

# Saniona enters 2022 with three clinical trials underway: two Phase 2b trials of Tesomet<sup>™</sup> and a Phase 1 trial of SAN711

Three Months Ended December 31, 2021 (2020)	Twelve Months Ended December 31, 2021 (2020)
Revenue was SEK 2.9 M (1.6 M)	Revenue was SEK 10.5 M (8.2 M)
Operating loss was SEK -125.7 M (-68.6 M)	Operating loss was SEK -411.6 M (-159.4 M)
Net loss was SEK -129.9 M (-44.4 M)	Net loss was SEK -410.9 M (-73.4 M)
Basic loss per share was SEK -2.08 (-0.71)	Basic loss per share was SEK -6.59 (-1.79)
Diluted loss per share was SEK -2.08 (-0.71)	Diluted loss per share was SEK -6.59 (-1.79)

## **Business highlights in Q4 2021**

- Saniona **initiated a Phase 2b clinical trial** of Tesomet in patients with Prader-Willi syndrome (PWS); data are expected in the first half of 2023.
- Saniona initiated a Phase 2b clinical trial of Tesomet in patients with hypothalamic obesity (HO); data are expected in the second half of 2023.
- Saniona **completed the submission** of all information previously requested by the U.S. Food and Drug Administration (FDA) regarding its chemistry, manufacturing and controls program for Tesomet capsules. Tesomet capsules are being utilized in both ongoing Phase 2b trials.
- Saniona's Chairman and the CEO, as well as additional members of the Board of Directors and executive management team, **purchased shares of the company** in the open market.

# Significant events after the reporting period

- Saniona initiated the Multiple Ascending Dose stage of its Phase 1 trial of SAN711; data are expected by the end of the first half of 2022.
- Saniona received SEK 7.3 million (US\$0.8 million) from Novartis related to Novartis's January 2021 acquisition of
  Cadent Therapeutics, in which Saniona held a 3% ownership stake. This payment, in addition to the previously received
  SEK 24.2 million (US\$2.9 million), together complete Saniona's portion of the upfront payment connected to the
  acquisition. Saniona may also receive a portion of the remaining SEK 5.1 billion (US\$560 million) in contingent
  payments associated with the achievement of undisclosed future milestones relative to its previous ownership stake
  and class of shares held, when and if these milestones are achieved.

#### Comments from the CEO

"In 2021, we significantly strengthened the fundamentals of our business. We initiated three rare disease clinical trials: two Phase 2b trials of our lead candidate Tesomet for HO and PWS, and a Phase 1 trial of SAN711 for rare neuropathic disorders. We also secured orphan drug designation from the FDA for Tesomet in both HO (the first time ever granted for this indication) and PWS, and we reduced manufacturing risks by completing the transition to Tesomet capsules," said Rami Levin, President & Chief Executive Officer of Saniona. "As we enter 2022, we look forward to continuing to advance our pipeline: delivering Phase 1 data for SAN711, advancing SAN903 into the clinic, and selecting a new ion channel modulator for our pipeline. We will also continue to focus on business development opportunities to generate non-dilutive capital and continuing to ensure Saniona is well-positioned for the future."

## For more information, please contact

Trista Morrison, Chief Communications Officer, Saniona. Office: + 1 (781) 810-9227. Email: trista.morrison@saniona.com

# Letter from the CEO

2021 was a year filled with challenges related to the COVID-19 pandemic and global biotech stock markets. Despite these challenges, Saniona made significant progress strengthening the fundamentals of our business. As we enter 2022, our investment rationale continues to be strong:

- **Tesomet** is being evaluated in two international Phase 2b clinical trials, one for HO and one for PWS. Both trials are progressing, and we continue to expect top-line data for PWS in the first half of 2023 and for HO in the second half of 2023. Both trials are being conducted under U.S. Investigational New Drug Applications (INDs) with the FDA. In addition to the U.S., we have submitted our trial protocols to regulatory agencies in several countries outside the U.S. To date we have regulatory approvals in the UK, Sweden and Australia and are in the process of working to obtain approvals in additional countries. The FDA has granted Tesomet Orphan Drug Designation (ODD) in both indications, and Saniona is the first company to receive this designation in HO. Initial Phase 2 clinical trials have already generated positive data in both of these indications, where there is a significant unmet need.
- Our ion channel drug discovery engine is driving a deep pipeline of potential new medicines. SAN711 is in a
  Phase 1 clinical trial, with data expected by the end of the first half of this year, and may be applicable in the
  treatment of rare neuropathic disorders. SAN903 is in preclinical development for rare inflammatory, fibrotic and
  hematological disorders and is expected to enter the clinic later this year. Behind these lead molecules, Saniona
  continues to advance additional molecules from drug discovery utilizing our database of more than 20,000
  proprietary ion channel modulators. We anticipate advancing our next development candidate into our pipeline this
  year as well.
- We have validation of our scientific capabilities from strategic partnerships. We are actively exploring business
  development opportunities that could generate non-dilutive funding. Additionally, in 2022 we anticipate that our
  partner Medix may receive an approval decision from the Mexican regulatory authorities regarding their application
  for tesofensine as an obesity treatment in Mexico, which would result in milestone and royalty payments to
  Saniona.
- Our experienced executive team includes biotechnology industry veterans with decades of regulatory, clinical, operational and financial experience. Several of our executives have helped to build successful rare disease companies including Genzyme, Sobi and others.

Looking forward, we see the potential for multiple value-creating milestones in 2022, including data from the Phase 1 study of SAN711, initiation of a Phase 1 study with SAN903, advancement of a new ion channel modulator program into our pipeline, and a potential approval determination for tesofensine in Mexico, as well as other potential business development transactions.

I am proud of what our team has accomplished and the progress they have made in 2021 towards our vision of improving the lives of rare disease patients through scientific innovation. I'm also grateful for the support of our shareholders. We look forward to keeping you updated on our journey and, as travels hopefully continue to open up again, we look forward to being able to provide some of these updates in-person.

Rami Levin
President & CEO



# **About Saniona**

Saniona is a clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing innovative therapies for patients suffering from rare diseases for which there are a lack of available treatment options. The company's lead product candidate, Tesomet<sup>TM</sup>, is in mid-stage clinical trials for hypothalamic obesity and Prader-Willi syndrome, serious rare disorders characterized by severe weight gain, disturbances of metabolic function and uncontrollable hunger. Saniona has developed a proprietary ion channel drug discovery engine anchored by IONBASE, Saniona's database of more than 130,000 compounds, of which more than 20,000 are Saniona's proprietary ion channel modulators. Through its ion channel expertise, Saniona is advancing two wholly-owned ion channel modulators, SAN711 and SAN903. SAN711 is in a Phase 1 clinical trial and may be applicable in the treatment of rare neuropathic disorders, and SAN903 is in preclinical development for rare inflammatory, fibrotic and hematological disorders. Led by an experienced scientific and operational team, Saniona has an established research organization in the Copenhagen area, Denmark and a corporate office in the Boston, Massachusetts area, U.S. The company's shares are listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at www.saniona.com.

## **Our vision**

Improve the lives of rare disease patients around the world through scientific innovation.

## **Our mission**

We leverage our ion channel targeting expertise to discover, develop and deliver innovative rare disease treatments.

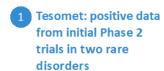
#### **Our values**

- Put People First
  - Treat all people with kindness, respect and equity. Support people on their journey and enable a sense of belonging.
- Innovation With Impact
  - Push boundaries with courage. Embrace empowerment. And deliver excellence.
- Integrity, Always
  - Maintain the highest ethical standards in all that we do as we deliver with urgency for patients in need.

# **Our Strategy**

Our strategy is to discover, develop and commercialize innovative treatments for patients suffering from rare diseases around the world. We intend to achieve this initially by advancing our lead asset, Tesomet, for HO and PWS, and our ion channel modulators, SAN711 and SAN903, for rare neuropathic and rare inflammatory, fibrotic and hematological disorders, respectively. We also intend to utilize our ion channel drug discovery engine to identify additional novel assets for new indications, with a focus on rare diseases for which there are currently no FDA-approved treatment options or those for which there remains significant unmet medical need.

## Investment rationale:



**Hypothalamic obesity (HO)** Phase 2b trial initiated; top-line data expected in H2 2023

**Prader-Willi syndrome (PWS)**Phase 2b trial initiated; top-line

data expected in H1 2023

drug discovery engine driving pipeline

Proprietary ion-channel

#### **SAN711**

For rare neuropathic disorders, Phase 1 data expected in H1 2022

#### **SAN903**

For rare inflammatory, fibrotic, and hematological disorders, expected to enter Phase 1 in H2 2022

## IONBASE Database

20,000 proprietary ion channel modulators



CAD-1883\* for movement

disorders

Novel target for schizophrenia

Tesofensine



# Financed into H2 2022

Strong institutional

RA Capital, Pontifax Venture Capital and others

<sup>\*</sup> Strategic partnership with Cadent Therapeutics, which was acquired by Novartis AG



