Saniona Achieves Key Milestones in Q3 2021 and Subsequent Period, including Orphan Drug Designation and Phase 2b Trial Initiation

Three Months Ended September 30, 2021 (2020)	Nine Months Ended September 30, 2021 (2020)
Revenue was SEK 2.3 M (2.2 M)	Revenue was SEK 7.6 M (6.6 M)
Operating loss was SEK -88.2 M (-37.3 M)	Operating loss was SEK -286.7 M (-90.8 M)
Net loss was SEK -93.7 M (-48.3 M)	Net loss was SEK -281.8 M (-29.0 M)
Basic loss per share was SEK -1.50 (-1.14)	Basic loss per share was SEK -4.52 (-0.86)
Diluted loss per share was SEK -1.50 (-1.14)	Diluted loss per share was SEK -4.52 (-0.86)

Business highlights in Q3 2021

- Saniona achieved **orphan drug designation (ODD)** from the FDA for Tesomet for the treatment of hypothalamic obesity (HO). Tesomet is the first and only investigational treatment for HO to receive ODD, and it previously received ODD for Prader-Willi syndrome (PWS). ODD qualifies Saniona for certain benefits including tax credits, elimination of certain FDA license application fees, and seven years of market exclusivity in the U.S. following approval.
- Saniona entered into a **non-dilutive term loan agreement** for SEK 87 million ($10 million) with Formue Nord Fokus A/S to support new activities aimed at accelerating clinical development programs.
- Saniona appointed Wendy Dwyer as **Chief Business Officer** to focus on out-licensing of assets in non-core markets and/or non-core therapeutic areas in order to generate non-dilutive capital while expanding the potential reach of Saniona's medicines globally.
- Finance veteran Robert E. Hoffman was appointed as a member of the **board of directors** and Chairman of the Audit Committee, as resolved at an extraordinary shareholders' meeting.

Significant events after the reporting period

- 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.
- Saniona **initiated a Phase 2b clinical trial of Tesomet in patients with HO.** The company also confirmed, and continues to confirm, that it remains on track to initiate its Phase 2b clinical trial of Tesomet for PWS before the end of 2021, as planned.

Comments from the CEO

"With two clinical trials now underway and a third poised to begin before the end of this year, Saniona has made significant progress on our mission to discover, develop and ultimately commercialize our medicines to treat rare diseases," said Rami Levin, President & Chief Executive Officer of Saniona. "This progress is a direct result of the hard work by the talented and experienced team we have hired, and it positions us well to continue to achieve important milestones in the fourth quarter of 2021 as well as throughout 2022 and 2023."

For more information, please contact

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Letter from the CEO

I would like to start this letter by stating that Saniona has achieved multiple valuable milestones so far in 2021, including initiating our Phase 2b clinical trial of Tesomet in hypothalamic obesity (HO), initiating our Phase 1 clinical trial of neuropathic disorder drug SAN711 and obtaining orphan drug designations from the U.S. FDA for Tesomet in both HO and Prader-Willi syndrome (PWS). These achievements were made possible by the experienced professionals we have hired in the U.S. across clinical development, regulatory affairs, technical operations, and quality assurance. These are areas of expertise that Saniona previously did not have, and it is these experts who have driven our major milestones over the past two years.

As always, we are committed to executing on our mission as quickly as possible, and we believe that value for patients and shareholders will follow. I can assure you that our plans remain on track, and our fundamental business remains strong.

Saniona has a strong investment rationale, and with each milestone we achieve to move our programs forward, we get one step closer to bringing our treatments to the market and making them available to the patients who desperately need them, and with that the investment rationale grows stronger:

- **Tesomet** is in a Phase 2b clinical trial for HO and will enter a Phase 2b clinical trial for PWS before the end of the year. Initial Phase 2 clinical trials have already generated positive data in both of these indications, where there is a significant unmet need.

- We have a **deep pipeline** of more potential new medicines driven from our proprietary ion-channel drug discovery engine. SAN711 is in a Phase 1 clinical trial and may be applicable in the treatment of rare neuropathic disorders. SAN903 is in preclinical development for rare inflammatory, fibrotic and hematological disorders. Behind these lead molecules, Saniona continues to advance additional programs from its database of more than 20,000 proprietary ion channel modulators.

- We are financed to drive our current operating plan, and we enhanced our **working capital position** during 2021 through the receipt of partnership payments and our securing of a non-dilutive loan. We continue to have ongoing dialogues with new potential investors and existing shareholders, including our large institutional investors such as RA Capital, Pontifax, New Leaf Ventures, AP4 and AP3. We continue to evaluate all relevant financing options, including the possibility of a listing on the U.S. Nasdaq, as well as non-dilutive transactions. We recently hired a Chief Business Officer whose focus will be on securing such non-dilutive business development opportunities.

Looking forward, we expect top-line data from the Tesomet Phase 2b study in PWS in the first half of 2023 and from HO in the second half of 2023. In addition, 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, and advancement of a new ion channel modulator program into our pipeline. In 2022, our partner Medix expects feedback from the regulatory authorities in Mexico regarding the potential approval of tesofensine for general obesity in Mexico, and we continue to explore additional business development opportunities.

We are excited about the future of the company. Our vision is to transform Saniona into a fully-integrated rare disease company and follow in the footsteps of the successful rare disease companies that many of us have worked for in the past, including Genzyme and Sobi. We appreciate the continued support of our shareholders. We look forward to keeping you updated on our journey.

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, 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:

1 Tesomet: positive data from initial Phase 2 trials in two rare disorders

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

Prader-Willi syndrome (PWS)
Phase 2b trial expected to begin H2 2021; top-line data expected in H1 2023

