be held at Setterwalls Advokatbyrå AB's office at Stortorget 23, Malmö, Sweden on May 29, 2019 at 4 pm CET.

#### NOMINATION COMMITTEE

At the Annual General Meeting on May 24, 2018, it was resolved to adopt instructions and a charter for the Nomination Committee pursuant to which the Nomination Committee shall comprise three members, who should represent the two largest shareholders as of last September, together with the Chairman of the Board.

If one of the two largest shareholders abstains from appointing an owner representative, or such owner representative resigns before the assignment is completed without the relevant shareholder appointing a new member, the Chairman of the Board is to request the next owner in line (e.g. initially the third-largest owner) to appoint an owner representative within one week of such request. The procedure shall be continued until the Nominating Committee consists of three members.

If there is a significant change in ownership six weeks prior to the Annual General Meeting, a new owner representative shall be elected. The Chairman shall then contact the one of the two largest shareholders who does not have an owner representative and ask him to appoint one. The new owner representative is to replace the previous member of the Nomination Committee who no longer represents one of the two largest shareholders.

The Nominating Committee shall appoint the Chairman of the Nomination Committee. The Chairman of the Nomination Committee must not be the Chairman or any other member of the Board. The term of office of the appointed Nominating Committee shall run until a new Nomination Committee has been appointed. The composition of the Nomination Committee for the 2018 Annual General Meeting was announced in a press release on December 13, 2018 and is as follows:

Name/Represented	Share of votes December 31, 2018	Share of votes September 30, 2018
Søren Skjærbæk (Chair) Owner of Ursus law firm, Vejle, Denmark. Appointed by Jørgen Drejer	10.1%	10.3%
John Haurum Professional board member of life science companies and former CEO of F-star Biotechnology Limited Cambridge, UK Appointed by Thomas Feldthus	8.0%	8.2%
J. Donald deBethizy Chairman of Saniona AB's Board	-	-
Total	18.1%	18.5%

In 2018/19, the Nomination Committee held one (2017/18: two) meeting and also maintained contact by telephone. As a basis for its work, the Nomination Committee has taken note of the Chairman's presentation of the Board's work.

The Nomination Committee has prepared proposals to the Annual General Meeting, including proposals for Board members, remuneration of Board and Committee members, proposals for auditors and fees to the auditors and the Chairman of the AGM. When preparing its proposals, the Nomination Committee has applied paragraph 4.1 of the Code as its Diversity Policy.

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, Attn. Thomas Feldthus, Baltorpvej 157, DK-2750 Ballerup, Denmark.

## **BOARD OF DIRECTORS**

The Board of Directors is the highest decision-making body under the Annual General Meeting.

The Board is responsible for the company's organization and management of the company's affairs, for example by setting objectives and strategy, establishing procedures and systems for monitoring of the established objectives, continuously assessing the company's financial position and the operational management. Furthermore, it is the Board's responsibility to ensure that accurate information is provided to the company's stakeholders, that the company complies with laws and regulations and that the company develops and implements internal policies and ethical guidelines. The Board also appoints the CEO and determines the salary and other remuneration of the latter based on the guidelines adopted by the general meeting. The work of the Board of Directors is regulated by applicable legislation and recommendations, and by the Board of Directors' rules of procedure, which are adopted annually. The rules of procedure contain stipulations regulating the division of responsibilities between the Board of Directors and the CEO, financial reporting and audit matters. At the statutory Board meeting, the Board of Directors adopts other requisite rules of procedure, policies and guidelines that form the basis of the company's internal regulatory framework.

#### Composition of the Board

Members of the Board are to be appointed for a period extending no longer than to the end of the next Annual General Meeting.

Pursuant to the company's articles of association, the Board of Directors shall be composed of not fewer than three and not more than eight ordinary members. Following the 2018 Annual General Meeting, the Board consisted of five members, all of whom were re-elected at the AGM on May 24, 2018.

One of the current board members is a woman and four are men. The company will continue to pursue the objective of achieving a better gender balance. For more information about the Board, see Board of Directors.

