

Major Milestones met with Positive Topline Results in Hypothalamic Obesity and successful direct issue raising USD \$65 million. Saniona advancing into late stage clinical development with its rare eating disorder programs

Financial highlights

H1 2020 (H1 2019)

- Net revenues were SEK 2.5 M (2.4 M)
- EBIT was SEK -56.1 (-49.7 M)
- Net profit/loss was SEK -64.6 M (-44.6)
- Earnings per share were SEK -2.18 (-1.89)
- Diluted earnings per share were SEK -2.18 (-1.89)

Q2 2020 (Q2 2019)

- Net revenues were SEK 2.0 M (0.7 M)
- EBIT was SEK -25.5 M (-20.6 M)
- Net profit/loss was SEK -36.4 (-19.8 M)
- Earnings per share were SEK -1.23 (-0.83)
- Diluted earnings per share were SEK -1.23 (-0.83)

Business highlights in Q2 2020

- In April, Saniona reported positive topline results from its Phase 2 trial of Tesomet in hypothalamic obesity. The double-blind, placebo-controlled results showed that Tesomet was safe, well tolerated and led to statistically significant reductions in the key efficacy endpoints, including change in body weight, waist circumference and glycemic control compared to placebo.
- On May 1, 2020 Saniona appointed Rudolf Baumgartner, M.D., as Chief Medical Officer and Head of Clinical Development.
- In June, Saniona announced that it received positive feedback from the United States Food and Drug Administration (FDA) following a pre-investigational new drug (IND) meeting regarding the proposed regulatory pathway for Tesomet in Prader-Willi syndrome (PWS). The agency confirmed that Tesomet may be advanced via the 505(b)2 pathway, and indicated agreement with Saniona on the design, proposed doses, and duration of Saniona's planned Phase 2b clinical trial in PWS.
- Saniona strengthened its balance sheet through the sale of shares in Scandion Oncology A/S, which raised SEK 38.2 million, and through the execution of a warrant exercise resulting in proceeds of approximately SEK 24.3 million before issue costs.

Significant events after the reporting period

- On August 10, 2020 Saniona announced the successful direct issue of shares raising USD \$65 million with a syndicate of U.S. and international institutional investors and sector specialists. The Directed Issue was led by RA Capital Management with participation from Pontifax Venture Capital, New Leaf Venture Partners, and other U.S. and international investors including the Second Swedish National Pension Fund (AP2), the Third Swedish National Pension Fund (AP3) and the Fourth Swedish National Pension Fund (AP4).
- On August 26, 2020 Saniona announced the expansion of its executive team with the appointments of Jason A. Amello as Chief Financial Officer, Trista Morrison as Chief Communications Officer, and Linea Aspesi as Chief Human Resources Officer.

Comments from the CEO

- "Saniona has met some major milestones since last quarter by advancing our clinical programs for rare eating disorders and further establishing our presence in the U.S. Our recent raise of \$65 million through a direct offering of shares to well-respected U.S. and international institutional healthcare investors leaves us well positioned to rapidly advance Tesomet's clinical development and is a testament to the potential of our programs and growing U.S. presence. In addition, the appointment of Rudolf Baumgartner, M.D., as Chief Medical Officer and Head of Clinical Development strengthens our management team and further bolsters our establishment as a U.S.-based rare disease company. On the clinical and regulatory front, we are excited to build upon positive data from our Phase 2 study in patients with hypothalamic obesity (HO) showing statistically significant changes in key efficacy endpoints as we move toward a pre-IND meeting with the FDA in the second half of the year. Importantly, we also achieved a key milestone in our Prader-Willi syndrome program, with Saniona and the FDA agreeing on a 505(b)2 regulatory pathway and Phase 2b trial design following a positive pre-IND meeting. Together, these accomplishments bring us closer to our ultimate goal of advancing Tesomet to the market to provide a solution for patients with these rare eating disorders," says Rami Levin, President & Chief Executive Officer of Saniona.

For more information, please contact

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Letter from the CEO

The second quarter has been transformative for Saniona with important accomplishments across clinical, regulatory and organizational objectives. Our progress across key areas includes:

Advancing our clinical development programs: This quarter we reported positive data from our 24-week double-blind, placebo-controlled Phase 2 trial evaluating Tesomet for the treatment of hypothalamic obesity (HO). Results from twenty-one patients showed that Tesomet treatment was safe and well tolerated, and led to statistically significant improvements in bodyweight, waist circumference, and glycemic control compared to placebo. In addition, eighteen out of the original twenty-one study participants have proceeded into the open-label extension phase of the study. We look forward to the continued advancement of this program, with a pre-IND meeting with the U.S. FDA expected in 2H 2020, which will facilitate the initiation of a Phase 3 study during the first half of next year. Considerable progress has also been made in advancing our Prader-Willi syndrome (PWS) program, as we recently completed a successful pre-IND meeting with the FDA. Importantly, we received confirmation that Tesomet may be advanced via the 505(b)2 pathway and secured agreement on the design, proposed doses, and duration of Saniona's planned pivotal Phase 2b clinical trial in PWS, which we expect to initiate by year-end.

Building our presence in the U.S.: In the second quarter we were thrilled to announce the appointment of Dr. Rudolf Baumgartner, M.D., as Chief Medical Officer and Head of Clinical Development for Saniona. This appointment strengthens our management team, bringing extensive pharmaceutical development expertise from early stage development through to commercial launch, and importantly, also bolsters our U.S. presence.

Strengthening our balance sheet: Since the end of the second quarter we have continued to execute on our corporate objectives and have significantly strengthened our balance sheet. Excitingly, this month we successfully raised USD \$65 million through a direct issue of shares. Participants in the offering included well respected U.S. and international institutional healthcare investors, signifying confidence in our pipeline, strategy and execution, and also further establishing Saniona as a U.S.-based rare disease company. In addition to this direct offering, Saniona also recently strengthened its balance sheet through the second quarter sale of shares in Scandion Oncology A/S, which raised SEK 38.2 million, and through the execution of a warrant exercise resulting in proceeds of approximately SEK 24.3 million before issue costs. Together, these funds leave us well positioned to move Tesomet toward registrational studies and approvals, and simultaneously drive the advancement of our early-stage assets into the clinic.

While we, and the larger biopharma community still face challenges due to the ongoing COVID-19 pandemic, we are fortunate to continue with progress and execution at Saniona. Our team remains dedicated to developing effective treatments for rare diseases of the central nervous system and we have adapted to efficiently continue our efforts under the new, and ever-changing public health guidelines across our global locations. We look forward to providing updates on our HO and PWS clinical programs, with a HO pre-IND meeting with the FDA planned for 2H 2020, and the initiation of our Phase 2b trial for PWS by expected year-end.

The progress we've made since the first quarter would not have been possible without the dedication of our employees, partners, and of course patients. I would like to extend my gratitude to all of these individuals who are key in the advancement of our mission and progress as a fully integrated company focused on rare diseases of the central nervous system.

