

Saniona is set for progress through partnerships

Three Months Ended December 31, 2022 (2021)	Twelve Months Ended December 31, 2022 (2021)
Revenue was SEK 3.3 M (2.9 M)	Revenue was SEK 15.3 M (10.5 M)
Operating profit/loss was SEK -22.6 M (-125.7 M)	Operating profit/loss was SEK -225.7 M (-411.6 M)
Net profit/loss was SEK -40.9 M (-129.9 M)	Net profit/loss was SEK -245.4 M (-410.9 M)
Basic earnings/loss per share was SEK -0.66 (-2.08)	Basic earnings/loss per share was SEK -3.93 (-6.59)
Diluted earnings/loss per share were SEK -0.66 (-2.08)	Diluted earnings/loss per share were SEK -3.93 (-6.59)

Business highlights in Q4 2022

- On November 3, Saniona announced that **SAN903 is ready to start the regulatory process for entering Phase 1 clinical trials.**
- On December 20, Saniona announced that **SAN2219 is selected as the first preclinical development candidate** from its GABA-A $\alpha 2/\alpha 3$ activator program.

Significant events after the reporting period

- On January 17, Saniona announced **successful preclinical in vivo validation** for treatment of migraine in the Cephagenix joint venture program.

Comments from the CEO

“Saniona has successfully reached all the expected milestones and important inflection points for 2022 in our pipeline programs, with the exception of Tesomet, which was put on hold in March. We continue to make strong progress with our partnering efforts and are engaging in constructive discussions on structures and financial terms with several potential partners. As a result of these concrete discussions, our current objective is to establish at least two new partnerships this year, with the aim of concluding at least one by the end of H1. I’m proud of what our team has accomplished following the restructuring in 2022 and grateful for the support of our shareholders. I look forward to keeping you updated on our exciting journey in the coming year.”

For more information, please contact

Thomas Feldthus, CEO, +45 22109957; thomas.feldthus@saniona.com

Forward-looking statements

The report contains certain forward-looking information that reflects Saniona’s current views of future events and financial and operational performance. Words such as “intends”, “anticipates”, “expects”, “can”, “plans”, “estimates” and similar expressions regarding indications or forecasts of future developments or trends, and which are not based on historical facts, constitute forward-looking information. Forward-looking information is inherently associated with both known and unknown risks and uncertainties because it is dependent on future events and circumstances. Forward-looking information is not a guarantee of future results or developments and actual results may differ materially from results referred to in forward-looking information. Forward-looking information in the report is only applicable on the date of issue of the report. Saniona does not commit to publishing updates or revision of any forward-looking statements as a result of new information, future events or similar circumstances other than those required by applicable legislation.

Letter from the CEO

2022 was a very unusual year for the biotech industry, as for Saniona. Challenging global developments and markets have impacted the company and our peers, and I am proud to be able to say that Saniona has continued to progress in these volatile times, even though we found it necessary to close our Tesomet Phase 2b study and U.S. operations.

I was honored to be offered the position as CEO in April 2022. My first short-term goal was to secure a solid financial runway, independent of dilutive funding. The restructuring of the company and the renegotiation of the maturity date for an outstanding loan were important components of saving and optimizing the use of the company's cash position. We have thereby reached our target of reducing operating expenses by about 75% and extending the company's runway by about 18 months. This means that the current cash position is expected to fund the planned activities until the end of January 2024, when the loan becomes payable.

We have refocused our efforts 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 further solidify our balance sheet and finance our internal develop programs, thereby enabling us to deliver new valuable breakthrough medicine from our advanced programs in the longer term.

We continue to make progress on partnering and are exploring opportunities on several of our clinical stage and preclinical assets as well as our platform. We have had numerous non-confidential and confidential meetings. Many biopharmaceutical companies have entered our program data rooms and we are engaged in constructive discussions about deal structure and financial terms with several potential partners, some of whom are interested in the same program. As a result of these concrete discussions, our current objective is to establishing at least two new partnerships this year, with the aim of concluding at least one by the end of H1.

In parallel to these restructuring and partnering activities, I am pleased to report that apart from Tesomet, we have reached all the set milestones and important inflection points for 2022 on our pipeline programs.

- In June, we reported the successful completion of our Phase 1 clinical trial of SAN711. 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 α 3 concept for effective and tolerable pain management in severely impacted neuropathic patient populations and/or in various types of epilepsies including absence seizures and rare epileptic syndromes such as pediatric patients living with ESES (electrical status epilepticus during slow-wave sleep).
- In November we announced that SAN903 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.
- In December, we selected SAN2219 as the first preclinical development candidate from our GABA_A α 2/ α 3 activator program. SAN2219 has demonstrated highly encouraging efficacy in several in vivo seizure models and has the potential to fulfill important unmet medical needs within epilepsy with strong seizure control, high tolerability, and low potential for tachyphylaxis (loss of effect)..
- In August, we progressed our Kv7 ion channel epilepsy program into lead optimization phase, the last drug discovery phase before potential drug candidate selection. While Kv7 modulation is a clinically proven concept for treatment of epilepsy, no drugs of this class are currently on the market, and we see significant potential for delivering new breakthrough epilepsy treatments in this field. This potential is also illustrated by the increasing numbers of mutations in Kv7.2 and Kv7.3 that are found to be associated with severe inherited forms of epilepsy.