2 Proprietary ion-channel drug discovery engine driving pipeline

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

3 Validation from multiple strategic partnerships

CAD-1883
for movement disorders — NOVARTIS

Novel target
for schizophrenia — Boehringer Ingelheim

Tesofensine
for obesity — medix

4 Financed to drive current operating plan

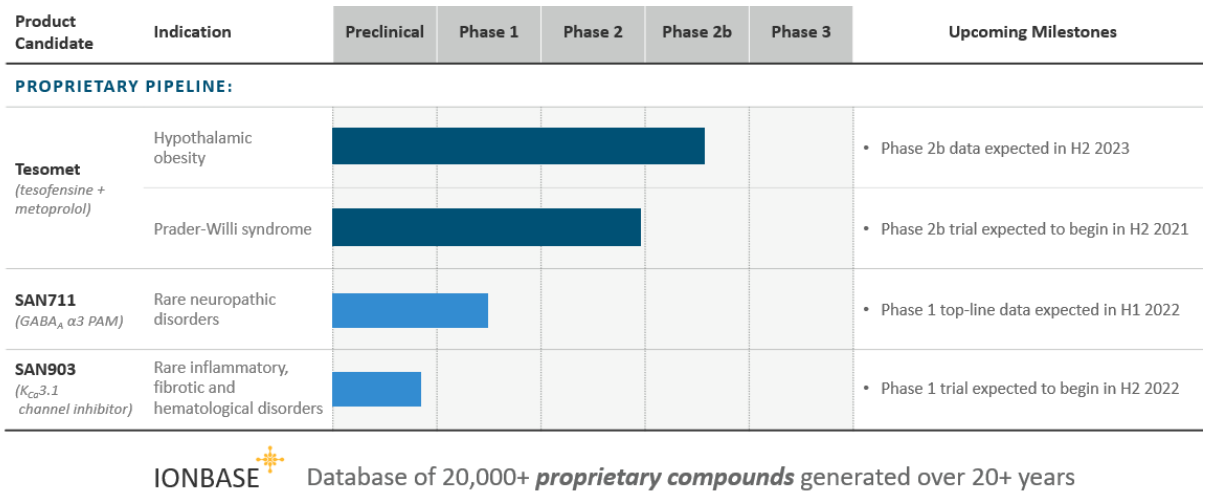
Funded into H2 2022

Strong institutional support
RA Capital, Pontifax Venture Capital, New Leaf Venture Partners

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 a Phase 2b clinical trial in HO and plan to initiate a Phase 2b clinical trial in PWS before the end of the year. 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, respectively.
- ***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 in 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 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



Tesomet

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 disease. 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).

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 dose-dependent 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 HO. The Phase 2b clinical trial includes a randomized, double-blind, placebo-controlled 36-week treatment period followed by a 36-week open-label extension period. The trial will seek to enroll approximately 110 participants 16 years of age and older with hypothalamic obesity – a rare disease caused by damage to the hypothalamus. 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 36-week 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.

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 www.hypothalamicstudy.com or www.clinicaltrials.gov.

We plan to initiate a Phase 2b clinical trial in PWS before the end of the year. We expect to report top-line data from the PWS clinical trial in the first half of 2023 and top-line data from the HO clinical trial in the second half of 2023.

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 in the first half of 2022.

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.

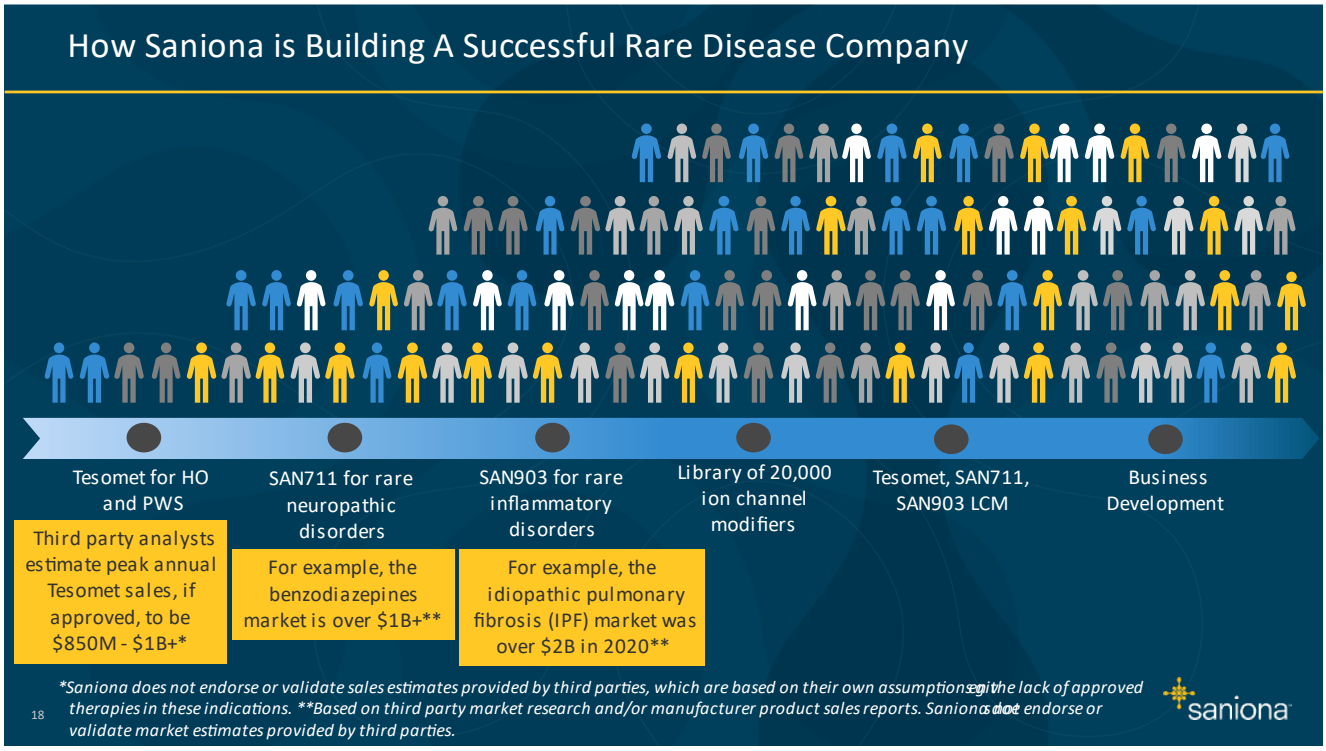
Even though orphan diseases affect relatively fewer people than more common diseases, several biopharmaceutical companies have built successful, sustainable business by developing innovative medicines for orphan diseases. The pioneers in this space include Genzyme Corporation, which was acquired by Sanofi 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, which third-party market research reports estimate 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 in order 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 global pharmaceutical companies, 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 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 defined in 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 September 30, 2021 and 2020

KSEK		2021-07-01 2021-09-30	2020-07-01 2020-09-30 (Restated)^	Increase (Decrease)
Revenue		2,264	2,155	109
Total operating expenses		-90,466	-39,451	-51,015
Operating loss	*	-88,202	-37,296	-50,906

** = Alternative performance measures*

^ = Refer to Note 12 to our Unaudited Condensed Consolidated Interim Financial Statements below for more details regarding restatements of comparative amounts

Key figures		2021-07-01 2021-09-30	2020-07-01 2020-09-30 (Restated)^
Operating margin, %	*	-3,896%	-1,731%
Basic earnings per share, SEK		-1.50	-1.14
Diluted earnings per share, SEK		-1.50	-1.14
Cash flow per share, SEK	*	-0.11	13.35

** = Alternative performance measures*

^ = Refer to Note 12 to our Unaudited Condensed Consolidated Interim Financial Statements below for more details regarding restatements of comparative amounts

Alternative performance measures are derived as follows:

	2021-07-01 2021-09-30	2020-07-01 2020-09-30 (Restated)^
Operating loss, KSEK	-88,202	-37,296
Revenue, KSEK	2,264	2,155
Operating margin, %	**-3,896%**	**-1,731%**
Cash flow for the period, KSEK	-6,681	565,833
Average shares outstanding	62,385,677	42,380,854
Cash flow per share, SEK	**-0.11**	**13.35**

^ = Refer to Note 12 to our Unaudited Condensed Consolidated Interim Financial Statements below for more details regarding restatements of comparative amounts

Revenue

Revenue increased by SEK 0.1 million from SEK 2.2 million for the three months ended September 30, 2020 to SEK 2.3 million for the three months ended September 30, 2021.