Rami Levin

President & CEO, Saniona AB

About Saniona

Saniona is a rare disease biopharmaceutical company focused on discovering, developing, and commercializing treatments for central nervous system disorders. The company has a diverse pipeline of wholly owned assets led by Tesomet, which is currently in clinical development as a treatment for hypothalamic obesity and Prader-Willi syndrome. Saniona also has a broad portfolio of research and out-licensed programs derived from its ion channel discovery platform. These programs are being developed through partnerships with companies such as Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and Cadent Therapeutics. Saniona has offices in Copenhagen, Denmark and Boston, US. The company's shares are listed at Nasdaq Stockholm Small Cap (OMX: SANION).

Our vision

To become a leading global rare disease biopharmaceutical company focused on treatments for the central nervous system.

Our mission

To deliver innovative therapies to patients with rare diseases including hypothalamic obesity and Prader-Willi syndrome.

Saniona's focus is on the development and commercialization of proprietary product candidates for the treatment of rare diseases with high unmet medical need. Saniona's lead programs aim to develop Tesomet for the treatment of hypothalamic obesity and Prader-Willi syndrome in the U.S. and Europe. Saniona made the strategic decision to internally develop Tesomet in these indications and markets due to relatively small size and manageable nature of the investments and commercial infrastructure required to serve these patient populations.

Saniona has also partnered multiple assets with other pharmaceutical companies and continues to develop additional product candidates internally with the aim of either filling our proprietary pipeline or out licensing candidates for later stage development or commercialization. The structure of Saniona's partnership and out licensing agreements vary by product, indication, size of investment, and risk, as well as the interest and capabilities of Saniona's partners. Saniona generally grants its partners global or region specific commercial licenses in exchange for upfront payments, research funding, milestone payments and royalties on future product sales when the product candidates are commercialized.

Saniona's short term strategic priorities are the following:

- To develop and attain market approval for Tesomet in the U.S. and Europe for the treatment of the rare eating disorders hypothalamic obesity and Prader-Willi syndrome
- To build an internal organization to support the late stage clinical development of our rare disease programs and to adequately finance these activities through commercialization
- To strengthen the company's position and corporate presence in the U.S.
- To internally develop at least one drug candidate derived from our unique ion channel research platform
- To leverage our industry-leading ion channel research through out-licensing and partnerships with other pharmaceutical companies

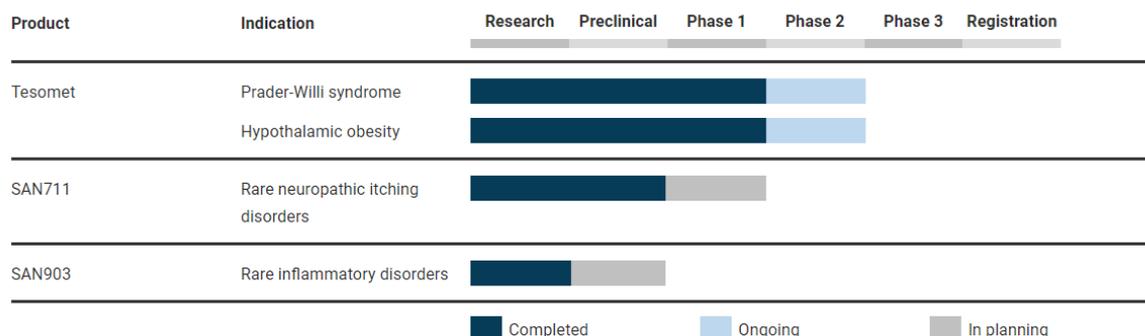
Proprietary pipeline

Saniona's most advanced proprietary clinical program is Tesomet for the treatment of rare eating disorders. Saniona has completed a dose-finding Phase 2a proof-of-concept study in PWS and is currently planning to initiate pivotal Phase 2b/3 studies by year-end. In parallel, Saniona is currently conducting the open label extension portion of its Phase 2 study in HO. Saniona recently reported positive topline data from the placebo controlled portion of this study and is planning to advance the program by holding a pre-IND meeting with the U.S. FDA in Q-4 2020.

Saniona's preclinical pipeline is derived from its ion channel discovery platform. Ion channels comprise a unique class of proteins that are central to the control of numerous physiological functions including the activity of muscles and nerves. Currently, Saniona is working to advance two early stage assets into Phase 1 studies. The first of these assets is SAN711, a first-in-class positive allosteric modulator of GABAA $\alpha 3$ receptors in development for rare itching disorders. Preclinical development of SAN711 has been completed and the molecule is Phase 1 ready. Saniona's second preclinical asset, SAN903, is an IK potassium channel inhibitor currently in

preclinical development for the treatment of rare inflammatory and fibrotic disorders.

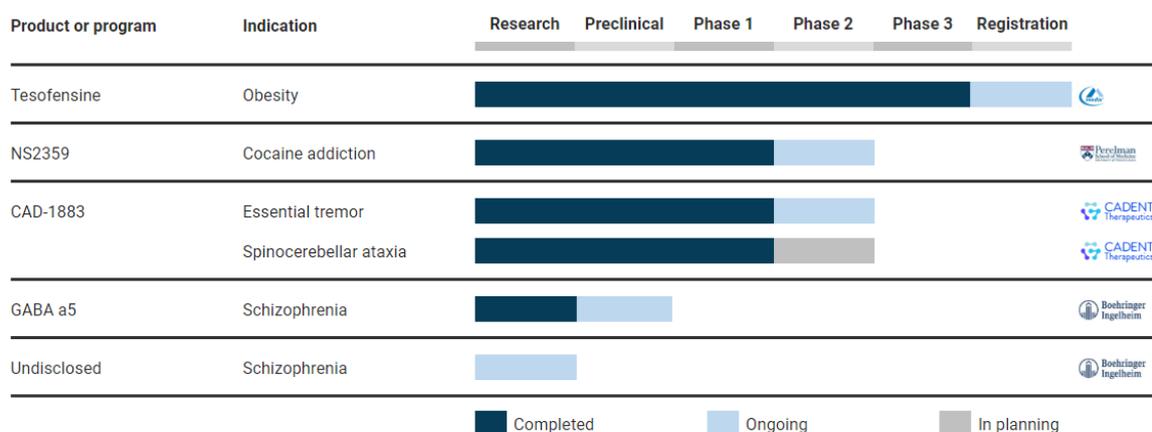
Proprietary Pipeline



Out-licensing and partnerships

Saniona maintains a robust pipeline of out-licensed programs, which allows the Company to benefit from promising research discoveries that do not fit our strategic development focus on rare diseases. The most advanced out-licensed program is partnered with Medix and is centered around the development of tesofensine as a treatment for obesity. Medix submitted a new drug application to the Mexican food and drug administration in December 2019 and expects the approval and launch of tesofensine in the Mexican market during 2020. The approval and launch may be delayed into 2021, due to the ongoing COVID-19 pandemic. In addition, Saniona's out-licensed pipeline includes programs for essential tremor and ataxia in partnership with Cadent Therapeutics. Cadent Therapeutics has previously announced the completion of a Phase 2a study for the treatment of essential tremor and expects to initiate a separate Phase 2a trial for the treatment of Ataxia shortly. Saniona has also entered into multiple research collaboration agreements with Boehringer Ingelheim concerning the development of two separate preclinical assets for the treatment of schizophrenia.