- Earlier in the year Saniona announced that the ongoing ion channel research collaboration for schizophrenia with Boehringer Ingelheim has advanced to the 'hit-to-lead' stage. The collaboration is focused on a novel, undisclosed CNS ion channel target. Saniona receives ongoing research funding and may receive up to €76.5 million in milestone payments as well as royalties on worldwide net sales.
- Finally, in January 2023 we announced successful preclinical in vivo validation in the Cephagenix joint venture program, which is aimed at identifying subtype-selective ATP-sensitive potassium channel (KATP) inhibitors for the treatment of migraine. In this program, we have identified the first generation of novel highly selective inhibitors of the specific KATP channel subtype expressed in the intracranial arteries and demonstrated that these compounds are effective in relevant in vivo animal models.

We see significant potential for multiple value-creating milestones in 2023 including the establishment of partnerships around our programs. This may generate funding for the partnered programs and also for internal development programs. With this expectation, we have developed plans for our clinical stage assets and initiated activities to ensure that these programs can be advanced as quickly as possible, as and when we have the resources to develop them internally.

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 enable us to progress our pipeline, both with external partners and internally, and provide the foundation for delivering valuable new breakthrough medicines.

I am proud of what our team has accomplished, and the progress made following the restructuring in 2022. I'm also grateful for the support of our shareholders. We look forward to keeping you updated on our exciting journey in the coming year.

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 three product candidates, SAN711, SAN903 and SAN2219. 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. SAN2219 is in preclinical development for epilepsy. 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>	Neuropathic pain and epilepsy							<ul style="list-style-type: none"> Positive Phase 1 data reported
SAN903 <i>(IK channel blocker)</i>	Fibrotic and inflammatory disorders							<ul style="list-style-type: none"> Phase 1 ready
SAN2219 <i>(GABA α2/3/5 PAM)</i>	Epilepsy							<ul style="list-style-type: none"> Entered into Preclinical Development

Tesofensine

Saniona's partner Medix has completed a successful Phase 3 study and submitted a new drug application to the Mexican food and drug administration for approval of tesofensine for the treatment of patients with obesity. Medix has informed that they have a constructive dialogue with the Mexican regulatory authority (COFEPRIS) about the process for obtaining market approval for tesofensine in Mexico. Medix holds an exclusive license to commercialize tesofensine in Mexico and Argentina, while Saniona is entitled to milestone payments and royalties on product sales. Saniona retains commercial rights in the rest of the world and rights to use any data generated from the Phase 3 trial.

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 initiated a Phase 2b study in 2021, which was put on hold in March 2022 because of the funding situation. The Company is actively exploring partnership options, including worldwide partnerships, that could generate immediate non-dilutive income and enable Tesomet to move forward. Saniona has in parallel explored an alternative 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 additional financing has been secured.

HO is a rare neuroendocrine disorder most commonly caused by damage to the hypothalamus sustained during the removal of a craniopharyngioma (CP), a rare, non cancerous 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.

Saniona has completed a 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. 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 growth

hormone therapy does not reduce the hyperphagia symptoms experienced by these patients.

Saniona has completed a 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.

SAN711

SAN711 is a novel potentially first-in-class selective positive allosteric modulator (PAM) of GABA_A α 3 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 α 3 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 α 3 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 α 1 and α 5 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 α 3 GABA_A 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 GABA_A 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 dose-limiting adverse effects or 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.

Consequently, SAN711 shows clear differentiation in its side effect profile compared to classical, non-selective GABA_A modulators of the benzodiazepine type, such as valium, which is dose limited by sedation. Importantly, Saniona has 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 study results provide a clear guidance for the design of the Phase 2 studies with 0.8 mg/kg twice daily projected to be 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 neuropathic pain and/or in various types of epilepsies including absence seizures and rare epileptic syndromes such as pediatric patients living with ESES (electrical status epilepticus during sleep). Saniona is currently developing clinical plans within rare- as well as more common therapeutic areas to carry out either by Saniona alone or together with a partner.

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 successfully completed the preclinical development and the program is now ready 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.

SAN2219

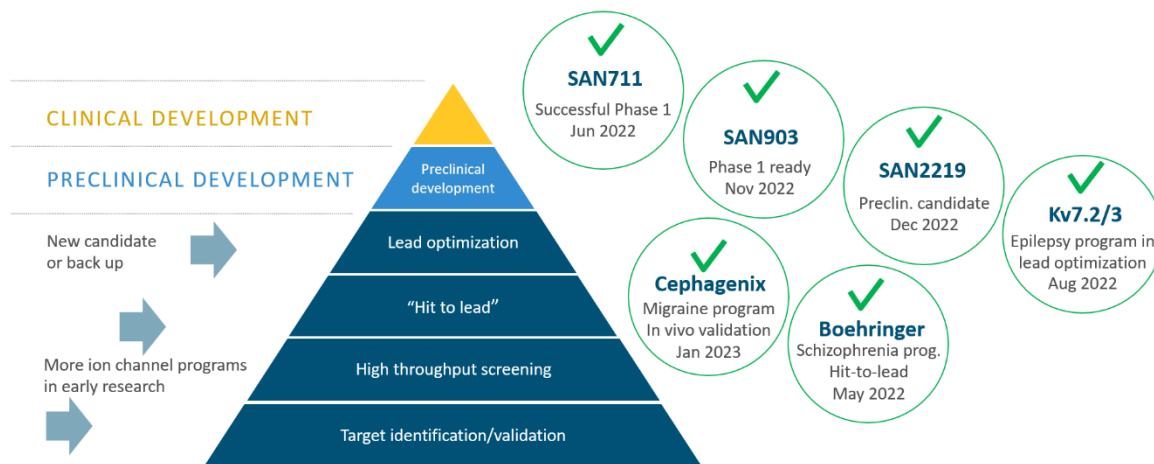
SAN2219 is a subtype selective activator of GABA_A α 2/ α 3/ α 5 receptors specifically designed to exert robust anti-seizure activity by dampening excessive neuronal activation. The program has been advanced to preclinical development and hence represents the first preclinical development candidate from Saniona's GABA_A α 2/ α 3 activator program.

