Saniona poised for success in epilepsy

Three Months Ended September 30, 2023 (2022)	Nine Months Ended September 30, 2023 (2022)
Revenue was SEK 5.5 M (2.4 M)	Revenue was SEK 11.5 M (12.0 M)
Operating profit/loss was SEK -18.4 M (21.8 M)	Operating profit/loss was SEK -61.3 M (-203.1 M)
Net profit/loss was SEK -24.1 M (17.5 M)	Net profit/loss was SEK -67.1 M (-204.4 M)
Basic earnings/loss per share was SEK -0.38 (0.28)	Basic earnings/loss per share was SEK -1.05 (-3.28)
Diluted earnings/loss per share were SEK -0.38 (0.28)	Diluted earnings/loss per share were SEK -1.05 (-3.28)

Business highlights in Q3 2023

- In July, Saniona announced a new collaboration agreement with AstronauTx in Alzheimer's disease. Saniona may receive up to SEK 1.9 billion ($177 million) in milestone payments as well as royalties on worldwide net sales of resulting products under the collaboration.
- In August, Saniona announced a change to the terms of the loan agreement with Formue Nord. The parties agreed to reduce the loan value, through a repayment of SEK 3 million by Saniona and a conversion of SEK 10 million into shares at 8.50 SEK per share. Formue Nord has also received a commitment fee of SEK 4.8 million, which also was converted into shares at 8.50 SEK per share. The maturity date of the loan agreement changed to January 31, 2025.

Significant events after the reporting period

- In October, Saniona's new partner, AstronauTx, closed a $61 million Series A financing led by the Novartis Venture Fund and backed by several other leading global venture investors, including Brandon Capital, Bristol Myers Squibb, EQT Life Sciences investing from the LSP Dementia Fund, MPM Capital and the Dementia Discovery Fund.
- Professor Vincenzo Crunelli, Cardiff University, U.K., presented preclinical data on Saniona's lead ion-channel drug candidate and phase 2 ready asset, SAN711, at the annual meeting of the Society for Neuroscience (SfN) 11th-15th November 2023, Washington DC. The data shows strong suppression of absence seizures, which demonstrates that SAN711 represents a novel precision approach for treatment of non-convulsive generalized seizures.
- In November, Saniona announced that it has initiated the candidate selection phase with a proprietary subtype selective frontrunner molecule from Kv7 lead optimization program for epilepsy.

Comments from the CEO

"We have a broad pipeline, which we develop in collaboration with partners. We have a long and successful history of finding and negotiating partnerships, such as the new collaboration with AstronauTx in Alzheimer's disease. Based on our business discussions, I am confident that we will reach additional partnerships. In parallel we are leveraging our expertise in ion-channel drug discovery to identify and advance additional clinical candidates in a range of epilepsy indications. Saniona has a lot to offer in epilepsy and may create significant value for the shareholders in this field."

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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 in the past quarter has been twofold; 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 advance additional selective ion channel clinical candidates in a range of epilepsy indications.

Early in the quarter, we announced a new research collaboration with AstronauTx in Alzheimer's disease. We may receive up to SEK 1.9 billion ($177 million) in milestone payments as well as royalties on worldwide net sales of resulting products under the collaboration. A core component of the research collaboration will be based on our proprietary platform, IonBaseTM, for the modulation of ion channels. We will receive research funding during the research period and during the first year of the collaboration, we expect to receive research funding of around SEK 15 million (€ 1.3 million).

We have also made significant progress in our internal epilepsy portfolio which has provided us with three promising active epilepsy programs; Kv7, SAN2219 and SAN711. Our efforts in our advanced Kv7 epilepsy program have resulted in several novel, potent and selective compounds with promising efficacy and tolerability. We recently announced that we have now selected a lead compound for final testing with the aim of a selection for preclinical development shortly.

Our novel anti-epileptic preclinical candidate SAN2219 has been specifically designed to selectively modulate $GABA_A$ α2, α3 and α5-containing receptors, resulting in a robust inhibition of seizure activity without the well-known $GABA_A$ α1 mediated side effects of benzodiazepines. The preclinical data support that SAN2219 may be used for acute and chronic treatment of prevalent epilepsy forms as well as specific epilepsy syndromes.

In addition, the preclinical data recently presented at the annual meeting of the Society for Neuroscience (SfN), demonstrate that our lead ion-channel drug candidate and phase 2 ready asset, SAN711, represents a novel precision approach for treatment of non-convulsive generalized seizures. SAN711's unique differentiated pharmacological profile makes it a potential new treatment for various epilepsy patients with non-convulsive seizures including patients with childhood absence seizures, juvenile absence seizures and various type of pediatric epileptic syndromes.

Epilepsy is a chronic neurological disease that causes recurring seizures due to abnormal electrical activity in the brain. Being one of the most common and disabling chronic neurological disorders, epilepsy affects all age groups and is characterized by an enduring predisposition to generate epileptic seizures with the associated cognitive, psychological, and social consequences and increased mortality.

For most patients with epilepsy there is currently no cure, and most patients rely on symptomatic pharmacological treatment with antiseizure medications (ASM), which prevent or suppress the generation, propagation, and severity of epileptic seizures. However, about one third of patients are drug resistant to the available ASM, and only a small fraction of them may obtain complete seizure control through surgery. Therefore, despite many ASMs currently available, there is a significant unmet medical need within epilepsy, which can be divided into two major areas: the resistant patients in the large adult patient populations with focal and generalized epilepsy; and the difficult to treat pediatric epilepsy syndromes.

