Tesofensine progressed in Q1 with favorable opinion from COFEPRIS' New Molecule Committee in Mexico

Q1 2023 (2022)
Revenue was SEK 2.2 M (6.6 M)
Operating profit/loss was SEK -21.1 M (-133.2 M)
Net profit/loss was SEK -21.7 M (-133.4 M)
Basic earnings/loss per share was SEK -0.35 (-2.14)
Diluted earnings/loss per share were SEK -0.35 (-2.14)

Business highlights in Q1 2023

- On January 17, Saniona announced **successful preclinical in vivo validation** for treatment of migraine in the Cephagenix joint venture program.
- On February 25, Saniona announced that its partner Medix **received favorable opinion** for tesofensine for the treatment of obesity and weight management in Mexico.

Significant events after the reporting period

- There have been no events after the reporting period.

Comments from the CEO

"Good progress on partnering negotiations and a potential approval of tesofensine in Mexico for treatment of obesity."

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

Saniona's short-term strategy is based around an intention to capitalize part of the value of some of the assets in our broad pipeline. The objective is three-fold: to secure optimal development and upside potential of the partnered assets, generate funding to finance development of other assets internally, and to improve the balance sheet in general and reduce reliance on financial markets for financing.

Financing our internal development programs will enable us to deliver new valuable breakthrough medicine in the longer term. We have developed plans for our clinical stage assets and initiated activities to ensure that these can be advanced as quickly as possible, when we have the resources to develop them internally.

In the first quarter of 2023, we have made good progress with partnering negotiations on several of our pipeline programs and the aim remains to establish at least two new partnerships this year.

Tesofensine opportunity in Mexico

In February, the Mexican regulatory authority's technical committee on new molecules gave a favorable opinion on tesofensine for treatment of obesity. This is an important step for our partner Medix towards the approval of tesofensine in Mexico as a new treatment option for obesity. It also represents a potential new source of income for Saniona, which is entitled to royalties on product sales in Mexico.

The obesity market in Mexico is growing, as in other countries around the world, due to increasing incidence of obesity and the introduction of new and highly effective injectables, the GLP-1 analogs. We believe that tesofensine will be a powerful new and competitive product in this market since it is safe and well tolerated, can be taken as a tablet, and provides the same level of efficacy as some of best GLP-1 analogs.

According to Medix's estimates, the market for obesity in Mexico is growing at about 16% per year and is expected to reach about USD 190 million in 2023.

Solid pipeline progress

During the first quarter, we also made important advances in our ongoing research projects including our Kv7 program and the two programs in collaboration with Boehringer Ingelheim and Cephagenix.

The promising Kv7 epilepsy program moved into the lead optimization phase in 2022, the final stage before potential selection of a clinical candidate. We have now taken an important step towards candidate selection by identifying several novel and very potent and selective compounds with promising biological, physical, and chemical properties.

We are also identifying novel ion channel modulators to treat cognitive deficits in schizophrenia in our partnership with Boehringer Ingelheim. This innovative program passed an important drug discovery milestone in 2022 and we have now made significant progress towards moving into lead optimization already in 2023, triggering the first financial milestone payment to Saniona.

In January, we announced successful preclinical in vivo validation in the Cephagenix joint venture program, which is aimed at identifying subtype-selective ATP-sensitive potassium channel (K_{ATP}) inhibitors for the treatment of migraine. In this program, we have identified the first generation of novel highly selective inhibitors of the specific K_{ATP} channel subtype expressed in the intracranial arteries and demonstrated that these compounds are effective in relevant in vivo animal models.

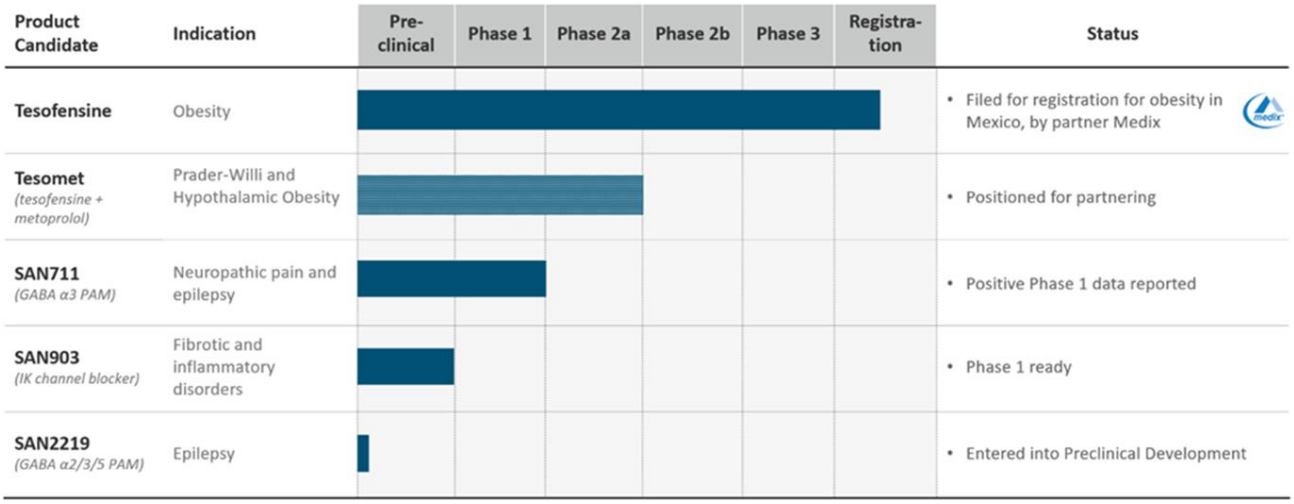
Overall, Saniona has made significant advances in the first quarter and negotiations continue on potential partnership agreements on our research and clinical-stage assets. I look forward to providing further updates on our work as we move through 2023.

