

Laying the foundation for success through solid progress on partnering efforts, pipeline development activities and finance management

Three Months Ended September 30, 2022 (2021)	Nine Months Ended September 30, 2022 (2021)
Revenue was SEK 2.4 M (2.3 M)	Revenue was SEK 12.0 M (7.6 M)
Operating profit/loss was SEK 21.8 M (-88.2 M) Net profit/loss was SEK 17.5 M (-93.7 M)	Operating profit/loss was SEK -203.1 M (-286.7 M) Net profit/loss was SEK -204.4 M (-281.8 M)
Basic earnings/loss per share was SEK 0.28 (-1.50)	Basic earnings/loss per share was SEK -3.28 (-4.52)
Diluted earnings/loss per share were SEK 0.28 (-1.50)	Diluted earnings/loss per share were SEK -3.28 (-4.52)

Business highlights in Q3 2022

- On August 16, **Saniona progressed its Kv7 ion channel epilepsy program into lead optimization phase**, the last drug discovery phase before potential drug candidate selection.
- On September 30, Saniona **extended its runway** and amended the loan agreement with Formue Nord. The loan was extended with 7 months and the maturing date of the loan has been changed from June 30, 2023, to January 31, 2024.

Significant events after the reporting period

- On November 3, Saniona announced that **SAN903 is ready to start the regulatory process for entering Phase 1 clinical trials**.

Comments from the CEO

“We continue to make progress on our partnering efforts and development of our pipeline in Q3 while we have reduced costs and extended runway until 2024 without having to raise additional financing. Saniona has a broad pipeline of products, a highly motivated and professional team and significant experience with partnering. I am confident that our business development efforts will help us through this difficult period for listed biotech companies and that our pipeline will deliver new valuable breakthrough medicine.”

For more information, please contact

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Letter from the CEO

We are currently focusing on partnering to secure non-dilutive funding while building long term value from our leading ion channel platform and pipeline. Our short-term objectives from our partnering efforts are to help solidify our balance sheet and finance our internal develop programs, thereby enabling us deliver new valuable breakthrough medicine from our advanced programs in the longer term.

The partnering process is time-consuming, and time can be the limiting factor for identifying the right partner and obtain the best possible terms. At the end of September, we entered into a new agreement with Formue Nord where Saniona repaid part of its existing loan to Formue Nord in exchange of a postponement of the maturity date for the outstanding loan value. We have thereby extended our runway. The current cash position is now expected to fund the planned activities until at the end of January 2024 where the balance of loan value to Formue Nord becomes payable. This will allow us to continue to pursue our partnering efforts at the best possible terms without impacting share capital.

We continue to make progress on our partnering efforts, and I remain optimistic about being able to establish valuable partnerships and becoming less dependent on the financial markets. We initiated the partnering process in May and are exploring partnership opportunities on several of our clinical stage and preclinical assets. Saniona has a broad pipeline, and we are exploring the opportunities for three of our clinical stage assets, three of our preclinical assets and our research platform. We have had numerus meetings on non-confidential and confidential basis and many companies have entered a data room for due diligence on our assets.

In parallel to our partnering activities, we have made good progress on our pipeline.

Our partner, Medix, has informed us that they have had a constructive dialogue with the Mexican regulatory authority (COFEPRIS) about the process for obtaining market approval for tesofensine in Mexico. We are encouraged by Medix' commitment and share their excitement about the prospect for tesofensine in general obesity in Mexico. We hope to be able to provide further information about this development in the coming periods.

During the quarter, we have continued interactions with our Tesomet clinical research service provider, to ensure an orderly closing of the Phase 2b trial for Tesomet, which was put on hold in March. We have in parallel explored an alternative and less ambitious development plan for Tesomet in hypothalamic obesity, which potentially could be financed by Saniona. This work requires further analysis and interactions with regulators and will not be finalized before we have secured additional financing through partnerships on one or several of our promising preclinical and clinical assets.

Just prior to the start of the third quarter, we reported the successful completion of our Phase 1 clinical trial of SAN711, which is positioned for the treatment of neuropathic pain disorders. The study demonstrated that SAN711 was safe and well tolerated and that it was possible to obtain high 24-hour exposure levels corresponding to expected desired therapeutic effect at a well-tolerated dose. As the first company in the world, we now have the ability - either on our own or with a partner - to evaluate this new and highly promising GABA-A $\alpha 3$ concept for effective and tolerable pain management in severely impacted patient populations.

During autumn, we completed the preclinical development of SAN903 and in early November we announced that the candidate is ready to start the regulatory process for entering Phase 1 clinical trials - either on our own or with a partner. The SAN903 candidate is positioned for inflammatory bowel disease where it could be the first maintenance drug with independent actions on both acute inflammation and chronic fibrotic complications. This is highly relevant in inflammatory bowel disease as many patients experience repeated episodes of acute inflammation leading to progressed intestinal fibrosis that ultimately requires surgical intervention to resolve potentially life-threatening gut obstructions.

The two candidates, SAN711 and SAN903, are based on our leading position and technology within ion channel research. They represent two novel and highly valuable potentially first-in-class assets. They are based on innovative and robust science and address high unmet medical need with a clear differentiation to existing therapies and competing development activities. Moreover, the two candidates have potential for multiple indications including rare diseases that Saniona could potentially pursue internally. Thus, as an alternative to neuropathic pain Saniona may develop SAN711 in

pediatric patients living with ESES (electrical status epilepticus during sleep). ESES typically presents in children between 3 and 5 years of age and typically leads to stagnation or regression of the development often resulting in the need for lifelong care and a poor quality of life. Due to the benign safety profile and highly specific pharmacology, SAN711 may address the high unmet need in this pediatric indication. This approach fits well with our activities within epilepsy and our rare disease strategy. Similarly, as an alternative to inflammatory bowel disease, Saniona may develop SAN903 for fibrotic disorders such as chronic kidney disease, CKD, or the fatal lung disease idiopathic pulmonary fibrosis, IPF.

On our internal preclinical programs, we are focusing resources on our two epilepsy assets: the Kv7 program entered lead optimization in August, the last drug discovery phase before potential drug candidate selection, and for the next epilepsy program, we expect to be able to select our first development candidate by the end of this year.

With rising inflation and interest rates and a war in Europe, the macroenvironment has not been favorable for the stock market. This period is challenging for also the biotech sector. Saniona has a broad pipeline of products, a highly motivated and professional team and significant experience with partnering. I am confident that our business development efforts will help us through this difficult period and that our pipeline will deliver new valuable breakthrough medicines.

Thomas Feldthus
CEO

About Saniona

Saniona is a clinical-stage biopharmaceutical company focused on the discovery and development of medicines modulating ion channels. The company's most advanced product candidate, Tesomet™, has been progressed to mid-stage clinical trials for rare eating disorders. Through its ion channel expertise, Saniona is advancing two product candidates, SAN711 and SAN903. SAN711 has successfully completed a Phase 1 clinical trial for the treatment of neuropathic pain conditions. SAN903 is ready for Phase 1 clinical studies for the treatment of inflammatory and fibrotic disorders. The company has research and development partnerships with Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and Cephagenix ApS. Saniona is based in Copenhagen, Denmark, and listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at www.saniona.com.

