

# Saniona Refocused Strategy Leverages our Core Competences and Builds Value to our Ion Channel Pipeline

## Q1 2022 (Q1 2021)

Revenue was SEK 6.6 M (3.4 M) Operating loss was SEK -133.2 M (-94.1 M) Net loss was SEK -133.4 M (-83.4 M) Loss per share was SEK -2.14 (-1.34) Diluted loss per share was SEK -2.14 (-1.34)

## **Business highlights in Q1 2022**

- Saniona initiated the Multiple Ascending Dose (MAD) stage and the Positron Emission Tomography (PET) stage of its Phase 1 trial of SAN711; The ongoing Phase 1 trial is placebo-controlled, and the data remain blinded. Saniona continues to expect data from the trial by mid-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, when and if these milestones are achieved.
- Saniona and Boehringer Ingelheim advanced the ongoing research collaboration into the "hit-to-lead" stage. The collaboration is focused on a novel, undisclosed CNS ion channel target for schizophrenia. Saniona receives ongoing research funding and may receive up to €76.5 million in milestone payments as well as royalties on worldwide net sales.
- On March 29, 2022, Saniona announced a program reprioritization and restructuring comprising a voluntary pause of the Phase 2b clinical trials of Tesomet<sup>™</sup> for hypothalamic obesity (HO) and Prader-Willi syndrome (PWS) and a workforce reduction of approximately 30%. The decision to voluntarily pause the Phase 2b clinical trials of Tesomet<sup>™</sup> is not related to the safety or efficacy of Tesomet<sup>™</sup> and is entirely due to funding limitations.

## Significant events after the reporting period

On April 30, 2022, Saniona appointed Thomas Feldthus as Chief Executive Officer and Anita Milland as Chief Financial Officer. Thomas Feldthus will oversee Saniona's refocused strategy on ion channel research and development and explore partnering opportunities to advance its lead assets. The Board of Directors elected Jørgen Drejer as interim Chairman until the Annual General Meeting (AGM) to be held on May 25, 2022. In connection with this refocused strategy, the company terminated its plans to list its shares in the U.S., closed its U.S. operations and terminated the positions of all U.S. personnel, including the U.S. executive management team. These restructuring actions are anticipated to reduce future annual operating expenses by approximately 70-75%.

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## **Comments from the CEO**

"We are transforming the company into a more focused and cost-effective organization that leverages our core strengths within ion channel drug discovery and development. We have closed our operation in the United States and are seeking strategic partnerships in order to maximize the value of Tesomet<sup>™</sup> and SAN711. By improving our operational efficiency and targeting business development efforts, we aim to fully leverage the value of our most advanced assets and develop new ion channel-based therapies through 2022 and beyond."

## For more information, please contact

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## Letter from the CEO

Prior to taking office in May I said that we are going to reduce the burn rate to Scandinavian levels, focus on affordable value creating activities and restore investor confidence.

## **Reducing burn rate**

We have reduced the costs with about 75% for the continued operation. This means that the base cost for running the company and its research and development operation has been reduced to about 70 MSEK on annual basis. On the top of this, we would have to add external expenses for investment in program specific clinical development activities e.g., a pre-clinical IND enabling development program requires an investment of typical 20-25 MSEK over an 18-month period, a clinical Phase 1 program requires an investment of about 30 MSEK over a 12-15 month period.

## **Creating value**

We are now focusing on affordable value creating activities by investing in development programs, which we can afford to run internally, and by establishing partnerships on development programs, which we cannot afford to do internally.

In accordance with this, we will over the next 6-12 months focus on establishing partnerships and collaborations on programs, which we cannot afford to develop internally due to company's financial position and market cap.

Saniona has many valuable assets, which seem to be highly interesting for potential partners. After just three weeks in the company, I have had the pleasure to spend about one third of my time in meetings with about 20 different companies, where our scientists have made presentations on confidential and non-confidential basis. Many of these companies have reached out to us following the announcements of the revised strategy in April. Several companies have asked for access to our data room. I believe that this is a very encouraging start.

## **Restoring investor confidence**

The company's market cap reflects the company's reputation and investor confidence. This is the most important asset for any biotech company. Without investor confidence, the science and clinical programs have no value. And without investor confidence, a biotech company will not be able to retain its talented employees.

The company's market cap has fallen significantly over the last 18-months without any clinical failure. It may take longer than 18 months to restore the company's market cap and investor confidence. However, a successful collaboration on one or more of our assets may not only restore the company's balance sheet but also provide a first step towards restoring the investor confidence and thereby the market cap. This is the reason for our focus on this now.

## Saniona remains a rare disease company although the short-term strategy is opportunistic

In April the company decided to close its U.S. operation and to go back to the traditional partnering and licensing model, which has worked successfully for Saniona in the past. This strategy is not dependent on developing therapies for rare diseases. This strategy requires a more opportunistic approach since the objective is to maximize the value of the individual asset for the purpose of out licensing activities. Some of our clinical and advanced research programs may be developed for both rare diseases and common diseases. This includes SAN711, SAN903 and several of the advanced research programs. Therefore, in the short to medium term, we will also take a more opportunistic approach on our research and development activities to maximize the value for out-licensing purpose.