Operating expenses

Operating expenses increased by SEK 51.0 million from SEK 39.5 million for the three months ended September 30, 2020 to SEK 90.5 million for the three months ended September 30, 2021.

Within operating expenses, *external expenses* increased by SEK 18.8 million from SEK 23.8 million for the three months ended September 30, 2020 to SEK 42.6 million for the three months ended September 30, 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 three months ended September 30, 2021 comprised primarily of development costs of Tesomet, including costs for the preparation 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 the second quarter of 2021. The external per patient costs of the third-party Clinical Research Organization (CRO) supporting the two Phase 2b trials of Tesomet are expected to range between SEK 1,800,000 and SEK 2,200,000. For the three months ended September 30, 2020, external expenses comprised primarily of development costs of Tesomet followed by preclinical development costs of SAN711 and research and development costs of the SAN903 program.

The average number of employees of Saniona increased by 24.50 from 26.33 for the three months ended September 30, 2020 to 50.83 for the three months ended September 30, 2021, corresponding to the hiring of 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 31.5 million from SEK 12.7 million for the three months ended September 30, 2020 to SEK 44.2 million for the three months ended September 30, 2021. Non-cash share-based compensation expense is included in personnel costs and increased by SEK 11.7 million from SEK 1.2 million for three months ended September 30, 2020 to SEK 12.9 million for the three months ended September 30, 2021.

Compared to the three months ended September 30, 2020, the average exchange rate of 1 SEK against the DKK and the USD for the three months ended September 30, 2021 has appreciated by approximately 2% and 2%, 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 expenses decreased by SEK 5.6 million from SEK 11.0 million for the three months ended September 30, 2020 to SEK 5.4 million for the three months ended September 30, 2021, primarily due to a reduction of realized foreign exchange losses from foreign currency transactions of SEK 5.8 million.

Tax Benefit

The Group did not recognize a tax benefit for the three months ended September 30, 2020 and the three months ended September 30, 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 31.9 million from SEK 54.3 million for the three months ended September 30, 2020 to SEK 86.2 million for the three months ended September 30, 2021. The operating cash flow for the three months ended September 30, 2021 is primarily attributable to our operating loss of SEK 73.1 million (net of non-cash operating expenses for share-based payments of SEK 12.9 million and for depreciation of SEK 2.2 million). Increases in working capital resulted in an additional net cash adjustment of SEK -2.6 million. The operating cash flow for the three months ended September 30, 2020 is primarily attributable to our operating loss of SEK 35.1 million (net of non-cash operating expenses for share-based payments of SEK 1.2 million and for depreciation of SEK 1.0 million).

For the three months ended September 30, 2021, net cash provided by *financing activities* was SEK 80.0 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. For the three months ended September 30, 2020, net cash provided by financing activities was SEK 555.8 million, primarily related to the receipt of net proceeds of SEK 556.9 million from the issuance of new shares.

Parent Company

Operating expenses increased by SEK 3.0 million from SEK 2.2 million for the three months ended September 30, 2020 to SEK 5.2 million for the three months ended September 30, 2021. The main component of the Parent Company's operating expenses are general and administrative expenses.

Profit decreased by SEK 59.0 million from SEK 54.0 million for the three months ended September 30, 2020 to SEK -5.0 million for the three months ended September 30, 2021.

Comparison of the Nine Months Ended September 30, 2021 and 2020

KSEK		2021-01-01 2021-09-30	2020-01-01 2020-09-30 (Restated)^	Increase (Decrease)
Revenue		7,597	6,576	1,021
Total operating expenses		-294,284	-97,342	-196,942
Operating loss	*	-286,687	-90,766	-195,921

** = Alternative performance measures*

^ = Refer to Note 12 to our Unaudited Condensed Consolidated Interim Financial Statements below for more details regarding restatements of comparative amounts

Key figures		2021-01-01 2021-09-30	2020-01-01 2020-09-30 (Restated)^
Operating margin, %	*	-3,774%	-1,380%
Basic earnings per share, SEK		-4.52	-0.86
Diluted earnings per share, SEK		-4.52	-0.86
Cash flow per share, SEK	*	-2.92	17.67

** = Alternative performance measures*

^ = Refer to Note 12 to our Unaudited Condensed Consolidated Interim Financial Statements below for more details regarding restatements of comparative amounts

Alternative performance measures are derived as follows:

	2021-01-01 2021-09-30	2020-01-01 2020-09-30 (Restated)^
Operating loss, KSEK	-286,687	-90,766
Revenue, KSEK	7,597	6,576
Operating margin, %	**-3,774%**	**-1,380%**
Cash flow for the period, KSEK	-182,264	597,559
Average shares outstanding	62,380,030	33,822,473
Cash flow per share, SEK	**-2.92**	**17.67**

^ = Refer to Note 12 to our Unaudited Condensed Consolidated Interim Financial Statements below for more details regarding restatements of comparative amounts

Revenue

Revenue increased by SEK 1.0 million from SEK 6.6 million for the nine months ended September 30, 2020 to SEK 7.6 million for the nine months ended September 30, 2021. The increase was primarily attributable to an increase in annual licenses payments from Medix.

Operating expenses

Operating expenses increased by SEK 196.9 million from SEK 97.3 million for the nine months ended September 30, 2020 to SEK 294.3 million for the nine months ended September 30, 2021.

Within operating expenses, *external expenses* increased by SEK 96.3 million from SEK 61.0 million for the nine months ended September 30, 2020 to SEK 157.3 million for the nine months ended September 30, 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 nine months ended September 30, 2021 comprised primarily of development costs of Tesomet, including costs for the preparation 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 1,800,000 and SEK 2,200,000. For the nine months ended September 30, 2020, external expenses comprised primarily of development costs of Tesomet followed by preclinical development costs of SAN711 and research and development costs of the SAN903 program.

The average number of employees of Saniona increased by 22.67 from 25.33 for the nine months ended September 30, 2020 to 48.00 for the nine months ended September 30, 2021, corresponding to the hiring of 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 95.7 million from SEK 31.4 million for the nine months ended September 30, 2020 to SEK 127.1 million for the nine months ended September 30, 2021. Non-cash share-based compensation expense is included in personnel costs and increased by SEK 34.1 million from SEK 3.4 million for the nine months ended September 30, 2020 to SEK 37.5 million for the nine months ended September 30, 2021.

Compared to the nine months ended September 30, 2020, the average exchange rate of 1 SEK against the DKK and the USD for the nine months ended September 30, 2021 has appreciated by approximately 4% and 10%, 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 62.8 million from SEK 67.6 million for the nine months ended September 30, 2020 to SEK 4.8 million for the nine months ended September 30, 2021. Net financial gains for the nine months ended September 30, 2021 include a gain of SEK 4.8 million related to the fair value measurement of warrants only. Net financial gains for the nine months ended September 30, 2020 included a gain from losing significant influence over Scandion Oncology as of March 31, 2020 of SEK 53.3 million and a gain of SEK 13.5 million related to the fair value measurement of warrants.

