YEAR-END REPORT FOR SANIONA AB (PUBL)
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January – December 2023
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Rights issue paves the way for epilepsy pipeline and partnerships

Three Months Ended December 31, 2023 (2022 restated)	Twelve Months Ended December 31, 2023 (2022 restated)
Revenue was SEK 5.4 M (3.3 M)	Revenue was SEK 16.8 M (15.3 M)
Operating profit/loss was SEK -19.8 M (-22.6 M)	Operating profit/loss was SEK -81.1 M (-225.7 M)
Net profit/loss was SEK -28.7 M (-7.2 M)	Net profit/loss was SEK -95.8 M (-211.6 M)
Cash and cash equivalent SEK 31.0 M (111.7 M)	Cash and cash equivalent SEK 31.0 M (111.7 M)
Basic earnings/loss per share was SEK -0.45 (-0.11)	Basic earnings/loss per share was SEK -1.49 (-3.39)
Diluted earnings/loss per share were SEK -0.45 (-0.11)	Diluted earnings/loss per share were SEK -1.49 (-3.39)

Business highlights in Q4 2023

- In October, Saniona's partner, AstronauTx, closed a $61 million financing led by the Novartis Venture Fund.
- In November, Professor Vincenzo Crunelli presented preclinical data at the annual meeting of the Society for Neuroscience demonstrating that SAN711 represents a novel precision approach for treatment of absence seizures.
- In November, Saniona announced that it has initiated the candidate selection phase with a frontrunner molecule from its Kv7 program for epilepsy.
- In December, Saniona announced that it plans to carry out a right issue of units.
- In December, Saniona announced that the research collaboration with Boehringer Ingelheim has been extended with up to two years.
- In December, Saniona strengthened its epilepsy pipeline with selection of SAN2355 as the first preclinical candidate from the Kv7 program.

Significant events after the reporting period

- In January, Saniona announced selection of SAN2465 as a preclinical candidate for major depressive disorder.
- In January, the board of directors resolved on an issue of units consisting of shares and warrants with preferential rights for the existing shareholders, which was approved at the extraordinary general meeting on January 16, 2024.
- In January, Saniona announced the preliminary 2023 financials.
- In February, Saniona announced outcome in rights issue of a proceed of approximately SEK 88.9 million before issue costs and a directed issue of units to guarantors in the rights issue as well as convertibles of SEK 10 million to Formue Nord.

Comments from the CEO

"Since the beginning of 2023 we have established a new and fully funded research collaboration, selected two new unique development candidates, reduced our debt with about 45%, and developed a sustainable and coherent business strategy for creating value with a focus on epilepsy. Our development pipeline is stronger than ever comprising three epilepsy assets and four non-epilepsy assets of which the most advanced program has progressed to final regulatory evaluation together with a partner. Our research activities are now fully funded through three partnerships and cover a fair share of our operating overheads. In February we completed a rights issue. The proceeds will be used to progress our epilepsy assets, including SAN711 and SAN2355, as well as to support our business development efforts. With a potential market approval on tesofensine and new potential partnerships underway, I am looking forward to providing further updates in the coming year."

For more information, please contact

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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

Our focus during 2023 was two-fold; to keep establishing productive commercial collaborations through our business development efforts and, at the same time, progressing our portfolio by leveraging Saniona's expertise in the field of ion-channel drug discovery to identify and propel additional selective ion channel clinical candidates in a range of epilepsy indications and beyond. I am proud of the significant advancements we made during the year, in particular in our epilepsy pipeline.

During the fourth quarter, we selected two clinical candidates: SAN2355 for epilepsy and SAN2465 for major depressive disorder (MDD). The selection of SAN2355 as the first clinical candidate from our Kv7 epilepsy program marks a significant epilepsy pipeline milestone as Kv7 activation, based on the existing clinical experience represents a validated mechanism of action to control seizures. SAN2355 could represent a promising new generation of subtype selective, effective, and well-tolerated anti-seizure medication. The selection of SAN2465 as a clinical candidate for MDD follows encouraging results which positions SAN2465 as an innovative and rapid-acting approach to treating MDD and its associated comorbidities. Development of rapid-acting treatments for depression has been a major hurdle for the pharmaceutical industry during the past decades, and we see a huge commercial potential for SAN2465. Following the selection announcement in January we have started to reach out to companies with an interest in MDD.

Earlier in 2023, we partnered with AstronauTx on Alzheimer's research, potentially earning up to SEK 1.9 billion ($177 million) in milestones and royalties on global sales. Together with the prolonged research collaboration with Boehringer Ingelheim announced in December 2023, we expect total research funding of about SEK 27.3 million (€2.4 million) on annual basis. The objective of the collaboration with Boehringer Ingelheim is to identify new treatment options for schizophrenia. Saniona may receive up to SEK 860 million (€76.5 million) in milestone payments as well as royalties on worldwide net sales.

Medix, our Mexican partner, considers tesofensine to have a significant commercial potential for the treatment of patients with obesity in Mexico and that it will be a key product for Medix going forward. The regulatory committee gave an initial positive opinion in 2023, and Medix has formally applied for approval. Medix is in dialogue with the regulatory agency, anticipating a favorable outcome. Tesofensine, a well-tolerated treatment with efficacy comparable to injectable GLP-1 analogs, could be a strong contender in the $190 million Mexican obesity market. Saniona stands to gain royalties if approved, and we'll explore further commercialization in other regions, using Mexico as a reference for regulatory approval.

In February, the rights issue announced in mid-December was subscribed. Initially, Saniona will receive approximately SEK 88.9 million before issue costs, and in the following exercise of issued series TO 4 warrants, Saniona may receive additional proceeds in April 2025. The rights issue was subscribed to a total of approximately 63 percent and no issue guarantees needed to be used. I want to thank all new and existing shareholders for your trust and support.

Prior to this financing we agreed with Formue Nord to use SEK 20 million of the net proceeds to pay off debt. Following the rights issue, we have taken certain initiatives to reduce our operational costs further without affecting our research activities, which are fully funded through partnerships and cover a fair share of our overheads. The cost reduction means that the lion's share of the net proceeds following repayment of debt will be allocated to progress our epilepsy assets, including SAN711 and SAN2355, as well as to support our business development efforts with the objective of improving the likelihood of establishing additional collaborations. This will enable us to initiate the proof-of-concept studies for SAN711 and progress other epilepsy assets into clinical development either in collaboration with partners or internally based on income from new partnerships, milestones under existing collaboration agreements, and potential royalties under the agreement with Medix.

Our research platform has demonstrated significant potential in creating innovative treatment candidates for a range of neurological and psychiatric diseases. With a track record of successful partnerships, we're poised for further engagements. Confident in ongoing discussions, I anticipate securing additional partnerships this year. Moving ahead, we will intensify our initiatives to discover, develop and deliver innovative treatments to patients worldwide. I look forward to providing further updates on our progress.

Thomas Feldthus
CEO

About Saniona

Saniona (OMX: SANION) is a clinical-stage biopharmaceutical company leading the way in ion channel modulation for the treatment of epilepsy and other neurological disorders. Saniona's epilepsy pipeline features SAN711, a Phase 2-ready candidate drug targeting absence seizures, SAN2219 for acute repetitive seizures, and SAN2355, addressing refractory focal onset seizures. Beyond epilepsy, Saniona oversees four clinical programs poised for collaboration. Tesofensine, Saniona's most advanced candidate, is progressing towards regulatory approval for obesity in Mexico through a partnership with Medix. Tesomet™ is ready for Phase 2b, targeting rare eating disorders, while SAN903 is ready for Phase 1 for inflammatory bowel disease and SAN2465 is set for preclinical development for major depressive disorder. Saniona has esteemed partners, including Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V, AstronauTx Limited, and Cephagenix ApS. Saniona is based in Copenhagen and listed on Nasdaq Stockholm Main Market. For more information, please visit www.saniona.com.