GABA is a neurotransmitter that inhibits signals between nerve cells in the brain. Most forms of epilepsy are caused by an over-excitability in specific neural circuits. By inhibiting the over-excitability in epilepsy, benzodiazepines have proven to be among the most effective treatment principles for control of seizure activity. Benzodiazepines are non-selective GABA_A modulators that broadly activate GABA receptors including the GABA_A α 1 receptor subtype. Benzodiazepines are often used as rescue medicine in acute epilepsy, and their long-term use is often hampered by the development of tolerance to seizure control, withdrawal symptoms, and adverse events, such as cognitive impairment and sedation.

The dose limiting side effects and tolerance development of benzodiazepines are primarily mediated by the GABA_A α 1 receptors. SAN2219 has been designed to selectively modulate GABA_A α 2, α 3 and α 5, resulting in a robust inhibition of seizure activity without the well-known GABA_A α 1 mediated side effects of benzodiazepines. The preclinical data supports that SAN2219 may be used for acute and chronic treatment of prevalent epilepsy forms as well as specific epilepsy syndromes.

R&D Ion Channel Pipeline

Saniona Drug Discovery Engine Generates Continual Pipeline*



* All 2022/2023 ion channel milestones achieved

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, ADME, 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, SAN903 and SAN2219. The latter was selected as a preclinical development candidate for epilepsy in 2022.

Further, in 2023, we have obtained important in vivo validation of a novel potentially transformative principle for treatment of migraine developed in the Saniona-Cephagenix joint venture program. This program is headed by Professor Jes Olesen, who recently was awarded the very prestigious Lundbeck foundation Brain-prize for his life-long contribution to migraine research.

In addition, we have currently several active research programs of which one is developed together with Boehringer Ingelheim, further validating Saniona's strong expertise and powerful drug discovery capabilities. 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.

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

	2022-10-01	2021-10-01	2022-01-01	2021-01-01
	2022-12-31	2021-12-31	2022-12-31	2021-12-31
Revenue, KSEK	3,306	2,881	15,283	10,478
Total operating expenses, KSEK	-25,912	-128,544	-241,002	-422,048
Operating profit (loss), KSEK	* -22,606	* -125,663	* -225,719	* -411,570
Operating margin, %	* -684%	* -4,362%	* -1,477%	* -3,928%
Cash flow for the period, KSEK	-19,849	-69,797	-295,215	-251,280
Cash flow per share, SEK	* -0.32	* -1.12	* -4.73	* -4.03
Average shares outstanding	62,385,677	62,385,677	62,385,677	62,381,454
Diluted average shares outstanding	62,385,677	62,385,677	62,385,677	62,381,501
Shares outstanding at the end of the period	62,385,677	62,385,677	62,385,677	62,385,677
Average number of employees	23.7	52.7	34.39	49.2

	2022-10-01	2021-10-01	2022-01-01	2021-01-01
	2022-12-31	2021-12-31	2022-12-31	2021-12-31
Profit/loss for the period, KSEK	-40,949	-129,918	-245,357	-410,898
Shares outstanding at the end of the period	62,385,677	62,385,677	62,385,677	62,385,677
Earnings per share, SEK	-0.66	-2.08	-3.93	-6.59
Diluted earnings per share, SEK	-0.66	-2.08	-3.93	-6.59

	2022-12-31	2021-12-31
Cash and cash equivalent, KSEK	111,707	356,855
Equity, KSEK	52,708	281,999
Total Equity and liabilities, KSEK	153,696	440,248
Liquidity ratio, %	* 556%	* 599%
Equity ratio, %	* 34%	* 64%
Equity per share, SEK	* 0.84	* 4.52

* = Alternative performance measures

Results of Operations

Revenue

Three Months Ended December 31, 2021 and 2022

Revenue increased by SEK 0.4 million from SEK 2.9 million for the three months ended December 31, 2021, to SEK 3.3 million for the three months ended December 31, 2022.

Twelve Months Ended December 31, 2021 and 2022

Revenue increased by SEK 4.8 million from SEK 10.5 million for the twelve months ended December 31, 2021, to SEK 15.3 million for the twelve months ended December 31, 2022.

Operating expenses

In spring 2022, Saniona initiated a two-step process to reduce its annual base cost by closing the Phase 2b clinical trials of Tesomet and closed its U.S. operations. This has significantly reduced the company's operating expenses, personnel costs, external development costs and other costs.

Three Months Ended December 31, 2021 and 2022

Operating expenses decreased by SEK 102.6 million from SEK 128.5 million for the three months ended December 31, 2021, to SEK 25.9 million for the three months ended December 31, 2022.

Within operating expenses, external expenses decreased by SEK 69.0 million from SEK 82.7 million for the three months ended December 31, 2021, to SEK 13.7 million for the three months ended December 31, 2022. The main components of our external expenses are external research and development expenses, which are primarily attributable to contract research organizations (CROs) and contract manufacturing organizations for our clinical trials. External research and development expenses for the three months ended December 31, 2022, comprised primarily of development costs of Tesomet (SEK 2.0 million), development costs of SAN711 (SEK 1.6 million) and pre-clinical development costs of the SAN903 program (SEK 0.8 million) and other research costs. For the three months ended December 31, 2021, external expenses comprised primarily of development costs of Tesomet (SEK 30.7 million) followed by preclinical development costs of SAN711 (SEK 15.8 million) and pre-clinical development costs of the SAN903 program (SEK 4.6 million) and other research costs. In April 2022 Saniona closed its operations in U.S. and closed the Phase 2b clinical trials of Tesomet for HO and PWS, therefore external expenses of development costs of Tesomet have decreased.