Tax Benefit

The tax benefit on net loss recognized with regard to a Tax Credit Scheme in Denmark decreased by SEK 0.4 million from SEK 7.9 million for the nine months ended September 30, 2020 to SEK 7.5 million for the nine months ended September 30, 2021 because of exchange rate fluctuations.

Cash flow

Net cash used in *operating activities* increased by SEK 149.1 million from SEK 128.5 million for the nine months ended September 30, 2020 to SEK 277.6 million for the nine months ended September 30, 2021. The operating cash flow for the nine months ended September 30, 2021 is primarily attributable to our operating loss of SEK 242.7 million (net of non-cash operating expenses for share-based payments of SEK 37.5 million and for depreciation of SEK 6.5 million). The operating cash flow for the nine months ended September 30, 2020 is primarily attributable to our operating loss of SEK 85.9 million (net of non-cash operating expenses for share-based payments of SEK 3.4 million and for depreciation of SEK 1.5 million).

For the nine months ended September 30, 2021, net cash provided by *financing activities* was SEK 52.0 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 nine months ended September 30, 2020, net cash provided by financing activities was SEK 624.9 million, primarily related to the receipt of net proceeds of SEK 601.0 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 6.9 million from SEK 9.8 million for the nine months ended September 30, 2020 to SEK 16.7 million for the nine months ended September 30, 2021. The main component of the Parent Company's operating expenses are general and administrative expenses.

Profit decreased by SEK 87.5 million from SEK 97.1 million for the nine months ended September 30, 2020 to SEK 9.6 million for the nine months ended September 30, 2021.

Financial position

Balance sheet, KSEK	2021-09-30	2020-09-30 (Restated)^	2020-12-31
Cash and cash equivalent, KSEK	425,699	647,058	573,866
Equity, KSEK	390,525	728,158	603,458
Total equity and liabilities, KSEK	534,154	817,626	692,181

^ = Refer to Note 12 to our Unaudited Condensed Consolidated Interim Financial Statements below for more details regarding restatements of comparative amounts

Key figures		2021-09-30	2020-09-30 (Restated)^	2020-12-31
Liquidity ratio, %	*	1,003%	958%	846%
Equity ratio, %	*	73%	89%	87%
Equity per share, SEK	*	6.26	11.67	9.67

** = Alternative performance measures*
^ = Refer to Note 12 to our Unaudited Condensed Consolidated Interim Financial Statements below for more details regarding restatements of comparative amounts

Alternative performance measures were derived as follows:

	2021-09-30	2020-09-30 (Restated)^	2020-12-31
Current assets, KSEK	479,244	695,949	595,812
Current liabilities, KSEK	47,781	72,625	70,416
Liquidity ratio, %	**1,003%**	**958%**	**846%**
Equity, KSEK	390,525	728,158	603,458
Total assets, KSEK	534,154	817,626	692,181
Equity ratio, %	**73%**	**89%**	**87%**
Equity, KSEK	390,525	728,158	603,458
Shares outstanding at the end of the period	62,385,677	62,372,831	62,398,523
Equity per share, SEK	**6.26**	**11.67**	**9.67**

^ = Refer to Note 12 to our Unaudited Condensed Consolidated Interim Financial Statements below for more details regarding restatements of comparative amounts

The share, share capital and ownership structure

Share data, #	2021-07-01 2021-09-30	2020-07-01 2020-09-30	2021-01-01 2021-09-30	2020-01-01 2020-09-30
Average shares outstanding	62,385,677	42,380,854	62,380,030	33,822,473
Diluted average shares outstanding	62,385,677	42,449,176	62,427,889	33,847,441
Shares outstanding at the end of the period	62,385,677	62,372,831	62,385,677	62,372,831

On September 30, 2021 and 2020, the company had 9,651 (8,395) shareholders excluding holdings in life insurance and foreign custody account holders.

Personnel

As of September 30, 2021, Saniona had 52 employees including 14 employees with Ph.D. degrees. Of these employees, 35 were engaged in research and clinical development activities and 17 were engaged in general and administrative activities. Of the 52 employees, 28 (54%) 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 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

This Interim Report has been subject to a limited review by the company's auditors.

Financial calendar

Year-End Report 2021	February 24, 2022 at 8:00 CET
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

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, November 18, 2021
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*. Certain comparative amounts have been restated, reclassified or re-presented, as a result of a correction of prior-period errors (refer to Note 12 *Restatements)*.

Unaudited condensed consolidated statement of comprehensive income – Group

KSEK	Note	2021-07-01 2021-09-30	2020-07-01 2020-09-30 (Restated)	2021-01-01 2021-09-30	2020-01-01 2020-09-30 (Restated)
Revenue	4	2,264	2,155	7,597	6,576
Total operating income		2,264	2,155	7,597	6,576
Raw materials and consumables		-1,497	-516	-3,352	-2,076
Other external costs		-42,563	-23,751	-157,348	-60,951
Personnel costs	5	-44,214	-12,706	-127,097	-31,423
Depreciation and write-downs		-2,192	-2,478	-6,487	-2,892
Total operating expenses		-90,466	-39,451	-294,284	-97,342
Operating loss		**-88,202**	**-37,296**	**-286,687**	**-90,766**
Share of result of associate	10	—	—	—	-433
Financial income		18	1,587	1,640	1,931
Financial expenses		-5,466	-10,706	-8,988	-15,211
Net gains (losses) on financial items		—	-1,924	4,793	67,598
Total financial items		-5,448	-11,043	-2,555	53,885
Loss before tax		**-93,650**	**-48,339**	**-289,242**	**-36,881**
Tax benefit on net loss	6	—	—	7,482	7,852
Loss for the period		**-93,650**	**-48,339**	**-281,760**	**-29,029**
Other comprehensive income for the period					
Item that may be reclassified to profit and loss					
Translation differences		10,219	24,202	26,050	24,944
Items that will not be reclassified to profit and loss					
Equity instruments at FVOCI – net change fair value	7	—	17,107	5,063	101,689
Total other comprehensive income for the period, net after tax		**10,219**	**41,309**	**31,113**	**126,633**
Total comprehensive income (loss) for the period		**-83,431**	**-7,030**	**-250,647**	**97,604**
Loss per share, SEK		**-1.50**	**-1.14**	**-4.52**	**-0.86**
Diluted Loss per share, SEK		**-1.50**	**-1.14**	**-4.52**	**-0.86**

