Saniona Secures Transformational Licensing Agreement, Strengthening Financial Position and Advancing Pipeline

Three Months Ended September 30, 2024 (2023)	Nine Months Ended September 30, 2024 (2023)
Revenue was SEK 7.2 M (5.5 M)	Revenue was SEK 21.3 M (11.5 M)
Operating profit/loss was SEK -18.9 M (-18.4 M)	Operating profit/loss was SEK -48.5 M (-61.3 M)
Net profit/loss was SEK -29.5 M (-24.1 M)	Net profit/loss was SEK -58.4 M (-67.1 M)
Cash and cash equivalent SEK 41.3 M (49.3)	Cash and cash equivalent SEK 41.3 M (49.3)
Basic earnings/loss per share was SEK -0.26 (-0.38)	Basic earnings/loss per share was SEK -0.53 (-1.05)
Diluted earnings/loss per share were SEK -0.26 (-0.38)	Diluted earnings/loss per share were SEK -0.53 (-1.05)

Business highlights in Q3 2024

- September 18, Saniona receives regulatory approval for SAN711 Biomarker Study.

Significant events after the reporting period

- October 1, Saniona provides update on major progress for SAN2355. The company has identified a stable solid form of the substance and completed the synthesis optimization.
- October 7, Saniona initiates SAN711 Biomarker study.
- October 14, Saniona Ion Channel Research Collaborations with Boehringer Ingelheim Reaches Milestone, resulting in a research milestone payment of €500,000 (approximately SEK 5.7 million).
- October 23, Fenja Capital II A/S (previously Formue Nord Fokus A/S) requested conversion of outstanding convertibles for a total nominal amount of SEK 2 million.
- November 6, Saniona's partner, Productus Medix, did not receive approval from Mexican regulatory agency (COFEPRIS) for tesofensine for obesity. Medix is entering a dialogue with the agency regarding the path forward as it appears that the decision by COFEPRIS has not been based on the full data package submitted by Medix.
- November 12, Saniona comments on Medix's recent regulatory submission for tesofensine in obesity.
- November 26, Saniona Announces Licensing Agreement with Acadia Pharmaceuticals for SAN711 in Neurological Diseases.

Comments from the CEO

"The deal with Acadia Pharmaceuticals is transformational for Saniona, as it validates our R&D approach, secures progress of one of our lead assets, and provides a strong cash position allowing us to bring several pipeline assets to key value-inflection points over the next years".

For more information, please contact

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

Forward-looking statements

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

Letter from the CEO

During the third quarter of 2024, Saniona focused on advancing our pipeline and strengthening our financial position through new strategic partnerships. This effort culminated in a significant licensing agreement with Acadia Pharmaceuticals for SAN711, underscoring the value of Saniona's innovative R&D and product pipeline. This deal is transformational for Saniona, as it validates our R&D approach, secures progress of one of our lead assets, and provides a strong cash position.

Under the agreement, Saniona will receive $28 million upfront and a $10 million early milestone payment upon initiation of the first Phase 2 study. Additional $572 million future milestone payments are payable, including $137 million tied to clinical and regulatory achievements and up to $435 million tied to global annual net sales thresholds. Saniona is also eligible for tiered royalties ranging from mid single digits to low double digits on net sales of SAN711-derived commercial products.

As a first indication, Acadia intends to develop SAN711 for essential tremor, a debilitating neurological condition, and expects to initiate a Phase 2 study in 2026. Acadia will finance and lead the clinical development, regulatory submissions, and commercialization efforts. Saniona will coordinate and oversee the completion of the ongoing Phase 1 multiple dose escalation (MAD) and biomarker study fully reimbursed by Acadia.

In October, we announced the commencement of dosing in our Phase 1 MAD and biomarker study for SAN711, with topline data anticipated by end of 2024. However, following the licensing agreement, Acadia Pharmaceuticals assumes overall responsibility for future development and communication regarding SAN711. While Saniona continues to manage the ongoing Phase 1 study and supports preparations for Phase 2, future updates on the results of the Phase 1 study and subsequent clinical developments will be at Acadia's discretion. We appreciate your understanding as we align with our partner's communication policies and remain committed to advancing our pipeline and keeping you informed within the framework of our agreements.