Our vision

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


Our mission

We leverage our ion channel targeting expertise to discover, develop and deliver innovative therapies in collaboration with partners.

Our values

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

Clinical Pipeline

Product Candidate	Indication	Pre-clinical	Phase 1	Phase 2a	Phase 2b	Phase 3	Registration	Status
Tesofensine	Obesity							<ul style="list-style-type: none"> Filed for registration for obesity in Mexico, by partner Medix 
Tesomet <i>(tesofensine + metoprolol)</i>	Prader-Willi and Hypothalamic Obesity							<ul style="list-style-type: none"> Positioned for partnering
SAN711 <i>(GABA α3 PAM)</i>	Migraine and neuropathic pain disorders							<ul style="list-style-type: none"> Positive Phase 1 data reported June 2022
SAN903 <i>(IK channel blocker)</i>	Fibrotic and inflammatory disorders							<ul style="list-style-type: none"> Phase 1 ready

Tesomet™

Tesomet is a novel, potentially first-in-class, once-daily oral investigational therapy for the treatment of hypothalamic obesity (HO) and Prader-Willi syndrome (PWS). The Company is actively exploring all partnership options, including worldwide partnerships, that could generate immediate non-dilutive income and enable Tesomet to move forward.

Tesomet is a fixed-dose combination of two active ingredients: tesofensine and metoprolol. Tesofensine is a 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 β 1 receptor blocker historically used to treat a number of cardiovascular conditions and which has been approved for use in the United States since 1978. We selected metoprolol not only for its pharmacological effects but also for its well-established safety profile since its approval. Following discussions with the FDA on the proposed regulatory path for Tesomet in HO and PWS, the FDA confirmed that Tesomet may be advanced via the 505(b)(2) pathway for the treatment of HO and PWS. The FDA has granted orphan drug designation to Tesomet for the treatment of HO and PWS, respectively. We hold exclusive worldwide rights to Tesomet.

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

Saniona has completed an initial Phase 2 clinical trial of Tesomet for the treatment of HO. This trial was a single-center, 24-week, randomized, double-blind, placebo-controlled trial with an optional 24-week Open Label Extension (OLE). A total of 21 adult patients, 13 of whom were randomized to Tesomet and eight to placebo, were included within the protocol-specified modified intent-to-treat analysis pertaining to the double-blind period (i.e., all randomized patients with measurement after at least one dose of study drug or placebo). Tesomet was generally well tolerated throughout the 48 weeks of this clinical trial. The majority of adverse events (AEs) were mild or moderate in severity. The primary endpoint of the study was to establish the overall safety and tolerability of Tesomet in patients with HO, which was achieved. Several secondary endpoints relating to efficacy were also achieved. Double-blind treatment with Tesomet for 24 weeks resulted in statistically significant placebo-adjusted weight loss of 6.28% ($p < 0.0169$) and a mean reduction in waist

circumference of 5.68 cm or 5.00%. In the 24-week OLE, Tesomet continued to demonstrate persistent improvements in body weight and waist circumference.

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

Saniona has completed an initial Phase 2 clinical trial of Tesomet for the treatment of PWS. This trial was a two-center, randomized, double-blind, placebo-controlled trial. Nine adults and nine adolescents were treated daily with Tesomet or placebo for three months for the double-blind portion of the trial, with two open-label three-month extensions, referred to as OLE1 and OLE2, for adolescent patients. The primary endpoint was change in body weight; secondary objectives included hyperphagia, body composition, lipids and other metabolic parameters. The adult patients receiving Tesomet achieved a 5.4% reduction in body weight, which is notable in the small patient population, and a statistically significant 8.1 point reduction in hyperphagia as measured by the Hyperphagia Questionnaire for Clinical Trials (HQ-CT), a caregiver questionnaire that is the generally accepted standard for evaluating hyperphagia in patients with PWS. In adolescents, upon the dose increase of Tesomet from 0.125 mg to 0.25 mg during the OLE2 portion of the trial, Tesomet-treated patients experienced a decrease in body weight and a further reduction in hyperphagia as measured by the HQ-CT questionnaire.

Saniona sees significant value in Tesomet and believes that the initial Phase 2 data support further development of Tesomet. Financial analysts have estimated annual peak sales for Tesomet between USD \$850M - \$1B+ (SEK 9B – 10B) (Saniona does not endorse or validate sales estimates provided by third parties).

SAN711

SAN711 is a novel potentially first-in-class selective positive allosteric modulator (PAM) of GABA_A α3 receptors positioned for the treatment of neuropathic pain. SAN711 has successfully completed a Phase 1 clinical trial in healthy volunteers, and the results from this trial open the path for continued clinical development of SAN711.

The unique mode of action of SAN711 is enhancement of the effect of GABA at GABA_A α3 receptors at the spinal cord. GABA is a neurotransmitter, or chemical messenger, that inhibits signals between nerve cells in the brain. It is believed that a dysfunction or reduction of GABA signaling in the spinal cord is associated with aberrant pain signaling to the brain and consequently perception of pain. SAN711 is specifically designed to enhance the effect of GABA, the brain's own inhibitory neurotransmitter, at α3 containing receptors in the spinal cord. This is believed to restore spinal inhibitory tone and prevent abnormal pain signaling to the brain.

GABA_A is the target of most broad GABA_A PAMs such as the highly effective medicines belonging to the chemical group referred to as "benzodiazepines". Importantly, unlike benzodiazepines, SAN711 does not have an impact on GABA_A α1 and α5 subunits, thus being devoid of the sedation, motor instability, abuse liability, and memory impairing effects that limit the use and tolerability of benzodiazepines.

Preclinical assessments in *in vitro* and *in vivo* models, conducted in the labs of Saniona have confirmed that because SAN711 only activates $\alpha 3$ GABAA receptors, this selectivity may allow SAN711 to provide pain relief and other benefits in the central nervous system while avoiding the typical adverse effects associated with non-selective GABAA activation mentioned above.

Saniona has recently successfully completed a Phase 1 clinical trial. The study was a randomized, placebo-controlled Phase 1 clinical trial in 66 healthy male and female volunteers. The primary objective of the study was to determine the safety and tolerability of SAN711, which was evaluated through single ascending dose and multiple ascending dose phases of the study. The secondary objective was to measure binding to target receptors, which was assessed during a positron emission tomography (PET) evaluation phase of the study.

Data from the trial showed that SAN711 was safe and well tolerated across all dosing cohorts, confirming the improved tolerability of the unique subtype selective profile. There were no serious adverse events, and all subjects completed the study. There were no safety laboratory concerns or cardiovascular concerns. Further, there were no abnormal neurological examinations and no evidence of emergent cognitive deficits as assessed by Mini Mental State Examinations. SAN711 had a favorable absorption and distribution profile and the maximum plasma levels of SAN711 resulted in more than 80% occupancy of target receptors. Importantly, the PET results confirmed that a pharmacologically active receptor occupancy may be achieved at well-tolerated doses of SAN711 as the MAD part of the study showed that a well-tolerated dose of 0.8 mg/kg twice daily led to plasma levels consistent with 24-hour receptor occupancy ranging from 50% to 72%. Based on pre-clinical data, this exposure level is predicted to result in the desired therapeutic effects.