Personnel costs include salaries, variable compensation, social security, and other employee benefits. Personnel costs decreased by SEK 32.9 million from SEK 42.4 million for the three months ended December 31, 2021, to SEK 9.5 million for the three months ended December 31, 2022. Non-cash share-based compensation expense decreased by SEK 8.6 million from SEK 9.6 million for the three months ended December 31, 2021, to SEK 1.0 million for the three months ended December 31, 2022.

Twelve Months Ended December 31, 2021 and 2022

Operating expenses decreased by SEK 181.0 million from SEK 422.0 million for the twelve months ended December 31, 2021, to SEK 241.0 million for the twelve months ended December 31, 2022.

Within operating expenses, external expenses decreased by SEK 92.8 million from SEK 239.3 million for the twelve months ended December 31, 2021, to SEK 146.5 million for the twelve months ended December 31, 2022. The main components of our external expenses are external research and development expenses, which are primarily attributable to contract research organizations (CROs) and contract manufacturing organizations for our clinical trials. External research and development expenses for the twelve months ended December 31, 2022, comprised primarily of development costs of Tesomet (SEK 49.9 million), development costs of SAN711 (SEK 35.3 million) and pre-clinical development costs of the SAN903 program (SEK 11.2 million) and other research costs. For the twelve months ended December 31, 2021, external expenses comprised primarily of development costs of Tesomet (SEK 121.3 million) followed by preclinical development costs of SAN711 (SEK 26.7 million) and pre-clinical development costs of the SAN903 program (SEK 7.7 million) and other research costs. In April 2022 Saniona closed its operations in U.S. and closed the Phase 2b clinical trials of Tesomet for HO and PWS, therefore external expenses of development costs of Tesomet have decreased.

Personnel costs, which includes salaries, variable compensation, social security, and other employee benefits, decreased by SEK 87.3 million from SEK 169.5 million for the twelve months ended December 31, 2021, to SEK 82.2 million for the twelve months ended December 31, 2022. Non-cash share-based compensation expense decreased by SEK 65.1 million from SEK 47.1 million for the twelve months ended December 31, 2021, to a profit of SEK 18.0 million for the twelve months ended December 31, 2022. SEK 47.0 million of the total personnel costs in the twelve months ended December 31, 2022, are related to closure of our US business and 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 twelve months ended December 31, 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, costs related to ongoing evaluation of a U.S. listing 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 December 31, 2021 and 2022

Net loss from total financial items increased from SEK 4.3 million for the three months ended December 31, 2021, to SEK 18.6 million for the three months ended December 31, 2022, of which SEK 11.5 million represents a decrease in the fair value of the long-term asset, Cadent.

Twelve Months Ended December 31, 2021 and 2022

Net loss from total financial items increased from SEK 6.8 million for the twelve months ended December 31, 2021, to SEK 26.2 million for the twelve months ended December 31, 2022.

Tax Benefit

Three Months Ended December 31, 2021 and 2022

The Group recognized a tax income of SEK 0.3 million for the three months ended December 31, 2022, compared to SEK 0 for the three months ended December 31, 2021. The increase is a tax income recognized in Saniona Inc.

Twelve Months Ended December 31, 2021 and 2022

The tax benefit on net loss recognized under the Tax Credit Scheme in Denmark increased by SEK 0.7 million from SEK 7.5 million for the twelve months ended December 31, 2021, to SEK 8.2 million for the twelve months ended December 31, 2022, because of exchange rate fluctuations. The net tax benefit for the Group is SEK 6.6 million for the twelve months ended December 31, 2022, and also consist of a tax cost in Saniona Inc of SEK 1.6 million.

Cash flow

Three Months Ended December 31, 2021 and 2022

Net cash used in operating activities decreased by SEK 49.9 million from SEK -68.2 million for the three months ended December 31, 2021, to SEK -18.3 million for the three months ended December 31, 2022.

The operating cash flow for the three months ended December 31, 2022, is primarily attributable to our operating loss of SEK 19.9 million (net of non-cash operating expenses for share-based payments of SEK 1.0 million and for expenses depreciation of SEK 1.7 million). The operating cash flow for the three months ended December 31, 2021, is primarily attributable to our operating loss of SEK 113.8 million (net of non-cash operating expenses for share-based payments of SEK 9.6 million and for depreciation of SEK 2.2 million).

For the three months ended December 31, 2022, net cash used by investing activities was SEK 0.7 million, due to purchase of equipment. For the three months ended December 31, 2021, net cash used by investing activities was SEK 0.2 million, due to purchase of equipment.

For the three months ended December 31, 2022, net cash used by financing activities was SEK 0.9 million, due to repayment of lease liabilities. For the three months ended December 31, 2021, net cash provided by financing activities was SEK 1.4 million, due to repayment of lease liabilities.

For the three months ended December 31, 2022 and 2021, cash and cash equivalents amounted to SEK 111.7 million and SEK 356.9 million, respectively. Approx 45% and 55% of cash and cash equivalents is denominated in USD and DKK, respectively as of December 31, 2022.

Twelve Months Ended December 31, 2021 and 2022

Net cash used in operating activities decreased by SEK 63.5 million from SEK -345.0 million for the twelve months ended December 31, 2021, to SEK -281.5 million for the twelve months ended December 31, 2022.

The operating cash flow for the twelve months ended December 31, 2022, is primarily attributable to our operating loss of SEK 235.9 million (net of non-cash operating profit for share-based payments of SEK 18.0 million and expenses for depreciation of SEK 7.8 million). The operating cash flow for the twelve months ended December 31, 2021, is primarily attributable to our operating loss of SEK 355.7 million (net of non-cash operating expenses for share-based payments of SEK 47.2 million and for depreciation of SEK 8.7 million).