Out-licencing and Partnerships



Financial review

Financial key figures

	2020-04-01	2019-04-01	2020-01-01	2019-01-01	2019-01-01
	2020-06-30	2019-06-30	2020-06-30	2019-06-30	2019-12-31
Net sales, KSEK	1,991	687	2,451	2,402	2,658
Total operating expenses, KSEK	-27,482	-21,276	-58,548	-52,140	-106,563
Operating profit/loss, KSEK	*	-25,491	-20,589	-56,097	-49,738
Operating margin, %	*	-1280%	-2995%	-2289%	-2070%
Cash flow from operating activities, KSEK	-19,495	-27,469	-68,318	-53,222	-98,469
Cash flow per share, SEK	*	1.33	-0.88	1.16	-1.23
Earnings per share, SEK	-1.23	-0.83	-2.18	-1.89	-2.95
Diluted earnings per share, SEK	-1.23	-0.83	-2.18	-1.89	-2.95
Average shares outstanding	29,496,259	23,925,605	29,689,890	23,641,457	25,719,586
Diluted average shares outstanding	29,513,193	23,931,555	29,705,828	23,655,043	25,732,676
Shares outstanding at the end of the period	30,383,316	24,066,238	30,383,316	24,066,238	28,412,519
Average number of employees, #	22.9	22.4	22.9	22.5	22.4
			2020-06-30	2019-06-30	2019-12-31
Cash and cash equivalent, KSEK			68,604	30,203	40,248
Equity, KSEK			145,961	69,075	58,437
Total equity and liabilities, KSEK			218,975	131,447	96,000
Liquidity ratio, %	*		142%	186%	152%
Equity ratio, %	*		67%	53%	61%
Equity per share, SEK	*		4.80	2.49**	2.06

* = Alternative performance measures

**=When calculating equity per share as of June 30, 2019, the 3,697,109 shares issued in connection with the rights issue has been included in "Shares outstanding at the end of the period".

Definitions and relevance of 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 considers 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 set-out 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

	2020-04-01 2020-06-30	2019-04-01 2019-06-30	2020-01-01 2020-06-30	2019-01-01 2019-06-30	2019-01-01 2019-12-31
Operation profit/loss, KSEK	-25,491	-20,589	-56,097	-49,738	-103,906
Net sales, KSEK	1,991	687	2,451	2,402	2,658
Operating margin, %	-1280%	-2995%	-2289%	-2070%	-3909%
Cash flow for the period, KSEK	39,241	-21,172	34,554	-29,181	-22,491
Average shares outstanding	29,496,259	23,925,605	29,689,890	23,641,457	25,719,586
Cash flow per share, SEK	1.33	-0.88	1.16	-1.23	-0.87

	2020-06-30	2019-06-30	2019-12-31
Current assets, KSEK	86,893	110,322	53,883
Current liabilities, KSEK	61,107	59,433	35,416
Liquidity ratio, %	142%	186%	152%
Equity, KSEK	145,961	69,075	58,437
Total equity and liabilities, KSEK	218,975	131,447	96,000
Equity ratio, %	67%	53%	61%
Equity, KSEK	145,961	69,075	58,437
Shares outstanding at the end of the period	30,383,316	27,763,347*	24,066,238
Equity per share, SEK	4.80	2.49	2.06

* When calculating equity per share as of June 30, 2019, the 3,697,109 shares issued in connection with the rights issue has been included in "Shares outstanding at the end of the period".

Revenues and result of the operation

Revenue

Total revenues during the second quarter of 2020 was SEK 2.0 million (0.7).

Total revenues during the first six months of 2020 was SEK 2.5 million (2.4).

In 2020, revenues comprised research funding under the agreement with Boehringer Ingelheim and Cephagenix. In 2019, revenues comprised research funding under the agreement with Boehringer Ingelheim.

Operating profit/loss

The operating loss for the second quarter was SEK 25.5 million (20.6). The company recognized operating expenses of SEK 27.3 million (21.3) for the second quarter of 2020. External expenses amounted to SEK 17.7 million (13.3) and personnel costs amounted to SEK 8.7 million (6.6). In the second quarter of 2020, external expenses comprised primarily development costs in relation to Tesomet.

The company recognized an operating loss of SEK 56.1 million (49.7) for the first six months of 2020. The company recognized operating expenses of SEK 58.5 million (52.1) whereof external expenses amounted to SEK 38.8 million (35.6) and personnel costs amounted to SEK 17.8 million (13.7). In 2020 external expenses comprised primarily development costs in relation to Tesomet. In 2019 external expenses comprised primarily development costs in relation to Tesomet followed by preclinical development costs in relation to SAN711 and research and development costs in relation to the IK program.

Cash flow

Operating cash flow for the second quarter of 2020 was an outflow of SEK 7.7 million (outflow of 27.3). Consolidated cash flow for the second quarter of 2020 was an inflow of SEK 39.2 million (outflow of 21.2).

Operating cash flow for the first 6 months of 2020 was an outflow of SEK 56.1 million (outflow of 52.8). Consolidated cash flow for the first 6 months of 2020 was an inflow of SEK 34.6 million (outflow of 29.2).

In 2020, the operating cash flow for the first six months is explained by the operating loss. The consolidated cash flow in 2020 is further explained by an inflow from finance activities of SEK 71.5 million through the issue of loan notes to Formue Nord totaling SEK 25 million, issue of share to Formue Nord totaling SEK 25 million, exercise of warrants of Series TO 1 of SEK 24 million, and an inflow from investing activities of sale of Scandion shares of SEK 38 million.

In 2019, the operating cash flow for the first six months is explained by the operating loss. The consolidated cash flow in 2019 is further explained by an inflow from finance activities of SEK 23.2 million through the issue of convertible loan notes to Nice & Green totaling SEK 24 million of which SEK 4.5 million has not been converted at the balance sheet date. The balance of SEK 19.5 million was converted into equity the first six months of 2019 and the net proceeds of SEK 18.7 million is recorded under new share issues after deduction of issuing expenses.

Financial position

The equity ratio was 67 (53) % as of June 30, 2020, and equity was SEK 146 million (69.1). Cash and cash equivalents amounted to SEK 68.6 million (30.2) as of June 30, 2020. Total assets as of June 30, 2020, were SEK 131.5 million (77.7).

The share, share capital and ownership structure

At June 30, 2020, the number of shares outstanding amounted to 30,383,316 (24,066,238). At June 30, 2020, the company had 6,272 (5,592) shareholders excluding holdings in life insurance and foreign custody account holders.

The company established a warrant program on July 1, 2017, totaling 38,750 warrants, on January 19, 2018 totaling 286,003 warrants, on July 1, 2018, totaling 45,013 warrants, on September 1, 2019, totaling 50,270 warrants and on February 7, 2020, totaling 710,313 warrants.

The extraordinary shareholders' meeting on February 7, 2020, approved the board of director's decision to carry out a directed issue of 465,518 units, consisting of 1,396,554 warrants of the series TO 1, TO 2 and TO 3, to two external investors (Formue Nord Markedsneutral A/S and Formue Nord Fokus A/S), and to carry out a rights issue to shareholders of 1,014,224 units consisting of a total of 3,042,672 warrants of the same series.

