Exciting Autumn with Clinical Data, potential New Collaborations and potential First Market Approval

Three Months Ended June 30, 2024 (2023)	Six Months Ended June 30, 2024 (2023)
Revenue was SEK 8.0 M (3.9 M)	Revenue was SEK 14.1 M (6.0 M)
Operating profit/loss was SEK -16.0 M (-21.8 M)	Operating profit/loss was SEK -29.7 M (-42.9 M)
Net profit/loss was SEK -19.7 M (-21.2 M)	Net profit/loss was SEK -29.0 M (-43.0 M)
Cash and cash equivalent SEK 54.4 M (69.4)	Cash and cash equivalent SEK 54.4 M (69.4)
Basic earnings/loss per share was SEK -0.18 (-0.34)	Basic earnings/loss per share was SEK -0.26 (-0.69)
Diluted earnings/loss per share were SEK -0.18 (-0.34)	Diluted earnings/loss per share were SEK -0.26 (-0.69)

Business highlights in Q2 2024

- On May 7, Saniona reported progress on pipeline and other activities.
- John Haurum was at the Annual General meeting May 29, 2024, elected as a new ordinary board member.
- On June 17, Saniona comments on article addressing the potential mechanism of action behind tesofensine's unique weight loss effect.

Comments from the CEO

"Our partner, Medix, has submitted an updated application with additional information and documentation for approval of tesofensine in Mexico. The regulatory agency has had no further comments or questions. We remain optimistic about an approval of tesofensine this year for treatment of obesity. We have discussions with potential partners around several assets which may lead to new collaborations this year. Our objective is to make at least one new collaboration on one of our preclinical or clinical assets in 2024 to secure funding for continued development of our company and assets. The two pipeline programs, SAN711 and SAN2355, are progressing in accordance with our plans, which means that we are on track to deliver top-line results for SAN711 by year-end and finalize a GLP tox batch for SAN2355 during the third quarter."

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

In the first half of 2024, Saniona made significant strides across its pipeline and strategic initiatives. We remain equally focused on progressing our portfolio and nurturing productive commercial partnerships and are driven by an unwavering commitment to advancing innovative treatments for neurological and psychiatric disorders.

Medix filed for regulatory approval for tesofensine in Mexico in May 2023. Following a dialog with the regulatory agency in 2023/24, Medix submitted an updated application with additional information and documentation in May 2024. The regulatory agency has had no further comments or questions, and we are now awaiting the final decision for approval of tesofensine for obesity in Mexico. If successful, Saniona will be entitled to an upfront payment and double-digit royalties on product sales. Tesofensine may be an important product for treatment of obesity in Mexico and a regulatory approval may also open new opportunities in other territories. Therefore, it could be a major source of income and news flow going forward.

In June, we filed a Clinical Trial Application (CTA) for a Phase 1 multiple ascending dose (MAD) / Biomarker study in adults for SAN711. Pending regulatory greenlight, we anticipate patient recruitment to begin in September, which means we remain on track to deliver top-line results by year end. Together with some other pre-clinical activities, this study will pave the way for starting a clinical proof of concept study in children with absence seizures during spring 2025.

In July, we finalized the process optimization for SAN2355, a best in class and completely new generation of Kv7.2/Kv7.3 activators for treatment of focal onset seizures. We expect to complete analytical development and the GLP tox batch in the third quarter. Subject to funding, this should enable us to finalize the remaining preclinical work and file for start of phase 1 clinical studies in nine months.

On the partnership front, discussions regarding one of our clinical programs are progressing. We are also exploring interest in two of our preclinical candidates and a research program. Our objective is to make at least one new collaboration on one of our preclinical or clinical assets in 2024 to secure funding for continued development of other assets. The advancements made in the first half of 2024 reflect our commitment to innovation and strategic growth as we continue to build momentum in the second half of 2024.

I am confident in our ability to secure additional partnerships and deliver significant advancements through the identification of novel clinical candidates. I look forward to sharing 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								**Under regulatory review with potential approval in 2024** – partnership with market leader **Medix**, representing near-term revenue potential through double digit royalty
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	IBD, Fibrotic / inflammatory								**Positioned for partnering** following successful IND/CTA enabling studies
SAN2355	Epilepsy								**Positioned for focal/generalized epilepsy** and paediatric epilepsy
SAN2219	Epilepsy								**Positioned for epilepsy acute repetitive seizures** with multiple expansion opportunities in rare and severe 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 (marked in yellow in pipeline overview) 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 where it was shown to be safe and well tolerated at very high receptor occupancies. SAN711 is now being further investigated in a phase 1 multiple ascending dose (MAD)/biomarker study in adults to enable the start of a clinical proof of concept study in children with absence seizures during spring 2025. In addition to investigate the safety, tolerability, and pharmacokinetics of using higher doses of SAN711 in multiple dose settings, the Phase 1 MAD/Biomarker study will also provide food interaction data and relevant pharmacodynamic effect data of SAN711 on EEG in healthy volunteers during awake and sleep settings. The biomarker effect of SAN711 would provide evidence of relevant central pharmacological activity that together with the exposure – receptor occupancy previously provided by the PET study - will help define the dosing strategy for future studies in patients. To enable pediatric studies, Saniona will also conduct a preclinical juvenile toxicity study and PBPK-modelling for translating the Phase 1 data in adults into corresponding doses for children.

