Saniona Starts Strong in 2021 with Orphan Drug Designation for PWS and Alignment on the Regulatory Path for Tesomet

Q1 2021 (Q1 2020)

Revenue was SEK 3.4 M (2.4 M)
Operating loss was SEK -94.1 (-27.4 M)
Net profit/loss was SEK -83.4 M (43.2 M)
Earnings per share were SEK -1.34 (1.47)
Diluted earnings per share were SEK -1.34 (1.47)

Business highlights in Q1 2021

- The U.S. Food and Drug Administration ('FDA') granted **orphan drug designation** to Tesomet for the treatment of Prader-Willi syndrome (PWS). This designation qualifies Saniona for certain development benefits, including tax credits, elimination of certain FDA license application fees, and seven years of market exclusivity in the U.S. following approval.
- The U.S. FDA provided further clarity on a **regulatory path for Tesomet in the treatment of hypothalamic obesity (HO)**. The FDA indicated overall agreement with Saniona's Risk Evaluation and Mitigation Strategy (REMS) proposal and cardiovascular monitoring proposal.
- Saniona continued to make progress in **preparing for its Phase 2b Tesomet clinical trials**, including selecting the clinical research organization (CRO) that will support the clinical trials, identifying clinical trial sites in the U.S. and globally, engaging the contract manufacturer to produce Tesomet for Phase 2b and Phase 3 clinical trials, and establishing partnerships with patient advocacy organizations relating to patient community education and insights.
- Saniona received an upfront payment of approximately **USD 2.9 million (SEK 24.2 million)** relating to Novartis AG's acquisition of Cadent Therapeutics Inc. ('Cadent Therapeutics'), in which Saniona held an ownership stake of approximately 3%. The acquisition may result in additional contingent consideration upon the achievement of future milestones.
- Saniona's **Board of Directors and executive management team purchased shares** of the company in the open market for a total value of approximately SEK 1.5 million.

Significant events after the reporting period

- Saniona announced the receipt of **manufacturing feedback from the FDA** that will delay the start of the Tesomet Phase 2b trials into the second half of 2021.
- Saniona announced a **partnership with the Foundation for Prader-Willi Research** (FPWR) to increase awareness about Saniona's upcoming Phase 2b clinical trial of Tesomet for the treatment of PWS.
- Saniona **successfully monetized its position** in the 2017 spin-out Scandion Oncology A/S ('Scandion Oncology'), completing the sale of its remaining shares on the open market.
- Saniona **presented preclinical data on SAN903** in a model of idiopathic pulmonary fibrosis at the American Society of Pharmacology and Experimental Therapeutics (ASPET) Annual Meeting at Experimental Biology (EB) 2021.
- Saniona hosted a **research and development (R&D) day** featuring presentations highlighting its ion channel drug discovery engine, including its IONBASE™ database now consisting of more than 20,000 proprietary molecules targeting various ion channels, and data from ion channel modulators SAN711 and SAN903.

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- Saniona **received a 33.3% ownership stake in Cephagenix**, as per the terms of the previously announced February 2020 collaboration agreement through which the company was formed to explore ion channel modulators for the treatment of migraine.

Comments from the CEO

"In the first quarter of 2021, Saniona began to leverage the foundations we built in 2020 and execute on our strategies. Specifically, we received Orphan Drug Designation from the FDA for Tesomet in Prader-Willi syndrome, and we completed many of the necessary preparations to initiate our Phase 2b trials of Tesomet in both PWS and hypothalamic obesity, which we plan on starting in the second half of this year," said Rami Levin, President & Chief Executive Officer of Saniona. "Additionally, we have made progress with our ion channel drug discovery engine: we presented data on our ion channel programs at the ASPET conference and at our first R&D Day, and we look forward to advancing SAN711 into the clinic shortly."

For more information, please contact

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Letter from the CEO

2020 was a year of transformation for Saniona. We transformed our business strategy from one focused on out-licensing to a strategy of retaining our innovation and developing it ourselves, which we believe will create the highest value. We also transformed from a discovery focused company to one focused on discovery, development and delivery – bringing medicines all the way to patients. In order to move from discovery into development, we transformed from a company that historically had raised very small amounts of capital to a company with sufficient funding to conduct the larger clinical trials required and to hire the talent and expertise needed.

Our transformation will continue in 2021, and the first quarter of 2021 already brought several important accomplishments in the execution of our strategies:

- **Tesomet in the treatment of hypothalamic obesity (HO) and Prader-Willi syndrome (PWS):** In the first quarter of 2021, the hard work of our clinical and regulatory teams paid off in the receipt of orphan drug designation from the FDA for Tesomet in the treatment of PWS. This designation qualifies Saniona for certain development benefits, including tax credits, elimination of certain FDA license application fees, and seven years of market exclusivity in the U.S. following approval. Our clinical and regulatory team also worked closely with FDA in the first quarter to advance our HO program, gaining further clarity on a regulatory path for Tesomet in HO. Subsequent to the end of the quarter, we did receive manufacturing feedback from the FDA that will delay the start of the Tesomet Phase 2b trials into the second half of 2021, but importantly, we feel that we now have good alignment with the agency on our work to transition Tesomet from tablets to capsules, which we believe will provide multiple benefits as we move into later-stage trials and eventual commercialization.

- **Ion channel pipeline and drug discovery engine:** One of the most exciting opportunities for Saniona during the first quarter of 2021 and subsequent months was the opportunity to highlight that, in addition to Tesomet, we have multiple prospects to create value through our ion channel drug discovery engine. In April, we presented preclinical data on SAN903 in a model of idiopathic pulmonary fibrosis at the American Society of Pharmacology and Experimental Therapeutics (ASPET) Annual Meeting, and in May, we hosted our first R&D Day, in which we presented information and data on our ion channel drug discovery engine, our IONBASE™ database now consisting of more than 20,000 proprietary molecules targeting various ion channels, and our ion channel modulators SAN711 and SAN903.

- **Partnerships and spinouts:** Although Saniona's current strategy is to retain and develop our innovative molecules, we continue to see value from our past partnerships and spinouts. During the first quarter, we received an upfront payment of approximately USD 2.9 million (SEK 24.2 million) relating to Novartis's acquisition of Cadent Therapeutics, in which Saniona held an ownership stake due to a previous spin-out. After the close of the quarter, we also successfully completed the monetization of our position in the 2017 spin-out Scandion Oncology. We continue to eagerly await a regulatory decision from the Mexican authorities on our partner Medix's application for approval of tesofensine in general obesity; Medix has communicated that they expect this milestone around mid-year.

Overall, 2021 is off to an exciting start for Saniona. During the first quarter, our board of directors and executive management team showed their commitment to Saniona's future by purchasing shares of the company in the open market for a total value of approximately SEK 1.5 million. As always, we appreciate the support of our shareholders as we continue on our journey to transform Saniona into a fully-integrated biopharmaceutical company with the ability to discover, develop and ultimately commercialize our own innovative treatments for rare disease patients around the world.

Rami Levin
President & CEO

About Saniona

Saniona is a biopharmaceutical company focused on discovering, developing, and delivering innovative treatments for rare disease patients around the world. The company's lead product candidate, Tesomet, is in mid-stage clinical trials for hypothalamic obesity and Prader-Willi syndrome, severe rare disorders characterized by uncontrollable hunger and intractable weight gain. Saniona's robust drug discovery engine has generated a library now consisting of more than 20,000 proprietary modulators of ion channels, a significantly untapped drug class that is scientifically validated. Lead candidate SAN711 is entering Phase 1 for rare neuropathic disorders, with SAN903 for rare inflammatory and fibrotic disorders advancing through preclinical development. Led by an experienced scientific and operational team, Saniona has an established research organization in Copenhagen, Denmark and is building its corporate office in the Boston, Massachusetts area, U.S. The company's shares are listed on Nasdaq Stockholm Small Cap (OMX: SANION). Read more at www.saniona.com.

Our vision

Improve the lives of rare disease patients around the world through scientific innovation.

Our mission

We leverage our ion channel targeting expertise to discover, develop and deliver innovative rare disease treatments.