Each warrant, regardless of series, carries the entitlement to subscribe for one (1) new share in Saniona at a subscription price corresponding to 70% of the volume-weighted average share price for the Saniona's share during a two-week period ending two trading days prior to the start of each series' exercise period, though not less than SEK 25 and not more than SEK 30 per share.

In May, Saniona announced outcome of warrant exercise TO 1, where Saniona received SEK 24.3 million, before issues costs. The maximum number of shares that may be issued in TO 2 and TO 3 is 2,959,484. The measurement period for TO 2 is August 20, 2020 to September 2, 2020 and for TO 3 the measurement period is March 17 to March 30, 2021. The exercise period for series TO 2 warrants September 7–21, 2020 and for series TO 3 warrants April 6–20, 2021. The warrants will be subject to customary conversion conditions in conjunction with issues.

After the reporting period, in August, Saniona received the gross proceeds of USD 65 million (approximately SEK 567 million) in a directed issue of 30,660,374 shares at a subscription price of USD 2.12 per share (SEK 18.50). The number of shares has therefore increased by 30,660,374 to 61,043,690, and the share capital has increase by SEK 1,533,018.70 to SEK 3,052,184.50 at the time for the publication of this report. For more information about this directed issue, please see the prospectus published August 11th that is available at Saniona's webpage.

Personnel

As of June 30, the number of employees was 25 (24) of which 13 (13) are women. Of these employees, 5 (3) are part-time employees and 20 (21) are full-time employees, and a total of 21 (19) work in the company's research and development operations. 11 (11) of Saniona's employees hold PhDs, 3 (2) hold university degrees, 8 (8) have laboratory training and the remaining 3 (3) have other degrees.

Operational risks and uncertainties

All business operations involve risk. Managed risk-taking is necessary to maintain good profitability. Risk may be due to events in the external environment and may affect a certain industry or market. Risk may also be company specific. The main risks and uncertainties which Saniona is exposed to are related to drug development, the company's collaboration agreements, competition, technology development, patent, regulatory requirements, capital requirements and currencies.

The Group's programs are sold primarily to pharmaceutical companies and spin-outs funded by pharmaceutical companies and venture capital firms. Historically, the Group has not sustained any losses on trade receivables and other receivables. The Group doesn't expect any losses on the current research and development collaboration with Boehringer Ingelheim, that was initiated in March 2020.

Currency risks is the risk that the fair value of future cash flows fluctuate because of changed exchange rates. Exposure to currency risk is primarily sourced from payment flows in foreign currency and from the translation of balance sheet items in foreign currency, as well as upon the translation of foreign subsidiaries' income statements and balance sheets to the Group's reporting currency, which is SEK.

A more detailed description of the Group's risk exposure and risk management is included in Saniona's 2019 Annual Report.

There are no major changes in the Group's risk exposure and risk management in 2020, besides risk related to COVID-19 as described below, and the positively effect on the financial risk after the direct issued raising USD \$65 million.

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 we currently have, was able to conclude and close in March 2020 despite the COVID-19 pandemic.

Medix submitted a new drug application to the Mexican food and drug administration in December 2019 and expects the approval and launch of tesofensine in the Mexican market during 2020. The approval and launch may be delayed into 2021, due to the ongoing COVID-19 pandemic

Audit review

This Interim Report has not been subject to review by the company's auditors.

Financial calendar

Interim Report Q3	November 26, 2020
Year-End Report 2020	February 25, 2021

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.

Ballerup, 27 August 2020
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

Condensed consolidated statement of comprehensive income – Group

KSEK	Note	2020-04-01	2019-04-01	2020-01-01	2019-01-01	2019-01-01
		2020-06-30	2019-06-30	2020-06-30	2019-06-30	2019-12-31
	1-2					
Net sales	3	1,991	687	2,451	2,402	2,658
Total operating income		1,991	687	2,451	2,402	2,658
Raw materials and consumables		-840	-830	-1,559	-1,808	-3,517
Other external costs		-17,711	-13,307	-38,796	-35,609	-74,984
Personnel costs	4	-8,728	-6,622	-17,779	-13,696	-25,860
Depreciation and write-downs		-204	-517	-414	-1,027	-2,202
Total operating expenses		-27,482	-21,276	-58,548	-52,140	-106,563
Operating profit/loss		-25,491	-20,589	-56,097	-49,738	-103,906
Share of result of associates	8	-	-719	-	-2,179	20,214
Financial income		310	8	309	-	674
Financial expenses		-256	-205	-737	-394	-483
Net gains/losses on financial items		-13,469	-	-15,933	-	-
Total financial items		-13,415	-916	-16,361	-2,573	20,404
Profit/loss after financial items		-38,905	-21,505	-72,458	-52,311	-83,501
Tax on net profit	5	2,483	1,712	7,853	7,708	7,713
Profit/loss for the period		-36,422	-19,793	-64,605	-44,603	-75,788
Other comprehensive income						
<i>Item that may be reclassified to profit and loss</i>						
Translation differences		56	123	1,202	477	-187
<i>Item that will not be reclassified to profit and loss</i>						
Fair value financial assets	8	86,276	-	107,187	-	10,657
Total other comprehensive income net after tax		86,332	123	108,389	477	10,470
Total comprehensive income		49,910	-19,670	43,784	-44,125	-65,319
Earnings per share, SEK		-1.23	-0.83	-2.18	-1.89	-2.95
Diluted earnings per share, SEK		-1.23	-0.83	-2.18	-1.89	-2.95

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	2020-06-30	2019-06-30	2019-12-31
	1-2			
ASSETS				
Fixtures, fittings, tools and equipment		15,425	5,818	3,415
Tangible assets		15,425	5,818	3,415
Non-current tax assets	5	7,735	7,780	-
Other financial assets	8, 12	106,441	-	37,376
Investments in associated companies	8	-	4,326	-
Other long-term receivables	9	2,414	3,138	1,260
Financial assets		116,589	15,244	38,635
Deferred tax		68	63	67
Non-current assets		132,082	21,125	42,117
Trade receivables		2,894	684	-
Current tax assets	5	7,735	7,780	7,682
Other receivables		4,753	57,006	4,430
Prepayments and accrued income		2,907	14,649	1,523
Current receivables		18,288	80,119	13,636
Cash and cash equivalent		68,604	30,203	40,248
Current assets		86,893	110,322	53,883
Total assets		218,975	131,447	96,000
EQUITY AND LIABILITIES				
Share capital	10	1,519	1,203	1,421
Additional paid in capital	10	283,598	229,509	239,592
Reserves		88,205	-299	9,693
Retained earnings including profit or loss for the period		-227,361	-161,338	-192,268
Equity		145,961	69,075	58,437
Lease liabilities	13	10,053	2,939	1,420
Other payables		1,854	-	727
Non-current liabilities		11,907	2,939	2,147
Trade payables		6,214	5,213	29,248
Convertible loan	10	-	10,500	-
Loan	11	25,000	-	-
Other payables		1,545	12,125	745
TO 2 & TO 3 warrants	12	18,290	-	-
Accrued expenses and deferred income	13	10,058	31,595	5,423
Current liabilities		61,107	59,433	35,416
Total liabilities		73,014	62,372	37,563
Total equity and liabilities		218,975	131,447	96,000