SAN711 is a Positive Allosteric Modulator, or PAM, of GABAA α3 containing receptors. GABA is a neurotransmitter, that mediates inhibitory electrical signals between nerve cells in the brain. GABAA 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 GABAA 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 are 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 seizures in adulthood have poor long-term vocational, educational, and social outcomes.

First line treatment of childhood absence epilepsy is 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, is 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 GABAA 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 GABAA receptors, Saniona 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 including negative impact on cognitive function.

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.

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 GABAA 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 GABAA α2/α3 PAM program.

SAN2219 is specifically designed to exert broad antiseizure activity by enhancing the effect of GABAA α2, α3 and α5 containing receptors. As there is no enhancement of GABAA 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 models 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 highly differentiated subtype selective Kv7.2/Kv7.3 activator for treatment-resistant focal onset seizures, with the potential to become best in class. Focal onset seizures are the most common type of epileptic seizure and affect up to about 60 percent of patients with epilepsy. Saniona has made considerable progress in the preclinical development of SAN2355 within chemical optimization and manufacturing of SAN2355. Saniona therefore believes that a scalable process and a suitable and stable drug substance for clinical and commercial use are now available, keeping the timelines for this CTA/IND-enabling process.

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). A more potent retigabine analogue, XEN1101, is currently in Phase 3 development 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 associated with Retigabine and XEN1101. In contrast to Retigabine and XEN1101, SAN2355 selectively activates Kv7.2 and Kv7.3 channels and blocking Kv7.5 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.

GABA program

Saniona has progressed other compounds from its GABAA 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. 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 (NDA) 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. These are all 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 on par with the best GLP-1 analogs. Importantly, and as opposed to the GLP-1 analogs, tesofensine is provided in tablets and will not require injection.

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 or 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, while statistically significant reduction in other key obesity-related risk factors were also 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 statistically 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, as well as in other geographies, and in 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 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 percent ($p<0.0169$) and a mean reduction in waist circumference of 5.68 cm or 5.00 percent. 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 percent reduction in body weight, which is notable in the small patient population, and a statistically significant 8.1 percentage 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 and Saniona is 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 Saniona sees 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 with a two-hit mode of action having anti-inflammatory as well as antifibrotic activity.

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.

SAN2465

SAN2465 is a highly potent and selective negative allosteric modulator (NAM) of GABAA α5 containing receptors with a pharmacological profile different from conventional antidepressant therapies, novel NMDA-antagonists, as well as psychedelic investigational drugs. It shows an unprecedented affinity towards the GABAA a5 target with low picomolar potency. SAN2465 is positioned as a first-in-class treatment opportunity for rapid resolution of depression.

Depressive disorders affect 280 million people globally and stand as the leading cause of disability. Current conventional treatment relies on modulation of the monoaminergic system such as selective serotonin reuptake inhibitors, monoamine oxidase inhibitors and tricyclic antidepressants. However, existing conventional therapies exhibit delayed clinical responses, low remission rates, and a substantial portion of patients (more than 30 percent) do not respond adequately, leading to treatment resistant depression. In 2019, the FDA approved esketamine (Spravato™), the first prescription NMDA-antagonist-based fast-acting antidepressant. However, esketamine is associated with significant risks, including sedation, dissociation, respiratory depression, and abuse and misuse. Therefore, use of esketamine is restricted by a Risk Evaluation and Mitigation Strategy (REMS) Program.

Because of the risk associated with esketamine, there is a significant medical need for improved safe treatment options with rapid-onset and clinical response devoid of the use limitations associated with NMDA-antagonists, in the large population of treatment-resistant patients.

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. Results indicate that a single oral treatment of SAN2465 effectively reverses depressive-like symptoms, as assessed by stress-induced reduction of sucrose intake already within 24 hours after dosing. Furthermore, anxiogenic-like behaviors and cognitive impairments induced by stress were also significantly normalized after a single oral treatment with SAN2465, without any adverse effects observed. Importantly, the onset and robustness of the effects are comparable to the NMDA antagonist ketamine, suggesting that SAN2465 may induce rapid antidepressant effects like those observed with esketamine (Spravato™), which has demonstrated clinical response within hours after the first dose in patients.

Importantly, in contrast to NMDA-antagonists (e.g., esketamine (Spravato™) and psychedelics (e.g., Psilocybin), the mechanism of action of SAN2465 does not predict adverse effects related to sedation, dissociation, respiratory depression, perceptual changes/hallucinations and abuse and misuse.

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.

R&D Ion Channel Pipeline

Saniona's 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). The company's 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 the company's proprietary compounds, generated over 20 years and enriched for properties conferring optimal ion channel modulation.

As a result of Saniona's ion channel drug discovery engine, the company has generated a robust pipeline of orally available, potent, highly selective and differentiated ion channel modulators, including SAN711, SAN903, SAN2219, SAN2355 and SAN2465. Saniona anticipates that this robust discovery engine will continue to generate multiple new drug candidates to add to the Saniona pipeline.