Thomas Feldthus
CEO

About Saniona

Saniona is a clinical-stage biopharmaceutical company focused on the discovery and development of medicines modulating ion channels. Saniona's most advanced candidate, tesofensine, has progressed towards regulatory approval for obesity by Saniona's partner Medix. Saniona is advancing four product candidates including Tesomet™ and three ion channel modulators SAN711, SAN903 and SAN2219. Tesomet™ has progressed to mid-stage clinical trials for rare eating disorders. SAN711 has completed Phase 1 for neuropathic pain conditions. SAN903 is ready for Phase 1 for inflammatory and fibrotic disorders. SAN2219 is in preclinical development for epilepsy. Saniona has research and development partnerships with Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and Cephagenix ApS. Saniona is based in Copenhagen, and listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at www.saniona.com.

Pipeline



Tesofensine

Saniona's partner Medix has completed a successful Phase 3 study and submitted a new drug application to the Mexican food and drug administration, COFEPRIS, for approval of tesofensine for the treatment of patients with obesity. In February 2023 COFEPRIS' technical committee expressed a favorable opinion on tesofensine for treatment of obesity. This non-binding technical opinion is issued as one of the steps in the process of reviewing new molecules. Medix holds an exclusive license to commercialize tesofensine in Mexico and Argentina, while Saniona is entitled to milestone payments and royalties on product sales. Saniona retains commercial rights in the rest of the world and rights to use any data generated from the Phase 3 trial.

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. Tesofensine is a monoamine reuptake inhibitor that modulates brain activity by increasing the levels of three neurotransmitters – dopamine, serotonin and noradrenaline – which are each intimately involved in regulating appetite, food-seeking behavior and metabolism. Metoprolol is a cardio-selective β1 receptor blocker historically used to treat a number of 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. Financial analysts have estimated annual peak sales for Tesomet between USD 850M - 1B+ (SEK 8B – 9.5B) (Saniona does not endorse or validate sales estimates provided by third parties).

HYPOTHALAMIC OBESITY (HO)

HO is a rare neuroendocrine disorder most commonly caused by damage to the hypothalamus sustained during the removal of a craniopharyngioma (CP), a rare, non-cancerous central nervous system tumor. The number of patients with HO is estimated to be as high as 25,000 in the United States and 40,000 in Europe. Currently, there are no FDA-approved treatments for HO and there is no cure for this disorder.

Saniona has completed a Phase 2 clinical trial of Tesomet for the treatment of HO. This trial was a single-center, 24-week, randomized, double-blind, placebo-controlled trial with an optional 24-week Open Label Extension (OLE). A total of 21 adult patients, 13 of whom were randomized to Tesomet and eight to placebo, were included within the protocol-specified modified intent-to-treat analysis pertaining to the double-blind period. The primary endpoint of the study was to establish the overall safety and tolerability of Tesomet in patients with HO, which was achieved. Several secondary endpoints relating to efficacy were also achieved. Double-blind treatment with Tesomet for 24 weeks resulted in statistically significant placebo-adjusted weight loss of 6.28% ($p<0.0169$) and a mean reduction in waist circumference of 5.68 cm or 5.00%. In the 24-week OLE, Tesomet continued to demonstrate persistent improvements in body weight and waist circumference.

PRADER-WILLI SYNDROME (PWS)

PWS is a rare, genetic, complex, multisystem disorder that is the most common genetic cause of childhood obesity globally. The number of patients with PWS is estimated to be as high as 34,000 in the United States and 50,000 in Europe. The only FDA-approved treatment currently available for PWS is growth hormone therapy; however growth hormone therapy does not reduce the hyperphagia symptoms experienced by these patients.

Saniona has completed a Phase 2 clinical trial of Tesomet for the treatment of PWS. This trial was a two-center, randomized, double-blind, placebo-controlled trial. Nine adults and nine adolescents were treated daily with Tesomet or placebo for three months for the double-blind portion of the trial, with two open-label three-month extensions, referred to as OLE1 and OLE2, for adolescent patients. The primary endpoint was change in body weight; secondary objectives included hyperphagia, body composition, lipids and other metabolic parameters. The adult patients receiving Tesomet achieved a 5.4% reduction in body weight, which is notable in the small patient population, and a statistically significant 8.1 point reduction in hyperphagia as measured by the Hyperphagia Questionnaire for Clinical Trials (HQ-CT), a caregiver questionnaire that is the generally accepted standard for evaluating hyperphagia in patients with PWS. In adolescents, upon the dose increase of Tesomet from 0.125 mg to 0.25 mg during the OLE2 portion of the trial, Tesomet-treated patients experienced a decrease in body weight and a further reduction in hyperphagia as measured by the HQ-CT questionnaire.

SAN711

SAN711 is a novel first-in-class selective positive allosteric modulator (PAM) of $GABA_A$ α3 receptors positioned for the treatment of neuropathic pain and epilepsy. SAN711 has successfully completed a Phase 1 clinical trial in healthy volunteers, and the results from this trial open the path for continued clinical development of SAN711.

GABA is a neurotransmitter, or chemical messenger, that inhibits signals between nerve cells in the brain. It is believed that a dysfunction or reduction of GABA signaling in the spinal cord is associated with aberrant pain signaling to the brain and consequently perception of pain. SAN711 is specifically designed to enhance the effect of GABA, the brain's own inhibitory neurotransmitter, at α3 containing receptors in the spinal cord. This is believed to restore spinal inhibitory tone and prevent abnormal pain signaling to the brain.

$GABA_A$ is the target of the non-selective and highly effective medicines belonging to the chemical group referred to as "benzodiazepines". Unlike benzodiazepines, SAN711 does not have an impact on $GABA_A$ α1 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.

