



**ANNUAL REPORT 2019**

SANIONA AB (PUBL)





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# 2019 IN BRIEF

## SIGNIFICANT EVENTS IN 2019

### \* SANIONA'S NEW GLOBAL STRATEGY

In 2019, Saniona reviewed and updated its global strategy with the goal of transforming from an organization with main focus on research to a fully integrated biopharmaceutical company with a clinical development organization focused on rare diseases with eventual plans for commercialization.

As part of this global strategy, Saniona is increasing its presence and focus on the U.S. market. As a first step, the Company has begun its efforts to build a U.S. based management team, first hiring Boston based Rami Levin as President and Chief Executive Officer. Appointed in January 2020, he brings extensive commercial experience in the CNS and rare disease space both in the U.S. and globally.

In addition, as part of this strategic transformation, Saniona has now initiated the search for a Chief Medical Officer and Head of Clinical Development and a Chief Financial Officer who will both be based in Boston with the CEO Rami Levin. These organizational changes will facilitate our access to key US based investors and development, regulatory, and commercial experts.

### \* POSITIVE RESULTS OF PHASE 2A STUDY OF TESOMET IN PRADER WILLI SYNDROME

In September 2019, Saniona reported positive results from its Phase 2a study of Tesomet in Prader Willi Syndrome (PWS), a rare genetic disease with no approved treatment. The data showed that both in adult and adolescent patients there was a meaningful reduction in hyperphagia and weight loss from once-daily oral treatment.

These data provide guidance for the pivotal Ph2b/3 studies in PWS that are currently in planning stages.

Saniona's priority is to develop, gain market approval and independently commercialize Tesomet in the U.S. and Europe for this indication.

### \* INITIATION OF PHASE 2A STUDY OF TESOMET IN HYPOTHALAMIC OBESITY

In March 2019, Saniona initiated a Phase 2 study of Tesomet in Hypothalamic Obesity. Top-line results are expected in Q2 2020.

The randomized, double-blind, placebo-controlled Phase 2 trial in patients with hypothalamic obesity was conducted at Rigshospitalet in Copenhagen, Denmark. Patients received

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.

The primary endpoint of the study is safety and tolerability, which will be judged from all safety data collected during the study including recorded adverse events, laboratory data, blood pressure and heart rate. The secondary endpoints relate to satiety and appetite; bodyweight; body composition; lipids and metabolic parameters; quality of life; and craving for sweet, salty and fatty foods.

Saniona aims is to develop Tesomet in Hypothalamic Obesity, up to market approval and commercialization in the U.S. and Europe.

### \* SUBMISSION OF TESOFENSINE FOR APPROVAL IN MEXICO

In December 2019 Saniona's partner Medix submitted a New Drug Application for approval of tesofensine for the treatment of patients with obesity to the Mexican food and drug administration (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS). Saniona anticipates an approval in 2020.

## KEY FIGURES

KSEK	2019	2018
Net sales	2,658	54,884
Operating expenses	-106,563	-109,089
Operating profit/loss*	-103,906	-54,206
Financial items, net	20,404	5,913
Profit/loss before tax	-83,501	-48,292
Tax on net profit	7,713	7,233
<b>Profit/loss for the year</b>	<b>-75,788</b>	<b>-41,059</b>
Non-current assets	42,117	12,407
Current receivables	13,636	15,990
Cash and cash equivalent	40,248	54,678
<b>Total assets</b>	<b>96,000</b>	<b>83,075</b>
Equity	58,437	39,457
Non-current and current liabilities	37,563	43,617
<b>Total equity and liabilities</b>	<b>96,000</b>	<b>83,075</b>
Cash flow from operating activities	-98,469	-22,920
Cash flow for the year	-22,491	24,738
	2019	2018
Operating margin, %*	Negative	Negative
Equity ratio, %*	61%	47%
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 on page 24.





# LETTER FROM THE CEO

It is an honor to assume the role as President and Chief Executive Officer of Saniona, and thus to introduce the Annual Report for the first time.

I am thrilled to accept the challenge of leading the company through a transformative and exciting time in its development as we move Tesomet towards pivotal clinical trials in rare eating disorders Prader Willi Syndrome (PWS) and Hypothalamic Obesity (HO), and ultimately advance towards market approval and commercialization.

In 2019, we updated and refocused our global strategy with the overall aim of transforming Saniona from a research-focused to a clinical development organization. Our objective was to build a combined drug development and commercial organization focused on rare diseases of the central nervous system, while capitalizing on opportunities to partner with companies on programs in larger therapeutic areas, which we do not intend to develop internally. This strategy ensures a continuing future revenue stream from the commercialization of Saniona's core products as well as non-dilutive funding in the form of royalties from out-licensing and partnerships.

Our first focus is building a U.S.-based, fully integrated organization to address key future opportunities. This will be a vital step towards our longer-term aim of becoming a global company. As part of these efforts, we are currently preparing and planning for commercialization, with an initial focus on the U.S. which is the largest market in the world. Being Boston-based, I will leverage my presence in the U.S. while also working to expand our management presence in the U.S. with an ongoing CFO search.

We will also build our capabilities to support late-stage clinical development for rare diseases, first with a U.S.-based Chief Medical Officer and Head of Clinical Development, which will then be followed with a comprehensive clinical team in the U.S. In 2019, Saniona made significant progress towards our strategic targets. On our proprietary drugs in development, we reported positive Phase 2a results with Tesomet in patients with Prader Willi Syndrome (PWS), which will inform the trial design for the Phase 2b and Phase 3 studies. In addition, Saniona initiated a double-blind placebo-controlled phase 2 study in Hypothalamic obesity (HO) for 24 weeks followed by an additional 24 weeks of an open label phase, where all patients were offered the opportunity to switch to active treatment. Top-line results from the double-blind part of the ongoing Phase 2 in HO are expected in Q2 2020.



We have successfully completed a full regulatory preclinical toxicological program for our first in class compound, SAN711, which offers a new treatment paradigm for rare neuropathic itching disorders such as brachioradial pruritus; and we selected a development candidate, SAN903, in the IK potassium channel program for treatment of rare inflammatory and fibrotic disorders such as idiopathic pulmonary fibrosis.

On our out-licensing and partnerships, our partner Medix has submitted a New Drug Application to the Mexican regulatory authority for approval of tesofensine for the treatment of patients with obesity. With an expected 2020 launch, Saniona would be entitled to double digit royalties on product sales, creating an important source of revenue for the Company.

Saniona has a unique ion channel discovery platform that fuels its future internal proprietary pipeline and also creates partnership and out licensing opportunities. I am proud of our leading ion channel drug discovery team which has delivered numerous first in class drug candidates addressing significant medical needs in the rare disease space and also in broader indications developed with partners. Our partner Cadent Therapeutics has completed a Phase 2a study of CAD-1883 in essential tremor with positive results and received acceptance of an Investigational New Drug (IND) application for a Phase 2a study in ataxia, which is a lack of voluntary coordination of muscle movements. Cadent Therapeutics also intends to explore a third, undisclosed indication. Our partner Boehringer Ingelheim continues its preclinical development program of Saniona candidates in Schizophrenia.

The opportunity at Saniona is truly exciting and I am privileged to take the helm at an emerging leader in ion channel drug discovery, development and eventually commercialization. I look forward to collaborating with the team who have unparalleled experience and skill in this domain.

As you can see, we have built a strong foundation for the transformation of Saniona into the next phase of its history. We have highly promising products moving towards commercialization and are expanding our incredible team to capitalize on these outstanding opportunities.

I look forward to speaking with you regularly and keeping you up to date as Saniona becomes a fully integrated biopharmaceutical company focused on rare diseases of the central nervous system.



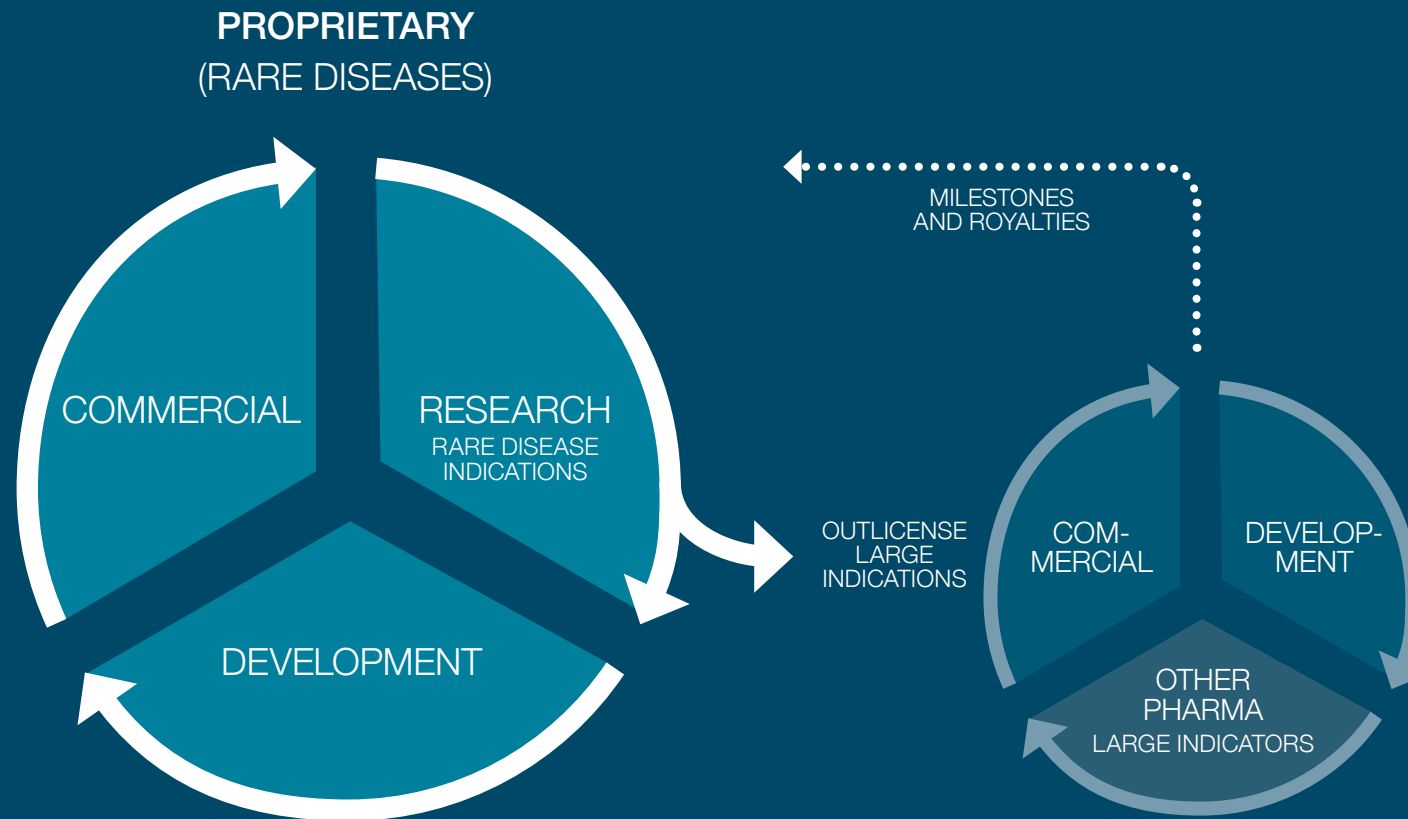
Rami Levin,  
President & CEO

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**I am proud of our leading ion channel drug discovery team which has delivered numerous first in class drug candidates addressing significant medical needs in the rare disease space and also in broader indications developed with partners.**

# STRATEGY AND BUSINESS MODEL

- \* Saniona's main focus is on Research, Development and Commercialization of treatments for Rare Diseases. That is our proprietary focus.
- \* We also have strategic research partnerships and out-licensing agreements with other pharmaceutical companies in larger indications, which we do not intend to pursue ourselves.





## OUR VISION

To become a leading global rare disease biopharmaceutical company focused on treatments for the central nervous system.

## OUR MISSION

To deliver innovative therapies to patients with rare diseases including Prader-Willi syndrome and hypothalamic obesity.

Saniona's focus is on the development and commercialization of proprietary products for the treatment of rare diseases with high unmet medical need. 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.

Saniona also has research partnerships with other pharmaceutical companies and is developing products internally with the aim of out licensing the products to pharmaceutical companies for later stage development or commercialization. The structure of Saniona's partnerships and out licensing agreements vary by product, indication, the investment and 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 along with upfront payments, research funding, milestone payments and royalties on future product sales when the product candidates are commercialized.

Saniona's short term strategic priorities are the following:

- \* To build internal capabilities in the organization to support late stage clinical development for rare disease programs and to adequately finance these activities through commercialization
- \* To develop and attain market approval for Tesomet in the U.S. and Europe for treatment of the rare eating disorders Prader-Willi syndrome and hypothalamic obesity
- \* To strengthen the company's position and presence in the U.S.
- \* To develop at least one drug candidate internally from our unique ion channel research platform
- \* To leverage our leading position within ion channel research through out-licensing and partnerships with other pharmaceutical companies

## BUILDING INTERNAL CAPABILITIES IN THE ORGANIZATION TO SUPPORT LATE STAGE CLINICAL DEVELOPMENT FOR RARE DISEASES

A top priority for Saniona is to build our internal clinical development capabilities, particularly with Tesomet entering into late mid/ stage development in both Prader Willi Syndrome and Hypothalamic Obesity. Building a strong clinical development team is critical and with clinical development activities mainly taking place in the US, it is important to build the team in close proximity to our U.S.-based investigators and trial sites.

Most importantly in these efforts, we have started the search for a Chief Medical Officer & Head of Clinical Development. This position will be Boston-based and will drive the creation of a clinical development team internally in the US.

Another key role will be Head of Regulatory Affairs, which will also be based in Boston and will be responsible for all the interactions with health authorities and regulatory agencies globally, with a first focus on the FDA in the U.S.

## DEVELOPING AND ATTAINING MARKET APPROVAL FOR TESOMET IN THE U.S. AND EUROPE FOR TREATMENT OF THE RARE EATING DISORDERS PRADER-WILLI SYNDROME AND HYPOTHALAMIC OBESITY

Saniona's most advanced internal program is Tesomet. Due to the mechanism of action, we believe Tesomet may have tremendous potential for the treatment of obsessive eating disorders such as Prader-Willi syndrome and hypothalamic obesity. In addition, we believe the clinical and regulatory pathway for the development of Tesomet in eating disorders may be faster and more economical as compared to metabolic indications. Saniona is currently in the planning stages to initiate a potentially registration enabling Phase 2b/3 program in Prader-Willi syndrome and conducting a Phase 2a study in hypothalamic obesity. Based on these studies, Saniona may file New Drug Applications in the U.S. and Europe within two to three years. By pursuing orphan indications such as Prader-Willi syndrome and hypothalamic obesity, we are creating a unique opportunity to develop and commercialize our own product in U.S. and European markets.

## STRENGTHENING THE COMPANY'S POSITION AND PRESENCE IN THE U.S.

As the U.S. is the main market for rare diseases, we intend to focus our clinical trials in the U.S., moving forward. In addition to the advantages of U.S. -based clinical programs, we believe the U.S. also offers the most in terms of potential financing opportunities. These two factors are driving our efforts to build a strong presence in the U.S. We intend to build a fully-fledged organization in Boston with most leadership roles based in the U.S., supplemented with the research team and facility in Copenhagen led by Jorgen Drejer, Chief Scientific Officer. The first U.S.- based role to have been recruited in Boston was the CEO, Rami Levin and we intend to hire a CMO & Head of Clinical Development, and a CFO. Additional key roles will be recruited after those positions are filled.

#### **ADVANCING INTERNAL CANDIDATES FROM OUR UNIQUE ION CHANNEL RESEARCH PLATFORM**

Several of Saniona's internal and early stage development programs have the potential to be developed and commercialized for rare diseases by Saniona. SAN711 with the potential to be developed for rare neuropathic itching disorders (e.g. brachioradial pruritus), is entering a Phase 1 clinical program. In addition, SAN903 can be developed for rare inflammatory and fibrotic disorders (e.g. idiopathic pulmonary fibrosis).

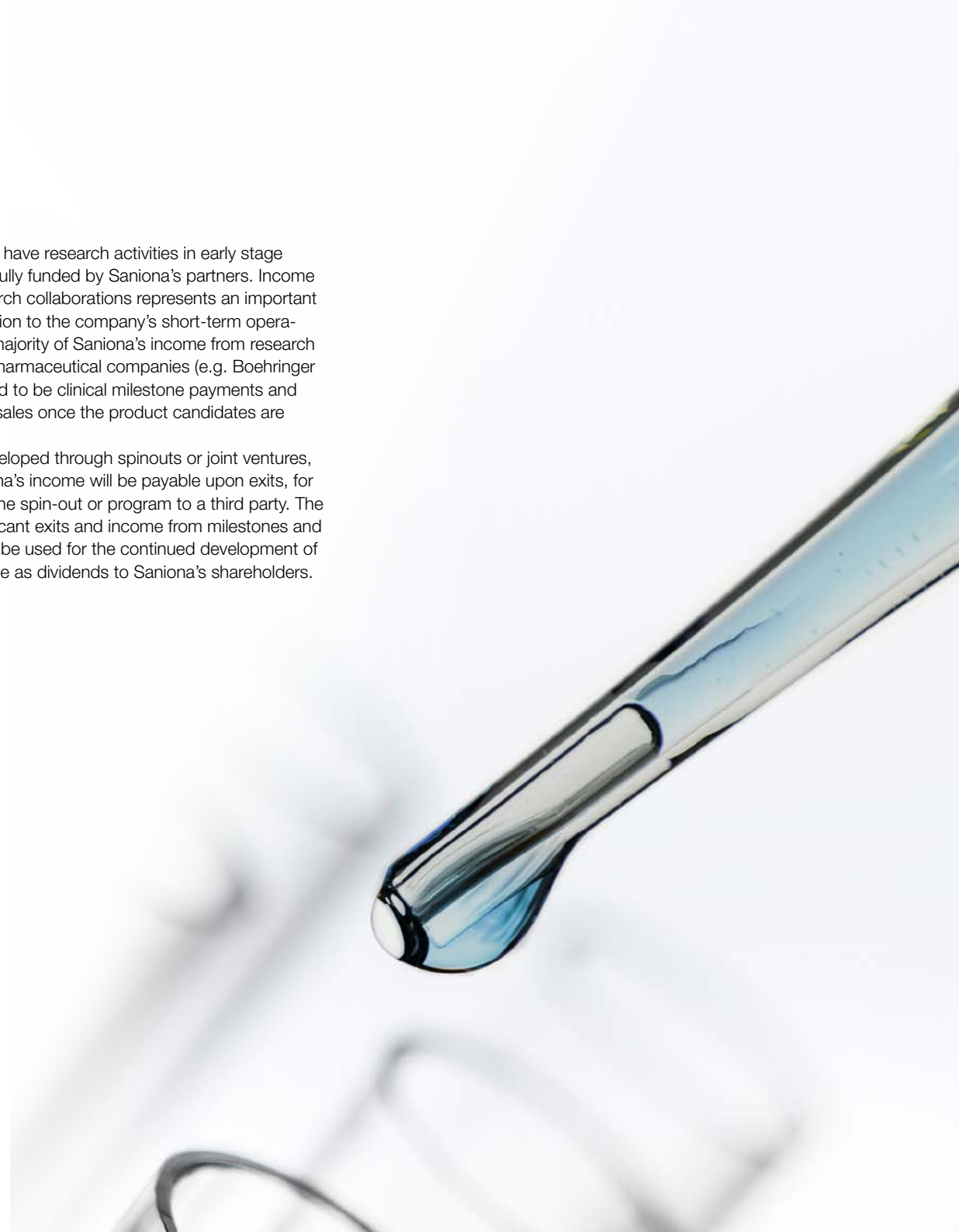
One of Saniona's short term objectives is to develop at least one of its preclinical programs through to Phase 2, with the aim of positioning the product for rare disease indications to support our internal pipeline and product portfolio.