PARTNERSHIPS AND SPINOUTS

Leveraging Saniona's expertise in the field of ion channel drug discovery and the company's proprietary focused compound library and robust database (IONBASE), Saniona is continuously advancing its research programs to identify and advance additional selective ion channel clinical candidates in a range of therapeutic areas, including rare genetic and neurological disorders. Saniona's 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

	2024-04-01 2024-06-30	2023-04-01 2023-06-30	2024-01-01 2024-06-30	2023-01-01 2023-06-30	2023-01-01 2023-12-31
Revenue, KSEK	8,019	3,853	14,053	6,015	16,840
Total operating expenses, KSEK	-24,061	-25,672	-43,745	-48,947	-97,905
Operating profit (loss), KSEK*	-16,042	-21,819	-29,692	-42,932	-81,065
Cash flow for the period, KSEK	-19,038	-22,773	19,945	-49,011	-93,627
Weighted average number of shares	111,238,252	62,385,677	101,227,376	62,385,677	63,067,885
Diluted average shares outstanding	111,238,252	62,385,677	101,227,376	62,385,677	63,067,885
Shares outstanding at the end of the period	111,238,252	62,385,677	111,238,252	62,385,677	64,126,978
Average number of employees	23	23	23	23	23
Operating margin*					
Operating profit (loss), KSEK	-16,042	-21,819	-29,692	-42,932	-81,065
Revenue, KSEK	8,019	3,853	14,053	6,015	16,840
Operating margin, %	**-200 %**	**-566 %**	**-211 %**	**-714 %**	**-481 %**
Cash flow per share*					
Cash flow for the period, KSEK	-19,038	-22,773	19,945	-49,011	-93,627
Shares outstanding at the end of the period	111,238,252	62,385,677	111,238,252	62,385,677	64,126,978
Cash flow per share, SEK	**-0.17**	**-0.37**	**0.18**	**-0.79**	**-1.46**
Earnings per share					
Profit (loss) for the period, KSEK	-19,735	-21,232	-28,973	-42,977	-95,810
Shares outstanding at the end of the period	111,238,252	62,385,677	111,238,252	62,385,677	64,126,978
Earnings per share, SEK	**-0.18**	**-0.34**	**-0.26**	**-0.69**	**-1.49**
Diluted earnings per share, SEK	**-0.18**	**-0.34**	**-0.26**	**-0.69**	**-1.49**

	2024-06-30	2023-06-30	2023-12-31
Cash and cash equivalent, KSEK	54,390	69,409	30,962
Equity, KSEK	6,934	16,754	-21,940
Total Equity and liabilities, KSEK	92,461	116,042	64,143
Equity per share*			
Equity, KSEK	6,934	16,754	-21,940
Shares outstanding at the end of the period	111,238,252	62,385,677	64,126,978
Equity per share, SEK	**0.06**	**0.27**	**-0.34**
Equity ratio*			
Equity, KSEK	6,934	16,754	-21,940
Total assets, KSEK	92,461	116,042	64,143
Equity ratio, %	**7 %**	**14 %**	**-34 %**
Liquidity ratio*			
Current assets, KSEK	74,219	85,799	45,166
Current liabilities, KSEK	17,516	94,049	17,695
Liquidity ratio, %	**424 %**	**91 %**	**255 %**

** = Alternative performance measures*

Results of Operations

April – June

Revenue for the second quarter amounted to SEK 8.0 million (3.9). Revenues in second quarter 2024 include amounts from Saniona's licensing and partnership agreements with Boehringer Ingelheim and AstronauTx. Revenues in second quarter 2023 include amounts from Saniona's licensing and partnership agreements with Boehringer Ingelheim, AstronauTx and Cephagenix. The increase is related to the research collaboration agreement with AstronauTx, entered mid-July 2023.

Operating expenses for the second quarter amounted to SEK 24.1 million (25.7). Within operating expenses, external expenses decreased by SEK 1.4 million from SEK 13.8 million to SEK 12.4 million.

A part of Saniona's external expenses are external research and development expenses, which are primarily attributable to contract research organizations (CROs) and contract manufacturing organizations for Saniona's clinical trials. External research and development expenses for the second quarter, comprised SEK 8.9 million (6.5). We refer to Note 5.

Personnel costs include salaries, variable compensation, social security, and other employee benefits. Personnel costs for the second quarter amounted to SEK 8.8 million (8.8). Non-cash share-based compensation expense is included in personnel costs and amounted to SEK 0.8 million (0.9).

Net loss from total financial items for the second quarter amounted to SEK 6.0 million (2.7). The financial loss includes interest expenses and commitment fee to Formue Nord of SEK 1.3 million (2.2) and SEK 0.1 million (0.8), respectively, other interest expenses SEK 0.8 million (0.4), fair value loss of TO 4 warrants SEK 4.3 million (0), and financial income of SEK 0.5 million (0.7). The TO 4 warrants are valued with the Black & Scholes model and has no cash effect. We refer to note 8.

The Group recognized a tax income in the second quarter of SEK 2.3 million (3.3).

Net cash used in operating activities in the period decreased by SEK 3.9 million from SEK -21.6 million to SEK -17.7 million.

The operating cash flow in the second quarter is primarily attributable to the operating loss of SEK 22.0 million (24.5).

For the second quarter net cash used by investing activities was SEK 0 million (0).