For the twelve months ended December 31, 2022, net cash provided by investing activities was SEK 6.8 million, due to purchase of equipment of SEK 1.0 million and sale of financial assets of SEK 7.5 million. For the twelve months ended December 31, 2021, net cash provided by investing activities was SEK 43.2 million, due to purchase of equipment of SEK 1.5 million and sale of financial assets of SEK 44.6 million.

For the twelve months ended December 31, 2022, net cash used by financing activities was SEK 20.5 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 5.5 million. For the twelve months ended December 31, 2021, net cash provided by financing activities was SEK 50.6 million, primarily attributable to the receipt of net proceeds of SEK 81.8 million from 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 6.4 million.

Parent Company

In spring 2022, Saniona initiated a two-step process to reduce its annual base cost. This has significantly reduced the company's operating expenses during the last three quarters of 2022.

Three Months Ended December 31, 2021 and 2022

Operating expenses decreased by SEK 46.9 million from SEK 48.8 million for the three months ended December 31, 2021, to SEK 1.9 million for the three months ended December 31, 2022.

Loss decreased by SEK 46.9 million from a loss of SEK 53.4 million for the three months ended December 31, 2021, to a loss of SEK 6.5 million for the three months ended December 31, 2022.

Twelve Months Ended December 31, 2021 and 2022

Operating expenses decreased by SEK 37.2 million from SEK 65.6 million for the twelve months ended December 31, 2021, to SEK 28.4 million for the twelve months ended December 31, 2022.

Loss decreased by SEK 679.6 million from a loss of SEK 721.9 million for the twelve months ended December 31, 2021, to a loss of SEK 42.3 million for the twelve months ended December 31, 2022.

The share, share capital and ownership structure

On December 31, 2022, the company had 10,145 (9,289) shareholders excluding holdings in life insurance and foreign custody account holders. Equity was SEK 52.7 million (282.0).

Personnel

As of December 31, 2022, Saniona had 23 (53) employees including 10 (14) employees with Ph.D. degrees. Of these employees, 17 (36) were engaged in research and clinical development activities and 6 (17) were engaged in general and administrative activities. Of the 23 (53) employees, 12 (29) 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 have 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 DKK, and the USD 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 balances its currency exposure primarily by matching expenses in the same currency. Approx 55% and 45% of cash and cash equivalents is denominated in DKK and USD, respectively as of December 31, 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.

Audit review

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

Financial calendar

Interim Report Q1	May 25, 2023, at 8:00 CEST
Annual General Meeting	May 25, 2023, at 10:00 CEST
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

Annual General Meeting 2023

Saniona's Annual General Meeting will be held at Setterwalls Advokatbyrå AB's office at Stortorget 23, Malmö, Sweden on May 25, 2023, at 10 am CEST.

The Board of Directors proposes that no dividend will be paid for the 2022 financial year.

The Annual Report for 2022 will be published on www.saniona.com no later than April 30, 2023. It will also be available at Saniona's head office at Smedeland 26B, 2600 Glostrup, Denmark.

Shareholders who wish to have a matter addressed at the Annual General Meeting should, to ensure that the proposal may be considered, send such proposal at least seven weeks prior to the meeting or at least in such time that the item, if necessary, can be included in the notice to attend the meeting. The Board of Directors can be contacted by email to clo@saniona.com marked "Annual General Meeting" or through regular mail to: Saniona AB, Att.: Anita Milland, Smedeland 26B, DK-2600 Glostrup, Denmark.

The Nomination Committee's member are: John Haurum, professional board member for life science companies and former CEO of F-star Biotechnology Limited, Cambridge, UK, appointed by Jørgen Drejer; Søren Skjærbæk, CEO at BiOrigin ApS, appointed by Dan Peters; and Jørgen Drejer, Chairman of Saniona AB's Board of Directors.

Shareholders who would like to submit proposals to the Nomination Committee can do so via e-mail to clo@saniona.com marked "Recommendation to the Nomination Committee" or by ordinary mail to the address: Saniona AB, Att. Anita Milland, Smedeland 26B, DK-2600 Glostrup, Denmark.

YEAR-END REPORT FOR SANIONA AB (PUBL)
January – December 2022

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

Glostrup, 23 February 2023
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	2022-10-01 2022-12-31	2021-10-01 2021-12-31	2022-01-01 2022-12-31	2021-01-01 2021-12-31
Revenue	1,2,3 4	3,306	2,881	15,283	10,478
Total operating income		3,306	2,881	15,283	10,478
Raw materials and consumables		-1,042	-1,278	-4,475	-4,630
Other external costs		-13,675	-82,699	-146,486	-239,267
Personnel costs	5	-9,512	-42,381	-82,223	-169,478
Depreciation and write-downs		-1,683	-2,186	-7,818	-8,673
Total operating expenses		-25,912	-128,544	-241,002	-422,048
Operating profit (loss)		-22,606	-125,663	-225,719	-411,570
Share of result of associate	10	50	—	346	—
Financial income		979	282	9,726	1,922
Financial expenses		-7,991	-4,140	-24,659	-13,128
Net gains on financial items		-11,661	-397	-11,661	4,396
Total financial items		-18,623	-4,255	-26,248	-6,810
Profit (loss) before tax		-41,229	-129,918	-251,967	-418,380
Income tax	6	280	—	6,610	7,482
Profit (loss) for the period		-40,949	-129,918	-245,357	-410,898
Other comprehensive income (loss) for the period					
<i>Item that may be reclassified to profit and loss</i>					
Translation differences		1,303	6,524	34,047	32,574
<i>Items that will not be reclassified to profit and loss</i>					
Equity instruments at FVOCI – net change fair value		—	—	—	5,063
Total other comprehensive income for the period, net after tax		1,303	6,524	34,047	37,637
Total comprehensive profit (loss)		-39,646	-123,394	-211,310	-373,261
Loss per share, SEK		-0.66	-2.08	-3.93	-6.59
Diluted loss per share, SEK		-0.66	-2.08	-3.93	-6.59