#### **LEVERAGING OUR LEADING POSITION IN ION CHANNEL RESEARCH THROUGH PARTNERSHIPS WITH PHARMACEUTICAL COMPANIES**

Saniona's research strategy is also focused on the establishment of partnerships for early stage drug discovery programs with pharmaceutical companies, through partnerships or out-licensing. Saniona aims to effectively utilize its key competencies 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 intends to have research activities in early stage collaborations to be fully funded by Saniona's partners. Income from Saniona's research collaborations represents an important non-dilutive 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 once the product candidates are commercialized.

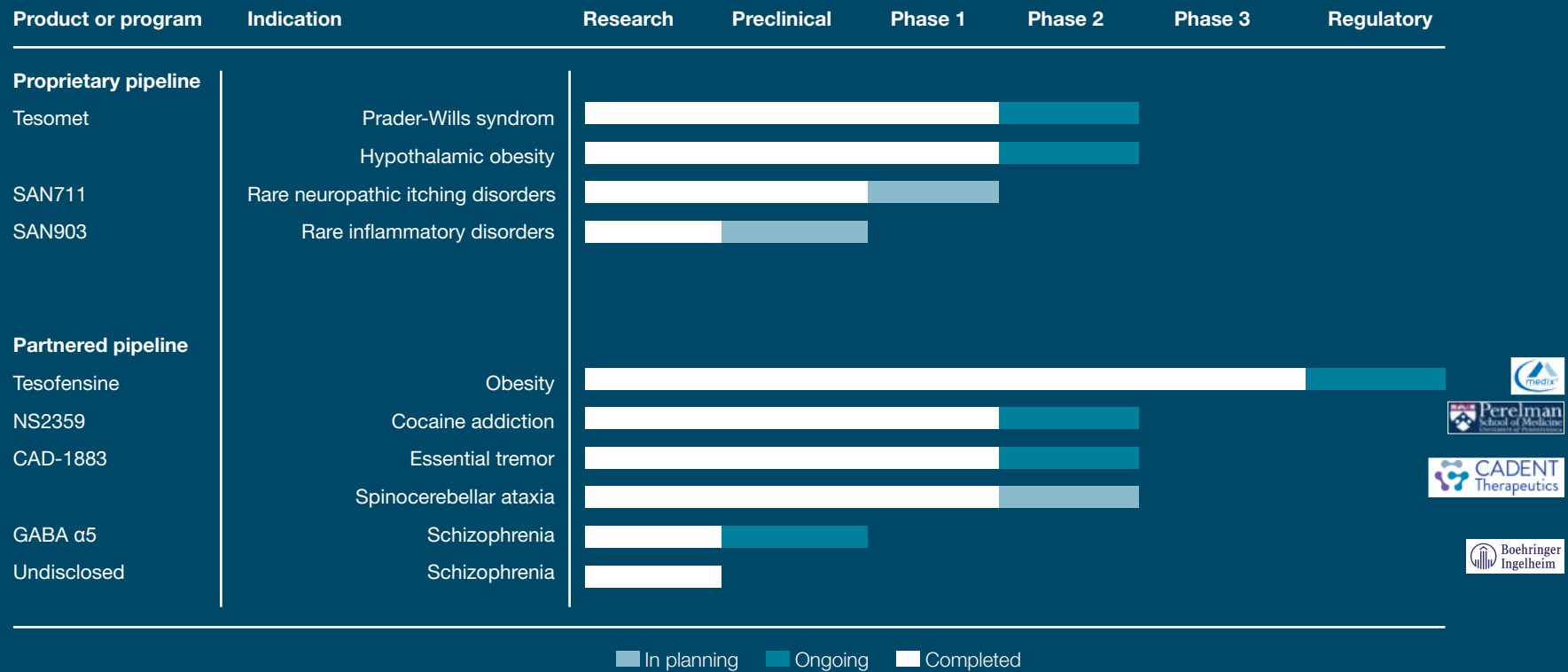
If a program is developed through spinouts or joint ventures, the majority of Saniona's income will be payable upon exits, for example the sale of the spin-out or program to a third party. The proceeds from significant exits and income from milestones and royalty payments will be used for the continued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



# PIPELINE

Saniona has three proprietary programs in clinical development and four clinical development programs in partnership. In addition to this Saniona has two pre-clinical development programs of which one program is financed through partnerships as well as a number of active research programs (not shown in pipeline below).

Saniona's pipeline is set out below.



# PROPRIETARY PIPELINE

Saniona’s most advanced proprietary clinical program is Tesomet for the treatment of rare eating disorders. Saniona has completed a dose-finding Phase 2a proof-of-concept study in PWS and is currently planning for pivotal Phase 2b/3 studies. In parallel Saniona is currently conducting a Phase 2 study in HO with the aim of preparing for Phase 3 study in this indication. Saniona intends to initiate pivotal Phase 2b/3 studies in at least one of these two indications in 2020.

Saniona’s early stage pipeline has been established via discovery efforts from its ion channel platform. 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. Currently, Saniona has two preclinical assets from its ion channel platform that are advancing to the clinic. SAN711, in development for rare itching disorders has completed the preclinical development and is Phase 1 ready. In addition, Saniona has initiated preclinical development for SAN903 in preparation for Phase 1 studies in rare inflammatory and fibrotic disorders.

## 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 mid/stage clinical trials for treatment of Prader-Willi syndrome (PWS) and hypothalamic obesity. Tesomet is covered by several patent applications and certain issued patents which together may provide patent protection until 2036.

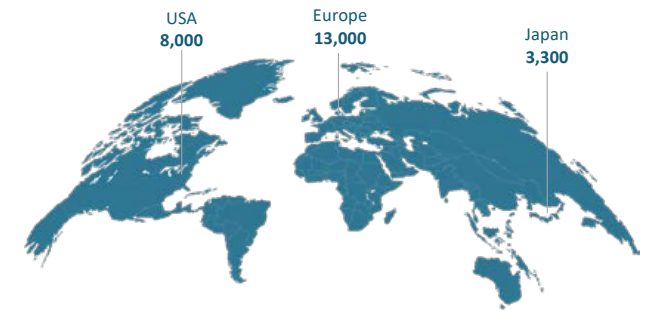
### Prader-Willi syndrome

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 food craving (Hyperphagia) affects the quality of life for the patients as well as their families.

Saniona has completed a dose-finding Phase 2a proof-of-concept study in PWS and is currently planning for pivotal Phase 2b/3 studies.

The Phase 2a study was an exploratory, randomized, double-blind, placebo-controlled trial in 18 patients with PWS, which was divided into two parts; the first was performed in nine adult patients with PWS and the second in nine adolescent patients. The primary endpoint was to examine the change in body weight with Tesomet compared to placebo. Secondary objectives included eating behavior and Hyperphagia, body composition, lipids and other metabolic parameters.

The first part was successfully concluded and with data first reported in 2018. The results showed that Tesomet at 0.5 mg/daily for three months provided clinically meaningful weight loss and a significant reduction in hyperphagia in adult patients. The study results also suggested that the optimal dose of Tesomet in patients with PWS may be lower than in other indications such as normal non-syndromic obese patients.



The second part of the study consisted of a 3-month double blind phase with adolescent patients followed by two 3-month open label extension phases (a total of 9 months study). The patients initially received Tesomet at a quarter of the Tesomet dose given to adult PWS patients (0.125 mg daily) and in the last extension phase of the study, the dose was doubled (0.25 mg daily). The results were reported in September 2019. The study showed that Tesomet appears to be safe and well tolerated at the lower doses with dose dependent effects on weight, BMI and hyperphagia consistent with the observations in adult patients at the higher dose. Saniona’s conclusion is that a broad spectrum of patients with PWS are likely to receive significant reductions in body weight, BMI and hyperphagia at a dose of 0.25 mg Tesomet per day.

Therefore, the completed Phase 2a study indicates a positive effect of Tesomet in this serious rare genetic disease and these data provide guidance and significantly de-risk our planned pivotal Ph2b/3 studies.

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 approx. 20,000 patients in the U.S. and Europe.



“Weight gain, hyperphagia and obsession with food are the greatest burden on both patients with Prader-Willi syndrome and their families.

Tesomet helps to control weight and appetite and it decreases preoccupation with food.

Therefore, patients are more available to other activities, and life as a whole becomes easier for the patients and their families.”

Dóra Török  
Primary Investigator



### Hypothalamic obesity

Like Prader-Willi syndrome, hypothalamic obesity is a rare disease characterized by a loss of appetite control 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, or 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 surgical removal of the tumor, is the most common cause of hypothalamic obesity. Hypothalamic obesity is therefore sometimes also referred to as craniopharyngioma associated obesity.

Saniona is conducting a Phase 2 clinical study of Tesomet to treat hypothalamic obesity. The trial comprises a total of 21 patients and is conducted at Rigshospitalet in Copenhagen, Denmark. In this exploratory randomized, double-blind, placebo-controlled study, patients 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.

The placebo-controlled part of the Phase 2 clinical study was completed in March 2020 and 18 patients have decided to continue into the open label extension study. We expect to report top line results from the double-blind part of the study in Q2 2020. If this trial is successful Saniona may be able to continue into pivotal Phase 2b/3 studies for hypothalamic obesity.

A craniopharyngioma is a rare type of brain tumor derived from pituitary gland embryonic tissue that occurs most commonly in children, but also affects adults. It may present at any age, even in the prenatal and neonatal periods, but peak incidence rates are childhood-onset at 5–14 years and adult-onset at 50–74 years.

Craniopharyngioma has 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”.

Hypothalamic obesity reduces quality of life and there is no approved treatment available today for appetite control in these patients.

### SAN711 FOR TREATMENT OF RARE NEUROPATHIC PAIN AND ITCHING DISORDERS

SAN711 is a first-in-class molecule with a unique profile which acts on the receptors for GABA, the main inhibitory signaling mediator in the nervous system. It is specifically designed to normalize aberrant activity associated with rare neuropathic pain disorders such as Burning Mouth Syndrome or rare intractable neuropathic itch conditions such as prurigo nodularis and brachio-radial pruritus; all rare conditions where no efficient treatment exists today resulting in poor quality of life for the affected patients. SAN711 is a new chemical entity covered by a recently filed patent application which may provide composition-of-matter protection until 2038.

SAN711 works selectively on receptors containing the GABAA  $\alpha 3$  proteins without acting on the other main GABAA receptors, making it the first molecule with this unique profile. 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.

### SAN903 FOR TREATMENT OF RARE INFLAMMATORY/FIBROTIC DISORDERS AND CERTAIN HEREDITARY HEMATOLOGICAL DISEASES

Saniona has selected a drug candidate, SAN903, currently under preclinical development and positioned for treatment of rare inflammatory/fibrotic diseases with no or very inefficient current treatment options. SAN903 inhibits the IK potassium channel (a calcium activated potassium channel also known as KCa3.1, encoded by the gene KCNN4), which is important for activation of immune cells in both peripheral tissues (T-cells, macrophages) and brain (microglia), and is also involved in the abnormal production of connective tissue (by fibroblasts), which leads to fibrosis in chronic diseases.

SAN903 is safe and shows excellent efficacy in standard models of inflammatory diseases. Our current focus is idiopathic lung fibrosis (IPF), which is a serious and fatal lung disease with very limited treatment options. 30,000-150,000 patients suffer from IPF in the U.S. SAN903 is a new chemical entity covered by a recently filed patent application which may provide composition-of-matter protection until 2039.

Due to the role of the IK potassium channel in immune cell function, we are also actively evaluating SAN903 for potential treatment of a rare haematological disease called hereditary xerocytosis (HX) estimated to affect 8-40,000 patients in the U.S. Recent literature evidence demonstrates that HX is caused by gain-of-function mutations in the IK channel gene or in a closely associated Ca-channel and SAN903 is expected to reverse this condition.

A precise pharmacological modulation of the IK channel can thus potentially treat rare diseases, which involve overactive or mis-timed immune reactions, such as idiopathic pulmonary fibrosis (IPF) and hereditary xerocytosis.



# OUT-LICENSING AND PARTNERSHIPS

Saniona's most advanced out-licensed program is tesofensine, which is being developed for obesity by Medix. Medix submitted a new drug application to the Mexican food and drug administration in December 2019 for approval of tesofensine for the treatment of patients with obesity. Saniona's partner Cadent Therapeutics has completed a Phase 2a study for the treatment of essential tremor and expects to start another Phase 2a study in the first half of 2020 for the treatment of Ataxia. Saniona's partner Boehringer Ingelheim is currently conducting a preclinical development program in preparation for Phase 1 studies in schizophrenia.

## TESOFENSINE 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. 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. The trial met its primary endpoints and in December 2019 Saniona reported that Medix has submitted a new drug application to the Mexican food and drug administration for approval of tesofensine for the treatment of patients with obesity.

Mexico ranks among the most obese countries in the world with an estimated more than 70% of 128 million Mexicans being overweight or obese. Eight in ten deaths are caused by chronic, non-communicable diseases that are strongly linked to the overweight and obese population with standardized mortality rates for diabetes, acute myocardial infarction, and hypertension increasing 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 US\$ 200 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 older generics. Tesofensine is believed to be more efficacious and better tolerated than the currently available 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.

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

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.

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,” like 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.

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.

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. Cadent Therapeutics has completed a Phase 2a study of CAD-1883 in essential tremor, demonstrating an improvement in the “Essential Tremor Rating Assessment Scale Performance Score”. In May 2019, the FDA granted Orphan Drug Designation to CAD-1883 as an investigational treatment for spinocerebellar ataxia. In January 2020 Cadent received an acceptance from the FDA to initiate a Phase 2a clinical trial in patients with spinocerebellar ataxia.

Saniona has a 3.4% ownership in Cadent Therapeutics as of December 31, 2019. In addition to ownership in Cadent Thera-

peutics, Saniona is eligible to receive royalties on any potential products developed and commercialized from the SK-program including CAD-1883.

Cadent Therapeutics is a precision neuroscience company developing novel medicines that tune and modulate brain rhythms to restore motor and cognitive function in patients with serious neurological disease. The company leverages its 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, Clal Biotechnology Industries, Slater Technology Fund and Novartis.

#### **BOEHRINGER INGELHEIM PROGRAMS FOR TREATMENT OF SCHIZOPHRENIA (BOEHRINGER INGELHEIM)**

Saniona and Boehringer Ingelheim GmbH (“Boehringer Ingelheim”) have two ongoing partnerships 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.

The first Schizophrenia collaboration with Boehringer Ingelheim was initiated in 2016 and Boehringer Ingelheim selected the first

candidate for preclinical and clinical development in July 2018, triggering a milestone payment of €4 million to Saniona. The program is in the preclinical development phase in preparation 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 2019, Saniona has received a total of €9 million under the collaboration excluding earned income under the research collaboration.

The second research and development collaboration with Boehringer Ingelheim was initiated in March 2020. The objective is to identify new treatment options for schizophrenia, by exploring a novel undisclosed CNS ion channel target using Saniona’s ion channel drug discovery platform. Boehringer Ingelheim has exclusive worldwide rights to research, develop, manufacture and commercialize therapeutics identified through the collaboration. In addition, Saniona will receive research funding during the joint research period. During the first year of the collaboration, Saniona expects to receive research funding of around SEK 5 million (€ 0.45 million).

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.

# 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 25.70 at the end of the year representing a decrease of 20% compared to the previous year. In 2019, the highest price paid during the year was SEK 35.60 on January 9 and the lowest price was SEK 15.56 on August 15. In 2018, the highest price paid during the year was SEK 40.9 on June 12 and the lowest price paid was SEK 24.75 on April 24.

The average volume and trading values were 76,122 (50,291) shares and SEK 1,845,151 (1,618,508). Market capitalization was 730 MSEK at the end of the year, compared to 746 MSEK at the end of the previous year.

## SHARE CAPITAL

At December 31, 2019, the number of shares outstanding was 28,412,519 (23,324,413).

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 1,420,625 (1,166,221) equal to a par value per share of SEK 0.05.