Consequently, SAN711 shows clear differentiation in its side effect profile compared to classical, non-selective GABA modulators of the benzodiazepine type such as valium which is dose limited by sedation. Importantly, Saniona have in this study demonstrated that it is possible to safely exceed human exposure levels of SAN711 beyond what is needed to show strong efficacy in the preclinical pain models. Further, the PET result provides a clear guidance for the design of the Phase 2 studies with 0.8 mg/kg twice daily as an effective and well tolerated dose. More information is available at www.clinicaltrials.gov.

The preclinical data package thus far indicates substantial potential value for SAN711 in migraine, trigeminal neuralgia and neuropathic pain. As these are larger, non-rare indications, Saniona has decided to actively explore opportunities to out-license SAN711 and generate non-dilutive income.

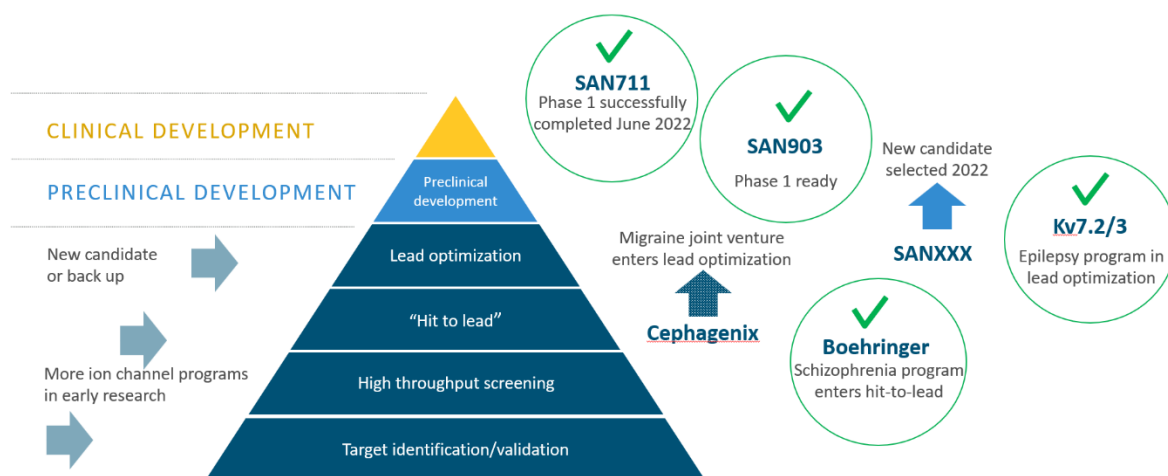
SAN903

SAN903 is designed as an inhibitor of the calcium-activated potassium channel, KCa3.1. KCa3.1 is important for activation of immune cells in the brain (microglia) and other tissues (T-cells, macrophages), and it is also involved in the abnormal production of connective tissue that can lead to fibrosis in chronic diseases.

SAN903 has demonstrated preclinical proof of concept in standard animal models of inflammatory and fibrotic diseases, including idiopathic pulmonary fibrosis, kidney fibrosis and inflammatory bowel disease.

Saniona has completed the preclinical development and fulfilled other requirements for initiation of Phase 1 clinical trials either by Saniona alone or together with a partner for treatment of inflammatory and fibrotic disorders such as inflammatory bowel disease.

R&D Ion Channel Pipeline



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

The core of this engine is Saniona's proprietary IONBASE database, which contains structure-activity data for more than 130,000 compounds. Of these, more than 20,000 are our proprietary compounds, generated over 20 years and enriched for properties conferring optimal ion channel modulation.

As a result of our ion channel drug discovery engine, we have generated a robust pipeline of orally available, potent, highly selective and differentiated ion channel modulators, including SAN711 and SAN903.

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

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

Partnerships and Spinouts

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

Financial review

Alternative Performance Measures

Saniona presents certain financial measures in the interim report that are not defined according to International Financial Reporting Standards (IFRS), so called alternative performance measures. These have been noted with an “**” in the tables below. The company believes that these measures provide valuable supplementary information for investors and company management as they enable an assessment of relevant trends of the company's performance. These financial measures should not be regarded as substitutes for measures defined per IFRS. Since not all companies calculate financial measures in the same way, these are not always comparable to measures used by other companies.

The definition and relevance of key figures not calculated according to IFRS are listed in the table below.

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

Financial key figures

	2022-07-01	2021-07-01	2022-01-01	2021-01-01	2021-01-01
	2022-09-30	2021-09-30	2022-09-30	2021-09-30	2021-12-31
Revenue, KSEK	2,388	2,264	11,977	7,597	10,478
Total operating expenses, KSEK	19,464	-90,466	-215,090	-294,284	-422,048
Operating profit (loss), KSEK	21,852	-88,202	-203,113	-286,687	-411,570
Operating margin, %	915%	-3,896%	-1,696%	-3,774%	-3,928%
Cash flow for the period, KSEK	-51,979	-6,681	-275,367	-182,264	-251,280
Cash flow per share, SEK	-0.83	-0.11	-4.41	-2.92	-4.03
Earnings per share, SEK	0.28	-1.50	-3.28	-4.52	-6.59
Diluted earnings per share, SEK	0.28	-1.50	-3.28	-4.52	-6.59
Average shares outstanding	62,385,677	62,385,677	62,385,677	62,380,030	62,381,454
Diluted average shares outstanding	62,385,677	62,385,677	62,385,677	62,427,889	62,381,501
Shares outstanding at the end of the period	62,385,677	62,385,677	62,385,677	62,385,677	62,385,677
Average number of employees	24.7	55.5	38.0	46.6	49.2
			2022-09-30	2021-09-30	2021-12-31
Cash and cash equivalent, KSEK			117,555	425,699	356,855
Equity, KSEK			91,333	390,525	281,999
Total Equity and liabilities, KSEK			192,628	534,154	440,248
Liquidity ratio, %	*		643%	1,003%	599%
Equity ratio, %	*		47%	73%	64%
Equity per share, SEK	*		1.46	6.26	4.52

* = Alternative performance measures

Results of Operations

Revenue

Three Months Ended September 30, 2022 and 2021

Revenue increased by SEK 0.1 million from SEK 2.3 million for the three months ended September 30, 2021, to SEK 2.4 million for the three months ended September 30, 2022.

Nine Months Ended September 30, 2022 and 2021

Revenue increased by SEK 4.4 million from SEK 7.6 million for the nine months ended September 30, 2021, to SEK 12.0 million for the nine months ended September 30, 2022.

Operating expenses

Three Months Ended September 30, 2022 and 2021

Operating expenses decreased by SEK 109.9 million from SEK 90.5 million for the three months ended September 30, 2021, to a profit of SEK 19.5 million for the three months ended September 30, 2022.