According to the World Health Organization, around 50 million people worldwide have epilepsy, making it one of the most common neurological diseases globally. With a CAGR of 5 percent, the total market for epilepsy medication is expected to reach USD 8.3 billion by 2028, according to Evaluate Pharma.

We intend to continue utilizing our expertise in ion channel drug discovery in collaborations with pharmaceutical companies outside epilepsy. Historically, this activity has led to several out-licensing arrangements, spinouts, and collaborations with pharmaceutical companies globally. These transactions serve as a source of non-dilutive capital, in the form of upfront payments, research funding, milestone payments, royalties and/or equity stakes that Saniona intends to reinvest in both the discovery engine and its core development efforts within epilepsies. In addition, Saniona has two non-epilepsy clinical assets, SAN903 and Tesomet, which we intend to progress in collaboration with partners under similar transactions.

Our Mexican partner Medix is positive about the potential approval of tesofensine in Mexico as a new treatment option for obesity. The Mexican regulatory authority's technical committee on new molecules gave a favorable opinion earlier in the year on tesofensine for treatment of obesity. Medix has subsequently filed a formal application to the regulatory agency which potentially could lead to an approval of tesofensine in Mexico. Tesofensine could be a powerful new and

competitive product in this market since it is safe and well tolerated, can be taken as a tablet, and provides the same level of efficacy as some of best injectable GLP-1 analogs. The Mexican obesity market is expected to reach about USD 190 million in 2023.

According to Medix, the regulatory agency should decide on tesofensine within short. An approval would represent a new source of income for Saniona, and we are entitled to royalties on product sales in Mexico. If tesofensine obtains approval in Mexico, we will explore the potential commercialization in other geographies including other central- and South American countries, which may accept Mexico as a reference country for regulatory approval.

In our collaboration with Boehringer Ingelheim we are identifying novel ion channel modulators to treat cognitive deficits in schizophrenia. This innovative program has made significant progress towards moving into lead optimization, which would trigger the first financial milestone payment. In total, we may receive up to SEK 0.9 billion (€76.5 million) in milestone payments as well as royalties on worldwide net sales of resulting products under the collaboration.

In August, we agreed with Formue Nord to reduce our loan with SEK 13 million to SEK 61 million through a repayment (SEK 3 million) and a conversion into shares (SEK 10 million). At the same time, the maturity date was extended to January 31, 2025. The reduction and the extension strengthen our negotiation position and provide more flexibility until income and proceeds from partnership agreements have started to kick in.

Our research platform has proven its potential for developing novel treatment opportunities for various neurological and psychiatric diseases. We have a long and successful history of finding and negotiating partnerships for our research and clinical-stage assets, such as the new research collaboration with AstronauTx in Alzheimer's disease. Based on the discussions we have, I am confident that we will reach additional partnerships.

Going forward we will increase our efforts to discover, develop and deliver innovative treatments to patients suffering from epilepsies around the world. I look forward to providing further updates on our work.

Thomas Feldthus
CEO

About Saniona

Saniona is an epilepsy focused clinical-stage biopharmaceutical company engaged in the discovery and development of medicines modulating ion channels. Saniona's epilepsy pipeline includes the Phase 2 ready asset SAN711 positioned for treatment of absence seizures, the preclinical development compound SAN2219 for acute repetitive seizures and the drug-discovery program on Kv7 modulators for refractory focal onset seizures. Outside epilepsy Saniona has three clinical programs, which are positioned for partnering. The most advanced candidate, tesofensine, has progressed towards regulatory approval for obesity in Mexico by Saniona's partner Medix, whereas Tesomet™ is ready for Phase 2b for rare eating disorders, and SAN903 is ready for Phase 1 for inflammatory bowel disease. Saniona has research and development partnerships with 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 Small Cap (OMX: SANION). Read more at 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 disorders*								**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
GABA program	*Epilepsy*								**Positioned for rare pediatric epilepsy syndrome** with multiple expansion opportunities in rare and severe epilepsy
Kv7 program	*Epilepsy*								Focal/Generalized Epilepsy Lead optimization
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 comprise two clinical candidates, SAN711 and SAN2219, and two mature research programs, a GABA program and a Kv7 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 July 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.

In contrast to SAN711, where the profile is precisely tailored to abort absence seizures by enhancing the effect of $GABA_A$ α3 containing receptors, the profile of SAN2219 is specifically designed to exert broad antiseizure activity by enhancing the effect of $GABA_A$ α2 and α5 containing receptors in addition to α3. 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.

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.

It 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.

Kv7 program

Saniona has progressed the first compound from its Kv7 program to the candidate selection phase. While Kv7 modulation is a clinically proven concept for the treatment of treatment resistant focal epilepsy, no drugs of this class are currently on the market, and the Company sees significant potential for delivering new breakthrough epilepsy treatments in this field.

The Kv7.2/Kv7.3 ion channel is a voltage-gated ion channel, which is activated during periods of strong neuronal activity, where it reestablishes the membrane potential to the resting state by mediating a selective outward flux of potassium ions. When Kv7.2/ Kv7.3 ion channel activity is facilitated by Saniona's Kv7 lead compound for treatment of epilepsy, these channels revert the epileptic activity of neurons and prevent new attacks to occur.