Condensed consolidated statement of changes in equity – Group

	Share capital	Share premium	Translation reserves	Fair value reserve	Retained earnings	Shareholders' equity
January 1, 2019	1,166	157,118	-777	0	-118,051	39,457
Comprehensive income						
Profit/loss for the year					-44,603	-44,603
Other comprehensive income:						0
Translation differences			477			477
Total comprehensive income	0	0	477	0	-44,603	-44,125
Transactions with owners						
Shares issued for cash	37	86,011*				86,048
Expenses related to capital increase		-13,621				-13,621
Share-based compensation expenses					1,316	1,316
Total transactions with owners	37	72,390	0	0	1,316	73,743
June 30, 2019	1,203	229,509	-299	0	-161,338	69,075
January 1, 2020	1,421	239,592	-964	10,657	-192,268	58,437
Comprehensive income						
Profit/loss for the year					-64,605	-64,605
Other comprehensive income:						
Fair value reserve				105,493		105,493
Translation differences			1,202			1,202
Total comprehensive income	0	0	1,202	105,493	-64,605	42,090
Transactions with owners						
Shares issued for cash	99	49,171				49,270
Expenses related to capital increase		-5,165				-5,165
Share-based compensation expenses					1,329	1,329
Total transactions with owners	99	44,006	0	0	1,329	45,434
June 30, 2020	1,519	283,598	238	116,150	-255,545	145,961

* Include share capital of 185 KSEK, which is recorded in July 2019 upon registration of shares in the rights issue.

Condensed consolidated statement of cash flows – Group

KSEK	Note	2020-04-01	2019-04-01	2020-01-01	2019-01-01	2019-01-01
		2020-06-30	2019-06-30	2020-06-30	2019-06-30	2019-12-31
Profit/loss before tax		-38,905	-21,505	-72,458	-52,311	-83,501
Adjustments for non-cash transactions		23,047	-1,900	27,825	1,021	-15,941
Changes in working capital		8,205	-3,868	-11,439	-1,538	783
Cash flow from operating activities before financial items		-7,654	-27,273	-56,072	-52,828	-98,660
Interest income received		310	8	309	-	674
Interest expenses paid		-13,725	-205	-16,670	-394	-483
Tax paid		-	-	-	-	-
Cash flow from operating activities		-21,068	-27,469	-72,433	-53,222	-98,469
Investing activities						
Investment in tangible assets		-35	5	-1,507	-3	-3,488
Sale of financial assets		38,243	-	38,243	-	-
Investment in other financial assets		-1,682	440	-1,211	861	2,739
Cash flow from investing activities		36,526	445	35,524	857	-749
Financing activities						
Convertible loan	10	-	2,500	-	4,500	-6,000
Loan	11	-	-	25,000	-	-
New share issue	10, 11	23,784	3,353	46,462	18,684	82,728
Cash flow from financing activities		23,784	5,853	71,462	23,184	76,728
Cash flow for the period		39,242	-21,172	34,553	-29,181	-22,491
Cash and cash equivalents at beginning of period		37,354	46,881	40,248	54,678	54,678
Exchange rate adjustments		-7,992	4,493	-6,197	4,706	8,061
Cash and cash equivalents at end of period		68,604	30,203	68,604	30,203	40,248

Statement of income – Parent Company

KSEK	Note	2020-04-01	2019-04-01	2020-01-01	2019-01-01	2019-01-01
		2020-06-30	2019-06-30	2020-06-30	2019-06-30	2019-12-31
	1-2					
Other operating income		-	338	-	677	1,354
Total operating income		0	338	0	677	1,354
Raw materials and consumables		-7	-2	-15	-5	-13
Other external costs		-2,511	-1,639	-4,214	-3,455	-6,416
Personnel costs		-2,375	-990	-3,055	-1,888	-4,046
Total operating expenses		-4,894	-2,632	-7,283	-5,348	-10,475
Operating profit/loss		-4,894	-2,294	-7,283	-4,671	-9,121
Share of result of associates	8	-	-719	-	-2,179	-1,092
Financial income	8	37,268	2,030	37,361	4,006	8,657
Financial expenses		-164	-101	-246	-136	-269
Net gains/losses on financial items		-13,469	-	-15,933	-	-
Total financial items		23,635	1,210	21,182	1,691	7,295
Profit/loss after financial items		18,741	-1,084	13,899	-2,980	-1,826
Tax on net profit		-	-	-	-	-
Profit/loss		18,741	-1,084	13,899	-2,980	-1,826

Balance Sheet – Parent Company

KSEK	Note	2020-06-30	2019-06-30	2019-12-31
	1-2			
ASSETS				
Subscribed capital unpaid	11	-	53,744	-
Investment in subsidiaries		204,100	11,832	204,100
Other financial assets	8	3,719	-	5,413
Investments in associated companies	8	-	4,326	-
Financial assets		207,818	69,902	209,512
Non-current assets		207,818	69,902	209,512
Receivables from group companies		74,614	123,410	-
Other receivables		506	518	286
Prepayments and accrued income		1,465	13,910	763
Current receivables		76,585	137,837	1,049
Cash and cash equivalent		38,113	23,147	9,899
Current assets		114,698	160,984	10,948
Total assets		322,516	230,886	220,460
EQUITY AND LIABILITIES				
<i>Restricted equity</i>				
Share capital	10	1,519	1,203	1,421
Share capital to be paid in (new share issue)	11	-	185	-
<i>Unrestricted equity</i>				
Share premium reserve	10, 11	282,087	227,812	238,080
Retained earnings		-19,786	-17,960	-17,960
Profit/loss for the period		13,899	-2,980	-1,826
Equity		277,719	208,261	219,715
Convertible loan	10	-	10,500	-
Loan	11	25,000	-	-
Other payables		1,507	12,125	745
TO 2 & TO3 warrants	12	18,290	-	-
Current liabilities		44,797	22,625	745
Total liabilities		44,797	22,625	745
Total equity and liabilities		322,516	230,886	220,460

Notes

Note 1 General Information

Saniona AB (publ), Corporate Registration Number 556962-5345, the Parent Company and its subsidiaries, collectively the Group, is a publicly listed research and development company focused on drugs for diseases of the central nervous system, autoimmune diseases, metabolic diseases and treatment of pain. The Parent Company is a limited liability company registered in the municipality of Malmö in the county of Skåne, Sweden. The address of the head office is Smedeland 26B, DK-2600 Glostrup, Denmark. Saniona is listed on Nasdaq Stockholm Small Cap. The Parent Company's share is traded under the ticker SANION and the ISIN code SE0005794617.

Note 2 Significant accounting policies

The interim report has been prepared in accordance with IAS 34 Interim reporting. The Group applies the International Financial Reporting Standards (IFRS) and interpretations of IFRS IC as adopted by the EU, the Annual Accounts Act and the Financial Reporting Board's recommendation RFR 1, Supplementary Accounting Rules for Groups.

The condensed consolidated financial statements have been prepared under the historical cost convention, except in the case of certain financial assets and liabilities, which are measured at fair value. The condensed consolidated financial statements are presented in Swedish kronor (SEK) which is also the functional currency of the Parent Company.