Preclinical assessments in in vitro and in vivo models, conducted in the labs of Saniona have confirmed that because SAN711 only activates α3 $GABA_A$ receptors, this selectivity may allow SAN711 to provide pain relief and other benefits in the central nervous system while avoiding the typical adverse effects associated with non-selective $GABA_A$ activation mentioned above.

Saniona has recently successfully completed a Phase 1 clinical trial. The study was a randomized, placebo-controlled Phase 1 clinical trial in 66 healthy male and female volunteers. The primary objective of the study was to determine the safety and tolerability of SAN711, which was evaluated through single ascending dose and multiple ascending dose phases of the study. The secondary objective was to measure binding to target receptors, which was assessed during a positron emission tomography (PET) evaluation phase of the study.

SAN711 was safe and well tolerated across all dosing cohorts, confirming the improved tolerability of the unique subtype selective profile. There were no dose-limiting adverse effects or serious adverse events, and all subjects completed the study. There were no safety laboratory concerns or cardiovascular concerns. Further, there were no abnormal neurological examinations and no evidence of emergent cognitive deficits as assessed by Mini Mental State Examinations. SAN711 had a favorable absorption and distribution profile and the maximum plasma levels of SAN711 resulted in more than 80% occupancy of target receptors. Importantly, the PET results confirmed that a pharmacologically active receptor occupancy may be achieved at well-tolerated doses of SAN711.

Consequently, SAN711 shows clear differentiation in its side effect profile compared to classical, non-selective $GABA_A$ modulators of the benzodiazepine type, which is dose limited by sedation. Importantly, Saniona has in this study demonstrated that it is possible to safely exceed human exposure levels of SAN711 beyond what is needed to show strong efficacy in the preclinical pain models. Further, the PET study results provide a clear guidance for the design of the Phase 2 studies with 0.8 mg/kg twice daily projected to be an effective and well tolerated dose. More information is available at www.clinicaltrials.gov.

The preclinical data package indicates substantial potential value for SAN711 in neuropathic pain and/or in various types of epilepsies including absence seizures and rare epileptic syndromes such as pediatric patients living with ESES (electrical status epilepticus during sleep). Saniona is currently developing clinical plans within rare- as well as more common therapeutic areas to be carried out either by Saniona alone or together with a partner.

SAN903

SAN903 has successfully completed preclinical development in 2022 and we intend to start the regulatory process for entering Phase 1 clinical trials in 2023 either by Saniona alone or together with a partner. The primary indication for SAN903 is inflammatory bowel diseases (IBD) and we see a potential of SAN903 as a medicine with independent actions on intestinal inflammation and fibrosis.

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

This ion channel is found on several types of immune cells, where it participates in the control of the cellular pathways that maintain pathogenic activation and inflammation in chronic diseases. The KCa3.1 channel is also expressed on fibroblasts, especially on myofibroblasts, where it supports the overproduction of connective tissue that can lead to fibrosis. Prevention of fibrotic complications is an aspect of the disease, which is poorly treated by current standard-of-care IBD medicines, and progressed fibrosis often requires surgical intervention to resolve potentially life-threatening gut obstructions. SAN903 dampens inflammation and fibrosis by preventing cell division and cell migration of activated immune cells and fibroblast and by impeding cytokine release and collagen secretion of the respective cell types.

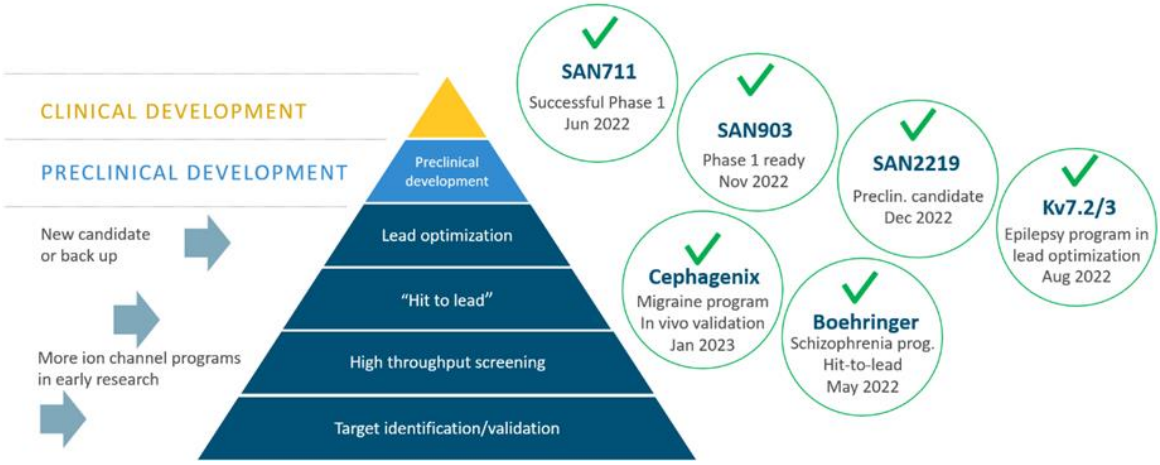
SAN2219

SAN2219 is a subtype selective activator of $GABA_A$ α2/α3/α5 receptors specifically designed to exert robust anti-seizure activity by dampening excessive neuronal activation. The program has been advanced to preclinical development and hence represents the first preclinical development candidate from Saniona´s $GABA_A$ α2/α3 activator program.

GABA is a neurotransmitter that inhibits signals between nerve cells in the brain. Most forms of epilepsy are caused by an over-excitability in specific neural circuits. By inhibiting the over-excitability in epilepsy, benzodiazepines have proven to be among the most effective treatment principles for control of seizure activity. Benzodiazepines are non-selective $GABA_A$ modulators that broadly activate $GABA_A$ receptors including the $GABA_A$ α1 receptor subtype. Benzodiazepines are often used as rescue medicine in acute epilepsy, and their long-term use is often hampered by the development of tolerance to seizure control, withdrawal symptoms, and adverse events, such as cognitive impairment and sedation.