#### Independence

The company complies with the Swedish Corporate Governance Code such that the majority of the Board members elected at the Annual General Meeting are independent of the company and management, and that at least two of them are independent in relation to the major shareholders. In 2018, four of the five Board members were independent of the company, management and major shareholders.

## Chairman of the Board

The Chairman represents the Board of Directors externally and internally. The Chairman leads the Board's work, monitors the work and assumes responsibility for the Board completing its duties according to applicable legislation, the Articles of Association, the Swedish Code of Corporate Governance and the Board of Director's rules of procedure.

The Chairman shall monitor the company's progress through contact with the CEO, consultation with the CEO on strategic matters and by ensuring that strategic considerations are recorded and addressed by the Board of Directors. The Chairman is also to ensure that the Board of Directors, through the CEO's agency, receives information on the company on an ongoing basis to enable analysis of the company's position.

The Chairman is responsible for contacts with the shareholders regarding ownership issues and for communicating the shareholders' views to the Board.

## Evaluation of the work of the Board of Directors

The Board evaluates the work of the Board at least annually. The work is evaluated along various parameters such as whether the number of Board meetings and their duration are appropriate, the quality of the Board material, whether the agenda items are relevant and comprehensive, the preparedness and performance of individual Board members, the composition of the Board and desirable experience of potential new Board members, the role and performance of the Chairman and the executive management. The conclusions are included in the minutes and shared with the Nomination Committee.

#### Number of meetings

The Board is to meet at least six times per year, usually in conjunction with the publication of interim and annual financial statements and the AGM. Additional meetings or teleconferences are convened as necessary. The Board carries out an in-depth strategic review of the operations during at least one Board meeting each year.

## The Board's work in 2018

In 2018, the Board held a total of 9 (10) meetings, of which 6 were scheduled and 3 (4) were unscheduled meetings. In addition, the Board passed additional resolutions on 11 (11) occasions through written resolutions. Saniona's CEO is member of the Board and Saniona's CFO participates in Board meetings. Other Saniona employees participate and present reports as needed.

#### February

Review and adoption of Year-end report, strategy matters, finance matters, resolution about internal audit.

#### April

Adoption of Corporate Governance Report and Annual report. Questions related to the AGM, including the Board's proposal regarding guidelines for remuneration of senior management.

#### May

Adoption of Q1 Interim Report. Review of general policies. Strategy and finance matters.

Statutory Board meeting. Rules and procedure for the Board of Directors, Instruction for the CEO, Instruction for financial Reporting, Rules of Procedure for the Remuneration Committee, Resolution to authorize Saniona's auditor to review Saniona's nine-month report, establishment of a work plan for the Board in the period ahead and appointing members of Board Committees. Determination on other policies and guidelines.

## July

Implementation of share option program.

#### August

Adoption of Q2 Interim Report. Strategy matters, business plan and finance matters. Review of rules and procedure for the Audit Committee.

#### November

Adoption of Q3 Interim Report. Strategy and finance matters, revision of business plan and guidelines for budget. Review of the company's insurance coverage including insurance for the Board. Evaluation of the Board' work and the work of the CEO, respectively. Review of general policies.

#### December

Adoption of the business plan and budget for the coming fiscal year including investment budget. Resolution on allotment of shares.

	Elected	Independence	Audit Committee	Remuneration Committee	Attendance Board of Directors	Attendance Audit Committee	Attendance Remuneration Committee
J. Donald deBethizy	2018	Yes		Chair	9/9		2/2
Anna Ljung	2018	Yes	Chair		9/9	6/6	
Claus Bræstrup	2014	Yes	Member	Member	9/9	6/6	2/2
Jørgen Drejer	2014	1)			9/9		
Carl Johan Sundberg	2015	Yes	Member	Member	9/9	6/6	
Leif Andersson 2)	2014	Yes			5/5		2/2

1) Affiliated to the company, Management and major shareholders

2) At the AGM on May 24, 2018, Leif Andersson stepped down from the Board of Directors

#### **Board committees**

The company has established two committees to support the Board: the Audit Committee and the Remuneration Committee. The Board has adopted rules of procedure for both committees.