Kv7 channels are a family of voltage-dependent potassium channels which control the generation of nerve-impulses in neurons of the central nervous system, and the contraction of muscle cells in heart-, blood vessel-, and bladder tissues. There are five subtypes of Kv7 channels (Kv7.1 to Kv7.5). The Kv7.2/Kv7.3 subtypes are the major Kv7 channel in CNS neurons and the target for anti-epileptic treatment. Kv7.1 is expressed in the heart muscle cells, whereas Kv7.4 is broadly expressed in many non-CNS tissues, including the smooth muscle in blood vessels and bladder. Kv7.5 is also expressed quite broadly, including CNS neurons, but with different distribution and functional role than Kv7.2/Kv7.3 in the brain.

Kv7 channels are clinically validated targets for epilepsy. In 2010 GSK launched retigabine (Ezogabine, Trobalt) for treatment-resistant focal onset seizures based on convincing Phase 3 studies. Retigabine is a non-selective activator of Kv7.2-Kv7.5 and based on adverse findings the product received a black-box warning for the risk of causing urinary retention (a potentially life-threatening condition) in some patients. The drug was withdrawn from the market in 2017 due to discoloration of skin and retina with long-term use in patients. Whereas the urinary retention issue was related to bladder Kv7.4 channels, the skin problem was due to chemical instability of the chemical class that retigabine belongs to. Xenon Pharmaceuticals reported positive Phase 2 data with XEN1101- a potent analogue of retigabine – in 2022 and is currently conducting a Phase 3 study with the compound in focal onset epilepsy patients. 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 study.

The Saniona Kv7 program is in the lead-optimization phase, and a front runner is currently under evaluation in the candidate selection program. Saniona's lead compound is a subtype selective Kv7.2/Kv7.3 activator with limited or no activation of other Kv7 subtypes at normal membrane potentials. The lead compound has a clearly differentiated profile compared to reference compounds, retigabine and XEN1101, since it is subtype selective and belongs to a different chemical series than these two molecules. This means a reduced risk of inducing urinary retention (no activation of Kv7.4), probably reduced CNS side-effects (partly related to Kv7.5), and no issue with chemical instability, which eventually led to the withdrawal of retigabine from the market. Furthermore, since the dose-projection to humans indicates one daily dosing of 50 mg, the lead compound is more potent than retigabine (600-900 mg, three times daily) and on par with XEN1101 (20 mg once daily).

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

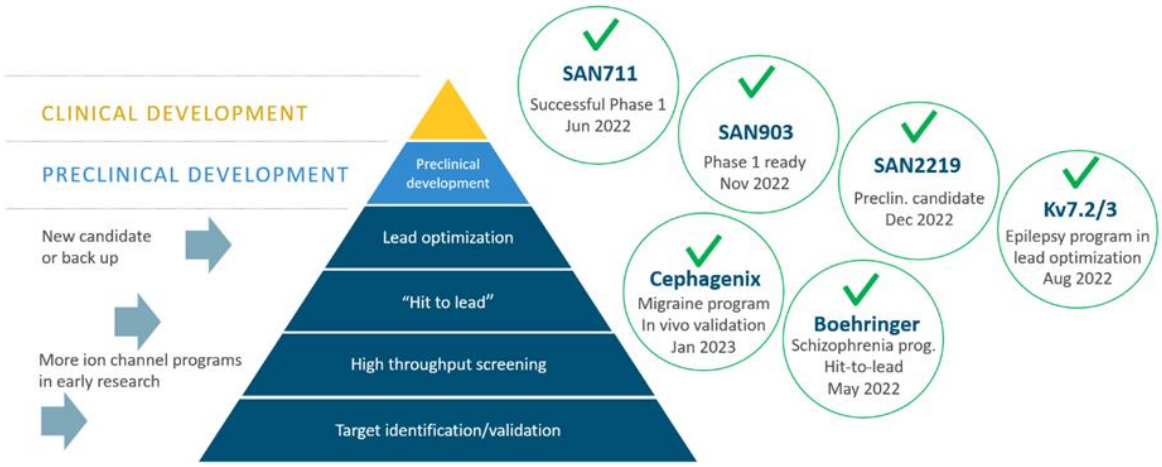
SAN903 has successfully completed preclinical development in 2022 and we are preparing a Clinical Trial Application (CTA) for submission to the European Medicines Regulatory Agencies (EMA) enabling Phase 1 clinical trials either by Saniona alone or together with a partner. The primary indication for 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

Saniona Drug Discovery Engine Generates Continual 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 and SAN2219. 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 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