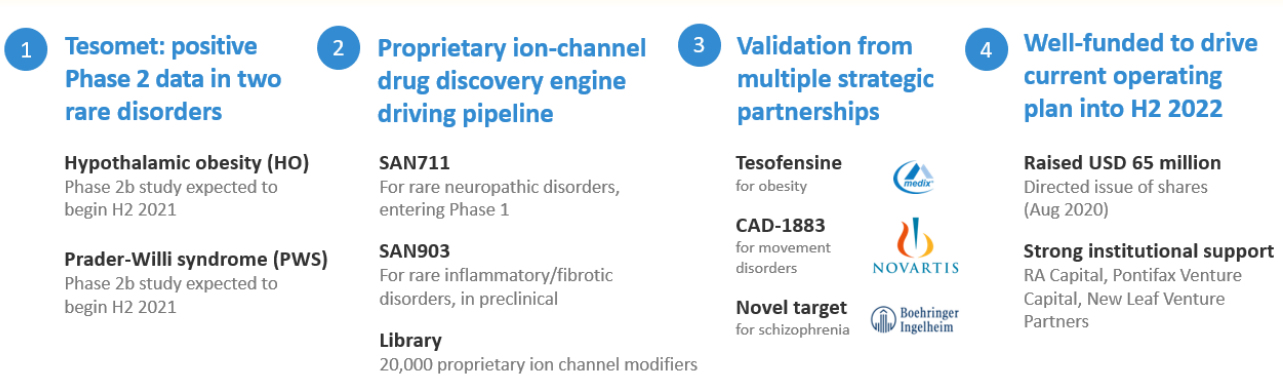
Our values

- **Put People First**
  Treat all people with kindness, respect and equity. Support people on their journey and enable a sense of belonging.
- **Innovation With Impact**
  Push boundaries with courage. Embrace empowerment. And deliver excellence.
- **Integrity, Always**
  Maintain the highest ethical standards in all that we do as we deliver with urgency for patients in need.

Our Strategy

Saniona's focus is on the discovery, development and delivery of proprietary product candidates for the treatment of rare diseases with high unmet medical need. We believe our research, clinical development, and commercial expertise, and our ability to leverage our ion channel research engine, will enable us to advance Tesomet and generate a robust pipeline of clinical candidates with preferred pharmacological properties that we believe will make a meaningful difference in the lives of patients.

Investment rationale:

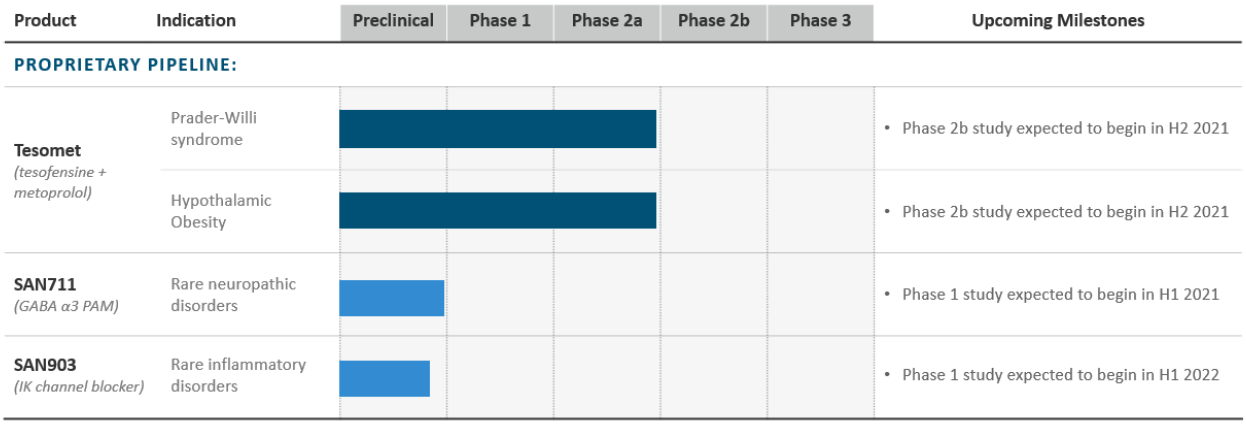


Strategic priorities:

- **Advance our clinical development programs:** Saniona's most advanced internal program is Tesomet. We intend to initiate Phase 2b trials of Tesomet in HO and PWS in the second half of 2021. Additionally, Saniona plans to initiate a first-in-human study of SAN711 for rare neuropathic disorders in the first half of 2021.
- **Identify novel preclinical programs to build our pipeline:** We will continue to progress SAN903 to Phase 1 studies, currently planned for H1 2022. Additionally, we will leverage our proprietary, ion channel drug discovery engine to seek to qualify new programs and preclinical candidates.
- **Build technical operations capabilities:** As Tesomet advances into mid-stage clinical trials, we have begun to build our technical operations capabilities to support this advancement. We will continue to develop these capabilities to ensure timely product supply, in line with clinical development activities and timelines and potential commercialization
- **Build commercial operations:** As we advance towards launch, Saniona will build an experienced commercial team, including, marketing, sales and market access, to prepare the market and the company for the launch of Tesomet.
- **Evaluate strategic external innovation opportunities:** We will assess potential business development opportunities, including mergers and acquisitions (M&A) and licensing opportunities, that complement our areas of expertise and allow us to expand our portfolio in rare diseases.
- **Explore life cycle management:** We will explore and develop our treatments in new rare disease indications beyond the leading indications.
- **Integrate stakeholder insights:** Saniona will build relationships with and collaborate respectfully and compliantly with key stakeholders across the healthcare ecosystem, including patients, caregivers, physicians and payors. We will seek to ensure that their voices and insights inform our strategies and decisions, optimizing outcomes for all.

Our Pipeline

Saniona's wholly-owned pipeline consists of four programs in clinical and preclinical development and a portfolio of programs in discovery and lead optimization, each of which has well-established biology.



Tesomet

Our most advanced proprietary clinical program is Tesomet for the treatment of hypothalamic obesity (HO) and Prader-Willi syndrome (PWS), severe rare disorders characterized by near total loss of appetite control, also called hyperphagia, intractable weight gain, and disturbances of metabolic functions. Tesomet is an investigational first-in-class, once-daily oral fixed-dose combination therapy of tesofensine (a triple monoamine reuptake inhibitor) and metoprolol (a beta-1 selective blocker). Saniona has completed Phase 2 studies in HO and PWS and is planning to initiate Phase 2b trials in both indications in the second half of 2021.

Hypothalamic obesity (HO) is a rare disorder caused by injury to the hypothalamus, most commonly sustained during surgery to remove a rare, noncancerous tumor called a craniopharyngioma (CP). HO is characterized by rapid, excessive and intractable weight gain that persists despite limited food intake. Patients may have hyperphagia, an uncontrollable hunger, and may display abnormal food seeking behaviors such as stealing food. Additional symptoms may include memory impairment, attention deficit, excessive daytime sleepiness and lethargy, issues with impulse control, depression, and suicide. HO patients are also at increased risk of developing obesity-related comorbid conditions such as type 2 diabetes, non-alcoholic fatty liver disease, hypertension, stroke, and congestive heart failure. Ultimately CP survivors with hypothalamic injury report at least three times higher 20-year mortality than CP survivors without hypothalamic injury. There are no medications approved specifically for HO, and there is no cure for this disease. Many HO patients are treated with approaches used for general obesity such as surgery, medication and lifestyle counseling, but these are often ineffective. The prevalence of HO is estimated to be between 10,000 and 25,000 in the U.S. and between 16,000 and 40,000 in Europe. It occurs most often in children and older adults, creating a burden for both patients and families.

We evaluated Tesomet in a 24-week randomized, double-blind (DB), placebo-controlled Phase 2 study for HO followed by a 24-week open label extension (OLE). Patients treated with Tesomet for nearly one year (24 weeks DB + 24 weeks OLE) demonstrated statistically significant and clinically meaningful reductions in body weight and waist circumference, as well as improvements in glycemic control. Patients who received placebo in the DB portion of the study and were subsequently switched to Tesomet for the OLE also achieved reductions in body weight and waist circumference compared to baseline. Tesomet was well tolerated, and no clinically meaningful differences in heart rate or blood pressure were observed over the course of the 48-week trial.