Pipeline

Product Candidate	Indication	Research	LOP/CS	Pre-clinical	Phase 1	Phase 2a	Phase 2b	Phase 3	Comment
Tesofensine	Obesity								**Potential market launch 2024** – partnership with market leader **Medix**, representing near-term revenue potential through mid-teens royalties and milestone
Tesomet	HO, PWS								**Positioned for partnering** following successful phase 2a data (2019)
SAN711	Epilepsy								**Positioned for absence seizures** following positive phase 1 data (2022). Value-inflection points in 2024/25
SAN903	Fibrotic and inflammatory								**Positioned for partnering** following successful IND/CTA enabling studies
SAN2219	Epilepsy								**Positioned for acute repetitive seizures** with multiple expansion opportunities in rare and severe epilepsy
SAN2355	Epilepsy								**Positioned for focal/generalized epilepsy** and paediatric epilepsy
SAN2465	Depressive disorder								**Positioned for partnering** following candidate selection for rapid onset major depressive disorder
GABA program	Epilepsy								**Positioned for rare pediatric epilepsy syndrome** with multiple expansion opportunities in rare and severe epilepsy
AstronauTx	Alzheimer's								Partnership agreement entitling Saniona to **milestone payments of up to USD 177m plus royalties**
Boehringer Ingelheim	Schizophrenia								Partnership agreement entitling Saniona to **milestone payments of up to EUR 76.5m plus royalties**
Cephagenix	Migraine								Joint venture, Saniona owns 33%

SANIONA'S EPILEPSY PIPELINE

Saniona's epilepsy pipeline comprises the clinical candidates, SAN711, two preclinical candidates, SAN2219 and SAN2355, and a mature research program.

SAN711

Saniona's most advanced proprietary ion channel modulator is SAN711, which is being developed for absence seizures. 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.

SAN711 is a Positive Allosteric Modulator, or PAM, of $GABA_A$ α3 containing receptors. GABA is a neurotransmitter, that mediates inhibitory electrical signals between nerve cells in the brain. $GABA_A$ is the target of the non-selective and highly effective medicines belonging to the chemical group referred to as "benzodiazepines". Unlike benzodiazepines, SAN711 does not have an impact on $GABA_A$ α1, α2 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.

Absence seizures are caused by short bursts of uncontrolled electrical activity in specific neuronal circuits in the brain. During an absence seizure, the patient is unresponsive and has impaired consciousness, typically observed as "staring spells". Absence seizures normally last a few seconds (usually less than 15 seconds) and can occur up to 200 times a day. Absence seizures occur in multiple genetic generalized epilepsies, including childhood absence epilepsy (CAE), juvenile absence epilepsy (JAE), and juvenile myoclonic epilepsy (JME).

Childhood absence epilepsy is a pediatric epilepsy with an incidence of approximately 6.3 to 8.0 children per 100,000 per year. The age of onset is usually between 4-10 years and is often resolved in adolescence. Although the majority obtain good seizure control, 20-30 percent is refractory to current treatment and have associated attention problems. Further, young adults with a history of childhood absence epilepsy, many of them continuing to have absence in adulthood have poor long-term vocational, educational, and social outcomes.

First line treatment of childhood absence epilepsy consists of ethosuximide and valproate. Both ethosuximide and valproate adversely affect cognitive functioning. In addition, valproate poses an embryofetal risk making it unsuitable for young women of childbearing potential. The effectiveness of ethosuximide and valproate, in terms of seizure control, are comparable, as shown by similar response rate reported as freedom from failure rates of 45 percent and 44 percent

respectively. Consequently, the currently most optimal initial monotherapy fails in 55 percent of children, leaving a significant need for improved treatment options with better efficacy without detrimental effects on attention and cognition. Saniona has specifically designed SAN711 to enhance the effect of the α3 containing $GABA_A$ receptors with high selectivity. The α3 subunit is highly expressed in parts of the brain that are critically involved in initiation and maintenance of absence seizures. By selectively enhancing the effect of GABA at α3 $GABA_A$ receptors, the Company believes that SAN711 is a precision approach for specific abortion of absence seizures while avoiding the adverse effects associated with the current first line therapy such as cognitions.

Preclinical data generated in a highly translatable rodent model for absence seizures (Genetic Absence Epilepsy Rat from Strasbourg, GAERS), confirms marked suppression of absence seizures.

Besides absence seizures, the preclinical data package indicates substantial potential value for SAN711 in neuropathic pain exemplified by Trigeminal Neuralgia, migraine, Neuropathic pruritus (exemplified by brachioradial pruritis and prurigo nodularis), and Essential tremor as well as sleep disorders.

Superior tolerability was confirmed in Saniona's Phase 1 clinical trial of SAN711 in June 2022. The primary objective of the trial was to determine safety and tolerability through single ascending dose- and multiple ascending dose arms and confirm target engagement by a Positron Emission Tomography (PET) imaging biomarker study. The study demonstrated SAN711 to be safe and well tolerated even at receptor occupancies exceeding 80 percent, confirming the safety profile of this asset.

SAN2219

SAN2219 is a subtype selective Positive Allosteric Modulator (PAM) of $GABA_A$ α2- α3- and α5 containing receptors specifically designed to exert robust anti-seizure activity by dampening excessive neuronal activation broadly in the brain. The program has been advanced to preclinical development and hence represents the first preclinical development candidate from Saniona's $GABA_A$ α2/α3 PAM program.

SAN2219 is specifically designed to exert broad antiseizure activity by enhancing the effect of $GABA_A$ α2, α3 and α5 containing receptors. As there is no enhancement of $GABA_A$ α1 subtype containing receptors, the adverse effects mediated by non-selective benzodiazepines are anticipated to be avoided.

Saniona believes that this profile would be highly effective in aborting acute repetitive seizures, where seizures break through despite the patient being on maintenance antiseizure medications.

There is no universally accepted definition of acute repetitive seizures, but seizure clusters are generally distinct from a patient's usual seizure patterns and are often defined as two to four seizures per < 48 hours, 3 seizures per 24 hours or three times the baseline seizure frequency. Acute repetitive seizures occur in a subset of individuals with epilepsy with a reported prevalence ranging from 10 and up to 50 percent of patients depending on the definition and study design.

Acute repetitive seizures require immediate attention. In the absence of prompt and effective treatment, acute repetitive seizures can evolve into status epilepticus, a potentially life-threatening seizure emergency. Benzodiazepines constitute the standard-of-care for acute on demand repetitive seizures, but the use is restricted to 2 doses per epileptic episode, and it is recommended to treat no more than five episodes per month due to the limitations associated with benzodiazepines including tolerance development.

SAN2219 demonstrates potent and robust effects in a variety of rodent seizure models for epilepsy indications including focal onset seizures, generalized tonic-clonic seizures, and generalized non-motor seizures (absence seizures). Furthermore, SAN2219 is not sedative in standard rodent model assessing sedation. Therefore, SAN2219 is anticipated to arrest acute repetitive seizures without use limitations imposed on benzodiazepines.