## Long-term strategic priorities:

- Completing the clinical development of, and seeking FDA approval for, Tesomet for the treatment of HO and PWS. We have completed initial Phase 2 clinical trials of Tesomet for HO and PWS. We are currently conducting Phase 2b clinical trials in both indications. The FDA has confirmed that Tesomet may be advanced via the 505(b)(2) pathway for both indications and granted orphan drug designation status for Tesomet for the treatment of HO and PWS.
- Advancing our earlier stage programs, SAN711 and SAN903, through clinical development in rare neuropathic
  disorders and rare inflammatory, fibrotic and hematological disorders, respectively. We have identified two ion
  channel modulator product candidates, SAN711 and SAN903, from our proprietary ion channel discovery engine. We
  dosed the first participant in our Phase 1 clinical trial of SAN711 in healthy volunteers in June 2021 in the United
  Kingdom and anticipate reporting top-line data by the end of the first half of 2022. Additionally, we are continuing to
  progress SAN903 through preclinical studies and anticipate initiating a Phase 1 clinical trial in the second half of 2022.
- Continuing to expand our pipeline and develop innovative therapies targeting underserved patient populations by leveraging our rare disease expertise and ion channel drug discovery engine. We have been pioneers in the field of ion channel modulation since our founding and believe that the market for this recognized drug class has significant, untapped potential across many disease areas. We believe that our proprietary drug discovery engine overcomes many of the significant limitations of historical ion channel drug development, as does our IONBASE database of more than 130,000 compounds, of which more than 20,000 are our proprietary ion channel modulators. We expect to continue to leverage our drug discovery engine and IONBASE to expand our wholly-owned pipeline in rare diseases. We expect to select a new lead candidate from a new ion channel modulator program to advance into our pipeline during 2022.
- Commercializing Tesomet independently in the key major markets, if approved, and exploring other markets through strategic collaborations. We have worldwide development and commercialization rights for Tesomet. Due to the rare incidence and prevalence of HO and PWS, the market for these indications is concentrated around key opinion leaders (KOLs) and key centers of excellence. Since our founding, we have built and continue to expand our established relationships with leading KOLs, clinicians and patient advocacy groups to help inform our product development. We plan to build a targeted sales force, initially in North America. We may explore expanding into other select markets, either alone or in collaboration with one or more global or regional partners to provide patients around the world with access to our therapies. In markets where we do not intend to build a near-term commercial presence, we will explore out-licensing Tesomet rights.
- Maximizing the value of our ion channel engine and IONBASE by collaborating with global pharmaceutical and biotechnology companies as appropriate. Our expertise in the field of ion channel drug discovery has led to several out-licensing arrangements, spin-outs and collaborations with pharmaceutical companies globally, including Cadent (acquired by Novartis) and Boehringer Ingelheim, particularly for assets outside of our focus area of rare diseases. Future business development transactions will serve as a potential source of non-dilutive capital, which we intend to reinvest in both our discovery engine and core development efforts to treat rare diseases. We intend to continue to strategically evaluate additional opportunities to out-license certain of our technology or rights or collaborate with leading industry partners in disease areas addressing larger patient populations.



# **Our Pipeline**



IONBASE

Database of 20,000+ proprietary compounds generated over 20+ years

## Tesomet<sup>™</sup>

Our lead product candidate, Tesomet, is a novel, potentially first-in-class, once-daily oral investigational therapy for the treatment of hypothalamic obesity (HO) and Prader-Willi syndrome (PWS).

Tesomet is a fixed-dose combination of two active ingredients: tesofensine and metoprolol. Tesofensine is a novel molecule developed in the labs of our founding scientists. It is a monoamine reuptake inhibitor that modulates brain activity by increasing the levels of three neurotransmitters – dopamine, serotonin and noradrenaline – which are each intimately involved in regulating appetite, food-seeking behavior and metabolism. Metoprolol is a cardio-selective β1 receptor blocker historically used to treat a number of cardiovascular conditions and which has been approved for use in the United States since 1978. We selected metoprolol not only for its pharmacological effects but also for its well-established safety profile since its approval. Following discussions with the FDA on the proposed regulatory path for Tesomet in HO and PWS, the FDA confirmed that Tesomet may be advanced via the 505(b)(2) pathway for the treatment of HO and PWS. The FDA has granted orphan drug designation to Tesomet for the treatment of HO and PWS, respectively. We hold exclusive worldwide rights to Tesomet.

HO is a rare neuroendocrine disorder most commonly caused by damage to the hypothalamus sustained during the removal of a craniopharyngioma (CP), a rare, noncancerous central nervous system tumor. The number of patients with HO is estimated to be as high as 25,000 in the United States and 40,000 in Europe. Currently, there are no FDA-approved treatments for HO and there is no cure for this disorder. Standard of care is mainly palliative and fails to provide adequate management of weight or hyperphagia. The hypothalamus is a master regulator of metabolism and appetite that integrates both hormonal and nutritional signals from the peripheral and central nervous systems. Damage to the hypothalamus can cause severe dysregulation of energy homeostasis and, as a result, patients with HO often suffer rapid, excessive and intractable weight gain, uncontrollable hunger, memory impairment, attention deficits, excessive daytime sleepiness and lethargy, issues with impulse control and depression. Patients with HO are also at increased risk of developing obesity-related comorbid conditions such as Type 2 diabetes, hypertension, stroke and congestive heart failure. Ultimately, CP survivors with hypothalamic injury report a 20-year mortality rate at least three times higher than CP survivors without hypothalamic injury.

We have completed an initial Phase 2 clinical trial of Tesomet for the treatment of HO. This trial was a single-center, 24-week, randomized, double-blind, placebo-controlled trial with an optional 24-week Open Label Extension (OLE). A total of 21 adult patients, 13 of whom were randomized to Tesomet and eight to placebo, were included within the protocol-specified modified intent-to-treat analysis pertaining to the double-blind period (i.e., all randomized patients with measurement after at least one dose of study drug or placebo). All 18 patients who completed the double-blind portion of the trial also participated

in and completed the OLE portion. Tesomet was generally well tolerated throughout the 48 weeks of this clinical trial. The majority of adverse events (AEs) were mild or moderate in severity.

The primary endpoint of the study was to establish the overall safety and tolerability of Tesomet in patients with HO, which was achieved. Several secondary endpoints relating to efficacy were also achieved. Patients treated with Tesomet for nearly one year (24-week double-blind followed by 24-week OLE) demonstrated statistically significant reductions in body weight and improvements in waist circumference and glycemic control. Double-blind treatment with Tesomet for 24 weeks resulted in statistically significant placebo-adjusted weight loss of 6.28% (p<0.0169) and a mean reduction in waist circumference of 5.68 cm or 5.00%. In the 24-week OLE, Tesomet continued to demonstrate persistent improvements in body weight and waist circumference. Patients who received placebo in the double-blind period of the trial and were switched to Tesomet for the OLE also achieved a 4.95% and 3.04% reduction in body weight and waist circumference, respectively, after being switched to Tesomet. A key secondary endpoint of this trial was Tesomet's impact on glycemic control, as measured by HbA1c. HbA1c is a commonly referenced biomarker for insulin resistance in metabolic conditions, and HbA1c typically rapidly increases in HO patients. In non-diabetic patients treated with Tesomet, no notable changes in HbA1c were observed. In two patients with Type 2 diabetes, Tesomet lowered HbA1c by 48.80% at Week 24. The two patients with Type 2 diabetes continued to receive Tesomet and their reductions in HbA1c levels were sustained (an average of 46.17% reduction at Week 48).

We are currently conducting a Phase 2b clinical trial to further evaluate Tesomet in HO. The Phase 2b clinical trial includes a randomized, double-blind, placebo-controlled 36-week treatment period followed by an open-label extension period. The trial will seek to enroll approximately 110 participants 18 years of age and older with HO. During the 36-week double-blind period, participants will be randomized to receive daily dosing with Tesomet at one of three dose levels or placebo. During the open-label extension period, all participants, including those who originally received placebo, will receive the highest tolerated dose of Tesomet as established during the double-blind period. The primary endpoint of the study is the percentage change in body weight from baseline to week 36. Secondary endpoints include the proportion of participants who meet pre-specified thresholds for weight loss at week 36, as well as change from baseline to week 36 in body weight (kg), waist circumference, and body mass index. We expect to report top-line data from the Phase 2b HO clinical trial in the second half of 2023.

The clinical trial is being conducted at multiple sites around the world including in the United States, New Zealand, Australia, and in multiple countries in Europe including the United Kingdom, Sweden, Italy, Spain and others. More information is available at <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a>.

PWS is a rare, genetic, complex, multisystem disorder that is the most common genetic cause of childhood obesity globally. The number of patients with PWS is estimated to be as high as 34,000 in the United States and 50,000 in Europe. The only FDA-approved treatment currently available for PWS is growth hormone therapy; however, studies have not shown that growth hormone therapy reduces the hyperphagia symptoms experienced by these patients. Typically, PWS patients are diagnosed during early infancy. Patients can suffer from a variety of symptoms, most notably hyperphagia, and may display abnormal food-seeking behavior, such as stealing food. Additional symptoms include abnormal growth and body composition, low muscle tone or hypotonia, and social, emotional or cognitive deficits. Complications of obesity, such as respiratory and cardiovascular failure, infection, choking, gastric rupture and pulmonary embolism, are major causes of morbidity and mortality among patients with PWS.

We completed an initial Phase 2 clinical trial of Tesomet for the treatment of PWS. This trial was a two-center, randomized, double-blind, placebo-controlled trial. Nine adults and nine adolescents were treated daily with Tesomet or placebo for three months for the double-blind portion of the trial, with two open-label three-month extensions, referred to as OLE1 and OLE2, for adolescent patients. The primary endpoint was change in body weight; secondary objectives included hyperphagia, body composition, lipids and other metabolic parameters. Adult patients receiving Tesomet achieved a reduction in body weight and a statistically significant reduction in hyperphagia. In adolescent patients in the double-blind and OLE1 periods, Tesomet appeared to be generally well tolerated at lower doses (0.125 mg/day and 0.25 mg/day); data from OLE2 suggested dosedependent effects on weight and hyperphagia when the dose was increased to 0.25 mg/day.



The adult patients receiving Tesomet achieved a 5.4% reduction in body weight, which is notable in the small patient population, and a statistically significant 8.1 point reduction in hyperphagia as measured by the Hyperphagia Questionnaire for Clinical Trials (HQ-CT), a caregiver questionnaire that is the generally accepted standard for evaluating hyperphagia in patients with PWS. In adolescents, upon the dose increase of Tesomet from 0.125 mg to 0.25 mg during the OLE2 portion of the trial, Tesomet-treated patients experienced a decrease in body weight and a further reduction in hyperphagia as measured by the HQ-CT questionnaire.