PWS is recognized as the most common genetic cause of life-threatening obesity, with an estimated number of patients between 11,000 and 34,000 in the U.S. and between 17,000 and 50,000 in Europe. The disease results from a deletion or loss of function of a cluster of genes on chromosome 15, which leads to dysfunctional signaling in the brain's appetite/satiety center (hypothalamus). Many of those affected with PWS suffer from insatiable appetite (hyperphagia); abnormal growth and body composition; low muscle tone (hypotonia); and social, emotional, or cognitive deficits. Hyperphagia is reported by caregivers to be among the most worrisome aspects of PWS, as this insatiable hunger persists no matter how much the patients eat and often requires caregivers to install locks on refrigerators and cabinets where food is stored. Many of those affected with PWS become morbidly obese and suffer shortened life expectancy and significant mortality. Common causes of mortality in PWS include respiratory disease, cardiac disease, infection, choking, gastric rupture, and pulmonary embolism. There are no medications approved specifically for the hyperphagia associated with PWS, and there is no cure for this disease. Treatment depends on symptoms and often includes hormone replacement.

We evaluated Tesomet in a randomized, double-blind, placebo-controlled Phase 2a trial in adults and adolescents with PWS. Adult patients receiving Tesomet achieved a statistically significant reduction in hyperphagia, as well as a clinically meaningful reduction in body weight at a dose of 0.5 mg per day. A smaller study extension in an adolescent population showed that Tesomet appeared to be well tolerated at lower doses (0.125 mg/day and 0.25 mg/day) and suggested dose-dependent effects on weight and hyperphagia.

Saniona has received U.S. FDA Orphan Drug Designation for Tesomet in PWS. The company intends to initiate Phase 2b trials in HO and PWS in the second half of 2021.

SAN711

SAN711 is a novel, first-in-class positive allosteric modulator of GABAA α3 receptors in development for rare neuropathic disorders. SAN711 has the potential to provide pain relief and other benefits in the central nervous system with fewer side effects than benzodiazepines (i.e. Valium), which affect all of the GABAA receptors indiscriminately. Using Saniona's ion channel drug discovery engine, SAN711 was designed to bind with high selectivity to the α3 subunit of the GABAA receptor, which in preclinical models showed efficacy with fewer side effects. SAN711 is expected to enter the clinic in H1 2021.

SAN903

SAN903 is a novel, potential first-in-class inhibitor of the calcium-activated potassium ion channel, KCa3.1. It is currently in preclinical development for the treatment of rare inflammatory and fibrotic disorders. SAN903 was designed using Saniona's ion channel drug discovery engine and is expected to enter the clinic by H1 2022.

Ion channel drug discovery engine

Ion channels comprise a unique class of proteins that are central to the control of numerous physiological functions including the activity of muscles, nerves, immune cells and fibroblasts. They are a scientifically validated drug class, but they are significantly untapped due to their complexities.

Robust domain expertise is required to design an ion channel modulator that impacts activity on a sub-type and state-specific level. The Saniona scientific team have been pioneers in ion channel pharmacology research for more than 20 years. Our proprietary ion channel drug discovery engine draws on our expertise in assay design, electrophysiological approaches, advanced imaging methodology, and various other proprietary techniques, databases and methods.

Our wholly-owned proprietary ion channel modifier library, IONBASE™, now consists of more than 20,000 new chemical entities enriched for ion channel activity, and it is supplemented by a collection of more than 100,000 compounds for screening purposes. SAN711 and SAN903 were derived from IONBASE, and we believe our ion channel drug discovery engine will allow Saniona to generate a continuous stream of new programs and preclinical candidates.

Partnerships and Spinouts

Saniona has out licensed and may continue to out license promising research discoveries that do not fit our strategic focus on rare diseases, and in exchange we may receive upfront consideration, milestone payments, royalties and/or equity stakes. Some of our current out-licensed programs include:

- Medix licensed from Saniona the rights to develop and commercialize tesofensine for general obesity in Mexico and Argentina. A new drug application is under review by the Mexican Health Authority. Saniona will receive a milestone payment upon approval and double-digit royalties on product sales.
- Cadent Therapeutics (now part of Novartis) previously acquired Ataxion, a spin-out established by Saniona and Atlas Venture Inc. in 2013. Novartis acquired Cadent Therapeutics for an upfront payment of USD 210 million, with up to USD 560 million in milestones, for a total of $770 million. This resulted in an upfront payment of approximately USD 2.9 million (SEK 24.2 million) to Saniona in February 2021 and may result in additional contingent consideration upon the achievement of future milestones. Separately, Saniona is entitled to receive royalties on any potential products developed and commercialized from the SK ion channel program that originated with Ataxion.
- Boehringer Ingelheim entered into a research collaboration agreement with Saniona for development of a proprietary ion channel program for the treatment of schizophrenia. Saniona may receive up to EUR 76.5 million in milestone payments as well as royalties on worldwide net sales of resulting products.

Financial review

During the first quarter of 2021, as part of Saniona's evaluation of a potential listing of its shares on the U.S. Nasdaq exchange, Saniona conducted a company-initiated restatement of prior period financial statements. As a result of that initiative, certain of the amounts presented in the Financial review section for the three months ended March 31, 2020 have been restated. Refer to Note 12 in our Condensed Consolidated Financial Statements for more details.

Income Statement, KSEK		2021-01-01 2021-03-31	2020-01-01 2020-03-31 (Restated)	2020-01-01 2020-12-31
Revenue, KSEK		3,438	2,430	8,198
Total operating expenses, KSEK		-97,574	-29,852	-167,573
Operating loss, KSEK	*	-94,136	-27,422	-159,375

Balance sheet, KSEK	2021-03-31	2020-03-31 (Restated)	2020-12-31
Cash and cash equivalent, KSEK	497,397	37,354	573,866
Equity, KSEK	560,665	93,330	603,458
Total equity and liabilities, KSEK	624,006	156,553	692,181

Alternative Performance Measures

Key figures, %		2021-01-01 2021-03-31	2020-01-01 2020-03-31 (Restated)	2020-01-01 2020-12-31
Operating margin, %	*	-2,738%	-1,128%	-1,944%
Liquidity ratio, %	*	1,232%	115%	846%
Equity ratio, %	*	90%	60%	87%

Share data, SEK		2021-01-01 2021-03-31	2020-01-01 2020-03-31 (Restated)	2020-01-01 2020-12-31
Earnings per share		-1.34	1.47	-1.79
Diluted earnings per share		-1.34	1.47	-1.79
Equity per share	*	8.99	4.12	9.68
Dividend		0.00	0.00	0.00
Cash flow per share	*	-1.68	-0.16	13.33

Share data, #	2021-01-01 2021-03-31	2020-01-01 2020-03-31	2020-01-01 2020-12-31
Average shares outstanding	62,372,831	29,302,629	62,372,831
Diluted average shares outstanding	62,462,233	29,317,755	62,465,236
Shares outstanding at the end of the period	62,372,831	29,412,519	62,372,831

* = *Alternative performance measures*

Saniona presents certain financial measures in the interim report that are not defined according to IFRS, so called alternative performance measures. These have been noted with an "*" in the table above. 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.

Derivation of alternative performance measurers

	2021-01-01 2021-03-31	2020-01-01 2020-03-31 (Restated)	2020-01-01 2020-12-31
Operating loss, KSEK	-94,136	-27,422	-159,375
Revenue, KSEK	3,438	2,430	8,198
Operating margin, %	**-2,738%**	**-1,128%**	**-1,944%**
Cash flow for the period, KSEK	-104,617	-4,686	546,412
Average shares outstanding	62,372,831	29,302,629	40,999,066
Cash flow per share, SEK	**-1.68**	**-0.16**	**13.33**

	2021-03-31	2020-03-31 (Restated)	2020-12-31
Current assets, KSEK	559,414	54,133	595,812
Current liabilities, KSEK	45,400	47,197	70,416
Liquidity ratio, %	**1,232%**	**115%**	**846%**
Equity, KSEK	560,665	93,330	603,458
Total assets, KSEK	624,006	156,553	692,181
Equity ratio, %	**90%**	**60%**	**87%**
Equity, KSEK	560,665	93,330	603,458
Shares outstanding at the end of the period	62,372,831	29,412,519	62,372,831
Equity per share, SEK	**8.99**	**3.17**	**9.68**

Revenue and results of operations

Saniona generated total revenues of 3.4 MSEK (2.4) for the three months ended March 31, 2021 (March 31, 2020). Revenues included amounts related to out licensing of intellectual property of 2.8 MSEK (2.0) and amounts from providing research and development services of 0.6 MSEK (0.4) all related to our out licensing and partnership agreements with Boehringer Ingelheim, Medix, and Cephagenix.