The applied accounting principles are in accordance with those described in the Annual Report for 2019. More detailed information about the Group's and the Parent Company's accounting and valuation principles can be found in the Annual Report for 2019, which is available on www.saniona.com.

Disclosures in accordance with IAS 34 Interim Financial Reporting are presented either in the notes or elsewhere in the interim report.

Effects of new accounting policies

International Accounting Standards Board (IASB) has adopted a number of standards and amendments that will come into effect 2020 and these have not had any effect on the group. Standards which will come into effect in 2021 or later have not been early adopted.

Note 3 Segment reporting

The Group is managed as a single business unit. The basis for identifying reportable segments is the internal reporting as reported to and followed up by the highest executive decision maker. The Group has identified the highest executive decision maker as the CEO. The internal management and reporting structure comprises only one business unit, and the Group therefore has only one operating segment, for which reason no segment information is provided.

Note 4 Share based payments

Share-based compensation expenses for the Q2 2020 totaled SEK 226 (235) thousand and the first six months of 2020 totaled SEK 1,329 thousand (1,316). The Group accounts for share-based compensation by recognizing compensation expenses related to share-based instruments granted to the board, management, employees and consultants in the income statement. Such compensation expenses represent the fair market values of warrants granted and do not represent actual cash expenditures.

	Options allotted in 2017	Options allotted in 2018	Options allotted in 2019	Options allotted in 2020	Total
Share-based payment					
Outstanding at 1 January 2020	38,292	329,308	50,270	-	417,870
Granted during the period	-	-	-	710,313	710,313
Forfeited during the period	-	-	-	-	0
Outstanding at 30 June 2020	38,292	329,308	50,270	710,313	1,128,183

Incentive program after rights issues**	2017	2018:1	2018:2	2018:3	2019:1	2019:2	2020:1	Total
Allotted options	38,750	286,003	34,500	10,513	34,500	15,770	710,313	1,130,349
Forfeited	-458	-	-1,708	-	-	-	-	-2,166
Outstanding	38,292	286,003	32,792	10,513	34,500	15,770	710,313	1,128,183
Subscriptions price after rights issues (SEK)	40.63	33.20	29.71	29.71	17.83	17.83	29.36	
Equal to no of shares	40,228	300,474	34,450	11,044	34,845	15,927	717,416	1,154,384

** The subscription price for the options and the number of shares that each option entitles to subscription of have been recalculated as a result of rights issues carried out after the implementation of each respective program.

If all issued warrants are exercised for subscription of new shares, the Parent Company's will issue a total of 1,154,384 new shares corresponding to a dilution of approximately 3.80%. The data below has been used for the calculation.

Incentive program	2017	2018:1	2018:2	2018:3	2019:1	2019:2	2020:1
Allotted options	38,750	286,003	34,500	10,513	34,500	15,770	710,313
Fair value per option (SEK)	29.48	12.67	18.89	18.89	7.55	6.69	12.94
Share price for underlying shares (SEK)	45.50	26.95	33.85	33.85	17.76	17.76	28.85
Subscription price (SEK)	41.13	33.60	30.08	30.08	17.86	17.86	29.42
Vesting period	4 years	3 years	4 years	3 years	4 years	3 years	4 years
Estimated life of the option	5.50 years	6.25 years	5.5 years	4 years	5.5 years	4 years	5 years
Risk-free interest rate during the life of the option	-0.0584%	0.2389%	-0.0713%	-0.0356%	-0.6929%	-0.6995%	-0.1963%
Assumed volatility*	76.75%	57.41%	63.58%	63.58%	51.03%	51.03%	52.14%
Expected dividends	0	0	0	0	0	0	0

* In 2017, the volatility equals the historical volatility for the longest period where trading activity is available (for the period since listing at the Spotlight Stock Market on April 22, 2014 to date of grant). In 2018, 2019 and 2020, the volatility equals a twelve-month period.

A detailed description of the warrant program in 2017, 2018:1, 2018:2, 2018:3, 2019:1 and 2019:2 can be found in the annual report 2019.

2020:1 On February 7, 2020, the extraordinary shareholders' meeting voted in favor of establishing an employee option program for the CEO, Rami Levin. The Employee Option Program 2020/2025 comprises 710,313 employee options. Allotment took place on February 7, 2020. Each employee option entitles the holder a right to acquire one new share in the Saniona for a subscription price of SEK 29.42. The allotted employee options will be vested with 1/4 each at the dates falling 12, 24, 36 and 48 months after allotment. The employee options shall be allotted without consideration. The holder can exercise allotted and vested employee options during 30 days from the day following after the announcement of the Company's quarterly reports, or for full year, the year-end re-port, the first time after the announcement of the quarterly report for the fourth quarter of 2022 and the last time after the announcement of the quarterly report for the third quarter of 2025.

Note 5 Income tax and deferred tax subsidiaries in Denmark

Tax on income for the year, consisting of the year's current tax and deferred tax, is recognized in the income statement to the extent that it relates to the income or loss for the period and in other comprehensive income or equity to the extent that it relates thereto.

The Group recognized a tax income of SEK 7.7 (7.7) million during the first half of 2020. This amount has been recognized under non-current tax assets in accordance to the accounting policies described below.

Under the Danish R&D tax credit scheme (Skatte kreditordningen), loss-making R&D entities can obtain a tax credit which is equal to the tax value of the incurred research and development expenses. The tax credit is payable in November in the following financial year. In 2019 and 2020 the R&D expense tax-base is capped to DKK 25 million equal to a tax credit of DKK 5.5 million at a tax rate of 22%. Research and development tax-credits under the Danish R&D tax credit scheme is recognized in the income statement to the extent that it relates to the research and development expenses for the period and Saniona expects to fulfil the requirement for tax

credit for the year. The tax credit under the Danish R&D tax credit scheme is recognized in the balance sheet under current tax assets if payable within 12 months and under non-current tax assets if payable after 12 months. As of June 30, 2020, the Group had SEK 7.8 million (SEK 7.8 million) in current tax asset, which was paid in July 2020 and SEK 7.8 million (SEK 7.8 million) in non-current tax assets which will be payable in November 2021.

Note 6 Pledged assets and contingent liabilities

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, 2021. Saniona A/S had no external net debt as of June 30, 2020.

Note 7 Related parties

Related parties comprise the Group's Executive Management, Board of Directors and companies within the Group. Apart from intercompany transaction and board fees as well as remuneration of management in accordance to the remuneration policy as resolved at the annual general meeting, there has been no transaction with related parties during 2019 and 2020.

Note 8 Other financial assets

On May 3, 2017, Saniona participated in formation of a new company, Scandion Oncology A/S. Scandion Oncology has been listed on the Spotlight Stock Market on November 8, 2018.

In Q2 2019 the asset was accounted for as investment in associated companies.

Scandion Oncology A/S	Equity*	Saniona's share of net profit/(loss) (ownership 29.17%)
January 1, 2019*	22,300,870	6,505,164
June 30, 2019**	14,831,046	4,326,216
		(2,178,948)

* The calculation of equity based on Scandion Oncology's interim report Q3 2018 and the capital increase in Q4 2018.

** The calculation of equity based on Scandion Oncology's Q1 report 2019.

Since Scandion Oncology completed a rights issue in 2019 Saniona's holdings of shares and votes decreased from 29.17 % to 18.23 % and were reclassified from Investment in associate to Financial assets as of October 1, 2019.