We are currently conducting a Phase 2b clinical trial to further evaluate Tesomet in PWS. The Phase 2b clinical trial includes a randomized, double-blind, placebo-controlled 16-week treatment period followed by an open-label extension period. The trial is expected to enroll approximately 120 patients with genetically-confirmed PWS. Initially, the trial will enroll adults (18 to 65 years of age) and then, following confirmation by the data monitoring committee and by the FDA, the trial is planned to expand into adolescents (13 to 17 years of age). During the 16-week double-blind period, participants will be randomized to receive daily dosing with Tesomet at one of three dose levels or a placebo. During the open-label extension period, participants who wish to continue treatment, including those who originally received placebo, will receive the highest tolerated dose of Tesomet as established during the double-blind period. The primary objective of the study will be change in hyperphagia at week 16 as measured by the Hyperphagia Questionnaire for Clinical Trials (HQ-CT), a caregiver-reported survey that evaluates food-seeking behavior, such as frequency of sneaking food or time spent talking about food, and which has been used as the primary outcome measure for most PWS clinical trials. Secondary endpoints include change in body weight, change in caregiver impression of hyperphagia, change in clinician impression of overall clinical trial in the first half of 2023.

The clinical trial is being conducted at multiple sites around the world including in the United States, New Zealand, Australia, and in multiple countries in Europe including the United Kingdom, Sweden, Italy, Spain and others. More information is available at <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a>.

## **SAN711**

SAN711 is designed as a positive allosteric modulator (PAM) of GABAA α3. GABA is a neurotransmitter, or chemical messenger, that inhibits signals between nerve cells in the brain. Inhibiting these signals can result in outcomes such as sedation, pain relief, itch relief or seizure inhibition. We have specifically designed SAN711 to activate the α3 subunit of GABAA with high selectivity. By selectively activating α3 GABAA receptors, we believe SAN711 has the potential to restore spinal inhibitory tone and prevent abnormal pain signaling to the brain. Preclinical studies have indicated that because SAN711 only activates α3 GABAA receptors, this selectivity may allow SAN711 to provide pain relief and other benefits in the central nervous system while avoiding the typical adverse effects associated with non-selective GABAA activation such as sedation, motor instability, cognitive impairment, abuse liability and physical dependence. We initiated our Phase 1 clinical trial of SAN711 in June 2021 and anticipate reporting top-line data by the end of the first half of 2022. More information is available at <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a>.

## **SAN903**

SAN903 is designed as an inhibitor of the calcium-activated potassium channel, KCa3.1. KCa3.1 is important for activation of immune cells in the brain (microglia) and other tissues (T-cells, macrophages), and it is also involved in the abnormal production of connective tissue that can lead to fibrosis in chronic diseases. SAN903 has demonstrated proof of concept in standard preclinical animal models of inflammatory diseases, such as idiopathic pulmonary fibrosis. We intend to initiate a Phase 1 clinical trial of SAN903 in the second half of 2022.

# Ion channel drug discovery engine

Our earlier stage discovery and development efforts are focused on the validated drug class of ion channels, which have been implicated in the pathophysiology of many disease settings and include many successful drugs such as Norvasc (amlodipine), Xylocaine (lidocaine) and Valium (diazepam). Our ion channel drug discovery engine combines in-house expertise in chemistry, precision biology, in vivo stability/distribution, target engagement, in vivo pharmacology, and artificial intelligence to accelerate the discovery of highly selective, subtype-specific, and state-dependent ion channel modulators.



The core of this engine is Saniona's proprietary IONBASE database, which contains structure-activity data for more than 130,000 compounds. Of these, more than 20,000 are our proprietary compounds, generated over 20 years and enriched for properties conferring optimal ion channel modulation. As a result of our ion channel drug discovery engine, we have generated a robust pipeline of orally available, potent, highly selective and differentiated ion channel modulators, including SAN711 and SAN903. We expect to select a new lead candidate from a new ion channel modulator program to advance into our pipeline during 2022.

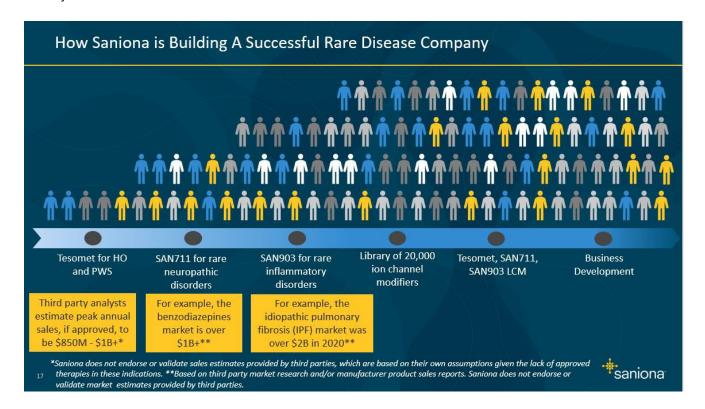
#### **Market Potential**

Saniona made the strategic decision to focus on rare diseases because of the tremendous unmet need: there are an estimated 7,000 rare diseases, according to the National Organization for Rare Disorders (NORD), and less than 10% have FDA-approved treatments. Additionally, clinical trials and regulatory reviews of medicines for rare diseases can potentially require less time and/or less financial investment than in more common disorders, and the commercial infrastructure required to serve rare patient populations is generally smaller.

Even though orphan diseases affect relatively fewer people than more common diseases, several biopharmaceutical companies have built successful, sustainable business by developing innovative medicines for orphan diseases. The pioneers in this space were Genzyme Corporation, which was acquired by Sanofi in 2011 for USD \$20 billion, and Sobi (a result of a merger between Swedish Orphan and Biovitrum), an international rare disease company with headquarters in Stockholm, Sweden. Other examples of companies focused on rare diseases include Alexion, Argenx and BioMarin.

Companies usually provide market estimates either based on their own sales in the respective indication or sales of other existing drugs for the respective indication. In the case of HO, there are no currently approved medicines, and in the case of PWS, there are currently no treatments approved for hyperphagia. This speaks to both the unmet need and the lack of competition Saniona faces in these markets, as well as the difficulty in estimating the market potential for Tesomet. Saniona cannot provide Tesomet market estimates at this time, as they would depend on many different factors including the size of the patient population, which we have estimated, and on certain pricing assumptions, which are too premature to provide guidance on. Reports from independent and commissioned external financial analysts covering Saniona generally estimate annual peak sales for Tesomet between USD \$850M - \$1B+.\*

Market estimates for SAN711 and SAN903 are not possible for Saniona to provide at this point as an indication has not been selected for either product. There is publicly available information about multiple approved products against which we have compared SAN711 and SAN903 in preclinical studies. For example, we have preclinical data demonstrating that SAN711 has the potential to provide pain relief and other benefits in the central nervous system with fewer side effects than benzodiazepines; third-party market research reports estimate the benzodiazepine market is worth well over USD \$1B. As another example, we have preclinical data demonstrating that SAN903 reduced inflammation and fibrosis in a model of idiopathic pulmonary fibrosis (IPF) with greater efficacy than two marketed products, nintedanib and pirfenidone, each of which have manufacturer-reported 2020 sales greater than USD \$1B. Again, Saniona does not endorse or validate market estimates provided by third parties, which are based on their own assumptions.



\*Any opinions, estimates or forecasts regarding Saniona's performance made by these analysts are theirs alone and do not represent opinions, forecasts or predictions of Saniona or its management. Saniona does not endorse or validate such information, conclusions or recommendations.

## **Partnerships and Spinouts**

Leveraging our expertise in the field of ion channel drug discovery and the robustness of our existing database, we are continuously advancing our research programs to identify and advance additional selective ion channel clinical candidates in a range of therapeutic areas, including rare genetic and neurological disorders. Our priority is to develop molecules internally focused on rare diseases, and we will retain the optionality to pursue select partnerships or out-licensing arrangements outside our core focus areas. Our industry-leading research has formed the basis of many successful spinouts, partnerships, and licensing agreements with pharmaceutical companies internationally, such as Boehringer Ingelheim, Ataxion Therapeutics (later known as Cadent Therapeutics, acquired by Novartis AG), Cephagenix, Initiator Pharma, Scandion Oncology and Medix.



# Financial review

## **Alternative Performance Measures**

Saniona presents certain financial measures in the Year-End Report that are not defined according to International Financial Reporting Standards (IFRS), so called alternative performance measures. These have been noted with an "\*" in the tables below. The company believes 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 listed 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.

# **Results of Operations**

# Comparison of the Three Months Ended December 31, 2021 and 2020

KSEK		2021-10-01 2021-12-31	2020-10-01 2020-12-31	Increase (Decrease)
Revenue		2,881	1,622	1,259
Total operating expenses		-128,544	-70,231	-58,313
Operating loss	*	-125,663	-68,609	-57,054

<sup>\* =</sup> Alternative performance measures

Key figures		2021-10-01 2021-12-31	2020-10-01 2020-12-31
Operating margin, %	*	-4,362%	-4,230%
Basic earnings per share, SEK		-2.08	-0.71
Diluted earnings per share, SEK		-2.08	-0.71
Cash flow per share, SEK	*	-1.12	-0.71

<sup>\* =</sup> Alternative performance measures

Alternative performance measures are derived as follows:

	2021-10-01 2021-12-31	2020-10-01 2020-12-31
Operating loss, KSEK	-125,663	-68,609
Revenue, KSEK	2,881	1,622
Operating margin, %	-4,362%	-4,230%
Cash flow for the period, KSEK	-69,797	-44,407
Average shares outstanding	62,385,677	62,372,831
Cash flow per share, SEK	-1.12	-0.71

## Revenue

Revenue increased by SEK 1.3 million from SEK 1.6 million for the three months ended December 31, 2020 to SEK 2.9 million for the three months ended December 31, 2021.