The company recognized operating expenses of 97.6 MSEK (29.9), an increase of 226%. Within operating expenses, external expenses amounted to 54.2 MSEK (20.0), an increase of 171%. In the three months ended March 31, 2021, external expenses comprised primarily of development costs of Tesomet, including costs for the preparation of our upcoming Phase 2b trials of Tesomet in PWS and HO, and costs for the preparation of our upcoming first-in-human study of SAN711. In the three months ended March 31, 2020, external expenses comprised primarily of development costs of Tesomet followed by preclinical development costs of SAN711 and research and development costs of the SAN903 program. Personnel costs amounted to 40.5 MSEK (8.9), an increase of 355%. Personnel costs have increased as a result of the hiring of the executive team and the clinical development team in the U.S. in 2020 and 2021. In addition, the option programs had a non-cash impact on personnel costs of 12.1 MSEK (0.9). Compared to the first quarter of 2020, the average exchange rate of 1 SEK against the DKK and the USD has appreciated by approximately 5% and 17%, respectively. The vast majority of the company's operating expenses are denominated in DKK or USD, resulting in a positive effect on the company's operating expenses since the Group's reporting currency is SEK.

The operating loss for the three months ended March 31, 2021 was 94.1 MSEK (27.4). Net financial items amounted to 3.3 MSEK (65.2). The net financial items for the three months ended March 31, 2020 included a one-time gain of 53.3 MSEK related to a change in accounting for our investment in Scandion Oncology, and a gain from the recurring fair value measurement of warrants of 15.3 MSEK. The loss for the three months ended March 31, 2021 was 83.4 MSEK (profit 43.2). Saniona recognized a tax credit for the three months ended March 31, 2021 of 7.5 MSEK (5.4) under the Danish R&D tax credit scheme.

Financial position

Total assets as of March 31, 2021, were 624.0 MSEK (156.6). Cash and cash equivalents amounted to 497.4 MSEK (37.3). The equity ratio was 90 % (60) as of March 31, 2021, and equity was 560.7 MSEK (93.3).

Cash flow

Operating cash flow for the three months ended March 31, 2021 was an outflow of 116.5 MSEK (51.4). The operating cash flow is explained by the operating loss and prepayments made with regard to our upcoming Phase 2b trials of Tesomet in PWS and HO. Consolidated cash flow for the three months ended March 31, 2021 was an outflow of 104.6 MSEK (4.7). The total cash flow in the three months ended March 31, 2021 is further explained by an inflow from investing activities from the sale of the investment in Cadent Therapeutics of 23.6 MSEK, the sale of Scandion Oncology shares of 15.5 MSEK, and an outflow from finance activities for the repayment of loan notes to Formue Nord totaling 25 MSEK.

For the three months ended March 31, 2020, the operating cash flow is explained by the operating loss and change in working capital. The consolidated cash flow for the three months ended March 31, 2020 is further explained by an inflow from finance activities of 25.0 MSEK through the directed issue of 1,000,000 shares to Formue Nord at SEK 25 per share. The net proceeds of 22.7 MSEK were recorded under new share issues after deduction of issuing expenses. Furthermore, a loan of 25 MSEK was drawn under the loan facility agreement with Formue Nord.

The share, share capital and ownership structure

On March 31, 2021, the number of shares outstanding amounted to 62,372,831 (29,412,519). On March 31, 2021, the company had 10,126 (6,058) shareholders excluding holdings in life insurance and foreign custody account holders.

Personnel

As of March 31, 2021 the number of employees was 47 (24), of which 21 (1) were based in the U.S. and 26 (23) were based in Denmark, and 25 (13) are women and 22 (11) men. Of these employees, 5 (5) are part-time employees and 42

(19) are full-time employees, and a total of 35 (19) work in the company's research and development operations. 14 (11) of Saniona's employees hold PhDs, 17 (2) hold other university degrees, 8 (8) have laboratory training and the remaining 8 (3) have other degrees.

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 2020 Annual Report.There are no major changes in the Group's risk factors and risk management in 2021.

Risk related to COVID-19

An outbreak of an infectious disease, a pandemic or a similar public health threat, such as the recent outbreak of the novel coronavirus disease known as COVID-19, could adversely impact the company by causing operating, clinical trial and project development delays and disruptions, labour shortages, travel and shipping disruption and shutdowns (including as a result of government regulation and prevention measures). The Company may incur expenses or delays relating to such events outside of its control, which could have a material adverse impact on its business, operating results and the company's ability to raise capital.

To date, Saniona's clinical trials have not been significantly impacted by COVID-19. The hypothalamic obesity phase 2 clinical trial, the last active clinical trial, was concluded in March 2020, and the open-label extension study was concluded in November 2020, despite the COVID-19 pandemic.

Medix submitted a new drug application to the Mexican food and drug administration in December 2019. Our partners at Medix saw the review of their application for approval of tesofensine in the treatment of general obesity in Mexico delayed by the pandemic, but they have indicated that application reviews are now moving forward again, and they expect a decision mid-year 2021.

Audit review

This interim report has not been subject to review by the company's auditors.

Financial calendar

Annual General Meeting	May 26, 2021
Interim Report Q2	August 26, 2021 at 8:00 CEST
Interim Report Q3	November 18, 2021 at 8:00 CET
Year-End Report 2021	February 24, 2022 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, 26 May 2021
Saniona AB

J. Donald deBethizy – Chairman	Rami Levin, CEO
Jørgen Drejer – Board member	Anna Ljung – Board member
Carl Johan Sundberg – Board member	Edward Saltzman – Board member

THE GROUP'S CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Group's condensed consolidated financial statements have been prepared based on the accounting policies described in Note 2 *Basis of Accounting and Significant Accounting Policies*. Certain comparative amounts in the statement of comprehensive income and the statement of financial position have been restated, reclassified or re-presented, as a result of a correction of prior-period errors. These restatements have also resulted in changes to the statement of changes in equity and the statement of cash flows. Refer to Note 12 *Restatements* for details.

Condensed consolidated statement of comprehensive income – Group

KSEK	Note	2021-01-01 2021-03-31	2020-01-01 2020-03-31 (Restated)	2020-01-01 2020-12-31
Revenue	4	3,438	2,430	8,198
Total operating income		3,438	2,430	8,198
Raw materials and consumables		-743	-720	-3,252
Other external costs		-54,174	-19,993	-97,107
Personnel costs	5	-40,520	-8,929	-62,417
Depreciation and write-downs		-2,137	-210	-4,797
Total operating expenses		-97,574	-29,852	-167,573
Operating loss		**-94,136**	**-27,422**	**-159,375**
Share of result of associates		-	-433	-433
Financial income		1,554	-	312
Financial expenses		-1,672	-498	-18,655
Net gains on financial items		3,388	66,174	96,935
Total financial items		3,270	65,243	78,159
Profit/loss after financial items		**-90,866**	**37,821**	**-81,216**
Tax on net profit/loss	6	7,482	5,369	7,786
Profit/loss for the period		**-83,384**	**43,190**	**-73,430**
Other comprehensive income for the period				
Item that may be reclassified to profit and loss				
Translation differences		29,175	2,980	-28,262
Items that will not be reclassified to profit and losses				
Equity instruments at FVOCI – net change fair value		-707	-	68,466
Total other comprehensive income for the period, net after tax		**28,468**	**2,980**	**40,204**
Total comprehensive income for the period		**-54,916**	**46,170**	**-33,226**
Earnings per share, SEK		**-1.34**	**1.47**	**-1.79**
Diluted earnings per share, SEK		**-1.34**	**1.47**	**-1.79**

The recognized loss and total comprehensive income are all attributable to the shareholders of the Parent Company, since there is no non-controlling interest in the subsidiaries of the Group.