SAN2355

SAN2355 represents the first development compound from the Saniona Kv7 program. SAN2355 is a subtype selective Kv7.2/Kv7.3 activator for patients with treatment-resistant focal onset seizures. Focal onset seizures are the most common type of epileptic seizure and affect up to about 60% of patients with epilepsy.

Kv7 channels are voltage-dependent potassium channels which control the generation of nerve-impulses in CNS neurons. There are five subtypes of Kv7 channels (Kv7.1 to Kv7.5). Kv7.2 and Kv7.3 are the major Kv7 subtypes in CNS

neurons and the Kv7.2/Kv7.3 channel is the relevant target for anti-epileptic treatment. Targeting the other subtypes of Kv7 channels may lead to severe CNS and peripheral side effects.

Kv7 channels are clinically validated targets for epilepsy as the non-selective Kv7.2-7.5 activator, Retigabine, proved effective in treatment-refractory focal onset epilepsy. However, the use of Retigabine was limited due to adverse effects (discoloration of skin and retina, urinary retention, and CNS adverse effects) and the drug was withdrawn from the market in 2017 for commercial reasons. The discoloration of skin and retina was known to be caused by chemical instability of the chemical class retigabine belongs to, whereas the urinary retention most likely resulted from activation of Kv7.4 and Kv7.5 in the bladder. Xenon Pharmaceuticals subsequently acquired retigabine for child epilepsies caused by Kv7.2 mutations (program stopped in spring 2023), but a potent retigabine analogue, XEN1101, is currently in Phase 3 for focal onset and generalized epilepsy as well as major depression.

Just as retigabine, XEN1101 is unselective among the Kv7.2-Kv7.5 subtypes and the Phase 2 data suggests that the urinary retention problem persists as does also the retigabine-like CNS adverse effects that caused a high drop-out rate from the Phase 2 study.

SAN2355 has a highly differentiated profile that is specifically designed to avoid the use limitations what are associated with Retigabine and XEN1101. In contrast to Retigabine and XEN1101, SAN2355 selectively activates Kv7.2 and Kv7.3 channels. This is anticipated to improve CNS tolerability and reduce urinary retention. Further, it belongs to a different chemical series thereby avoiding the discoloration of skin and retina. This highly differentiated profile is consequently anticipated to maintain strong seizure control while mitigating the limitations that caused Retigabine to be withdrawn from the market.

SAN2465

SAN2465 is a potent and selective negative allosteric modulator (NAM) of GABAA α5 containing receptors. SAN2465 has been tested in the chronic mild stress model of depression, which is widely acknowledged as the most valid animal model of depression with translational potential to human disease. In this model, SAN2465 has demonstrated rapid and sustained reversal of chronic stress-induced depressive-like symptoms, including anhedonia, anxiety, and cognitive impairment. The onset and robustness of the antidepressive effect was similar to ketamine, which was used as a positive control in the study. The data suggests that SAN2465 may induce rapid antidepressant effects like those observed with ketamine and esketamine (Spravato™), which has demonstrated clinical response within hours after the first dose in patients. Importantly, as opposed to ketamine and esketamine, negative modulation of GABAA α5 receptors is not anticipated to lead to significant adverse effects, as the expression of these receptors are more localized and mainly restricted to limbic areas.

Consequently, this innovative approach for the treatment of major depressive disorder differs substantially from conventional antidepressant drugs in its mechanism of action, and it has the potential to become a first-in-class rapid-acting antidepressant without the significant adverse effects associated with esketamine.

GABA program

Saniona has progressed other compounds from its $GABA_A$ α2/α3 PAM program to the candidate selection phase. These compounds have other electrophysiologic profiles than SAN2219. Saniona is currently evaluating the potential value of one of these compounds for treatment of patients with a pediatric syndrome (Developmental/Epileptic Encephalopathy with Spike Wave Activation in Sleep (D/EE-SWAS), which has severe consequences for the patients and their families. This is a rare form of epilepsy. The number of patients is estimated to be between 2,400 and 7,000 children in the U.S. The disease starts in children between 2 and 12 years of age. Most often it starts between 4 and 5 years of age.

The common symptoms are 1) failure to attain new development skills and loss of skills and 2) an EEG showing significant activation of abnormal discharge in sleep, compared to being awake. In some cases, children can develop normally before the onset of this syndrome. But then they regress or fail to gain new skills with the onset of this syndrome. In this case, the syndrome is known as epileptic encephalopathy with spike-wave activation in sleep (EE-SWAS). In other cases, children have some degree of developmental delay prior to the onset of this syndrome, but this becomes more severe with regression of skills. In this case, the syndrome is known as developmental and epileptic encephalopathy with spike-wave activation in sleep (DEE-SWAS).

There are no approved treatments for this syndrome. Patients are typically treated with high doses of benzodiazepines and/or steroids, none of which are good options due to safety issues and tolerance development. There is currently no industry sponsored clinical trials ongoing and the objective of the only ongoing non-industry sponsored clinical trial is to evaluate which of the current treatments, benzodiazepines or steroids, are superior.

SANIONA'S NON-EPILEPSY PIPELINE

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, COFEPRIS, for approval of tesofensine for the treatment of patients with obesity. In February 2023, COFEPRIS' technical committee expressed a favorable opinion on tesofensine for treatment of obesity. This non-binding technical opinion is issued as one of the steps in the process of reviewing new molecules. 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.

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. The weight reducing effect of tesofensine has been confirmed in a six-month Phase 2 clinical trial in patients with obesity (the TIPO-1 trial). The TIPO-1 trial in adult patients with obesity indicates that tesofensine at the expected recommended dose of 0.50 mg per day provides a weight loss of 10 percent or more in 24 weeks, which is in the same ballpark of some of the best GLP-1 analogs. As opposed to the GLP-1 analogs, tesofensine is provided in tablets and will not require titration.

Saniona's partner Medix` Phase 3 program was a 24-week, randomized, double-blinded, placebo-controlled, three-armed, parallel, longitudinal trial comparing the efficacy, safety, and satisfaction of two dose levels of once-daily oral tesofensine vs placebo in people with obesity treated with diet and exercise only. 372 patients were enrolled in the Phase 3 study and randomized 1:1:1 to receive either a dose of oral tesofensine (0.25 and 0.50 mg) or placebo once daily. The study's primary endpoint was the average percentage and absolute change in body weight compared to placebo. Secondary endpoints included the percentage of patients achieving weight loss of at least 5 percent and 10 percent of baseline body weight.

The Phase 3 study confirmed the compelling efficacy and favorable safety profile of tesofensine in obesity previously observed in Phase 2. At the 0.50 mg dose patients obtained about 10 percent average weight loss in 24 weeks, more than half of patients experienced a weight loss of more than ten percent and statistically significant reduction in key obesity-related risk factors were observed.

In general, tesofensine was very well tolerated with low incidence of adverse events and very similar to placebo. A similar pattern was observed when measuring cardiovascular effects, with a low but statically significant increase in heart rate and no significant effect on blood pressure at any of the doses tested.

Following this study, the combined clinical safety data base from more than 20 clinical trials with tesofensine contains approximately 1,600 patients exposed to relevant therapeutic doses for up to one year, providing a robust safety data set to support filings in Mexico and Argentina and potentially in other geographies, as well as the further development of Tesomet in rare eating disorders.

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 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.

Tesomet is a fixed-dose combination of two active ingredients: tesofensine and metoprolol. Metoprolol is a cardio-selective β1 receptor blocker historically used to treat several cardiovascular conditions and which has been approved for use in the United States since 1978.

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.