192	2023-07-01 2023-09-30	2022-07-01 2022-09-30	2023-01-01 2023-09-30	2022-01-01 2022-09-30	2022-01-01 2022-12-31
Revenue, KSEK	5,451	2,388	11,466	11,977	15,283
Total operating expenses, KSEK	-23,808	19,464	-72,755	-215,090	-241,002
Operating profit (loss), KSEK*	-18,357	21,852	-61,289	-203,113	-225,719
Cash flow for the period, KSEK	-23,130	-51,979	-72,140	-275,367	-295,215
Average shares outstanding	63,256,328	62,385,677	62,823,381	62,385,677	62,385,677
Diluted average shares outstanding	63,813,956	62,385,677	63,210,886	62,385,677	62,385,677
Shares outstanding at the end of the period	64,126,978	62,385,677	64,126,978	62,385,677	62,385,677
Average number of employees	23	25	23	38	34
Operating margin*					
Operating profit (loss), KSEK	-18,357	21,852	-61,289	-203,113	-225,719
Revenue, KSEK	5,451	2,388	11,466	11,977	15,283
Operating margin, %	**-337%**	**915%**	**-535%**	**-1,696%**	**-1,477%**
Cash flow per share*					
Cash flow for the period, KSEK	-23,130	-51,979	-72,140	-275,367	-295,215
Shares outstanding at the end of the period	64,126,978	62,385,677	64,126,978	62,385,677	62,385,677
Cash flow per share, SEK	**-0.36**	**-0.83**	**-1.12**	**-4.41**	**-4.73**
Earnings per share					
Profit (loss) for the period, KSEK	-24,092	17,517	-67,069	-204,408	-245,357
Shares outstanding at the end of the period	64,126,978	62,385,677	64,126,978	62,385,677	62,385,677
Earnings per share, SEK	**-0.38**	**0.28**	**-1.05**	**-3.28**	**-3.93**
Diluted earnings per share, SEK	**-0.38**	**0.28**	**-1.05**	**-3.28**	**-3.93**

	2023-09-30	2022-09-30	2022-12-31
Cash and cash equivalent, KSEK	49,278	117,555	111,707
Equity, KSEK	6,670	91,333	52,708
Total Equity and liabilities, KSEK	94,405	192,628	153,696
Equity per share*			
Equity, KSEK	6,670	91,333	52,708
Shares outstanding at the end of the period	64,126,978	62,385,677	62,385,677
Equity per share, SEK	**0.10**	**1.46**	**0.84**
Equity ratio*			
Equity, KSEK	6,670	91,333	52,708
Total assets, KSEK	94,405	192,628	153,696
Equity ratio, %	**7%**	**47%**	**34%**
Liquidity ratio*			
Current assets, KSEK	64,509	144,939	127,345
Current liabilities, KSEK	23,313	22,552	22,897
Liquidity ratio, %	**277%**	**643%**	**556%**

** = Alternative performance measures*

Results of Operations

Third quarter 2023

Revenue for the third quarter amounted to SEK 5.5 million (2.4). Revenues in third quarter 2023 include amounts from our licensing and partnership agreements with Boehringer Ingelheim, AstronauTx and Cephagenix. Revenues in third 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 third quarter amounted to SEK 23.8 million (profit 19.5). Within operating expenses, external expenses decreased by SEK 14.4 million from a profit of SEK 2.4 million to an expense of SEK 12.0 million. The reason for the profit on external expenses in the three months ended September 30, 2022, is that we had finalized the contract with our main external CRO of Tesomet, which has decreased the accruals from June 30, 2022, with net SEK 8.5 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 third quarter, comprised development costs of Tesomet SEK 0.6 million (profit 8.5), development costs of SAN711 SEK 3.4 million (profit 1.6) and pre-clinical development costs of the SAN903 program SEK 0 million (0.3) and other research costs SEK 8.0 million (12.2).

Personnel costs include salaries, variable compensation, social security, and other employee benefits. Personnel costs for the third quarter amounted to SEK 8.3 million (profit 19.7). Non-cash share-based compensation expense is included in personnel costs and amounted to SEK 1.1 million (profit 26.3). 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 SEK 2.9 million to SEK 8.1 million. The financial expenses include interest and commitment fee to Formue Nord of SEK 3.1 million (2.6) and SEK 6.1 million (0.7), respectively, other interest expenses SEK 0.3 million (3.4) and financial income of SEK 1.4 million (3.8).

The Group recognized a tax income in the period of SEK 2.3 million (expense 1.4). The tax benefit in 2023 is on net loss recognized in Saniona A/S under the Tax Credit Scheme in Denmark. The tax expense in 2022 is a tax cost recognized in Saniona Inc.

Net cash used in operating activities in the period decreased by SEK 16.9 million from SEK -35.5 million to SEK -18.6 million.

The operating cash flow in the period is primarily attributable to the operating loss of SEK 15.5 million (2.8). The operating cashflow is net of non-cash operating expenses for share-based payments of SEK 1.1 million (profit 26.3) and for expenses depreciation of SEK 1.8 million (1.6).

For the period net cash used by investing activities was SEK 0.1 million (0.1). The investing activities in 2022 and 2023 are purchases of minor equipment.

For the period net cash used by financing activities was SEK 4.4 million (16.4), due to repayment of lease liabilities of SEK 1.3 million (1.4), and SEK 3 million (15.0) of repayment of loan to Formue Nord. 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 shares. Formue Nord also received a commitment fee of SEK 4.8 million, which also was converted into shares. 1,741,301 new shares were issued at a subscription price of SEK 8.50 per share. The maturity date for the remaining outstanding loan value of SEK 61 million, including commitment fee of SEK 2.1 million from 2021, has been changed from January 31, 2024, to January 31, 2025.