R&D Ion Channel Pipeline

Saniona Drug Discovery Engine Generates Continual Pipeline



Our earlier stage discovery and development efforts are focused on the validated drug class of ion channels, which have been implicated in the pathophysiology of many disease settings and include many successful drugs such as Norvasc (amlodipine), Xylocaine (lidocaine) and Valium (diazepam). Our ion channel drug discovery engine combines in-house expertise in chemistry, precision biology, in vivo stability/distribution, target engagement, in vivo pharmacology, and artificial intelligence to accelerate the discovery of highly selective, subtype-specific, and state-dependent ion channel modulators.

The core of this engine is Saniona's proprietary IONBASE database, which contains structure-activity data for more than 130,000 compounds. Of these, more than 20,000 are our proprietary compounds, generated over 20 years and enriched for properties conferring optimal ion channel modulation.

As a result of our ion channel drug discovery engine, we have generated a robust pipeline of orally available, potent, highly selective and differentiated ion channel modulators, including SAN711, SAN903 and SAN2219. We anticipate that this robust discovery engine will continue to generate multiple new drug candidates to add to the Saniona pipeline.

PARTNERSHIPS AND SPINOUTS

Leveraging our expertise in the field of ion channel drug discovery, our proprietary focused compound library and robust database (IONBASE), we are continuously advancing our research programs to identify and advance additional selective ion channel clinical candidates in a range of therapeutic areas, including rare genetic and neurological disorders. Our industry-leading research has formed the basis of many successful spinouts, partnerships, and licensing agreements with pharmaceutical companies internationally, such as Boehringer Ingelheim, 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

	2023-01-01 2023-03-31	2022-01-01 2022-03-31	2022-01-01 2022-12-31
Revenue, KSEK	2,162	6,625	15,283
Total operating expenses, KSEK	-23,275	-139,825	-241,002
Operating profit (loss), KSEK*	-21,113	-133,200	-225,719
Cash flow for the period, KSEK	-26,238	-89,885	-295,215
Average shares outstanding	62,385,677	62,385,677	62,385,677
Diluted average shares outstanding	62,385,677	62,385,677	62,385,677
Shares outstanding at the end of the period	62,385,677	62,385,677	62,385,677
Average number of employees	23	55	34
Operating margin*			
Operating profit (loss), KSEK	-21,113	-133,200	-225,719
Revenue, KSEK	2,162	6,625	15,283
Operating margin, %	**-977%**	**-2,011%**	**-1,477%**
Cash flow per share*			
Cash flow for the period, KSEK	-26,238	-89,885	-295,215
Shares outstanding at the end of the period	62,385,677	62,385,677	62,385,677
Cash flow per share, SEK	**-0.42**	**-1.44**	**-4.73**
Earnings per share			
Profit (loss) for the period, KSEK	-21,745	-133,357	-245,357
Shares outstanding at the end of the period	62,385,677	62,385,677	62,385,677
Earnings per share, SEK	**-0.35**	**-2.14**	**-3.93**
Diluted earnings per share, SEK	**-0.35**	**-2.14**	**-3.93**

	2023-03-31	2022-03-31	2022-12-31
Cash and cash equivalent, KSEK	87,768	279,335	111,707
Equity, KSEK	33,116	165,954	52,708
Total Equity and liabilities, KSEK	132,327	348,289	153,696
Equity per share*			
Equity, KSEK	33,116	165,954	52,708
Shares outstanding at the end of the period	62,385,677	62,385,677	62,385,677
Equity per share, SEK	**0.53**	**2.66**	**0.84**
Equity ratio*			
Equity, KSEK	33,116	165,954	52,708
Total assets, KSEK	132,327	348,289	153,696
Equity ratio, %	**25%**	**48%**	**34%**
Liquidity ratio*			
Current assets, KSEK	104,994	304,057	127,345
Current liabilities, KSEK	92,940	89,888	22,897
Liquidity ratio, %	**113%**	**338%**	**556%**

** = Alternative performance measures*

Results of Operations

Revenue

Three Months Ended March 31, 2022 and 2023

Revenue decreased by SEK 4.4 million from SEK 6.6 million for the three months ended March 31, 2022, to SEK 2.2 million for the three months ended March 31, 2023.

Operating expenses

Three Months Ended March 31, 2022 and 2023

Operating expenses decreased by SEK 116.6 million from SEK 139.8 million for the three months ended March 31, 2022, to SEK 23.2 million for the three months ended March 31, 2023.

Within operating expenses, external expenses decreased by SEK 72.8 million from SEK 84.6 million for the three months ended March 31, 2022, to SEK 11.8 million for the three months ended March 31, 2023. The significant decrease in external operating expenses is due to close of the Phase 2b clinical trials of Tesomet for HO and PWS in March 2022, completion of SAN711 Phase 1 for neuropathic pain conditions in June 2022, and finalization of preclinical development of SAN903 in November 2022.

The main components of our external expenses are external research and development expenses, which are primarily attributable to contract research organizations (CROs) and contract manufacturing organizations for our clinical trials. External research and development expenses for the three months ended March 31, 2023, comprised primarily of development costs of Tesomet (SEK 1.4 million), development costs of SAN711 (SEK 2.0 million) and pre-clinical development costs of the SAN903 program (SEK 0.8 million) and other research costs. For the three months ended March 31, 2022, external expenses comprised primarily of development costs of Tesomet (SEK 46.5 million) followed by development costs of SAN711 (SEK 18.1 million) and pre-clinical development costs of the SAN903 program (SEK 5.0 million) and other research costs.