Condensed consolidated statement of financial position – Group

KSEK	Note	2021-03-31	2020-03-31 (Restated)	2020-12-31
ASSETS				
Intangible assets		6,194	8,162	6,072
Fixtures, fittings, tools and equipment		5,368	1,166	5,089
Right of use assets		21,885	2,249	23,035
Tangible assets		27,253	3,415	28,124
Other financial assets	7,9	23,574	84,911	61,660
Financial assets		23,574	84,911	61,660
Other assets		-	279	513
Tax assets	6	7,571	5,582	-
Deferred tax		-	71	-
Non-current assets		**64,592**	**102,420**	**96,369**
Trade receivables		2,338	3,936	5,043
Current tax assets		7,571	8,162	7,421
Other assets		52,108	4,681	9,482
Current receivables		62,017	16,779	21,946
Cash and cash equivalent		497,397	37,354	573,866
Current assets		**559,414**	**54,133**	**595,812**
Total assets		**624,006**	**156,553**	**692,181**

Condensed consolidated statement of financial position – Group (continued)

KSEK	Note	2021-03-31	2020-03-31 (Restated)	2020-12-31
EQUITY AND LIABILITIES				
Share capital		3,119	1,471	3,119
Additional paid in capital		808,607	231,880	808,607
Reserves		65,376	-316	36,908
Retained earnings including profit or loss for the period		-316,437	-139,705	-245,176
Equity		**560,665**	**93,330**	**603,458**
Other financial liabilities	8,9	14,951	14,639	16,228
Other liabilities		2,988	1,388	2,079
Non-current liabilities		17,939	16,027	18,307
Trade payables		28,716	9,516	18,875
Other financial liabilities	9	8,666	26,626	40,623
Other liabilities		8,020	11,054	10,918
Current liabilities		45,402	47,196	70,416
Total liabilities		**63,341**	**63,223**	**88,723**
Total equity and liabilities		**624,006**	**156,553**	**692,181**

Condensed consolidated statement of changes in equity – Group

	Share capital	Share premium (Restated)	Translation reserves (Restated)	Fair value reserve (Restated)	Retained earnings (Restated)	Shareholders' equity (Restated)
January 1, 2020 (previously reported)	1,421	239,592	-964	10,657	-192,268	58,437
Restatements			-2,332	-10,657	8,435	-4,553
January 1, 2020 (restated)	**1,421**	**239,592**	**-3,296**	**-**	**-183,833**	**53,884**
Comprehensive income						
Profit for the period					43,190	43,190
Other comprehensive income:						
Translation differences			2,980			2,980
Total comprehensive income			**2,980**		**43,190**	**46,170**
Transactions with owners						
Shares issued for cash	50	24,950				25,000
Expenses related to capital increase		-4,863				-4,863
Issuance of Investor Warrants		-27,799				-27,799
Share-based compensation expenses					938	938
Total transactions with owners	**50**	**-7,712**			**938**	**-6,724**
March 31, 2020	**1,471**	**231,880**	**-316**		**-139,705**	**93,330**
January 1, 2021	**3,119**	**808,607**	**-31,558**	**68,466**	**-245,176**	**603,458**
Comprehensive income						
Loss for the year					-83,384	-83,384
Other comprehensive income:						
Fair value reserve				-707		
Translation differences			29,175			8,733
Total comprehensive income			**29,175**	**-707**	**-83,384**	**-54,916**
Transactions with owners						
Shares issued for cash						-
Expenses related to capital increase						-
Issuance of Investor Warrants						-
Share-based compensation expenses					12,123	12,123
Total transactions with owners					**12,123**	**12,123**
March 31, 2021	**3,119**	**808,607**	**-2,383**	**67,759**	**-316,437**	**560,665**

Condensed consolidated statement of cash flows – Group

KSEK	Note	2021-01-01 2021-03-31	2020-01-01 2020-03-31 (Restated)	2020-01-01 2020-12-31
Profit/loss before tax		-90,866	37,821	-81,216
Adjustments for non-cash transactions		18,893	-63,530	-79,972
Changes in working capital		-40,559	-25,171	-19,955
Cash flow from operating activities before financial items and tax		**-112,533**	**-50,880**	**-181,143**
Interest income received		110	-	275
Interest expenses paid		-4,110	-482	-1,069
Tax income received		-	-	7,657
Cash flow from operating activities		**-116,533**	**-51,362**	**-174,280**
Investing activities				
Investment in tangible assets		-548	-1,473	-4,999
Sale of financial assets		39,000	-	104,511
Investment in other financial assets		-	471	-
Cash flow from investing activities		**38,452**	**-1,002**	**99,512**
Financing activities				
Loan		-25,000	25,000	25,000
New share issue, net of expenses		-	22,678	598,510
Payment of lease liabilities		-1,536	-	-2,332
Cash flow from financing activities		**-26,536**	**47,678**	**621,178**
Cash flow for the period		**-104,617**	**-4,686**	**546,412**
Cash and cash equivalents at beginning of period		**573,866**	**40,248**	**40,248**
Exchange rate adjustments		28,148	1,794	-12,794
Cash and cash equivalents at end of period		**497,397**	**37,356**	**573,866**

PARENT COMPANY'S FINANCIAL STATEMENTS

The Parent Company's financial statements have been prepared based on the accounting policies described in Note 2 *Basis of Accounting and Significant Accounting Policies*. Certain comparative amounts in the statement of comprehensive income and the statement of financial position have been restated, reclassified or re-presented, as a result of a correction of prior-period errors.

Statement of income – Parent Company

KSEK	Note	2021-01-01 2021-03-31	2020-01-01 2020-03-31 (Restated)	2020-01-01 2020-12-31
	1,2,3			
Other operating income		1,175		5,721
Total operating income		1,175	0	5,721
Raw materials and consumables		-3	-7	-25
Other external costs		-1,467	-1,703	-6,248
Personnel costs	5	-3,590	-896	-7,424
Total operating expenses		-5,060	-2,606	-13,697
Operating profit/loss		**-3,885**	**-2,606**	**-7,976**
Share of result of associates		-	-433	-433
Financial income		201	94	41,334
Financial expenses		-396	-36	-16,214
Net gains/losses on financial items		16,916	13,234	131,469
Total financial items		16,721	12,859	156,156
Profit/loss after financial items		**12,836**	**10,253**	**148,180**
Tax on net profit		-	-	-
Profit/loss		**12,836**	**10,253**	**148,180**

Balance Sheet – Parent Company

KSEK	Note	2021-03-31	2020-03-31 (Restated)	2020-12-31
ASSETS				
Investment in subsidiaries		940,923	206,254	929,244
Other financial assets	7,9	500	5,413	1,746
Financial assets		941,423	211,667	930,990
Non-current assets		**941,423**	**211,667**	**930,990**
Receivables from group companies		-	26,253	5,721
Other assets		5,698	1,276	3,388
Current receivables		5,698	27,529	9,109
Cash and cash equivalent		33,552	28,700	45,733
Current assets		**39,250**	**56,229**	**54,842**
Total assets		**980,673**	**267,896**	**985,832**
EQUITY AND LIABILITIES				
Restricted equity				
Share capital		3,119	1,471	3,119
Unrestricted equity				
Share premium reserve		808,607	231,880	808,607
Retained earnings		152,502	-16,378	-7,804
Profit/loss for the period		12,836	10,253	148,180
Equity		**977,064**	**227,226**	**952,102**
Trade payables		613	533	754
Payables to group companies		1,501	-	-
Other financial liabilities	8	1,406	40,023	32,861
Other liabilities		89	114	114
Current liabilities		3,609	40,670	33,729
Total liabilities		**3,609**	**40,670**	**33,729**
Total equity and liabilities		**980,673**	**267,896**	**985,832**

NOTES

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 financial statements comprise the Parent Company and its subsidiaries (collectively the 'Group'). The Group is a biopharmaceutical company focused on discovering, developing, and delivering innovative treatments for rare disease patients around the world. The legal address of the head office and the research facility is Smedeland 26B, DK-2600 Glostrup, Denmark. The majority of Saniona's Executive team members are based in Saniona's United States offices, located at 500 Totten Pond Road, Waltham, MA 02451. 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 condensed consolidated financial statements for the three months ended March 31, 2021 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 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, 2020 ('last annual financial statements'). They do not include all of 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.

These condensed consolidated financial statements were authorized for issue by the Parent Company's Board of Directors (the 'Board') on May 26, 2021.