## THE AUDIT COMMITTEE

The main task of the Audit Committee is to oversee the company's financial position, to monitor the effectiveness of the company's internal control, internal audit and risk management, to keep itself informed of the audit of the annual accounts and consolidated accounts and to review and monitor the independence of the auditor. The Audit Committee is also to assist the Nominating Committee in the proposal for a decision on the choice of and remuneration of the auditor. The Audit Committee consists of three members, all of whom are independent of management. In 2018, the Audit Committee was composed of Anna Ljung (Chairman), Claus Bræstrup and Carl Johan Sundberg.

#### THE REMUNERATION COMMITTEE

The Remuneration Committee is to primarily propose guidelines and principles for remuneration and other terms of employment of the CEO and senior executives. The Remuneration Committee is also to monitor and evaluate ongoing and completed application for variable remuneration of executive management and monitor and evaluate the implementation of the guidelines for remuneration of senior executives as resolved by the Annual General Meeting. In 2018, the Remuneration Committee consisted of J. Donald deBethizy (Chairman), Claus Bræstrup and Carl Johan Sundberg.

## CHIEF EXECUTIVE OFFICER AND OTHER SENIOR MANAGERS

The CEO is appointed by the Board of Directors. The CEO's work follows the written instructions adopted annually by the Board of Directors at the statutory Board meeting.

The instructions for the CEO regulate customary areas such as the CEO's undertaking in relation to the company and the Board of Directors, including responsibility for presenting expedient reports to the Board of Directors relevant to the Board's completion of its evaluation of the company. The CEO is to ensure that ongoing planning, including business plans and budgets, is completed and presented to the Board of Directors for resolution.

The CEO shall exercise good leadership in the management of operations to ensure that the company progresses according to plan and follows the strategies and policies adopted. When departure from these plans and special events of a significant nature is feared, the CEO must immediately inform the Board of Directors through the Chairman. The CEO is to ensure that the company's operations, including its administration, are organized so that they satisfy market requirements, and efficient and secure organizational control of operations.

Within the framework of the directives provided by the Board of Directors for the company's operations, management deals with consultation regarding, and monitoring of, strategies and budgets, the distribution of resources, the monitoring of operations and preparation for Board meetings.

In addition to the CEO, executive management consists of Saniona's CFO and CSO. For information about executive management, see Board of Directors and Management and Auditors below.

For information about salaries and remuneration of the CEO and senior executives, see the table under remuneration below and note 9.

## REMUNERATION OF THE BOARD OF DIRECTORS AND EXECUTIVE MANAGEMENT

The Annual General Meeting resolves on remuneration of the Chairman of the Board and other Board members. The Annual General Meeting also resolves on guidelines for remunerating the CEO and other senior executives.

At the Annual General Meeting on May 24, 2018 it was resolved that the Board members who are not co-founders of Saniona AB will be entitled to a Board fee. Furthermore, it was resolved that the Board be remunerated so that SEK 275,000 is paid to the Chairman of the Board and SEK 110,000 to each of Anna Ljung and Carl Johan Sundberg. Finally, it was resolved that remuneration for committee work will be paid in an amount of SEK 30,000 to the Chairman of the Audit Committee. No additional remuneration shall be paid for other committee work.