Personnel costs include salaries, variable compensation, social security, and other employee benefits. Personnel costs decreased by SEK 42.8 million from SEK 51.4 million for the three months ended March 31, 2022, to SEK 8.6 million for the three months ended March 31, 2023. Non-cash share-based compensation expense decreased by SEK 5.4 million from SEK 6.3 million for the three months ended March 31, 2022, to SEK 0.9 million for the three months ended March 31, 2023. The significant decrease in personnel costs is due to closing of the U.S. operation and termination of the positions of all U.S. personnel, including the U.S. executive management team.

Financial items

Three Months Ended March 31, 2022 and 2023

Net loss from total financial items increased from SEK 3.3 million for the three months ended March 31, 2022, to SEK 3.5 million for the three months ended March 31, 2023. The financial expenses include interest and commitment fee to Formue Nord SEK of 3.0 million (SEK 3.3 million).

Tax Benefit

Three Months Ended March 31, 2022 and 2023

The Group recognized a tax income of SEK 2.9 million for the three months ended March 31, 2023, compared to SEK 3.2 for the three months ended March 31, 2022.

Cash flow

Three Months Ended March 31, 2022 and 2023

Net cash used in operating activities decreased by SEK 70.6 million from SEK -95.8 million for the three months ended March 31, 2022, to SEK -25.2 million for the three months ended March 31, 2023.

The operating cash flow for the three months ended March 31, 2023, is primarily attributable to the operating loss of SEK 18.4 million (net of non-cash operating expenses for share-based payments of SEK 0.9 million and for expenses depreciation of SEK 1.7 million). The operating cash flow for the three months ended March 31, 2022, is primarily

attributable to the operating loss of SEK 124.6 million (net of non-cash operating expenses for share-based payments of SEK 6.3 million and for depreciation of SEK 2.3 million).

For the three months ended March 31, 2023, net cash used by investing activities was SEK 0 million. For the three months ended March 31, 2022, net cash received by investing activities was SEK 7.5 million. Net cash received include Saniona's portion of the upfront payment connected to Novartis acquisition of Cadent Therapeutics in January 2021, in which Saniona held a 3% ownership stake.

For the three months ended March 31, 2023 and 2022, net cash used by financing activities was SEK 1.1 million and SEK 1.6 million, respectively, due to repayment of lease liabilities.

For the three months ended March 31, 2023 and 2022, cash and cash equivalents amounted to SEK 87.8 million and SEK 279.3 million, respectively.

Parent Company

Three Months Ended March 31, 2022 and 2023

Operating expenses decreased by SEK 14.5 million from SEK 16.0 million for the three months ended March 31, 2022, to SEK 1.5 million for the three months ended March 31, 2023.

Loss decreased by SEK 11.7 million from a loss of SEK 18.2 million for the three months ended March 31, 2022, to a loss of SEK 6.5 million for the three months ended March 31, 2023.

The share, share capital and ownership structure

On March 31, 2023 and 2022, the company had 11,025 (9,231) shareholders excluding holdings in life insurance and foreign custody account holders. Equity was SEK 33.1 million (165.9).

Personnel

As of March 31, 2023, Saniona had 23 (56) employees including 10 (14) employees with Ph.D. degrees. Of these employees, 17 (38) were engaged in research and clinical development activities and 6 (18) were engaged in general and administrative activities. Of the 23 (56) employees, 12 (31) were women.

Risk factors and risk management

All business operations involve risk. Managed risk-taking is necessary to maintain operations. Risk may be due to events in the external environment and may affect a certain industry or market. Risk may also be company specific.

Saniona is exposed to various kinds of risks that may impact the Group's results and financial position. The risks can be divided into operational risks and financial risks. The main risks and uncertainties which Saniona is exposed to are related to drug development, the company's collaboration agreements, competition, technology development, patents, regulatory requirements, capital requirements and currencies.

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

Audit review

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

Financial calendar

Annual General Meeting	May 25, 2023 at 10:00 CEST
Interim Report Q2	August 31, 2023 at 8:00 CEST
Interim Report Q3	November 30, 2023 at 8:00 CET
Year-End Report 2023	February 22, 2024 at 8:00 CET

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, 25 May 2023
Saniona AB

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

THE GROUP'S CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Condensed consolidated interim statement of comprehensive income – Group

KSEK	Note	2023-01-01 2023-03-31	2022-01-01 2022-03-31	2022-01-01 2022-12-31
	1,2,3			
Revenue	4	2,162	6,625	15,283
Total operating income		2,162	6,625	15,283
Raw materials and consumables		-1,033	-1,525	-4,475
Other external costs		-11,838	-84,581	-146,486
Share of result of associate	9	-85	—	—
Personnel costs	5	-8,590	-51,430	-82,223
Depreciation and write-downs		-1,729	-2,289	-7,818
Total operating expenses		-23,275	-139,825	-241.002
Operating profit (loss)		**-21,113**	**-133,200**	**-225,719**
Share of result of associate	9	—	193	346
Financial income		599	619	9,726
Financial expenses		-4,100	-4,126	-24,659
Net gains on financial items		—	—	-11,661
Total financial items		3,501	3,314	-26.248
Profit (loss) before tax		**-24,614**	**-136,514**	**-251,967**
Income tax	6	2,869	3,157	6,610
Profit (loss) for the period*		**-21,745**	**-133,357**	**-245,357**
Other comprehensive income (loss) for the period				
Item that may be reclassified to profit and loss				
Translation differences		1,248	10,987	34,047
Items that will not be reclassified to profit and loss				
Equity instruments at FVOCI – net change fair value		—	—	—
Total other comprehensive income for the period, net after tax		**1,248**	**10,987**	**34,047**
Total comprehensive profit (loss)**		**-20,497**	**-122,370**	**-211.310**
Loss per share, SEK		-0.35	-2.14	-3.93
Diluted loss per share, SEK		-0.35	-2.14	-3.93