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 financial statements. Certain comparative amounts in the statement of comprehensive income and the statement of financial position have been restated, reclassified or re-presented, as a result of a correction of prior-period errors (refer to Note 12 *Restatements*).

i. Segment reporting

Saniona is organized as a single business unit, focused on discovering, developing, and commercializing innovative treatments for rare disease patients. Consistent with its organizational structure, the Group's President and Chief Executive Officer, who is also the chief operating decision maker, views and manages the Group's operations and business as a single operating segment.

ii. Fair value measurement

A number of the Group's accounting policies require the measurement of fair values, for both financial and non-financial assets and liabilities.

The Group regularly reviews significant unobservable inputs and valuation adjustments. Significant valuation issues are reported to the group audit committee.

The Group uses the following hierarchy for determining and disclosing the fair value of financial instruments by valuation technique:

Level 1: Quoted (unadjusted) prices in active markets for identical assets or liabilities.

Level 2: Other techniques for which all inputs which have a significant effect on the recorded fair value are observable, either directly or indirectly.

Level 3: Techniques which use inputs that have a significant effect on the recorded fair value that are not based on observable market data.

When one is available, the Group measures the fair value of an instrument using the quoted price in an active market for that instrument. A market is regarded as 'active' if transactions for the asset or liability take place with sufficient frequency and volume to provide pricing information on an ongoing basis.

If there is no quoted price in an active market, then the Group uses valuation techniques that maximize the use of relevant observable inputs and minimize the use of unobservable inputs. The chosen valuation technique incorporates all of the factors that market participants would take into account in pricing a transaction.

iii. Adoption of new or revised standards

A number of amendments to standards are effective for annual periods beginning on or after January 1, 2021, and earlier application is permitted. The amendments had no material impact on the Group's financial position or results of operations for the three months ended March 31, 2021.

Note 3 Critical accounting judgments and key sources of estimation uncertainty

In preparing these consolidated financial statements, management has made judgements, assumptions, and estimates that affect the application of the Group's accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates.

The significant judgements made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were the same as those described in the last annual financial statements.

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, 2021 and 2020, revenue for the Group by category was as follows:

KSEK	2021-01-01 2021-03-31	2020-01-01 2020-03-31 (Restated)
Out-licensing (other event-based payments)	2,504	1,971
Out-licensing (bundle, over time)	265	-
Research and development services (standalone)	669	459
Total	**3,438**	**2,430**

In the three months ended March 31, 2021 and 2020, revenue for the Group by major customers was as follows:

KSEK	2021-01-01 2021-03-31	2020-01-01 2020-03-31 (Restated)
Customer #1	2,504	1,971
Customer #2	669	459
Customer #3	265	-
Total	**3,438**	**2,430**

In the three months ended March 31, 2021 and 2020, revenue for the Group by primary geographical market was as follows:

KSEK	2021-01-01 2021-03-31	2020-01-01 2020-03-31 (Restated)
Sweden	-	-
Other European countries	934	459
The Americas	2,504	1,971
Total	**3,438**	**2,430**

Note 5 Share-based payments

A. Description of share-based payment arrangements

A detailed description of the Group's share-based payment arrangements as of December 31, 2020 is provided in the last annual financial statements. During the three months ended March 31, 2021, the Group made the following additional grant under the Option Program 2020:

2021:1 A total of 902,000 options were allotted at various points in time in the first quarter of 2021. Each option entitles the holder a right to acquire one new share in Saniona for a subscription price equal to the closing price of our common stock on the day before the allotment. The options are subject to a service condition, 25% vest on the 12-month anniversary, and the remaining 75% vest gradually on a quarterly basis at a rate of 6.25% over the following 36 months, resulting in a total vesting period of 48 months. The holder can exercise vested options from the time of vesting until the date that falls 10 years after the allotment date. However, for a participant that ceases to be employed or in a service relationship in the Group, vested options have to be exercised within 90 days from the date when the participant ceased to be employed or in a service relationship in the Group (or, in the case such cessation is due to the participant's death or disability, 12 months from such date).

B. Measurement of fair values and compensation expense

Share-based compensation expenses for the three months ended March 31, 2021 and 2020 totaled SEK 12.1million and SEK 0.9million, 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 and the reconciliation of options outstanding are as follows.

Incentive program	2017	2018:1	2018:2	2018:3	2019:1	2019:2
Options outstanding at January 1	38,292	286,003	32,792	10,513	34,500	15,770
Granted during the year	-	-	-	-	-	-
Forfeited during the year	-	-	-	-	-	-
Options outstanding at March 31	38,292	286,003	32,792	10,513	34,500	15,770
Grant Date Fair Value* (SEK)	27.94	12.06	17.38	12.89	7.23	6.00
Share Price at Grant Date* (SEK)	49.60	26.95	33.85	33.85	17.76	17.76
Exercise Price* (SEK)	41.13	33.60	30.08	30.08	17.86	17.86
Expected volatility*	73.41%	69.24%	67.77%	53.67%	57.29%	53.67%
Estimated life*	3.75 years	3.88 years	3.73 years	2.80 years	3.67 years	2.8 years
Expected dividends*	0	0	0	0	0	0
Risk-free rate*	-0.2602%	-0.1092%	-0.2773%	-0.4218%	-0.6903%	-0.6709%
Remaining contractual life*	1.75 years	3.25 years	2.71 years	1.23 years	3.75 years	2.5 years

Incentive program	2020:1	2020:2	2020:3	2021:1	Total
Options outstanding at January 1	710,313	5,915,648	308,000	-	7,351,831
Granted during the year	-	-	-	902,000	902,000
Forfeited during the year	-	-	-	-	-
Options outstanding at March 31	710,313	5,915,648	308,000	902,000	8,253,831
Grant Date Fair Value* (SEK)	12.26	13.13	7.98	10.75	
Share Price at Grant Date* (SEK)	28.10	23.50	23.55	19.31	
Exercise Price*(SEK)	29.42	24.12	25.40	19.38	
Expected volatility*	58.66%	63.64%	57.00%	62.56%	
Estimated life*	4.2 years	6.11 years	2.8 years	6.11 years	
Expected dividends*	0	0	0	0	
Risk-free rate*	-0.2280%	-0.2772%	-0.3602%	-0.2046%	
Remaining contractual life	4.75 years	9.61 years	3.67 years	9.86 years	

** Weighted average*

Note 6 Income taxes

In the three months ended March 31, 2021, the Group recognized a current tax income of SEK 7.5million related to the Danish 'Skattekreditordningen' (the 'Tax Credit Scheme'), based on which 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 costs of up to DKK 25.0million (approx. SEK 33.8million). The Group's Danish subsidiary Saniona A/S has reached that threshold during the three months ended March 31, 2021, and as it is expected that Saniona A/S will have a full year 2021 in excess of that threshold, the Group has recorded the full amount of the benefit.

For the three months ended March 31, 2020, the Group recognized a current tax income of SEK 5.4million related to the Tax Credit Scheme.

Note 7 Other financial assets

A. Composition

Other financial assets were comprised of the following:

KSEK	2021-03-31	2020-03-31 (Restated)	2020-12-31
Contingent consideration receivable	14,244	-	-
Investment in equity instruments - privately-held	-	26,624	37,319
Investment in equity instruments - publicly traded	6,735	58,287	22,241
Long-term deposits for property lease agreements	2,595	-	2,100
Total non-current other financial assets	**23,574**	**84,911**	**61,660**

B. Investment in equity instruments - privately-held and Contingent consideration receivable

Through January 2021, Saniona A/S, a wholly-owned subsidiary of the Parent Company, owned approximately 3% of the share capital of Cadent Therapeutics, Inc. ('Cadent Therapeutics'), a private company based in Cambridge, MA, United States. In January 2021, Novartis AG closed its acquisition of Cadent Therapeutics that was announced in December 2020. At that point, the Group exchanged its investment in equity instruments – privately-held for a receivable for an upfront payment in the amount of SEK 24.2million, and a contingent consideration receivable in the amount of SEK 14.2million. The upfront payment was received in January 2021.

C. Investment in equity instruments – publicly traded

The asset as of March 31, 2021 and 2020, and December 31, 2020, represents the fair value of the Group's investment in Scandion Oncology A/S ('Scandion Oncology'). In the three months ended March 31, 2021, the Group recognized a net loss in other comprehensive income resulting from an decrease of Scandion Oncology's share price of SEK 0.7million. Of that, SEK 1.1million is a loss that was realized upon sale of Scandion Oncology shares. A gain of SEK 0.4million is unrealized.