# Operating expenses

Operating expenses increased by SEK 58.3 million from SEK 70.2 million for the three months ended December 31, 2020 to SEK 128.5 million for the three months ended December 31, 2021.

Within operating expenses, external expenses increased by SEK 46.5 million from SEK 36.2 million for the three months ended December 31, 2020 to SEK 82.7 million for the three months ended December 31, 2021. The main components of our external expenses are external research and development expenses, which are primarily attributable to contract research organizations (CROs) and contract manufacturing organizations for our clinical trials. External research and development expenses for the three months ended December 31, 2021 comprised primarily of development costs of Tesomet, including costs for the preparation and initiation of our Phase 2b trials of Tesomet in PWS and HO, and development costs of SAN711. The external per patient costs of the third-party CRO supporting the two Phase 2b trials of Tesomet are expected to range between SEK 1.8 million and SEK 2.2 million. In addition, SEK 18.8 million of costs associated with our ongoing evaluation of a U.S. listing were expensed during the three months ended December 31, 2021.

For the three months ended December 31, 2020, external expenses comprised primarily of development costs of Tesomet followed by preclinical development costs of SAN711 and research and pre-clinical development costs of the SAN903 program.

The average number of employees of Saniona increased by 17.5 from 35.2 for the three months ended December 31, 2020 to 52.7 for the three months ended December 31, 2021, corresponding to the hiring of additional members to the executive team and other employees in general and administrative functions primarily in the United States (U.S.), and the increase in headcount related to the U.S.-based clinical development and regulatory team. As a result, *personnel costs*, which includes salaries, variable compensation, social security, and other employee benefits, increased by SEK 11.4 million from SEK 31.0 million for the three months ended December 31, 2020 to SEK 42.4 million for the three months ended December 31, 2021. Non-cash share-based compensation expense is included in personnel costs and increased by SEK 0.9 million from SEK 8.7 million for three months ended December 31, 2021 to SEK 9.6 million for the three months ended December 31, 2021.

Compared to the three months ended December 31, 2020, the average exchange rate of 1 SEK against the DKK and the USD for the three months ended December 31, 2021 has appreciated (depreciated) by approximately 1% and -4%, respectively. The vast majority of the company's operating expenses are denominated in DKK or USD, resulting in a net negative effect on the company's operating expenses since the Group's reporting currency is the SEK.

## Financial items

Net income from total financial items decreased by SEK 28.5 million from a net income of SEK 24.3 million for the three months ended December 31, 2020 to a net loss of SEK 4.3 million for the three months ended December 31, 2021. Within *net gains (losses) on financial items*, we have a recorded a gain from fair value measurement of a contingent consideration receivable of SEK 4.0 million for the three months ended December 31, 2021, offset by SEK 4.4 million expense to adjust for certain immaterial financial items that were previously recorded to additional paid-in capital. For the three months ended December 31, 2020, we had recorded a gain from fair value measurement of an investment in privately-held equity instruments of SEK 13.4 million, and a gain from changes in the fair value of outstanding warrants of SEK 15.9 million.

## Tax Benefit

The Group did not recognize a tax benefit for the three months ended December 31, 2020 and the three months ended December 31, 2021 as the entire benefit to Saniona resulting from the Tax Credit Scheme in Denmark was already recorded in prior quarters.

## Cash flow

Net cash used in operating activities increased by SEK 25.0 million from SEK 43.2 million for the three months ended December 31, 2020 to SEK 68.2 million for the three months ended December 31, 2021. The operating cash flow for the three months ended December 31, 2021 is primarily attributable to our operating loss of SEK 113.9 million (net of non-cash operating expenses for share-based payments of SEK 9.6 million and for depreciation of SEK 2.2 million). Increases in working capital resulted in an additional net cash adjustment of SEK 45.0 million. The operating cash flow for the three months ended December 31, 2020 is primarily attributable to our operating loss of SEK 58 million (net of non-cash operating expenses for share-based payments of SEK 8.7 million and for depreciation of SEK 1.9 million).

For the three months ended December 31, 2021 and 2020, net cash used by financing activities was SEK 1.4 million and SEK 1.2 million, respectively, due to the scheduled repayment of lease liabilities.

## Parent Company

Operating expenses increased by SEK 43.4 million from SEK 5.4 million for the three months ended December 31, 2020 to SEK 48.8 million for the three months ended December 31, 2021. This increase is commensurate to the increase of operating expenses at the Group level to the extent that it relates to general and administrative expenses.

The result for the period decreased by SEK 105.2 million from a profit of SEK 51.7 million for the three months ended December 31, 2020 to a loss of SEK 53.4 million for the three months ended December 31, 2021.

# Comparison of the Twelve Months Ended December 31, 2021 and 2020

KSEK		2021-01-01 2021-12-31	2020-01-01 2020-12-31	Increase (Decrease)
Revenue		10,478	8,198	2,280
Total operating expenses		-422,048	-167,573	-254,475
Operating loss * = Alternative performance measures	*	-411,570	-159,375	-252,195

Key figures		2021-01-01 2021-12-31	2020-01-01 2020-12-31
Operating margin, %	*	-3,928%	-1,944%
Basic earnings per share, SEK		-6.59	-1.79
Diluted earnings per share, SEK		-6.59	-1.79
Cash flow per share, SEK	*	-4.03	13.33

<sup>\* =</sup> Alternative performance measures

Alternative performance measures are derived as follows:

	2021-01-01 2021-12-31	2020-01-01 2020-12-31
Operating loss, KSEK	-411,570	-159,375
Revenue, KSEK	10,478	8,198
Operating margin, %	-3,928%	-1,944%
Cash flow for the period, KSEK	-251,280	546,412
Average shares outstanding	62,381,454	40,999,066
Cash flow per share, SEK	-4.03	13.33

## Revenue

Revenue increased by SEK 2.3 million from SEK 8.2 million for the twelve months ended December 31, 2020 to SEK 10.5 million for the twelve months ended December 31, 2021. The increase was primarily attributable to an increase in annual licenses payments from Medix, and increased research activities with Boehringer Ingelheim and Cephagenix.

## Operating expenses

Operating expenses increased by SEK 254.5 million from SEK 167.6 million for the twelve months ended December 31, 2020 to SEK 422.0 million for the twelve months ended December 31, 2021.

Within operating expenses, external expenses increased by SEK 142.2 million from SEK 97.1 million for the twelve months ended December 31, 2020 to SEK 239.3 million for the twelve months ended December 31, 2021. The main components of our external expenses are external research and development expenses, which are primarily attributable to contract research organizations and contract manufacturing organizations for our clinical trials. External research and development expenses for the twelve months ended December 31, 2021 comprised primarily of development costs of Tesomet, including costs for the preparation and initiation of our Phase 2b trials of Tesomet in PWS and HO, and development costs of SAN711 which we advanced into a Phase 1 clinical trial during second quarter of 2021. The external per patient costs of the third-party CRO supporting the two Phase 2b trials of Tesomet are expected to range between SEK 1.8 million and SEK 2.2 million. In addition, SEK 18.8 million of costs associated with our ongoing evaluation of a U.S. listing were expensed during the twelve months ended December 31, 2021. For the twelve months ended December 31, 2020, external expenses comprised primarily of development costs of Tesomet followed by preclinical development costs of SAN711 and research and pre-clinical development costs of the SAN903 program.

The average number of employees of Saniona increased by 21.4 from 27.8 for the twelve months ended December 31, 2020 to 49.2 for the twelve months ended December 31, 2021, corresponding to the hiring of additional members to the executive team and other employees in general and administrative functions primarily in the U.S., and the increase in headcount related to the U.S.-based clinical development and regulatory team. As a result, *personnel costs*, which includes salaries, variable compensation, social security, and other employee benefits, increased by SEK 107.1 million from SEK 62.4 million for the twelve months ended December 31, 2020 to SEK 169.5 million for the twelve months ended December 31, 2021. Non-cash share-based compensation expense is included in personnel costs and increased by SEK 35.1 million from SEK 12.1 million for the twelve months ended December 31, 2020 to SEK 47.1 million for the twelve months ended December 31, 2021.

Compared to the twelve months ended December 31, 2020, the average exchange rate of 1 SEK against the DKK and the USD for the twelve months ended December 31, 2021 has appreciated by approximately 3% and 7%, respectively. The vast majority of the company's operating expenses are denominated in DKK or USD, resulting in a positive effect on the company's operating expenses since the Group's reporting currency is the SEK.

## Financial items

Net financial gains decreased by SEK 92.5 million from SEK 96.9 million for the twelve months ended December 31, 2020 to SEK 4.4 million for the twelve months ended December 31, 2021. Net financial gains for the twelve months ended December 31, 2021 include a gain of SEK 4.8 million related to the fair value measurement of warrants, a gain of SEK 4.0 million related to the fair value measurement of a contingent consideration receivable, offset by SEK 4.4 million expense to adjust for certain immaterial financial items that were previously recorded to additional paid-in capital. Net financial gains for the twelve months ended December 31, 2020 included a gain from the cessation of the equity-method of accounting for our investment in Scandion Oncology as of March 31, 2020 of SEK 53.3 million, a gain of SEK 30.2 million related to the fair value measurement of warrants, and a gain of SEK 13.4 million from fair value measurement of an investment in privately-held equity instruments of SEK 13.4 million.

# Tax Benefit

The tax benefit on net loss recognized with regard to a Tax Credit Scheme in Denmark decreased by SEK 0.3 million from SEK 7.8 million for the twelve months ended December 31, 2020 to SEK 7.5 million for the twelve months ended December 31, 2021 because of exchange rate fluctuations.