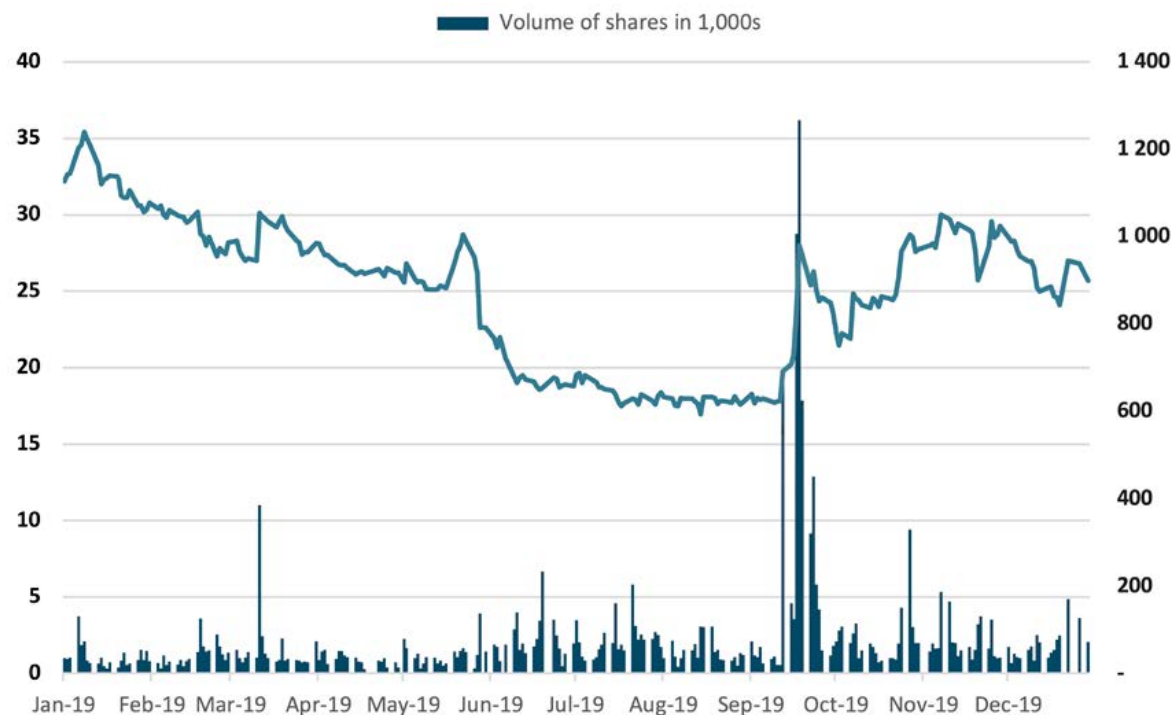
Saniona established a warrant program on July 1, 2017, totaling 38,500 warrants, on January 19, 2018 totaling 286,003 warrants, on July 1, 2018, totaling 45,013 warrants and September 15, 2019, totaling 50,270 warrants. For further details, please see note 9.

## SHAREHOLDERS

At December 31, 2019, Saniona had 6,108 (5,569) shareholders, excluding holdings in life insurance and foreign custody account holders.

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.

## DEVELOPMENT IN PRICE AND VOLUME IN 2019



### LARGEST SHAREHOLDERS AS OF DECEMBER 31, 2019

Shareholder	Number of shares	Ownership and votes
BNY MELLON SA/NV (former BNY), W8IMY*	2,677,790	9.4%
Försäkringsaktiebolaget, Avanza Pension	1,731,810	6.1%
Feldthus, Thomas**	1,220,000	4.3%
Leif Andersson Consulting APS	950,000	3.3%
Nordnet Pensionsförsäkring AB	839,398	3.0%
Christoffersen, Palle	820,000	2.9%
Brästrup, Claus Tycho	735,700	2.6%
NA***	711,296	2.5%
Credit Suisse (Switzerland) LTD	650,000	2.3%
Nordea Livförsäkring Sverige AB	633,971	2.2%
Other shareholders (6,098)	17,442,554	61.4%
<b>Total</b>	<b>28,412,519</b>	<b>100.0%</b>

\* 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

\*\*\* Physical persons

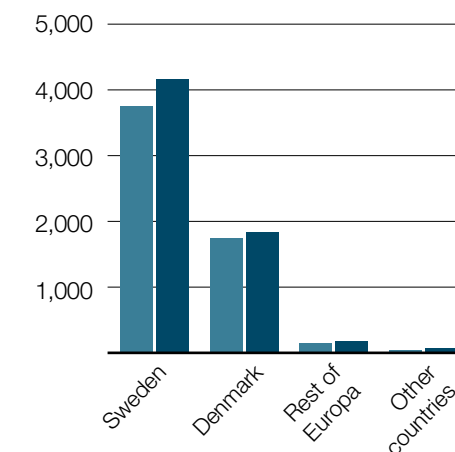
### SHAREHOLDERS AND OWNERSHIP DISTRIBUTION BY SIZE AT THE END OF YEAR IN 2018 AND 2019

Shareholder	Number of shareholders		Shareholding and votes	
	2018	2019	2018	2019
1 - 500	3,068	3,096	2.4%	1.9%
501 - 1,000	882	915	3.1%	2.5%
1,001 - 5,000	1,249	1,545	12.0%	12.2%
5,001 - 10,000	186	282	5.6%	7.1%
10,001 - 15,000	62	96	3.3%	4.2%
15,001 - 20,000	30	57	2.3%	3.6%
20,001 -	92	117	71.4%	68.6%
<b>Total</b>	<b>5,569</b>	<b>6,108</b>	<b>100.0%</b>	<b>100.0%</b>

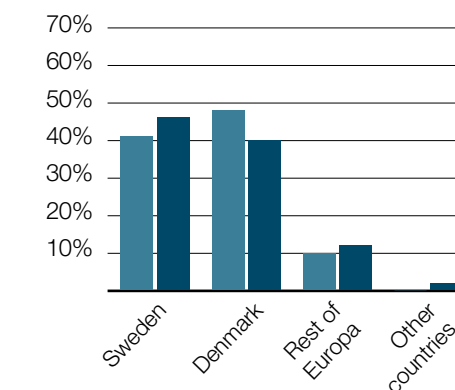
### INSIDERS

All members of the Board and management have insider status.

### SHAREHOLDERS BY COUNTRY



### OWNERSHIP BY COUNTRY



2018  
2019

# 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 severe chronic diseases such as Friedreich's ataxia, which is an autosomal recessive inherited disease that causes progressive damage to the nervous system which manifests in initial symptoms of poor coordination that progresses until a wheelchair is required for mobility.

## ATLAS VENTURE

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

## BENEVOLENTAI

BenevolentAI 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.

## 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 as 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 most 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

**GABAA  $\alpha$ 2/ $\alpha$ 3 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 (HO)**

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 inhibit IK channels, which are expressed by immune cells and believed to be key mediator of inflammation in auto inflammatory diseases such as inflammatory bowel diseases.

**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 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 several 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  $\alpha$ 6 PROGRAM**

The Nic  $\alpha$ 6 program is a small molecule program designed to positively modulate (PAM) the  $\alpha$ 6 ion channels. The  $\alpha$ 6 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 (PWS)**

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 GABAA  $\alpha$ 3 modulator (PAM), which increases the activity of the GABAA 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.

**SAN903**

SAN903 is a selective IK channel modulator, which inhibits the potassium outflux from cells through the IK channels, which are expressed by immune cells and believed to be key mediator of inflammation in auto inflammatory diseases such as inflammatory bowel diseases.

**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.

**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	2019	2018	2017	2016	2015
Net sales	2,658	54,884	20,692	74,921	13,630
Operating expenses	-106,563	-109,089	-77,881	-70,764	-41,705
Operating profit/loss*	-103,906	-54,206	-57,189	4,156	-28,075
Financial items, net	20,404	5,913	914	757	-1,183
Profit/loss before tax	-83,501	-48,292	-56,275	4,913	-29,258
Tax on net profit	7,713	7,233	7,086	-2,696	6,311
<b>Profit/loss for the year</b>	<b>-75,788</b>	<b>-41,059</b>	<b>-49,190</b>	<b>2,217</b>	<b>-22,947</b>

Balance sheet, KSEK	2019	2018	2017	2016	2015
Non-current assets	42,117	12,407	7,806	2,703	2,300
Financial assets	38,635	10,504	6,439	1,519	1,547
Current receivables	13,636	15,990	18,256	14,804	8,369
Cash and cash equivalent	40,248	54,678	22,313	53,261	47,004
<b>Total assets</b>	<b>96,000</b>	<b>83,075</b>	<b>48,375</b>	<b>70,769</b>	<b>57,673</b>
Equity	58,437	39,457	37,628	54,252	52,943
Non-current and current liabilities	37,563	43,617	10,747	16,517	4,730
<b>Total equity and liabilities</b>	<b>96,000</b>	<b>83,075</b>	<b>48,375</b>	<b>70,769</b>	<b>57,673</b>

Cash flow, KSEK	2019	2018	2017	2016	2015
Cash flow from operating activities	-98,469	-22,920	-57,339	7,953	-28,820
Cash flow from investing activities	-749	914	-5,970	-816	-975
Cash flow from financing activities	76,728	46,745	33,175	-403	66,693
<b>Cash flow for the year</b>	<b>-22,491</b>	<b>24,738</b>	<b>-30,134</b>	<b>6,735</b>	<b>36,898</b>

Key figures, %	2019	2018	2017	2016	2015
Operating margin*	Negative	Negative	Negative	6%	Negative
Liquidity ratio*	152%	162%	377%	412%	1171%
Equity ratio*	61%	47%	78%	77%	92%

Share data, SEK	2019	2018	2017	2016	2015
Earnings per share	-2.95	-1.84	-2.30	0.11	-1.29
Diluted earnings per share	-2.95	-1.84	-2.30	0.11	-1.29
Equity per share*	2.06	1.69	1.73	2.60	2.54
Dividend	0.00	0.00	0.00	0.02	0.00
Cash flow per share*	-0.87	1.11	-1.41	0.32	2.08

Share data, #	2019	2018	2017	2016	2015
Average shares outstanding	25,719,586	22,288,524	21,416,810	20,841,467	17,775,099
Diluted average shares outstanding	25,732,676	22,314,283	21,452,001	20,905,467	17,839,099
Shares outstanding at the end of the period	28,412,519	23,324,413	21,762,520	20,841,467	20,841,467

\* Financial measures marked with \* are not defined under IFRS, so called alternative performance measures.

Saniona presents certain financial measures in the annual 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 financial items and tax.	The operating profit/loss is used to measure the profit/loss generated by the operating activities.
Operating margin	Operating profit/loss as a proportion of revenue.	The operating margin shows the proportion of revenue that remains as profit before financial items and taxes and has been included to allow investors to get an impression of the company's profitability.
Liquidity ratio	Current assets divided by current liabilities.	Liquidity ratio has been included to show the company's short-term payment ability.
Equity ratio	Shareholders' equity as a proportion of total assets.	The equity ratio shows the proportion of total assets covered by equity and provides an indication of the company's financial stability and ability to survive in the long term.
Equity per share	Equity divided by the shares outstanding at the end of the period.	Equity per share has been included to provide investors with information about the equity reported in the balance sheet as represented by one share.
Cash flow per share	Cash flow for the period divided by 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

	2019	2018	2017	2016	2015
Operation profit/loss, KSEK	-103,906	-54,206	-57,189	4,156	-28,075
Net sales, KSEK	2,658	54,884	20,692	74,921	13,630
<b>Operating margin, %</b>	<b>-3909%</b>	<b>99%</b>	<b>-276%</b>	<b>6%</b>	<b>-206%</b>
Cash flow for the year, KSEK	-22,491	24,738	-30,134	6,735	36,898
Average number of shares outstanding	25,719,586	22,288,524	21,416,810	20,841,467	17,775,099
<b>Cash flow per share, SEK</b>	<b>-0.87</b>	<b>1.11</b>	<b>-1.41</b>	<b>0.32</b>	<b>2.08</b>

	2019-12-31	2018-12-31	2017-12-31	2016-12-31	2015-12-31
Current assets, KSEK	53,883	70,668	40,569	68,066	55,373
Current liabilities, KSEK	35,416	43,617	10,747	16,517	4,730
<b>Liquidity ratio, %</b>	<b>152%</b>	<b>162%</b>	<b>377%</b>	<b>412%</b>	<b>1171%</b>
Equity, KSEK	58,437	39,457	37,628	54,252	52,943
Total equity and liabilities, KSEK	96,000	83,075	48,375	70,769	57,673
<b>Equity ratio, %</b>	<b>61%</b>	<b>47%</b>	<b>78%</b>	<b>77%</b>	<b>92%</b>
Equity, KSEK	58,437	39,457	37,628	54,252	52,943
Shares outstanding at the end of the period	28,412,519	23,324,413	21,762,520	20,841,467	20,841,467
<b>Equity per share, SEK</b>	<b>2.06</b>	<b>1.69</b>	<b>1.73</b>	<b>2.60</b>	<b>2.54</b>



# 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, 2019 – December 31, 2019.

The Group comprises the Parent Company Saniona AB and the subsidiaries 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 rare disease biopharmaceutical company focused on research, development and commercialization of treatments for the central nervous system. The company has four programs in clinical development. Saniona intends to develop and commercialize treatments for rare disease indications such as Prader-Willi syndrome and hypothalamic obesity on its own. The research is focused on ion channels and the company has a broad portfolio of research programs. Saniona has partnerships with Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and Cadent Therapeutics. Saniona is based in Copenhagen, Denmark, and the company's shares are listed at Nasdaq Stockholm Small Cap (OMX: SANION).

Saniona is developing products internally with the aim of attaining market approval itself in the U.S. and Europe for rare diseases 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.

Several of Saniona's internal and early stage development programs may potentially be developed and commercialized for both rare diseases 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 yet 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 world-wide 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 11-14).

## BUSINESS REVIEW FOR 2019

**In 2019, Saniona decided to establish its management and clinical operation in the U.S, to focus its efforts on the key market for its rare disease indications and to get better access to the U.S. financial market**

In 2019, we reviewed our global strategy and decided to focus our efforts in the U.S., where we intend to build up a full-fledged organization to address key future opportunities. This will be a vital step towards our longer-term aim of becoming a global company.

As part of this strategy, Saniona decided to hire a new, U.S.-based Chief Executive Officer. Appointed as President and CEO in January 2020, Rami Levin brings extensive commercial experience in CNS and rare diseases both in the U.S. and globally. Rami Levin is based in Boston. As part of this strategic transformation, Saniona has now initiated the search for a Chief Medical Officer and Head of Clinical Development and a Chief Financial Officer who will both be based in Boston with the CEO.

**Phase 2a proof-of-concept and dose finding study in adult and adolescent patients successfully completed**

In 2019, Saniona has completed a dose-finding Phase 2a proof-of-concept study in PWS and is currently planning for pivotal Phase 2b/3 studies.

The Phase 2a study was an exploratory, randomized, double-blind, placebo-controlled trial in 18 patients with PWS, which was divided into two parts; the first was performed in nine adult patients with PWS and the second in nine adolescent patients. The primary endpoint was to examine the change in body weight with Tesomet compared to placebo. Secondary objectives included eating behavior and food craving (hyperphagia), body composition, lipids and other metabolic parameters.

The first part was successfully concluded with data and first reported in 2018. The results showed that Tesomet at 0.5 mg/day (tesofensine 0.5 mg + metoprolol 50 mg daily) for three months provided clinically meaningful weight loss and a significant reduction in hyperphagia in adult patients. The study results also suggested that the optimal dose of Tesomet in patients with PWS may be lower than in other indications such as normal non-syndromic obese patients.

The second part of the study consisted of a 3-month double blind phase with adolescent patients followed by two 3-month open label extension phases. The patients initially received Tesomet at a quarter of the tesofensine dose given to adult PWS patients (tesofensine 0.125 mg + metoprolol 25 mg daily) and in the last extension study half of the tesofensine dose given to adult PWS patients (tesofensine 0.25 mg + metoprolol 25 mg daily). The results were reported in September 2019. The study showed that Tesomet appears to be safe and well tolerated at the lower doses with dose dependent effects on weight, BMI and hyperphagia consistent to the observations in adult patients at the higher dose. Saniona's conclusion is that a broad spectrum of patients with PWS are likely to receive significant benefits on body weight, BMI and hyperphagia at a dose of 0.25 mg tesofensine per day.

Therefore, the completed Phase 2a study indicates a positive effect of Tesomet in this serious rare genetic disease and these data provide guidance and significantly de-risk our planned pivotal Phase 2b/3 studies.

### **Phase 2 proof of concept study for treatment of hypothalamic obesity ongoing**

In parallel with PWS, Saniona initiated in February 2019 a Phase 2 proof of concept study for Tesomet in hypothalamic obesity (HO) at Rigshospitalet in Copenhagen, Denmark.

The Phase 2 study is an exploratory randomized, double-blind, placebo-controlled study in up to 25 patients with HO. The 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.

In November 2019, Saniona reported that it has completed the recruitment of patients and that the first patients, who were recruited in March, have elected to continue as part of the open-label extension part of the study.

The placebo-controlled part of the Phase 2 clinical study was completed in March 2020 and 18 patients have decided to continue into the open label extension study. We expect to report top line results from the double-blind part of the study

in Q2 2020 and the full data for the open label extension at the end of the year. If this trial is successful Saniona may be able to continue into pivotal Phase 2b/3 studies for hypothalamic obesity.

### **Saniona's partner, Medix, filed a new drug application in Mexico for tesofensine as a new treatment in obesity**

In December 2019, Saniona's partner Medix submitted a new drug application to the Mexican regulatory authority for approval of tesofensine for the treatment of patients with obesity. Medix successful 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. Medix, which owns commercial rights in Mexico and Argentina, expects to launch tesofensine in Mexico in 2020, which would create a new revenue stream as Saniona is entitled to double digit royalties on product sales in the two countries. Saniona retains all rights to tesofensine in the rest of the world including the exclusive rights to use the clinical data generated by Medix. The royalty income from Medix and the obtained Phase 3 results support development of Saniona's wholly-owned Tesomet, a fix-dosed combination of tesofensine and metoprolol in Phase 2 for rare eating disorders.

### **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, successful completes Phase 2a for the Saniona collaboration compound, CAD-1883, in essential tremor**

Saniona's partner, Cadent Therapeutics, has made significant progress on the collaboration compound, CAD-1883. Cadent Therapeutics is developing CAD-1883 for the serious movement disorders, essential tremor and spinocerebellar ataxia. In 2019, Cadent Therapeutics has completed a Phase 2a study of CAD-1883 in essential tremor with positive results and received acceptance of an Investigational New Drug (IND) application for a Phase 2a study in spinocerebellar ataxia. Cadent Therapeutics has also informed that they intend to explore a third, undisclosed indication. 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 rare neuropathic pain and itching disorders**

In 2019, we successfully completed a full regulatory toxicological program for our first in class compound, SAN711. SAN711 offers a new treatment paradigm for rare neuropathic pain disorders such as Burning Mouth Syndrome and rare intractable neuropathic itch conditions such prurigo nodularis. SAN711 may also be used for treatment of more common itching indications and neuropathic pain. Therefore, SAN711 represents a valuable program which may be pursued for rare indications internally or for common diseases together with a potential partner.