For the second quarter net cash expense by financing activities was SEK 1.3 million (expense 1.2). The cash expense includes repayment of lease liabilities of SEK 1.3 million (1.2).

Cash and cash equivalents for the Group amounted to SEK 54.4 million (69.4) as of June 30, 2024.

January – June

Revenue for the period amounted to SEK 14.1 million (6.0). Revenues in the period 2024 include amounts from Saniona's licensing and partnership agreements with Boehringer Ingelheim and AstronauTx. Revenues in the period 2023 include amounts from Saniona's licensing and partnership agreements with Boehringer Ingelheim, AstronauTx and Cephagenix. The increase is related to the research collaboration agreement with AstronauTx, entered mid-July 2023.

Operating expenses for the period amounted to SEK 43.7 million (48.9). Within operating expenses, external expenses decreased by SEK 5.4 million from SEK 25.7 million to SEK 20.3 million.

A part of Saniona's external expenses are external research and development expenses, which are primarily attributable to contract research organizations (CROs) and contract manufacturing organizations for Saniona's clinical trials. External research and development expenses for the first quarter, comprised SEK 11.8 million (13.6). We refer to Note 5.

Personnel costs include salaries, variable compensation, social security, and other employee benefits. Personnel costs for the period amounted to SEK 17.1 million (17.4). Non-cash share-based compensation expense is included in personnel costs and amounted to SEK 1.6 million (1.9).

Net loss from total financial items for the period amounted to SEK 3.3 million (6.2). The financial loss includes interest expenses and commitment fee to Formue Nord of SEK 2.6 million (4.5) and SEK 0.2 million (1.6), respectively, other interest expenses SEK 1.7 million (1.4), fair value gain of TO 4 warrants SEK 0.2 million (0), and financial income of SEK 1.0 million (1.3). The TO 4 warrants are valued with the Black & Scholes model and has no cash effect. We refer to note 8.

The Group recognized a tax income in the period of SEK 4.1 million (6.1).

Net cash used in operating activities in the period decreased by SEK 9.8 million from SEK -46.8 million to SEK -37.0 million.

The operating cash flow in the period is primarily attributable to the operating loss of SEK 33.0 million (49.1).

For the period net cash used by investing activities was SEK 0 million (0).

For the period net cash income by financing activities was SEK 57.0 million (expense 2.3). The cash income includes net proceeds from a rights issue of SEK 79.6 million (0), repayment of loan to Formue Nord of SEK 20.0 million (0), and repayment of lease liabilities of SEK 2.6 million (2.3).

Cash and cash equivalents for the Group amounted to SEK 54.4 million (69.4) as of June 30, 2024.

Parent Company
January - June

Operating expenses for the period amounted to SEK 4.2 million (3.7). The main component of the Parent Company's operating expenses are other external costs of SEK 2.6 million (2.1), personnel costs of SEK 1.0 million (1.0) and other operating expenses of SEK 0.6 million (0.6).

Loss amounted for the period to SEK 10.4 million (13.8). The main component of the Parent Company's loss also includes financial income loss of SEK 7.2 million (10.9), which is interest expenses and commitment fee to Formue Nord of SEK 2.6 million (4.5) and SEK 0.2 million (1.6), respectively, other interest expenses SEK 4.8 million (4.9), fair value gain of TO 4 warrants SEK 0.2 million (0) and interest income of SEK 0.2 million (0.1). The TO 4 warrants are valued with the Black & Scholes model and has no cash effect. We refer to note 8.

Financial position, share, share capital and ownership structure

The equity ratio for the Group was 7% (14%) as of June 30, 2024, and equity for the Group was SEK 6.9 million (16.8). Cash and cash equivalents for the Group amounted to SEK 54.4 million (69.4) as of June 30, 2024. Total assets for the Group as of June 30, 2024, were SEK 92.5 million (116.0).

The equity ratio for the Parent company was 70% (60%) as of June 30, 2024, and equity for the Parent company was SEK 243.9 million (209.7). Cash and cash equivalents for the parent company amounted to SEK 0.8 million (2.7) as of June 30, 2024. Total assets for the parent company as of June 30, 2024, were SEK 348.3 million (346.9).

In February 2024, Saniona raised SEK 88.9 million before issue costs through a rights issue. Prior to this financing Saniona agreed with Formue Nord to use SEK 20 million of the proceeds to pay off debt. The net proceeds after issue costs of SEK 9.3 million and payment to Formue Nord was SEK 59.6 million.

As of June 30, 2024, Saniona had 111,238,252 (62,385,677) shares outstanding at SEK 0.05 per share equal to a share capital of SEK 5,561,912.60 (3,119,283.85).

On June 30, 2024, the company had 12,070 (11,090) shareholders excluding holdings in life insurance and foreign custody account holders.

Personnel

As of June 30, 2024, Saniona had 22 (23) employees including 10 (10) employees with Ph.D. degrees. Of these employees, 17 (17) were engaged in research and clinical development activities and 5 (6) were engaged in general and administrative activities. Of the 22 (23) employees, 11 (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 2023 Annual Report and Prospectus dated January 18, 2024. There are no major changes in the Group's risk factors and risk management in 2024.

Audit review

The interim report has not been audited or reviewed by the company's independent auditor.