Unaudited condensed consolidated statement of financial position – Group

KSEK	Note	2021-09-30	2020-09-30 (Restated)	2020-12-31
ASSETS				
Intangible assets		6,173	6,370	6,072
Property and equipment		5,243	3,950	5,089
Right of use assets		18,339	20,269	23,035
Investment in associate	10	864	—	—
Other financial assets	7,9	16,746	83,234	61,660
Other assets		—	—	513
Tax assets	6	7,545	7,786	—
Deferred tax		—	68	—
Non-current assets		**54,910**	**121,677**	**96,369**
Trade receivables		2,936	6,224	5,043
Current tax assets	6	7,545	—	7,421
Other financial assets	7,9	404	—	—
Other assets		42,660	42,667	9,482
Cash and cash equivalents		425,699	647,058	573,866
Current assets		**479,244**	**695,949**	**595,812**
Total assets		**534,154**	**817,626**	**692,181**

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

KSEK	Note	2021-09-30	2020-09-30 (Restated)	2020-12-31
EQUITY AND LIABILITIES				
Share capital		3,119	3,119	3,119
Additional paid-in capital		808,847	811,119	808,607
Reserves		68,021	123,337	36,908
Accumulated deficit		-489,462	-209,417	-245,176
Equity		**390,525**	**728,158**	**603,458**
Other financial liabilities	8,9	93,718	14,680	16,228
Other liabilities		2,130	2,163	2,079
Non-current liabilities		**95,848**	**16,843**	**18,307**
Trade payables		18,962	18,506	18,875
Other financial liabilities	9	7,200	48,452	40,623
Other liabilities		21,619	5,667	10,918
Current liabilities		**47,781**	**72,625**	**70,416**
Total liabilities		**143,629**	**89,468**	**88,723**
Total equity and liabilities		**534,154**	**817,626**	**692,181**

Unaudited condensed consolidated statement of changes in equity – Group

	Share capital	Additional paid-in capital (Restated)	Translation reserves (Restated)	Fair value reserve (Restated)	Accumulated deficit (Restated)	Equity (Restated)
January 1, 2020 (as previously reported)	1,421	239,592	-964	10,657	-192,268	58,437
Restatements	—	—	-2,332	-10,657	8,435	-4,553
January 1, 2020 (restated)	**1,421**	**239,592**	**-3,296**	**—**	**-183,833**	**53,884**
Comprehensive income						
Loss for the period	—	—	—	—	-29,029	-29,029
Other comprehensive income:						
Fair value reserve	—	—	—	101,689	—	101,689
Translation differences	—	—	24,944	—	—	24,944
Total comprehensive income (loss)	**—**	**—**	**24,944**	**101,689**	**-29,029**	**97,604**
Transactions with owners						
Shares issued for cash	1,698	650,537	—	—	—	652,235
Expenses related to capital increase	—	-51,218	—	—	—	-51,218
Issuance of Investor Warrants	—	-27,792	—	—	—	-27,792
Share-based compensation expenses	—	—	—	—	3,445	3,445
Total transactions with owners	**1,698**	**571,527**	**—**	**—**	**3,445**	**576,670**
September 30, 2020	**3,119**	**811,119**	**21,648**	**101,689**	**-209,417**	**728,158**
January 1, 2021	**3,119**	**808,607**	**-31,558**	**68,466**	**-245,176**	**603,458**
Comprehensive income						
Loss for the period	—	—	—	—	-281,760	-281,760
Other comprehensive income:						
Fair value reserve	—	—	—	5,063	—	5,063
Translation differences	—	—	26,050	—	—	26,050
Total comprehensive income (loss)	**—**	**—**	**26,050**	**5,063**	**-281,760**	**-250,647**
Transactions with owners						
Shares issued for cash	0	321	—	—	—	321
Expenses related to capital increase	—	-81	—	—	—	-81
Share-based compensation expenses	—	—	—	—	37,474	37,474
Total transactions with owners	**—**	**240**	**—**	**—**	**37,474**	**37,714**
September 30, 2021	**3,119**	**808,847**	**-5,508**	**73,529**	**-489,462**	**390,525**

Unaudited condensed consolidated statement of cash flows – Group

KSEK	Note	2021-07-01 2021-09-30	2020-07-01 2020-09-30 (Restated)	2021-01-01 2021-09-30	2020-01-01 2020-09-30 (Restated)
Loss before tax		-93,650	-48,339	-289,242	-36,881
Adjustments for non-cash transactions		13,175	38,011	53,577	-32,933
Changes in working capital		-2,646	-44,954	-34,470	-59,153
Cash flow from operating activities before financial and tax items		**-83,121**	**-55,282**	**-270,135**	**-128,967**
Interest income received		69	1,656	246	1,965
Interest expenses paid		-3,104	-8,372	-7,703	-9,111
Tax credit received		—	7,657	—	7,657
Cash flow from operating activities		**-86,156**	**-54,341**	**-277,592**	**-128,456**
Investing activities					
Purchases of property and equipment		-548	-2,239	-1,310	-3,746
Proceeds from sale of financial assets		—	66,635	44,646	104,878
Cash flow from investing activities		**-548**	**64,396**	**43,336**	**101,132**
Financing activities					
Proceeds from issuance of loan		81,780	—	81,780	25,000
Repayment of loan		—	—	-25,000	—
Proceeds from issuance of new shares		—	556,917	321	649,715
Costs related to issuance of new shares		—	—	-81	-48,693
Payment of lease liabilities		-1,757	-1,139	-5,028	-1,139
Cash flow from financing activities		**80,023**	**555,778**	**51,992**	**624,883**
Net increase (decrease) in cash and cash equivalents		**-6,681**	**565,833**	**-182,264**	**597,559**
Cash and cash equivalents at beginning of period		**420,783**	**68,604**	**573,866**	**40,248**
Exchange rate adjustments		11,597	12,621	34,097	9,251
Cash and cash equivalents at end of period		**425,699**	**647,058**	**425,699**	**647,058**

PARENT COMPANY'S UNAUDITED INTERIM FINANCIAL STATEMENTS

The Parent Company's unaudited interim financial statements have been prepared based on the accounting policies described in Note 2 *Basis of Accounting and Significant Accounting Policies*. Certain comparative amounts in the statement of comprehensive income and the statement of financial position have been restated, reclassified or re-presented, as a result of a correction of prior-period errors.