### **Development candidate, SAN903, selected for treatment of rare inflammatory and fibrotic disorders**

In 2019, we selected a development candidate, SAN903, in the IK program for treatment of rare inflammatory and fibrotic disorders such as idiopathic pulmonary fibrosis where patients have no good available treatment options today. SAN903 is first in class compound and represents a new concept in



inflammatory and autoimmune diseases. This concept may also be used as new treatment paradigm for treatment of common diseases such as Crohn's disease and colitis. Therefore, SAN903 represents a valuable program which may be pursued for rare indications internally or for common diseases together with a potential partner.

#### **Boehringer Ingelheim and Saniona establish collaboration on new target while preclinical development on existing collaboration program is ongoing**

In 2016, Boehringer Ingelheim and Saniona established a collaboration for development of new therapeutics targeting GABA  $\alpha 5$  ion channels for treatment of cognitive impairment in schizophrenia and other central nervous diseases. In 2018, Boehringer Ingelheim selected a clinical candidate and the program is currently in preclinical development phase in preparation for clinical studies.

In March 2020, Boehringer Ingelheim and Saniona established a second collaboration program for development of therapeutics for schizophrenia. Boehringer Ingelheim has exclusive worldwide rights to research, develop, manufacture and commercialize therapeutics identified through the collaboration. Under the new collaboration Saniona may receive up to € 76.5 million in milestone payments and royalties on worldwide net sales of any resulting products under the collaboration. The program is in early research stage.

#### **Edward C. Saltzman elected as new member of the Board of Directors**

At the annual general meeting, Saniona's shareholders elected Edward C. Saltzman as a new member of the Board of Directors, bringing his extensive strategic and commercial experience within rapidly growing biotechnology companies to Saniona. Edward is Executive Chairman of Cello Health BioConsulting (previously Defined Health), a leading strategic business development advisory firm that has been serving the pharmaceutical, biotech and healthcare investment industries for more than 25 years.

#### **Establishment of Scientific Advisory Board (SAB) for Tesomet in PWS**

In 2019, Saniona established a Scientific Advisory Board (SAB) for Tesomet in PWS comprising several highly regarded experts from the U.S. and Europe with a profound experience in the disease including Tony Holland, MD, CBE; Theresa Strong, PhD; Janice Forster, MD; and Susanne Blichfeldt, MD. The SAB provides valuable contributions to Saniona by reviewing our clinical plans and providing advice regarding preparations for the Phase 2b and Phase 3 meetings with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA).

#### **Financing secure further development of Tesomet in PWS and HO**

During the first four months of 2019, Saniona draw four tranches totaling SEK 24 million under the financing agreement with Nice and Green of which all has been converted to shares.

In June 2019, the company secured a financing round with gross proceeds of SEK 66.5 million. The rights issue secured Saniona's near term financing requirements and enabled the company to complete the ongoing Phase 2a studies with Tesomet for the treatment of PWS and HO and initiate discussions with regulatory agencies for start of Phase 2b/3 studies in 2020.

In January 2020 Saniona completed a private placement of SEK 25 million and proposed a financing of up to SEK 158 million comprising a combination of the directed issue and rights issue of warrants totaling SEK 111 million – 133 million at a strike price of SEK 25 – 30 per share as well as a loan facility of SEK 25 million. The proposal was approved at a general meeting in February and the rights issue was completed in March 2020. The net proceeds from the private placement and the loan facility together with the potential subsequent proceeds from utilization of the warrants replaced the existing financing agreement with Nice & Green dated 28 December 2017, and will be used for the continued development of the company's key asset, Tesomet, for the rare diseases Prader-Willi syndrome and hypothalamic induced obesity.

## **FINANCIAL REVIEW FOR 2019**

### **Revenue and results of operation**

Saniona generated total revenues of 2.7 MSEK (54.9) for the full year of 2019. In 2019, revenues comprised research funding under the agreement with Boehringer Ingelheim. In 2018, revenues comprised a research milestone payment of SEK 41.8 million (€ 4 million) as a result of the candidate selection by Boehringer Ingelheim and research funding totaling SEK 13.1 million under the agreements with Boehringer Ingelheim and BenevolentAI.

The company recognized operating expenses of 106.6 MSEK (109.1), a decrease of 2%. External expenses amounted to 75.0 MSEK (80.1), a decrease of 6%. In 2019, external expenses comprised primarily development costs in relation to Tesomet totaling 40.9 MSEK and preclinical development costs in relation to SAN711 with 2.4 MSEK and research and development costs in relation to other research programs including SAN903 totalling 11.7 MSEK. 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. Personnel costs amounted to 25.9 MSEK (24.2), an increase of 6%. The average exchange rate of SEK against DKK decreased with 3% in 2019 compared to 2018 leading to an increase in some of Saniona costs when presented in SEK.

The operating loss for the full year of 2019 was 103.9 MSEK (54.2). Net financial items amounted to SEK 20.4 MSEK (5.9). The loss for the full year of 2019 was 75.8 MSEK (41.1). Saniona recognize a tax credit for the full year of 2019 of 7.7 MSEK (7.2) 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, 2019, were 96.0 MSEK (83.1). Cash and cash equivalents amounted to 40.2 MSEK (54.7) as of December 31, 2019. The equity ratio was 61 (47) % as of December 31, 2019, and equity was 58.4 MSEK (39.5).

Saniona is in an expansion phase where the company will continue to invest significant resources in research and development aiming at generating future income. Saniona intends to finance its operations for the next 12 months through available cash and other assets, as well as revenues from current collaboration agreements. Should the opportunity rise for faster growth, Saniona may raise additional capital through issuing new shares. Also, warrants such as in the financing agreement with Formue Nord entered in January 2020 can be used.

#### Cash flow

Operating cash flow for the full year of 2019 was an outflow of SEK 98.5 million (outflow 22.9). Consolidated cash flow for the full year of 2019 was outflow of SEK 22.5 million (inflow 24.7).

In 2019, the operating cash flow is explained by the loss before tax of SEK 83.5 million and adjustment for non-cash transaction of 15.9 million where reclassification of the company ownership in Scandion Oncology accounts for SEK 20.2 million which is partly offset by non-cash transacting relating to depreciation and share based payments. The consolidated cash flow in 2019 is further explained by an inflow from finance activities of SEK 76.7 million through a rights issue providing net proceeds of SEK 53.6 million and the issue of convertible loan notes to Nice & Green totaling SEK 24 million. In 2019, the convertible loan notes of SEK 24 million together with the outstanding loan notes at year-end 2018 totaling SEK 6 million have been converted into equity and the net proceeds of SEK 29 million is recorded under new share issues after deduction of issuing expenses.

In 2018, the operating cash flow is explained by the loss before tax of SEK 48.3 million and an improvement in working capital of SEK 29.4 million 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 SEK 46.7 million through the issue of convertible loan notes to Nice & Green totaling SEK 48 million of which SEK 6 million has not been converted at the balance sheet date. The balance of SEK 42 million was converted into equity during 2018 and the net proceeds of SEK 40.7 million is recorded under new share issues after deduction of issuing expenses.

#### 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 1.4 MSEK (0). Operating expenses amounted to 10.5 MSEK (7.9), an increase of 32%. The Parent Company recognized a profit on net financial items of 7.3 MSEK (7.9). The loss for the full year of 2019 was 1.8 MSEK as opposed to a profit of 19 KSEK in 2018.

#### 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.

The risks presented below could have a material negative impact on Saniona's operations, earnings and financial position.

#### Risk related to the company and industry

##### Risk related to COVID-19

An outbreak of an infectious disease, a pandemic or a similar public health threat, such as the recent outbreak of the novel coronavirus known as COVID-19, could adversely impact the company by causing operating, clinical trial and project development delays and disruptions, labour shortages, travel and shipping disruption and shutdowns (including as a result of government regulation and prevention measures). The Company may incur expenses or delays relating to such events outside of its control, which could have a material adverse impact on its business, operating results and the company's ability to raise capital.

To date, Saniona's clinical trials have not been impacted by COVID-19. The hypothalamic obesity phase 2 clinical trial, the last active clinical trial we currently have, was able to conclude and close in March 2020 despite COVID-19 Pandemic.

##### 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 will be unable to raise additional capital, maintain or achieve additional partnerships or raise other financing. This may lead to a temporary halt on the clinical development activities or result in Saniona operating at a slower rate than desired, which may affect the company's operations.

##### Clinical studies

Saniona has three proprietary products in four different clinical programs. All the programs require continued clinical studies to prove acceptable safety, and efficiency profiles before they can be commercialized in the market. If Saniona cannot obtain, or is 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 may not be possible to reach commercialization.

To perform clinical studies, Saniona is dependent on the participation of patients, external service providers who help manage the run the studies. In case the patient participation cannot be obtained, or in case our service providers do not perform, this can delay or impact the results in those trials.

##### 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 approvals must be obtained from the relevant authorities in the respective market, such as FDA in the US and EMA in EU. Future changes in applicable legislation may also lead to delays and increased costs. In case Saniona does not obtain required regulatory approvals for one or more of its products, the product 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 received marketing authorization, including requirements for supervision of the marketing practices and, safety reporting. In case Saniona does not meet the applicable regulatory requirements, the company may be subject to fines or even withdrawals of products.

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, CSO 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.

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.

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 hurt the company.

Out Licensing Agreements

Saniona has chosen to enter into out licensing agreements with several pharmaceutical companies. Part of Saniona's activities have been financed through such agreements. In case any of the company's partners would choose to terminate the cooperation or if the clinical development is delayed or fails, these would have a financial impact on Saniona as development milestone payments would either be delayed or seize,

In such out licensing agreements, Saniona is also entitled to royalty payments once the products are approved and commercialized. If such a product is not approved in commercialized, Saniona will not receive royalty payments.

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 annually. 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 22.4 (23.5), of whom 12.0 (12.2) were women. As of December 31, 2019, the number of employees was 24 (25) of which 13 (13) were women. Of these employees, 5 (3) were part-time employees and 19 (22) were full-time employees, and a total of 19 (20) worked in the company's research and development operations. 11 (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 29, 2019 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 2020. The management is defined as the CEO and the senior executives who report to the CEO, which during 2019 has been 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.

In connection with the employment of Rami Levin as new CEO of Saniona, the Board of Directors resolved to deviate from the guidelines for remuneration resolved by the Annual General Meeting 2019. The deviations are further described below under the heading "Deviations from the guidelines adopted by the Annual General Meeting 2019".

**Proposal for new guidelines for remuneration to senior executives**

For the Annual General Meeting 2020, the Board of Directors proposes that the guidelines for remuneration are updated according to the new rules in the Swedish Companies Act as of January 1, 2020 pertaining to guidelines for remuneration to senior executives. The proposed new guidelines are set out below.

**Scope and applicability of the guidelines**

These guidelines comprise the persons who are part of Saniona's group management, currently the CEO, CFO and CSO. The guidelines also encompass any remuneration to members of the Board of Directors (e.g. consultancy fees), in addition to board remuneration.

These guidelines are applicable to remuneration agreed, and amendments to remuneration already agreed, after adoption of the guidelines by the Annual General Meeting 2020. These guidelines do not apply to any remuneration resolved by the general meeting, such as e.g. board remuneration and share-based incentive programs.

**The guidelines' promotion of the company's business strategy, long-term interests and sustainability**

Saniona is a rare disease biotechnology company focused on research, development and commercialization of treatments for the central nervous system. In brief, Saniona's business strategy is to develop products internally with the aim of attaining market approval by itself in the U.S. and Europe for certain orphan indications where the required investments are limited. 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. For more information about Saniona's business strategy, see Saniona's latest annual report.

A successful implementation of Saniona's business strategy and safeguarding of Saniona's long-term interests, including its sustainability, require that the company is able to recruit and retain highly competent senior executives with a capacity to

achieve set goals. In order to achieve this, Saniona must offer a competitive total remuneration on market terms, which these guidelines enable.

Long-term share-based incentive programs have been established in Saniona. For further information about these programs, see Saniona's latest annual report. The share-based incentive programs have been approved by the general meeting and are therefore not covered by these guidelines.

Variable cash remuneration covered by these guidelines shall be based on criteria aimed at promoting the company's business strategy and long-term interests, including its sustainability.

**Types of remuneration, etc.**

The remuneration shall be on market terms and be competitive and may consist of the following components: fixed salary, variable cash remuneration, pension benefits and other benefits.

For the individual senior executive, the level of remuneration shall be based on factors such as work duties, expertise, position, responsibilities and performances. Additionally, the general meeting may – irrespective of these guidelines – resolve on, e.g. share and share price-related remuneration. For employments governed by rules other than Swedish, pension benefits and other benefits may be duly adjusted for compliance with mandatory rules or established local practice, considering, to the extent possible, the overall purpose of these guidelines.

**Fixed salary**

The CEO and other senior executives shall be offered a fixed annual cash salary. The fixed cash salary shall be determined per calendar year with salary revision on an annual basis on 1 January each year.

**Variable cash remuneration**

In addition to fixed salary, the CEO and other senior executives may, according to separate agreements, receive variable cash remuneration. Variable cash remuneration covered by these guidelines is intended to promote Saniona's business strategy and long-term interests, including its sustainability.

The satisfaction of criteria for awarding variable cash remuneration shall be measured over a period of one year. Any variable cash remuneration may not exceed 50 percent of the

fixed annual cash salary. Variable cash remuneration shall not qualify for pension benefits, save as required by mandatory collective bargaining agreements.

The variable cash remuneration shall be linked to one or several predetermined and measurable criteria, which can be financial, such as completing a financing of a specified amount by a specified time, or non-financial, such as successful completion of a development activity such as a clinical trial by a specified date. Less than 80 percent of the variable cash remuneration shall depend on non-financial criteria. By linking the goals in a clear and measurable way to the remuneration of the senior executives to Saniona's financial and operational development, they contribute to the implementation of the company's business strategy, long-term interests and sustainability.

To which extent the criteria for awarding variable cash remuneration has been satisfied shall be evaluated and determined when the measurement period has ended. The Remuneration Committee is responsible for the evaluation. For financial objectives, the evaluation shall be based on the latest financial information made public by the company.

The Board of Directors shall have the possibility to, in whole or in part, reclaim variable cash remuneration paid on incorrect grounds.

Additional variable cash remuneration may be awarded in extraordinary circumstances, provided that such extraordinary arrangements are only made on an individual basis, either for the purpose of recruiting or retaining senior executives, or as remuneration for extraordinary performance beyond the individual's ordinary tasks. Such remuneration may not exceed an amount corresponding to 100 percent of the fixed annual cash salary and may not be paid more than once each year per individual. Any resolution on such remuneration shall be made by the Board of Directors based on a proposal from the Remuneration Committee.

#### **Pension benefits**

Pension benefits, including a US-based 401 (k) retirement plan, shall be defined contribution, insofar as the senior executive is not covered by defined benefit pension under mandatory

collective bargaining agreements. Pension premiums for defined contribution pensions may not exceed standard biotech industry practices in the geography where the benefits are implemented and may in no event amount to a total of more than 15 percent of the fixed annual cash salary.

#### **Other benefits**

Other benefits may include life insurance, medical insurance, dental insurance, vision insurance, flexible spending accounts (FSA), Health & Dependent Care, Life and AD&D Insurance, Short- and Long-Term Disability, Voluntary Supplemental Life Insurance, Employee Assistance Program (EAP) and a company car. Premiums and other costs relating to such benefits may not exceed standard biotech industry practices in the geography where the benefits are implemented and may in no event amount to a total of more than 20 per cent of the fixed annual cash salary.

#### **Termination of employment and severance payment**

Senior executives shall be employed until further notice or for a specified period of time. Upon termination of an employment by Saniona, the notice period may not exceed 12 months. Fixed cash salary during the notice period and severance pay may not together exceed an amount corresponding to the fixed cash salary for 24 months. Upon termination by the senior executive, the notice period may not exceed six months, without any right to severance pay.

In addition to fixed cash salary during the period of notice and severance pay, additional remuneration may be paid for non-compete undertakings. Such remuneration shall compensate for loss of income and shall only be paid in so far as the previously employed senior executive is not entitled to severance pay for the period for which the non-compete undertaking applies. The remuneration shall be based on the fixed cash salary at the time of termination of employment and amount to not more than 60 percent of the fixed cash salary at the time of termination of employment, save as otherwise provided by mandatory collective bargaining agreements, and shall be paid during the time as the non-compete undertaking applies, however not for more than 12 months following termination of employment.

#### **Salary and employment conditions for employees**

In the preparation of the Board of Directors' proposal for these remuneration guidelines, salary and employment conditions for employees of Saniona have been taken into consideration by including information on the employees' total income, the components of the remuneration and increase and growth rate over time, in the Remuneration Committee's and the Board of Directors' basis of decision when evaluating whether the guidelines and the limitations set out herein are reasonable.

#### **Consultancy fees to the members of the Board of Directors**

To the extent a member of the Board of Directors renders services for the company, in addition to his or her assignment as a member of the Board of Directors, an additional consultancy fee on market terms may be paid to the member of the Board of Directors, or to a company controlled by such member of the Board of Directors, provided that such services contribute to the implementation of Saniona's business strategy and the safeguarding of Saniona's long-term interests, including its sustainability.

#### **Preparation and decision-making progress**

The Board of Directors has established a Remuneration Committee. The Remuneration Committee's duties include i.a. preparing the Board of Directors' resolution to propose guidelines for remuneration to senior executives. The Board of Directors shall prepare a proposal for new guidelines at least every fourth year and submit it to the general meeting. The guidelines shall be in force until new guidelines have been adopted by the general meeting. The Remuneration Committee shall also monitor and evaluate programs for variable remuneration for the senior executives as well as the current remuneration structures and compensation levels in the company. The members of the Remuneration Committee are independent in relation to the company and its senior management. The CEO and other members of the senior management do not participate in the Board of Directors' processing of and resolutions regarding remuneration-related matters in so far as they are affected by such matters.



**Deviation from these guidelines**

The Board of Directors may temporarily resolve to deviate from these guidelines, in whole or in part, if in a specific case there is special cause for the deviation and a deviation is necessary to serve the company's long-term interests, including its sustainability, or to ensure the company's financial viability. As set out above, the Remuneration Committee's tasks include preparing the Board of Directors' resolutions in remuneration-related matters, which include any resolutions to deviate from these guidelines.

**Deviations from the guidelines adopted by the Annual General Meeting 2019**

In connection with the employment of Rami Levin as new CEO of Saniona, the Board of Directors deemed that special cause existed (that is, the ability to recruit a CEO with such experience and skills that can contribute to Saniona's continued development and growth) to deviate from the guidelines for remuneration to senior executives adopted by the Annual General Meeting 2019. The deviations are that the new CEO has been offered variable cash remuneration linked to corporate and individual performance targets, severance payment, in addition to salary and other benefits during the notice period, pension benefits and other customary benefits.