Financial calendar

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, August 29, 2024
Saniona AB

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

THE GROUP'S CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Condensed consolidated interim statement of comprehensive income – Group

KSEK	Note	2024-04-01 2024-06-30	2023-04-01 2023-06-30	2024-01-01 2024-06-30	2023-01-01 2023-06-30	2023-01-01 2023-12-31
	1,2,3					
Revenue	4	8,019	3,853	14,053	6,015	16,840
Total operating income		8,019	3,853	14,053	6,015	16,840
Raw materials and consumables		-1,254	-1,134	-2,603	-2,167	-5,059
Other external costs	5	-12,406	-13,820	-20,268	-25,658	-47,664
Share of result of associate	10	—	-119	—	-204	-1,719
Personnel costs	6	-8,768	-8,818	-17,146	-17,408	-33,812
Depreciation and write-downs		-1,633	-1,781	-3,728	-3,510	-9,651
Total operating expenses		-24,061	-25,672	-43,745	-48,947	-97,905
Operating loss		**-16,042**	**-21,819**	**-29,692**	**-42,932**	**-81,065**
Financial income	8	478	698	1,242	1,297	3,131
Financial expenses		-6,457	-3,367	-4,590	-7,467	-26,346
Total financial items		-5,979	-2,669	-3,348	-6,170	-23,215
Loss before tax		**-22,021**	**-24,488**	**-33.040**	**-49,102**	**-104,280**
Income tax	7	2,286	3,256	4,067	6,125	8,470
Loss for the period*		**-19,735**	**-21,232**	**-28,973**	**-42,977**	**-95,810**
Other comprehensive income (loss) for the period						
Item that may be reclassified to profit and loss						
Translation differences		-1,386	3,892	806	5,140	3,084
Total other comprehensive income for the period, net after tax		**-1,386**	**3,892**	**806**	**5,140**	**3,084**
Total comprehensive profit (loss)**		**-21,121**	**-17,340**	**-28,167**	**-37,837**	**-92,726**
Loss per share, SEK		-0.18	-0.34	-0.26	-0.69	-1.49
Diluted loss per share, SEK		-0.18	-0.34	-0.26	-0.69	-1.49

* 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	2024-06-30	2023-06-30	2023-12-31
ASSETS				
Intangible assets		4,832	7,122	4,947
Property and equipment		3,493	5,094	3,297
Right of use assets		5,258	7,873	7,248
Investment in associate	10	397	768	392
Other financial assets	9	243	3,055	3,093
Tax assets		4,019	6,331	—
Non-current assets		**18,242**	**30,243**	**18,977**
Trade receivables		4,154	3,831	2,526
Current tax assets	7	8,311	8,704	8,206
Other assets		7,364	3,855	3,472
Cash and cash equivalents		54,390	69,409	30,962
Current assets		**74,219**	**85,799**	**45,166**
Total assets		**92,461**	**116,042**	**64,143**

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

KSEK	Note	2024-06-30	2023-06-30	2023-12-31
EQUITY AND LIABILITIES				
Share capital		5,562	3,119	3,206
Additional paid-in capital		880,863	813,261	827,803
Reserves		5,165	113,732	4,359
Accumulated deficit		-884,656	-913,358	-857,308
Equity		**6,934**	**16,754**	**-21,940**
Loan	8,9	39,859	—	65,238
Other financial liabilities	8,9	25,205	—	—
Lease liabilities	9	418	2,648	686
Other liabilities		2,529	2,591	2,464
Non-current liabilities		68,011	5,239	68,388
Trade payables		10,716	13,638	8,245
Loan	8,9	—	72,293	—
Lease liabilities	9	4,859	5,859	5,485
Other liabilities		1,941	2,259	3,965
Current liabilities		17,516	94,049	17,695
Total liabilities		**85,527**	**99,288**	**86,083**
Total equity and liabilities		**92,461**	**116,042**	**64,143**

Condensed consolidated interim statement of changes in equity – Group

	Share capital	Additional paid-in capital	Translation reserves	Accumulated deficit	Shareholders' equity
January 1, 2023	**3,119**	**813,261**	**1,275**	**-764,947**	**52,708**
Comprehensive income					
Loss for the period	—	—	—	-42,977	-42,977
Other comprehensive income	—	—	5,140	—	5,140
Total comprehensive income (loss)	**—**	**—**	**5,140**	**-42,977**	**-37,837**
Transactions with owners					
Shares issued for cash and conversion of loan	—	—	—	—	—
Expenses related to capital increase	—	—	—	—	—
Share-based compensation expenses	—	—	—	1,883	1,883
Total transactions with owners	**—**	**—**	**—**	**1,883**	**1,883**
June 30, 2023	**3,119**	**813,261**	**6,415**	**-806,041**	**16,754**
January 1, 2024	**3,206**	**827,803**	**4,359**	**-857,308**	**-21,940**
Comprehensive income					
Loss for the period	—	—	—	-28,973	-28,973
Other comprehensive income	—	—	806	—	806
Total comprehensive income (loss)	**—**	**—**	**806**	**-28,973**	**-28,167**
Transactions with owners					
Shares issued for cash	2,356	69,472	—	—	71,828
Equity component of the convertible loan	—	1,287	—	—	1,287
Expenses related to capital increase	—	-17,699	—	—	-17,699
Share-based compensation expenses	—	—	—	1,625	1,625
Total transactions with owners	**2,356**	**53,060**	**—**	**1,625**	**57,041**
June 30, 2024	**5,562**	**880,863**	**5,165**	**-884,656**	**6,934**