This strategy is supported by the fact that Saniona is a leading CNS company. Apart from SAN903 all the company's products are positioned for treatment of diseases within CNS. The company has some of the most experienced scientist within this field. Saniona's employees and its research platform within CNS represent a unique asset, which has enabled the company to enter long-term research collaboration with some of the largest pharmaceutical companies in the world including Pfizer, Janssen and Boehringer Ingelheim.

Saniona is also a rare disease company. Tesomet, SAN903 and several of the advanced research programs are positioned for rare diseases. By focusing on rare diseases, Saniona may retain a significant part of the value by developing the assets internally and potentially even by commercializing the products itself. The successful harvesting of the created value under this strategy requires direct access to the U.S. market. However, this does not necessary mean



that the company must be headquartered in the U.S. Other Scandinavian companies have with success commercialised products for rare diseases in the U.S. by building a relatively small commercial operation there. These companies will be our reference point and serve as inspiration when it becomes relevant.

We are now a Scandinavian biotech company and with a Scandinavian cost base for the continued operation. The encouraging start on the business development activities provide us good reasons to believe that we will be able to deliver on the second objective and create significant value through partnerships for one or more of our assets within the next 6-12 months. This would provide the first step for restoring the investor confidence. We will be more opportunistic in our strategic approach in the short to medium term to support the collaboration and licensing strategy. However, we will continue to position programs for rare diseases with the aim of taking one of these products forward ourselves. The long-term goal is to become a Scandinavian rare disease company with commercial operation in the U.S. and ultimately with broader global reach.

Thomas Feldthus CEO



## **About Saniona**

Saniona is a clinical-stage biopharmaceutical company with a mission to leverage its ion channel targeting expertise to discover, develop and deliver innovative rare disease treatments. The company's most advanced product candidate, Tesomet<sup>™</sup>, has been progressed into mid-stage clinical trials for hypothalamic obesity and Prader-Willi syndrome, serious rare disorders characterized by severe weight gain, disturbances of metabolic functions and uncontrollable hunger. These clinical trials are voluntarily paused due to funding limitations and Saniona is actively exploring partnering opportunities. Saniona has developed a proprietary ion channel drug discovery engine anchored by IONBASE<sup>™</sup>, a 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 is positioned for the treatment of neuropathic pain conditions, and SAN903 is in preclinical development for rare inflammatory, fibrotic and hematological disorders. Saniona is based in the Copenhagen area, Denmark, and is listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at http://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

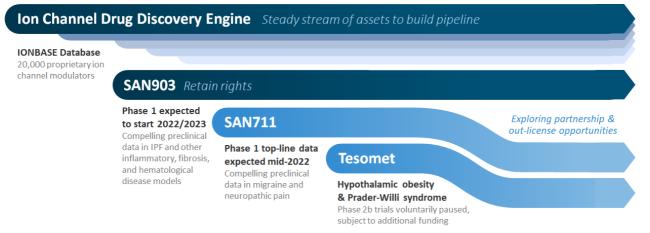
Push boundaries with courage. Embrace empowerment. And deliver excellence.

Integrity, Always

Maintain the highest ethical standards in all that we do as we deliver with urgency for patients in need.



# **Clinical Pipeline**



## Tesomet™

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 has been advanced into Phase 2b clinical trials for HO and PWS, which are voluntarily paused due to funding limitations. The Company is actively exploring all partnership options, including worldwide partnerships, that could generate immediate non-dilutive income and enable Tesomet to move forward.

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  $\beta$ 1 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.

Saniona has 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). 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. 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.

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.

Saniona has 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. 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.

Saniona sees significant value in Tesomet. The Company's decision to voluntarily pause the Phase 2b Tesomet studies in HO and PWS was not related to safety or efficacy, and Saniona believes that the initial Phase 2 data support further development of Tesomet in both indications. Financial analysts have estimated annual peak sales for Tesomet between USD \$850M - \$1B+ (SEK 8B – 9.5B) (Saniona does not endorse or validate sales estimates provided by third parties). Given the current economic climate and Saniona's withdrawal from the U.S., the Company will no longer seek to independently raise the funding needed to advance Tesomet; instead, the Company is actively exploring all partnership options, including worldwide partnerships, that could generate immediate non-dilutive income and enable Tesomet to move forward.

## SAN711

SAN711 is designed as a positive allosteric modulator (PAM) of GABAA  $\alpha$ 3. 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  $\alpha$ 3 subunit of GABAA with high selectivity. By selectively activating  $\alpha$ 3 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  $\alpha$ 3 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.