Unaudited condensed consolidated interim statement of financial position – Group

KSEK	Note	2022-12-31	2021-12-31
ASSETS			
Intangible assets		6,737	6,189
Property and equipment		5,703	5,100
Right of use assets		9,998	16,652
Investment in associate	10	799	670
Other financial assets	7,9	3,114	20,793
Non-current assets		26,351	49,404
Trade receivables		4,628	3,615
Current tax assets	6	8,234	7,564
Other financial assets	7,9	—	414
Other assets		2,776	22,396
Cash and cash equivalents		111,707	356,855
Current assets		127,345	390,844
Total assets		153,696	440,248

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

KSEK	Note	2022-12-31	2021-12-31
EQUITY AND LIABILITIES			
Share capital		3,119	3,119
Additional paid-in capital		813,261	813,261
Reserves		108,592	74,545
Accumulated deficit		-872,264	-608,926
Equity		52,708	281,999
Other financial liabilities	8,9	75,699	92,972
Other liabilities		2,392	—
Non-current liabilities		78,091	92,972
Trade payables		14,073	29,115
Other financial liabilities	8,9	5,822	6,799
Other liabilities		3,002	29,363
Current liabilities		22,897	65,277
Total liabilities		100,988	158,249
Total equity and liabilities		153,696	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	—	—	—	—	-410,898	-410,898
Reclassification of previously recorded net financial items from Additional paid-in capital to Loss for the period	—	4,414	—	—	—	4,414
Other comprehensive income:						
Fair value reserve	—	—	—	5,063	—	5,063
Translation differences	—	—	32,574	—	—	32,574
Total comprehensive income (loss)	—	4,414	32,574	5,063	-410,898	-368,847
Transactions with owners						
Shares issued for cash	—	321	—	—	—	321
Expenses related to capital increase	—	-81	—	—	—	-81
Share-based compensation expenses	—	—	—	—	47,148	47,148
Total transactions with owners	—	240	—	—	47,148	47,388
December 31, 2021	3,119	813,261	1,016	73,529	-608,926	281,999
January 1, 2022	3,119	813,261	1,016	73,529	-608,926	281,999
Comprehensive income						
Loss for the period	—	—	—	—	-245,357	-245,357
Other comprehensive income:						
Fair value reserve	—	—	—	—	—	—
Translation differences	—	—	34,047	—	—	34,047
Total comprehensive income (loss)	—	—	34,047	—	-245,357	-211,310
Transactions with owners						
Shares issued for cash	—	—	—	—	—	—
Expenses related to capital increase	—	—	—	—	—	—
Share-based compensation expenses	—	—	—	—	-17,981	-17,981
Total transactions with owners	—	—	—	—	-17,981	-17,981
December 31, 2022	3,119	813,261	35,063	73,529	-872,264	52,708

Unaudited condensed consolidated interim statement of cash flows – Group

KSEK	Note	2022-10-01	2021-10-01	2022-01-01	2021-01-01
		2022-12-31	2021-12-31	2022-12-31	2021-12-31
Loss before tax		-41,229	-129,918	-251,967	-418,380
Adjustments for non-cash transactions		2,706	12,257	-8,799	51,425
Changes in working capital		14,358	44,989	-17,554	24,929
Cash flow from operating activities before financial and tax items		-24,165	-72,672	-278,320	-342,026
Interest income received		364	32	593	278
Interest expenses paid		-2,576	-3,074	-11,936	-10,777
Tax credit received		8,126	7,487	8,126	7,487
Cash flow from operating activities		-18,251	-68,227	-281,537	-345,038
Investing activities					
Purchases of property and equipment		-676	-174	-985	-1,484
Proceeds from sale of financial assets		—	—	7,522	44,646
Proceeds from sale of tangible assets		1	—	306	—
Cash flow from investing activities		-675	-174	6,843	43,162
Financing activities					
Proceeds from issuance of loan		—	—	—	81,780
Repayment of loan		—	—	-15,000	-25,000
Proceeds from issuance of new shares		—	—	—	321
Costs related to issuance of new shares		—	—	—	-81
Payment of lease liabilities		-923	-1,396	-5,521	-6,424
Cash flow from financing activities		-923	-1,396	-20,521	50,596
Net increase (decrease) in cash and cash equivalents		-19,849	-69,797	-295,215	-251,280
Cash and cash equivalents at beginning		117,555	425,699	356,855	573,866
Exchange rate adjustments		14,001	853	50,067	34,269
Cash and cash equivalents at end of		111,707	356,855	111,707	356,855

PARENT COMPANY'S UNAUDITED FINANCIAL STATEMENTS

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

Unaudited statement of income – Parent Company

KSEK	Note	2022-10-01 2022-12-31	2021-10-01 2021-12-31	2022-01-01 2022-12-31	2021-01-01 2021-12-31
	1,2,3				
Other operating income		403	181	3,418	3,877
Total operating income		403	181	3,418	3,877
Raw materials and consumables		-7	-3	-30	-10
Other external costs		-1,049	-26,102	-10,602	-31,514
Personnel costs	5	-889	-22,729	-17,728	-34,038
Total operating expenses		-1,945	-48,834	-28,360	-65,562
Operating income (loss)		-1,542	-48,653	-24,942	-61,685
Financial income		28	3,138	391	5,875
Financial expenses		-4,997	-3,282	-17,785	-7,642
Net gains (losses) on financial items		—	-4,629	—	-658,449
Total financial items		-4,969	-4,773	-17,394	-660,216
Profit (loss) before tax		-6,511	-53,426	-42,336	-721,901
Tax on net profit (loss)		—	—	—	—
Profit (loss) for the period		-6,511	-53,426	-42,336	-721,901