**Information regarding resolved remunerations that have not yet fallen due**

Apart from the commitments to pay ongoing remuneration such as salary, pension and other benefits, there are no previously resolved remuneration to any senior executives that have not yet fallen due. For further information on remuneration to senior executives, please see note 9 in Saniona's annual report.

**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, 2019, the company had 6,108 (5,569) shareholders excluding holdings in life insurance and foreign custody account holders. The company's CSO, Jørgen Drejer, was the largest shareholder with 8.3 percent (10.1) of the share capital and voting rights. The ten largest shareholders jointly accounted for 38.6 percent (42.9) of the share capital and voting rights.

Saniona's share capital totaled SEK 1,420,625.95 divided between 28,412,519 shares as of December 31, 2019. In 2018, Saniona's share capital totaled SEK 1,166,220.65 divided between 23,324,413 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 29, 2019, 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 or convertibles, other than in relation to the now terminated financing agreement with Nice & Green S.A. (see below), the total number of shares that may be issued (or issued upon conversion of convertibles) shall not exceed 11,961,240 shares and the subscription price shall be on market terms (subject to customary new issue discount, as applicable). The purpose of this part of the authorization 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 in relation to the financing agreement that the company on 29 December 2017 entered into with Nice & Green S.A.

("N&G"), 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 per cent 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 has to 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 per cent 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 this part of the authorization is to be able to draw tranches under the financing agreement with N&G.

Upon full utilization of the authorization, a maximum of 23,961,240 shares will be issued or alternatively be issued upon conversion, which corresponds to a total dilution effect of approximately 50 per cent. Note, however, that Saniona concluded its financing agreement with N&G in January 2020.

## OTHER INFORMATION

For additional information, please see the Corporate Governance Report on page 66.

## EVENTS AFTER THE BALANCE SHEET DATE

- \* On January 7, 2020, Saniona appointed Rami Levin as President and Chief Executive Officer. Rami Levin will oversee the transition of Saniona to a fully-fledged biopharmaceutical company. He has extensive commercial experience in CNS and rare diseases, both in U.S and globally. Jørgen Drejer, previous CEO, will continue in the role of Chief Scientific Officer.
- \* In January 2020 Saniona, Inc. was registered in the commonwealth of Massachusetts, U.S.A.
- \* On January 10, 2020, Saniona completed a private placement of SEK 25 million and proposed a financing of up to SEK 158 million comprising a combination of the directed issue and rights issue of warrants totaling SEK 111 million – 133 million at a strike price of SEK 25 – 30 per share as well as a loan facility of SEK 25 million.
- \* On February 7, 2020, the extraordinary shareholders' meeting resolved on approval of the board of directors' proposed financing comprising a combination of the directed issue and rights issue of warrants. Furthermore, the extraordinary shareholders meeting resolved to adopt an employee option program for the CEO, Rami Levin, involving the allotment of a maximum of 710,313 employee options.
- \* On February 14, 2020, Saniona published prospectus relating to the rights issue of units.
- \* On February 18, 2020, Saniona co-founds new migraine therapy company Cephagenix.
- \* On February 18, 2020, Saniona announced CFO Thomas Feldthus will be departing the company and Saniona initiated search for new, U.S.-based CFO.
- \* On February 19, 2020, Saniona publishes supplementary prospectus.
- \* On March 4, 2020, Saniona publishes that the rights issue of free-of-payment units is oversubscribed.
- \* On 18 March 2020, Saniona announced that the six-month double-blind Phase 2 trial of Tesomet in hypothalamic obesity had been completed.

- \* On 24 March 2020, Saniona announced that Anita Milland, the current VP of Finance and Administration, had been appointed interim CFO and Head of IR, and Jørgen Drejer would assume the role of Deputy CEO.
- \* On 26 March 2020, Saniona announced that they had signed a second research collaboration concerning schizophrenia with Boehringer Ingelheim.

## FINANCIAL CALENDAR

Interim Report Q1 .....	May 6, 2020
Annual General Meeting.....	May 6, 2020
Interim Report Q2 .....	August 27, 2020
Interim Report Q3 .....	November 26, 2020
Year-End Report 2020 .....	February 25, 2021

## PROPOSED APPROPRIATION OF FUNDS

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

SEK	
Share premium reserve	238,080,108
Profit/loss carried forward	-17,959,722
Profit/loss for the year	-1,825,982
<b>Total</b>	<b>218,294,404</b>

The Board of Directors propose that the funds at their disposal, SEK 218,294,404, 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



54.12	- 0.50
05.26	+ 2.22
45.00	- 2.32
95.41	- 0.02
08.15	- 0.08
95.02	+ 0.23
04.02	- 2.22
05.03	+ 5.00
09.01	+ 1.02
78.56	- 1.03
90.03	- 3.57
25.12	+ 0.56
24.65	+ 1.00
00.59	- 0.05
03.05	- 2.02
58.26	+ 0.56
21.50	+ 0.01
00.31	- 0.05
73.05	- 1.07
07.06	- 0.28
91.45	+ 0.11
32.17	+ 1.09
02.08	- 2.24
04.55	- 0.05
07.01	+ 0.03
09.00	- 0.04
03.00	+ 0.02
04.02	- 0.03

54.12	- 0.50
05.26	+ 2.22
45.00	- 2.32
95.41	- 0.02
08.15	- 0.08
95.02	+ 0.23
04.02	- 2.22
05.03	+ 5.00
09.01	+ 1.02
78.56	- 1.03
90.03	- 3.57
25.12	+ 0.56
24.65	+ 1.00
00.59	- 0.05
03.05	- 2.02
58.26	+ 0.56
21.50	+ 0.01
00.31	- 0.05
73.05	- 1.07
07.06	- 0.28
91.45	+ 0.11
32.17	+ 1.09
02.08	- 2.24
04.55	- 0.05
07.01	+ 0.03
09.00	- 0.04
03.00	+ 0.02
04.02	- 0.03

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME – GROUP

KSEK	Note	2019	2018
Net sales	1-5 6-7	2,658	54,884
<b>Total operating income</b>		<b>2,658</b>	<b>54,884</b>
Raw materials and consumables		-3,517	-4,089
Other external costs	8	-74,984	-80,149
Personnel costs	9	-25,860	-24,219
Depreciation and write-downs	15	-2,202	-632
<b>Total operating expenses</b>		<b>-106,563</b>	<b>-109,089</b>
<b>Operating profit/loss</b>		<b>-103,906</b>	<b>-54,206</b>
Share of result of associates	16	20,214	6,174
Financial income	10	674	-
Financial expenses	11	-483	-261
<b>Total financial items</b>		<b>20,404</b>	<b>5,913</b>
<b>Profit/loss after financial items</b>		<b>-83,501</b>	<b>-48,292</b>
Tax on net profit	12	7,713	7,233
<b>Profit/loss for the year</b>		<b>-75,788</b>	<b>-41,059</b>
<b>Other comprehensive income for the period</b>			
<i>Item that may be reclassified to profit and loss</i>			
Translation differences		-187	625
<i>Item that will not be reclassified to profit and loss</i>			
Fair value financial assets	16	10,657	-
<b>Total other comprehensive income for the year, net after tax</b>		<b>10,470</b>	<b>625</b>
<b>Total comprehensive income for the year</b>		<b>-65,319</b>	<b>-40,434</b>
Earnings per share, SEK	13	-2.95	-1.84
Diluted earnings per share, SEK	13	-2.95	-1.84

The recognized loss and total comprehensive income for 2018 and 2019 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	2019-12-31	2018-12-31
<b>ASSETS</b>	1-5		
Fixtures, fittings, tools and equipment	14-15	3,415	1,841
Tangible assets		3,415	1,841
Other financial assets	16	37,376	-
Investment in associated companies	16	-	6,505
Other long-term receivables	17	1,260	3,999
Financial assets		38,635	10,504
Deferred tax		67	62
<b>Non-current assets</b>		<b>42,117</b>	<b>12,407</b>
Trade receivables	18	-	2,093
Current tax assets	19	7,682	7,568
Other receivables	20	4,430	4,654
Prepayments and accrued income	20	1,523	1,675
Current receivables		13,636	15,990
Cash and cash equivalent	21	40,248	54,678
<b>Current assets</b>		<b>53,883</b>	<b>70,668</b>
<b>Total assets</b>		<b>96,000</b>	<b>83,075</b>
<b>EQUITY AND LIABILITIES</b>			
Share capital	22	1,421	1,166
Additional paid in capital		239,592	157,118
Reserves		9,693	-777
Retained earnings including profit or loss for the period		-192,268	-118,051
<b>Equity</b>		<b>58,437</b>	<b>39,457</b>
Lease liabilities	23, 31	1,420	-
Other payables	23	727	-
Non-current liabilities		2,147	0
Trade payables		29,248	7,243
Convertible loan	24	-	6,000
Other payables		745	616
Accrued expenses and deferred income	25, 31	5,423	29,759
Current liabilities		35,416	43,617
<b>Total liabilities</b>		<b>37,563</b>	<b>43,617</b>
<b>Total equity and liabilities</b>		<b>96,000</b>	<b>83,075</b>



# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY - GROUP

	Share capital	Additional paid in capital	Translation reserves	Fair value reserve	Retained earnings	Shareholders' equity
January 1, 2018	1,088	116,452	-1,402	0	-78,511	37,628
<b>Comprehensive income</b>						
Profit/loss for the year					-41,059	-41,059
Other comprehensive income:						
Translation differences			625			625
<b>Total comprehensive income</b>			<b>625</b>		<b>-41,059</b>	<b>-40,434</b>
<b>Transactions with owners</b>						
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
<b>Total transactions with owners</b>	<b>78</b>	<b>40,666</b>	<b>0</b>		<b>1,519</b>	<b>42,263</b>
<b>December 31, 2018</b>	<b>1,166</b>	<b>157,118</b>	<b>-777</b>	<b>0</b>	<b>-118,051</b>	<b>39,457</b>
January 1, 2019	1,166	157,118	-777	0	-118,051	39,457
<b>Comprehensive income</b>						
Profit/loss for the year					-75,788	-75,788
Other comprehensive income:						
Fair value reserve				10,657		10,657
Translation differences			-187			-187
<b>Total comprehensive income</b>			<b>-187</b>	<b>10,657</b>	<b>-75,788</b>	<b>-65,319</b>
<b>Transactions with owners</b>						
Shares issued for cash	254	96,347				96,601
Expenses related to capital increase		-13,874				-13,874
Share-based compensation expenses					1,571	1,571
<b>Total transactions with owners</b>	<b>254</b>	<b>82,473</b>			<b>1,571</b>	<b>84,299</b>
<b>December 31, 2019</b>	<b>1,421</b>	<b>239,592</b>	<b>-964</b>	<b>10,657</b>	<b>-192,268</b>	<b>58,437</b>

# CONSOLIDATED STATEMENT OF CASH FLOWS - GROUP

KSEK	Note	2019	2018
Profit/loss before tax		-83,501	-48,292
Adjustments for non-cash transactions	30	-15,941	-3,795
Changes in working capital	30	783	29,428
<b>Cash flow from operating activities before financial items</b>		<b>-98,660</b>	<b>-22,659</b>
Interest income received		674	-
Interest expenses paid		-483	-261
Tax paid		-	-
<b>Cash flow from operating activities</b>		<b>-98,469</b>	<b>-22,920</b>
<b>Investing activities</b>			
Investment in tangible assets		-3,488	-1,107
Repayment of financial assets		2,739	2,021
<b>Cash flow from investing activities</b>		<b>-749</b>	<b>914</b>
<b>Financing activities</b>			
Convertible loan	24	-6,000	6,000
New share issue	22	82,728	40,745
<b>Cash flow from financing activities</b>		<b>76,728</b>	<b>46,745</b>
<b>Cash flow for the year</b>		<b>-22,491</b>	<b>24,738</b>
<b>Cash and cash equivalents at beginning of year</b>		<b>54,678</b>	<b>22,313</b>
Exchange rate adjustments		8,061	7,626
<b>Cash and cash equivalents at end of year</b>	21	<b>40,248</b>	<b>54,678</b>

## STATEMENT OF INCOME – PARENT COMPANY

## STATEMENT OF COMPREHENSIVE INCOME – PARENT COMPANY

KSEK	Note	2019	2018
	1-5		
Other operating income		1,354	-
<b>Total operating income</b>		<b>1,354</b>	<b>-</b>
Raw materials and consumables		-13	-10
Other external costs	8	-6,416	-5,524
Personnel costs	9	-4,046	-2,379
<b>Total operating expenses</b>		<b>-10,475</b>	<b>-7,912</b>
<b>Operating profit/loss</b>		<b>-9,121</b>	<b>-7,912</b>
Share of result of associates	16	-1,092	6,174
Financial income	10	8,657	1,900
Financial expenses	11	-269	-144
<b>Total financial items</b>		<b>7,295</b>	<b>7,931</b>
<b>Profit/loss after financial items</b>		<b>-1,826</b>	<b>19</b>
Tax on net profit	12	-	-
<b>Profit/loss for the year</b>		<b>-1,826</b>	<b>19</b>

KSEK	Note	2019	2018
<b>Profit/loss for the year</b>	1-5	<b>-1,826</b>	<b>19</b>
<b>Other comprehensive income for the period</b>			
Item that may be reclassified to profit and loss			
Other comprehensive income for the year		-	-
<b>Total other comprehensive income for the year, net after tax</b>		<b>0</b>	<b>0</b>
<b>Total comprehensive income for the year</b>		<b>-1,826</b>	<b>19</b>

# STATEMENT OF FINANCIAL POSITION – PARENT COMPANY

KSEK	Note	2019-12-31	2018-12-31
<b>ASSETS</b>	1-5		
Investment in subsidiaries	26	204,100	11,832
Other financial assets	16	5,413	-
Investment in associated companies	16	-	6,505
<b>Financial assets</b>		<b>209,512</b>	<b>18,337</b>
<b>Non-current assets</b>		<b>209,512</b>	<b>18,337</b>
Receivables from group companies		-	112,424
Other receivables	20	286	257
Prepayments and accrued income	20	763	977
<b>Current receivables</b>		<b>1,049</b>	<b>113,658</b>
Cash and cash equivalent	21	9,899	13,435
<b>Current assets</b>		<b>10,948</b>	<b>127,093</b>
<b>Total assets</b>		<b>220,460</b>	<b>145,429</b>
<b>EQUITY AND LIABILITIES</b>			
<i>Restricted equity</i>			
Share capital	22	1,421	1,166
<i>Unrestricted equity</i>			
Additional paid in capital	24	238,080	155,607
Retained earnings		-17,960	-17,979
Profit/loss for the period		-1,826	19
<b>Equity</b>		<b>219,715</b>	<b>138,813</b>
Convertible loan	24	-	6,000
Other payables		745	616
<b>Current liabilities</b>		<b>745</b>	<b>6,616</b>
<b>Total liabilities</b>		<b>745</b>	<b>6,616</b>
<b>Total equity and liabilities</b>		<b>220,460</b>	<b>145,429</b>

# STATEMENT OF CHANGES IN EQUITY – PARENT COMPANY

	Share capital	Additional paid in capital	Retained earnings	Shareholders' equity
	Restricted capital	Unrestricted capital		
January 1, 2018	1,088	114,941	-17,979	98,050
Total comprehensive income			19	19
<b>Transactions with owners</b>				
Shares issued for cash	78	41,922		42,000
Expenses related to capital increase		-1,255		-1,255
<b>December 31, 2018</b>	<b>1,166</b>	<b>155,607</b>	<b>-17,960</b>	<b>138,813</b>
January 1, 2019	1,166	155,607	-17,960	138,813
Total comprehensive income			-1,826	-1,826
<b>Transactions with owners</b>				
Shares issued for cash	254	96,347		96,601
Expenses related to capital increase		-13,874		-13,874
<b>December 31, 2019</b>	<b>1,421</b>	<b>238,080</b>	<b>-19,786</b>	<b>219,715</b>



# STATEMENT OF CASH FLOWS – PARENT COMPANY

KSEK	Note	2019	2018
Profit/loss after financial items		-1,826	19
Adjustments for non-cash transactions	30	-7,295	-7,931
Changes in working capital	30	-79,530	-44,274
<b>Cash flow from operating activities before financial items</b>		<b>-88,651</b>	<b>-52,186</b>
Interest income received		8,657	1,900
Interest expenses paid		-269	-144
<b>Cash flow from operating activities</b>		<b>-80,263</b>	<b>-50,430</b>
<b>Cash flow from investing activities</b>		<b>0</b>	<b>0</b>
<b>Financing activities</b>			
Convertible loan	24	-6,000	6,000
New share issue	22	82,728	40,745
<b>Cash flow from financing activities</b>		<b>76,728</b>	<b>46,745</b>
<b>Cash flow for the period</b>		<b>-3,536</b>	<b>-3,685</b>
<b>Cash and cash equivalents at beginning of period</b>		<b>13,435</b>	<b>17,120</b>
<b>Cash and cash equivalents at end of period</b>	21	<b>9,899</b>	<b>13,435</b>

# NOTES TO THE CONSOLIDATED AND PARENT COMPANY'S FINANCIAL STATEMENTS

## NOTE 1 GENERAL INFORMATION

The Annual Report for Saniona AB 2019 was approved for publication by decision of the Board on April 15, 2020. The Annual Report will be submitted to the Annual General Meeting (AGM) for adoption on May 6, 2020. Saniona AB (publ), Corporate Registration Number 556962-5345, the Parent Company and its subsidiaries, collectively the Group, is a publicly listed rare disease biopharmaceutical company focused on research, development and commercialization for treatments for the central nervous system. 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 Baltorpsvej 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 INTERPRETATIONS FROM 2019 AND LATER

International Accounting Standards Board (IASB) has adopted a number of standards and interpretations that will come into effect 2020 or later. Standards and interpretations, which will come into effect in 2020 or later have not been early adopted. The standards and amendments taking effect in 2019 has been implemented. The new standard and the relevance for the Group's financial statements are set-out below.

### IFRS 16 Leases

As of January 1, 2019, IAS 17 was replaced by IFRS 16 Leasing. Saniona has used the modified retrospective method allowed under IFRS 16, valuing the lease liability at the net present value of the future payments under the lease term. The corresponding right of use asset has been valued at an amount equal to the lease liability as allowed under IFRS 16 transition rules.