Saniona is currently conducting a randomized, placebo-controlled Phase 1 clinical trial of SAN711 in approximately 80 healthy volunteers. The primary objective of the study is to determine the tolerability and the maximum tolerated dose of SAN711, as evaluated through the single ascending dose and multiple ascending dose phases of the study. The secondary objective is to measure binding to target receptors, as assessed during a positron emission tomography



(PET) evaluation phase of the study. Saniona has initiated all three stages of this trial and top-line data are expected in mid-2022. More information is available at www.clinicaltrials.gov.

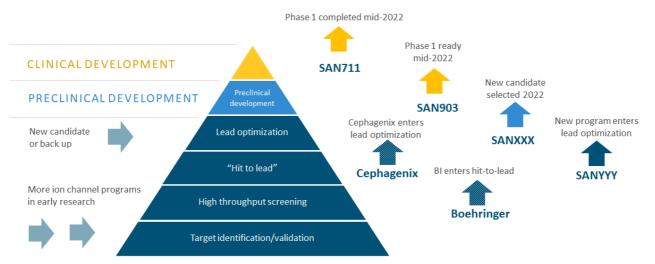
Saniona has also spent more than a year conducting preclinical assessments in in vitro and in vivo models for multiple disease states. The most compelling data obtained thus far indicate substantial potential value for SAN711 in migraine, trigeminal neuralgia and neuropathic pain. As these are larger, non-rare indications, Saniona has decided to actively explore opportunities to out-license SAN711 and generate non-dilutive income.

## **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 or first half of 2023.



# **R&D Ion Channel Pipeline**

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.

In 2022, we expect to select a new lead candidate, SANXXX in the figure above, from a new ion channel modulator program to advance into our clinical pipeline.



We have currently several active research programs of which two are developed together with partners. We anticipate that this robust discovery engine will continue to generate additional partnering opportunities and deliver multiple new drug candidates to add to the Saniona pipeline.

## **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, Pfizer, Johnson & Johnson, Proximagen, 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 interim 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 March 31, 2022 and 2021

KSEK		2022-01-01	2021-01-01	Increase
		2022-03-31	2021-03-31	(Decrease)
Revenue		6,625	3,438	3,187
Total operating expenses		-139,825	-97,574	-42,251
Operating loss	*	-133,200	-94,136	-39,064

\* = Alternative performance measures



## INTERIM REPORT FOR SANIONA AB (PUBL) January – March 2022

Key figures		2022-01-01 2022-03-31	2021-01-01 2021-03-31
Operating margin, %	*	-2,011%	-2,738%
Basic earnings per share, SEK		-2.14	-1.34
Diluted earnings per share, SEK		-2.14	-1.34
Cash flow per share, SEK	*	-1.44	-1.68

\* = Alternative performance measures

Alternative performance measures are derived as follows:

	2022-01-01 2022-03-31	2021-01-01 2021-03-31
	2022-03-31	2021-03-31
Operating loss, KSEK	-133,200	-94,136
Revenue, KSEK	6,625	3,438
Operating margin, %	-2,011%	-2,738%
Cash flow for the period, KSEK	-89,885	-104,617
Average shares outstanding	62,385,677	62,372,831
Cash flow per share, SEK	-1.44	-1.68

## Revenue

Revenue increased by SEK 3.2 million from SEK 3.4 million for the three months ended March 31, 2021 to SEK 6.6 million for the three months ended March 31, 2022.

## Operating expenses

Operating expenses increased by SEK 42.3 million from SEK 97.6 million for the three months ended March 31, 2021 to SEK 139.8 million for the three months ended March 31, 2022.

Within operating expenses, *external expenses* increased by SEK 30.4 million from SEK 54.2 million for the three months ended March 31, 2021 to SEK 84.6 million for the three months ended March 31, 2022. 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 March 31, 2022 comprised primarily of development costs of Tesomet and SAN711. For the three months ended March 31, 2021, 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 20.1 from 35.2 for the three months ended March 31, 2021 to 55.2 for the three months ended March 31, 2022, 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. In the first quarter of 2022, Saniona recorded a provision for severance related to the termination of certain employees under the first step of the two-step strategic reprioritization and restructuring of SEK 5.5 million. As a result, *personnel costs*, which includes salaries, variable compensation, social security, and other employee benefits, increased by SEK 10.9 million from SEK 40.5 million for the three months ended March 31, 2021 to SEK 51.4 million for the three months ended March 31, 2022. Non-cash share-based compensation expense is included in personnel costs and decreased by SEK 5.8 million from SEK 12.1 million for three months ended March 31, 2021 to SEK 6.3 million for the three months ended March 31, 2022.

## Financial items

Net gains from total financial items decreased from SEK 3.3 million for the three months ended March 31, 2021 to zero for the three months ended March 31, 2022. For the three months ended March 31, 2021, we had recorded a gain from changes in the fair value of warrants of SEK 3.3 million.



## Tax Benefit

The Group recognized a tax benefit for the three months ended March 31, 2022 and the three months ended March 31, 2021 of SEK 3.2 million and SEK 7.5 million, respectively, resulting from the Tax Credit Scheme in Denmark. The decrease is related to a decrease in qualified R&D expenses incurred in Denmark during these periods. Saniona expects to recognize the maximum benefit for the Tax Credit Scheme in Denmark for 2022 during upcoming quarters.