Within operating expenses, external expenses decreased by SEK 45.0 million from SEK 42.6 million for the three months ended September 30, 2021, to a profit of SEK 2.4 million for the three months ended September 30, 2022. The main components of our external expenses are external research and development expenses, which are primarily attributable to contract research organizations (CROs) and contract manufacturing organizations for our clinical trials. External research and development expenses for the three months ended September 30, 2022, comprised primarily of development profit of Tesomet (SEK 8.5 million) and profit of SAN711 (SEK 1.6 million) and pre-clinical development costs of the SAN903 program (SEK 0.3 million) and other research costs. The reason for the profit on external expenses in the three months ended September 30, 2022, is that we have finalized the contract with our main external CRO of Tesomet, which have decreased the accruals from June 30, 2022, with net SEK 8.5 million. For the three months ended September 30, 2021, external expenses comprised primarily of development costs of Tesomet (SEK 29.1 million)

followed by preclinical development costs of SAN711 (SEK 2.1 million) and pre-clinical development costs of the SAN903 program (profit of SEK 0.3 million) and other research costs.

Personnel costs includes salaries, variable compensation, social security, and other employee benefits. Personnel costs decreased by SEK 63.9 million from SEK 44.2 million for the three months ended September 30, 2021, to a profit of SEK 19.7 million for the three months ended September 30, 2022. The reduction in personnel costs is partly explained by a reduction in non-cash share-based compensation expenses, which decreased by SEK 39.2 million from an expense of SEK 12.9 million for three months ended September 30, 2021, to a profit of SEK 26.3 million for the three months ended September 30, 2022. The recognized profit from non-cash share-based compensation in 2022 is caused by a reversal off expenses on units that forfeited during the three months ended September 30, 2022, as the underlying service conditions were not met.

Nine Months Ended September 30, 2022 and 2021

Operating expenses decreased by SEK 79.2 million from SEK 294.3 million for the nine months ended September 30, 2021, to SEK 215.1 million for the nine months ended September 30, 2022.

Within operating expenses, external expenses decreased by SEK 24.5 million from SEK 157.3 million for the nine months ended September 30, 2021, to SEK 132.8 million for the nine months ended September 30, 2022. The main components of our external expenses are external research and development expenses, which are primarily attributable to contract research organizations (CROs) and contract manufacturing organizations for our clinical trials. External research and development expenses for the nine months ended September 30, 2022, comprised primarily of development costs of Tesomet (SEK 47.9 million) and SAN711 (SEK 33.6 million) and pre-clinical development costs of the SAN903 program (SEK 10.4 million) and other research costs. For the nine months ended September 30, 2021, external expenses comprised primarily of development costs of Tesomet (SEK 90.6 million) followed by preclinical development costs of SAN711 (SEK 10.9 million) and pre-clinical development costs of the SAN903 program (SEK 3.1 million) and other research costs.

Personnel costs, which includes salaries, variable compensation, social security, and other employee benefits, decreased by SEK 54.4 million from SEK 127.1 million for the nine months ended September 30, 2021, to SEK 72.7 million for the nine months ended September 30, 2022. Non-cash share-based compensation expense decreased by SEK 56.4 million from SEK 37.4 million for the nine months ended September 30, 2021, to a profit of SEK 19.0 million for the nine months ended September 30, 2022. SEK 47.0 million of the total personnel costs in the nine months ended September 30, 2022, are related to winding down of our US activities, hereof are non-cash share-based compensation a profit of SEK 26.8 million. The profit from the non-cash share-based compensation is reversal off expenses on the units that were forfeited during the three months ended September 30, 2022, as the underlying service conditions were not met.

Restructuring costs

In second quarter of 2022, Saniona closed its operations in U.S. Total expenses for the U.S. operations were SEK 34.7 million for the three and nine months ended September 30, 2022. The expenses include April salaries and provision for severance payments related to the termination of employees of SEK 30.6 million as well as other expenses related to legal services, IPO costs and other costs of SEK 4.1 million. In the second quarter of 2022, all contract costs to external CRO's etc., for the closing the Phase 2b clinical trials of Tesomet for hypothalamic obesity (HO) and Prader-Willi syndrome (PWS), are included in *Other external expenses*.

With the two-step strategic initiated in spring 2022, Saniona has reduced its annual base cost to approximate SEK 70 million for running the company and its research and development operation excluding program specific external costs for conducting clinical trials on e.g. SAN903, SAN711 or Tesomet.

Financial items

Three Months Ended September 30, 2022 and 2021

Net loss from total financial items decreased from SEK 5.5 million for the three months ended September 30, 2021, to SEK 2.9 million for the three months ended September 30, 2022.

Nine Months Ended September 30, 2022 and 2021

Net loss from total financial items increased from SEK 2.6 million for the nine months ended September 30, 2021, to SEK 7.6 million for the nine months ended September 30, 2022.

Tax Benefit

Three Months Ended September 30, 2022 and 2021

The Group recognized a tax cost of SEK 1.4 million for the three months ended September 30, 2022, compared to SEK 0 for the three months ended September 30, 2021. The increase is a tax cost recognized in Saniona Inc.

Nine Months Ended September 30, 2022 and 2021

The tax benefit on net loss recognized under the Tax Credit Scheme in Denmark increased by SEK 0.3 million from SEK 7.5 million for the nine months ended September 30, 2021, to SEK 7.8 million for the nine months ended September 30, 2022, because of exchange rate fluctuations. The net tax benefit for the Group is SEK 6.3 million for the nine months ended September 30, 2022, and also consist a tax cost in Saniona Inc of SEK 1.4 million.

Cash flow

Three Months Ended September 30, 2022 and 2021

Net cash used in operating activities decreased by SEK 50.7 million from SEK 86.2 million for the three months ended September 30, 2021, to SEK 35.5 million for the three months ended September 30, 2022.

The operating cash flow for the three months ended September 30, 2022, is primarily attributable to our operating loss of SEK 2.8 million (net of non-cash operating profit for share-based payments of SEK 26.3 million and for expenses depreciation of SEK 1.6 million). 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).

For the three months ended September 30, 2022, net cash used by financing activities was SEK 16.4 million, primarily due to repayment of SEK 15 million to Formue Nord Fokus A/S on a term loan agreement entered in July 2021, and a repayment of lease liabilities of SEK 1.6 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 a term loan agreement with Formue Nord Fokus A/S, and a repayment of lease liabilities of SEK 1.8 million.

For the three months ended September 30, 2022 and 2021, cash and cash equivalents amounted to SEK 117.6 million and SEK 425.7 million, respectively. Approx 45% and 55% of cash and cash equivalents is denominated in USD and DKK, respectively as of September 30, 2022.

Nine Months Ended September 30, 2022 and 2021

Net cash used in operating activities decreased by SEK 15.9 million from SEK 270.1 million for the nine months ended September 30, 2021, to SEK 254.2 million for the nine months ended September 30, 2022.

The operating cash flow for the nine months ended September 30, 2022, is primarily attributable to our operating loss of SEK 216.0 million (net of non-cash operating profit for share-based payments of SEK 19.0 million and expenses for depreciation of SEK 6.1 million). 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).

For the nine months ended September 30, 2022, net cash used by financing activities was SEK 19.6 million, primarily attributable to the repayment of SEK 15.0 million to Formue Nord Fokus A/S on a term loan agreement entered in July 2021, and repayment of lease liabilities of SEK 4.6 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 a term loan agreement with Formue Nord Fokus A/S, partially offset by repayment of a SEK 25.0 million loan with Formue Nord that originated in 2020 and repayment of lease liabilities of SEK 5.0 million.