Saniona sees significant value in Tesomet. Saniona believes that the initial Phase 2 data support further development of Tesomet in both indications. The Company initiated Phase 2b studies in 2021, which was put on hold and subsequently closed in 2022 due to lack of funding. Prior to closing the Phase 2b studies in 2022, financial analysts have estimated annual peak sales for Tesomet between USD 850M – 1B+ (SEK 8B – 9.5B) (Saniona does not endorse or validate sales estimates provided by third parties).

HYPOTHALAMIC OBESITY (HO)

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.

PRADER-WILLI SYNDROME (PWS)

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.

SAN903

SAN903 has successfully completed preclinical development in 2022 and we are preparing a Clinical Trial Application (CTA) for submission to the European Medicines Regulatory Agencies (EMA) enabling Phase 1 clinical trials either by Saniona alone or together with a partner. The primary indication for SAN903 is inflammatory bowel diseases (IBD) and we see a potential of SAN903 as a medicine with independent actions on intestinal inflammation and fibrosis.

SAN903 is a novel, potential first-in-class medicine based on inhibition of the calcium-activated potassium ion channel, KCa3.1.

This ion channel is found on several types of immune cells, where it participates in the control of the cellular pathways that maintain pathogenic activation and inflammation in chronic diseases. The Kca3.1 channel is also expressed on fibroblasts, especially on myofibroblasts, where it supports the overproduction of connective tissue that can lead to fibrosis. Prevention of fibrotic complications is an aspect of the disease, which is poorly treated by current standard-of-care IBD medicines, and progressed fibrosis often requires surgical intervention to resolve potentially life-threatening gut obstructions. SAN903 dampens inflammation and fibrosis by preventing cell division and cell migration of activated immune cells and fibroblast and by impeding cytokine release and collagen secretion of the respective cell types.

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 25,000 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, SAN2219, SAN2355 and SAN2465. We anticipate that this robust discovery engine will continue to generate multiple new drug candidates to add to the Saniona pipeline.

PARTNERSHIPS AND SPINOUTS

Leveraging our expertise in the field of ion channel drug discovery, our proprietary focused compound library and robust database (IONBASE), 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 industry-leading research has formed the basis of many successful spinouts, partnerships, and licensing agreements with pharmaceutical companies internationally, such as Boehringer Ingelheim, AstronauTx, 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 year-end report that are not defined according to International Financial Reporting Standards (IFRS), so called alternative performance measures. These have been noted with an "*" in the tables below. The company believes that these measures provide valuable supplementary information for investors and company management as they enable an assessment of relevant trends of the company's performance. These financial measures should not be regarded as substitutes for measures defined per IFRS. Since not all companies calculate financial measures in the same way, these are not always comparable to measures used by other companies.

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

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

Financial key figures

	2023-10-01 2023-12-31	2022-10-01 2022-12-31 (Restated)	2023-01-01 2023-12-31	2022-01-01 2022-12-31 (Restated)
Revenue, KSEK	5,374	3,306	16,840	15,283
Total operating expenses, KSEK	-25,150	-25,912	-97,905	-241,002
Operating profit (loss), KSEK*	-19,776	-22,606	-81,065	-225,719
Cash flow for the period, KSEK	-21,487	-19,849	-93,627	-295,215
Weighted average number of shares	64,126,978	62,385,677	63,067,885	62,385,677
Diluted average shares outstanding	64,126,978	62,385,677	63,067,885	62,385,677
Shares outstanding at the end of the period	64,126,978	62,385,677	64,126,978	62,385,677
Average number of employees	23	23	23	34
Operating margin*				
Operating profit (loss), KSEK	-19,776	-22,606	-81,065	-225,719
Revenue, KSEK	5,374	3,306	16,840	15,283
Operating margin, %	**-368%**	**-684%**	**-481%**	**-1,477%**
Cash flow per share*				
Cash flow for the period, KSEK	-21,487	-19,849	-93,627	-295,215
Shares outstanding at the end of the period	64,126,978	62,385,677	64,126,978	62,385,677
Cash flow per share, SEK	**-0.34**	**-0.32**	**-1.46**	**-4.73**
Earnings per share				
Profit (loss) for the period, KSEK	-28,741	-7,161	-95,810	-211,569
Shares outstanding at the end of the period	64,126,978	62,385,677	64,126,978	62,385,677
Earnings per share, SEK	**-0.45**	**-0.11**	**-1.49**	**-3.39**
Diluted earnings per share, SEK	**-0.45**	**-0.11**	**-1.49**	**-3.39**

	2023-12-31	2022-12-31
Cash and cash equivalent, KSEK	30,962	111,707
Equity, KSEK	-21,940	52,708
Total Equity and liabilities, KSEK	64,143	153,696
Equity per share*		
Equity, KSEK	-21,940	52,708
Shares outstanding at the end of the period	64,126,978	62,385,677
Equity per share, SEK	**-0.34**	**0.84**
Equity ratio*		
Equity, KSEK	-21,940	52,708
Total assets, KSEK	64,143	153,696
Equity ratio, %	**-34%**	**34%**
Liquidity ratio*		
Current assets, KSEK	45,166	127,345
Current liabilities, KSEK	17,695	22,897
Liquidity ratio, %	**255%**	**556%**

** = Alternative performance measures*

Results of Operations

Fourth quarter 2023

Revenue for the fourth quarter amounted to SEK 5.4 million (3.3). Revenues in fourth quarter 2023 include amounts from our licensing and partnership agreements with Boehringer Ingelheim and AstronauTx. Revenues in fourth quarter 2022 include amounts from our licensing and partnership agreements with Boehringer Ingelheim and Cephagenix. The increase is mainly related to the new research collaboration agreement with AstronauTx, entered mid-July 2023.

Operating expenses for the fourth quarter amounted to SEK 25.2 million (25.9). Within operating expenses, external expenses decreased by SEK 3.7 million from an expense of SEK 13.7 million to an expense of SEK 9.9 million.

A part 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 fourth quarter, comprised development costs of Tesomet SEK 0.6 million (2.0), development costs of SAN711 SEK 0.4 million (1.6) and pre-clinical development costs of SAN903 SEK 0 million (0.8) and other research costs SEK 4.1 million (3.5).

Personnel costs include salaries, variable compensation, social security, and other employee benefits. Personnel costs for the fourth quarter amounted to SEK 8.1 million (9.5). Non-cash share-based compensation expense is included in personnel costs and amounted to SEK 0.5 million (1.0).

Net loss from total financial items increased from an income of SEK 15.2 million to a loss of SEK 9.0 million. The financial expenses include interest and commitment fee to Formue Nord of SEK 3.7 million (2.2) and SEK 4.7 million (0.8), respectively, other interest expenses SEK 1.0 million (5.0), net loss from change in fair value for investment in equity instruments 0 (11.7), net income from translation reserve due to the liquidation of Saniona Inc of 0 (33.8) and financial income of SEK 0.4 million (1.0).

The Group recognized a tax income in the period of SEK 0.0 million (0.3). The tax income in 2022 is recognized in Saniona Inc. Saniona Inc. was closed in December 2022.

Net cash used in operating activities in the period increased by SEK 1.9 million from SEK -18.3 million to SEK -20.2 million.

The operating cash flow in the period is primarily attributable to the operating loss of SEK 19.8 million (22.6).

For the period net cash used by investing activities was SEK 0 million (0.7). The investing activities in 2022 are purchases of minor equipment.

For the period net cash used by financing activities was SEK 1.3 million (0.9), due to repayment of lease liabilities of SEK 1.3 million (0.9).