Unaudited statement of income – Parent Company

KSEK	Note	2021-07-01 2021-09-30	2020-07-01 2020-09-30 (Restated)	2021-01-01 2021-09-30	2020-01-01 2020-09-30 (Restated)
	1,2,3				
Other operating income		1,084	—	3,696	—
Total operating income		1,084	0	3,696	0
Raw materials and consumables		-2	-8	-7	-23
Other external costs		-1,265	-795	-5,412	-5,009
Personnel costs	5	-3,966	-1,427	-11,310	-4,803
Total operating expenses		-5,233	-2,230	-16,729	-9,835
Operating loss		**-4,149**	**-2,230**	**-13,033**	**-9,835**
Share of result of associates		—	—	—	-433
Financial income		2,434	3,641	2,737	95
Financial expenses		-47	-22	-98	-67
Net gains on financial items		-3,214	52,647	20,019	107,365
Total financial items		-827	56,266	22,658	106,960
Profit (loss) before tax		**-4,976**	**54,036**	**9,625**	**97,125**
Tax on net profit (loss)		—	—	—	—
Profit (loss) for the period		**-4,976**	**54,036**	**9,625**	**97,125**

Unaudited balance Sheet – Parent Company

KSEK	Note	2021-09-30	2020-09-30 (Restated)	2020-12-31
ASSETS				
Investment in subsidiaries		965,647	204,100	929,244
Other financial assets	7,9	—	1,746	1,746
Financial assets		965,647	205,846	930,990
Non-current assets		**965,647**	**205,846**	**930,990**
Receivables from group companies		80,896	623,797	5,721
Other assets		20,820	34,127	3,388
Current receivables		101,716	657,924	9,109
Cash and cash equivalents		19,977	75,190	45,733
Current assets		**121,693**	**733,114**	**54,842**
Total assets		**1,087,340**	**938,960**	**985,832**
EQUITY AND LIABILITIES				
Restricted equity				
Share capital		3,119	3,119	3,119
Unrestricted equity				
Share premium reserve		808,847	811,119	808,607
Retained earnings (accumulated deficit)		177,965	-1,623	-7,804
Profit for the period		9,625	97,125	148,180
Equity		**999,556**	**909,740**	**952,102**
Other financial liabilities		87,000	—	—
Non-current liabilities		87,000	—	—
Trade payables		599	4,106	754
Payables to group companies		—		—
Other financial liabilities	8	—	25,000	32,861
Other liabilities		185	114	114
Current liabilities		784	29,220	33,729
Total liabilities		**87,784**	**29,220**	**33,729**
Total equity and liabilities		**1,087,340**	**938,960**	**985,831**

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 nine months ended September 30, 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 September 30, 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 November 18, 2021.

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 interim condensed consolidated financial statements. Certain comparative amounts in the statement of comprehensive income and the statement of financial position have been restated, reclassified or re-presented, as a result of a correction of prior-period errors (refer to Note 12 *Restatements*).

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 take into account in pricing a transaction.

The Group regularly reviews significant unobservable inputs and valuation adjustments. Significant valuation issues are reported to the group 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 is permitted. However, the Group has not early adopted any of the forthcoming amended standards in preparing these unaudited condensed consolidated interim financial statements. The 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 consolidated 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 and nine months ended September 30, 2021 and 2020, revenue for the Group by category was as follows:

KSEK	2021-07-01 2021-09-30	2020-07-01 2020-09-30 (Restated)	2021-01-01 2021-09-30	2020-01-01 2020-09-30 (Restated)
License agreements (other event-based payments)	—	—	2,504	1,971
Research and collaboration agreements (bundle, over time)	1,860	1,483	3,777	2,785
Research and development services (standalone)	404	672	1,316	1,820
Total	**2,264**	**2,155**	**7,597**	**6,576**

In the three and nine months ended September 30, 2021 and 2020, revenue for the Group by major customers was as follows:

KSEK	2021-07-01 2021-09-30	2020-07-01 2020-09-30 (Restated)	2021-01-01 2021-09-30	2020-01-01 2020-09-30 (Restated)
Customer #1	—	—	2,504	1,971
Customer #2	404	672	1,316	1,820
Customer #3	1,860	1,483	3,777	2,785
Total	**2,264**	**2,155**	**7,597**	**6,576**

In the three and nine months ended September 30, 2021 and 2020, revenue for the Group by primary geographical market was as follows:

KSEK	2021-07-01 2021-09-30	2020-07-01 2020-09-30 (Restated)	2021-01-01 2021-09-30	2020-01-01 2020-09-30 (Restated)
Sweden	—	—	—	—
Other European countries	2,264	2,155	5,093	4,605
The Americas	—	—	2,504	1,971
Total	**2,264**	**2,155**	**7,597**	**6,576**

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 nine months ended September 30, 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 September 30, 2021 and 2020 totaled SEK 12.9 million and SEK 1.2 million, respectively. Share-based compensation expenses for the nine months ended September 30, 2021 and 2020 totaled SEK 37.5 million and SEK 3.4 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 at January 1	38,292	286,003	32,792	10,513	34,500	15,770
Granted during the year	—	—	—	—	—	—
Forfeited during the year	—	—	—	—	—	—
Options outstanding at September 30	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)	41.13	33.60	30.08	30.08	17.86	17.86
Expected volatility*	73.41%	69.24%	67.77%	53.67%	57.29%	53.67%
Estimated life*	3.75 years	3.88 years	3.73 years	2.8 years	3.67 years	2.8 years
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*	1.25 years	2.75 years	2.21 years	0.73 years	3.25 years	2.00 years

Incentive program	2020:1	2020:2	2020:3	2021:1	2021:2	Total
Options outstanding at January 1	710,313	5,915,648	308,000	—	—	7,351,831
Granted during the year	—	—	—	902,000	148,350	1,050,350
Forfeited during the year	—	—	—	—	—	—
Options outstanding at September 30	710,313	5,915,648	308,000	902,000	148,350	8,402,181
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)	29.42	24.12	25.40	19.38	19.26	
Expected volatility*	58.66%	63.64%	57.00%	62.56%	61.32%	
Estimated life*	4.2 years	6.11 years	2.8 years	6.11 years	6.11 years	
Expected dividends*	0	0	0	0	0	
Risk-free rate*	-0.2280%	-0.2772%	-0.3602%	-0.2046%	-0.5225%	
Remaining contractual life	4.25 years	9.15 years	3.17 years	9.36 years	9.67 years	

** Weighted average*

Note 6 Income tax

In the nine months ended September 30, 2021 and 2020, the Group recognized a current tax benefit of SEK 7.5 million and SEK 7.9 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 34.3 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 and 2020 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	2021-09-30	2020-09-30 (Restated)	2020-12-31
Contingent consideration receivable	14,195	—	—
Investment in equity instruments - privately-held	—	25,397	37,319
Investment in equity instruments - publicly traded	—	55,464	22,241
Long-term deposits for property lease agreements	2,551	2,373	2,100
Total non-current other financial assets	**16,746**	**83,234**	**61,660**
Short-term deposit for property lease agreement	404	—	—
Total current other financial assets	**404**	**—**	**—**

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 14.2 million as of September 30, 2021. The upfront payment was received in January 2021.

C. Investment in equity instruments – publicly traded

The asset as of September 30, 2020 and 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 nine months ended September 30, 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 nine months ended September 30, 2020, the Group recognized a net gain in other comprehensive income resulting from an increase in Scandion Oncology's share price of SEK 17.1 million and SEK 101.7 million, respectively.

Note 8 Other financial liabilities

A. Composition

Other financial liabilities were comprised of the following:

KSEK	2021-09-30	2020-09-30 (Restated)	2020-12-31
Lease liabilities	11,398	14,680	16,228
Formue Nord Loan	82,320	—	—
Total non-current other financial liabilities	**93,718**	**14,680**	**16,228**
Lease liabilities	7,200	5,353	6,937
Formue Nord Loan	—	22,383	24,346
Warrants	—	20,716	4,794
Other	—	—	4,546
Total non-current other financial liabilities	**7,200**	**48,452**	**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 quarterly. The loan matures in June 2023.