## Cash flow

Net cash used in operating activities increased by SEK 170.7 million from SEK 174.3 million for the twelve months ended December 31, 2020 to SEK 345.0 million for the twelve months ended December 31, 2021. The operating cash flow for the twelve months ended December 31, 2021 is primarily attributable to our operating loss of SEK 355.7 million (net of non-cash operating expenses for share-based payments of SEK 47.2 million and for depreciation of SEK 8.7 million). The operating



cash flow for the twelve months ended December 31, 2020 is primarily attributable to our operating loss of SEK 142.5 million (net of non-cash operating expenses for share-based payments of SEK 12.1 million and for depreciation of SEK 4.8 million).

For the twelve months ended December 31, 2021, net cash provided by financing activities was SEK 50.6 million, primarily attributable to the receipt of net proceeds of SEK 81.8 million from our new non-dilutive term loan agreement with Formue Nord Fokus A/S, partially offset by the repayment of our SEK 25.0 million loan with Formue Nord that originated in 2020. For the twelve months ended December 31, 2020, net cash provided by financing activities was SEK 621.2 million, primarily related to the receipt of net proceeds of SEK 598.5 million from the issuance of new shares and SEK 25.0 million related to the receipt of proceeds from the 2020 Formue Nord Loan.

## Parent Company

Operating expenses increased by SEK 51.9 million from SEK 13.7 million for the twelve months ended December 31, 2020 to SEK 65.6 million for the twelve months ended December 31, 2021. This increase is commensurate to the increase of operating expenses at the Group level to the extent that it relates to general and administrative expenses.

The result for the period decreased by SEK 192.0 million from a profit of SEK 148.2 million for the twelve months ended December 31, 2020 to a loss of SEK 43.8 million for the twelve months ended December 31, 2021.

## **Financial position**

Balance sheet, KSEK	2021-12-31	2020-12-31
Cash and cash equivalents, KSEK	356,855	573,866
Equity, KSEK	281,999	603,458
Total equity and liabilities, KSEK	440,248	692,181

As of December 31, 2021 and December 31, 2020, approximately 95% and 80%, respectively, of our cash and cash equivalents were held in U.S. dollar.

Key figures		2021-12-31	2020-12-31
Liquidity ratio, %	*	599%	846%
Equity ratio, %	*	64%	87%
Equity per share, SEK	*	4.52	9.68
* = Alternative performance measures			

Alternative performance measures were derived as follows:

	2021-12-31	2020-12-31
0 1 1/05//	000.044	505.040
Current assets, KSEK	390,844	595,812
Current liabilities, KSEK	65,277	70,416
Liquidity ratio, %	599%	846%
Equity, KSEK	281,999	603,458
Total assets, KSEK	440,248	692,181
Equity ratio, %	64%	87%
Equity, KSEK	281,999	603,458
Shares outstanding at the end of the period	62,385,677	62,372,831
Equity per share, SEK	4.52	9.68

## The share, share capital and ownership structure

Share data, #	2021-10-01 2021-12-31	2020-10-01 2020-12-31	2021-01-01 2021-12-31	2020-01-01 2020-12-31
Average shares outstanding	62,385,677	62,372,831	62,381,454	40,999,066
Diluted average shares outstanding	62,385,677	62,465,236	62,381,501	41,919,662
Shares outstanding at the end of the period	62,385,677	62,372,831	62,385,677	62,372,831

On December 31, 2021 and 2020, the company had 9,289 (8,150) shareholders excluding holdings in life insurance and foreign custody account holders.

#### Personnel

As of December 31, 2021, Saniona had 53 employees including 14 employees with Ph.D. degrees. Of these employees, 36 were engaged in research and clinical development activities and 17 were engaged in general and administrative activities. Of the 53 employees, 29 (55%) were women. At the VP level, we had 13 employees, of which 6 (46%) were women. At the Executive Committee level, exclusive of the CEO, we had 8 FTEs, of which 4 (50%) were women.

# Risk factors and risk management

All business operations involve risk. Managed risk-taking is necessary to maintain operations. Risk may be due to events in the external environment and may affect a certain industry or market. Risk may also be company specific.

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 main risks and uncertainties which Saniona is exposed to are related to drug development, the company's collaboration agreements, competition, technology development, patents, regulatory requirements, capital requirements and currencies.

A detailed description of the Group's risk factors and risk management is included in Saniona's 2020 Annual Report. There are no major changes in the Group's risk factors and risk management in 2021.

## Risk related to COVID-19

As of the date of this Year-End Report, our clinical trials have not been significantly impacted by the ongoing COVID-19 pandemic. We have licensed some of our technologies to third parties, and their development efforts have been and may continue to be impacted by the ongoing COVID-19 pandemic. There are still uncertainties with regard to the continued spread of COVID-19, including the identification of new variants of the virus and its implications, and we will continue to assess the situation and seek to put in place relevant mitigating measures where necessary.

Although we believe we have implemented strategies to potentially minimize the impact of the COVID-19 pandemic to our business, including following local recommendations regarding COVID-19 safety, we may experience delays with respect to the initiation of certain additional trials or receipt of any governmental or regulatory approvals. The extent to which the COVID-19 pandemic impacts the timing of these matters will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the identification of new variants of the virus, the duration of the pandemic, any restrictions on the ability of hospitals and trial sites to conduct trials that are not designed to address the COVID-19 pandemic and the perceived effectiveness of actions taken in the United States and other countries to contain and treat the disease. We will continue to evaluate the impact of the COVID-19 pandemic to our business.

#### **Audit review**

The Year-End Report has not been audited or reviewed by the company's independent auditor.



# Financial calendar

Annual Report 2021 April 29, 2022 at 8:00 CEST Interim Report Q1 May 25, 2022 at 8:00 CEST

Annual General Meeting May 25, 2022

Interim Report Q2 August 25, 2022 at 8:00 CEST
Interim Report Q3 November 17, 2022 at 8:00 CET
Year-End Report 2022 February 23, 2023 at 8:00 CET



YEAR-END REPORT FOR SANIONA AB (PUBL)
January – December 2021

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

Glostrup, February 24, 2022 Saniona AB	
J. Donald deBethizy – Chairman	Rami Levin, President and CEO
Jørgen Drejer – Board member	Anna Ljung – Board member
Carl Johan Sundberg – Board member	Edward Saltzman – Board member
Robert Hoffman – Board member	

# THE GROUP'S UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

The Group's unaudited condensed consolidated interim financial statements have been prepared based on the accounting policies described in Note 2 Basis of Accounting and Significant Accounting Policies.

# Unaudited condensed consolidated interim statement of comprehensive income - Group

KSEK	Note	2021-10-01	2020-10-01	2021-01-01	2020-01-01
		2021-12-31	2020-12-31	2021-12-31	2020-12-31
_					
Revenue	4	2,881	1,622	10,478	8,198
Total operating income		2,881	1,622	10,478	8,198
Raw materials and consumables		-1,278	-1,176	-4,630	-3,252
Other external costs		-82,699	-36,156	-239,267	-97,107
Personnel costs	5	-42,381	-30,994	-169,478	-62,417
Depreciation and write-downs		-2,186	-1,905	-8,673	-4,797
Total operating expenses		-128,544	-70,231	-422,048	-167,573
Operating loss		-125,663	-68,609	-411,570	-159,375
Share of result of associate	10	_	_	_	-433
Financial income		282	-1,619	1,922	312
Financial expenses		-4,140	-6,061	-13,128	-18,655
Net gains (losses) on financial items		-397	31,954	4,396	96,935
Total financial items		-4,255	24,274	-6,810	78,159
Loss before tax		-129,918	-44,335	-418,380	-81,216
Tax benefit (expenses) on net loss	6	_	-66	7,482	7,786
Loss for the period		-129,918	-44,401	-410,898	-73,430
Other comprehensive income (loss) for					
the period					
Item that may be reclassified to profit and loss					
Translation differences		6,524	-53,522	32,574	-28,262
Items that will not be reclassified to profit and loss		-,		,	
Equity instruments at FVOCI – net change					00.40
fair value		_	-33,223	5,063	68,466
Total other comprehensive income (loss) period, net after tax	for the	6,524	-86,745	37,637	40,204
Total comprehensive loss for the period		-123,394	-131,146	-373,261	-33,226
Loss per share, SEK		-2.08	-0.71	-6.59	-1.79
Diluted Loss per share, SEK		-2.08	-0.71	-6.59	-1.79

# Unaudited condensed consolidated interim statement of financial position – Group

KSEK	Note	2021-12-31	2020-12-31
ASSETS			
Intangible assets		6,189	6,072
Property and equipment		5,100	5,089
Right of use assets		16,652	23,035
Investment in associate	10	670	_
Other financial assets	7,9	20,793	61,660
Other assets		_	513
Tax assets	6	_	_
Deferred tax		_	_
Non-current assets		49,404	96,369
Trade receivables		3,615	5,043
Current tax assets	6	7,564	7,421
Other financial assets	7,9	414	_
Other assets		22,396	9,482
Cash and cash equivalents		356,855	573,866
Current assets		390,844	595,812
Total assets		440,248	692,181

# Unaudited condensed consolidated interim statement of financial position – Group (continued)

KSEK	Note	2021-12-31	2020-12-31
EQUITY AND LIABILITIES			
Share capital		3,119	3,119
Additional paid-in capital		813,261	808,607
Reserves		74,545	36,908
Accumulated deficit		-608,926	-245,176
Equity		281,999	603,458
Other financial liabilities	8,9	92,972	16,228
Other liabilities	2,2	_	2,079
Non-current liabilities		92,972	18,307
Trade payables		29,115	18,875
Other financial liabilities	9	6,799	40,623
Other liabilities		29,363	10,918
Current liabilities		65,277	70,416
Total liabilities		158,249	88,723
Total equity and liabilities		440,248	692,181