Parent Company

Three Months Ended September 30, 2022 and 2021

Operating expenses decreased by SEK 3.9 million from SEK 5.2 million for the three months ended September 30, 2021, to SEK 1.3 million for the three months ended September 30, 2022.

Profit decreased by SEK 0.6 million from a loss of SEK 5.0 million for the three months ended September 30, 2021, to a loss of SEK 5.6 million for the three months ended September 30, 2022.

Nine Months Ended September 30, 2022 and 2021

Operating expenses increased by SEK 9.7 million from SEK 16.7 million for the nine months ended September 30, 2021, to SEK 26.4 million for the nine months ended September 30, 2022.

Profit decreased by SEK 45.4 million from a profit of SEK 9.6 million for the nine months ended September 30, 2021, to a loss of SEK 35.8 million for the nine months ended September 30, 2022.

The share, share capital and ownership structure

On September 30, 2022, the company had 10,416 (9,651) shareholders excluding holdings in life insurance and foreign custody account holders. Equity was SEK 91.3 million (390.5).

Personnel

As of September 30, 2022, Saniona had 25 (52) employees including 11 (14) employees with Ph.D. degrees. Of these employees, 18 (35) were engaged in research and clinical development activities and 7 (17) were engaged in general and administrative activities. Of the 25 (52) employees, 14 (28) 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.

While the war in Ukraine has not had a material economic impact on the financial reports, there is the possibility that it could in the future. We are carefully monitoring the market, where we see rising inflation and higher commodity, component and freight costs, as well as higher and greater uncertainty about interest rates.

Saniona's currency risk is primarily sourced from payment flows in foreign currency and from the translation of balance sheet items in foreign currency, as well as upon the translation of foreign subsidiaries' income statements and balance sheets to the Groups' reporting currency, which is SEK. Accordingly, future changes in the exchange rates of the SEK against the USD and the DKK will expose the company to currency gains or losses that will impact the reported amounts of assets, liabilities, income and expenses and the impact could be material. Saniona hedges its currency exposure primarily by matching expenses in the same currency. Approx 45% and 55% of cash and cash equivalents is denominated in USD and DKK, respectively as of September 30, 2022.

A detailed description of the Group's risk factors and risk management is included in Saniona's 2021 Annual Report. There are no major changes in the Group's risk factors and risk management in 2022.

Annual General Meeting

Saniona's Annual General Meeting for 2023 will be held in Malmö on May 25, 2023. For more information, visit www.saniona.com.

Audit review

The interim report has been subject to a limited review by the company's independent auditor.

Financial calendar

Year-End Report 2022	February 23, 2023, at 8:00 CET
Interim Report Q1	May 25, 2023, at 8:00 CEST
Annual General Meeting	May 25, 2023
Interim Report Q2	August 31, 2023 at 8:00 CEST
Interim Report Q3	November 30, 2023 at 8:00 CET
Year-End Report 2023	February 22, 2024 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, 17 November 2022
Saniona AB

Jørgen Drejer – Chairman

Thomas Feldthus – CEO

Anna Ljung – Board member

Carl Johan Sundberg – Board member

THE GROUP'S UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

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

Unaudited condensed consolidated interim statement of comprehensive income – Group

KSEK	Note	2022-07-01 2022-09-30	2021-07-01 2021-09-30	2022-01-01 2022-09-30	2021-01-01 2021-09-30	2021-01-01 2021-12-31
Revenue	1,2,3 4	2,388	2,264	11,977	7,597	10,478
Total operating income		2,388	2,264	11,977	7,597	10,478
Raw materials and consumables		-967	-1,497	-3,433	-3,352	-4,630
Other external costs		2,388	-42,563	-132,811	-157,348	-239,267
Personnel costs	5	19,688	-44,214	-72,711	-127,097	-169,478
Depreciation and write-downs		-1,645	-2,192	-6,135	-6,487	-8,673
Total operating expenses		19,464	-90,466	-215,090	-294,284	-422,048
Operating profit (loss)		21,852	-88,202	-203,113	-286,687	-411,570
Share of result of associate	10	87	—	296	—	—
Financial income		3,757	18	8,747	1,640	1,922
Financial expenses		-6,735	-5,466	-16,668	-8,988	-13,128
Net gains on financial items		—	—	—	4,793	4,396
Total financial items		-2,891	-5,448	-7,625	-2,555	-6,810
Profit (loss) before tax		18,961	-93,650	-210,738	-289,242	-418,380
Income tax	6	-1,444	—	6,330	7,482	7,482
Profit (loss) for the period		17,517	-93,650	-204,408	-281,760	-410,898
Other comprehensive income (loss) for the period						
<i>Item that may be reclassified to profit and loss</i>						
Translation differences		4,093	10,219	32,744	26,050	32,574
<i>Items that will not be reclassified to profit and loss</i>						
Equity instruments at FVOCI – net change fair value		—	—	—	5,063	5,063
Total other comprehensive income for the period, net after tax		4,093	10,219	32,744	31,113	37,637
Total comprehensive profit (loss)		21,610	-83,431	-171,664	-250,647	-373,261
Loss per share, SEK		0.28	-1.50	-3.28	-4.52	-6.59
Diluted loss per share, SEK		0.28	-1.50	-3.28	-4.52	-6.59

Unaudited condensed consolidated interim statement of financial position – Group

KSEK	Note	2022-09-30	2021-09-30	2021-12-31
ASSETS				
Intangible assets		6,601	6,173	6,189
Property and equipment		3,702	5,243	5,100
Right of use assets		12,683	18,339	16,652
Investment in associate	10	2,241	864	670
Other financial assets	7,9	14,395	16,746	20,793
Tax assets	6	8,067	7,545	—
Non-current assets		47,689	54,910	49,404
Trade receivables		2,961	2,936	3,615
Current tax assets	6	8,067	7,545	7,564
Other financial assets	7,9	—	404	414
Other assets		16,356	42,660	22,396
Cash and cash equivalents		117,555	425,699	356,855
Current assets		144,939	479,244	390,844
Total assets		192,628	534,154	440,248

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

KSEK	Note	2022-09-30	2021-09-30	2021-12-31
EQUITY AND LIABILITIES				
Share capital		3,119	3,119	3,119
Additional paid-in capital		813,261	808,847	813,261
Reserves		107,289	68,021	74,545
Accumulated deficit		-832,337	-489,462	-608,926
Equity		91,333	390,525	281,999
Other financial liabilities	8,9	76,413	93,718	92,972
Other liabilities		2,330	2,130	—
Non-current liabilities		78,743	95,848	92,972
Trade payables		14,569	18,962	29,115
Other financial liabilities	8,9	5,557	7,200	6,799
Other liabilities		2,426	21,619	29,363
Current liabilities		22,552	47,781	65,277
Total liabilities		101,295	143,629	158,249
Total equity and liabilities		192,628	534,154	440,248