C. Warrants

As of September 30, 2020 and 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.

September 30, 2021	Note	Carrying amount					Fair value			
		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	—	14,195	—	—	14,195	—	—	14,195	14,195
		—	**14,195**	**—**	**—**	**14,195**	**—**	**—**	**14,195**	**14,195**
Financial assets not measured at fair value										
Trade receivables		2,936	—	—	—	2,936	—	—	—	—
Other non-current financial assets	7	2,551	—	—	—	2,551	—	—	—	—
Other current financial assets	7	404	—	—	—	404	—	—	—	—
Cash and cash equivalents		425,699	—	—	—	425,699	—	—	—	—
		431,590	**—**	**—**	**—**	**431,590**	**—**	**—**	**—**	**—**
Financial liabilities not measured at fair value										
Trade payables		—	—	—	18,962	18,962	—	—	—	—
Formue Nord Loan	8	—	—	—	82,320	82,320	—	—	—	—
Lease liabilities	8	—	—	—	18,598	18,598	—	—	—	—
		—	**—**	**—**	**119,880**	**119,880**	**—**	**—**	**—**	**—**

December 31, 2020	Note	Carrying amount					Fair value			
		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 - 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**	**—**	**37,319**	**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	—	—	—	24,346	24,346	—	—	—	—
Other financial liabilities		—	—	—	4,546	4,546	—	—	—	—
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 September 30, 2020 and December 30, 2020, respectively. The series TO3 warrants have been measured at their respective trading prices on Nasdaq Stockholm on September 30, 2020 and December 30, 2020, respectively.

The contingent consideration receivable from Novartis as of September 30, 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 are as follows:

- Undiscounted expected cash flows range from SEK 23 million to SEK 137 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 (9% - 34%).
- The probability-weighted cash flows have been discounted using a risk-adjusted discount rate was 11.5%.

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
September 30, 2021		
Risk-neutral expected payments to the Group (+/- 1,000bps)	1,048	-1,048
September 30, 2020		
Discount rate (+/- 75bps)	-2,669	2,669

The investment in Cadent Therapeutics as of September 30, 2020 has been measured using a combination of a Contingent Claims Analysis valuation technique, which determines the value of equity in a company based on the principles of option pricing theory, and a probability-weighted discounted cash flow valuation technique, which considers the present value of expected payments, discounted using a risk-adjusted discount rate.

ii. Transfers

During the three and nine months ended September 30, 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 on January 1, 2021	37,319	—
Cash received	-23,390	—
Exchange	-14,244	14,244
Foreign currency (included in 'net gains/losses on financial items')	315	-49
Balance on September 30, 2021	0	14,195

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 September 30, 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 into in January 2020. Saniona recognized gross revenue of SEK 0.7 million from this agreement after Cephagenix became an associate, 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 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 September 30, 2021 and December 31, 2020, balances of SEK — million and SEK 0.4 million, respectively, were outstanding.

During the three and nine months ended September 30, 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 September 30, 2021.

Note 12 Restatements

A. General

During 2020, we became aware of certain errors in our previously issued consolidated financial statements as of and for the year ended December 31, 2019, and the quarterly reporting periods in 2019 and 2020. As a result, the unaudited condensed consolidated interim financial statements for the Group that were previously issued for the three and nine months ended September 30, 2020 (the 'Previously Issued Consolidated Financial Statements') have been restated for the correction of certain errors with respect to certain items within the condensed consolidated statement of comprehensive income, condensed consolidated statement of financial position, statement of changes in equity and condensed consolidated statement of cash flows in accordance with the requirements in IAS 8 *Accounting Policies, Changes in Accounting Estimates and Errors*.

B. Nature and impact of restatements

The nature and impact of each restatement is described below.

(a) *Cadent Therapeutics (Investment in equity instruments - privately-held):* In our Previously Issued Consolidated Financial Statements, we had concluded that the fair value of our investment in Cadent Therapeutics could not be determined reliably and we had recorded the investment at zero cost. We have determined that the fair value of our investment in Cadent Therapeutics was SEK 25.4 million as of September 30, 2020. In the three and nine months ended September 30, 2020, we recorded gains (losses) of SEK -1.4 million and SEK 0.2 million, respectively, for the effect of foreign currency translation in other comprehensive income.

(b) *Investment in associate:* In 2019, we inappropriately discontinued accounting for our investment in Scandion Oncology as an investment in associate under the equity-method of accounting. As a result of this conclusion, we accounted for our investment in Scandion Oncology as a financial asset, measured at fair value through other comprehensive income, in the three months ended March 31, 2020. We subsequently determined that we did in fact continue to have significant influence through March 31, 2020 and therefore should have continued to account for our investment in Scandion Oncology under the equity-method of accounting through March 31, 2020. As a result, the other comprehensive income of SEK 20.9 million that was previously recognized during the first quarter of 2020 has been reversed. Instead, we recorded Saniona's share of Scandion Oncology's profit and loss for the first quarter of 2020 (SEK 0.4 million), and a gain from losing significant influence as of March 31, 2020 of SEK 53.3 million.

(c) *Intangible assets:* In our Previously Issued Consolidated Financial Statements, we had recorded a payment related to the purchase of certain intellectual property from NeuroSearch as a prepaid asset and presented it within current prepayments and accrued income. We should have accounted for this payment as a separate acquisition of an intangible assets that are not yet available for use. During the three and nine months ended September 30, 2020, we had recorded SEK 0.5 million and SEK 1.5 million, respectively, of depreciation regarding this asset. This depreciation has been reversed. In September 2020, we recorded an impairment charge for the entire recorded value of the NS2359 intangible asset of SEK 1.4 million.

(d) *Revenue Medix*: In February 2019 and 2020, Saniona became entitled to annual license payments of SEK 0.9 million and SEK 2.0 million, respectively. In our Previously Issued Consolidated Financial Statements, we had not recognized revenues and receivables for these.

(e) *Operating expenses:* We have adjusted for the allocation of certain costs between prior reporting periods. In addition, we have performed new grant-date valuations of existing share-based payment grants.

(f) *Measurement of financial liabilities:* Upon issuance of the Warrants during the Unit Rights Issue 2020, and prior to the underlying financial instruments being publicly traded, we had estimated the total fair value of the Warrants to be SEK 2.5 million and recorded that amount as a reduction in equity and a corresponding increase in financial liabilities. IFRS 13 *Fair Value Measurement*, which defines fair value as the price that would be received to sell an

asset in an orderly transaction between market participants at the measurement date (exit price), requires the use of valuation techniques when an exit price for an identical asset is not observable. Using an appropriate valuation technique, we have determined that the fair value of the Lender Warrants was SEK 7.2 million at the issuance date. In accordance with IFRS 9 *Financial Instruments*, this amount should have been recorded as a reduction of the loan balance as transaction costs and should have been amortized over the term of the loan based on the effective interest method. We have determined that the fair value of the Investor Warrants at the issuance date was SEK 27.8 million, based on the trading price of the underlying listed financial instrument on Nasdaq Nordic. We should have recorded that amount as a reduction of equity at the issuance date. Subsequent changes to the fair value of the Warrants, based on the trading price of the underlying listed instruments, were recorded through profit or loss.