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

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

Condensed consolidated interim statement of financial position – Group

KSEK	Note	2023-03-31	2022-03-31	2022-12-31
ASSETS				
Intangible assets		6,809	6,263	6,737
Property and equipment		5,316	4,743	5,703
Right of use assets		8,815	15,074	9,998
Investment in associate	9	590	700	799
Other financial assets	8	2,921	14,343	3,114
Tax assets		2,882	3,109	—
Non-current assets		**27,333**	**44,232**	**26,351**
Trade receivables		4,537	7,835	4,628
Current tax assets	6	8,322	7,654	8,234
Other financial assets		—	427	—
Other assets		4,367	8,806	2,776
Cash and cash equivalents		87,768	279,335	111,707
Current assets		**104,994**	**304,057**	**127,345**
Total assets		**132,327**	**348,289**	**153,696**

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

KSEK	Note	2023-03-31	2022-03-31	2022-12-31
EQUITY AND LIABILITIES				
Share capital		3,119	3,119	3,119
Additional paid-in capital		813,261	813,261	813,261
Reserves		109,840	85,532	108,592
Accumulated deficit		-893,104	-735,958	-872,264
Equity		**33,116**	**165,954**	**52,708**
Other financial liabilities	7,8	3,842	92,447	75,699
Other liabilities		2,429	—	2,392
Non-current liabilities		6,271	92,447	78,091
Trade payables		13,479	43,738	14,073
Other financial liabilities	7,8	77,250	6,237	5,822
Other liabilities		2,211	39,913	3,002
Current liabilities		92,940	89,888	22,897
Total liabilities		**99,211**	**182,335**	**100,988**
Total equity and liabilities		**132,327**	**348,289**	**153,696**

Condensed consolidated interim statement of changes in equity – Group

	Share capital	Additional paid-in capital	Translation reserves	Fair value reserve	Accumulated deficit	Shareholders' equity
January 1, 2022	**3,119**	**813,261**	**1,016**	**73,529**	**-608,926**	**281,999**
Comprehensive income						
Loss for the period	—	—	—	—	-133,357	-133,357
Other comprehensive income	—	—	10,987	—	—	10,987
Total comprehensive income	**—**	**—**	**10,987**	**—**	**-133,357**	**-122,370**
Transactions with owners						
Shares issued for cash	—	—	—	—	—	—
Expenses related to capital increase	—	—	—	—	—	—
Share-based compensation expenses	—	—	—	—	6,325	6,325
Total transactions with owners	**—**	**—**	**—**	**—**	**6,325**	**6,325**
March 31, 2022	**3,119**	**813,261**	**12,003**	**73,529**	**-735,958**	**165,954**
January 1, 2023	**3,119**	**813,261**	**35,063**	**73,529**	**-872,264**	**52,708**
Comprehensive income						
Loss for the period	—	—	—	—	-21,745	-21,745
Other comprehensive income			1,248	—		1,248
Total comprehensive income (loss)	**—**	**—**	**1,248**	**—**	**-21,745**	**-20,497**
Transactions with owners						
Shares issued for cash	—	—	—	—	—	—
Expenses related to capital increase	—	—	—	—	—	—
Share-based compensation expenses	—	—	—	—	905	905
Total transactions with owners	**—**	**—**	**—**	**—**	**905**	**905**
March 31, 2023	**3,119**	**813,261**	**36,311**	**73,529**	**-893,104**	**33,116**

Condensed consolidated interim statement of cash flows – Group

KSEK	Note	2023-01-01 2023-03-31	2022-01-01 2022-03-31	2022-01-01 2022-12-31
Loss before tax		-24,614	-136,514	-251,967
Adjustments for non-cash transactions		4,184	9,293	-8,799
Changes in working capital		-3,067	34,478	-17,554
Cash flow from operating activities before financial and tax items		**-23,497**	**-92,743**	**-278,320**
Interest income received		895	9	593
Interest expenses paid		-2,560	-3,074	-11,937
Tax credit received		—	—	8,126
Cash flow from operating activities		**-25,162**	**-95,808**	**-281,537**
Investing activities				
Purchases of property and equipment		—	-32	-985
Proceeds from sale of financial assets		—	7,522	7,522
Proceeds from sale of tangible assets		—	9	306
Cash flow from investing activities		**—**	**7,499**	**6,843**
Financing activities				
Repayment of loan		—	—	-15,000
Payment of lease liabilities		-1,076	-1,576	-5,521
Cash flow from financing activities		**-1,076**	**-1,576**	**-20,521**
Net increase (decrease) in cash and cash equivalents		**-26,238**	**-89,885**	**-295,215**
Cash and cash equivalents at beginning of period		**111,707**	**356,855**	**356,855**
Exchange rate adjustments		2,299	12,365	50,067
Cash and cash equivalents at end of period		**87,768**	**279,335**	**111,707**

PARENT COMPANY'S FINANCIAL STATEMENTS

Statement of income – Parent Company

KSEK	Note	2023-01-01 2023-03-31	2022-01-01 2022-03-31	2022-01-01 2022-12-31
	1,2,3			
Other operating income		297	1,516	3,418
Total operating income		297	1,516	3,418
Raw materials and consumables		-9	—	-30
Other external costs		-680	-5,639	-10,602
Personnel costs	5	-784	-10,345	-17,728
Total operating expenses		-1,473	-15,984	-28,360
Operating income (loss)		**-1,176**	**-14,468**	**-24,942**
Financial income		13	81	391
Financial expenses		-5,356	-3,817	-17,785
Total financial items		-5,343	-3,736	-17,394
Profit (loss) before tax		**-6,519**	**-18,204**	**-42,336**
Tax on net profit (loss)		—	—	—
Profit (loss) for the period		**-6,519**	**-18,204**	**-42,336**