## Cash flow

Net cash used in operating activities decreased by SEK 20.7 million from SEK 116.5 million for the three months ended March 31, 2021 to SEK 95.8 million for the three months ended March 31, 2022. The operating cash flow for the three months ended March 31, 2022 is primarily attributable to our operating loss of SEK 124.6 million (net of non-cash operating expenses for share-based payments of SEK 6.3 million and for depreciation of SEK 2.3 million). Increases in working capital resulted in an additional net cash adjustment of SEK 34.5 million. The operating cash flow for the three months ended March 31, 2021 is primarily attributable to our operating loss of SEK 79.9 million (net of non-cash operating expenses for share-based payments of SEK 12.1 million and for depreciation of SEK 2.1 million).

For the three months ended March 31, 2022 and 2021, net cash used by financing activities was SEK 1.6 million and SEK 26.5 million, respectively, due to the scheduled repayment of lease liabilities.

## Parent Company

Operating expenses increased by SEK 10.9 million from SEK 5.1 million for the three months ended March 31, 2021 to SEK 16.0 million for the three months ended March 31, 2022. 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 31.0 million from a profit of SEK 12.8 million for the three months ended March 31, 2021 to a loss of SEK 18.2 million for the three months ended March 31, 2022.

## **Financial position**

Balance sheet, KSEK	2022-03-31	2021-03-31	2021-12-31
Cash and cash equivalents, KSEK	279,335	497,397	356,855
Equity, KSEK	165,954	560,665	281,999
Total equity and liabilities, KSEK	348,289	624,006	440,248

As of March 31, 2022 and 2021, and December 31, 2021, approximately 95%, 87%, and 95% respectively, of our cash and cash equivalents were held in U.S. dollar.

Key figures		2022-03-31	2021-03-31	2021-12-31
Liquidity ratio, %	*	338%	1,232%	599%
Equity ratio, %	*	48%	90%	64%
Equity per share, SEK	*	2.66	8.99	4.52
* = Alternative performance measures				



Alternative performance measures were derived as follows:

	2022-03-31	2021-03-31	2021-12-31
Current assets, KSEK	304.057	559,414	390,844
Current liabilities, KSEK	89,888	45,402	65,277
Liquidity ratio, %	338%	1,232%	599%
Equity, KSEK	165,954	560,665	281,999
Total assets, KSEK	348,289	624,006	440,248
Equity ratio, %	48%	90%	64%
Equity, KSEK	165,954	560,665	281,999
Shares outstanding at the end of the period	62,385,677	62,372,831	62,385,677
Equity per share, SEK	2.66	8.99	4.52

## The share, share capital and ownership structure

Share data, #	2022-01-01 2022-03-31	2021-01-01 2021-03-31	2021-01-01 2021-12-31
Average shares outstanding	62,385,677	62,372,831	62,381,454
Diluted average shares outstanding	62,385,677	62,462,233	62,381,501
Shares outstanding at the end of the period	62,385,677	62,372,831	62,385,677

On March 31, 2022 and 2021, the company had 9,231 (10,126) shareholders excluding holdings in life insurance and foreign custody account holders.

## Personnel

As of March 31, 2022, Saniona had 56 (47) employees including 14 (14) employees with Ph.D. degrees. Of these employees, 38 (35) were engaged in research and clinical development activities and 18 (12) were engaged in general and administrative activities. Of the 56 (47) employees, 31 (25) 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 2021 Annual Report. There are no major changes in the Group's risk factors and risk management in 2022.



## **Risk related to COVID-19**

As of the date of this interim 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 interim report has not been audited or reviewed by the company's independent auditor.

## **Financial calendar**

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



The Board of Directors and the CEO of Saniona AB (publ) provide their assurance that the interim 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, 25 May 2022 Saniona AB

Jørgen Drejer – Interim Chairman

Thomas Feldthus - CEO

J. Donald deBethizy - 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	2022-01-01 2022-03-31	2021-01-01 2021-03-31	2021-01-01 2021-12-31
Revenue	4	6,625	3,438	10,478
Total operating income		6,625	3,438	10,478
Raw materials and consumables		-1,525	-743	-4,630
Other external costs		-84,581	-54,174	-239,267
Personnel costs	5	-51,430	-40,520	-169,478
Depreciation and write-downs		-2,289	-2,137	-8,673
Total operating expenses		-139,825	-97,574	-422,048
Operating loss	_	-133,200	-94,136	-411,570
Share of result of associate	10	193	_	_
Financial income		619	1,554	1,922
Financial expenses		-4,126	-1,672	-13,128
Net gains on financial items			3,388	4,396
Total financial items		-3,314	3,270	-6,810
Loss before tax	_	-136,514	-90,866	-418,380
Tax benefit on net loss	6	3,157	7,482	7,482
Loss for the period	-	-133,357	-83,384	-410,898
Other comprehensive income (loss) for the period				
Item that may be reclassified to profit and loss				
Translation differences		10,987	29,175	32,574
Items that will not be reclassified to profit and loss				
Equity instruments at FVOCI – net change fair value		—	-707	5,063
Total other comprehensive income for the perio after tax	d, net	10,987	28,468	37,637
Total comprehensive loss for the period	_	-122,370	-54,916	-373,261
Loss per share, SEK		-2.14	-0.71	-6.59
Diluted Loss per share, SEK		-2.14	-0.71	-6.59