Note 8 Other financial liabilities

A. Composition

Other financial liabilities were comprised of the following:

KSEK	2021-03-31	2020-03-31 (Restated)	2020-12-31
Lease liabilities	14,951	-	16,228
Warrants	-	14,639	-
Total non-current other financial liabilities	**14,951**	**14,639**	**16,228**
Lease liabilities	7,260	-	6,937
Formue Nord Loan	-	18,458	24,346
Warrants	1,406	6,847	4,794
Other	-	1,321	4,546
Total non-current other financial liabilities	**8,666**	**26,626**	**40,623**

B. Formue Nord Loan

On January 10, 2020, the Group entered into a fixed-rate loan facility agreement with Formue Nord entitling the Group to draw loans in an aggregate amount of SEK 25.0million. In March 2020 Saniona drew loans of SEK 25.0million under the loan facility agreement. The loans were subject to market interest rates and matured on February 7, 2021. They were repaid on February 5, 2021.

C. Warrants

As of March 31, 2021 and December 31, 2020, all warrants of the series TO 3 as part of the Unit Rights Issue 2020 were outstanding, the carrying value of these warrants was SEK 1.4million and SEK 4.5million, respectively. They were listed for trading on Nasdaq Stockholm with the short name "SANION TO 3" and ISIN SE0013775319. The last day for trading in warrants of series TO 3 was April 16, 2021. Holders of warrants of series TO 3 were entitled to subscribe for one new share in the Parent Company for each warrant of series TO3 during the exercise period April 6 – April 20, 2021. Refer to Note 13 *Subsequent Events to the Balance Sheet Date* for details regarding the exercise.

As of March 31, 2020 all warrants of the series TO 1, TO 2, and TO 3 as part of the Unit Rights Issue 2020 were outstanding, the carrying value of these warrants was SEK 21.5million.

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 if the carrying amount is a reasonable approximation of fair value.

March 31, 2021	Note	Carrying amount					Fair value			
		Financial assets at amortized cost	Mandatorily at FVTPL - others	FVOCI - equity instruments	Other financial liabilities	Total	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value										
Investment in equity instruments - publicly traded	7	-	-	6,735	-	6,735	6,735	-	-	6,735
Contingent consideration receivable	7	-	14,244	-	-	14,244	-	-	14,244	14,244
		-	**14,244**	**6,735**	**-**	**20,979**	**6,735**	**-**	**14,244**	**20,979**
Financial assets not measured at fair value										
Trade receivables		2,338	-	-	-	2,338	-	-	-	-
Other non-current financial assets	7	2,595	-	-	-	2,595	-	-	-	-
Cash and cash equivalents		497,397	-	-	-	497,397	-	-	-	-
		502,330	**-**	**-**	**-**	**502,330**	**-**	**-**	**-**	**-**
Financial liabilities measured at fair value										
Warrants	8	-	-1,406			-1,406	-	-1,406	-	-1,406
		-	**-1,406**	**-**	**-**	**-1,406**	**-**	**-1,406**	**-**	**-1,406**
Financial liabilities not measured at fair value										
Trade payables		-	-	-	-28,716	-28,716	-	-	-	-
Other financial liabilities	8	-	-	-	-	-	-	-	-	-
Lease liabilities	8	-	-	-	-22,211	-22,211	-	-	-	-
		-	**-**	**-**	**-50,927**	**-50,927**	**-**	**-**	**-**	**-**

December 31, 2020	Note	Carrying amount					Fair value			
		Financial assets at amortized cost	Mandatorily at FVTPL - others	FVOCI - equity instruments	Other financial liabilities	Total	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value										
Investment in equity instruments - publicly traded	7	-	-	22,241		22,241	22,241	-	-	22,241
Investment in equity instruments - privately-held	7	-	37,319	-	-	37,319	-	-	37,319	37,319
		-	**37,319**	**22,241**	**-**	**59,560**	**22,241**	**-**	**-**	**59,560**
Financial assets not measured at fair value										
Trade receivables		5,043	-	-	-	5,043	-	-	-	-
Other non-current financial assets	7	2,100	-	-	-	2,100	-	-	-	-
Cash and cash equivalents		573,866	-	-	-	573,866	-	-	-	-
		581,009	**-**	**-**	**-**	**581,009**	**-**	**-**	**-**	**-**
Financial liabilities measured at fair value										
Warrants	8	-	-4,794	-	-	-4,794	-	-4,794	-	-4,794
		-	**-4,794**	**-**	**-**	**-4,794**	**-**	**-4,794**	**-**	**-4,794**
Financial liabilities not measured at fair value										
Trade payables		-	-	-	-18,875	-18,875	-	-	-	-
Loan	8	-	-	-	-24,346	-24,346	-	-	-	-
Other financial liabilities	7	-	-	-	-4,546	-4,546	-	-	-	-
Lease liabilities	8	-	-	-	-23,165	-23,165	-	-	-	-
		-	**-**	**-**	**-70,932**	**-70,932**	**-**	**-**	**-**	**-**

B. Measurement of fair values

i. Valuation techniques and significant unobservable inputs

The investment in Scandion Oncology has been measured using Scandion Oncology's closing share price at the Spotlight Stock Exchange on March 31, 2021 and 2020, and December 30, 2020, respectively. The TO 3 Warrants are valued at the TO 3 trading price on Nasdaq on March 31, 2021 and 2020, and December 30, 2020, respectively.

The contingent consideration receivable as of March 31, 2021 has been measured using a discounted cash flow valuation technique, which considers the present value of expected payments, discounted using a risk-adjusted discount rate. Expected cash flows range from SEK 23million to SEK 137million. Expected cash flows resulting from development and regulatory-milestone based contingent consideration have been adjusted for estimated probabilities that underlying milestones are achieved (9% - 34%). The risk-adjusted discount rate was 11.5%. The estimated fair value would increase (decrease) if the expected cash flows were higher (lower); or the probability of achieving milestones increases (decreases); or the risk-adjusted discount rate were lower (higher).

The investment in Cadent Therapeutics as of December 31, 2020 has been measured using the same valuation technique and inputs. The investment in Cadent Therapeutics as of March 31, 2020 has been measured using a combination and linear interpolation based on the values as of December 31, 2020 and January 1, 2019, absent any additional publicly available information.

ii. Transfers

Compared with 2020, no transfers have been made between the different levels in the hierarchy.

ii. 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	Investment in equity instruments – privately held	Contingent consideration
Balance on January 1, 2021	37,319	-
Cash received	-23,390	-
Exchange	-14,244	14,244
Foreign currency (included in 'net gains/losses on financial items')	315	-
Balance on March 31, 2021	0	14,244

Note 10 Related parties

During 2021 and 2020, the Group had a business advisor agreement with one of its Directors, Edward Saltzman, for the provision of advisory services regarding the general business development of the Group. As of March 31, 2021 and December 31, 2020, balances of SEK 0.3million and SEK 0.2million, respectively, were outstanding.

Note 11 Commitments and contingencies

The Parent Company has provided a guarantee to the subsidiary Saniona A/S to ensure that Saniona A/S will be able to pay its creditors as the obligations fall due for the period until June 30, 2022. Saniona A/S had no external net debt as of March 31, 2021.

Note 12 Restatements

The condensed consolidated financial statements for the Group that were previously issued for the three months ended March 31, 2020 (the 'Previously Issued Consolidated Financial Statements') have been restated for the correction of certain errors with respect to certain items within the consolidated statement of comprehensive income, consolidated statement of financial position/balance sheet, statement of changes in equity and consolidated statement of cash flows in accordance with the requirements in IAS 8 *Accounting Policies, Changes in Accounting Estimates and Errors*.

A detailed descrition of the nature of each restatement is provided in the Group's last annual financial statements. A summary description of the impact of each restatement is below.

(a) *Measurement of financial assets:* In our Previously Issued Consolidated Financial Statements, we had concluded that the fair value of our investment in Cadent Therapeutics could not be determined reliably and we had recorded the investment at zero cost. Using an appropriate valuation technique, we have determined that the fair value of our investment in Cadent Therapeutics was SEK 25.1million and SEK 26.6million as of December 31, 2019 and March 31, 2020, respectively. Accordingly, we recorded an increase in other financial assets and a corresponding decrease in other comprehensive income for the effect of foreign currency translation of SEK 1.5million in the three months ended March 31, 2020.