This licensing agreement underscores the strength of Saniona's early-stage pipeline, which includes additional promising candidates such as SAN2219, SAN2355, and SAN2465. Our significantly improved financial position enables us to progress these assets towards Phase 2 proof-of-concept studies over the next years:

- **SAN2355:** A next-generation Kv7.2/Kv7.3 activator with the potential to become best-in-class for epilepsy and other conditions, including major depressive and bipolar disorders. Phase 1 could start in late 2025.
- **SAN2219:** A GABAA α2/α3 PAM asset targeting refractory focal onset seizures and other neurological and psychiatric disorders. Phase 1 could start in 2026.
- **SAN2465:** A GABAA α5 NAM asset aimed at addressing major depressive disorders. Phase 1 could start in 2026.

These programs and the licensing agreement with Acadia highlight Saniona's value potential beyond epilepsy, including neurological and psychiatric disorders of high unmet need.

Meanwhile, our partner Medix continues to work to secure regulatory approval for tesofensine for the treatment of obesity in Mexico. Medix has faced delays but remains in dialogue with COFEPRIS, hoping to resolve the outstanding issues. Approval would not only unlock milestone and royalty payments for Saniona but also create potential opportunities in additional markets.

Our collaboration with Boehringer Ingelheim continues to deliver results. In October, the joint ion channel research program progressed to the lead optimization phase, triggering a €500,000 milestone payment. This achievement reflects our ability to drive innovation in treatments for cognitive impairment related to schizophrenia.

Following the out-licensing of SAN711, Saniona is well-positioned to bring several pipeline assets to key value-inflection points over the next years. We continue to explore partnership opportunities, but since the Acadia agreement has strengthened our financial position, we will put a stronger focus on the development on our proprietary programs going forward.

I remain confident in Saniona's ability to deliver significant progress across our pipeline and partnerships, and I look very much forward to update you on our future achievements.

Sincerely,

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 includes SAN2219, targeting acute repetitive seizures; and SAN2355, addressing refractory focal onset seizures. Beyond epilepsy, Saniona oversees four clinical programs poised for collaboration. Tesofensine for obesity is Saniona's most advanced candidate and is out licensed to Medix in Mexico and Argentina. 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 partners include Acadia Pharmaceuticals, 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, 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** – partnership with Mexican market leader **Medix**, representing near-term revenue potential through double digit royalties
Tesomet	HO, PWS								**Positioned for partnering** following successful phase 2a data (2019)
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
Acadia	Essential tremor								Partnership agreement entitling Saniona to **milestone payments of up to USD 582m plus royalties**
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 two preclinical candidates, SAN2219 and SAN2355, and a mature research program.

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 Acadia Pharmaceuticals, 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

Results of Operations

July – September

Revenue for the third quarter amounted to SEK 7.2 million (5.5). Revenues in third quarter 2024 include amounts from Saniona's licensing and partnership agreements with Boehringer Ingelheim and AstronauTx. Revenues in third quarter 2023 also include amounts from Cephagenix. The increase is related to the research collaboration agreement with AstronauTx.

Operating expenses for the third quarter amounted to SEK 26.1 million (23.8). Within operating expenses, external expenses increased by SEK 2.6 million from SEK 12.0 million to SEK 14.6 million. The increase in external expenses is related to external research and development expenses. We refer to Note 5.

A part of Saniona's external expenses is 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 third quarter, comprised SEK 10.0 million (6.4).

Personnel costs include salaries, variable compensation, social security, and other employee benefits. Personnel costs for the third quarter amounted to SEK 8.2 million (8.3). Non-cash share-based compensation expense is included in personnel costs and amounted to SEK 0.7 million (1.1).

Net loss from total financial items for the third quarter amounted to SEK 13.6 million (8.1). The financial loss includes interest expenses and commitment fee to Fenja Capital of SEK 1.2 million (3.1) and SEK 0.1 million (6.1), respectively, other interest expenses SEK 0.4 million (0.3), fair value loss of TO 4 warrants (valued with the Black & Scholes model, and no cash effect) SEK 12.0 million (0), and financial income of SEK 0.1 million (1.4). We refer to note 8.