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

Balance Sheet – Parent Company

KSEK	Note	2023-03-31	2022-03-31	2022-12-31
ASSETS				
Investment in subsidiaries		342,552	366,056	341,703
Other financial assets		—	684	—
Financial assets		342,552	366,740	341,703
Non-current assets		**342,552**	**366,740**	**341,703**
Other assets		987	384	222
Current receivables		987	384	222
Cash and cash equivalents		1,976	6,709	2,228
Current assets		**2,963**	**7,093**	**2,450**
Total assets		**345,515**	**373,833**	**344,153**
EQUITY AND LIABILITIES				
Restricted equity				
Share capital		3,119	3,119	3,119
Unrestricted equity				
Share premium reserve		813,261	813,261	813,261
Retained earnings (accumulated deficit)		-593,788	-528,051	-552,357
Profit (loss) for the period		-6,519	-18,204	-42,336
Equity		**216,073**	**270,125**	**221,687**
Other financial liabilities	7	—	83,631	70,636
Non-current liabilities		—	83,631	70,636
Trade payables		585	3,641	806
Payables to group companies		57,210	16,208	50,790
Other financial liabilities	7	71,508	—	—
Other liabilities		139	228	234
Current liabilities		129,442	20,077	51,830
Total liabilities		**129,442**	**103,708**	**122,466**
Total equity and liabilities		**345,515**	**373,833**	**344,153**

Notes to the condensed consolidated interim financial statements

Note 1 General Information

Saniona AB (publ), (the 'Parent Company'), Corporate Registration Number 556962-5345, is a limited liability company registered in the municipality of Malmö in the county of Skåne, Sweden. These condensed consolidated interim financial statements comprise the Parent Company and its subsidiaries (collectively the 'Group' or 'Saniona'). The Group is a clinical-stage biopharmaceutical company focused on the discovery and development of medicines modulating ion channels. The legal address of the head office is Smedeland 26B, DK-2600 Glostrup, Denmark. The Parent Company is listed on Nasdaq Stockholm Small Cap, and its shares are traded under the ticker SANION and the ISIN code SE0005794617.

Note 2 Basis of Accounting and Significant Accounting Policies

A. Basis of Accounting

These condensed consolidated interim financial statements for the three months ended March 31, 2023, have been prepared in accordance with IAS 34 *Interim Financial Reporting*, the Annual Accounts Act, and the Financial Reporting Board's recommendation RFR 1, Supplementary Accounting Rules for Groups. The interim financial statements for the Parent Company are prepared under the requirements of chapter 9 of the Swedish Accounting Act (1995:1554). These condensed consolidated interim financial statements should be read in conjunction with the Group's last annual consolidated financial statements as at and for the year ended December 31, 2022 ('last annual financial statements'). They do not include all the information required for a complete set of financial statements prepared in accordance with IFRS Standards. However, selected explanatory notes are included to explain events and transactions that are significant to an understanding of the changes in the Group's financial position and performance since the last annual financial statements.

The condensed consolidated interim financial statements have been prepared on a going concern basis. As of March 31, 2023, the Group's current assets exceed current liabilities by SEK 12.1 million. Current assets include cash and cash equivalents of SEK 87.8 million.

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

These condensed consolidated financial statements were authorized for issue by the Parent Company's Board of Directors (the 'Board') on May 25, 2023.

B. Significant Accounting Policies

The Group has consistently applied the accounting policies described in the last annual financial statements to all periods presented in these condensed consolidated interim financial statements.

i. Adoption of new or revised standards

No new or changed accounting standards that came into effect on January 1, 2023, had a material impact on Saniona. The policies applied in the preparation of this interim report apply to all periods and are consistent with the accounting policies presented in the 2022 Annual Report.

Note 3 Critical accounting judgments and key sources of estimation uncertainty

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

Note 4 Revenue

The Group's revenue generating activities are those described in the last annual financial statements.
In the three months ended March 31, 2023 and 2022, revenue for the Group by category was as follows:

KSEK	2023-01-01 2023-03-31	2022-01-01 2022-03-31
Research and collaboration agreements (bundle, over time)	1,730	1,926
Research and development services (standalone)	432	939
License agreements (other event-based payments)	—	3,760
Total	**2,162**	**6,625**

In the three months ended March 31, 2023 and 2022, revenue for the Group by major customers was as follows:

KSEK	2023-01-01 2023-03-31	2022-01-01 2022-03-31
Customer #1	1,730	1,926
Customer #2	432	939
Customer #3	—	3,760
Total	**2,162**	**6,625**

In the three months ended March 31, 2023 and 2022, revenue for the Group by primary geographical market was as follows:

KSEK	2023-01-01 2023-03-31	2022-01-01 2022-03-31
Sweden	—	—
Germany	1,730	1,926
Denmark	432	939
Mexico	—	3,760
Total	**2,162**	**6,625**

Note 5 Share-based payments

A. Description of share-based payment arrangements

A detailed description of the Group's share-based payment arrangements as of March 31, 2023, is provided in the last annual financial statements.

B. Measurement of fair values and compensation expense

Share-based compensation expenses for the three months ended March 31, 2023 and 2022 totaled SEK 0.9 million and SEK 6.3 million, respectively. The fair value of the service that entitles an employee and board member to allotment of options under Saniona's option programs is recognized as a personnel cost with a corresponding increase in equity. Such compensation expenses represent the fair market values of warrants granted and do not represent actual cash expenditures.