Saniona recognizes all leases on the balance sheet as assets with a corresponding lease liability. The lease liability is equal to the discounted value of all future lease payments. The lease assets, right-of-use-assets, correspond to the lease liability adjusted by the amount of any prepaid or accrued lease payments recognized in the statement of financial position immediately before the date of initial application. Implementation of IFRS 16 has no impact on the cash flows. However, due to the lease payments being split into interest costs and a repayment of the lease liability, the presentation in the cash flow statement has changed.

Please refer to table below for a specification of the amounts recognized under initial recognition of IFRS 16 as of January 1, 2019. This asset is Sanionas current premises in Ballerup. This agreement has been terminated during 2019 by the Landlord.

KSEK	2018-12-31	Adjustments	2019-01-01
<b>Assets</b>			
Tangible assets	-	4,233	4,233
<b>Total</b>	<b>0</b>	<b>4,233</b>	<b>4,233</b>
<b>Liabilities</b>			
Lease liabilities, long-term	-	2,901	2,901
Lease liabilities, short-term	-	1,332	1,332
<b>Total</b>	<b>0</b>	<b>4,233</b>	<b>4,233</b>

## 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 group enterprises comprise Saniona A/S as of December 31, 2019. In 2020, the group enterprises also comprise Saniona, Inc.

## 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 between 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.

### Leasing

The lease liability is measured on initial recognition at the present value of the lease payments not made as of the start date, discounted by application of the interest rate that is implicit in the lease. If this interest rate cannot easily be established, the Group uses the incremental borrowing rate. The lease liability is recognized in subsequent periods via an increase in the liability to reflect the effect of interest and a reduction to reflect the effect of lease fees paid.

The right-of-use asset is initially recognized at the value of the lease liability plus lease fees paid on or before the start date of the lease, as well as initial direct fees. The right-of-use asset is recognized in subsequent periods at cost less depreciations and impairments.

Refer to the 2018 Annual Report for accounting policies related to leases in 2018.

Equipment leases and all lease payments associated with low-value assets are expensed on a straight-line basis. Short-term leases are leases with a term not exceeding 12 months.

### 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 share-based 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 2018 and 2019 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.

**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.

**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.

Under certain conditions there is a possibility to make an irrevocable election to designate investments in equity instruments as at fair value through other comprehensive income (FVTOCI). Designation at FVTOCI is not permitted if the equity investment is held for trading or if it is contingent consideration. The Group has made an irrevocable election to classify the investment in Scandion Oncology as at fair value through other comprehensive income because the investment has a strategic purpose and is not intended for trading.

All other financial assets are measured subsequently at fair value through profit or loss (FVTPL).

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

### 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. The Group measures the allowance under the general approach (applying the low credit risk exception) based on the counterparty's rating and probability of default.

### 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 in December 2017, which was extended in 2019. In January 2020, Saniona terminated the convertible notes funding agreement without having drawn any tranches under the extended agreement. Please see note 24 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, other financial assets and associated companies**

Investments in subsidiaries and other financial assets are recognized at cost in the Parent Company's financial statements subject to potential impairment. 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 and Productos Medix, S.A de S.V have been subject to such evaluation by management.

The Group did not receive any upfront payments in 2018 and 2019. 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.

#### 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.

Based on the review of the criteria, management believes that there are no recognition of intangible assets arising from development projects in 2019.

Saniona has not recognized such assets at this time that meet the criteria for capitalization 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. On July 4, 2017, Saniona acquired NeuroSearch's remaining interest in the preclinical and clinical assets, which Saniona acquired from NeuroSearch during the period 2012-2016. See note 17.

## 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.

The table below shows the effect on the net profit/(loss) and equity of probable changes in FX against SEK on the balance sheet date.

KSEK	2019	
	Fluctuation	Effect
DKK	+/-5%	5,586
USD	+/-5%	455
EUR	+/-5%	984

The consolidated income statement is also affected by changes in the exchange rate of DKK to SEK, because the results of the subsidiary Saniona A/S are translated into SEK at the end of the year using average exchange rates.

#### 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 as of 31 December 2019, and accordingly, any exposure to interest risk is limited.

### LIQUIDITY AND FINANCING RISK

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 annually. The Board of Directors can decide on temporary departures from its predetermined framework.

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 as of 31 December 2019. Current liabilities amount to KSEK 35,416 (2018: 43,617) 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 13,636 (15,990). The Group has cash and cash equivalents of KSEK 40,248 (54,678).

### 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. Based on history the Group calculates a loss allowance percentage by considering current and forward-looking factors and adjusting the historical outcome. Historically, the Group has not sustained any losses on trade receivables and other receivables. This was also the case in 2019.

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 held at the Group's bank accounts at the Group's bank, Nordea A/S. 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.

## MEASUREMENTS OF FINANCIAL INSTRUMENTS

All financial asset and financial liabilities, except for the investment in Cadent Therapeutics as described below, are classified as 'Other financial assets', 'Loans and receivables' and 'Other financial liabilities' respectively. Loans and receivables and Other financial liabilities are measured at amortized cost and the carrying amount is a reasonable approximation of fair value. Other Financial assets are measured at fair value at the balance sheet date and differences in fair value is recognized through FVTPL or FVTOCI as described above. The Group has made an irrevocable election to classify the investment in Scandion Oncology as at FVTOCI because the investment has a strategic purpose and is not intended for trading purposes.

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 Ataxia-program. Considering the significant risk and duration of the development period related to the development of pharmaceutical products, management has concluded that the future economic benefits cannot be estimated with sufficient certainty until Cadent Therapeutics is sold or public listed or the project has been finalized and the necessary regulatory final approval of the product has been obtained. Accordingly, the value of Cadent Therapeutics is measured at costs since the fair value cannot be determined reliable.

## 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 58,437 (39,457). 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 1,504 (1,452) and sales between the Parent Company and subsidiaries to KSEK 1,354 (1,354). The Parent Company recognized an interest income of KSEK 8,657 (1,900) pertaining to loans from the subsidiary. The Parent Company has receivables of KSEK 0 (112,424) 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 2019 Saniona's customer was Boehringer Ingelheim with a sale of KSEK 2,658 (54,884 Boehringer Ingelheim and BenevolentAI) 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

KSEK	Group		Parent Company	
	2019	2018	2019	2018
Sweden	-	-	-	-
Other European countries	2,658	54,884	-	-
USA	-	-	-	-
<b>Total</b>	<b>2,658</b>	<b>54,884</b>	<b>0</b>	<b>0</b>

## Prepayments from customers

KSEK	Group		Parent Company	
	2019	2018	2019	2018
Contract liabilities:				
Prepayment from customers	-	-	-	-
<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

## Whereof:

Non-current liabilities	-	-	-	-
Current liabilities	-	-	-	-
<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

Contract liability at January 1	-	604	-	-
Additions	-	-	-	-
Revenue recognized	-	604	-	-
<b>Carrying amount December 31</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

## NOTE 8 AUDITORS FEES AND REMUNERATION

KSEK	Group		Parent Company	
	2019	2018	2019	2018
Deloitte				
Audit assignment	414	474	320	290
Audit activities other than audit assignment	263	335	131	239
Tax consultancy services	10	28	-	18
Other assignments	-	89	-	-
<b>Total</b>	<b>687</b>	<b>829</b>	<b>451</b>	<b>547</b>

## 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 22.4 (23.5), of whom 12.0 (12.2) were women.

As of December 31, 2019, the number of employees including the CEO was 24 (25) of which 13 (13) were women. Of these employees, 19 (22) were full-time employees 5 (3) were part-time employees, and a total of 19 (20) work in the Group's research and development operations. The level of education among the personnel is high, 11 employees (12) hold PhDs, 2 (2) 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. On January 7, 2020, Saniona appointed Rami Levin as CEO. Jørgen Drejer, previous CEO, continued as CSO and Palle Christophersen stepped down from executive management as Senior Vice President Research.



**Salaries and remuneration for the year 2019 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*	353	-	-	916	-	-	1,269
Claus Bræstrup, Board member	-	-	-	-	-	-	-
Carl Johan Sundberg, Board member*	173	-	-	29	55	-	257
Anna Ljung, Board member*	186	-	-	29	59	-	274
Edward Saltzman, Board member*	93	-	-	-	-	-	93
<b>Total Board</b>	<b>805</b>	<b>0</b>	<b>0</b>	<b>974</b>	<b>114</b>	<b>0</b>	<b>1,893</b>
Jørgen Drejer, CEO and Board member*, **	-	1,618	-	-	5	15	1,638
Thomas Feldthus, CFO***	-	2,044	204	-	5	15	2,269
Palle Christophersen, CSO**	-	1,364	-	-	5	15	1,384
<b>Total CEO, CFO and CSO</b>	<b>0</b>	<b>5,026</b>	<b>204</b>	<b>0</b>	<b>15</b>	<b>45</b>	<b>5,290</b>
Other Employees	-	16,179	1,512	597	98	291	18,677
<b>Total</b>	<b>805</b>	<b>21,205</b>	<b>1,716</b>	<b>1,571</b>	<b>227</b>	<b>336</b>	<b>25,860</b>

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

\*\*On January 7, 2020, Saniona appointed Rami Levin as CEO. Jørgen Drejer, previous CEO, continued as CSO and Palle Christophersen stepped down from executive management as Senior Vice President Research

\*\*\*On February 18, 2020, Saniona announced that Thomas Feldthus has resigned as CFO. On March 24, 2020, Saniona announced that Anita Milland, VP of Finance & Administration was appointed interim CFO & Head of IR

**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
<b>Total Board</b>	<b>525</b>	<b>0</b>	<b>0</b>	<b>878</b>	<b>79</b>	<b>0</b>	<b>1,482</b>
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
<b>Total CEO, CFO and CSO</b>	<b>0</b>	<b>4,945</b>	<b>197</b>	<b>0</b>	<b>15</b>	<b>78</b>	<b>5,235</b>
Other Employees	-	14,756	1,512	608	99	527	17,502
<b>Total</b>	<b>525</b>	<b>19,701</b>	<b>1,709</b>	<b>1,486</b>	<b>193</b>	<b>605</b>	<b>24,219</b>

\*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

\*\*On January 7, 2020, Saniona appointed Rami Levin as CEO. Jørgen Drejer, previous CEO, continued as CSO and Palle Christophersen stepped down from executive management as Senior Vice President Research

\*\*\*On February 18, 2020, Saniona announced that Thomas Feldthus has resigned as CFO. On March 24, 2020, Saniona announced that Anita Milland, VP of Finance & Administration was appointed interim CFO & Head of IR

## SHARE BASED PAYMENTS

### 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 quarter 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 year-end 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 quarterly 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.

### 2019:1

The 2019 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 September 2019. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 17.86. The options are earned gradually over a period of 48 months. Holders can take advantage of assigned and earned stock options during 30 days from the day following the publication of the Group's quarterly reports, or in the case of full-year, full-year report, for the first time after publication of the quarterly report for the first quarter of 2023 and last time after publication of the quarterly report for the third quarter of 2024.

### 2019:2

The 2019 Annual General Meeting voted in favor of establishing an employee incentive program involving the allotment of a maximum of 12,000 options free of charge to certain members of the board of directors of the Group. Allotment of 12,000 options took place in September 2019. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 17.86. 1/3 of the options are vested when the annual shareholders' meeting takes place in 2020. Additional 1/3 of the options are vested when the annual shareholders' meeting takes place in 2021 and the last 1/3 of the options are vested when the annual shareholders' meeting takes place in 2022. 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 for full-year, the year-end 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 first quarter of 2023. 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 15,770 warrants to a wholly owned subsidiary in the Group.

### General terms

In case the Option Holder terminates the employment without the company being in material breach of the employment agreement or in case the Subsidiary terminates or expels the Option Holder due to the Option Holder's breach of the employment agreement, all rights to allotted unexercised Options expire at the time the employment terminates/ ceases, without separate notice or consideration and irrespective of whether or not the Options are vested.

No program is subject to any profit or market conditions.

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	2017	2018:1	2018:2	2018:3	2019:1	2019:2
Allotted options	38,750	286,003	34,500	10,513	34,500	15,770
Fair value per option (SEK)	29.48	12.67	18.89	18.89	7.55	6.69
Share price for underlying shares (SEK)	45.50	26.95	33.85	33.85	17.76	17.76
Subscription price (SEK)	41.13	33.60	30.08	30.08	17.86	17.86
Vesting period	4 years	3 years	4 years	3 years	4 years	3 years
Estimated life of the option	5.50 years	6.25 years	5.5 years	4 years	5.5 years	4 years
Risk-free interest rate during the life of the option	-0.0584%	0.2389%	-0.0713%	-0.0356%	-0.6929%	-0.6995%
Assumed volatility*	76.75%	57.41%	63.58%	63.58%	51.03%	51.03%
Expected dividends	0	0	0	0	0	0

\* In 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 and 2019, the volatility equals a twelve-month period.

Share-based compensation expenses for the full year of 2019 totaled SEK 1,571 (1,518) thousand. The Group accounts for share-based compensation by recognizing compensation expenses related to share-based instruments granted to the management, employees and consultants in the income statement. Such compensation expenses represent the fair market values of warrants granted and do not represent actual cash expenditures.

According to the table below, the Group had 417,870 (433,308) options outstanding as of December 31, 2019. If all issued warrants are exercised for subscription of new shares, the Parent Company's will issue a total of 417,870 new shares corresponding to a dilution of approximately 1.47%.

	Options allotted in 2015	Options allotted in 2017	Options allotted in 2018	Options allotted in 2019	Total
<b>Share-based payment</b>					
Outstanding at 1 January 2018	64,000	38,292	-	-	102,292
Granted during the period	-	-	331,016	-	331,016
Forfeited during the period	-	-	-	-	-
<b>Outstanding at 31 December 2018</b>	<b>64,000</b>	<b>38,292</b>	<b>331,016</b>	<b>0</b>	<b>433,308</b>
Outstanding at 1 January 2019	64,000	38,292	331,016	-	433,308
Granted during the period	-	-	-	50,270	50,270
Exercised during the period	-3,998*	-	-	-	-3,998
Expired	-60,002	-	-	-	-60,002
Forfeited during the period	-	-	-1,708	-	-1,708
<b>Outstanding at 31 December 2019</b>	<b>0</b>	<b>38,292</b>	<b>329,308</b>	<b>50,270</b>	<b>417,870</b>
<b>Exercisable options at 31 December 2019</b>					<b>0</b>

\* The subscription price for the options and the number of shares that each option entitles to subscription of, have been recalculated as a result of the rights issue. The 3,998 options granted in 2015 equal to 4,078 shares, which have been exercised in November 2019.

The weighted average share price at the date of exercise for share options, exercised during the period was SEK 28.67 per share option (no options were exercised in 2018). The number of exercisable options at the end of the year is 0 (64,000). Outstanding options have a weighted average remaining contractual life of 2.67 (3.00) years.

Incentive program after rights issue**	2017	2018:1	2018:2	2018:3	2019:1	2019:2
Allotted options	38,750	286,003	34,500	10,513	34,500	15,770
Subscriptions price after rights issue (SEK)	40.71	33.26	29.77	29.77		
Equal to no of shares	39,525	291,723	35,190	10,723	34,500	15,770

\*\* The subscription price for the options and the number of shares that each option entitles to subscription of have been recalculated as a result of the rights issue.

During 2019, the Group re-priced certain of its outstanding options. The strike price was, due to result of a right issue increased in accordance to above table.

## NOTE 10 FINANCIAL INCOME

KSEK	Group		Parent Company	
	2019	2018	2019	2018
Interest income	674	-	8,657	1,900
Foreign exchange gains	-	-	-	-
<b>Total</b>	<b>674</b>	<b>0</b>	<b>8,657</b>	<b>1,900</b>

## NOTE 11 FINANCIAL EXPENSES

KSEK	Group		Parent Company	
	2019	2018	2019	2018
Interest expense	221	159	142	81
Foreign exchange losses	262	102	127	63
<b>Total</b>	<b>483</b>	<b>261</b>	<b>269</b>	<b>144</b>

## NOTE 12 TAX

## TAX FOR THE YEAR

KSEK	Group		Parent Company	
	2019	2018	2019	2018
Current tax on net profit for the year	7,682	7,568	-	-
Deferred taxes attributable to temporary differences	-67	-62	-	-
Adjustments tax previous year	-	152	-	-
Exchange rate adjustments	98	-425	-	-
<b>Recognized tax on net profit for the year</b>	<b>7,713</b>	<b>7,233</b>	<b>0</b>	<b>0</b>

Income tax in Sweden is calculated at 21.4% (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.

KSEK	Group		Parent Company	
	2019	2018	2019	2018
Recognized profit/loss before tax	-83,501	-48,292	-1,826	19
Tax according to the applicable tax rate	18,359	10,624	391	-4
Tax effect of non-deductible income	-	-	-	-
Tax effect of non-deductible expenses	-27	-11	-	-
Tax effect on deductible costs in relation to share issues taken to equity	2,969	276	2,969	276
Not utilized tax losses carry forward	-17,796	-3,140	-3,360	-272
Exchange rate adjustments	4,213	-391	-	-
<b>Current Tax</b>	<b>7,719</b>	<b>7,358</b>	<b>0</b>	<b>0</b>
Change in deferred tax	-6	28	-	-
Adjustments tax previous year	-	-152	-	-
<b>Recognized tax on net profit for the year</b>	<b>7,713</b>	<b>7,233</b>	<b>0</b>	<b>0</b>
Applicable tax rates	22%	22%	21.4%	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.