Cash and cash equivalents for the Group amounted to SEK 31.0 million (111.7) as of December 31, 2023.

In February 2024, the rights issue that was announced in mid-December 2023 was subscribed. Initially, Saniona will receive approximately SEK 88.9 million before issue costs and due to the warrants series TO 4 that are issued, Saniona may receive additional proceeds in April 2025.

January – December

Revenue for the period amounted to SEK 16.9 million (15.3). Revenues in 2023 include amounts from our licensing and partnership agreements with Boehringer Ingelheim, AstronauTx and Cephagenix. Revenues in 2022 include amount from licensing and partnership agreements with Boehringer Ingelheim, Productos Medix and Cephagenix.

Operating expenses for the period amounted to SEK 97.9 million (241.0). Within operating expenses, external expenses decreased by SEK 98.8 million from SEK 146.5 million to SEK 47.7 million. The significant decrease in external operating expenses is due to close of the Phase 2b clinical trials of Tesomet for HO and PWS in March 2022, and

completion of SAN711 Phase 1 for neuropathic pain conditions in June 2022.

A part 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 period, comprised primarily of development costs of Tesomet SEK 4.0 million (49.9), development costs of SAN711 SEK 8.3 million (35.3) and pre-clinical development costs of SAN903 SEK 1.1 million (11.2) and other research costs SEK 9.3 million (17.4).

Personnel costs include salaries, variable compensation, social security, and other employee benefits. Personnel costs for the period amounted to SEK 33.8 million (82.2). Non-cash share-based compensation expense is included in personnel costs and amounted to SEK 3.4 million (profit 18.0). The significant decrease in personnel costs is due to closing of the U.S. operation in Q2-2022 and termination of the positions of all U.S. personnel, including the U.S. executive management team. The profit from the non-cash share-based compensation in 2022 is reversal of expenses on the units that were forfeited, as the underlying service conditions were not met.

Net loss from total financial items increased from an income of SEK 7.5 million to a loss of SEK 23.2 million. The financial expenses include interest and commitment fee to Formue Nord of SEK 11.3 million (10.1) and SEK 12.3 million (2.7), respectively, other interest expenses of SEK 2.8 million (11.8), loss from change in fair value for investment in equity instruments 0 (11.7), net income from translation reserve due to the liquidation of Saniona Inc of 0 (33.8) and financial income of SEK 3.2 million (9.7).

The Group recognized a tax income of SEK 8.5 million (6.6). The tax benefit in 2023 is on net loss recognized in Saniona A/S under the Tax Credit Scheme in Denmark. The tax benefit in 2022 is a tax cost recognized in Saniona Inc. of SEK 1.6 million, and a tax benefit of SEK 8.2 million in Saniona A/S under the Tax Credit Scheme in Denmark.

Net cash used in operating activities decreased by SEK 196.0 million from SEK -281.5 million to SEK -85.5 million.

The operating cash flow for the period, is primarily attributable to the operating loss of SEK 81.1 million (225.7).

For the period, net cash used by investing activities was SEK 0.1 million (received 6.8). Net cash received in 2022 includes Saniona's portion of the upfront payment of SEK 7.5 million connected to Novartis acquisition of Cadent Therapeutics in January 2021, in which Saniona held a 3% ownership stake. The cash used to purchase of minor equipment was SEK 0.1 million (0.7).

For the period, net cash used by financing activities was SEK 8.0 million (20.5), due to repayment of lease liabilities of SEK 4.8 million (5.5), costs related to issuance of new shares SEK 0.2 million (0) and SEK 3 million (15) of repayment of loan to Formue Nord.

Cash and cash equivalents for the Group amounted to SEK 31.0 million (111.7) as of December 31, 2023.

In February 2024, the rights issue that was announced in mid-December 2023 was subscribed. Initially, Saniona will receive approximately SEK 88.9 million before issue costs and due to the warrants series TO 4 that are issued, Saniona may receive additional proceeds in April 2025.

Parent Company

January - December

Operating expenses for the period amounted to SEK 7.5 million (28.4). The main component of the Parent Company's operating expenses are other external costs of SEK 4.1 million (10.6), personnel costs of SEK 2.0 million (2.2) and other operating expenses of SEK 1.4 million (15.6). The significant decrease in other operating expenses is due to closing of the U.S. operation in 2022.

Loss amounted for the period to SEK 42.5 million (42.3). The main component of the Parent Company's loss also includes financial items of SEK 36.7 million (17.4), which is interest and commitment fee to Formue Nord of SEK 11.3 million (10.1) and SEK 12.3 million (2.7), respectively, other interest expenses SEK 13.2 million (5.0), and interest income of SEK 0.1 million (0.4).

Financial position, share, share capital and ownership structure

The equity ratio for the Group was -34% (34%) as of December 31, 2023, and equity for the Group was SEK -21.9 million (52.7). Cash and cash equivalents for the Group amounted to SEK 31.0 million (111.7) as of December 31, 2023. Total assets for the Group as of December 31, 2023, were SEK 64.1 million (153.7).

The equity ratio for the Parent company was 57% (64%) as of December 31, 2023, and equity for the Parent company was SEK 197.2 million (221.7). Cash and cash equivalents for the parent company amounted to SEK 2.5 million (2.3) as of December 31, 2023. Total assets for the parent company as of December 31, 2023, were SEK 348.3 million (344.2).

In August, Saniona reduced the loan with Formue Nord with SEK 13 million from SEK 74 million to SEK 61 million, through a repayment of SEK 3 million and conversion of SEK 10 million into 1,741,301 shares. The number of shares in Saniona increased therefore with 1,741,301 from 62,385,677 to 64,126,978 and the share capital increase with SEK 87,065.05 from SEK 3,119,283.85 to SEK 3,206,348.90.

In July 2023, Saniona entered into a new collaboration agreement with AstronauTx. Saniona expects during the first year of collaboration with AstronauTx to receive research funding of around SEK 15 million.

As of December 31, 2023, Saniona has received research funding from AstronauTx and Boehringer Ingelheim of SEK 16.2 million. Saniona expects to receive research funding from AstronauTx and Boehringer Ingelheim of about SEK 27.3 million on annual basis.

In December 2023, Saniona announced in connection with the Rights Issue, a renegotiation of the outstanding loan. Saniona will, in connection with the Rights Issue, repay SEK 20 million of the loan in cash or by set-off. Approximately SEK 31.2 million of the remaining loan of approximately SEK 41.2 million will continue to run as a loan and SEK 10 million will be converted into new convertibles in the Company. The loan and the convertibles of approximately SEK 41.2 million shall accrue at an annual interest of STIBOR 3M plus an interest margin of eight (8) per cent, and the interest shall be paid in cash by the end of each calendar quarter. The loan matures hereafter on July 31, 2025.

In February 2024, Saniona announced the outcome of the rights issue. Through the rights issue, Saniona will initially receive approximately SEK 88.9 million before issue costs and in the event of exercise of warrants series TO 4 that are issued, Saniona may receive additional proceeds in April 2025.

On December 31, 2023, the company had 13,092 (10,145) shareholders excluding holdings in life insurance and foreign custody account holders.

Personnel

As of December 31, 2023, Saniona had 23 (23) employees including 10 (10) employees with Ph.D. degrees. Of these employees, 17 (17) were engaged in research and clinical development activities and 6 (6) were engaged in general and administrative activities. Of the 23 (23) employees, 12 (12) 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 on the Group's results and financial position. The risks can be divided into operational risks and financial risks. The main risks and uncertainties which Saniona is exposed to are related to drug development, the company's collaboration agreements, competition, technology development, patents, regulatory requirements, capital requirements and currencies.