(g) *Other restatements:* In accordance with presentation requirements under IAS 1, as well as other applicable recognition and measurement principles codified in other IFRS, the Company has made certain other adjustments and reclassifications which affect the consolidated statement of comprehensive income, consolidated statement of financial position, statement of changes in equity and consolidated statement of cash flows. Individually, such other restatements did not have a material impact on our consolidated financial statements.

C. Impact of restatements

The total impact of restatements on the three and nine months ended September 30, 2020 is presented in the tables below:

Reconciliation of the condensed statement of comprehensive income for the three months ended September 30, 2020

KSEK	2020-07-01 2020-09-30 (Restated)	Adjustments		2020-07-01 2020-09-30 (Previously Reported)
Revenue	2,155	—		2,155
Total operating income	2,155	—		2,155
Raw materials and consumables	-516	—		-516
Other external costs	-23,751	1,984	(e)	-25,735
Personnel costs	-12,706	2,977	(e)	-15,683
Depreciation and write-downs	-2,478	-1,367		-1,111
Total operating expenses	-39,451	3,594		-43,045
Operating profit/loss	**-37,296**	**3,594**		**-40,890**
Share of result of associates	—	—		—
Financial income	1,587	-68	(g)	1,655
Financial expenses	-10,706	-2,331	(g)	-8,375
Net gains on financial items	-1,924	3,116	(f),(g)	-5,040
Total financial items	-11,043	717		-11,760
Profit/loss after financial items	**-48,339**	**4,311**		**-52,650**
Tax on net profit/loss	—	—		—
Profit/loss for the period	**-48,339**	**4,311**		**-52,650**
Other comprehensive income				
Item that may be reclassified to profit and loss				
Translation differences	24,202	4,350		19,852
Items that will not be reclassified to profit and losses				
Fair value financial assets	17,107	1,695	(b)	15,412
Total Other comprehensive income	41,309	6,045		35,264
Total comprehensive income	**-7,030**	**10,356**		**-17,386**

Reconciliation of the condensed statement of comprehensive income for the nine months ended September 30, 2020

KSEK	2020-01-01 2020-09-30 (Restated)	Adjustments		2020-01-01 2020-09-30 (Previously Reported)
Revenue	6,576	1,971	(d)	4,605
Total operating income	6,576	1,971		4,605
Raw materials and consumables	-2,076	-1		-2,075
Other external costs	-60,951	3,580	(c),(e)	-64,531
Personnel costs	-31,423	2,039	(e)	-33,462
Depreciation and write-downs	-2,892	-1,367		-1,525
Total operating expenses	-97,342	4,251		-101,593
Operating loss	**-90,766**	**6,222**		**-96,988**
Share of result of associate	-433	-433	(b)	—
Financial income	1,931	-34	(g)	1,965
Financial expenses	-15,211	-6,099	(g)	-9,112
Net gains on financial items	67,598	88,571	(b),(f),(g)	-20,973
Total financial items	53,885	82,005		-28,120
Profit (loss) before tax	**-36,881**	**88,227**		**-125,108**
Tax benefit on net profit (loss)	7,852	-1		7,853
Profit (loss) for the period	**-29,029**	**88,226**		**-117,255**
Other comprehensive income				
Item that may be reclassified to profit and loss				
Translation differences	24,944	5,583		19,361
Items that will not be reclassified to profit and losses				
Fair value financial assets	101,689	-20,910	(b)	122,599
Total other comprehensive income for the period, net after tax	126,633	-15,327		141,960
Total comprehensive income for the period	**97,604**	**72,899**		**24,705**

Reconciliation of the condensed consolidated statement of financial position as of September 30, 2020

KSEK	2020-09-30 (Restated)	Adjustments		2020-09-30 (Previously Reported)
ASSETS				
Intangible assets	6,370	6,370	(c)	—
Property and equipment	3,950	—	(g)	3,950
Right of use assets	20,269	-5,378	(g)	25,647
Other financial assets	83,234	27,770	(a)	55,464
Tax assets	7,786	—		7,786
Deferred tax	68	—		68
Other long-term receivables	—	-2,373	(g)	2,373
Non-current assets	**121,677**	**26,389**		**95,288**
Trade receivables	6,224	2,697	(d)	3,527
Current tax assets	—	—		—
Other assets	42,667	42,667	(e),(g)	—
Cash and cash equivalent	647,058	—		647,058
Other receivables	—	-38,537	(g)	38,537
Prepayments and accrued income	—	-1,685	(e),(g)	1,685
Current assets	**695,949**	**5,142**		**690,807**
Total assets	**817,626**	**31,531**		**786,095**

Reconciliation of the condensed consolidated statement of financial position as of September 30, 2020 (continued)

KSEK	2020-09-30 (Restated)	Adjustments		2020-09-30 (Previously Reported)
EQUITY AND LIABILITIES				
Share capital	3,119	—		3,119
Additional paid-in capital	811,119	-27,797	(e),(f)	838,916
Reserves	123,337	36,290	(g)	87,047
Accumulated deficit	-209,417	29,785	(a),(b),(c),(d),(e),(f)	-239,202
Equity	**728,158**	**38,278**		**689,880**
Other financial liabilities	14,680	14,680		
Other liabilities	2,163	2,163		
Lease liabilities	—	-18,221	(g)	18,221
Other payables	—	-2,163	(g)	2,163
Non-current liabilities	**16,843**	**-3,541**		**20,384**
Trade payables	18,506	4,106	(g)	14,400
Other financial liabilities	48,452	41,534	(f),(g)	6,918
Other liabilities	5,667	5,667	(g)	
Loan	—	-25,000	(g)	25,000
Other payables	—	-6,627	(g)	6,627
TO2 & TO3 warrants	—	-20,968	(g)	20,968
Accrued expenses and deferred income	—	-1,920	(g)	1,920
Current liabilities	**72,625**	**-3,208**		**75,833**
Total liabilities	**89,468**	**-6,749**		**96,217**
Total equity and liabilities	**817,626**	**31,529**		**786,097**

Note 13 Subsequent Events to the Balance Sheet Date

No subsequent events to report.

Review Report

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

Introduction

We have reviewed the interim report for Saniona AB (publ) for the period January 1 - September 30, 2021. The Board of Directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, *Review of Interim Financial Information Performed by the Independent Auditor of the Entity*. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review has a different focus and is substantially less in scope than an audit conducted in accordance with ISA and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not, in all material respects, prepared for the Group in accordance with IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Malmö November 18, 2021

Deloitte AB

Jeanette Roosberg
Authorized Public Accountant

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 November 18, 2021.

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