Unaudited condensed consolidated interim statement of changes in equity – Group

	Share capital	Additional paid-in capital	Translation reserves	Fair value reserve	Accumulated deficit	Shareholders' equity
January 1, 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	—	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
January 1, 2022	3,119	813,261	1,016	73,529	-608,926	281,999
Comprehensive income						
Loss for the period	—	—	—	—	-204,408	-204,408
Other comprehensive income:						
Fair value reserve	—	—	—	—	—	—
Translation differences	—	—	32,744	—	—	32,744
Total comprehensive income (loss)	—	—	32,744	—	-204,408	-171,664
Transactions with owners						
Shares issued for cash	—	—	—	—	—	—
Expenses related to capital increase	—	—	—	—	—	—
Share-based compensation expenses	—	—	—	—	-19,003	-19,003
Total transactions with owners	—	—	—	—	-19,003	-19,003
September 30, 2022	3,119	813,261	33,760	73,529	-832,337	91,333

Unaudited condensed consolidated interim statement of cash flows – Group

KSEK	Note	2022-07-01	2021-07-01	2022-01-01	2021-01-01	2021-01-01
		2022-09-30	2021-09-30	2022-09-30	2021-09-30	2021-12-31
Loss before tax		18,961	-93,650	-210,738	-289,242	-418,380
Adjustments for non-cash transactions		-24,681	13,175	-11,505	53,577	51,425
Changes in working capital		-24,166	-2,646	-31,912	-34,470	24,929
Cash flow from operating activities before financial and tax items		-29,886	-83,121	-254,155	-270,135	-342,026
Interest income received		189	69	229	246	278
Interest expenses paid		-5,769	-3,104	-9,361	-7,703	-10,777
Tax credit received		—	—	—	—	7,487
Cash flow from operating activities		-35,466	-86,156	-263,287	-277,592	-345,038
Investing activities						
Purchases of property and equipment		-268	-548	-309	-1,310	-1,484
Proceeds from sale of financial assets		—	—	7,522	44,646	44,646
Proceeds from sale of tangible assets		106	—	305	—	—
Cash flow from investing activities		-162	-548	7,518	43,336	43,162
Financing activities						
Proceeds from issuance of loan		—	81,780	—	81,780	81,780
Repayment of loan		-15,000	—	-15,000	-25,000	-25,000
Proceeds from issuance of new shares		—	—	—	321	321
Costs related to issuance of new shares		—	—	—	-81	-81
Payment of lease liabilities		-1,351	-1,757	-4,598	-5,028	-6,424
Cash flow from financing activities		-16,351	80,023	-19,598	51,992	50,596
Net increase (decrease) in cash and cash equivalents		-51,979	-6,681	-275,367	-182,264	-251,280
Cash and cash equivalents at beginning		173,143	420,783	356,855	573,866	573,866
Exchange rate adjustments		-3,609	11,597	36,067	34,097	34,269
Cash and cash equivalents at end of		117,555	425,699	117,555	425,699	356,855

PARENT COMPANY'S UNAUDITED FINANCIAL STATEMENTS

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

Unaudited statement of income – Parent Company

KSEK		2022-07-01	2021-07-01	2022-01-01	2021-01-01	2021-01-01
	Note	2022-09-30	2021-09-30	2022-09-30	2021-09-30	2021-12-31
	1,2,3					
Other operating income		409	1,084	3,015	3,696	3,877
Total operating income		409	1,084	3,015	3,696	3,877
Raw materials and consumables		-7	-2	-23	-7	-10
Other external costs		-996	-1,265	-9,552	-5,412	-31,514
Personnel costs	5	-311	-3,966	-16,839	-11,310	-34,038
Total operating expenses		-1,314	-5,233	-26,414	-16,729	-65,562
Operating income (loss)		-905	-4,149	-23,399	-13,033	-61,685
Financial income		115	2,434	363	2,737	5,875
Financial expenses		-4,846	-47	-12,789	-98	-7,642
Net gains (losses) on financial items		—	-3,214	—	20,019	-658,449
Total financial items		-4,731	-827	-12,426	22,658	-660,216
Profit (loss) before tax		-5,636	-4,976	-35,825	9,625	-721,901
Tax on net profit (loss)		—	—	—	—	—
Profit (loss) for the period		-5,636	-4,976	-35,825	9,625	-721,901

Unaudited balance Sheet – Parent Company

KSEK	Note	2022-09-30	2021-09-30	2021-12-31
ASSETS				
Investment in subsidiaries		340,767	965,647	359,908
Financial assets		340,767	965,647	359,908
Non-current assets		340,767	965,647	359,908
Receivables from group companies		—	80,896	—
Other assets		523	16,140	1,541
Current receivables		523	97,036	1,541
Cash and cash equivalents		1,939	19,977	12,106
Current assets		2,462	117,013	13,647
Total assets		343,229	1,082,660	373,555
EQUITY AND LIABILITIES				
<i>Restricted equity</i>				
Share capital		3,119	3,119	3,119
<i>Unrestricted equity</i>				
Share premium reserve		813,261	808,847	813,261
Retained earnings (accumulated deficit)		-553,379	177,965	187,524
Profit (loss) for the period		-35,825	9,625	-721,901
Equity		227,176	999,556	282,003
Other financial liabilities	8	69,963	82,320	82,973
Non-current liabilities		69,963	82,320	82,973
Trade payables		755	599	1,935
Payables to group companies		45,197	—	6,436
Other liabilities		138	185	208
Current liabilities		46,090	784	8,579
Total liabilities		116,053	83,104	91,552
Total equity and liabilities		343,229	1,082,660	373,555

Notes to the unaudited condensed consolidated interim financial statements

Note 1 General Information

Saniona AB (publ), (the 'Parent Company'), Corporate Registration Number 556962-5345, is a limited liability company registered in the municipality of Malmö in the county of Skåne, Sweden. These unaudited condensed consolidated interim financial statements comprise the Parent Company and its subsidiaries (collectively the 'Group' or 'Saniona'). The Group is a clinical-stage biopharmaceutical company focused on the discovery and development of medicines modulating ion channels. The legal address of the head office is Smedeland 26B, DK-2600 Glostrup, Denmark. The Parent Company is listed on Nasdaq Stockholm Small Cap, and its shares are traded under the ticker SANION and the ISIN code SE0005794617.

Note 2 Basis of Accounting and Significant Accounting Policies

A. Basis of Accounting

These unaudited condensed consolidated interim financial statements for the three months ended September 30, 2022, have been prepared in accordance with IAS 34 *Interim Financial Reporting*, the Annual Accounts Act, and the Financial Reporting Board's recommendation RFR 1, Supplementary Accounting Rules for Groups. The unaudited interim financial statements for the Parent Company are prepared under the requirements of chapter 9 of the Swedish Accounting Act (1995:1554). These unaudited condensed consolidated interim financial statements should be read in conjunction with the Group's last annual consolidated financial statements as at and for the year ended December 31, 2021 ('last annual financial statements'). They do not include all the information required for a complete set of financial statements prepared in accordance with IFRS Standards. However, selected explanatory notes are included to explain events and transactions that are significant to an understanding of the changes in the Group's financial position and performance since the last annual financial statements.

The unaudited condensed consolidated interim financial statements have been prepared on a going concern basis. As of September 30, 2022, the Group's current assets exceed current liabilities by SEK 122.4 million. Current assets include cash and cash equivalents of SEK 117.6 million.

The Board has a reasonable expectation that the Group has and will have adequate resources to continue in operation existence through least January, 2024.