KSEK	Group		Parent Company	
	2019	2018	2019	2018
Loss carried forward January 1 for which no deferred tax assets were recognized	56,968	43,385	28,411	27,174
Loss carried forward for which no deferred tax assets were recognized	81,321	13,584	15,700	1,237
<b>Loss carried forward December 31 for which no deferred tax assets were recognized</b>	<b>138,289</b>	<b>56,968</b>	<b>44,111</b>	<b>28,411</b>

The Group has an accumulated unrecognized deferred tax asset of KSEK 30,159 (12,533). 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

KSEK	Group	
	2019	2018
Net profit/(loss) (KSEK)	-75,788	-41,059
Average number of outstanding shares (in thousands)	25,720	22,289
<b>Earnings per share for the year (SEK)</b>	<b>-2.95</b>	<b>-1.84</b>
<b>Diluted earnings per share for the year (SEK)</b>	<b>-2.95</b>	<b>-1.84</b>

Earnings/loss per share after dilution is the same as before dilution in 2019, since the result is negative in 2019. 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

KSEK	Group		Parent Company	
	2019	2018	2019	2018
Cost at January 1	5,704	4,469	-	-
Additions	2,280	1,107	-	-
Disposals	-25	-	-	-
Foreign exchange adjustment	86	128	-	-
<b>Cost at December 31</b>	<b>8,045</b>	<b>5,704</b>	<b>0</b>	<b>0</b>
Depreciation at January 1	3,863	3,103	-	-
Depreciation	737	632	-	-
Disposals	-20	-	-	-
Foreign exchange adjustment	50	128	-	-
<b>Depreciation at December 31</b>	<b>4,630</b>	<b>3,863</b>	<b>0</b>	<b>0</b>
<b>Carrying amount December 31</b>	<b>3,415</b>	<b>1,841</b>	<b>0</b>	<b>0</b>
<b>Carrying amount leased assets</b>	<b>2,172</b>	<b>0</b>	<b>0</b>	<b>0</b>

## NOTE 15 DEPRECIATION

KSEK	Group		Parent Company	
	2019	2018	2019	2018
Depreciation	737	632	-	-
Depreciation leasehold	1,465	-	-	-
<b>Total</b>	<b>2,202</b>	<b>632</b>	<b>0</b>	<b>0</b>

## NOTE 16 RECLASSIFICATION OF INVESTMENT IN SCANDION ONCOLOGY

On May 3, 2017, Saniona participated in formation of a new company, Scandion Oncology A/S. Scandion Oncology was listed on the Spotlight Stock Market on November 8, 2018.

In previous financial reports, Saniona has classified the investment in Scandion Oncology as an Investment in associates since the criteria for significant influence was met. The value of Saniona's investment has been 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. When recognizing the value, Saniona has used the published financial statements by Scandion Oncology in the previous quarter as Scandion Oncology's financial reports from the actual quarter had not been published at the time of publication of Saniona's financial report.

In July 2019, Scandion Oncology completed a rights issue, which led to a decrease of Saniona's holdings of shares and votes from 29.17 % to 18.23 %. Saniona has concluded that the requirement for significant influence is not met after this transaction due to the dilution of Saniona's shareholding in Scandion Oncology.

Therefore, Saniona's holding in Scandion Oncology has been reclassified from Investment in associate to Financial assets as of October 1, 2019.

## EFFECT OF RECLASSIFICATION IN THE PARENT COMPANY

For the Parent Company, the effect of the reclassification is that the investment in Scandion Oncology is recognized at cost subject to potential impairments.

As of October 1, 2019, the recognized value of Saniona's investment in Scandion Oncology is SEK 5.4 million, which has been calculated in accordance with the equity method by using the reported equity in Scandion Oncology's interim report Q3 2019. The calculation for the parent company is set-out in the table below.



KSEK	Valuation method	Value	P/L effect 2019
January 1, 2019	Equity method OB	6,505*	-6,505
October 1, 2019	Equity method CB	5,413**	5,413
Amounts recognized in P/L			-1,092

\* Valuation is based on the reported equity Scandion Oncology's interim report Q3 2018 and the capital increase in Q4 2018

\*\* Valuation is based on reported equity in Scandion Oncology's interim report Q3 2019

### EFFECT OF RECLASSIFICATION IN THE GROUP

For the Group, the effect of the reclassification is that the investment in Scandion Oncology is recognized in the balance sheet in accordance to the fair value and that changes in fair value is recognized under Other comprehensive income. The initial value of Saniona's investment has been recognized in the balance sheet in accordance with the fair value method as of October 1, 2019, and differences to the value in accordance to the equity method has been taken to the profit and loss statement as a financial income or expense.

As of October 1, 2019, the recognized value of Saniona's investment in Scandion Oncology is SEK 26.7 million, which has been calculated in accordance with the fair value method by using the market quotation of the shares in Scandion Oncology as of October 1, 2019. The effect of the reclassification is that the Group recognizes a financial income of SEK 20.2 million for the full year 2019. Furthermore, the Group recognizes a gain of SEK 10.7 million under Other comprehensive income the full year of 2019 due to an increase in fair value in Q4 2019. The calculation for the Group is set-out in the table below.

KSEK	Valuation method	Value	Derivation P/L effect 2019	Derivation FV change recognized in OCI
January 1, 2019	Equity method	6,505*	-6,505	
October 1, 2019	Fair value OB	26,719**	26,719	-26,719
December 31, 2019	Fair value CB	37,376**		37,376
Amounts recognized in P/L or OCI			20,214	10,657

\* Valuation is based on the reported equity Scandion Oncology's interim report Q3 2018 and the capital increase in Q4 2018.

\*\*Valuation is based on market value of Saniona's shareholding in Scandion Oncology as of Oct 1, 2019 and Dec 31, 2019.

### NOTE 17 OTHER LONG-TERM RECEIVABLES

On July 4, 2017, Saniona acquired NeuroSearch's remaining interest in the preclinical and clinical assets, which Saniona acquired from NeuroSearch during the period 2012-2016. According to the previous agreements, Saniona was obliged to pay NeuroSearch a milestone payment of EUR 400,000 when the first preclinical program was tested in humans. In addition, Saniona was obliged to pay royalties on its product sales or a percentage of its licensing income in relation to the acquired clinical assets including the clinical development compounds, tesofensine and NS2359. According to the new agreement, Saniona has paid NeuroSearch a onetime cash payment of DKK 5.5 million (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 2019 the onetime cash payment has been expensed with SEK 2.0 million (SEK 1.9 million) and as December 31, 2019, the recorded value of the asset is SEK 2.9 million (SEK 4.9 million). SEK 1.0 million of the recorded value is long term and SEK 1.9 million is short term.

In October 2019 Saniona entered into a lease agreement on laboratory equipment with a prepayment of SEK 0.3 million recorded as long-term receivables.

### NOTE 18 TRADE RECEIVABLES

As of December 31, 2019, the Group had KSEK 0 (2,093) in trade receivables. In 2018, trade receivables comprised FTE payment from Boehringer Ingelheim (Q4).

### NOTE 19 CURRENT TAX ASSETS

Under the Danish R&D tax credit scheme (Skatte kreditordningen), 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, 2019, the Group had recorded current tax assets under the Danish R&D tax credit scheme of KSEK 7,682 (7,568).

## NOTE 20 OTHER RECEIVABLES, PREPAYMENTS AND ACCRUED INCOME

KSEK	Group		Parent Company	
	2019	2018	2019	2018
VAT reimbursement	1,311	2,241	254	257
Other receivables	3,119	2,413	32	-
<b>Total other receivables</b>	<b>4,430</b>	<b>4,654</b>	<b>286</b>	<b>257</b>
Prepaid costs*	1,523	1,675	763	977
<b>Total prepaid expenses and accrued income</b>	<b>1,523</b>	<b>1,675</b>	<b>763</b>	<b>977</b>

\*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 21 CASH AND CASH EQUIVALENT

KSEK	Group		Parent Company	
	2019	2018	2019	2018
Money market accounts	40,248	54,678	9,899	13,435
<b>Total</b>	<b>40,248</b>	<b>54,678</b>	<b>9,899</b>	<b>13,435</b>

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 22 SHARE CAPITAL

	Number of shares	Quotient value, SEK	Share capital, SEK
January 1, 2018	21,762,520	0.05	1,088,125
Shares issued for cash	1,561,893	-	78,159
<b>December 31, 2018</b>	<b>23,324,413</b>	<b>0.05</b>	<b>1,166,284</b>
January 1, 2019	23,324,413	0.05	1,166,284
Shares issued for cash	5,088,106	-	254,341
<b>December 31, 2019</b>	<b>28,412,519</b>	<b>0.05</b>	<b>1,420,625</b>

As of December 31, 2019, Saniona had 28,412,519 (23,324,413) shares outstanding at SEK 0.05 per share equal to a share capital of SEK 1,420,625 (1,166,284).

## NOTE 23 NON-CURRENT LIABILITIES

Saniona' leases concern laboratory equipment. The leases are concluded as and when the new laboratory equipment is acquired and are motivated by financing requirements. The leases include options to buy the leased assets on expiry of the leases of 10% of the purchase price. Saniona expects to exercise these options.

As of December 31, 2019, Saniona had one lease agreement starting October 1, 2019 and ending September 30, 2022 of which SEK 1.4 million (0) is long-term liabilities.

As of December 31, 2019, Saniona had other payables of SEK 0.7 million (0), which is holiday funds. In Denmark a new Holiday Act come in effect from 1 September 2020.

The employee will in the transition year from 1 September 2019 to 21 August 2020 earn holiday funds, which will be frozen until 2021. The holiday funds will be deposit in a new fund "Lønmodtagernes Feriemidler". Saniona expect to deposit the frozen funds to the fund in 2021.

## NOTE 24 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 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.

The convertible notes did not bear any interest. Nice & Green had 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. The pricing of the shares was 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 had sent a conversion notice to Saniona. For further details, please see Saniona's press release dated December 29, 2017.

In 2019, Saniona has drawn four tranches totaling SEK 24 million (SEK 48 million) and Nice & Green has converted SEK 30 million (SEK 42 million) of which SEK 6 million (0) was outstanding as of December 31, 2018. The converted amount of SEK 30 million (SEK 42 million) is taken to equity after deducting expenses relating to capital increase totaling KSEK 949 (SEK 1.3 million). Therefore, Saniona has drawn all tranches (SEK 72 million) under the convertible notes funding agreement with Nice & Green and all outstanding loan notes (SEK 72 million) have been converted into shares during 2018 and 2019.

In 2019, Saniona extended the convertible notes funding agreement with Nice & Green for an additional SEK 72 million with the same terms. In January 2020, Saniona terminated the convertible notes funding agreement without having drawn any tranches under the extended agreement.

## NOTE 25 ACCRUED EXPENSES AND DEFERRED INCOME

KSEK	Group		Parent Company	
	2019	2018	2019	2018
Accrued social security expenses	28	29	-	-
Accrued vacation pay liability	1,750	2,603	-	-
Other accrued expenses	1,924	1,183	-	-
Short term liabilities	649	-	-	-
Reimbursement of costs	1,072	25,944	-	-
<b>Total</b>	<b>5,423</b>	<b>29,759</b>	<b>0</b>	<b>0</b>

## NOTE 26 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%	204,100

### Cost

KSEK	2019	2018
Opening cost	11,832	11,832
Share right issue	192,268	-
<b>Closing cost</b>	<b>204,100</b>	<b>11,832</b>
<b>Carrying amount at year-end</b>	<b>204,100</b>	<b>11,832</b>

As of December 31, 2019, equity in Saniona A/S equals KSEK 10,858 (-87,525).

## NOTE 27 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 2018 and 2019, please see note 5 and note 9.

There were no transactions with Scandion Oncology A/S in 2018 and 2019. As of October 1, 2019, Scandion Oncology is no longer a related party. See note 16.

## NOTE 28 CONTINGENT ASSETS, PLEDGED ASSETS, CONTINGENT LIABILITIES AND COMMITMENTS

### Pledged assets and contingent liabilities

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, 2021. Saniona A/S had no external net debt as of December 31, 2019.

### Contractual obligations

The Group has entered into a Research Collaboration with Boehringer Ingelheim 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, 2019. There is no material change of control clauses in the Group's partnership agreement.

### Unrecognized rental and lease commitments

KSEK	Group		Parent Company	
	2019	2018	2019	2018
Commitments under rental agreements or leases until expiry	1,042	1,142	-	-
<b>Total</b>	<b>1,042</b>	<b>1,142</b>	<b>0</b>	<b>0</b>

The above amounts relate to rental of the Group's domicile in Ballerup Denmark of 8 months, until end of August 2020. The company plans to move to new facilities in Q3 2020.

## NOTE 29 OTHER SECURITIES HELD AS NON-CURRENT ASSETS

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

Company / domicile	Share of equity	Share of voting power	Carrying amount 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.

The value of Cadent Therapeutics is measured at costs since the fair value cannot be determined reliable.

## NOTE 30 ADJUSTMENTS FOR NON-CASH TRANSACTIONS AND CHANGES IN WORKING CAPITAL

KSEK	Group		Parent Company	
	2019	2018	2019	2018
Adjustments for non-cash transactions:				
Share of result of associates	-20,214	-6,174	1,092	-6,174
Depreciation	717	632	-	-
Warrants	1,571	1,519	-	-
Other financial income and expenses	-191	261	-8,387	-1,756
Other provisions	2,147	-	-	-
Currency adjustment	29	-33	-	-
<b>Total adjustments for non-cash transactions</b>	<b>-15,941</b>	<b>-3,795</b>	<b>-7,295</b>	<b>-7,931</b>
Changes in working capital:				
Increase (-)/Decrease (+) in operating receivables	2,468	2,558	-79,659	-44,379
Increase (-)/Decrease (+) in operating liabilities	-1,685	26,870	129	105
<b>Total changes in working capital</b>	<b>783</b>	<b>29,428</b>	<b>-79,530</b>	<b>-44,274</b>

## NOTE 31 RIGHT-OF-USE-ASSETS

KSEK	Rent facility	Equipment	Total
Impact from applying IFRS 16 as of January 1, 2019	4,233	-	4,233
Additions	-	2,292	2,292
Depreciations	-1,461	-162	-1,623
Disposals	-2,772	-	-2,772
Exchange rate adjustments	-	42	42
<b>Right-of-use assets as of December 31, 2019</b>	<b>0</b>	<b>2,172</b>	<b>2,172</b>

KSEK	2019
Non-current	1,421
Current	648
<b>Lease liabilities</b>	<b>2,069</b>

KSEK	Due within 1 year	Due between 1 and 3 year	Total
Lease liabilities	648	1,421	2,069
<b>Total</b>	<b>648</b>	<b>1,421</b>	<b>2,069</b>

New leasing contract has been signed regarding premises with commence date Q3 2020.

## NOTE 32 PROPOSED APPROPRIATION OF FUNDS

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

SEK	
Share premium reserve	238,080,108
Profit/loss carried forward	-17,959,722
Profit/loss for the year	-1,825,982
<b>Total</b>	<b>218,294,404</b>

The Board of Directors propose that the funds at their disposal, SEK 218,294,404 be carried forward.

## NOTE 33 SUBSEQUENT EVENTS TO THE BALANCE SHEET DATE

- \* On January 7, 2020, Saniona appointed Rami Levin as President and Chief Executive Officer. Rami Levin will oversee the transition of Saniona to a fully-fledged biopharmaceutical company. He has extensive commercial experience in CNS and rare diseases, both in U.S and globally. Jørgen Drejer, previous CEO, will continue in the role of Chief Scientific Officer.
- \* In January 2020 Saniona, Inc. was registered in the commonwealth of Massachusetts, U.S.A.
- \* On January 10, 2020, Saniona completed a private placement of SEK 25 million and proposed a financing of up to SEK 158 million comprising a combination of the directed issue and rights issue of warrants totaling SEK 111 million – 133 million at a strike price of SEK 25 – 30 per share as well as a loan facility of SEK 25 million.
- \* On February 7, 2020, the extraordinary shareholders' meeting resolved on approval of the board of directors' proposed financing comprising a combination of the directed issue and rights issue of warrants. Furthermore, the extraordinary shareholders meeting resolved to adopt an employee option program for the CEO, Rami Levin, involving the allotment of a maximum of 710,313 employee options.
- \* On February 14, 2020, Saniona published prospectus relating to the rights issue of units.
- \* On February 18, 2020, Saniona co-founds new migraine therapy company Cephagenix.
- \* On February 18, 2020, Saniona announced CFO Thomas Feldthus will be departing the company and Saniona initiated search for new, U.S.-based CFO.
- \* On February 19, 2020, Saniona publishes supplementary prospectus.
- \* On March 4, 2020, Saniona publishes that the rights issue of free-of-payment units is oversubscribed.
- \* On 18 March 2020, Saniona announced that the six-month double-blind Phase 2 trial of Tesomet in hypothalamic obesity had been completed.
- \* On 24 March 2020, Saniona announced that Anita Milland, the current VP of Finance and Administration, had been appointed interim CFO and Head of IR, and Jørgen Drejer would assume the role of Deputy CEO.
- \* On 26 March 2020, Saniona announced that they had signed a second research collaboration concerning schizophrenia with Boehringer Ingelheim.



# 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 6, 2020, for adoption.

Ballerup, Denmark, April 15, 2020

J. Donald deBethizy  
*Chairman*

Rami Levin  
*CEO*

Claus Bræstrup  
*Board Member*

Jørgen Drejer  
*Board Member*

Anna Ljung  
*Board Member*

Carl Johan Sundberg  
*Board Member*

Edward Saltzman  
*Board Member*

Our Audit Report was presented on April 15, 2020  
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 2019-01-01 - 2019-12-31 except for the corporate governance statement on pages 66-74. The annual accounts and consolidated accounts of the company are included on pages 22-62 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 2019 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 2019 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 66-74. 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 company cash at year-end was 40 MSEK (55). 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.

### Valuation of investments in subsidiary

In the Balance Sheet of the Parent company as of 31 December, 2019, the investments in subsidiaries accounts to 204 MSEK (12) and current receivables from group companies accounts to 0 MSEK (112). 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 and investments in subsidiaries in note 26 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. Our valuation specialist has been involved in the review.

### 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 4-21. 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 2019-01-01 - 2019-12-31 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders 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 29 May, 2019 and has been the company's auditor since 19 February, 2014.

Malmö, 15 April 2020  
Deloitte AB

Jeanette Roosberg  
*Authorized Public Accountant*

# CORPORATE GOVERNANCE REPORT





# CORPORATE GOVERNANCE REPORT

## INTRODUCTION

Saniona AB (publ), Corporate Registration Number 556962-5345, the Parent Company and its subsidiaries, collectively the Group, is a publicly listed rare disease biopharmaceutical company focused on research, development and commercialization of treatments for the central nervous system. 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 2019.

## 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 Nasdaq's regulatory framework for issuers or generally accepted accounting practices on the stock market in the 2019 fiscal year.

## OWNERSHIP STRUCTURE, SHARE CAPITAL AND VOTING RIGHTS

At December 31, 2019, Saniona had 6,108 (5,569) shareholders, excluding holdings in life insurance and foreign custody account holders. The company's CSO, Jørgen Drejer, was the largest shareholder with 8.3 percent (10.1) of the share capital and voting rights. The ten largest shareholders jointly accounted for 38.6 percent (42.9) of the share capital and voting rights. There were no 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 1,420,625 divided among 28,412,519 shares as of December 31, 2018. In 2018, Saniona's share capital totaled SEK 1,166,284 divided among 23,324,413 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 2019 fiscal year.