Parent

Scandion Oncology is recognized at cost subject to potential impairments.

KSEK	Balance sheet	P/L effect
January 1, 2020	5,413	-
Divestment	-1,694	-
Amounts recognized in P/L	-	36,428
June 30, 2020	3,719	36,428

Group

Scandion Oncology is recognized in the balance sheet in accordance to the fair value and changes in fair value is recognized under Other comprehensive income.

KSEK	Balance sheet	Recognized in OCI
January 1, 2020	37,376	
Divestment	-38,122	
Amounts recognized in OCI	107,187	107,187
June 30, 2020	106,441	107,187

Note 9 Other long-term receivables

On July 4, 2017, Saniona acquired NeuroSearch's remaining interest in the preclinical and clinical assets, which Saniona acquired from NeuroSearch during the period 2012-2016. According to the previous agreements, Saniona was obliged to pay NeuroSearch a milestone payment of EUR 400,000 when the first preclinical program was tested in humans. In addition, Saniona was obliged to pay royalties on its product sales or a percentage of its licensing income in relation to the acquired clinical assets including the clinical development compounds, tesofensine and NS2359. According to the new agreement, Saniona has paid NeuroSearch a onetime cash payment of DKK 5.5 million. Following this, Saniona has no additional payment obligations to NeuroSearch. Saniona estimates that the onetime cash payment of DKK 5.5 million would have been payable to NeuroSearch within a four-year period under the previous agreements. Therefore, the amount will be expensed over a four-year period starting July 1, 2017. In 2020 the onetime cash payment has been expensed with SEK 1.0 million (SEK 1.0 million) and as June 30, 2020, the recorded value of the asset is SEK 1.9 (SEK 3.9 million).

Note 10 Convertible loan

Saniona entered into a convertible notes funding agreement with Nice & Green S.A on December 29, 2017. In January 2020, Saniona terminated the convertible notes funding agreement without having drawn any tranches under the extended agreement.

Note 11 Loan Formue Nord

On January 10, 2020, Saniona completed a private placement of SEK 25 million at SEK 25 per share to Formue Nord and entered into a loan facility agreement with Formue Nord entitling to draw loans in an aggregate amount of 25 MSEK.

Saniona's right to draw loans under the loan facility agreement was conditional upon that an extraordinary general meeting to be held on 7 February 2020 resolved to approve an issue of units (consisting of warrants in three different series) directed to the lenders and a rights issue of units (consisting of warrants in the same three series as issued to the lenders). The units in both the directed issue and the rights issue will be issued free of payment. February 7, 2020, the extraordinary general meeting resolved to approve the board of directors' resolution.

In March 2020 Saniona drew loans of SEK 25 million under the loan facility agreement. The loans raised under the loan facility agreement are subject to market interest rates and shall be repaid no later than February 7, 2021.

Note 12 Financial Instruments – Fair values

If not otherwise stated below we approximate the fair value with the carrying value on financial assets and liabilities as the time to maturity is short.

KSEK	Level 1		Level 2		Level 3	
	30 June 2020	31 December 2019	30 June 2020	31 December 2019	30 June 2020	31 December 2019
Financial assets and liabilities by fair value hierarchy level /for instruments measured at fair value/						
Equity investments	106,441	37,376	-	-	-	-
Warrants*	18,290	-	-	-	-	-

The Company 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.

Compared with 2019, no transfers have been made between the different levels in the hierarchy and no significant changes have been made to the measurement method.

* The warrants are valued with by the TO 2 and TO 3 trading price at Nasdaq at June 30, 2020.

Note 13 Right-of-use assets

KSEK	Rent facility	Equipment	Total
Right-of-use assets January 1, 2020	0	2,172	2,172
Additions	12,356*	-	12,356
Depreciations	-	-329	-329
Exchange rate adjustments	-	-84	-84
Right-of-use assets as of June 30, 2020	12,356	1,759	14,115

KSEK	Group
Non-current	10,053
Current	4,062
Lease liabilities	14,115

* New leasing contract has been signed regarding premises for Saniona A/S with commence date 1 June 2020.

New leasing contract has been signed regarding premises for Saniona Inc. with commence date 1 July 2020. The estimated lease liabilities will increase the balance sheet with SEK 9 million. This is not included in the table above.

Business terms - glossary

Alzheimer's disease

A chronic neurodegenerative disease that usually starts slowly and gets worse over time and accounts for 60% to 70% of cases of dementia. As the disease advances, symptoms can include problems with language, disorientation (including easily getting lost), mood swings, loss of motivation, not managing self-care, and behavioral issues. Gradually, body functions are lost, ultimately leading to death. The cause for most Alzheimer's cases is still mostly unknown except for 1% to 5% of cases where genetic differences have been identified. Several competing hypotheses exist trying to explain the cause of the disease.

Ataxia

A neurological sign consisting of lack of voluntary coordination of muscle movements. Ataxia is a non-specific clinical manifestation implying dysfunction of the parts of the nervous system that coordinate movement, such as the cerebellum. Several possible causes exist for these patterns of neurological dysfunction and they can be mild and short term or be symptoms of severe chronic diseases such as Friedreich's ataxia, which is an autosomal recessive inherited disease that causes progressive damage to the nervous system which manifests in initial symptoms of poor coordination that progresses until a wheelchair is required for mobility.

Atlas Venture

Atlas Venture Inc. For further details, please see description about Cadent Therapeutics under CAD-1883 in the Pipeline section.

BenevolentAI

BenevolentAI acquired Proximagen Ltd. in Q1 2017.

Boehringer Ingelheim

Boehringer Ingelheim GmbH. For further details, please see the Boehringer Program in the Pipeline section.

Cadent Therapeutics

Cadent Therapeutics was established in March 2017 through a merger between Saniona's spin-out company, Ataxion, and Luc Therapeutics.

Chronic itching

Chronic itching (also known as pruritus) is defined as an unpleasant sensation that provokes the desire to scratch. Prolonged itching and scratching may increase the intensity of the itch and lead to skin injury, infection and scarring. The possible causes are numerous and include dry skin, skin disorders such as eczema and psoriasis, infections such as chicken pox and scabies, underlying illness such liver disease, kidney failure and cancers, nerve disorders such as multiple sclerosis and diabetes mellitus, and allergic diseases including allergic reactions to medications such as antibiotics and chemotherapy. For some patients, there's no known cause. Chronic itching ranges in intensity from a mild annoyance to a disabling condition. The constant need to scratch can be as debilitating as chronic pain. Depending on the underlying cause, the current treatment options include moisturizing cream, antihistamines, corticosteroids, local anesthetics, calcineurin inhibitors and antidepressants. Many patients experience only a partial relief whereas others have no relief from existing treatment options.

CNS

Central Nervous System, a part of the nervous system consisting of the brain and spinal cord.

Cocaine addiction

The compulsive craving for use of cocaine despite adverse consequences.

Colitis

An inflammation of the inner lining of the colon. There are numerous causes of colitis including infection, inflammatory bowel disease (Crohn's disease, ulcerative colitis), ischemic colitis, allergic reactions, and microscopic colitis. Symptoms depend upon the cause and may include abdominal pain, cramping and diarrhea.