These condensed consolidated financial statements were authorized for issue by the Parent Company's Board of Directors (the 'Board') on November 17, 2022.

B. Significant Accounting Policies

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

i. Segment reporting

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

ii. Fair value measurement

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

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

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

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

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

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

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

iii. Adoption of new or revised standards

A number of new standards and amendments to standards are effective for annual periods beginning after January 1, 2022, and earlier application is permitted. However, the Group has not early adopted any of the forthcoming new or amended standards in preparing these unaudited condensed consolidated interim financial statements. The new or amendment standards are not expected to have a material impact on the Group's financial position or results of operations.

Note 3 Critical accounting judgments and key sources of estimation uncertainty

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

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

Note 4 Revenue

The Group's revenue generating activities are those described in the last annual financial statements. In the three and nine months ended September 30, 2022 and 2021, revenue for the Group by category was as follows:

KSEK	2022-07-01	2021-07-01	2022-01-01	2021-01-01
	2022-09-30	2021-09-30	2022-09-30	2021-09-30
License agreements (other event-based payments)	—	—	3,760	2,504
Research and collaboration agreements (bundle, over time)	1,698	1,860	5,685	3,777
Research and development services (standalone)	690	404	2,532	1,316
Total	2,388	2,264	11,977	7,597

In the three and nine months ended September 30, 2022 and 2021, revenue for the Group by major customers was as follows:

KSEK	2022-07-01	2021-07-01	2022-01-01	2021-01-01
	2022-09-30	2021-09-30	2022-09-30	2021-09-30
Customer #1	—	—	3,760	2,504
Customer #2	690	404	2,532	1,316
Customer #3	1,698	1,860	5,685	3,777
Total	2,388	2,264	11,977	7,597

In the three and nine months ended September 30, 2022 and 2021, revenue for the Group by primary geographical market was as follows:

KSEK	2022-07-01	2021-07-01	2022-01-01	2021-01-01
	2022-09-30	2021-09-30	2022-09-30	2021-09-30
Sweden	—	—	—	—
Other European countries	2,388	2,264	8,217	5,093
The Americas	—	—	3,760	2,504
Total	2,388	2,264	11,977	7,597

Note 5 Share-based payments

A. Description of share-based payment arrangements

A detailed description of the Group's share-based payment arrangements as of December 31, 2021, is provided in the last annual financial statements.

As a result of the termination of certain employees under the two-step strategic program reprioritization and restructuring in March and April 2022, a total of 6,448,622 units that were previously granted forfeited during the three and nine months ended September 30, 2022, as the underlying service conditions were not met.

2022:1 On August 18, 2022, the extraordinary shareholders' meeting voted in favor of establishing an Employee Option Program. The Employee Option Program 2022 comprises up to 2,129,821 employee options. Each employee option entitles the holders a right to acquire one new share in the company against cash consideration at an exercise price amounting to 130 per cent of the volume weighted average share price of the company's share on Nasdaq Stockholm during the 10 trading days immediately prior to the extraordinary general meeting on August 18, 2022. Allotment of 2,129,821 options took place August 25, 2022. The allotted employee options will vest with 1/3 each on the date that falls 12, 24 and 36 months, respectively, following the date of allotment. Allotted and vested employee options can be exercised during the period starting on the date that falls 3 years after the allotment date and ending on December 31,

2028. The board of directors has the right to limit the number of occasions during the exercise period when the employee options can be exercised.

B. Measurement of fair values and compensation expense

Share-based compensation profit for the three months ended September 30, 2022, totaled SEK 26.3 million and a loss for the three months ended September 30, 2021, totaled SEK 12.9 million. Share-based compensation profit for the nine months ended September 30, 2022, totaled SEK 19.0 million and a loss for the nine months ended September 30, 2021, SEK 37.5 million. The expenses for the forfeited options during the three and nine months ended September 30, 2022, have been reversed with SEK 27.2 million. 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	2019:1	2019:2	2020:1
Options outstanding, January 1	38,292	286,003	32,792	34,500	15,770	710,313
Granted during the year	—	—	—	—	—	—
Forfeited during the year	—	—	—	—	—	-355,157
Options outstanding, September 30	38,292	286,003	32,792	34,500	15,770	355,156
Maximum number of shares to be issued	39,440	294,583	33,775	34,845	15,927	358,707
Grant Date Fair Value* (SEK)	27.94	12.06	17.38	7.23	6.00	12.26
Share Price at Grant Date* (SEK)	49.60	26.95	33.85	17.76	17.76	28.10
Exercise Price* (SEK)	40.63	33.20	29.71	17.83	17.83	29.36
Expected volatility*	73.41%	69.24%	67.77%	57.29%	53.67%	58.66%
Estimated life (years)*	3.75	3.88	3.73	3.67	2.80	4.20
Expected dividends*	0	0	0	0	0	0
Risk-free rate*	-0.2602%	-0.1092%	-0.2773%	-0.6903%	-0.6709%	-0.2280%
Remaining contractual life (years)*	0.25	1.75	1.21	2.25	1.00	3.25

Incentive program	2020:2	2020:3	2021:1	2021:2	2022:1	Total
Options outstanding, January 1	5,915,648	308,000	902,000	148,350	0	8,391,668
Granted during the year	—	—	—	—	2,129,821	2,129,821
Forfeited during the year	-5,018,148	-25,667	-901,300	-148,350	—	-6,448,622
Options outstanding, September 30	897,500	282,333	700	0	2,129,821	4,072,867
Maximum number of shares to be issued	897,500	282,333	700	0	2,129,821	4,087,631
Grant Date Fair Value* (SEK)	13.13	7.98	10.75	10.18	1.59	
Share Price at Grant Date* (SEK)	23.50	23.55	19.31	18.88	4.24	
Exercise Price*(SEK)	24.12	25.40	19.38	19.26	5.89	
Expected volatility*	63.64%	57.00%	62.56%	61.32%	57.65%	
Estimated life (years)*	6.10	2.80	6.11	6.11	4.17	
Expected dividends*	0	0	0	0	0	
Risk-free rate*	-0.2772%	-0.3602%	-0.2046%	-0.5225%	2.0670%	
Remaining contractual life (years)	8.08	2.17	8.36	8.65	6.26	

* Weighted average

As of September 30, 2022, the company has 4,072,867 options outstanding entitling to the subscription of maximum 4,087,631 new shares representing a dilution of 6.2 percent.

The weighted average exercise price of the options that forfeited during the three months ended September 30, 2022, was SEK 21.95. The weighted average exercise price of the options outstanding as of January 1, 2022, and September 30, 2022, was SEK 24.39 and SEK 15.85, respectively.

Note 6 Income tax

In the three months ended September 30, 2022, the Group recognized a tax loss of SEK 1.4 million due to tax cost recognized in Saniona Inc. In the three months ended September 30, 2021, the Group recognized a current tax benefit of SEK 0 related to the Danish 'Skattekreditordningen' (the 'Tax Credit Scheme'). In the nine months ended September 30, 2022 and 2021, the Group recognized a current tax benefit of SEK 6.3 million and SEK 7.5 million, respectively, hereof is SEK 7.8 million in 2022 related to the Danish Tax Credit Scheme.