The inputs used in the measurement of the fair values at grant date based on the Black-Scholes formula and the reconciliation of options outstanding are as follows:

Incentive program	2018:1	2018:2	2019:1	2019:2	2020:1
Options outstanding, January 1	286,003	32,792	34,500	15,770	355,156
Granted during the year	—	—	—	—	—
Forfeited during the year	—	—	—	—	—
Options outstanding, March 31	286,003	32,792	34,500	15,770	355,156
Maximum number of shares to be issued	294,583	33,775	34,845	15,927	358,707
Grant Date Fair Value* (SEK)	12.06	17.38	7.23	6.00	12.26
Share Price at Grant Date* (SEK)	26.95	33.85	17.76	17.76	28.10
Exercise Price* (SEK)	33.20	29.71	17.83	17.83	29.36
Expected volatility*	69.24%	67.77%	57.29%	53.67%	58.66%
Estimated life (years)*	3.88	3.73	3.67	2.80	4.20
Expected dividends*	0	0	0	0	0
Risk-free rate*	-0.1092%	-0.2773%	-0.6903%	-0.6709%	-0.2280%
Remaining contractual life (years)*	1.25	0.71	1.76	0.50	2.76

Incentive program	2020:2	2020:3	2021:1	2022:1	Total
Options outstanding, January 1	884,700	282,333	700	2,129,821	4,021,775
Granted during the year	—	—	—	—	—
Forfeited during the year	—	—	—	—	—
Options outstanding, March 31	884,700	282,333	700	2,129,821	4,021,775
Maximum number of shares to be issued	884,700	282,333	700	2,129,821	4,035,391
Grant Date Fair Value* (SEK)	13.13	7.98	10.75	1.59	
Share Price at Grant Date* (SEK)	23.50	23.55	19.31	4.24	
Exercise Price*(SEK)	24.12	25.40	19.38	5.89	
Expected volatility*	63.64%	57.00%	62.56%	57.65%	
Estimated life (years)*	6.10	2.80	6.11	4.17	
Expected dividends*	0	0	0	0	
Risk-free rate*	-0.2772%	-0.3602%	-0.2046%	2.0670%	
Remaining contractual life (years)	7.58	1.67	8.01	5.76	

** Weighted average*

As of March 31, 2023, the company has 4,021,775 options outstanding entitling to the subscription of maximum 4,035,391 new shares representing a dilution of 6.1 percent.

Note 6 Income tax

In the three months ended March 31, 2023 and 2022, the Group recognized a non-current tax benefit of SEK 2.9 million and SEK 3.2 million, respectively, related to 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 7 Other financial liabilities

A. Formue Nord Loan

On July 12, 2021, the Group entered into a non-dilutive SEK-denominated fixed-rate term loan agreement for SEK 87.0 million with Formue Nord Focus A/S. After deduction of a 6% commitment fee, the Group received SEK 81.8 million in net proceeds from this agreement.

On September 30, 2022 the terms have been renegotiated and modified to include an amortization of SEK 15 million of the non-dilutive loan and the term of the loan has been extended with 7 months, which means that the maturing date of the loan has been changed from June 30, 2023, to January 31, 2024. A 3% commitment fee resulting in a nominal amount of SEK 2.2 million will be settled at maturity of the loan to Formue Nord, totaling SEK 74.2 million.
The loan value will continue to accrue at 1 per cent monthly interest until July 1, 2023, whereafter the monthly interest will increase to 1.5 per cent.

Note 8 Financial instruments – fair values

A. Accounting classifications and fair values

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

March 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		—	244	—	244	—	—	244	244
		—	**244**	**—**	**244**	**—**	**—**	**244**	**244**
Financial assets not measured at fair value									
Trade receivables		4,537	—	—	4,537	—	—	—	—
Other non-current financial assets		2,677		—	2,677	—	—	—	—
Other current financial assets		1,464	—	—	1,464	—	—	—	—
Cash and cash equivalents		87,768	—	—	87,768	—	—	—	—
		95,446	**—**	**—**	**95,446**	**—**	**—**	**—**	**—**
Financial liabilities not measured at fair value									
Trade payables		—	—	13,479	13,479	—	—	—	—
Formue Nord Loan	7	—	—	71,508	71,508	—	—	—	—
Lease liabilities		—	—	9,584	9,584	—	—	—	—
		—	**—**	**94,571**	**94,571**	**—**	**—**	**—**	**—**

December 31, 2022		Carrying amount				Fair Value			
KSEK	Note	Financial assets at amortized cost	Mandatorily at FVTPL - others	Financial liabilities at amortized cost	Total	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value									
Contingent consideration receivable		—	241	—	241	—	—	241	241
		—	**241**	**—**	**241**	**—**	**—**	**241**	**241**
Financial assets not measured at fair value									
Trade receivables		4,628	—	—	4,628	—	—	—	—
Other non-current financial assets		2,246		—	2,246	—	—	—	—
Other current financial assets		1,221	—	—	1,221	—	—	—	—
Cash and cash equivalents		111,707	—	—	111,707	—	—	—	—
		119,802	**—**	**—**	**119,802**	**—**	**—**	**—**	**—**
Financial liabilities not measured at fair value									
Trade payables		—	—	14,073	14,073	—	—	—	—
Formue Nord Loan	7	—	—	70,636	70,636	—	—	—	—
Lease liabilities		—	—	10,885	10,885	—	—	—	—
		—	**—**	**95,594**	**95,594**	**—**	**—**	**—**	**—**

B. Measurement of fair values

i. Valuation techniques and significant unobservable inputs

The contingent consideration receivable from Novartis as of December 31, 2021, has been measured using a probability-weighted discounted cash flow valuation technique, which considers the present value of expected payments, discounted using a risk-adjusted discount rate. As of March 31, 2023, the contingent consideration has been measured at SEK 0.2 million.

ii. Transfers

During the three months ended March 31, 2023 and 2022, there were no transfers of financial instruments between the different valuation hierarchy categories.

iii. Reconciliation of Level 3 fair values

The following table shows a reconciliation from the opening balances to the closing balances for Level 3 fair values.

KSEK	Contingent consideration
Balance, January 1, 2023	241
Cash received	—
Changes in Fair Value	—
Foreign currency (included in 'net gains/losses on financial items')	3
Balance, March 31, 2023	**244**

Note 9 Related parties

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

Note 10 Subsequent Events to the Balance Sheet Date

There have been no events after the reporting period.

This information is such information as Saniona AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 8.00 CEST on 25 May 2023.

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