A detailed description of the Group's risk factors, and risk management is included in Saniona's 2022 Annual Report and Prospectus dated January 18, 2024. There are no major changes in the Group's risk factors and risk management in 2023.

Audit review

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

Financial calendar

Interim Report Q1	May 29, 2024, at 8:00 CEST
Annual General Meeting	May 29, 2024
Interim Report Q2	August 29, 2024, at 8:00 CEST
Interim Report Q3	November 28, 2024, at 8:00 CET
Year-end Report 2024	February 27, 2025, at 8:00 CET

Annual General Meeting 2024

Saniona's Annual General Meeting will be held at Setterwalls Advokatbyrå AB's office at Stortorget 23, Malmö, Sweden on May 25, 2024, at 16.30 CEST.

The Board of Directors proposes that no dividend will be paid for the 2023 financial year.

The Annual Report for 2023 will be published on www.saniona.com no later than April 30, 2024. 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 and partner at Ursus law firm, 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.

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

Glostrup, February 29, 2024
Saniona AB

Jørgen Drejer – Chairman	Thomas Feldthus – CEO
Anna Ljung – Board member	Carl Johan Sundberg – Board member
Pierandrea Muglia – Board member	

THE GROUP'S CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Condensed consolidated interim statement of comprehensive income – Group

KSEK	Note	2023-10-01 2023-12-31	2022-10-01 2022-12-31 (Restated)	2023-01-01 2023-12-31	2022-01-01 2022-12-31 (Restated)
	1,2,3				
Revenue	4	5,374	3,306	16,840	15,283
Total operating income		5,374	3,306	16,840	15,283
Raw materials and consumables		-1,356	-1,042	-5,059	-4,475
Other external costs		-9,983	-13,675	-47,664	-146,486
Share of result of associate	9	-1,325	—	-1,719	—
Personnel costs	5	-8,126	-9,512	-33,812	-82,223
Depreciation and write-downs		-4,360	-1,683	-9,651	-7,818
Total operating expenses		-25,150	-25,912	-97,905	-241,002
Operating profit (loss)		**-19,776**	**-22,606**	**-81,065**	**-225,719**
Share of result of associate	9	—	50	—	346
Financial income		402	979	3,131	9,726
Financial expenses		-9,367	-7,991	-26,346	-24,659
Net gains on financial items		—	22,127	—	22,127
Total financial items		-8,965	15,165	-23,215	7,540
Profit (loss) before tax		**-28,741**	**-7,441**	**-104,280**	**-218,179**
Income tax	6	—	280	8,470	6,610
Profit (loss) for the period*		**-28,741**	**-7,161**	**-95,810**	**-211,569**
Other comprehensive income (loss) for the period					
Item that may be reclassified to profit and loss					
Translation differences		-409	-32,485	3,084	259
Items that will not be reclassified to profit and loss					
Equity instruments at FVOCI – net change fair value		—	—	—	—
Total other comprehensive income for the period, net after tax		**-409**	**-32,485**	**3,084**	**259**
Total comprehensive profit (loss)**		**-29,150**	**-39,646**	**-92,726**	**-211,310**
Loss per share, SEK		-0.45	-0.11	-1.49	-3.39
Diluted loss per share, SEK		-0.45	-0.11	-1.49	-3.39

* 100% of Profit (loss) for the period is attributable to Parent Company shareholders

** 100% of Total comprehensive profit (loss) the period is attributable to Parent Company shareholders

Condensed consolidated interim statement of financial position – Group

KSEK	Note	2023-12-31	2022-12-31
ASSETS			
Intangible assets		4,947	6,737
Property and equipment		3,297	5,703
Right of use assets		7,248	9,998
Investment in associate	9	392	799
Other financial assets	8	3,093	3,114
Non-current assets		**18,977**	**26,351**
Trade receivables		2,526	4,628
Current tax assets	6	8,206	8,234
Other assets		3,472	2,776
Cash and cash equivalents		30,962	111,707
Current assets		**45,166**	**127,345**
Total assets		**64,143**	**153,696**

Condensed consolidated interim statement of financial position – Group (continued)

KSEK	Note	2023-12-31	2022-12-31 (Restated)
EQUITY AND LIABILITIES			
Share capital		3,206	3,119
Additional paid-in capital		827,803	813,261
Reserves		4,359	1,275
Accumulated deficit		-857,308	-764,947
Equity		**-21,940**	**52,708**
Other financial liabilities	7,8	65,924	75,699
Other liabilities		2,464	2,392
Non-current liabilities		68,388	78,091
Trade payables		8,245	14,073
Other financial liabilities	7,8	5,485	5,822
Other liabilities		3,965	3,002
Current liabilities		17,695	22,897
Total liabilities		**86,083**	**100,988**
Total equity and liabilities		**64,143**	**153,696**

Condensed consolidated interim statement of changes in equity – Group

	Share capital	Additional paid-in capital	Translation reserves (Restated*)	Fair value reserve (Restated*)	Accumulated deficit (Restated*)	Shareholders' equity
January 1, 2022 (previously reported)	3,119	813,261	1,016	73,529	-608,926	281,999
Restatement	—	—	—	-73,529	73,529	—
January 1, 2022 (restated)	**3,119**	**813,261**	**1,016**	**—**	**-535,397**	**281,999**
Comprehensive income						
Loss for the period	—	—	—	—	-211,569	-211,569
Other comprehensive income	—	—	259	—	—	259
Total comprehensive	**—**	**—**	**259**	**—**	**-211,569**	**-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**	**1,275**	**—**	**-764,947**	**52,708**
January 1, 2023	**3,119**	**813,261**	**1,275**	**—**	**-764,947**	**52,708**
Comprehensive income						
Loss for the period	—	—	—	—	-95,810	-95,810
Other comprehensive income			3,084	—	—	3,084
Total comprehensive income (loss)	**—**	**—**	**3,084**	**—**	**-95,810**	**-92 726**
Transactions with owners						
Shares issued for cash	87	14,715	—	—	—	14,802
Expenses related to capital increase	—	-173	—	—	—	-173
Share-based compensation expenses	—	—	—	—	3,449	3,449
Total transactions with owners	**87**	**14,542**	**—**	**—**	**3,449**	**18,078**
December 31, 2023	**3,206**	**827,803**	**4,359**	**—**	**-857,308**	**-21,940**

* Components in Equity has been restated (we refer to note 10)

Condensed consolidated interim statement of cash flows – Group

KSEK	Note	2023-10-01 2023-12-31	2022-10-01 2022-12-31	2023-01-01 2023-12-31	2022-01-01 2022-12-31
Loss before tax		-28,741	-7,441	-104,280	-218,179
Adjustments for non-cash transactions		7,898	-31,082	13,629	-42,587
Changes in working capital		-4,104	14,358	6,770	-17,554
Cash flow from operating activities before financial and tax items		**-24,947**	**-24,165**	**-83,881**	**-278,320**
Interest income received		402	364	2,534	593
Interest expenses paid		-4,065	-2,576	-12,625	-11,937
Tax credit received		8,441	8,126	8,441	8,126
Cash flow from operating activities		**-20,169**	**-18,251**	**-85,531**	**-281,537**
Investing activities					
Purchases of property and equipment		-46	-676	-129	-985
Proceeds from sale of financial assets		—	—	—	7,522
Proceeds from sale of tangible assets		—	1	—	306
Cash flow from investing activities		**-46**	**-675**	**-129**	**6,843**
Financing activities					
Repayment of loan		—	—	-3,000	-15,000
Costs related to issuance of new shares		—	—	-173	—
Payment of lease liabilities		-1,272	-923	-4,794	-5,521
Cash flow from financing activities		**-1,272**	**-923**	**-7,967**	**-20,521**
Net increase (decrease) in cash and cash equivalents		**-21,487**	**-19,849**	**-93,627**	**-295,215**
Cash and cash equivalents at beginning of period		**49,278**	**117,555**	**111,707**	**356,855**
Exchange rate adjustments		3,171	14,001	12,882	50,067
Cash and cash equivalents at end of period		**30,962**	**111,707**	**30,962**	**111,707**