The Group recognized a tax income in the third quarter of SEK 3.0 million (2.3).

Net cash used in operating activities in the period decreased by SEK 3,6 million from SEK -18.6 million to SEK -15.0 million.

The operating cash flow in the third quarter is primarily attributable to the operating loss of SEK 18.9 million (18.4).

For the third quarter net cash used by investing activities was SEK 0.1 million (0.1).

For the third quarter net cash expense by financing activities was SEK 1.1 million (expense 4.4). The cash expense includes repayment of lease liabilities of SEK 1.1 million (1.3) and repayment of loan to Fenja Capital SEK 0 million (3).

Cash and cash equivalents for the Group amounted to SEK 41.3 million (49.3) as of September 30, 2024.

January – September

Revenue for the period amounted to SEK 21.3 million (11.5). Revenues in the period include amounts from Saniona's licensing and partnership agreements with Boehringer Ingelheim and AstronauTx. Revenues in the period 2023 also include amounts from Cephagenix. The increase is related to the research collaboration agreement with AstronauTx.

Operating expenses for the period amounted to SEK 69.8 million (72.8). Within operating expenses, external expenses decreased by SEK 2.9 million from SEK 37.7 million to SEK 34.8 million.

A part of Saniona's external expenses is 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 period amounted to SEK 21.8 million (17.6). 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 25.3 million (25.7). Non-cash share-based compensation expense is included in personnel costs and amounted to SEK 2.3 million (2.9).

Net loss from total financial items for the period amounted to SEK 17.0 million (14.3). The financial loss includes interest expenses and commitment fee to Fenja Capital of SEK 3.9 million (7.6) and SEK 0.2 million (7.6), respectively, other interest expenses SEK 2.5 million (1.8), fair value loss of TO 4 warrants (valued with the Black & Scholes model, and no cash effect) SEK 11.8 million (0), and financial income of SEK 1.4 million (2.7). We refer to note 8.

The Group recognized a tax income in the period of SEK 7.1 million (8.5).

Net cash used in operating activities in the period decreased by SEK 13.3 million from SEK -65.4 million to SEK -52.1 million.

The operating cash flow in the period is primarily attributable to the operating loss of SEK 48.5 million (61.3).

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

For the period net cash income by financing activities was SEK 55.9 million (expense 6.7). The cash income includes net proceeds from a rights issue after expenses of SEK 79.6 million (0), repayment of loan to Fenja Capital of SEK 20.0 million (3.0), costs related to issuance of new shares SEK 9.3 million (0.2) and repayment of lease liabilities of SEK 3.7 million (3.5).

Cash and cash equivalents for the Group amounted to SEK 41.3 million (49.3) as of September 30, 2024.

Parent Company
January - September

Operating expenses for the period amounted to SEK 5.9 million (5.5). The main component of the Parent Company's operating expenses are other external costs of SEK 3.6 million (2.9), personnel costs of SEK 1.5 million (1.5) and other operating expenses of SEK 0.8 million (1.0).

Loss amounted for the period to SEK 27.0 million (27.4). The main component of the Parent Company's loss also includes financial income loss of SEK 22.6 million (23.1), which is interest expenses and commitment fee to Fenja Capital of SEK 3.8 million (7.6) and SEK 0.2 million (7.6), respectively, other interest expenses SEK 7.0 million (8.0), fair value loss of TO 4 warrants (valued with the Black & Scholes model, and no cash effect) SEK 11.8 million (0) and interest income of SEK 0.2 million (0.1). We refer to note 8.

Financial position, share, share capital and ownership structure

The equity ratio for the Group was -25% (7%) as of September 30, 2024, and equity for the Group was SEK -20.9 million (6.7). Cash and cash equivalents for the Group amounted to SEK 41.3 million (49.3) as of September 30, 2024. Total assets for the Group as of September 30, 2024, were SEK 81.9 million (94.4).

The equity ratio for the Parent company was 65% (61%) as of September 30, 2024, and equity for the Parent company was SEK 228.0 million (211.8). Cash and cash equivalents for the parent company amounted to SEK 1.6 million (3.9) as of September 30, 2024. Total assets for the parent company as of September 30, 2024, were SEK 349.4 million (348.8).