# Unaudited condensed consolidated interim statement of changes in equity - Group

	Share capital	Additional paid-in capital	Translation reserves	Fair value reserve	Accumulated deficit	Shareholders' equity
January 1, 2020	1,421	239,592	-3,296	_	-183,833	53,884
Comprehensive income						
Loss for the period	_	_	_	_	-73,430	-73,430
Other comprehensive income:						
Fair value reserve	_	_	_	68,466	_	68,466
Translation differences	_	_	-28,262		_	-28,262
Total comprehensive income (loss)	_	_	-28,262	68,466	-73,430	-33,226
Transactions with owners						
Shares issued for cash	1,698	649,537	_	_	_	651,235
Expenses related to capital increase	_	-52,723	_	_	_	-52,723
Issuance of Investor Warrants	_	-27,799	_	_	_	-27,799
Share-based compensation expenses	_	_	_	_	12,087	12,087
Total transactions with owners	1,698	569,015	_	_	12,087	582,800
December 31, 2020	3,119	808,607	-31,558	68,466	-245,176	603,458
January 1, 2021	3,119	808,607	-31,558	68,466	-245,176	603,458
Comprehensive income Loss for the period Reclassification of previously	_	_	_	_	-410,898	-410,898
recorded net financial items from Additional paid-in capital to	_	4,414	_	_	_	4,414
Loss for the period Other comprehensive income:						
Fair value reserve Translation differences	_	_	32,574	5,063	_	5,063 32,574
Total comprehensive income (loss)	_	4,414	32,574	5,063	-410,898	-368,847
Transactions with owners						
Shares issued for cash	_	321	_	_	_	321
Expenses related to capital	_	-81	_	_	_	-81
increase						Ŭ.
Share-based compensation	_	_	_	_	47,148	47,148
expenses  Total transactions with						
Total transactions with owners	_	240	_	_	47,148	47,388
December 31, 2021	3,119	813,261	1,016	73,529	-608,926	281,999

# Unaudited condensed consolidated interim statement of cash flows – Group

KSEK	Note	2021-10-01	2020-10-01	2021-01-01	2020-01-01
		2021-12-31	2020-12-31	2021-12-31	2020-12-31
		100.010	44.005	440.000	04.040
Loss before tax		-129,918	-44,335	-418,380	-81,216
Adjustments for non-cash transactions		12,257	-10,825	51,425	-79,972
Changes in working capital		44,989	12,298	24,929	-19,955
Cash flow from operating activities before financial and tax items		-72,672	-42,862	-342,026	-181,143
financial and tax items					
Interest income received		32	230	278	275
Interest expenses paid		-3,074	-583	-10,777	-1,069
Tax credit received		7,487	_	7,487	7,657
Cash flow from operating activities		-68,227	-43,215	-345,038	-174,280
Investing activities					
Purchases of property and equipment		-174	_	-1,484	-4,999
Proceeds from sale of financial assets		_	_	44,646	104,511
Cash flow from investing activities		-174	_	43,162	99,512
Financing activities				04 700	05.000
Proceeds from issuance of loan		_	_	81,780	25,000
Repayment of loan Proceeds from issuance of new shares		_	_	-25,000 321	
Costs related to issuance of new shares		_	_	-81	651,235
		-1,396	-1,192	-6,424	-52,725
Payment of lease liabilities		•		50,596	-2,330
Cash flow from financing activities		-1,396	-1,192	50,596	621,180
Net increase (decrease) in cash and cash		00 =0=	44.40=	054 000	= 40,440
equivalents		-69,797	-44,407	-251,280	546,412
Cash and cash equivalents at beginning of period		425,699	647,058	573,866	40,248
Exchange rate adjustments		953	-28,785	34,269	-12,794
Cash and cash equivalents at end of period		356,855	573,866	356,855	573,866
•			•	•	,

# PARENT COMPANY'S UNAUDITED FINANCIAL STATEMENTS

The Parent Company's unaudited financial statements have been prepared based on the accounting policies described in Note 2 Basis of Accounting and Significant Accounting Policies.

# **Unaudited statement of income - Parent Company**

KSEK	2021-10-01	2020-10-01	2021-01-01	2020-01-01
Note	2021-12-31	2020-12-31	2021-12-31	2020-12-31
1,2,3				
Other operating income	181	5,721	3,877	5,721
Total operating income	181	5,721	3,877	5,721
Raw materials and consumables	-3	-3	-10	-25
Other external costs	-26,102	-2,766	-31,514	-6,248
Personnel costs 5	•	-2,621	-34,038	-7,424
Total operating expenses	-48,834	-5,390	-65,562	-13,697
Operating income (loss)	-48,653	331	-61,685	-7,976
Share of result of associates	_	_	_	-433
Financial income	3,138	35,218	5,875	41,334
Financial expenses	-3,282	-1,135	-7,574	-16,214
Net gains (losses) on financial items	-4,629	17,328	19,583	131,469
Total financial items	-4,773	51,411	17,884	156,156
Profit (loss) before tax	-53,426	51,742	-43,801	148,180
Tax on net profit (loss)	_	_	_	_
Profit (loss) for the period	-53,426	51,742	-43,801	148,180

# **Unaudited balance Sheet – Parent Company**

KSEK	Note	2021-12-31	2020-12-31
ASSETS			
Investment in subsidiaries		1,038,008	929,244
Other financial assets	7,9		1,746
Financial assets		1,038,008	930,990
Non-current assets		1,038,008	930,990
Receivables from group companies		<del>-</del>	5,721
Other assets		1,541	3,388
Current receivables		1,541	9,109
Cash and cash equivalents		12,106	45,733
Current assets		13,647	54,842
Total assets		1,051,655	985,832
EQUITY AND LIABILITIES			
Restricted equity			
Share capital		3,119	3,119
Unrestricted equity			
Share premium reserve		813,261	808,607
Retained earnings (accumulated deficit)		187,524	-7,804
Profit (loss) for the period		-43,801	148,180
Equity		960,103	952,102
Other financial liabilities		82,973	_
Non-current liabilities		82,973	_
Trade payables		1,935	754
Payables to group companies		6,436	_
Other financial liabilities	8	, <u> </u>	32,861
Other liabilities		208	115
Current liabilities		8,579	33,730
Total liabilities		91,552	33,730
Total equity and liabilities	_	1,051,655	985,832

# Notes to the unaudited condensed consolidated interim financial statements

## **Note 1 General Information**

Saniona AB (publ), (the 'Parent Company'), Corporate Registration Number 556962-5345, is a limited liability company registered in the municipality of Malmö in the county of Skåne, Sweden. These unaudited condensed consolidated interim financial statements comprise the Parent Company and its subsidiaries (collectively the 'Group' or 'Saniona'). The Group is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing innovative therapies for patients suffering from rare diseases for which there are a lack of available treatment options. The legal address of the head office and the research facility is Smedeland 26B, DK-2600 Glostrup, Denmark. The majority of Saniona's executive team members are based in Saniona's United States offices, located at 500 Totten Pond Road, Waltham, MA 02451. The Parent Company is listed on Nasdaq Stockholm Small Cap, and its shares are traded under the ticker SANION and the ISIN code SE0005794617.

# **Note 2 Basis of Accounting and Significant Accounting Policies**

## A. Basis of Accounting

These unaudited condensed consolidated interim financial statements for the three and twelve months ended December 31, 2021 have been prepared in accordance with IAS 34 *Interim Financial Reporting*, the Annual Accounts Act, and the Financial Reporting Board's recommendation RFR 1, Supplementary Accounting Rules for Groups. The unaudited interim financial statements for the Parent Company are prepared under the requirements of chapter 9 of the Swedish Accounting Act (1995:1554). These unaudited condensed consolidated interim financial statements should be read in conjunction with the Group's last annual consolidated financial statements as at and for the year ended December 31, 2020 ('last annual financial statements'). They do not include all of the information required for a complete set of financial statements prepared in accordance with IFRS Standards. However, selected explanatory notes are included to explain events and transactions that are significant to an understanding of the changes in the Group's financial position and performance since the last annual financial statements.

The unaudited condensed consolidated interim financial statements have been prepared on a going concern basis. We anticipate that we will meet payment obligations out of our cash and cash equivalents as of December 31, 2021 or from capital obtained through additional sources, including but not limited to, non-dilutive business development transactions and/or equity financings.

These condensed consolidated financial statements were authorized for issue by the Parent Company's Board of Directors (the 'Board') on February 24, 2022.

## **B. Significant Accounting Policies**

The Group has consistently applied the accounting policies described in the last annual financial statements to all periods presented in these unaudited condensed consolidated interim financial statements.

## i. Segment reporting

The Group is organized as a single business unit, focused on discovering, developing, and commercializing innovative treatments for rare disease patients. Consistent with its organizational structure, the Group's President and Chief Executive Officer ('CEO'), who is also the chief operating decision maker, views and manages the Group's operations and business as a single operating segment. Our intangible and tangible non-current assets are located predominantly in Denmark.



#### ii. Fair value measurement

The Group uses the following hierarchy for determining and disclosing the fair value of financial instruments by valuation technique:

Level 1: Quoted (unadjusted) prices in active markets for identical assets or liabilities.

Level 2: Other techniques for which all inputs which have a significant effect on the recorded fair value are observable, either directly or indirectly.

Level 3: Techniques which use inputs that have a significant effect on the recorded fair value that are not based on observable market data.

When one is available, the Group measures the fair value of an instrument using the quoted price in an active market for that instrument. A market is regarded as 'active' if transactions for the asset or liability take place with sufficient frequency and volume to provide pricing information on an ongoing basis.

If there is no quoted price in an active market, then the Group uses valuation techniques that maximize the use of relevant observable inputs and minimize the use of unobservable inputs. The chosen valuation technique incorporates all of the factors that market participants would consider in pricing a transaction.

The Group regularly reviews significant unobservable inputs and valuation adjustments. Significant valuation issues are reported to the Group's audit committee.