## Unaudited condensed consolidated interim statement of financial position - Group

KSEK	Note	2022-03-31	2021-03-31	2021-12-31
ASSETS				
Intangible assets		6,263	6,194	6,189
Property and equipment		4,743	5,368	5,100
Right of use assets		15,074	21,885	16,652
Investment in associate	10	700	_	670
Other financial assets	7,9	14,343	23,574	20,793
Tax assets	6	3,109	7,571	_
Non-current assets		44,232	64,592	49,404
Trade receivables		7,835	2,338	3,615
Current tax assets	6	7,654	7,571	7,564
Other financial assets	7,9	427	_	414
Other assets		8,806	52,108	22,396
Cash and cash equivalents		279,335	497,397	356,855
Current assets		304,057	559,414	390,844
Total assets		348,289	624,006	440,248



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

KSEK	Note	2022-03-31	2021-03-31	2021-12-31
EQUITY AND LIABILITIES				
Share capital		3,119	3,119	3,119
Additional paid-in capital		813,261	808,607	813,261
Reserves		85,532	65,376	74,545
Accumulated deficit		-735,958	-316,437	-608,926
Equity		165,954	560,665	281,999
Other financial liabilities	8,9	92,447	14,951	92,972
Other liabilities		_	2,988	_
Non-current liabilities		92,447	17,939	92,972
Trade payables		43,738	28,716	29,115
Other financial liabilities	9	6,237	8,666	6,799
Other liabilities		39,913	8,020	29,363
Current liabilities		89,888	45,402	65,277
Total liabilities		182,335	63,341	158,249
Total equity and liabilities		348,289	624,006	440,248



	Share capital	Additional paid-in capital	Translation reserves	Fair value reserve	Accumulated deficit	Shareholders' equity
January 1, 2021	3,119	808,607	-31,558	68,466	-245,176	603,458
Comprehensive income						
Loss for the period	—	—	—	—	-83,384	-83,384
Other comprehensive income:				707		-707
Fair value reserve Translation differences		—	20.175	-707		
	_		29,175			29,175
Total comprehensive income (loss)	-	—	29,175	-707	-83,384	-54,916
Transactions with owners						
Shares issued for cash	—	—	—	—	—	
Expenses related to capital increase	_	_	_	—	_	_
Share-based compensation expenses	—	_	_	—	12,123	12,123
Total transactions with	_	_	_	_	12,123	12,123
owners					,•	,
March 31, 2021	3,119	808,607	-2,383	67,759	-316,437	560,665
January 1, 2022	3,119	813,261	1,016	73,529	-608,926	281,999
<b>Comprehensive income</b> Loss for the period Other comprehensive income:	-	-	_	_	-133,357	-133,357
Fair value reserve	—	—	—	—	—	_
Translation differences	_		10,987			10,987
Total comprehensive income (loss)	-	-	10,987	-	-133,357	-122,370
Transactions with owners Shares issued for cash	_	_	_	_	_	_
Expenses related to capital increase	_	_	-	-	-	-
Share-based compensation expenses	_	_		_	6,325	6,325
Total transactions with owners	_	_	_	_	6,325	6,325
March 31, 2022	3,119	813,261	12,003	73,529	-735,958	165,954

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



## Unaudited condensed consolidated interim statement of cash flows - Group

KSEK	Note	2022-01-01	2021-01-01	2021-01-01
		2022-03-31	2021-03-31	2021-12-31
Loss before tax		-136,514	-90,866	-418,380
Adjustments for non-cash transactions		9,293	18,893	51,425
Changes in working capital		34,478	-40,560	24,929
Cash flow from operating activities before financial and tax	_	-92,743	-112,533	-342,020
items		-92,145	-112,555	-542,020
Interest income received		9	110	278
Interest expenses paid		-3,074	-4,110	-10,777
Tax credit received			_	7,487
Cash flow from operating activities		-95,808	-116,533	-345,038
Investing activities				
Purchases of property and equipment		-32	-548	-1,484
Proceeds from sale of financial assets		7,522	39,000	44,646
Proceeds from sale of tangible assets		9	_	_
Cash flow from investing activities		7,499	38,452	43,162
Financing activities				
Proceeds from issuance of loan			_	81,780
Repayment of loan			-25,000	-25,000
Proceeds from issuance of new shares		—	—	32
Costs related to issuance of new shares		—	—	-8
Payment of lease liabilities		-1,576	-1,536	-6,424
Cash flow from financing activities		-1,576	-26,536	50,590
Net increase (decrease) in cash and cash equivalents		-89,885	-104,617	-251,280
Cash and cash equivalents at beginning of period		356,855	573,866	573,860
Exchange rate adjustments		12,365	28,148	34,269
Cash and cash equivalents at end of period	_	279,335	497,397	356,855