Condensed consolidated interim statement of cash flows – Group

KSEK	Note	2024-04-01 2024-06-30	2023-04-01 2023-06-30	2024-01-01 2024-06-30	2023-01-01 2023-06-30	2023-01-01 2023-12-31
Loss before tax		-22,021	-24,488	-33,040	-49,102	-104,280
Adjustments for non-cash transactions		3,416	-1,258	4,131	2,926	13,629
Changes in working capital		2,050	3,805	-5,852	738	6,770
Cash flow from operating activities before financial and tax items		**-16,555**	**-21,941**	**-34,761**	**-45,438**	**-83,881**
Interest income received		363	657	892	1,552	2,534
Interest expenses paid		-1,549	-307	-3,179	-2,867	-12,625
Tax credit received		—	—	—	—	8,441
Cash flow from operating activities		**-17,741**	**-21,591**	**-37,048**	**-46,753**	**-85,531**
Investing activities						
Purchases of property and equipment		—	—	—	—	-129
Cash flow from investing activities		—	—	—	—	**-129**
Financing activities						
Repayment of loan	8	—	—	-20,000	—	-3,000
Proceeds from issuance of new shares and warrants		—	—	88,874	—	—
Costs related to issuance of new shares		—	—	-9,305	—	-173
Payment of lease liabilities		-1,297	-1,182	-2,576	-2,258	-4,794
Cash flow from financing activities		**-1,297**	**-1,182**	**56,993**	**-2,258**	**-7,967**
Net increase (decrease) in cash and cash equivalents		**-19,038**	**-22,773**	**19,945**	**-49,011**	**-93,627**
Cash and cash equivalents at		**71,445**	**87,768**	**30,962**	**111,707**	**111,707**
Exchange rate adjustments		1,983	4,414	3,483	6,713	12,882
Cash and cash equivalents at end of period		**54,390**	**69,409**	**54,390**	**69,409**	**30,962**

PARENT COMPANY'S FINANCIAL STATEMENTS

Statement of income – Parent Company

KSEK	Note	2024-01-01 2024-06-30	2023-01-01 2023-06-30	2023-01-01 2023-12-31
	1,2,3			
Other operating income		1,039	796	1,651
Total operating income		1,039	796	1,651
Raw materials and consumables		-21	-19	-37
Other external costs		-2,663	-2,052	-4,118
Other operating expenses		-573	-664	-1,337
Personnel costs	6	-958	-994	-1,978
Total operating expenses		-4,215	-3,729	-7,470
Operating income (loss)		**-3,176**	**-2,933**	**-5,819**
Financial income	8	436	53	111
Financial expenses		-7,641	-10,957	-36,811
Total financial items		-7,205	-10,904	-36,700
Profit (loss) before tax		**-10,381**	**-13,837**	**-42,519**
Tax on net profit (loss)		—	—	—
Profit (loss) for the period		**-10,381**	**-13,837**	**-42,519**

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	2024-06-30	2023-06-30	2023-12-31
ASSETS				
Investment in subsidiaries		346,590	343,473	344,965
Financial assets		346,590	343,473	344,965
Non-current assets		**346,590**	**343,473**	**344,965**
Other assets		933	779	903
Current receivables		933	779	903
Cash and cash equivalents		823	2,686	2,460
Current assets		**1,756**	**3,465**	**3,363**
Total assets		**348,346**	**346,938**	**348,328**
EQUITY AND LIABILITIES				
Restricted equity				
Share capital		5,562	3,119	3,206
Unrestricted equity				
Share premium reserve		880,863	813,261	827,803
Retained earnings (accumulated deficit)		-632,140	-592,810	-591,244
Profit (loss) for the period		-10,381	-13,837	-42,519
Equity		**243,904**	**209,733**	**197,246**
Loan	8	40,819	—	65,238
Other financial liabilities	8	24,245	—	—
Non-current liabilities		65,064	—	65,238
Trade payables		163	401	644
Loan	8	—	72,293	—
Payables to group companies		39,058	64,352	85,049
Other liabilities		157	159	151
Current liabilities		39,378	137,205	85,844
Total liabilities		**104,442**	**137,205**	**151,082**
Total equity and liabilities		**348,346**	**346,938**	**348,328**

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 and six months ended June 30, 2024, 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, 2023 ('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 June 30, 2024, the Group's current assets exceed current liabilities by SEK 56.7 million. Current assets include cash and cash equivalents of SEK 54.4 million.

In February 2024, Saniona raised SEK 88.9 million before issue costs through a rights issue. Saniona may receive additional proceeds in April 2025 in relation to the exercise of issued series TO4 warrants granted in connection with the rights issue. In the event that all 23,555,637 warrants series TO4 are exercised for subscription of new shares during April 2025 and the subscription price amounts to the quota value (SEK 0.05) as a minimum, Saniona will receive an additional amount of approximately SEK 1.2 million before deduction of issue costs. If, under the same conditions, the subscription price instead would amount to, for example, between SEK 3.0-5.0, Saniona will receive an amount between approximately SEK 71-118 million before deduction of issue costs.