PARENT COMPANY'S FINANCIAL STATEMENTS

Statement of income – Parent Company

KSEK	Note	2023-01-01 2023-12-31	2022-01-01 2022-12-31
	1,2,3		
Other operating income		1,651	3,418
Total operating income		1,651	3,418
Raw materials and consumables		-37	-30
Other external costs		-4,118	-10,602
Other operating expenses		-1,337	-15,585
Personnel costs	5	-1,978	-2,143
Total operating expenses		-7,470	-28,360
Operating income (loss)		**-5,819**	**-24,942**
Financial income		111	391
Financial expenses		-36,811	-17,785
Total financial items		-36,700	-17,394
Profit (loss) before tax		**-42,519**	**-42,336**
Tax on net profit (loss)		—	—
Profit (loss) for the period		**-42,519**	**-42,336**

Profit (loss) for the period is the same as Comprehensive income for the period as no items are identified in Other comprehensive income for the period.

Balance Sheet – Parent Company

KSEK	Note	2023-12-31	2022-12-31
ASSETS			
Investment in subsidiaries		344,965	341,703
Financial assets		344,965	341,703
Non-current assets		**344,965**	**341,703**
Other assets		903	222
Current receivables		903	222
Cash and cash equivalents		2,460	2,228
Current assets		**2,460**	**2,450**
Total assets		**348,328**	**344,153**
EQUITY AND LIABILITIES			
Restricted equity			
Share capital		3,206	3,119
Unrestricted equity			
Share premium reserve		827,803	813,261
Retained earnings (accumulated deficit)		-591,244	-552,357
Profit (loss) for the period		-42,519	-42,336
Equity		**197,246**	**221,687**
Other financial liabilities	7	65,238	70,636
Non-current liabilities		65,238	70,636
Trade payables		644	806
Payables to group companies		85,049	50,790
Other liabilities		151	234
Current liabilities		85,844	51,830
Total liabilities		**151,082**	**122,466**
Total equity and liabilities		**348,328**	**344,153**

Notes to the 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 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 interim financial statements for the three months ended December 31, 2023, 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 interim financial statements for the Parent Company are prepared under the requirements of chapter 9 of the Swedish Accounting Act (1995:1554). These 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, 2022 ('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 interim financial statements have been prepared on a going concern basis. As of December 31, 2023, the Group's current assets exceed current liabilities by SEK 27.5 million. Current assets include cash and cash equivalents of SEK 31.0 million.

In February 2024 Saniona announced outcome in rights issue of a proceeds of approximately SEK 88.9 million before issue of costs.

These financial statements were authorized for issue by the Parent Company's Board of Directors (the 'Board') on February 29, 2024.

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 condensed consolidated interim financial statements.

i. Adoption of new or revised standards

No new or changed accounting standards that came into effect on January 1, 2023, had a material impact on Saniona.

Note 3 Critical accounting judgments and key sources of estimation uncertainty

No significant changes have taken place. We refer to accounting judgments and estimate in the 2022 Annual report.

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, 2023 and 2022, revenue for the Group was distributed as follows:

Category

KSEK	2023-10-01 2023-12-31	2022-10-01 2022-12-31	2023-01-01 2023-12-31	2022-01-01 2022-12-31
Research and collaboration agreements (bundle, over time)	—	—	—	3,760
Research and development services (standalone)	5,363	2,608	16,207	8,293
License agreements (other event-based payments)	10	698	633	3,229
Total	**5,373**	**3,306**	**16,840**	**15,282**

Major customers

KSEK	2023-10-01 2023-12-31	2022-10-01 2022-12-31	2023-01-01 2023-12-31	2022-01-01 2022-12-31
Customer #1	2,007	2,608	8,721	8,293
Customer #2	3,356	—	7,486	—
Customer #3	10	698	633	3,229
Customer #4	—	—	—	3,760
Total	**5,373**	**3,306**	**16,840**	**15,282**

Primary geographical market

KSEK	2023-10-01 2023-12-31	2022-10-01 2022-12-31	2023-01-01 2023-12-31	2022-01-01 2022-12-31
Sweden	—	—	—	—
Germany	2,007	2,608	8,721	8,293
Denmark	10	698	633	3,229
United Kingdom	3,356	—	7,486	—
Mexico	—	—	—	3,760
Total	**5,373**	**3,306**	**16,840**	**15,282**

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, 2023, is provided in the last annual financial statements.

On May 25, 2023, the annual shareholders' meeting voted in favor of establishing an Employee Option program involving the allotment of a maximum of 750,000 options. The program implies that a maximum of 750,000 employee options shall be offered to senior executives (excluding the CEO and CFO) and other employees. 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. The holders shall be entitled to exercise allotted and vested employee options during the period starting on the date that falls 3 years after the allotment date and ending on December 31, 2028. Each employee option entitles the holder a right to acquire one new share in the company against cash consideration at a subscription price amounting to 130 percent of the volume weighted average share price of the company's share on Nasdaq Stockholm during the 10 trading days immediately after the annual shareholders' meeting on May 25, 2023. The employee options shall be allotted without consideration, the employee options shall not constitute securities and shall not be able to be transferred or pledged.

A total of 700,000 warrants were allotted to employees in June 2023.

B. Measurement of fair values and compensation expense

Fourth quarter 2023

Share-based compensation expenses for the period totaled SEK 0.5 million (1.0).

January – December 2023

Share-based compensation expenses for the period totaled SEK 3.4 million (profit 18.0). The profit from share-based compensation in 2022 is reversal of expenses on the units that were forfeited, as the underlying service conditions were not met.

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	2018:1	2018:2	2019:1	2019:2	2020:1
Options outstanding, January 1	286,003	32,792	34,500	15,770	355,156
Granted during the year	—	—	—	—	—
Forfeited during the year	—	-32,792	—	-15,770	—
Options outstanding, December 31	286,003	0	34,500	0	355,156
Maximum number of shares to be issued	294,583	0	34,845	0	358,707
Grant Date Fair Value* (SEK)	12.06	17.38	7.23	6.00	12.26
Share Price at Grant Date* (SEK)	26.95	33.85	17.76	17.76	28.10
Exercise Price* (SEK)	33.20	29.71	17.83	17.83	29.36
Expected volatility*	69.24%	67.77%	57.29%	53.67%	58.66%
Estimated life (years)*	3.88	3.73	3.67	2.80	4.20
Expected dividends*	0	0	0	0	0
Risk-free rate*	-0.1092%	-0.2773%	-0.6903%	-0.6709%	-0.2280%
Remaining contractual life (years)*	0.50	0.00	1.00	0.00	2.00

Incentive program	2020:2	2020:3	2021:1	2022:1	2023:1	Total
Options outstanding, January 1	884,700	282,333	700	2,129,821	—	4,021,775
Granted during the year	—	—	—	—	700,000	700,000
Forfeited during the year	-149,200	—	—	—	—	-197,762
Options outstanding, December 31	735,500	282,333	700	2,129,821	700,000	4,524,013
Maximum number of shares to be issued	735,500	282,333	700	2,129,821	700,000	4,536,489
Grant Date Fair Value* (SEK)	13.13	7.98	10.75	1.59	5.83	
Share Price at Grant Date* (SEK)	23.50	23.55	19.31	4.24	7.8	
Exercise Price*(SEK)	24.12	25.40	19.38	5.89	8.84	
Expected volatility*	63.64%	57.00%	62.56%	57.65%	64.39%	
Estimated life (years)*	6.10	2.80	6.11	4.17	3.71	
Expected dividends*	0	0	0	0	0	
Risk-free rate*	-0.2772%	-0.3602%	-0.2046%	2.0670%	1.6813%	
Remaining contractual life (years)	6.81	0.92	7.25	5.01	5.01	

** Weighted average*

As of December 31, 2023, the company has 4,524,013 options outstanding entitling to the subscription of maximum 4,536,489 new shares representing a dilution of 6.6 percent.