At the Annual General Meeting on May 24, 2018, it was resolved that the following guidelines should apply for remuneration of senior executives. In general, Saniona shall offer remuneration that enables the company to recruit and retain senior executives. The remuneration of senior executives is to consist of a basic salary and other customary benefits as may be considered reasonable in relation to market practices. The senior executives are to be offered a fixed salary based on the individual's work duties, expertise, position, responsibilities, performances and other considerations. Salary is to be determined per calendar year with salary revision on January 1 each year. Saniona shall not offer a variable remuneration or any separate pension benefits to the senior executives. However, a certain part of the senior executive's salary may be allocated to pension provisions. The amount of such pension provisions may be decided by the senior executive. The notice period shall be six months from both Saniona and the senior executives. However, an adjusted notice period may be applied for the CEO and the CFO during an initial period of six months after a transaction with the outcome that a majority shareholding in Saniona or Saniona A/S has been acquired by one or more persons. The adjustment will mean that the notice period, upon termination by Saniona, may be extended to twelve months immediately after the relevant change in ownership. Apart from the salary, no severance pay is to be defrayed during the notice period. The Board of Directors is entitled to deviate from the above guidelines if the Board considers there are special reasons to justify such departure in individual cases. The Board of Directors has proposed that the Annual General Meeting to be held on May 29, 2019, resolve on essentially unchanged guidelines for remuneration to apply until the Annual General Meeting in 2020.

The remuneration of the Board of Directors and senior executives is set out below.

KSEK	Board fee	Basic salary	Pension costs	Share- based payment	Social security expenses	Other staff expenses	Total
J. Donald deBethizy, Chairman*	275	-	-	878			1,153
Claus Bræstrup, Board member	-	-	-	-	-	-	-
Carl Johan Sundberg, Board member*	110	-	-	-	35	-	145
Anna Ljung, Board member*	140	-	-	-	44	-	184
Jørgen Drejer, CEO and Board member*	-	1,656	-	-	5	26	1,687
Thomas Feldthus, CFO	-	1,973	197	-	5	26	2,201
Palle Christophersen, CSO	-	1,316	-	-	5	26	1,347
Total CEO, CFO and CSO	0	4,945	197	0	15	78	5,235
Other employees	-	14,756	1,512	608	99	527	17,502
Total	525	19,701	1,709	1,486	193	605	24,219

#### Salaries and remuneration for 2018 Group and Parent Company

\*The Board fees to J. Donald deBethizy, Carl Johan Sundberg and Anna Ljung and the salary to Jørgen Drejer relate to fee and salaries in the Parent Company

Please see note 9 for additional details regarding employment terms and conditions for the Board and senior management.

#### AUDITORS

Saniona's auditor is the auditing firm Deloitte AB, with Authorized Public Accountant Jeanette Roosberg as auditor in charge.

Deloitte has been Saniona's auditor since the formation of the Group in 2014. At the Annual General Meeting on May 24, 2018, Deloitte was elected as auditor until the end of the 2019 Annual General Meeting.

The external auditors discuss the external audit plan and risk management with the Audit Committee. In 2018, the auditors performed a review of the interim report for the third quarter and audited the annual accounts and consolidated financial statements. The auditors also express an opinion on whether this Corporate Governance Report has been prepared in accordance with, and whether certain disclosures herein are consistent with, the annual accounts and consolidated financial statements.

The auditor's report the results of their audit of the annual accounts and consolidated financial statements, their review of the Corporate Governance Report in the auditor's report, and a separate opinion on the Corporate Governance Report, in a presentation to the Annual General Meeting. In addition, the auditors present detailed findings from their reviews to the Audit Committee and to the Board of Directors in its entirety once per year.

For information regarding fees for the company's auditors, see note 8.

## INTERNAL CONTROL AND RISK MANAGEMENT SYSTEMS IN RELATION TO FINANCIAL REPORTING

The Board of Directors is ultimately responsible for the internal control of the company. The responsibility is governed by the Swedish Companies Act, the Swedish Annual Reports Act and the Swedish Corporate Governance Code. The Board of Directors is required to ensure that Saniona has enough formalized procedures for ensuring compliance with established principles for financial reporting and internal control. The procedures for internal control with respect to financial reporting have been designed to ensure reliable and accurate reporting in accordance with IFRS, applicable laws and regulations as well as other requirements that apply to companies listed on Nasdaq Stockholm. Saniona has decided to adopt the COSO framework as a basis of internal control of financial reporting. The framework consists of the following five components: control environment, risk assessment, control activities, information and communication and monitoring.