## 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	Note	2022-01-01 2022-03-31	2021-01-01 2021-03-31	2021-01-01 2021-12-31
	1,2,3			
Other operating income		1,516	1,175	3,877
Total operating income		1,516	1,175	3,877
Raw materials and consumables		_	-3	-10
Other external costs		-5,639	-1,467	-31,514
Personnel costs	5	-10,345	-3,590	-34,038
Total operating expenses		-15,984	-5,060	-65,562
Operating income (loss)		-14,468	-3,885	-61,685
Financial income		81	201	5,875
Financial expenses		-3,817	-396	-7,642
Net gains (losses) on financial items		_	16,916	-658,449
Total financial items		-3,736	16,721	-660,216
Profit (loss) before tax		-18,204	12,836	-721,901
Tax on net profit (loss)		_	_	_
Profit (loss) for the period		-18,204	12,836	-721,901



## Unaudited balance Sheet – Parent Company

KSEK	Note	2022-03-31	2021-03-31	2021-12-31
ASSETS				
Investment in subsidiaries		366,056	940,923	359,908
Other financial assets	7,9	684	500	_
Financial assets		366,740	941,423	359,908
Non-current assets	_	366,740	941,423	359,908
Other assets	_	384	5,698	1,541
Current receivables	_	384	5,698	1,541
Cash and cash equivalents		6,709	33,552	12,106
Current assets	_	7,093	39,250	13,647
Total assets	_	373,833	980,673	373,555
EQUITY AND LIABILITIES				
Restricted equity				
Share capital		3,119	3,119	3,11
Unrestricted equity				
Share premium reserve		813,261	808,607	813,261
Retained earnings (accumulated deficit)		-528,051	152,502	187,524
Profit (loss) for the period		-18,204	12,836	-721,901
Equity		270,125	977,064	282,003
Other financial liabilities	_	83,631	_	82,973
Non-current liabilities		83,631	-	82,973
Trade payables		3,641	613	1,935
Payables to group companies		16,208	1,501	6,436
Other financial liabilities	8		1,406	_
Other liabilities		228	89	208
Current liabilities		20,077	3,609	8,579
Total liabilities	_	103,708	3,609	91,552
Total equity and liabilities	_	373,833	980,673	373,555



# 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 with a mission to leverage its ion channel targeting expertise to discover, develop and deliver innovative rare disease treatments. The legal address of the head office is Smedeland 26B, DK-2600 Glostrup, Denmark. 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 months ended March 31, 2022 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, 2021 ('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. As of March 31, 2022, the Group's current assets exceed current liabilities by SEK 214.2 million. Current assets include cash and cash equivalents of SEK 279.3 million. To ensure that the Group will be in a position to repay all of its current liabilities as of March 31, 2022, as well as its current liabilities to be incurred in connection with operating expenses during the next 12 months, management has taken immediate and significant actions in March and April 2022 to reduce costs and optimize the Group's cash flow and liquidity, including, but not limited to: voluntarily pausing the Phase 2b clinical trials of Tesomet for HO and PWS; closing the U.S. operations and terminating the positions of all U.S. personnel, including the U.S. executive management team; deferring or reducing all discretionary spend; and freezing non-essential hiring. In addition, management is pursuing partnerships for its later-stage clinical programs Tesomet and SAN711, proceeds received from such arrangements would provide the company with additional liquidity. There is however a risk that these efforts are not sufficient to fund the Company's operations until additional financing can be obtained. There is a risk that the Company will not be able to raise additional capital, retain or obtain additional partnerships or obtain other co-financing on acceptable terms or at all. This could result in a temporary halt to the Company's development programs or that the Company is forced to run operations at a lower rate than desired, which could adversely affect the Company's operations. Based on these factors, the Board has a reasonable expectation that the Group has and will have adequate resources to continue in operation existence through least March 31, 2023.

These condensed consolidated financial statements were authorized for issue by the Parent Company's Board of Directors (the 'Board') on May 25, 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 new standards and amendments to standards are effective for annual periods beginning after January 1, 2022, and earlier application is permitted. However, the Group has not early adopted any of the forthcoming new or amended standards in preparing these unaudited condensed consolidated interim financial statements. The new or amendment standards 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 three months ended March 31, 2022 and 2021, revenue for the Group by category was as follows:

KSEK	2022-01-01 2022-03-31	2021-01-01 2021-03-31
License agreements (other event-based payments)	3,760	2,504
Research and collaboration agreements (bundle, over time)	1,926	265
Research and development services (standalone)	939	669
Total	6,625	3,438

In the three months ended March 31, 2022 and 2021, revenue for the Group by major customers was as follows:

KSEK	2022-01-01 2022-03-31	2021-01-01 2021-03-31
Customer #1	3,760	2,504
Customer #2	939	669
Customer #3	1,926	265
Total	6,625	3,438