January – September

Revenue for the period amounted to SEK 11.5 million (12.0). 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 72.8 million (215.1). Within operating expenses, external expenses decreased by SEK 95.1 million from SEK 132.8 million to SEK 37.7 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 8.0 million (47.9), development costs of SAN711 SEK 3.4 million (33.6) and pre-clinical development costs of the SAN903 program SEK 1.1 million (10.4) and other research costs SEK 25.2 million (40.9).

Personnel costs include salaries, variable compensation, social security, and other employee benefits. Personnel costs for the period amounted to SEK 25.7 million (72.7). Non-cash share-based compensation expense is included in personnel costs and amounted to SEK 2.9 million (profit 19.0). 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 SEK 7.6 million to SEK 14.3 million. The financial expenses include interest and commitment fee to Formue Nord of SEK 7.6 million (2.0) and SEK 7.6 million (7.8), respectively, other interest expenses of SEK 1.8 million (6.8) and financial income of SEK 2.7 million (8.7).

The Group recognized a tax income of SEK 8.5 million (6.3). 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 1.4 million, and a tax benefit of SEK 7.7 million in Saniona A/S under the Tax Credit Scheme in Denmark.

Net cash used in operating activities decreased by SEK 197.9 million from SEK -263.3 million to SEK -65.4 million.

The operating cash flow for the period, is primarily attributable to the operating loss of SEK 53.1 million (216.0), net of non-cash operating expenses for share-based payments of SEK 2.9 million (profit 19.0) and for expenses depreciation of SEK 5.3 million (6.1).

For the period, net cash used by investing activities was SEK 0.1 million (received 7.6). 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 (0.0).

For the period, net cash used by financing activities was SEK 6.7 million (19.6), due to repayment of lease liabilities of SEK 3.5 million (4.6), costs related to issuance of new shares SEK 0.2 million (0) and SEK 3 million (15.0) of repayment of loan to Formue Nord. 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 shares. Formue Nord also received a commitment fee of SEK 4.8 million, which also was converted into shares. 1,741,301 new shares were issued at a subscription price of SEK 8.50 per share. The maturity date for the remaining outstanding loan value of SEK 61 million has been changed from January 31, 2024, to January 31, 2025.

Parent Company
January - September

Operating expenses for the period amounted to SEK 5.5 million (26.4). The main component of the Parent Company's operating expenses are other external costs of SEK 2.9 million (9.6), and personnel costs of SEK 2.5 million (16.8). The significant decrease in other external costs and personnel costs is due to closing of the U.S. operation in 2022.

Loss amounted for the period to SEK 27.4 million (35.8). The main component of the Parent Company's loss also includes financial items of SEK 23.1 million (12.4), which is interest and commitment fee to Formue Nord of SEK 7.6 million (2.0) and SEK 7.6 million (7.8), respectively, other interest expenses SEK 8.0 million (3.0), 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 7% (47%) as of September 30, 2023 and equity for the Group was SEK 6.7 million (91.3). Cash and cash equivalents for the Group amounted to SEK 49.3 million (117.6) as of September 30, 2023. Total assets for the Group as of September 30, 2023 were SEK 94.4 million (192.6).

The equity ratio for the Parent company was 61 (66) as of September 30, 2023 and equity for the Parent company was SEK 211.8 million (227.2). Cash and cash equivalents for the parent company amounted to SEK 3.9 million (1.9) as of September 30, 2023. Total assets for the parent company as of September 30, 2023 were SEK 348.8 million (343.2).

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 September 30, 2023 Saniona has received research funding from AstronauTx and Boehringer Ingelheim of SEK 11.5 million.
Saniona expects to receive research funding from AstronauTx and Boehringer Ingelheim the next two quarters totaling up to SEK 11.5 million. Together with the new agreement with AstronauTx and the collaboration agreement with Boehringer Ingelheim Saniona expects that the Group has and will have adequate resources to continue in operation existence at least into Q2 2024, which means that there is an uncertainty factor around the financing. 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 raise additional financing to fund the company's operation and further development of its pipeline programs. The board assesses that the conditions are good to acquire financing to secure at least 12 months of continuous operation. The company's financial report has therefore been prepared according to the going concern assumption.

On September 30, 2023, the company had 13,176 (10,416) shareholders excluding holdings in life insurance and foreign custody account holders.

Personnel

As of September 30, 2023, Saniona had 23 (25) employees including 10 (11) employees with Ph.D. degrees. Of these employees, 17 (18) were engaged in research and clinical development activities and 6 (7) were engaged in general and administrative activities. Of the 23 (25) employees, 12 (14) 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. There are no major changes in the Group's risk factors and risk management in 2023.

Annual General Meeting

Saniona's Annual General Meeting for 2024 will be held in Malmö on May 29, 2024, at 16:30. For more information, visit www.saniona.com.