## **Control environment**

The control environment constitutes the basis of Saniona's internal control. The control environment comprises a clear organizational structure, decisionmaking processes, powers and responsibilities that are documented and communicated in governing documents. The guidelines for Saniona's business activities include the following:

- Rules and procedure for the Board of Directors and the instruction to the CEO;
- Saniona's business model, vision, strategies, objectives, business plans and values;
- Saniona's Code of Conduct;
- Organizational structure and descriptions of positions; and
- Administrative processes, guidelines and instructions such as powers, authorization instructions, risk policy, finance policy, instruction for financial reporting and the finance manual.

The governing documents such as internal policies, guidelines and instructions relating to financial reporting have been adopted by the Board of Directors to ensure an effective control environment.

In accordance with the instruction to the CEO, the CEO is to keep the Board of Directors continuously informed about the development of the company's operations, profit/loss and financial position as well as other events that are likely to be significant to the company and its shareholders. The CEO is also responsible for preparing reports and compiling information from management before Board meetings and to present the material at Board meetings.

The CFO is responsible for ensuring that internal controls are performed and obeyed and that continuous work is conducted to strengthen the internal control of financial reporting. The responsibility and duties of the CFO, inter alia, are regulated in detail in the company's finance policy, instruction for financial reporting and the financing manual.

The Audit Committee is responsible for ensuring that the internal control regarding financial reporting and reporting to the Board of Directors is effective. The Audit Committee performs quarterly reconciliations with the company's CFO. In addition, the Audit Committee reviews and evaluates Saniona's internal control annually.

#### **Risk assessment**

At least once a year, the CFO conducts an overall risk assessment to assess the risk exposure in Saniona with regards to financial reporting, as well as identify potential problem areas. The risk assessment includes identifying risks that may arise if the fundamental standards of financial reporting in Saniona are not satisfied. A review takes place to ensure that the company has an infrastructure that enables effective and expedient control, and an assessment of the company's financial position and significant financial, legal and operational risks.

On an annual basis, the CFO conducts an operational risk assessment to identify and analyze relevant events and risks that could have a negative impact on Saniona's ability to achieve its set goals.

#### **Control activities**

To ensure that business is conducted efficiently, and that financial reporting gives a fair and accurate impression on each reporting date, control activities are implemented to address risks at all levels of the organization. Control activities include manuals, processes and policies that ensure that directives and decisions are implemented.

The aim of the control activities is to prevent and detect errors and irregularities with regards to the financial reporting, and to propose subsequent corrective actions should any such irregularities occur. Activities include analytical monitoring and comparison of financial performance; account reconciliation; monitoring, approval and reporting of business transactions and partnership agreements, policies and procedures, mandate and authorization instructions, as well as accounting and valuation principles.

The CFO is responsible for maintaining internal controls and ensuring that they are developed as necessary. The CFO monitors the operations through a variety of control measures, such as forecasts and budgets, income statement and balance sheet analyses and reconciliations. The result of this work is reported to the Audit Committee and/or the Board of Directors.

Saniona's VP of Finance is responsible for the recording and accounting financial transactions and ensuring that the performed transactions comply with the established signatory powers and authorization powers. The VP of Finance reviews the project costs and activities together with project and line management on quarterly basis. Furthermore, several control activities are carried out on monthly basis to further detect and correct errors and deviations. The results are presented to the CFO on monthly basis.

#### Information and communication

The company has information and communication paths intended to promote the accuracy of financial reporting and ensure reporting and feedback from operations to the Board of Directors and management. The information and communication procedures are described in several governing documents such as internal policies, guidelines and instructions relating to financial reporting. These documents are made available in company-wide IT drives and presented to the relevant employees.

In addition to written information, news, risk management and control, results are orally communicated and discussed in physical meetings. Meetings are held within the company in the Saniona Management Group as well as at meetings at which all employees participate. The Board of Directors receives quarterly financial updates relating to the company's financial position and performance.

To ensure timely communication of relevant, reliable and accurate information concerning Saniona's development and financial status to the market, the company has established procedures for providing external information and financial reporting. The information policy and the procedures include a description of the roles and tasks of the employees, finance department, executive management and Board as well the procedures in relation to publication of financial reports and press releases.