Under the Danish 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 35 million). The Group's Danish subsidiary Saniona A/S has reached that threshold during the first six months of 2022.

Note 7 Other financial assets

A. Composition

Other financial assets were comprised of the following:

KSEK	2022-09-30	2021-09-30	2021-12-31
Contingent consideration receivable	11,699	14,195	18,289
Investment in equity instruments – publicly traded	—	—	—
Long-term deposits for property lease agreements	2,696	2,551	2,504
Total non-current other financial assets	14,395	16,746	20,793
Short-term deposit for property lease agreement	—	404	414
Total current other financial assets	0	404	414

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

Through January 2021, Saniona A/S, a wholly-owned subsidiary of the Parent Company, owned approximately 3% of the share capital of Cadent Therapeutics, Inc. ('Cadent Therapeutics'), a private company based in Cambridge, MA, United States. In January 2021, Novartis AG ('Novartis') closed its acquisition of Cadent Therapeutics that was announced in December 2020, upon the occurrence of the closing of the acquisition, the Group exchanged its investment in equity instruments – privately-held for a receivable for an upfront payment and a contingent consideration receivable from Novartis. The upfront payment of SEK 23.4 million was received in February 2021. A portion of the contingent consideration receivable of SEK 7.5 million that was related to an escrow balance was received in January 2022.

Note 8 Other financial liabilities

A. Composition

Other financial liabilities were comprised of the following:

KSEK	2022-09-30	2021-09-30	2021-12-31
Lease liabilities	6,450	11,398	9,999
Formue Nord Loan	69,963	82,320	82,973
Other liabilities	2,330	—	—
Total non-current other financial liabilities	78,743	93,718	92,972
Lease liabilities	5,557	7,200	6,799
Formue Nord Loan	—	—	—
Total current other financial liabilities	5,557	7,200	6,799

B. Formue Nord Loan

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.

On September 30, 2022 the terms have been renegotiated and modified to include an amortization of SEK 15 million of the non-dilutive loan and the term of the loan has been extended with 7 months, which means that the maturing date of the loan has been changed from June 30, 2023, to January 31, 2024. A 3% commitment fee resulting in a nominal amount of SEK 2.2 million will be settled at maturity of the loan to Formue Nord. The new loan value is totaling SEK 74.2 million as of September 30, 2022. The loan value will continue to accrue at 1 per cent monthly interest until July 1, 2023, whereafter the monthly interest will increase to 1.5 per cent.

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 when the carrying amount is a reasonable approximation of fair value.

September 30, 2022		Carrying amount					Fair value			
	Note	Financial assets at amortized cost	Mandatorily at FVTPL - others	FVOCI - equity instruments	Financial liabilities at amortized cost	Total	Level 1	Level 2	Level 3	Total
KSEK										
Financial assets measured at fair value										
Contingent consideration receivable	7	—	11,699	—	—	11,699	—	—	11,699	11,699
		—	11,699	—	—	11,699	—	—	11,699	11,699
Financial assets not measured at fair value										
Trade receivables		2,961	—	—	—	2,961	—	—	—	—
Other non-current financial assets	7	2,696	—	—	—	2,696	—	—	—	—
Other current financial assets	7	—	—	—	—	—	—	—	—	—
Cash and cash equivalents		117,555	—	—	—	117,555	—	—	—	—
		123,212	—	—	—	123,212	—	—	—	—
Financial liabilities not measured at fair value										
Trade payables		—	—	—	14,569	14,569	—	—	—	—
Formue Nord Loan	8	—	—	—	69,963	69,963	—	—	—	—
Lease liabilities	8	—	—	—	12,007	12,007	—	—	—	—
		—	—	—	96,539	96,539	—	—	—	—

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December 31, 2021 KSEK	Note	Financial assets at amortized cost	Carrying amount				Fair value			
			Mandatorily at FVTPL - others	FVOCI - equity instruments	Financial liabilities at amortized cost	Total	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value										
Investment in equity instruments - privately-held	7	—	18,289	—	—	18,289	—	—	18,289	18,289
		—	18,289	—	—	18,289	—	—	18,289	18,289
Financial assets not measured at fair value										
Trade receivables		3,615	—	—	—	3,615	—	—	—	—
Other non-current financial assets	7	2,504	—	—	—	2,504	—	—	—	—
Other current financial assets		414	—	—	—	414	—	—	—	—
Cash and cash equivalents		356,855	—	—	—	356,855	—	—	—	—
		363,388	—	—	—	363,388	—	—	—	—
Financial liabilities not measured at fair value										
Trade payables		—	—	—	29,115	29,115	—	—	—	—
Loan	8	—	—	—	82,973	82,973	—	—	—	—
Lease liabilities	8	—	—	—	16,798	16,798	—	—	—	—
		—	—	—	128,886	128,886	—	—	—	—

B. Measurement of fair values

i. Valuation techniques and significant unobservable inputs

The contingent consideration receivable from Novartis as of September 30, 2022 and 2021, and December 31, 2021, has been measured using a probability-weighted discounted cash flow valuation technique, which considers the present value of expected payments, discounted using a risk-adjusted discount rate. Significant inputs to the valuation as of September 30, 2022 are as follows:

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

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

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KSEK	Profit or loss	
	Increase	Decrease
September 30, 2022		
Risk-neutral expected payments to the Group (+/- 1,000bps)	1,048	-1,048

ii. Transfers

During the three and nine months ended September 30, 2022 and 2021, there were no transfers of financial instruments between the different valuation hierarchy categories.

iii. Reconciliation of Level 3 fair values

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

KSEK	Contingent consideration
Balance, January 1, 2022	18,289
Cash received	-7,522
Exchange	—
Changes in Fair Value	—
Foreign currency (included in 'net gains/losses on financial items')	932
Balance, September 30, 2022	11,699

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, 2022, the Group held an ownership percentage of 27.6% 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 for the three months ended September 30, 2022, of which SEK 0.3 million was eliminated as it represents Saniona's share of the revenue and loss of Cephagenix for the period. Saniona recognized gross revenue of SEK 2.5 million from this agreement for the nine months ended September 30, 2022, of which SEK 0.6 million was eliminated since it represents Saniona's share of the revenue and loss of Cephagenix for the period.

In May 2022 the Group entered into a Consultancy Agreement with the Chairman of the board, Jørgen Drejer, for the provision of advisory services regarding Saniona's research and development, business development and financing effort. The fee is 80,000 DKK per month (113,000 SEK per month). The Agreement can be terminated by either party with sixty days' notice.

During the three months ended September 30, 2022, a total of 2,129,821 options, were granted to CEO and CFO. During the three and nine months ended September 30, 2022, and 2021, a total of 2,192,821 and 0 options, respectively, were granted to CEO and CFO, refer to Note 5 Share-based payments.

Note 11 Subsequent Events to the Balance Sheet Date

- On November 3, Saniona announced that **SAN903 is ready to start the regulatory process for entering Phase 1 clinical trials.**

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, 2022. 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 17, 2022

Deloitte AB

Jeanette Roosberg
Authorized Public Accountant

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This information is such information as Saniona AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out above, at 8.00 CET on 17 November 2022.

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