## iii. Adoption of new or revised standards

A number of amendments to standards are effective for annual periods beginning on or after January 1, 2021, and earlier application of those amendments that are effective for annual periods beginning on or after January 1, 2022 is permitted. None of the amendments that are effective for the twelve months ended December 31, 2021 had a material impact on the Group's financial position or results of operations. The Group has not early adopted any of the forthcoming amended standards in preparing these unaudited condensed consolidated interim financial statements, he amendments are not expected to have a material impact on the Group's financial position or results of operations.

## Note 3 Critical accounting judgments and key sources of estimation uncertainty

In preparing these unaudited condensed consolidated interim financial statements, management has made judgements, assumptions, and estimates that affect the application of the Group's accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates.

The significant judgements made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were the same as those described in the last annual financial statements.

## **Note 4 Revenue**

The Group's revenue generating activities are those described in the last annual financial statements. In the twelve months ended December 31, 2021 and 2020, revenue for the Group by category was as follows:

KSEK	2021-10-01	2020-10-01	2021-01-01	2020-01-01
	2021-12-31	2020-12-31	2021-12-31	2020-12-31
License agreements (other event-based payments)	_	_	2,504	1,971
Research and collaboration agreements (bundle, over time)	1,937	1,622	5,714	4,407
Research and development services (standalone)	944	_	2,260	1,820
Total	2,881	1,622	10,478	8,198

In the twelve months ended December 31, 2021 and 2020, revenue for the Group by major customers was as follows:

KSEK	2021-10-01	2020-10-01	2021-01-01	2020-01-01
	2021-12-31	2020-12-31	2021-12-31	2020-12-31
Customer #1	_	_	2,504	1,971
Customer #2	944	_	2,260	1,820
Customer #3	1,937	1,622	5,714	4,407
Total	2,881	1,622	10,478	8,198

In the twelve months ended December 31, 2021 and 2020, revenue for the Group by primary geographical market was as follows:

KSEK	2021-10-01	2020-10-01	2021-01-01	2020-01-01
	2021-12-31	2020-12-31	2021-12-31	2020-12-31
Sweden	_	_	_	_
Other European countries	2,881	1,622	7,974	6,227
The Americas	_	_	2,504	1,971
Total	2,881	1,622	10,478	8,198

## Note 5 Share-based payments

# A. Description of share-based payment arrangements

A detailed description of the Group's share-based payment arrangements as of December 31, 2020 is provided in the last annual financial statements. During the three and twelve months ended December 31, 2021, the Group made the following additional grants under the Option Program 2020:

2021:1 A total of 902,000 options were allotted at various points in time in the first quarter of 2021.

2021:2 A total of 148,350 options were allotted at various points in time in the second quarter of 2021.

Each option entitles the holder a right to acquire one new share in Saniona for a subscription price equal to the closing price of our common stock on the day before the allotment. The options are subject to a service condition, 25% vest on the 12-month anniversary, and the remaining 75% vest gradually on a quarterly basis at a rate of 6.25% over the following 36 months, resulting in a total vesting period of 48 months. The holder can exercise vested options from the time of vesting until the date that falls 10 years after the allotment date. However, for a participant that ceases to be employed or in a service relationship in the Group, vested options have to be exercised within 90 days from the date when the participant ceased to be employed or in a service relationship in the Group (or, in the case such cessation is due to the participant's death or disability, 12 months from such date).

## B. Measurement of fair values and compensation expense

Share-based compensation expenses for the three months ended December 31, 2021 and 2020 totaled SEK 9.6 million and SEK 8.7 million, respectively. Share-based compensation expenses for the twelve months ended December 31, 2021 and 2020 totaled SEK 47.1 million and SEK 12.1 million, respectively. The fair value of the service that entitles an employee and board member to allotment of options under Saniona's option programs is recognized as a personnel cost with a corresponding increase in equity. Such compensation expenses represent the fair market values of warrants granted and do not represent actual cash expenditures.

The inputs used in the measurement of the fair values at grant date based on the Black-Scholes formula and the reconciliation of options outstanding are as follows.

Incentive program	2017	2018:1	2018:2	2018:3	2019:1	2019:2
Options outstanding, January 1	38,292	286,003	32,792	10,513	34,500	15,770
Granted during the year	_	_	_	_	_	_
Forfeited during the year	_		_			
Options outstanding, December 31	38,292	286,003	32,792	10,513	34,500	15,770
Grant Date Fair Value* (SEK)	27.94	12.06	17.38	12.89	7.23	6.00
Share Price at Grant Date* (SEK)	49.60	26.95	33.85	33.85	17.76	17.76
Exercise Price* (SEK)	40.63	33.20	29.71	29.71	17.83	17.83
Expected volatility*	73.41%	69.24%	67.77%	53.67%	57.29%	53.67%
Estimated life (years)*	3.75	3.88	3.73	2.8	3.67	2.8
Expected dividends*	0	0	0	0	0	0
Risk-free rate*	-0.2602%	-0.1092%	-0.2773%	-0.4218%	-0.6903%	-0.6709%
Remaining contractual life (years)*	1	2.5	1.96	0.48	3	1.75
Incontive program	2020-4	2020-2	2020.2	2024.4	2024.2	Total
Incentive program	2020:1	2020:2	2020:3	2021:1	2021:2	Total
Incentive program  Options outstanding, January 1	<b>2020:1</b> 710,313	<b>2020:2</b> 5,915,648	<b>2020:3</b> 308,000	2021:1	2021:2	<b>Total</b> 7,351,831
				2021:1 — 902,000	2021:2 — 148,350	
Options outstanding, January 1				_	_	7,351,831
Options outstanding, January 1 Granted during the year				_	_	7,351,831
Options outstanding, January 1 Granted during the year Forfeited during the year Options outstanding, December 31	710,313 — —	5,915,648 — —	308,000 — —	902,000 —	— 148,350 —	7,351,831 1,050,350 —
Options outstanding, January 1 Granted during the year Forfeited during the year Options outstanding, December 31 Grant Date Fair Value* (SEK)	710,313 — — — 710,313	5,915,648 — — 5,915,648	308,000 — — 308,000	902,000 — 902,000	148,350 — 148,350	7,351,831 1,050,350 —
Options outstanding, January 1 Granted during the year Forfeited during the year Options outstanding, December 31 Grant Date Fair Value* (SEK) Share Price at Grant Date* (SEK)	710,313 — — 710,313	5,915,648 — — 5,915,648	308,000 — — 308,000 7.98	902,000 — 902,000 10.75	148,350 — 148,350	7,351,831 1,050,350 —
Options outstanding, January 1 Granted during the year Forfeited during the year Options outstanding, December 31 Grant Date Fair Value* (SEK)	710,313 — — 710,313 12.26 28.10	5,915,648 — — 5,915,648 13.13 23.50	308,000 — — 308,000 7.98 23.55	902,000 — 902,000 10.75 19.31	148,350 — 148,350 10.18 18.88	7,351,831 1,050,350 —
Options outstanding, January 1 Granted during the year Forfeited during the year Options outstanding, December 31  Grant Date Fair Value* (SEK) Share Price at Grant Date* (SEK) Exercise Price*(SEK)	710,313 — — 710,313 12.26 28.10 29.36	5,915,648 ————————————————————————————————————	308,000 — 308,000 7.98 23.55 25.40	902,000 — 902,000 10.75 19.31 19.38	148,350 — 148,350 10.18 18.88 19.26	7,351,831 1,050,350 —
Options outstanding, January 1 Granted during the year Forfeited during the year Options outstanding, December 31  Grant Date Fair Value* (SEK) Share Price at Grant Date* (SEK) Exercise Price*(SEK) Expected volatility*	710,313 — — 710,313 12.26 28.10 29.36 58.66%	5,915,648 ————————————————————————————————————	308,000  308,000 7.98 23.55 25.40 57.00%	902,000 902,000 10.75 19.31 19.38 62.56%	148,350 — 148,350 10.18 18.88 19.26 61.32%	7,351,831 1,050,350 —
Options outstanding, January 1 Granted during the year Forfeited during the year Options outstanding, December 31  Grant Date Fair Value* (SEK) Share Price at Grant Date* (SEK) Exercise Price*(SEK) Expected volatility* Estimated life (years)*	710,313 ———————————————————————————————————	5,915,648 ————————————————————————————————————	308,000  308,000 7.98 23.55 25.40 57.00% 2.8	902,000 902,000 10.75 19.31 19.38 62.56% 6.11	148,350 ————————————————————————————————————	7,351,831 1,050,350 —

<sup>\*</sup> Weighted average



## Note 6 Income tax

In the twelve months ended December 31, 2021 and 2020, the Group recognized a current tax benefit of SEK 7.5 million and SEK 7.8 million, respectively, related to the Danish 'Skattekreditordningen' (the 'Tax Credit Scheme'). Under the Tax Credit Scheme, loss-making companies can claim payment of the tax base of the portion of their loss which is attributable to certain research and development ('R&D') activities. Companies may obtain payment of the tax base of losses originating from R&D expenses of up to DKK 25.0 million (approx. SEK 34.1 million). The Group's Danish subsidiary Saniona A/S has reached that threshold before the third quarter of 2021 and 2020, respectively, and as it is expected that Saniona A/S will have a full year 2021 tax loss in excess of that threshold, the Group has recorded the full amount of the benefit.