(b) *Investments in associates:* In our previously issued Consolidated Financial Statements, we had accounted for our investment in Scandion Oncology as a financial asset. Based on a comprehensive analysis of all indicators for significant influence, including, but not limited to, representation on the Board of Directors and dispersion of shareholder base, we have determined that Saniona retained significant influence over Scandion Oncology through March 31, 2020. As a result, the other comprehensive income of SEK 20.9million that was previously recognized during the first quarter of 2020 has been reversed. Alternatively, we recorded Saniona's share of Scandion Oncology's profit and loss for the first quarter of 2020 (SEK 0.4million), and a gain from losing significant influence as of March 31, 2020 of SEK 53.3million.

(c) *Intangible assets:* In our Previously Issued Consolidated Financial Statements, we had recorded a payment related to the purchase of certain intellectual property from NeuroSearch as a prepaid asset and presented it within current prepayments and accrued income. During the first quarter of 2020, we had recorded SEK 0.5million of depreciation regarding this asset. This depreciation has been reversed.

(d) *Revenue Medix*: In February 2020, uncertainties pertaining to contingent payments from Medix in the amount of SEK 2.0million were resolved. In our Previously Issued Consolidated Financial Statements, we had not recognized revenue for these.

(e) *Operating expenses:* We have adjusted for the allocation of certain costs between prior reporting periods. In addition, we have performed new grant-date valuations of existing share-based payment grants.

(f) *Measurement of financial liabilities:* Upon issuance of the Warrants during the Unit Rights Issue 2020, and prior to the underlying financial instruments being publicly traded, we had estimated the total fair value of the Warrants to be SEK 2.5million and recorded that amount as a reduction in equity and a corresponding increase in financial liabilities. IFRS 13 *Fair Value Measurement*, which defines fair value as the price that would be received to sell an asset in an orderly transaction between market participants at the measurement date (exit

price), requires the use of valuation techniques when an exit price for an identical asset is not observable. Using an appropriate valuation technique, we have determined that the fair value of the Lender Warrants was SEK 7.2million at the issuance date. In accordance with IFRS 9 *Financial Instruments*, this amount should have been recorded as a reduction of the loan balance as transaction costs and should have been amortized over the term of the loan based on the effective interest method. We have determined that the fair value of the Investor Warrants at the issuance date was SEK 27.8million, based on the trading price of the underlying listed financial instrument on Nasdaq Nordic. We should have recorded that amount as a reduction of equity at the issuance date. Subsequent changes to the fair value of the Warrants, based on the trading price of the underlying listed instruments, were recorded through profit or loss.

(g) *Other restatements:* In accordance with presentation requirements under IAS 1, as well as other applicable recognition and measurement principles codified in other IFRS, the Company has made certain other adjustments and reclassifications which affect the consolidated statement of comprehensive income, consolidated statement of financial position, statement of changes in equity and consolidated statement of cash flows. Individually, such other restatements did not have a material impact on our consolidated financial statements.

The total impact of restatements on the three months ended March 31, 2020 is presented in the table below:

Reconciliation of the condensed statement of comprehensive income for the three months ended March 31, 2020

KSEK	2020-01-01 2020-03-31 (Restated)	Adjustments		2020-01-01 2020-03-31 (Previously Reported)
Revenue	2,430	1,971	(d)	459
Total operating income	2,430	1,971		459
Raw materials and consumables	-720	-		-720
Other external costs	-19,993	1,092	(c), (e)	-21,085
Personnel costs	-8,929	122	(e)	-9,051
Depreciation and write-downs	-210	-		-210
Total operating expenses	-29,852	1,214		-31,066
Operating profit/loss	**-27,422**	**3,185**		**-30,606**
Share of result of associates	-433	-433	(b)	-
Financial income	-	-		-
Financial expenses	-498	-17	(d)	-482
Net gains on financial items	66,174	68,638	(b), (f)	-2,464
Total financial items	65,243	68,188		-2,946
Profit/loss after financial items	**37,821**	**71,373**		**-33,553**
Tax on net profit/loss	5,369	-		5,369
Profit/loss for the period	**43,190**	**71,373**		**-28,184**
Other comprehensive income				
Item that may be reclassified to profit and loss				
Translation differences	2,980	1,834		1,146
Items that will not be reclassified to profit and losses				
Fair value financial assets	-	-20,911	(b)	20,911
Total Other comprehensive income	2,980	-19,077		22,057
Total comprehensive income	**46,170**	**52,296**		**-6,126**

Reconciliation of the condensed consolidated statement of financial position – Group

March 31, 2020

KSEK	2020-03-31 (Restated)	Adjustments		2020-03-31 (Previously Reported)
ASSETS				
Intangible assets	8,162	8,162	(c)	-
Property and equipment	1,166	-2,249	(g)	3,415
Right of use assets	2,249	2,249	(g)	-
Tangible assets	3,415	-		3,415
Other financial assets	84,911	26,624	(a)	58,287
Investments in associated companies	-	-		-
Other long-term receivables	279	-510		789
Financial assets	85,190	26,114		59,076
Other assets				
Tax assets	5,582	-		5,582
Deferred tax	71	-		71
Non-current assets	**102,420**	**34,276**		**68,144**
Trade receivables	3,936	3,021	(d)	915
Current tax assets	8,162	-		8,162
Other assets	2,649	-2,950	(e)	5,599
Prepayments and accrued income	2,032	-		2,032
Current receivables	16,779	71		16,709
Cash and cash equivalent	37,354	-		37,354
Current assets	**54,133**	**71**		**54,063**
Total assets	**156,553**	**34,347**		**122,207**

Reconciliation of the condensed consolidated statement of financial position – Group (continued)

March 31, 2020 (continued)

KSEK	2020-03-31 (Restated)		Adjustments	2020-03-31 (Previously Reported)
EQUITY AND LIABILITIES				
Share capital	1,471	-		1,471
Additional paid in capital	231,880	-27,799	(f)	259,679
Reserves	-316	-32,066		31,750
Retained earnings including profit or loss for the period	-139,705	79,644		-219,349
Equity	**93,330**	**19,779**		**73,550**
Other financial liabilities	14,639	14,639	(f),(g)	-
Lease liabilities	-	-1,321	(g)	1,321
Other liabilities	1,388	-		1,388
Non-current liabilities	16,027	13,318		2,709
Trade payables	9,516	-		9,516
Loan	-	-25,000	(g)	25,000
Other liabilities	11,054	5,319	(e)	5,735
Accrued expenses and deferred income	-	-5,696	(g)	5,696
Other financial liabilities	26,626	26,626	(f),(g)	-
Current liabilities	47,196	1,249		45,947
Total liabilities	63,223	14,567		48,657
Total equity and liabilities	**156,553**	**34,346**		**122,207**

Note 13 Subsequent Events to the Balance Sheet Date

- **On April 12, 2021:** Saniona successfully monetized its position in the 2017 spin-out Scandion Oncology, completing the sale of its remaining shares on the open market.
- **On April 14, 2021:** Saniona presented preclinical data on SAN903 in a model of idiopathic pulmonary fibrosis at the American Society of Pharmacology and Experimental Therapeutics (ASPET) Annual Meeting at Experimental Biology (EB) 2021.
- **On April 19, 2021:** Saniona announced a partnership with the Foundation for Prader-Willi Research (FPWR) to increase awareness about Saniona's upcoming Phase 2b clinical trial of Tesomet for the treatment of PWS.
- **On April 21, 2021:** Saniona announced the receipt of manufacturing feedback from the FDA that will delay the start of the Tesomet Phase 2b trials into the second half of 2021.
- **On April 30, 2021:** Saniona announced that the registered number of shares and votes in Saniona AB (publ) ("Saniona") has increased due to the exercising of warrants of series TO 3. As of April 30, 2020, the registered number of shares and votes in Saniona amounts to 62,385,677.
- **On May 20, 2021:** Saniona hosted a research and development (R&D) day featuring presentations highlighting its ion channel drug discovery engine, including its IONBASE™ database now consisting of more than 20,000 proprietary molecules targeting various ion channels, and data from ion channel modulators SAN711 and SAN903.
- Saniona **received a 33.3% ownership stake in Cephagenix**, as per the terms of the previously announced February 2020 collaboration agreement through which the company was formed to explore ion channel modulators for the treatment of migraine.

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 08:00 CEST on May 26, 2021.

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