Audit review

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

Financial calendar

Year-End Report 2023	February 29, 2024, at 8:00 CET
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

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

Glostrup, 30 November 2023
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	2023-07-01 2023-09-30	2022-07-01 2022-09-30	2023-01-01 2023-09-30	2022-01-01 2022-09-30	2022-01-01 2022-12-31
	1,2,3					
Revenue	4	5,451	2,388	11,466	11,977	15,283
Total operating income		5,451	2,388	11,466	11,977	15,283
Raw materials and consumables		-1,536	-967	-3,703	-3,433	-4,475
Other external costs		-12,023	2,388	-37,681	-132,811	-146,486
Share of result of associate	9	-190	—	-394	—	—
Personnel costs	5	-8,278	19,688	-25,686	-72,711	-82,223
Depreciation and write-downs		-1,781	-1,645	-5,291	-6,135	-7,818
Total operating expenses		-23,808	19,464	-72,755	-215,090	-241,002
Operating profit (loss)		**-18,357**	**21,852**	**-61,289**	**-203,113**	**-225,719**
Share of result of associate	9	—	87	—	296	346
Financial income		1,432	3,757	2,729	8,747	9,726
Financial expenses		-9,512	-6,735	-16,979	-16,668	-24,659
Net gains on financial items		—	—	—	—	-11,661
Total financial items		-8,080	-2,891	-14,250	-7,625	-26,248
Profit (loss) before tax		**-26,437**	**18,961**	**-75,539**	**-210,738**	**-251,967**
Income tax	6	2,345	-1,444	8,470	6,330	6,610
Profit (loss) for the period*		**-24,092**	**17,517**	**-67,069**	**-204,408**	**-245,357**
Other comprehensive income (loss) for the period						
Item that may be reclassified to profit and loss						
Translation differences		-1,647	4,093	3,493	32,744	34,047
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		**-1,647**	**4,093**	**3,493**	**32,744**	**34,047**
Total comprehensive profit (loss)**		**-25,739**	**21,610**	**-63,576**	**-171,664**	**-211,310**
Loss per share, SEK		-0.38	0.28	-1.05	-3.28	-3.93
Diluted loss per share, SEK		-0.38	0.28	-1.05	-3.28	-3.93

* 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	2023-09-30	2022-09-30	2022-12-31
ASSETS				
Intangible assets		6,965	6,601	6,737
Property and equipment		4,619	3,702	5,703
Right of use assets		6,381	12,683	9,998
Investment in associate	9	431	2,241	799
Other financial assets	8	2,987	14,395	3,114
Tax assets		8,513	8,067	—
Non-current assets		**29,896**	**47,689**	**26,351**
Trade receivables		2,906	2,961	4,628
Current tax assets	6	8,512	8,067	8,234
Other assets		3,813	16,356	2,776
Cash and cash equivalents		49,278	117,555	111,707
Current assets		**64,509**	**144,939**	**127,345**
Total assets		**94,405**	**192,628**	**153,696**

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

KSEK	Note	2023-09-30	2022-09-30	2022-12-31
EQUITY AND LIABILITIES				
Share capital		3,206	3,119	3,119
Additional paid-in capital		827,803	813,261	813,261
Reserves		112,085	107,289	108,592
Accumulated deficit		-936,424	-832,337	-872,264
Equity		**6,670**	**91,333**	**52,708**
Other financial liabilities	7,8	61,888	76,413	75,699
Other liabilities		2,534	2,330	2,392
Non-current liabilities		64,422	78,743	78,091
Trade payables		14,022	14,569	14,073
Other financial liabilities	7,8	5,425	5,557	5,822
Other liabilities		3,866	2,426	3,002
Current liabilities		23,313	22,552	22,897
Total liabilities		**87,735**	**101,295**	**100,988**
Total equity and liabilities		**94,405**	**192,628**	**153,696**

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, 2022	**3,119**	**813,261**	**1,016**	**73,529**	**-608,926**	**281,999**
Comprehensive income						
Loss for the period	—	—	—	—	-204,408	-204,408
Other comprehensive income	—	—	32,744	—	—	32,744
Total comprehensive	**—**	**—**	**32,744**	**—**	**-204,408**	**-171,664**
Transactions with owners						
Shares issued for cash	—	—	—	—	—	—
Expenses related to capital increase	—	—	—	—	—	—
Share-based compensation expenses	—	—	—	—	-19,003	-19,003
Total transactions with owners	**—**	**—**	**—**	**—**	**-19,003**	**-19,003**
September 30, 2022	**3,119**	**813,261**	**33,760**	**73,529**	**-832,337**	**91,333**
January 1, 2023	**3,119**	**813,261**	**35,063**	**73,529**	**-872,264**	**52,708**
Comprehensive income						
Loss for the period	—	—	—	—	-67,069	-67,069
Other comprehensive income			3,493	—	—	3,493
Total comprehensive income (loss)	**—**	**—**	**3,493**	**—**	**-67,069**	**-63,576**
Transactions with owners						
Shares issued for cash	87	14,715	—	—	—	14,802
Expenses related to capital increase	—	-173	—	—	—	-173
Share-based compensation expenses	—	—	—	—	2,909	2,909
Total transactions with owners	**87**	**14,542**	**—**	**—**	**2,909**	**17,538**
September 30, 2023	**3,206**	**827,803**	**38,556**	**73,529**	**-936,424**	**6,670**