## Note 7 Other financial assets

## A. Composition

Other financial assets were comprised of the following:

KSEK	2021-12-31	2020-12-31
Contingent consideration receivable	18,289	_
Investment in equity instruments - privately-held	_	37,319
Investment in equity instruments - publicly traded	_	22,241
Long-term deposits for property lease agreements	2,504	2,100
Total non-current other financial assets	20,793	61,660
Short-term deposit for property lease agreement	414	_
Total current other financial assets	414	_

## B. Investment in equity instruments - privately-held and Contingent consideration receivable

Through January 2021, Saniona A/S, a wholly-owned subsidiary of the Parent Company, owned approximately 3% of the share capital of Cadent Therapeutics, Inc. ('Cadent Therapeutics'), a private company based in Cambridge, MA, United States. In January 2021, Novartis AG ('Novartis') closed its acquisition of Cadent Therapeutics that was announced in December 2020, upon the occurrence of the closing of the acquisition, the Group exchanged its investment in equity instruments – privately-held for a receivable for an upfront payment in the amount of SEK 24.2 million, and a contingent consideration receivable from Novartis that had a carrying amount of SEK 18.3 million as of December 31, 2021. The upfront payment was received in February 2021.

## C. Investment in equity instruments – publicly traded

The asset as of December 31, 2020 represents the fair value of the Group's investment in Scandion Oncology A/S ('Scandion Oncology'). As of June 30, 2021, Saniona has sold of all its shares in Scandion Oncology in the open market.

In the three and twelve months ended December 31, 2021, the Group recognized a net gain in other comprehensive income resulting from changes in Scandion Oncology's share price of SEK 0.0 million and SEK 5.1 million, respectively. In the three and twelve months ended December 31, 2020, the Group recognized a net gain in other comprehensive income resulting from an increase in Scandion Oncology's share price of SEK 33.2 million and SEK 68.5 million, respectively.

## **Note 8 Other financial liabilities**

## A. Composition

Other financial liabilities were comprised of the following:

KSEK	2021-12-31	2020-12-31
Lease liabilities	9,999	16,228
Formue Nord Loan	82,973	_
Total non-current other financial liabilities	92,972	16,228
Lease liabilities	6,799	6,937
Formue Nord Loan	<del>_</del>	28,067
Warrants	<del>_</del>	4,794
Other	_	825
Total current other financial liabilities	6,799	40,623

## **B. Formue Nord Loan**

On January 10, 2020, the Group entered into a fixed-rate loan facility agreement with Formue Nord entitling the Group to draw loans in an aggregate amount of SEK 25.0 million. In March 2020 Saniona drew loans of SEK 25.0 million under the loan facility agreement. The loans were subject to market interest rates and matured on February 7, 2021. They were repaid on February 5, 2021.

On July 12, 2021, the Group entered into a new non-dilutive SEK-denominated fixed-rate term loan agreement for SEK 87.0 million with Formue Nord Focus A/S. After deduction of a 6% commitment fee, the Group received SEK 81.8 million in net proceeds from this agreement. The loan accrues interest at a rate of 1% on the gross amount of the loan for each 30-day period until the loan is repaid and settled, interest payments are due guarterly. The loan matures in June 2023.

## C. Warrants

As of December 31, 2020, all warrants of the series TO3 as part of the Unit Rights Issue 2020 were outstanding. In April 2021, a total of 12,846 series TO3 warrants were exercised, the remaining 1,466,896 series TO3 warrants were forfeited, resulting in a net gain on financial items of SEK 4.8 million. The Group received gross proceeds before expenses of SEK 0.3 million from this exercise.

## Note 9 Financial instruments – fair values

# A. Accounting classifications and fair values

The following table shows the carrying amounts and fair values of financial assets and financial liabilities, including their levels in the fair value hierarchy. It does not include fair value information for financial assets and financial liabilities not measured at fair value if the carrying amount is a reasonable approximation of fair value.

December 31, 2021		Carrying amount				Fair value				
KSEK	Note	Financial assets at amortized cost	Mandatorily at FVTPL - others	FVOCI - equity instruments	Other financial liabilities	Total	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value										
Contingent consideration receivable	7	_	18,289	_	_	18,289	_	_	18,289	18,289
		_	18,289	_	_	18,289	_	-	18,289	18,289
Financial assets not measured at fair value										
Trade receivables		3,615	_	_	<u> </u>	3,615	_	_		_
Other non-current financial assets	7	2,504	_	_	_	2,504	_	_	_	_
Other current financial assets	7	414	_	_	_	414	_	_	_	_
Cash and cash equivalents		356,855	_	_	_	356,855	_	_	_	_
		363,388	_	_	_	363,388	_	_	_	_
Financial liabilities not measured at fair value	9									
Trade payables		_	_		29,115	29,115	_	_	_	_
Formue Nord Loan	8	_	_	_	82,973	82,973	_	_	_	_
Lease liabilities	8	_	_	_	16,798	16,798	_	_	_	_
		_	_	_	128,886	128,886	_	_	_	

December 31, 2020				Carrying amo	unt			Fair va	lue	
KSEK	Note		Mandatorily at FVTPL - others	FVOCI - equity instruments	Other financial liabilities	Total	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value										
Investment in equity instruments - publicly traded	7	_	_	22,241		22,241	22,241	_	_	22,241
Investment in equity instruments - privately-held	7	_	37,319	_	_	37,319	_	_	37,319	37,319
		_	37,319	22,241	_	59,560	22,241	_	_	59,560
Financial assets not measured at fair value										
Trade receivables		5,043	_	_	_	5,043	_	_	_	_
Other non-current financial assets	7	2,100	_	_	_	2,100	_	_	_	_
Cash and cash equivalents		573,866	_	_	_	573,866	_	_	_	
		581,009	_	_	_	581,009	_	_	_	_
Financial liabilities measured at fair value										
Warrants	8	_	4,794	_	_	4,794	4,794	_	_	4,794
		_	4,794	_	_	4,794	4,794	_	_	4,794
Financial liabilities not measured at fair value										
Trade payables		_	_	_	18,875	18,875	_	_	_	_
Loan	8	_	_	_	28,067	28,067	_	_	_	_
Other financial liabilities		_	_	_	825	825	_	_	_	_
Lease liabilities	8	_	_	_	23,165	23,165	_	_	_	_
		_	_	_	70,932	70,932	_	_	_	_

## B. Measurement of fair values

## i. Valuation techniques and significant unobservable inputs

The investment in Scandion Oncology has been measured using Scandion Oncology's closing share price at the Spotlight Stock Exchange on December 30, 2020. The series TO3 warrants have been measured at their trading price on Nasdaq Stockholm on December 30, 2020.

The contingent consideration receivable from Novartis as of December 31, 2021 and the investment in Cadent Therapeutics as of December 31, 2020 have been measured using a probability-weighted discounted cash flow valuation technique, which considers the present value of expected payments, discounted using a risk-adjusted discount rate. Significant inputs to the valuation as of December 31, 2021 are as follows:

- Undiscounted expected cash flows to Saniona are up to to SEK 151 million.
- Undiscounted expected cash flows resulting from development and regulatory-milestone based contingent consideration have been adjusted for estimated probabilities that underlying milestones are achieved (0% - 34%).
- The probability-weighted cash flows have been discounted using a risk-adjusted discount rate of 11.0%.

The estimated fair value would increase (decrease) if the expected cash flows were higher (lower); or the probability of achieving milestones increases (decreases); or the risk-adjusted discount rate were lower (higher). Reasonably possible changes at the reporting date to one of the significant unobservable inputs, holding other inputs constant, would have the following effects.

KSEK	Profit or loss			
	Increase	Decrease		
December 31, 2021				
Risk-neutral expected payments to the Group (+/- 1,000bps)	1,048	-1,048		
December 31, 2020				
Discount rate (+/- 75bps)	-2,669	2,669		

## ii. Transfers

During the three and twelve months ended December 31, 2021 and 2020, there were no transfers of financial instruments between the different valuation hierarchy categories.

# iii. Reconciliation of Level 3 fair values

The following table shows a reconciliation from the opening balances to the closing balances for Level 3 fair values.

KSEK	Investment in equity instruments – privately held	Contingent consideration
Balance, January 1, 2021	37,319	_
Cash received	-23,390	_
Exchange	-14,244	14,244
Changes in Fair Value	_	4,017
Foreign currency (included in 'net gains/losses on financial items')	315	28
Balance, December 31, 2021	0	18,289

# **Note 10 Related parties**

In May 2021, Saniona became a minority shareholder of Cephagenix ApS ('Cephagenix'), a private Denmark-based company formed to explore ion channel modulators for the treatment of migraine. As of December 31, 2021, the Group held an ownership percentage of 21.4% of Cephagenix, and accounts for this holding as an investment in associate under the equity-method of accounting. Saniona has an existing research services agreement with Cephagenix which was entered

INTERIM REPORT FOR SANIONA AB (PUBL)
January – December 2021

into in January 2020. Saniona recognized gross revenue of SEK 1.8 million from this agreement after Cephagenix became an associate, of that SEK 0.4 million, which represents Saniona's share of this revenue and Saniona's share of the loss of Cephagenix for the period, were eliminated.

During 2021 and 2020, the Group had a business advisor agreement with one of its Directors, Edward Saltzman, for the provision of advisory services regarding the general business development of the Group. As of December 31, 2021 and December 31, 2020, balances of SEK 0 million and SEK 0.4 million, respectively, were outstanding.

During the three and twelve months ended December 31, 2021, a total of 0 and 511,000 options, respectively, were granted to key management personnel under the Option Program 2020, refer to Note 5 *Share-based payments*.

## Note 11 Commitments and contingencies

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, 2022. Saniona A/S had no external net debt as of December 31, 2021.

# Note 12 Subsequent Events to the Balance Sheet Date

 In February 2022, Saniona received SEK 7.3 million from Novartis related to the contingent consideration receivable from Novartis. The amount of this payment was included in the fair value of the receivable as of December 31, 2021. Net of this payment, the remaining fair value of the contingent consideration receivable as of December 31, 2021 is SEK 11.0 million.

This information is such information as Saniona AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out above, at 08:00 CET on February 24, 2022.

Saniona AB Smedeland 26B DK-2600 Glostrup Denmark www.saniona.com