In the three months ended March 31, 2022 and 2021, revenue for the Group by primary geographical market was as follows:

KSEK	2022-01-01 2022-03-31	2021-01-01 2021-03-31
Sweden	—	—
Other European countries	2,865	934
The Americas	3,760	2,50
Total	6,625	3,438

## 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, 2021 is provided in the last annual financial statements. During the three months ended March 31, 2022, the Group has not made any additional grants. As a result of the termination of certain employees under the first step of the two-step strategic program reprioritization and restructuring in March 2022, a total of 647,188 units that were previously granted were forfeited during the three months ended March 31, 2022, as the underlying service conditions were not met (an additional total of 3.6 million units will forfeit in the second quarter of 2022 as a result of the termination of employees under the second step of the two-step strategic program reprioritization and restructuring in April 2022, refer to Note 11 *Subsequent Events to the Balance Sheet Date*).

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 March 31, 2022 and 2021 totaled SEK 6.3 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, March 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)*	0.75	2.25	1.71	0.23	2.75	1.5

Incentive program	2020:1	2020:2	2020:3	2021:1	2021:2	Total
Options outstanding, January 1	710,313	5,915,648	308,000	902,000	148,350	8,402,181
Granted during the year	_	_	_	_	_	_
Forfeited during the year	_	(56,013)	_	(483,975)	(107,200)	(647,188)
Options outstanding, March 31	710,313	5,859,635	308,000	418,025	41,150	7,754,993
Grant Date Fair Value* (SEK)	12.26	13.13	7.98	10.75	10.18	
Share Price at Grant Date* (SEK)	28.10	23.50	23.55	19.31	18.88	
Exercise Price*(SEK)	29.36	24.12	25.40	19.38	19.26	
Expected volatility*	58.66%	63.64%	57.00%	62.56%	61.32%	
Estimated life (years)*	4.2	6.11	2.8	6.11	6.11	
Expected dividends*	0	0	0	0	0	
Risk-free rate*	-0.2280%	-0.2772%	-0.3602%	-0.2046%	-0.5225%	
Remaining contractual life (years)	3.75	8.58	2.67	8.86	9.15	

\* Weighted average

The weighted average exercise price of the options that forfeited during the three months ended March 31, 2022 was SEK 19.40. The weighted average exercise price of the options outstanding as of January 1, 2022 and March 31, 2022 was SEK 24.39 and SEK 24.81, respectively.



## Note 6 Income tax

In the three months ended March 31, 2022 and 2021, the Group recognized a current tax benefit of SEK 3.2 million and SEK 7.5 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 34.8 million). The Group's Danish subsidiary Saniona A/S is expected to have a full year 2022 tax loss in excess of this threshold, it has therefore recorded the amount of the benefit related to qualified R&D expenses incurred during the three months ended March 31, 2022.

## Note 7 Other financial assets

## A. Composition

Other financial assets were comprised of the following:

KSEK	2022-03-31	2021-03-31	2021-12-31
Contingent consideration receivable	11,100	14,244	18,289
Investment in equity instruments - publicly traded	_	6,735	_
Long-term deposits for property lease agreements	3,243	2,595	2,504
Total non-current other financial assets	14,343	23,574	20,793
Short-term deposit for property lease agreement	427	_	414
Total current other financial assets	427	_	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 and a contingent consideration receivable from Novartis. The upfront payment of SEK 23.4 million was received in February 2021. A portion of the contingent consideration receivable of SEK 7.5 million that was related to an escrow balance was received in January 2022.

## C. Investment in equity instruments - publicly traded

The asset as of March 31, 2021 represents the fair value of the Group's investment in Scandion Oncology A/S ('Scandion Oncology'). As of June 30, 2021, Saniona had sold of all its shares in Scandion Oncology in the open market. In the three months ended March 31, 2021, the Group recognized a net loss in other comprehensive income resulting from changes in Scandion Oncology's share price of SEK 0.7 million.



## Note 8 Other financial liabilities

## A. Composition

Other financial liabilities were comprised of the following:

KSEK	2022-03-31	2021-03-31	2021-12-31
Lease liabilities	8,816	14,951	9,999
Formue Nord Loan	83,631	—	82,973
Total non-current other financial liabilities	92,447	14,951	92,972
Lease liabilities	6,237	7,260	6,799
Warrants	—	1,406	—
Total current other financial liabilities	6,237	8,666	6,799

## **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 quarterly. The loan matures in June 2023.

## C. Warrants

As of March 31, 2021, all warrants of the series TO3 as part of the Unit Rights Issue 2020 were outstanding. In the three months ended March 31, 2021, the Group recognized a gain of SEK 3.4 million resulting from a decrease in the warrant's trading price. In April 2021, a total of 12,846 series TO3 warrants were exercised, the remaining 1,466,896 series TO3 warrants were forfeited.