## AUTHORIZATION FOR THE BOARD OF DIRECTORS REGARDING NEW ISSUES

The annual shareholders' meeting resolved, in accordance with the proposal from the board, to authorize the board 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 or convertibles, other than in relation to the financing agreement with Nice & Green S.A. (see below), the total number of shares that may be issued (or issued upon conversion of convertibles) shall not exceed 11,961,240 shares and the subscription price shall be on market terms (subject to customary new issue discount, as applicable). The purpose of this part of the authorization 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 in relation to the financing agreement that the company on 29 December 2017 entered into with Nice & Green S.A. ("N&G"), the total number of shares that may be issued upon conversion of convertibles issued thereunder shall not exceed 12,000,000 shares. The company has terminated the agreement with N&G without having issued convertibles under the above authorization. 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.

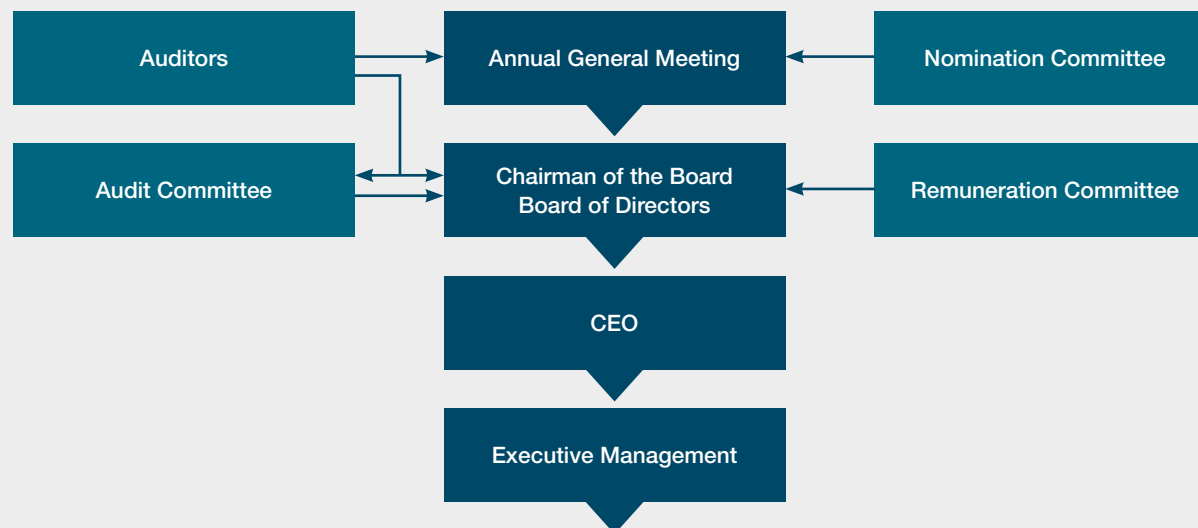
The general meeting is to be held in Malmö. Notice of general meetings should be made no earlier than six weeks and not later than four weeks before the meeting if the agenda includes an amendment of the Articles of Association. The notice of other

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 2019

The Annual General Meeting for 2019 was held on May 29, 2019 in Malmö. The meeting was attended by 7 (5) shareholders, in person or by proxy, representing about 22 percent (24) 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 Braestrup, Jørgen Drejer, Anna Ljung and Carl Johan Sundberg as ordinary Board members and election of Edward C. Saltzman as new ordinary board member. J. Donald deBethizy was also re-elected as Chairman of the Board.
- \* 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 2018 fiscal year.
- \* Approval of instruction and charter for the Nomination Committee.

The minutes and information from the Annual General Meeting 2019 are available on [www.saniona.com](http://www.saniona.com).

### Annual General Meeting 2020

The Annual General Meeting for 2020 will be held at Setterwalls Advokatbyrå AB's office at Stortorget 23, Malmö, Sweden on May 6, 2020 at 4pm CET.

### NOMINATION COMMITTEE

At the Annual General Meeting on May 29, 2019, 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 2020 Annual General Meeting was announced in a press release on November 27, 2019 and is as follows:

Name/Represented	Share of votes December 31, 2019	Share of votes September 30, 2019
Søren Skjærbæk (Chair) Owner of Ursus law firm, Vejle, Denmark. Appointed by Jørgen Drejer	8.3%	8.3%
John Haurum Professional board member of life science companies and former CEO of F-star Biotechnology Limited Cambridge, UK Appointed by Thomas Feldthus	6.6%	6.6%
J. Donald deBethizy Chairman of Saniona AB's Board	-	-

### Total

In 2019/20, the Nomination Committee held two (2018/19: one) 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 [anita.milland@saniona.com](mailto:anita.milland@saniona.com) marked "Recommendation to the Nomination Committee" or by ordinary mail to the address: Saniona AB, Attn. Nomination Committee, Baltorpevej 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.

On April 26, 2019 the nomination committee nominated Ed Saltzman as a new Board member, and he was elected at the

Annual General Meeting in May 2019. Following the 2019 Annual General Meeting, the Board consisted of six members, of which five were re-elected at the AGM on May 29, 2019.

One of the current board members is a woman and five 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 2019, five of the six 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 share-

holders' 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 2019

In 2019, the Board held a total of 6 (9) meetings, of which 5 (6) were scheduled and 1 (3) were unscheduled meetings. In addition, the Board passed additional resolutions on 12 (11) occasions through written resolutions. Saniona's CEO, current CSO, 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.

**August**

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

**September**

Implementation of share option program.

**November**

Adoption of Q3 Interim Report.

**December**

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.

The business plan and budget for the coming fiscal year including investment budget were reviewed and adopted at the following board meeting in February.

**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 2019, 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 2019, 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

	Elected	Independence	Audit Committee	Remuneration Committee	Attendance Board of Directors	Attendance Audit Committee	Attendance Remuneration Committee
J. Donald deBethizy	2018	Yes		Chair	6/6		3/3
Anna Ljung	2018	Yes	Chair		6/6	4/4	
Claus Bræstrup	2014	Yes	Member	Member	6/6	3/4	3/3
Jørgen Drejer	2014	<sup>1)</sup>			6/6		
Carl Johan Sundberg	2015	Yes	Member	Member	6/6	3/4	3/3
Edward Saltzman	2019	Yes			2/6		

1) Affiliated to the company, Management and major shareholders



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 2019, executive management consisted of Saniona's CEO, 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 29, 2019 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 300,000 is paid to the Chairman of the Board and SEK 160,000 to each of Anna Ljung, Carl Johan Sundberg and Edward Saltzman. Finally, it was resolved that remuneration for committee work will be paid in an amount of SEK 60,000 to the Chairman of the Audit Committee and with SEK 30,000 to each of the other members of the Audit Committee and with SEK 30,000 to each member of the Remuneration Committee. No additional remuneration shall be paid for other committee work.

At the Annual General Meeting on May 29, 2019, 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. For the Annual General Meeting May 6, 2020, the Board of Directors proposes that the guidelines for remuneration are updated according to the new rules in the Swedish Companies Act as of January 1, 2020 pertaining to guidelines for remuneration to senior executives.

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

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

## Salaries and remuneration for 2019 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*	353	-	-	916	-	-	1,269
Claus Bræstrup, Board member	-	-	-	-	-	-	-
Carl Johan Sundberg, Board member*	173	-	-	29	55	-	261
Anna Ljung, Board member*	186	-	-	29	59	-	270
Edward Saltzman*	93	-	-	-	-	-	93
<b>Total Board</b>	<b>805</b>	<b>0</b>	<b>0</b>	<b>974</b>	<b>114</b>	<b>0</b>	<b>1,893</b>
Jørgen Drejer, CEO and Board member*, **	-	1,618	-	-	5	15	1,638
Thomas Feldthus, CFO***	-	2,044	204	-	5	15	2,268
Palle Christophersen, CSO**	-	1,364	-	-	5	15	1,384
<b>Total CEO, CFO and CSO</b>	<b>0</b>	<b>5,026</b>	<b>204</b>	<b>0</b>	<b>15</b>	<b>45</b>	<b>5,290</b>
Other employees	-	16,179	1,512	597	98	291	18,677
<b>Total</b>	<b>805</b>	<b>21,205</b>	<b>1,716</b>	<b>1,571</b>	<b>227</b>	<b>336</b>	<b>25,860</b>

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

\*\*On January 7, 2020, Saniona appointed Rami Levin as CEO. Jørgen Drejer, previous CEO, continued as CSO and Palle Christophersen stepped down from executive management as Senior Vice President Research

\*\*\*On February 18, 2020, Saniona announced that Thomas Feldthus has resigned as CFO. On March 24, 2020, Saniona announced that Anita Milland, VP of Finance & Administration is appointed interim CFO & Head of IR

## 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 29, 2019, Deloitte was elected as auditor until the end of the 2020 Annual General Meeting.

The external auditors discuss the external audit plan and risk management with the Audit Committee. In 2019, 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, decision-making 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 CEO, the Audit Committee and/or the Board of Directors.

Saniona's CFO 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 CFO 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 CEO 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 since 2018

**Education and background:** Ph.D. and M.Sc. in toxicology from Utah State University and a B.Sc. in biology from the University of Maryland. J. Donald deBethizy is also a co-founder and former CEO of Targacept, Inc., an American biotech company listed on Nasdaq, 1997–2012, and CEO of Santaris Pharma A/S, from January to October 2014, when the company was sold to Roche Holdings.

**Other ongoing assignments:** Chairman in Albumedix Ltd. and Saniona A/S. Board member in argenx N.V., Newron Pharmaceuticals SpA, Noxxon NV and Proterris, Inc. Member of management (direktion) of Albumin Holding ApS and White City Consulting ApS.

**Previous assignments completed within the past five years:** Executive chairman of Contera Pharma A/S. Chairman of Novozymes Biopharma DK A/S and Rigontec GmbH. Board member of Asceneuron SA, Biosource Inc., Enbiotix Inc., LigoCyte Pharmaceuticals Inc., Serenova A/S (previously named Serendex Pharmaceuticals A/S) and Targacept, Inc. CEO and group chief executive of Roche Innovation Center Copenhagen A/S (previously named Santaris Pharma A/S).

**Independence:** Independent in relation to both the Company and its management as well as major shareholders.

**Holdings in Saniona:** 217,625 warrants, in the warrant program 2018/2024.



## CLAUS BRÆSTRUP Born 1945

Board member since 2014 (Chairman of Saniona AB 2014-2018 and of Saniona A/S since 2012). Co-founder of Saniona A/S and Saniona AB.

**Education and background:** Doctor of Medicine and graduate in biochemistry from the University of Copenhagen. Previous deputy CEO of research and development and CEO of H. Lundbeck A/S, listed on Nasdaq Copenhagen. Previous professor in neuro science at the University of Copenhagen. Author and co-author of more than 125 scientific articles.

**Other ongoing assignments:** Board member in Saniona A/S. CEO of Kastan ApS.

**Previous assignments completed within the past five years:** Chairman of Probiodrug AG and Saniona A/S. Board member of Ataxion Inc., Bavarian Nordic A/S, Evolva Holding SA, Gyros Protein Technologies AB, Evotec AG and Roche Innovation Center Copenhagen A/S (previous Santaris Pharma A/S).

**Independence:** Independent in relation to both the Company and its management as well as major shareholders.

**Holdings in Saniona:** 735,700 shares.



## ANNA LJUNG Born 1980

Board member since 2018

**Education and background:** M.Sc. in Economics and Business Administration from Stockholm School of Economics. Current CEO of Moberg Pharma AB and previous experience from different positions as CFO at Athera Biotechnologies AB, Moberg Pharma AB and Lipopeptide AB as well as independent consultant within in the field of technology licensing.

**Other ongoing assignments:** Chairman of Moberg Derma Incentives AB. Board member of Moberg Pharma 2019 AB and Saniona A/S. CEO of Moberg Pharma AB.

**Previous assignments completed within the past five years:** Board member of MPJ OTC AB. Deputy board member of Moberg Derma Incentives AB.

**Independence:** Independent in relation to both the Company and its management as well as major shareholders.

**Holdings in Saniona:** 4,000 warrants in the warrant program 2018/2022 and 4,000 warrants in the warrant program 2019/2023.


**CARL JOHAN SUNDBERG** Born 1958

Board member since 2015 (board member of Saniona A/S since 2016). Member of the Board since 2015

**Education and background:** Medical degree and Ph.D. from Karolinska Institutet, Stockholm. Professor in molecular and applied exercise physiology at Karolinska Institutet. Co-founder of, and previous Investment Manager at, Karolinska Investment Fund – a EUR 60 million biomedicine venture capital fund. Head of research at the department of Bioentrepreneurship at Karolinska Institutet, member of the Royal Swedish Academy of Engineering Sciences, previous member and previous chairman of Swedish Professional Associations for Physical Activity and the foundation Forska!Sverige and member of the International Olympic Committee Medical Commission. Many years of experience from board work within the academy and the business community. Professor at the department of Physiology and Pharmacology at Karolinska Institutet. Head of the department of Learning, Informatics, Management and Ethics at Karolinska Institutet.

**Other ongoing assignments:** Board member of Arne Ljungqvist Anti-doping Foundation AB, Cobra Biologics Holding AB, Medkay Konsulting AB and Saniona A/S.

**Previous assignments completed within the past five years:** Board member of Hypercure Medical AB, Karolinska Development AB and Cobra Biologics Holding AB. Deputy board member of Symbiont Law AB. Partner of Medkay Konsulting HB.

**Independence:** Independent in relation to both the Company and its management as well as major shareholders.

**Holdings in Saniona:** 4,000 warrants in the warrant program 2018/2022 and 4,000 warrants in the warrant program 2019/2023.


**JØRGEN DREJER** Born 1955

Board member since 2014. Board member of Saniona A/S since 2012. CSO since 2020. Previous CEO of Saniona AB and Saniona A/S. Co-founder of Saniona A/S and Saniona AB.

**Education and background:** Ph.D. in neurobiology from the University of Copenhagen. One of the co-founders of NeuroSearch A/S and long operated as the Company's deputy CEO and head of research. Member of the Danish Academy of Engineering Science and previous member of the board of Danish Research Council for Independent Research. Author of more than 75 scientific articles.

**Other ongoing assignments:** Board member of Saniona A/S. Board member of 2CureX AB and 2CureX A/S.

**Previous assignments completed within the past five years:** Chairman of Delta Reader A/S. Board member of Atonomics A/S, Azign Bioscience A/S, Ellegaard Göttingen Minipigs A/S, Force Technology and Monta Biosciences A/S. CEO of Saniona AB and Saniona A/S.

**Independence:** Not independent in relation to the Company and its management but independent in relation to major shareholders.

**Holdings in Saniona:** 2,344,711 shares.


**EDWARD C. SALTZMAN** Born 1955

Board member since 2019.

**Education and background:** Degree from New York University. Executive chairman of Cello Health BioConsulting ("CHBC"), previously Defined Health, after having led the sale of Defined Health to Cello Health in 2017. CHBC is a leading strategic business development advisory firm serving senior executives in pharma, biotech and investment. Edward C. Saltzman possesses a vast knowledge of the pharmaceutical and biotechnology industry accumulated over Defined Health's 25 years of consultancy to pharma, biotech, specialty pharma and investors. From this breadth and depth of experience, he provides guidance to CHBC's senior project leadership who work with clients across multiple therapeutic areas.

**Other ongoing assignments:** Chairman and member of management of Cello Health BioConsulting.

**Previous assignments completed within the past five years:** Board member of Vidac Pharmaceuticals Ltd.

**Independence:** Independent in relation to both the Company and its management as well as major shareholders.

**Holdings in Saniona:** 4,000 warrants in the warrant program 2019/2023.

# MANAGEMENT



## **RAMI LEVIN** Born 1969

CEO since 2020.

**Education and background:** Bachelor's degree in Biology and an MBA. Has previously held commercial leadership roles of increased strategic importance at Merck Serono in a number of countries, including the United States, Sweden, Switzerland and Israel.

**Other ongoing assignments:** Member of the board of advisors, Life Science Cares.

**Previous assignments completed within the past five years:** President of Sobi Inc., Vice President Marketing of EMD Serono, Inc., Managing Director of the Merck Group in Scandinavia, Global Marketing Director of the Merck Group.

**Holdings in Saniona:** 710,313 warrants in the warrant program 2020/2025.



## **JØRGEN DREJER** Born 1955

Board member since 2014. Board member of Saniona A/S since 2012. CSO since 2020. Previous CEO of Saniona AB and Saniona A/S. Co-founder of Saniona A/S and Saniona AB.

**Education and background:** Ph.D. in neurobiology from the University of Copenhagen. One of the co-founders of NeuroSearch A/S and long operated as the Company's deputy CEO and head of research. Member of the Danish Academy of Engineering Science and previous member of the board of Danish Research Council for Independent Research. Author of more than 75 scientific articles.

**Other ongoing assignments:** Board member of Saniona A/S. Board member of 2CureX AB and 2CureX A/S.

**Previous assignments completed within the past five years:** Chairman of Delta Reader A/S. Board member of Atonomics A/S, Azign Bioscience A/S, Ellegaard Göttingen Minipigs A/S, Force Technology and Monta Biosciences A/S. CEO of Saniona AB and Saniona A/S.

**Independence:** Not independent in relation to the Company and its management but independent in relation to major shareholders.

**Holdings in Saniona:** 2,344,711 shares.



## **ANITA MILLAND** Born 1968

Interim CFO & Head of IR since 2020, Vice President, Finance & Administration since 2016 and Consultant since 2014.

**Education and background:** Bachelor of Commerce in Accounting from Niels Brock. More than 20 years of experience in the pharmaceutical industry, within finance, administration and investor relations. Previous Vice President, Finance & Administration as well as Chief Financial Officer at NeuroSearch A/S.

**Other ongoing assignments:** Partner and owner of Jørgensen & Milland Search & Selection ApS.

**Previous assignments completed within the past five years:** Vice President, Finance & Administration as well as Chief Financial Officer NeuroSearch A/S.

**Holdings in Saniona:** 6,500 warrants in the warrant program 2017, 3,000 warrants in the warrant program 2018 and 3,500 warrants in the warrant program 2019. 11,000 shares.



# 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, 2019 through December 31, 2019 on pages 66-74 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 15, 2020

Deloitte AB

Jeanette Roosberg  
*Authorized Public Accountant*





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