Note 6 Income tax

Fourth quarter 2023

In the period, the Group recognized a non-current tax benefit of SEK 0 million (0.3). The tax benefit in 2022 is recognized in Saniona Inc. of SEK 0.3 million.

January – December 2023

In the period, the Group recognized a non-current tax benefit of SEK 8.5 million (6.6). The tax benefit in 2023 is on net loss recognized in Saniona A/S under the Danish 'Skattekreditordningen' (the 'Tax Credit Scheme'). The tax expenses in 2022 is a tax cost recognized in Saniona Inc. of SEK 1.1 million, and a tax benefit of SEK 7.7 million in Saniona A/S under the Danish 'Skattekreditordningen' (the '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 37.3 million).

Note 7 Other financial liabilities

A. Formue Nord Loan

In July 2021, the Group entered into a non-dilutive SEK-denominated fixed-rate term loan agreement for SEK 87.0 million with Formue Nord Focus A/S. During the period September 2022 until December 2023 the terms have been renegotiated, and the remaining loan value was SEK 61 million.

In December 2023, Saniona announced in connection with the Rights Issue, a renegotiation of the outstanding loan. Saniona will, in connection with the Rights Issue, repay SEK 20 million of the loan in cash or by set-off. Approximately SEK 31.2 million of the remaining loan of approximately SEK 41.2 million will continue to run as a loan and SEK 10 million will be converted into new convertibles in the Company. The loan and the convertibles of approximately SEK 41.2 million shall accrue at an annual interest of STIBOR 3M plus an interest margin of eight (8) per cent, and the interest shall be paid in cash by the end of each calendar quarter. The loan matures hereafter on July 31, 2025.

Note 8 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, 2023		Carrying amount				Fair value			
KSEK	Note	Financial assets at amortized cost	Mandatorily at FVTPL - others	Financial liabilities at amortized cost	Total	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value									
Contingent consideration receivable		—	240	—	240	—	—	240	240
		—	**240**	**—**	**240**	**—**	**—**	**240**	**240**
Financial assets not measured at fair value									
Trade receivables		2,526	—	—	2,526	—	—	—	—
Other non-current financial assets		2,853		—	2,853	—	—	—	—
Other current financial assets		1,570	—	—	1,570	—	—	—	—
Cash and cash equivalents		30,962	—	—	30,962	—	—	—	—
		37,911	**—**	**—**	**37,911**	**—**	**—**	**—**	**—**
Financial liabilities not measured at fair value									
Trade payables		—	—	8,245	8,245	—	—	—	—
Formue Nord Loan	7	—	—	65,238	65,238	—	—	—	—
Lease liabilities		—	—	6,171	6,171	—	—	—	—
		—	**—**	**79,654**	**79,654**	**—**	**—**	**—**	**—**

December 31, 2022		Carrying amount				Fair Value			
KSEK	Note	Financial assets at amortized cost	Mandatorily at FVTPL - others	Financial liabilities at amortized cost	Total	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value									
Contingent consideration receivable		—	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		2,246		—	2,246	—	—	—	—
Other current financial assets		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	7	—	—	70,636	70,636	—	—	—	—
Lease liabilities		—	—	10,885	10,885	—	—	—	—
		—	**—**	**95,594**	**95,594**	**—**	**—**	**—**	**—**

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, 2023, the contingent consideration has been measured at SEK 0.2 million.

ii. Transfers

During the three and twelve months ended December 31, 2023 and 2022, 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, 2023	241
Cash received	—
Changes in Fair Value	—
Foreign currency (included in 'net gains/losses on financial items')	-1
Balance, December 31, 2023	**240**

Note 9 Related parties

Pierandrea Muglia was at the Annual General Meeting May 25, 2023, elected as a new ordinary board member. The Group has a Consultancy Agreement with Pierandrea Muglia, for the provision of advisory services regarding Saniona's research and development. In the period May 25 until December 31, 2023, the fee for Pierandrea's services was SEK 0.4 million.

The Group has 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. In the period January until December 2023, the fee for Jørgen's services was SEK 1.5 million.

We also refer to Note 27 Related parties in the 2022 Annual report.

Note 10 Restatement

The condensed consolidated financial statement for the Group that were previously issued for the year ended December 31, 2022, has been restated with respect to translations differences related to Saniona Inc. within the consolidated statement of comprehensive income, and a restatement to statement of changes in equity as of January 1, 2022, of SEK 73.5 million with respect to Fair value reserve.

The restatements relate to accounting adjustments (IAS8), and do not impact Saniona's cash position.

The total impact of the restatements for previously reported period 2021 is as follows:

KSEK	Share capital	Additional paid-in capital	Translation reserve	Fair value reserve	Acc. deficit	Share-holders equity
January 1, 2022 (previously reported)	3,119	813,261	1,016	73,529	-608,926	281,999
Restatement				-73,529	73,529	0
January 1, 2022 (restated)	**3,119**	**813,261**	**1,016**	**0**	**-535,397**	**281,999**

The total impact of the restatements for the three months ended December 31, 2022 is as follows:

KSEK	2022-10-01 2022-12-31 (Restated)	Adjustment	2022-10-01 2022-12-31 (Previously reported)
Net gain on financial items	22,127	33,788	-11,661
Profit/loss for the period	-7,161	33,788	-40,949
Other comprehensive income: Translation differences	-32,485	-33,788	1,303
Total comprehensive profit (loss)	-39,646	0	-39,646

The total impact of the restatements for the full year ended December 31, 2022 is as follows:

KSEK	2022-01-01 2022-12-31 (Restated)	Adjustment	2022-01-01 2022-12-31 (Previously reported)
Net gain on financial items	22,127	33,788	-11,661
Profit/loss for the period	-211,569	33,788	-245,357
Other comprehensive income: Translation differences	259	-33,788	34,047
Total comprehensive profit (loss)	-211,310	0	-211,310

Note 11 Subsequent Events to the Balance Sheet Date

- In January, Saniona announced selection of SAN2465 as a preclinical candidate for major depressive disorder.
- In January, the board of directors resolved on an issue of units consisting of shares and warrants with preferential rights for the existing shareholders, which was approved at the extraordinary general meeting on January 16, 2024.
- In January, Saniona announced the preliminary 2023 financials.
- In February, Saniona announced outcome in rights issue of a proceed of approximately SEK 88.9 million before issue costs.
- In February, Saniona announced a directed issue of units to guarantors in the rights issue as well as convertibles of SEK 10 million to Formue Nord.

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