## INTERIM REPORT FOR SANIONA AB (PUBL) January – March 2022

## 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.

March 31, 2022				Carrying amo	ount			Fair value			
KSEK	Note	Financial assets at amortized cost	Mandatorily at FVTPL - others	EVOCI - edulity	Other financial liabilities	Total	Level 1	Level 2	Level 3	Total	
Financial assets measured at fair value											
Contingent consideration receivable	7		11,100		·	11,100		—	11,100	11,100	
		_	11,100	_	· –	11,100		—	11,100	11,100	
Financial assets not measured at fair value											
Trade receivables		7,835	_	_		7,835	_	_	_	_	
Other non-current financial assets	7	3,243	_	_	· _	3,243	—	—		_	
Other current financial assets	7	427	—	_	· _	427	—	—	—	—	
Cash and cash equivalents		279,335	_	_	· _	279,335	—	—	_	_	
		290,840	_		· _	290,840	-	_	_	_	
Financial liabilities not measured at fair value	9										
Trade payables		_	_	_	43,738	43,738	_	_	_	_	
Formue Nord Loan	8	_	_	_	83,631	83,631	—	_	_	_	
Lease liabilities	8	_	_	_	15,053	15,053	_	_	_	_	
		_	_		142,422	142,422	_	_		_	

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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											
Investment in equity instruments - privately-held	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	_	_		3,615	_	_	_	_	
Other non-current financial assets	7	2,504	_			2,504	_	_	_	_	
Other current financial assets		414	_	_		414	_	_	_	_	
Cash and cash equivalents		356,855	_	_	_	356,855	_	_	_	_	
		363,388	_	_	—	363,388	_	_	—	_	
Financial liabilities measured at fair value											
Warrants	8	_	_	_		—	_	_	_	_	
		_	_	_	—	_	_	_	—	_	
Financial liabilities not measured at fair value											
Trade payables		_	_	_	29,115	29,115	_	_	_	_	
Loan	8	_	_	_	82,973	82,973	_	_	_	_	
Lease liabilities	8	_	_		16,798	16,798	_	_	_	_	
		_	_		128,886	128,886	_	_	_	_	

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 March 31, 2021. The series TO3 warrants have been measured at their trading price on Nasdaq Stockholm on March 31, 2021.

The contingent consideration receivable from Novartis as of March 31, 2022 and 2021, and December 31, 2021, has 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 March 31, 2022 are as follows:

• Undiscounted expected cash flows to Saniona are up to SEK 151 million.

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- 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
March 31, 2022		
Risk-neutral expected payments to the Group (+/- 1,000bps)	1,048	-1,048

#### ii. Transfers

During the three months ended March 31, 2022 and 2021, 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	Contingent consideration
Balance, January 1, 2022	18,289
Cash received	-7,522
Exchange	—
Changes in Fair Value	—
Foreign currency (included in 'net gains/losses on financial items')	333
Balance, March 31, 2022	11,100

## 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 March 31, 2022, the Group held an ownership percentage of 15.8% 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 into in January 2020. Saniona recognized gross revenue of SEK 1.1 million from this agreement in the three months ended March 31, 2022, of that SEK 0.2 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, 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 March 31, 2022 and December 31, 2021, there were no balances outstanding under this agreement.

During the three months ended March 31, 2022 and 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 Subsequent Events to the Balance Sheet Date

In April 2022, Saniona announced the second step of a two-step strategic program reprioritization and restructuring. Due to funding limitations, Saniona had already announced during the first quarter of 2022 that it voluntarily pause its Phase 2b clinical trials of Tesomet for HO and PWS and that it is actively exploring partnerships for its late-stage clinical programs, Tesomet and SAN711. In connection with that, the company had already communicated a workforce reduction of 30%. In April 2022, the company further announced that it is refocusing on its core expertise in ion channel drug discovery. In connection with this revised strategy, coupled with the deteriorating biotech market conditions, the company terminated its plans to list its shares in the U.S. and, as a result, decided to close its U.S. operations and eliminate the positions of all remaining U.S. employees. Affected employees will be offered separation benefits, including severance payments and healthcare coverage. The group expects the reduction in workforce to cost between SEK 34.0 million and SEK 37.5 million in 2022, out of that, SEK 5.3 million were already recorded in the first quarter of 2022, as the remaining SEK 28.7 million to 32.2 million are expected to be incurred in the second quarter of 2022. As a result of the termination of certain employees under the second step of the two-step strategic program reprioritization and restructuring in April 2022, a total of 3.6 million stock options that were previously granted will forfeit in the second quarter of 2022, as the underlying service conditions can no longer be met.

In May 2022, Saniona announced that the Mexican regulatory authority COFEPRIS has published on Twitter that its technical committee on new molecules was unable to provide a favorable opinion on tesofensine following a meeting held on May 18, 2022. Saniona's partner Productos Medix, S.A de S.V, (Medix) has not received any official statement from COFEPRIS yet. Therefore, Medix is not able to comment on this statement and the possible implication for pursuing the process of seeking approval for tesofensine in Mexico.



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 8.00 CEST on 25 May 2022.

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