These financial statements were authorized for issue by the Parent Company's Board of Directors (the 'Board') on August 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, 2024, 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 2023 Annual report.

Note 4 Revenue

The Group's revenue generating activities are those described in the last annual financial statements.
In the three and six months ended June 31, 2024 and 2023, revenue for the Group was distributed as follows:

Category

KSEK	2024-04-01 2024-06-30	2023-04-01 2023-06-30	2024-01-01 2024-06-30	2023-01-01 2023-06-30	2023-01-01 2023-12-31
Research and collaboration agreements (bundle, over time)	8,019	3,364	14,053	5,094	16,207
Research and development services (standalone)	—	489	—	921	633
Total	**8,019**	**3,853**	**14,053**	**6,015**	**16,840**

Major customers

KSEK	2024-04-01 2024-06-30	2023-04-01 2023-06-30	2024-01-01 2024-06-30	2023-01-01 2023-06-30	2023-01-01 2023-12-31
Customer #1	4,393	819	8,380	819	7,486
Customer #2	3,626	2,545	5,673	4,275	8,721
Customer #3	—	489	—	921	633
Total	**8,019**	**3,853**	**14,053**	**6,015**	**16,840**

Geographical markets (based on customer)

KSEK	2024-04-01 2024-06-30	2023-04-01 2023-06-30	2024-01-01 2024-06-30	2023-01-01 2023-06-30	2023-01-01 2023-12-31
Sweden	—	—	—	—	—
Germany	3,626	2,545	5,673	4,275	8,721
Denmark	—	489	—	921	633
United Kingdom	4,393	819	8,380	819	7,486
Total	**8,019**	**3,853**	**14,053**	**6,015**	**16,840**

Note 5 External Research & Development expenses

KSEK	2024-04-01 2024-06-30	2023-04-01 2023-06-30	2024-01-01 2024-06-30	2023-01-01 2023-06-30	2023-01-01 2023-12-31
SAN711	4,310	2,528	5,005	4,576	8,392
SAN2355	2,303	—	2,635	—	—
SAN903	242	226	331	1,015	1,086
Tesomet	92	1,415	505	2,794	3,995
Other programs	1,930	2,322	3,296	5,198	9,311
Total	**8,877**	**6,491**	**11,772**	**13,583**	**22,784**

Note 6 Share-based payments

A. Description of share-based payment arrangements

A detailed description of the Group's share-based payment arrangements as of June 30, 2024, is provided in the last annual financial statements.

On May 29, 2024, the annual shareholders' meeting voted in favor of establishing an Employee Option program involving the allotment of a maximum of 3,050,000 options. The program implies that a maximum of 3,050,000 employee options shall be offered to senior executives 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 2029. 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 29, 2024. 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 2,970,000 warrants were allotted to employees in June 2024.

B. Measurement of fair values and compensation expense

April - June 2024
Share-based compensation expenses for the second quarter totaled SEK 0.8 million (0.9).

January - June 2024
Share-based compensation expenses for the period totaled SEK 1.6 million (1.9).

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	2019:1	2020:1	2020:2	2020:3
Options outstanding, January 1	286,003	34,500	355,156	735,500	282,333
Granted during the year	—	—	—	—	—
Forfeited during the year	-286,003	—	—	-1,600	—
Options outstanding, June 30	0	34,500	355,156	733,900	282,333
Maximum number of shares to be issued	0	35,190	362,259	741,239	285,156
Grant Date Fair Value* (SEK)	12.06	7.23	12.26	13.13	7.98
Share Price at Grant Date* (SEK)	26.95	17.76	28.10	23.50	23.55
Exercise Price* (SEK)	33.20	17.83	29.36	24.12	25.40
Expected volatility*	69.24%	57.29%	58.66%	63.64%	57.00%
Estimated life (years)*	3.88	3.67	4.20	6.10	2.80
Expected dividends*	0	0	0	0	0
Risk-free rate*	-0.1092%	-0.6903%	-0.2280%	-0.2772%	-0.3602%
Remaining contractual life (years)*	0.00	0.50	1.50	6.33	0.42

Incentive program	2021:1	2022:1	2023:1	2024:1	Total
Options outstanding, January 1	700	2,129,821	700,000	—	4,524,013
Granted during the year	—	—	—	2,970,000	2,970,000
Forfeited during the year	—	—	-3,333	—	-290,936
Options outstanding, June 30	700	2,129,824	696,667	2,970,000	7,203,077
Maximum number of shares to be issued	707	2,151,119	703,633	2,970,000	7,249,303
Grant Date Fair Value* (SEK)	10.75	1.59	5.83	0.57	
Share Price at Grant Date* (SEK)	19.31	4.24	7.8	1.84	
Exercise Price*(SEK)	19.38	5.89	8.84	4.04	
Expected volatility*	62.56%	57.65%	64.39%	54.7%	
Estimated life (years)*	6.11	4.17	3.71	5.55	
Expected dividends*	0	0	0	0	
Risk-free rate*	-0.2046%	2.0670%	1.6813%	2.199%	
Remaining contractual life (years)	6.75	4.51	4.51	5.51	

** Weighted average*

As of June 30, 2024, the company has 7,203,077 options outstanding entitling to the subscription of maximum 7,249,303 new shares representing a dilution of 6.1 percent, based on the 111,238,252 shared issued as of June 30, 2024.