All financial reports and press releases are published on the company's website and forwarded to the Board of Directors and all employees in connection with their publication.

#### Monitoring

The Board of Directors and the Audit Committee decide on the forms of monitoring activities of internal controls. The CFO is responsible for ensuring that internal controls are maintained in accordance with the Board of Directors' and the Audit Committee's decisions.

The Board of Directors is regularly updated on the company's financial position and profit/loss against budget as well as on development projects in relation to the relevant project budgets. The CEO and CFO present a written report at each regular Board meeting, or when the need arises.

The Audit Committee monitors the audit of internal controls. The company's external auditors personally report their observations and assessment of internal controls to the Audit Committee.

## **INTERNAL AUDIT**

In view of the company's size, with relatively few employees, and the scope of transactions, in which most significant transactions are similar in character and relatively uncomplicated, Saniona has not found it necessary to establish a formal internal audit function but has chosen to conduct monitoring and the annual evaluation of compliance with the internal control and risk management related to financial reporting through the existing organization. The Board of Directors and Audit Committee perform an annual assessment of whether there is a need for an internal audit function.

# **Board of Directors**

## J. DONALD deBETHIZY (born 1950)

Chairman of the Board since 2018

**Education:** Ph.D. and M.Sc. in Toxicology from Utah State University and a B.Sc. in Biology from the University of Maryland

**Other assignments:** Chairman of the Board of Saniona A/S, President of White City Consulting ApS, Chairman of the Boards of Albumedix A/S and Noxxon Pharma NV (ALNOX.EN Paris), board member of argenx N.V. (ARGX BR), Newron Pharmaceuticals SpA (NWRN.SWX) and Proterris, Inc.

**Previous assignments:** President and CEO of Santaris Pharma A/S. Executive Chairman of Contera Pharma ApS. Member of the board of Asceneuron SA, Biosource Inc., Enbiotix Inc., LigoCyte Pharmaceuticals Inc., Rigontec GmbH, Serendex Pharmaceuticals A/S, Targacept Inc. and Albumedix A/S. He was also the Co-Founder and CEO of Targacept, Inc., a NASDAQ-listed U.S. biotechnology company from 1997-2012

No. of shares: 0 (0) No. of warrants: 217,625 (0)

Non-affiliated to the management, the company and major shareholders



#### JØRGEN DREJER (born 1955)

Board member and CEO of Saniona AB since 2014 and co-founder of the company **Education:** Ph.D. in neurobiology

Other assignments: Member of the Board and CEO of Saniona A/S. Member of the Board of 2CureX AB.

**Previous assignments:** Executive Vice President, Research Director and co-founder of NeuroSearch A/S. Chairman of the Board of Delta Reader A/S. Member of the Board of Atonomics A/S, Delta, NsGene A/S, Origio A/S, Poseidon Pharmaceuticals A/S, Zgene A/S, Azign Bioscience A/S, Ellegaard Göttingen Minipigs ApS and Monta Biosciences A/S

**No. of shares:** 2,344,711 (2,344,711) privately owned Affiliated to the management, the company and major shareholders



#### ANNA LJUNG (born 1980)

Member of the Board and chairman of the Audit Committee since 2018 Education: M.Sc. in Economics and Business Administration from the Stockholm School of Economics Other assignments: Member of the Board of Saniona A/S. CFO of Moberg Pharma AB Previous assignments: CFO of Athera Biotechnologies AB, CFO of Lipopeptide AB and independent consultant in the field of technology licensing No. of shares: 0 (0) No. of warrants: 4,000 (0) Non-affiliated to the management, the company and major shareholders



CLAUS BRÆSTRUP (born 1945)

Member of the Board since 2014, Chairman and Board in 2014–2018 and co-founder of the company

Education: Doctor of Medicine and graduate in biochemistry

Other assignments: Member of the Board of Saniona A/S. Board member of Evotec AG and CEO of Kastan Aps