In February 2024, Saniona raised SEK 88.9 million before issue costs through a rights issue. Prior to this financing Saniona agreed with Fenja Capital 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 Fenja Capital was SEK 59.6 million.

In February 2024, Saniona raised SEK 88.9 million before issue costs through a rights issue. Prior to this financing Saniona agreed with Fenja Capital 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 Fenja Capital was SEK 59.6 million. 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.

In October 2024 Saniona received a research milestone payment of €500,000 (approximately SEK 5.7 million) from Boehringer Ingelheim. Together with this, Saniona also expects to receive research funding from AstronauTx and Boehringer Ingelheim agreements totaling up to SEK 26 million, until end of 2025. In November 2024, Saniona entered into a license agreement with Acadia Pharmaceuticals for SAN711 in neurological diseases. Under the agreement, Saniona will receive $28 million upfront as well as an upfront payment of $10 million when the first phase 2 study begins. This means that financing is secured for more than 12 months of continued operations.

As of September 30, 2024, Saniona had 111,238,252 (64,126,978) shares outstanding at SEK 0.05 per share equal to a share capital of SEK 5,561,912.60 (3,206,348.90).

On September 30, 2024, the company had 12,427 (13,176) shareholders excluding holdings in life insurance and foreign custody account holders.

Personnel

As of September 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.

Annual General Meeting

Saniona's Annual General Meeting for 2025 will be held in Malmö on May 28, 2025, 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 2024	February 27, 2025, at 8:00 CET
Annual report	April 30, 2025
Interim Report Q1	May 28, 2025, at 8:00 CEST
Annual General Meeting	May 28, 2025, at 16:30 CEST
Interim Report Q2	August 28, 2025, at 8:00 CEST
Interim Report Q3	November 27, 2025, at 8:00 CET
Year-end report 2025	February 26, 2026, 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, November 28, 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	2024-07-01 2024-09-30	2023-07-01 2023-09-30	2024-01-01 2024-09-30	2023-01-01 2023-09-30	2023-01-01 2023-12-31
	1,2,3					
Revenue	4	7,235	5,451	21,288	11,466	16,840
Total operating income		7,235	5,451	21,288	11,466	16,840
Raw materials and consumables		-1,326	-1,536	-3,929	-3,703	-5,059
Other external costs	5	-14,571	-12,023	-34,839	-37,681	-47,664
Share of result of associated company	10	—	-190	—	-394	-1,719
Personnel costs	6	-8,198	-8,278	-25,344	-25,686	-33,812
Depreciation and write-downs		-1,996	-1,781	-5,724	-5,291	-9,651
Total operating expenses		-26,091	-23,808	-69,836	-72,755	-97,905
Operating loss		**-18,856**	**-18,357**	**-48,548**	**-61,289**	**-81,065**
Financial income		113	1,432	1,355	2,729	3,131
Financial expenses	8	-13,754	-9,512	-18,344	-16,979	-26,346
Total financial items		-13,641	-8,080	-16,989	-14,250	-23,215
Loss before tax		**-32,497**	**-26,437**	**-65.537**	**-75,539**	**-104,280**
Income tax	7	3,043	2,345	7,110	8,470	8,470
Loss for the period*		**-29,454**	**-24,092**	**-58,427**	**-67,069**	**-95,810**
Other comprehensive income (loss) for the period						
Item that may be reclassified to profit and loss						
Translation differences		941	-1,647	1,747	3,493	3,084
Total other comprehensive income for the period, net after tax		**941**	**-1,647**	**1,747**	**3,493**	**3,084**
Total comprehensive profit (loss)**		**-28,513**	**-25,739**	**-56,680**	**-63,576**	**-92,726**
Loss per share, SEK		-0.26	-0.38	-0.53	-1.05	-1.49
Diluted loss per share, SEK		-0.26	-0.38	-0.53	-1.05	-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	2024-09-30	2023-09-30	2023-12-31
ASSETS				
Intangible assets		4,811	6,965	4,947
Property and equipment		3,260	4,619	3,297
Right of use assets		3,828	6,381	7,248
Investment in associated company	10	403	431	392
Other financial assets	9	247	2,987	3,093
Tax assets		7,136	8,513	—
Non-current assets		**19,685**	**29,896**	**18,977**
Trade receivables		4,303	2,906	2,526
Current tax assets	7	8,433	8,512	8,206
Other assets		8,181	3,813	3,472
Cash and cash equivalents		41,299	49,278	30,962
Current assets		**62,216**	**64,509**	**45,166**
Total assets		**81,901**	**94,405**	**64,143**