Condensed consolidated interim statement of cash flows – Group

KSEK	Note	2023-07-01 2023-09-30	2022-07-01 2022-09-30	2023-01-01 2023-09-30	2022-01-01 2022-09-30	2022-01-01 2022-12-31
Loss before tax		-26,437	18,961	-75,539	-210,738	-251,967
Adjustments for non-cash transactions		2,805	-24,681	5,731	-11,505	-8,799
Changes in working capital		10,136	-24,166	10,874	-31,912	-17,554
Cash flow from operating activities before financial and tax items		**-13,496**	**-29,886**	**-58,934**	**-254,155**	**-278,320**
Interest income received		580	189	2,132	229	593
Interest expenses paid		-5,693	-5,769	-8,560	-9,361	-11,937
Tax credit received		—	—	—	—	8,126
Cash flow from operating activities		**-18,609**	**-35,466**	**-65,362**	**-263,287**	**-281,537**
Investing activities						
Purchases of property and equipment		-83	-268	-83	-309	-985
Proceeds from sale of financial assets		—	—	—	7,522	7,522
Proceeds from sale of tangible assets		—	106	—	305	306
Cash flow from investing activities		**-83**	**-162**	**-83**	**7,518**	**6,843**
Financing activities						
Repayment of loan		-3,000	-15,000	-3,000	-15,000	-15,000
Costs related to issuance of new shares		-173	—	-173	—	—
Payment of lease liabilities		-1,264	-1,351	-3,522	-4,598	-5,521
Cash flow from financing activities		**-4,437**	**-16,351**	**-6,695**	**-19,598**	**-20,521**
Net increase (decrease) in cash and cash equivalents		**-23,129**	**-51,979**	**-72,140**	**-275,367**	**-295,215**
Cash and cash equivalents at beginning of period		**69,409**	**173,143**	**111,707**	**356,855**	**356,855**
Exchange rate adjustments		2,998	-3,609	9,711	36,067	50,067
Cash and cash equivalents at end of period		**49,278**	**117,555**	**49,278**	**117,555**	**111,707**

PARENT COMPANY'S FINANCIAL STATEMENTS

Statement of income – Parent Company

KSEK	Note	2023-01-01 2023-09-30	2022-01-01 2022-09-30	2022-01-01 2022-12-31
	1,2,3			
Other operating income		1,182	3,015	3,418
Total operating income		1,182	3,015	3,418
Raw materials and consumables		-28	-23	-30
Other external costs		-2,941	-9,552	-10,602
Personnel costs	5	-2,519	-16,839	-17,728
Total operating expenses		-5,488	-26,414	-28,360
Operating income (loss)		**-4,306**	**-23,399**	**-24,942**
Financial income		81	363	391
Financial expenses		-23,203	-12,789	-17,785
Total financial items		-23,122	-12,426	-17,394
Profit (loss) before tax		**-27,428**	**-35,825**	**-42,336**
Tax on net profit (loss)		—	—	—
Profit (loss) for the period		**-27,428**	**-35,825**	**-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	2023-09-30	2022-09-30	2022-12-31
ASSETS				
Investment in subsidiaries		344,442	340,767	341,703
Financial assets		344,442	340,767	341,703
Non-current assets		**344,442**	**340,767**	**341,703**
Other assets		439	523	222
Current receivables		439	523	222
Cash and cash equivalents		3,931	1,939	2,228
Current assets		**3,931**	**2,462**	**2,450**
Total assets		**348,812**	**343,229**	**344,153**
EQUITY AND LIABILITIES				
Restricted equity				
Share capital		3,206	3,119	3,119
Unrestricted equity				
Share premium reserve		827,803	813,261	813,261
Retained earnings (accumulated deficit)		-591,783	-553,379	-552,357
Profit (loss) for the period		-27,428	-35,825	-42,336
Equity		**211,798**	**227,176**	**221,687**
Other financial liabilities	7	60,555	69,963	70,636
Non-current liabilities		60,555	69,963	70,636
Trade payables		435	755	806
Payables to group companies		75,873	45,197	50,790
Other liabilities		151	138	234
Current liabilities		76,459	46,090	51,830
Total liabilities		**137,014**	**116,053**	**122,466**
Total equity and liabilities		**348,812**	**343,229**	**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 September 30, 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 September 30, 2023, the Group's current assets exceed current liabilities by SEK 41.2 million. Current assets include cash and cash equivalents of SEK 49.3 million.

These financial statements were authorized for issue by the Parent Company's Board of Directors (the 'Board') on November 30, 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 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 nine months ended September 30, 2023 and 2022, revenue for the Group as follows:

Category

KSEK	2023-07-01 2023-09-30	2022-07-01 2022-09-30	2023-01-01 2023-09-30	2022-01-01 2022-09-30
Research and collaboration agreements (bundle, over time)	5,184	1,698	10,844	5,685
Research and development services (standalone)	267	690	622	2,532
License agreements (other event-based payments)	—	—	—	3,760
Total	**5,451**	**2,388**	**11,466**	**11,977**

Major customers

KSEK	2023-07-01 2023-09-30	2022-07-01 2022-09-30	2023-01-01 2023-09-30	2022-01-01 2022-09-30
Customer #1	1,874	1,698	6,714	5,685
Customer #2	3,310	—	4,130	—
Customer #3	267	690	622	2,532
Customer #4	—	—	—	3,760
Total	**5,451**	**2,388**	**11,466**	**11,977**

Primary geographical market

KSEK	2023-07-01 2023-09-30	2022-07-01 2022-09-30	2023-01-01 2023-09-30	2022-01-01 2022-09-30
Sweden	—	—	—	—
Germany	1,874	1,698	6,714	5,685
Denmark	267	690	622	2,532
United Kingdom	3,310	—	4,130	—
Mexico	—	—	—	3,760
Total	**5,451**	**2,388**	**11,466**	**11,977**

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 September 30, 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 31 December 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 per cent 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

Third quarter 2023

Share-based compensation expenses for the period totaled SEK 1.1 million (profit 26.3). 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.