Unaudited balance Sheet – Parent Company

KSEK	Note	2022-12-31	2021-12-31
ASSETS			
Investment in subsidiaries		341,703	359,908
Financial assets		341,703	359,908
Non-current assets		341,703	359,908
Receivables from group companies		—	—
Other assets		222	1,541
Current receivables		222	1,541
Cash and cash equivalents		2,228	12,106
Current assets		2,450	13,647
Total assets		344,153	373,555
EQUITY AND LIABILITIES			
<i>Restricted equity</i>			
Share capital		3,119	3,119
<i>Unrestricted equity</i>			
Share premium reserve		813,261	813,261
Retained earnings (accumulated deficit)		-552,357	187,524
Profit (loss) for the period		-42,336	-721,901
Equity		221,687	282,003
Other financial liabilities	8	70,636	82,973
Non-current liabilities		70,636	82,973
Trade payables		806	1,935
Payables to group companies		50,790	6,436
Other liabilities		234	208
Current liabilities		51,830	8,579
Total liabilities		122,466	91,552
Total equity and liabilities		344,153	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 and twelve months ended December 31, 2022, have been prepared in accordance with IAS 34 *Interim Financial Reporting*, the Annual Accounts Act, and the Financial Reporting Board's recommendation RFR 1, Supplementary Accounting Rules for Groups. The unaudited interim financial statements for the Parent Company are prepared under the requirements of chapter 9 of the Swedish Accounting Act (1995:1554). These unaudited condensed consolidated interim financial statements should be read in conjunction with the Group's last annual consolidated financial statements as at and for the year ended December 31, 2021 ('last annual financial statements'). They do not include all 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 December 31, 2022, the Group's current assets exceed current liabilities by SEK 104.4 million. Current assets include cash and cash equivalents of SEK 111.7 million.

The Board has a reasonable expectation that the Group has and will have adequate resources to continue in operation existence through at least January 2024 where the loan to Formue Nord becomes payable. The company plans to enter into partnerships on several of its assets to fund the further development of these assets and generate non-dilutive funding for progressing its internal developed assets. If necessary, the company may also renegotiate the loan agreement with Formue Nord and/or raise additional financing to fund the company's operation and further development of its pipeline programs.

These condensed consolidated financial statements were authorized for issue by the Parent Company's Board of Directors (the 'Board') on February 23, 2023.

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

Several 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 and the amended 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 twelve months ended December 31, 2022 and 2021, revenue for the Group by category was as follows:

KSEK	2022-10-01	2021-10-01	2022-01-01	2021-01-01
	2022-12-31	2021-12-31	2022-12-31	2021-12-31
License agreements (other event-based payments)	—	—	3,760	2,504
Research and collaboration agreements (bundle, over time)	2,608	1,937	8,293	5,714
Research and development services (standalone)	698	944	3,229	2,260
Total	3,306	2,881	15,282	10,478

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

KSEK	2022-10-01	2021-10-01	2022-01-01	2021-01-01
	2022-12-31	2021-12-31	2022-12-31	2021-12-31
Customer #1	—	—	3,760	2,504
Customer #2	698	944	3,229	2,260
Customer #3	2,608	1,937	8,293	5,714
Total	3,306	2,881	15,282	10,478

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

KSEK	2022-10-01	2021-10-01	2022-01-01	2021-01-01
	2022-12-31	2021-12-31	2022-12-31	2021-12-31
Sweden	—	—	—	—
Other European countries	3,306	2,881	11,522	7,974
The Americas	—	—	3,760	2,504
Total	3,306	2,881	15,282	10,478

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 twelve months ended December 31, 2022, as the underlying service conditions were not met. The expenses for the forfeited options during the twelve months ended December 31, 2022, have been reversed with SEK 27.2 million.

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 expenses for the three months ended December 31, 2022 and 2021 totaled SEK 1.0 million and SEK 9.6 million, respectively. Share-based compensation profit for the twelve months ended December 31, 2022, totaled SEK 18.0 million and a loss for the twelve months ended December 31, 2021, SEK 47.1 million. The expenses for the forfeited options during the twelve months ended December 31, 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	2018:3	2019:1	2019:2
Options outstanding, January 1	38,292	286,003	32,792	10,513	34,500	15,770
Granted during the year	—	—	—	—	—	—
Forfeited during the year	-38,292	—	—	-10,513	—	—
Options outstanding, December 31	0	286,003	32,792	0	34,500	15,770
Maximum number of shares to be issued	0	294,583	33,775	0	34,845	15,927
Grant Date Fair Value* (SEK)	27.94	12.06	17.38	12.89	7.23	6.00
Share Price at Grant Date* (SEK)	49.60	26.95	33.85	33.85	17.76	17.76
Exercise Price* (SEK)	40.63	33.20	29.71	29.71	17.83	17.83
Expected volatility*	73.41%	69.24%	67.77%	53.67%	57.29%	53.67%
Estimated life (years)*	3.75	3.88	3.73	2.8	3.67	2.80
Expected dividends*	0	0	0	0	0	0
Risk-free rate*	-0.2602%	-0.1092%	-0.2773%	-0.4218%	-0.6903%	-0.6709%
Remaining contractual life (years)*	0.00	1.50	0.96	0.00	2.00	0.75