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

KSEK	Note	2024-09-30	2023-09-30	2023-12-31
EQUITY AND LIABILITIES				
Share capital		5,562	3,206	3,206
Additional paid-in capital		880,863	827,803	827,803
Reserves		6,105	112,085	4,359
Accumulated deficit		-913,399	-936,424	-857,308
Equity		**-20,869**	**6,670**	**-21,940**
Loan	8,9	—	60,555	65,238
Lease liabilities	9	280	1,333	686
Other liabilities		2,585	2,534	2,464
Non-current liabilities		2,865	64,422	68,388
Trade payables		16,802	14,022	8,245
Loan	8,9	40,139	—	—
Lease liabilities	9	3,714	5,425	5,485
Other financial liabilities	8,9	37,218	—	—
Other liabilities		2,032	3,866	3,965
Current liabilities		99,905	23,313	17,695
Total liabilities		**102,770**	**87,735**	**86,083**
Total equity and liabilities		**81,901**	**94,405**	**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	—	—	—	-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 and conversion of loan	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**	**4,768**	**-829,107**	**6,670**
January 1, 2024	**3,206**	**827,803**	**4,359**	**-857,308**	**-21,940**
Comprehensive income					
Loss for the period	—	—	—	-58,427	-58,427
Other comprehensive income	—	—	1,746	—	1,746
Total comprehensive income (loss)	**—**	**—**	**1,746**	**-58,427**	**-56,681**
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	—	—	—	2,336	2,336
Total transactions with owners	**2,356**	**53,060**	**—**	**2,336**	**57,752**
September 30, 2024	**5,562**	**880,863**	**6,105**	**-913,399**	**-20,869**

Condensed consolidated interim statement of cash flows – Group

KSEK	Note	2024-07-01 2024-09-30	2023-07-01 2023-09-30	2024-01-01 2024-09-30	2023-01-01 2023-09-30	2023-01-01 2023-12-31
Loss before tax		-32,497	-26,437	-65,537	-75,539	-104,280
Adjustments for non-cash transactions		14,807	2,805	18,938	5,731	13,629
Changes in working capital		3,812	10,136	-2,039	10,874	6,770
Cash flow from operating activities before financial and tax items		**-13,878**	**-13,496**	**-48,639**	**-58,934**	**-83,881**
Interest income received		344	580	1,235	2,132	2,534
Interest expenses paid		-1,474	-5,693	-4,652	-8,560	-12,625
Tax credit received		—	—	—	—	8,441
Cash flow from operating activities		**-15,008**	**-18,609**	**-52,055**	**-65,362**	**-85,531**
Investing activities						
Purchases of property and equipment		-124	-83	-124	-83	-129
Cash flow from investing activities		**-124**	**-83**	**-124**	**-83**	**-129**
Financing activities						
Repayment of loan	8	—	-3,000	-20,000	-3,000	-3,000
Proceeds from issuance of new shares and warrants		—	—	88,874	—	—
Costs related to issuance of new shares		—	-173	-9,305	-173	-173
Payment of lease liabilities		-1,110	-1,264	-3,686	-3,522	-4,794
Cash flow from financing activities		**-1,110**	**-4,437**	**55,883**	**-6,695**	**-7,967**
Net increase (decrease) in cash and cash equivalents		**-16,242**	**-23,129**	**3,704**	**-72,140**	**-93,627**
Cash and cash equivalents at		**54,390**	**69,409**	**30,962**	**111,707**	**111,707**
Exchange rate adjustments		3,151	2,998	6,633	9,711	12,882
Cash and cash equivalents at end of period		**41,299**	**49,278**	**41,299**	**49,278**	**30,962**