January – September 2023

Share-based compensation expenses for the period totaled SEK 2.9 million (profit 19.0). 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	—	—	—	-15,770	—
Options outstanding, September 30	286,003	32,792	34,500	0	355,156
Maximum number of shares to be issued	294,583	33,775	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)*	0.75	0.21	1.25	0.00	2.25

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	-74,600	—	—	—	—	-90,370
Options outstanding, September 30	810,100	282,333	700	2,129,821	700,000	4,631,405
Maximum number of shares to be issued	810,100	282,333	700	2,129,821	700,000	4,644,864
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)	7.07	1.17	7.50	5.26	5.26	

** Weighted average*

As of September 30, 2023, the company has 4,631,405 options outstanding entitling to the subscription of maximum 4,644,864 new shares representing a dilution of 6.8 percent.

Note 6 Income tax

Third quarter 2023

In the period, the Group recognized a non-current tax benefit of SEK 2.3 million (tax loss 1.4). 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 1.4 million.

January – September 2023

In the period, the Group recognized a non-current tax benefit of SEK 8.5 million (6.3), respectively. 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 1.4 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 38.7 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. After deduction of a 6% commitment fee, the Group received SEK 81.8 million in net proceeds from this agreement.

In September 2022, the terms have been renegotiated and modified to include an amortization of SEK 15 million of the 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.

In August 2023 Saniona announced a change to the terms of the loan agreement with Formue Nord. The terms have been renegotiated and modified to include an amortization of SEK 13 million of the loan of which SEK 3 million was repaid in cash and SEK 10 million was converted into shares. Furthermore, the parties have agreed to extend the term of the loan to January 31, 2025, and that the remaining loan value of SEK 61 million will continue to accrue at 1.5 per cent monthly interest until January 31, 2025. Formue Nord received a commitment fee of SEK 4.8 million in relation to the prolongation of the loan. The conversion of SEK 10 million of the loan, and the commitment fee of SEK 4.8 million have been converted into 1,741,301 shares, at a share price of SEK 8.50.

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.

September 30, 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		—	249	—	249	—	—	249	249
		—	**249**	**—**	**249**	**—**	**—**	**249**	**249**
Financial assets not measured at fair value									
Trade receivables		2,906	—	—	2,906	—	—	—	—
Other non-current financial assets		2,738		—	2,738	—	—	—	—
Other current financial assets		1,286	—	—	1,286	—	—	—	—
Cash and cash equivalents		49,278	—	—	49,278	—	—	—	—
		56,208	**—**	**—**	**56,208**	**—**	**—**	**—**	**—**
Financial liabilities not measured at fair value									
Trade payables		—	—	14,022	14,022	—	—	—	—
Formue Nord Loan	7	—	—	60,555	60,555	—	—	—	—
Lease liabilities		—	—	6,798	6,798	—	—	—	—
		—	**—**	**81,375**	**81,375**	**—**	**—**	**—**	**—**

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 September 30, 2023, the contingent consideration has been measured at SEK 0.2 million.

ii. Transfers

During the three and nine months ended September 30, 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')	8
Balance, September 30, 2023	**249**

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 25 May until September 30, 2023, the fee for Pierandrea's services was SEK 0.3 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 September 2023, the fee for Jørgen's services was SEK 1.1 million.

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

Note 10 Subsequent Events to the Balance Sheet Date

- In October, Saniona's new partner, AstronauTx, closed a $61 million Series A financing led by the Novartis Venture Fund and backed by several other leading global venture investors, including Brandon Capital, Bristol Myers Squibb, EQT Life Sciences investing from the LSP Dementia Fund, MPM Capital and the Dementia Discovery Fund.
- Professor Vincenzo Crunelli, Cardiff University, U.K., presented preclinical data on Saniona's lead ion-channel drug candidate and phase 2 ready asset, SAN711, at the annual meeting of the Society for Neuroscience (SfN) 11th-15th November 2023, Washington DC. The data shows strong suppression of absence seizures, which demonstrates that SAN711 represents a novel precision approach for treatment of non-convulsive generalized seizures
- In November, Saniona announced that it has initiated the candidate selection phase with a proprietary subtype selective frontrunner molecule from Kv7 lead optimization program for epilepsy.

Auditor's report

Saniona AB (publ), corp. reg. no 556962-5345

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

Introduction

We have reviewed the condensed interim financial information (interim report) of Saniona AB (publ) as of 30 September 2023 and the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

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

Material Uncertainty Related to Going Concern

We would like to draw attention to the section "Financial position, share, share capital and ownership structure" on page 16 in the interim report where it is described that the company does not, at the time of issuing the report, have secured funding. This condition indicates that there is a material uncertainty that may cast significant doubt on the company's ability to continue as a going concern. Our conclusion is not modified in respect of this matter.

Malmö, 30 November 2023

Öhrlings PricewaterhouseCoopers AB

Cecilia Andrén Dorselius
Authorized Public Accountant
Auditor in charge

This information is information that 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 2023-11-30 08:00 CET.

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