Incentive program	2020:1	2020:2	2020:3	2021:1	2021:2	2022:1	Total
Options outstanding, January 1	710,313	5,915,648	308,000	902,000	148,350	0	8,402,181
Granted during the year	—	—	—	—	—	2,129,821	2,129,821
Forfeited during the year	-355,157	-5,030,948	-25,667	-901,300	-148,350	—	-6,510,227
Options outstanding, December 31	355,156	884,700	282,333	700	0	2,129,821	4,021,775
Maximum number of shares to be issued	358,707	884,700	282,333	700	0	2,129,821	4,035,391
Grant Date Fair Value* (SEK)	12.26	13.13	7.98	10.75	10.18	1.59	
Share Price at Grant Date* (SEK)	28.10	23.50	23.55	19.31	18.88	4.24	
Exercise Price*(SEK)	29.36	24.12	25.40	19.38	19.26	5.89	
Expected volatility*	58.66%	63.64%	57.00%	62.56%	61.32%	57.65%	
Estimated life (years)*	4.20	6.10	2.80	6.11	6.11	4.17	
Expected dividends*	0	0	0	0	0	0	
Risk-free rate*	-0.2280%	-0.2772%	-0.3602%	-0.2046%	-0.5225%	2.0670%	
Remaining contractual life (years)	3.00	7.83	1.92	8.11	8.40	6.01	

* Weighted average

As of December 31, 2022, the company has 4,021,775 options outstanding entitling to the subscription of maximum 4,035,391 new shares representing a dilution of 6.1 percent.

The weighted average exercise price of the options that forfeited during the three months ended December 31, 2022, was SEK 21.95. The weighted average exercise price of the options outstanding as of January 1, 2022, and December 31, 2022, was SEK 24.39 and SEK 15.59, respectively.

Note 6 Income tax

In the three months ended December 31, 2022, the Group recognized a tax income of SEK 0.3 million due to tax income recognized in Saniona Inc. after a correct for the full year tax. In the three months ended December 31, 2021, the Group recognized a current tax benefit of SEK 0 related to the Danish 'Skattekreditordningen' (the 'Tax Credit Scheme'). In the twelve months ended December 31, 2022 and 2021, the Group recognized a current tax benefit of SEK 6.6 million and SEK 7.5 million, respectively, hereof is SEK 8.2 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 37 million).

Note 7 Other financial assets

A. Composition

Other financial assets were comprised of the following:

KSEK	2022-12-31	2021-12-31
Contingent consideration receivable	241	18,289
Long-term deposits for property lease agreements	2,873	2,504
Total non-current other financial assets	3,114	20,793
Short-term deposit for property lease agreement	—	414
Total current other financial assets	0	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. As of December 31, 2022, the contingent consideration has been measured at SEK 0.2 million.

Note 8 Other financial liabilities

A. Composition

Other financial liabilities were comprised of the following:

KSEK	2022-12-31	2021-12-31
Lease liabilities	5,063	9,999
Formue Nord Loan	70,636	82,973
Other liabilities	2,392	—
Total non-current other financial liabilities	78,091	92,972
Lease liabilities	5,822	6,799
Total current other financial liabilities	5,822	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 December 31, 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, totaling SEK 74.2 million. 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.

December 31, 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	—	241	—	—	241	—	—	241	241
		—	241	—	—	241	—	—	241	241
Financial assets not measured at fair value										
Trade receivables		4,628	—	—	—	4,628	—	—	—	—
Other non-current financial assets	7	2,246	—	—	—	2,246	—	—	—	—
Other current financial assets	7	1,221	—	—	—	1,221	—	—	—	—
Cash and cash equivalents		111,707	—	—	—	111,707	—	—	—	—
		119,802	—	—	—	119,802	—	—	—	—
Financial liabilities not measured at fair value										
Trade payables		—	—	—	14,073	14,073	—	—	—	—
Formue Nord Loan	8	—	—	—	70,636	70,636	—	—	—	—
Lease liabilities	8	—	—	—	10,885	10,885	—	—	—	—
		—	—	—	95,594	95,594	—	—	—	—

YEAR-END REPORT FOR SANIONA AB (PUBL)

January – December 2022

December 31, 2021		Carrying amount					Fair value			
KSEK	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
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 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. As of December 31, 2022, the contingent consideration has been measured at SEK 0.2 million.

ii. Transfers

During the three and twelve months ended December 31, 2022 and 2021, there were no transfers of financial instruments between the different valuation hierarchy categories.

YEAR-END REPORT FOR SANIONA AB (PUBL)

January – December 2022

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	-11,700
Foreign currency (included in 'net gains/losses on financial items')	1,174
Balance, December 31, 2022	241

Note 10 Related parties

In May 2021, Saniona became a minority shareholder of Cephagenix ApS ('Cephagenix'), a private Denmark-based company formed to explore ion channel modulators for the treatment of migraine. As of December 31, 2022, the Group held an ownership percentage of 23.5% of Cephagenix, and accounts for this holding as an investment in associate under the equity-method of accounting.

Saniona has an existing research services agreement with Cephagenix which was entered into in January 2020. Saniona recognized gross revenue of SEK 1.0 million from this agreement for the three months ended December 31, 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 3.2 million from this agreement for the twelve months ended December 31, 2022, of which SEK 0.9 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 twelve months ended December 31, 2022, and 2021, a total of 2,129,821 and 0 options, respectively, were granted to CEO and CFO, refer to Note 5 Share-based payments.

YEAR-END REPORT FOR SANIONA AB (PUBL)
January – December 2022

This information is such information as Saniona AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 8.00 CET on 23 February 2023.

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