PARENT COMPANY'S FINANCIAL STATEMENTS

Statement of income – Parent Company

KSEK	Note	2024-01-01 2024-09-30	2023-01-01 2023-09-30	2023-01-01 2023-12-31
	1,2,3			
Other operating income		1,447	1,182	1,651
Total operating income		1,447	1,182	1,651
Raw materials and consumables		-31	-28	-37
Other external costs		-3,554	-2,941	-4,118
Other operating expenses		-847	-1,011	-1,337
Personnel costs	6	-1,480	-1,508	-1,978
Total operating expenses		-5,912	-5,488	-7,470
Operating income (loss)		**-4,465**	**-4,306**	**-5,819**
Financial income		226	81	111
Financial expenses	8	-22,793	-23,203	-36,811
Total financial items		-22,567	-23,122	-36,700
Profit (loss) before tax		**-27,032**	**-27,428**	**-42,519**
Tax on net profit (loss)		—	—	—
Profit (loss) for the period		**-27,032**	**-27,428**	**-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	2024-09-30	2023-09-30	2023-12-31
ASSETS				
Investment in subsidiaries		347,301	344,442	344,965
Financial assets		347,301	344,442	344,965
Non-current assets		**347,301**	**344,442**	**344,965**
Other assets		441	439	903
Current receivables		441	439	903
Cash and cash equivalents		1,638	3,931	2,460
Current assets		**2,079**	**4,370**	**3,363**
Total assets		**349,380**	**348,812**	**348,328**
EQUITY AND LIABILITIES				
Restricted equity				
Share capital		5,562	3,206	3,206
Unrestricted equity				
Share premium reserve		880,863	827,803	827,803
Retained earnings (accumulated deficit)		-631,429	-591,783	-591,244
Profit (loss) for the period		-27,032	-27,428	-42,519
Equity		**227,964**	**211,798**	**197,246**
Loan	8	—	60,555	65,238
Non-current liabilities		0	60,555	65,238
Trade payables		68	435	644
Loan	8,9	40,139	—	—
Payables to group companies		43,825	75,873	85,049
Other financial liabilities	8,9	37,218	—	—
Other liabilities		166	151	151
Current liabilities		121,416	76,459	85,844
Total liabilities		**121,416**	**137,014**	**151,082**
Total equity and liabilities		**349,380**	**348,812**	**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 nine months ended September 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 September 30, 2024, the Group's current liabilities exceed current assets by SEK 37.7 million. Current assets include cash and cash equivalents of SEK 41.3 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 November 28, 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, except for the valuation of warrants.

In February 2024, 23,555,637 warrants TO 4 were issued in connection with the rights issue. The warrants are valued using the Black & Scholes model applied with the necessary variables. Due to the variable components in the calculation of the value of the TO 4 warrants, this will be calculated at each accounting period.

Critical assessments with a significant impact on reported amounts for financial instruments are made in connection with determining the fair value of financial instruments.

The assessments include the following:
• Selection of valuation methods.
• Calculation of fair value adjustments to account for relevant risk factors.
• Assessment of which market parameters that can be observed.

Information regarding the reported value and fair value of all financial instruments appears in note 9.

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 nine months ended September 30, 2024 and 2023, revenue for the Group was distributed as follows:

Category

KSEK	2024-07-01 2024-09-30	2023-07-01 2023-09-30	2024-01-01 2024-09-30	2023-01-01 2023-09-30	2023-01-01 2023-12-31
Research and collaboration agreements (bundle, over time)	7,235	5,184	21,288	10,844	16,207
Research and development services (standalone)	—	267	—	622	633
Total	**7,235**	**5,451**	**21,288**	**11,466**	**16,840**

Geographical markets based on customer

KSEK	2024-07-01 2024-09-30	2023-07-01 2023-09-30	2024-01-01 2024-09-30	2023-01-01 2023-09-30	2023-01-01 2023-12-31
Sweden	—	—	—	—	—
Germany	3,366	1,874	9,039	6,714	8,721
Denmark	—	267	—	622	633
United Kingdom	3,869	3,310	12,249	4,130	7,486
Total	**7,235**	**5,451**	**21,288**	**11,466**	**16,840**