**Previous assignments:** CEO of H. Lundbeck A/S, Executive Vice President for Research and Development of H. Lundbeck A/S. CEO of Nordic Biotech General Partner II ApS. Chairman of the Board of Probiodrug AG. Member of the Board of Santaris Pharma A/S, Gyros AB, Bavarian Nordic A/S and, Evolva Holding SA **No. of shares:** 735,700 (735,700) privately owned

Non-affiliated to the management, the company and major shareholders



CARL JOHAN SUNDBERG (born 1958) Member of the Board since 2015 Education: MD

Other assignments: Member of the Board of Saniona A/S. Professor at the Department of Physiology & Pharmacology at Karolinska Institute, Stockholm, Sweden. Board member of Cobra Biologics Holding AB, Arne Ljungqvist Anti-doping Foundation AB and Medkay Konsulting AB, partner in Medkay Konsulting HB. Head of the Department of Learning, Informatics, management and Ethics at Karolinska Institute, member of the International Olympic Committee's Medical Commission and an elected member of the Royal Swedish Academy of Engineering Sciences (IVA)

**Previous assignments:** Board member of Alfta Rehab Holding AB, KI Management AB, KI Management Partners AB, Karolinska Development AB and NsGene A/S **No. of shares:** 0 (0)

**No. of warrants:** 4,000 (0) Non-affiliated to the management, the company and major shareholders

# Management



#### JØRGEN DREJER (born 1955)

Board member and CEO of Saniona AB since 2014 and co-founder of the company **Education:** Ph.D. in neurobiology

Other assignments: Member of the Board and CEO of Saniona A/S. Member of the Board of 2CureX AB

**Previous assignments:** Executive Vice President, Research Director and co-founder of NeuroSearch A/S. Chairman of the Board of Delta Reader A/S. Member of the Board of Atonomics A/S, Delta, NsGene A/S, Origio A/S, Poseidon Pharmaceuticals A/S, Zgene A/S, Azign Bioscience A/S, Ellegaard Göttingen Minipigs ApS and Monta Biosciences A/S

No. of shares: 2,344,711 (2,344,711) privately owned



#### THOMAS FELDTHUS (born 1960)

CFO of Saniona AB since 2014, EVP since 2015 and co-founder of the company Education: M.Sc. in Engineering, M.Sc. in Management (MBA, Sloan Fellow) Other assignments: CFO of Saniona A/S. CEO of Fertilizer Invest ApS. Member of the Board of Scandion Oncology A/S Previous assignments: CFO and co-founder of Symphogen A/S New Society (New States) CFO and co-founder of Symphogen A/S

No. of shares: 1,870,000 (1,870,000) privately owned



PALLE CHRISTOPHERSEN (born 1958) CSO of Saniona AB since 2014 and co-founder of the company Education: Ph.D. in physiology Other assignments: CSO of Saniona A/S Previous assignments: Vice President and member of the NeuroSearch A/S VP management group. Director of in Vitro Pharmacology, NeuroSearch A/S No. of shares: 820,000 (820,000) privately owned

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# Auditors' report on the Corporate Governance Statement

## To the general meeting of the shareholders in Saniona AB (publ), corporate identity number 556962-5345

#### ENGAGEMENT AND RESPONSIBILITY

It is the Board of Directors that is responsible for the Corporate Governance Statement for the fiscal year from January 1, 2018 through December 31, 2018 on pages 80-92 and that it has been prepared in accordance with the Annual Accounts Act.

## THE SCOPE OF THE AUDIT

Our examination has been conducted in accordance with FAR's auditing standard RevU 16 The auditor's examination of the corporate governance statement. This means that our examination of the Corporate Governance Statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

#### OPINION

A corporate governance statement has been prepared. Disclosures in accordance with Chapter 6, Section 6, second paragraph, points 2-6 of the Annual Accounts Act and Chapter 7, Section 31, second paragraph of the same act are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Malmö, April 30, 2019

Deloitte AB

Jeanette Roosberg Authorized Public Accountant



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This is a translation of the Swedish language original. In the events of any differences between this translation and the Swedish original the latter shall prevail.

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