Note 7 Income tax

April – June 2024

In the second quarter, the Group recognized a non-current tax benefit of SEK 2.3 million (3.3). The tax benefit is on net loss recognized in Saniona A/S under the Danish 'Skattekreditordningen' (the 'Tax Credit Scheme').

January – June 2024

In the period, the Group recognized a non-current tax benefit of SEK 4.1 million (6.1). The tax benefit is on net loss recognized 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 37.8 million).

Note 8 Loan and other financial liabilities

A. Formue Nord Loan

In December 2023, Saniona announced in connection with the Rights Issue, a renegotiation of the outstanding loan, which came into effect as of February 15, 2024. The part related to the convertibles has been divided into a liability component amounting to SEK 8,7 million and an equity component (the conversion option) amounting to SEK 1,3 million as of February 15, 2024. The liability portion is measured on an amortised cost basis and will accrue with an interest that have no cash effect.

As of June 30, 2024, the total liabilities to Formue Nord were SEK 39.9 million whereof SEK 30.9 million as a loan and SEK 9.0 million as convertibles. The loan and the convertibles 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. Formue Nord has the right to request conversion of the Convertibles into shares at a conversion price of SEK 3.09 per share, which corresponds to 150 per cent of the subscription price per share in the Rights Issue. Conversion may be requested as from the date of registration of the Convertibles with the Swedish Companies Registration Office up to and including 31 July 2025 and each request for conversion must relate to an amount of at least SEK 2 million. Payment for the Convertibles will be made by offsetting Formue Nord's claims under the existing outstanding loan.

B. Other financial liabilities - TO 4 warrants

In February 2024, 23,555,637 TO 4 warrants were issued in connection with the rights issue. In the event that all 23,555,637 warrants series TO 4 are exercised for subscription of new shares during April 2025 and the subscription price amounts to the quota value (SEK 0.05) as a minimum, Saniona will receive an additional amount of approximately SEK 1.2 million before deduction of issue costs. If, under the same conditions, the subscription price instead would amount to, for example, between SEK 3.0-5.0, Saniona will receive an amount between approximately SEK 71-118 million before deduction of issue costs.

The warrants are valued with the Black & Scholes model and applied with necessary variables. In February 2024, after the rights issue the value of the TO 4 warrants was SEK 25.4 million. Due to the variable components in the calculation of the value of the TO 4 warrants, this will be calculated at each reporting period. As of June 30, 2024, the value of the TO 4 warrants was SEK 25.2 million, which gives a financial income of SEK 0.2 million end of June 30, 2024, with no cash effect.

Note 9 Financial instruments – fair values

A. Accounting classifications and fair values

The following table shows the carrying amounts and fair values of financial assets and financial liabilities, including their levels in the fair value hierarchy. It does not include fair value information for financial assets and financial liabilities not measured at fair value when the carrying amount is a reasonable approximation of fair value.

June 30, 2024		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		—	243	—	243	—	—	243	243
		—	**243**	**—**	**243**	**—**	**—**	**243**	**243**
Financial assets not measured at fair value									
Trade receivables		4,154	—	—	4,154	—	—	—	—
Other non-current financial assets		2,918		—	2,918	—	—	—	—
Other current financial assets		1,992	—	—	1,992	—	—	—	—
Cash and cash equivalents		54,390	—	—	54,390	—	—	—	—
		63,454	**—**	**—**	**63,454**	**—**	**—**	**—**	**—**
Financial liabilities measured at fair value									
Other financial liabilities	8	—	25,205	—	25,205	—	25,205	—	25,205
		—	**25,205**	**—**	**25,205**	**—**	**25,205**	**—**	**25,205**
Financial liabilities not measured at fair value									
Trade payables		—	—	10,716	10,716	—	—	—	—
Formue Nord Loan	8	—	—	39,859	39,859	—	—	—	—
Lease liabilities		—	—	5,277	5,277	—	—	—	—
		—	**—**	**55,852**	**55,852**	**—**	**—**	**—**	**—**

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	8	—	—	65,238	65,238	—	—	—	—
Lease liabilities		—	—	6,171	6,171	—	—	—	—
		—	**—**	**79,654**	**79,654**	**—**	**—**	**—**	**—**

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 June 30, 2024, the contingent consideration has been measured at SEK 0.2 million.

ii. Transfers

During the three and six months ended June 30, 2024 and 2023, 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, 2024	241
Cash received	—
Changes in Fair Value	—
Foreign currency (included in 'net gains/losses on financial items')	2
Balance, June 30, 2024	**243**

Note 10 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 January until June 30, 2024, the fee for Pierandrea's services was SEK 0.6 million (May 25, 2023 until June 30, 2023 - SEK 0.1 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 June 2024, the fee for Jørgen's services was SEK 0.2 million (0.7).

Cephagenix is also considered a related party. We refer to Note 29 Related parties in the 2023 Annual report.

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