Note 5 External Research & Development expenses

KSEK	2024-07-01 2024-09-30	2023-07-01 2023-09-30	2024-01-01 2024-09-30	2023-01-01 2023-09-30	2023-01-01 2023-12-31
SAN711	6,659	3,407	11,664	7,984	8,392
SAN2355	2,438	—	5,073	—	—
SAN903	-108	49	223	1,063	1,086
Tesomet	153	559	658	3,354	3,995
Other programs	849	2,401	4,145	5,214	9,311
Total	**9,991**	**6,416**	**21,763**	**17,615**	**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 September 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

July - September 2024
Share-based compensation expenses for the third quarter totaled SEK 0.7 million (1.1).

January - September 2024
Share-based compensation expenses for the period totaled SEK 2.3 million (2.9).

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, September 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	0.25	1.25	6.07	0.17

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, September 30	700	2,129,821	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)	6.50	4.25	4.25	5.25	

** Weighted average*

As of September 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 September 30, 2024.

Note 7 Income tax

In the third quarter, the Group recognized a non-current tax benefit of SEK 3.0 million (2.3). Corresponding figures for the interim period January-September were SEK 7.1 million (8.5). 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 38.3 million).

Note 8 Loan and other financial liabilities

A. Fenja Capital 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 September 30, 2024, the total liabilities to Fenja Capital were SEK 40.1 million whereof SEK 30.9 million as a loan and SEK 9.2 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. Fenja Capital 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 Fenja Capital's claims under the existing outstanding loan. On October 23, Fenja Capital has converted a total of nominal amount to SEK 2 million of the outstanding convertibles.

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 September 30, 2024, the value of the TO 4 warrants was SEK 37.2 million, which gives a financial expense of SEK 11.8 million end of September 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.

September 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		—	247	—	247	—	—	247	247
		—	**247**	**—**	**247**	**—**	**—**	**247**	**247**
Financial assets not measured at fair value									
Trade receivables		4,303	—	—	4,303	—	—	—	—
Other non-current financial assets		2,961		—	2,961	—	—	—	—
Other current financial assets		2,883	—	—	2,883	—	—	—	—
Cash and cash equivalents		41,299	—	—	41,299	—	—	—	—
		51,446	**—**	**—**	**51,446**	**—**	**—**	**—**	**—**
Financial liabilities measured at fair value									
Other financial liabilities*	8	—	37,218	—	37,218	—	37,218	—	37,218
		—	**37,218**	**—**	**37,218**	**—**	**37,218**	**—**	**37,218**
Financial liabilities not measured at fair value									
Trade payables		—	—	16,802	16,802	—	—	—	—
Fenja Capital Loan	8	—	—	40,139	40,139	—	—	—	—
Lease liabilities		—	—	3,994	3,994	—	—	—	—
		—	**—**	**60,935**	**60,935**	**—**	**—**	**—**	**—**

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

* The warrants are valued using the Black & Scholes model applied with the necessary variables.

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

ii. Transfers

During the three and nine months ended September 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	240
Cash received	—
Changes in Fair Value	—
Foreign currency (included in 'net gains/losses on financial items')	7
Balance, September 30, 2024	**247**

Note 10 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

	2024-07-01 2024-09-30	2023-07-01 2023-09-30	2024-01-01 2024-09-30	2023-01-01 2023-09-30	2023-01-01 2023-12-31
Revenue, KSEK	7,235	5,451	21,288	11,466	16,840
Total operating expenses, KSEK	-26,091	-23,808	-69,836	-72,755	-97,905
Operating profit (loss), KSEK*	-18,856	-18,357	-48,548	-61,289	-81,065
Cash flow for the period, KSEK	-16,241	-23,129	3,704	-72,140	-93,627
Weighted average number of shares	111,238,252	63,256,328	104,588,692	62,823,381	63,067,885
Diluted average shares outstanding	111,238,252	63,813,956	104,588,692	63,210,886	63,067,885
Shares outstanding at the end of the period	111,238,252	64,126,978	111,238,252	64,126,978	64,126,978
Average number of employees	22	23	23	23	23
Operating margin*					
Operating profit (loss), KSEK	-18,856	-18,357	-48,548	-61,289	-81,065
Revenue, KSEK	7,235	5,451	21,288	11,466	16,840
Operating margin, %	**-261%**	**-337%**	**-228%**	**-535%**	**-481 %**
Cash flow per share*					
Cash flow for the period, KSEK	-16,241	-23,129	3,704	-72,140	-93,627
Shares outstanding at the end of the period	111,238,252	64,126,978	111,238,252	64,126,978	64,126,978
Cash flow per share, SEK	**-0.15**	**-0.36**	**0.03**	**-1.12**	**-1.46**
Earnings per share					
Profit (loss) for the period, KSEK	-29,454	-24,092	-58,427	-67,069	-95,810
Shares outstanding at the end of the period	111,238,252	64,126,978	111,238,252	64,126,978	64,126,978
Earnings per share, SEK	**-0.26**	**-0.38**	**-0.53**	**-1.05**	**-1.49**
Diluted earnings per share, SEK	**-0.26**	**-0.38**	**-0.53**	**-1.05**	**-1.49**

	2024-09-30	2023-09-30	2023-12-31
Cash and cash equivalent, KSEK	41,299	49,278	30,962
Equity, KSEK	-20,869	6,670	-21,940
Total Equity and liabilities, KSEK	81,901	94,405	64,143
Equity per share*			
Equity, KSEK	-20,869	6,670	-21,940
Shares outstanding at the end of the period	111,238,252	64,126,978	64,126,978
Equity per share, SEK	**-0.19**	**0.10**	**-0.34**
Equity ratio*			
Equity, KSEK	-20,869	6,670	-21,940
Total assets, KSEK	81,901	94,405	64,143
Equity ratio, %	**-25 %**	**7 %**	**-34 %**
Liquidity ratio*			
Current assets, KSEK	62,216	64,509	45,166
Current liabilities, KSEK	99,905	23,313	17,695
Liquidity ratio, %	**62 %**	**277 %**	**255 %**

** = Alternative performance measures*

Note 11 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 September 30, 2024, the fee for Pierandrea's services was SEK 0.8 million (May 25, 2023 until September 30, 2023 - SEK 0.3 million).

John Haurum was at the Annual General Meeting May 29, 2024, elected as a new ordinary board member. The Group has entered into a Consultancy Agreement with John Haurum, for the provision of advisory services regarding Saniona's Business Development. In the period July until September 30, 2024, the fee for John's services was SEK 49 thousand.

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 2024, the fee for Jørgen's services was SEK 0.2 million (1.1).

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

Note 12 Subsequent Events to the Balance Sheet Date

- October 1, Saniona provides update on major progress for SAN2355. The company has identified a stable solid form of the substance and completed the synthesis optimization.
- October 7, Saniona initiates SAN711 Biomarker study.
- October 14, Saniona Ion Channel Research Collaborations with Boehringer Ingelheim Reaches Milestone, resulting in a research milestone payment of €500,000 (approximately SEK 5.7 million).
- October 23, Fenja Capital II A/S (previously Formue Nord Fokus A/S) requested conversion of outstanding convertibles for a total nominal amount of SEK 2 million.
- November 6, Saniona's partner, Productus Medix, did not receive approval from Mexican regulatory agency (COFEPRIS) for tesofensine for the treatment of obesity. Instead Medix is entering a dialogue with the agency regarding the path forward as it appears that the decision by COFEPRIS has not been based on the full data package as submitted by Medix.
- November 12, Saniona comments on Medix's recent regulatory submission for tesofensine in obesity.
- November 26, Saniona Announces Licensing Agreement with Acadia Pharmaceuticals for SAN711 in Neurological Diseases.

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 2024 and the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim 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.

Malmö, 28 November 2024
Öhrlings PricewaterhouseCoopers AB

Signature on Swedish original

Cecilia Andrén Dorselius
Authorized Public Accountant
Auditor in charge

Daniel Körner Rask
Authorized Public Accountant

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 persons set out above, at 2024-11-28 08:00 CET.

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