Crohn's disease

An IBD which causes inflammation of the digestive tract, which can lead to abdominal pain, severe diarrhea, fatigue, weight loss and malnutrition. Inflammation caused by Crohn's disease can involve different areas of the digestive tract in different people.

CTA

Clinical Trial Application which a pharmaceutical company file to EMA to obtain permission to ship and test an experimental drug in Europe before a marketing application for the drug has been approved. The approved application is called an Investigational New Drug (IND) in the US.

EMA

European Medicines Agency

Epilepsy

Epilepsy is a central nervous system (neurological) disorder in which brain activity becomes abnormal, causing seizures or periods of unusual behavior, sensations, and sometimes loss of awareness. Treatment with medications or sometimes surgery can control seizures for most people with epilepsy. Some people require lifelong treatment to control seizures, but for others, the seizures eventually go away.

Essential tremor

Essential tremor is the most common movement disorder with a prevalence of 4% in persons age 40 and older and considerably higher among persons in their 60s, 70s, 80s and 90s. It typically involves a tremor of the arms, hands or fingers but sometimes involving the head, vocal cords or other body parts during voluntary movements such as eating and writing. Although essential tremor is often mild, people with severe tremor have difficulty performing many of their routine activities of daily living.

Fatty liver disease (NASH)

Nonalcoholic steatohepatitis (NASH), or fatty liver disease, is a form of nonalcoholic fatty liver disease (NAFLD) in which a patient has hepatitis - inflammation of the liver - and liver cell damage, in addition to fat in the liver. Inflammation and liver cell damage can cause fibrosis, or scarring, of the liver. NASH may lead to cirrhosis or liver cancer.

FDA

US Food and Drug Administration

GABAA α 2/ α 3 program

A small molecule program which is designed to positively modulate (PAM) GABA-A α 2 and GABA-A α 3 ion channels, which are expressed in various central and peripheral neurons and are believed to be key mediator in the control of pain signaling and the control of anxiety.

Hypothalamic obesity (HO)

A common sequel to tumors of the hypothalamic region and their treatment with surgery and radiotherapy. Weight gain results from damage to the ventromedial hypothalamus which leads, variously, to hyperphagia, a low metabolic rate, autonomic imbalance, growth hormone deficiency and various other problems that contribute to weight gain.

IK program

A small molecule program which is designed to inhibit IK channels, which are expressed by immune cells and believed to be key mediator of inflammation in auto inflammatory diseases such as inflammatory bowel diseases.

IND

Investigational New Drug is a program by which a pharmaceutical company obtains permission to ship and test an experimental drug in the U.S. before a marketing application for the drug has been approved. In Europe, the application is called a Clinical Trial Application (CTA).

Inflammatory bowel disease (IBD)

IBD is an umbrella term used to describe disorders that involve chronic inflammation of the digestive tract. Types of IBD include ulcerative colitis and Crohn's disease.

Ion channel

Channels or pores in cell membranes which is made up of unique protein classes. Ion channels controls muscles and nerves and are central to the function of the body by governing the passage of charged ions across cell membranes.

Ion channel modulators

A drug which modulates the function of ion channels by blocking or opening ion channels or by decreasing or increasing throughput of ion channels. Agonists opens ion channels, Antagonists blocks ion channels, PAMs

(Positive Allosteric Modulators) increase throughput whereas NAMs (Negative Allosteric Modulators) decrease throughput of ion channels.

Kv7 programs

Saniona's Kv7 programs focus on developing effective new treatments for neurological diseases, such as treatment-resistant partial epilepsy, and various pain disorders. Furthermore, we have demonstrated that activators of the Kv7 family of potassium channels are also efficacious for relaxation of overactive bladder smooth muscle cells, a characteristic of urinary incontinence (UI).

Major Depressive Disorders

A mental disorder characterized by a pervasive and persistent low mood that is accompanied by low self-esteem and by a loss of interest or pleasure in normally enjoyable activities.

Medix

Productos Medix, S.A de S.V. For further details, please see under tesofensine in the Pipeline section.

Metoprolol

Metoprolol is a medication of the selective β 1 receptor blocker type, which work by blocking the neurotransmitter norepinephrine and epinephrine from binding to receptors. It is used to treat high blood pressure, chest pain due to poor blood flow to the heart, and several conditions involving an abnormally fast heart rate. It is also used to prevent further heart problems after myocardial infarction and to prevent headaches in those with migraines.

Multiple sclerosis

A demyelinating disease in which the insulating covers of nerve cells in the brain and spinal cord are damaged by the immune system. This damage disrupts the ability of parts of the nervous system to communicate, resulting in a wide range of signs and symptoms including physical, mental, and sometimes psychiatric problems.

Neuropathic pain

Pain caused by damage or disease affecting the somatosensory nervous system. Central neuropathic pain is found in spinal cord injury, multiple sclerosis, and some strokes. Aside from diabetes (diabetic neuropathy) and other metabolic conditions, the common causes of painful peripheral neuropathies are herpes zoster infection, HIV-related neuropathies, nutritional deficiencies, toxins, remote manifestations of malignancies, immune mediated disorders and physical trauma to a nerve trunk. Neuropathic pain is also common in cancer as a direct result of cancer on peripheral nerves (e.g., compression by a tumor), or as a side effect of chemotherapy, radiation injury or surgery. Neuropathic pain is often chronic and very difficult to manage with some 40-60% of people achieving only partial relief.

Nic α 6 program

The Nic α 6 program is a small molecule program designed to positively modulate (PAM) the α 6 ion channels. The α 6 subtype exhibits an extremely localized expression mainly confined to dopaminergic neurons in the area of the brain affected in Parkinson's disease patients, where they act as important regulators of dopamine signaling.

NS2359

A triple monoamine reuptake inhibitor, which blocks the reuptake of dopamine, norepinephrine, and serotonin in a similar manner to cocaine. However, NS2359 dissociates slowly from these transporters and has a long human half-life (up to 10 days) which makes frequent dosing unnecessary. NS2359's pharmacological profile means that it may be able to reduce cocaine withdrawal symptoms, reduce cocaine craving and reduce cocaine-induced euphoria. In preclinical trials, NS2359 has been shown to reduce the reinforcing effects of cocaine and may have effects on cue induced drug craving. Furthermore, human trials with NS2359 have shown that NS2359 has little or no abuse potential and does not have adverse interactions with cocaine.

Obesity

A medical condition in which body fat has accumulated to an extent that it may have a negative effect on health. Obesity is most commonly caused by a combination of excessive food intake, lack of physical activity and genetic susceptibility. A few cases are caused primarily by genes, endocrine disorders, medications or mental disorder.

Parkinson's disease

Parkinson's disease (PD) is a neurodegenerative disorder that affects predominately dopamine-producing neurons in a specific area of the brain called substantia nigra. Symptoms generally develop slowly over years and may include tremors, bradykinesia, limb rigidity and gait and balance problems. The cause remains largely unknown and there is still no cure.

Pharmacodynamics (PD)

Pharmacodynamics is the study of the biochemical and physiologic effects of a drug in the body including the relationship between the drug concentration and the desirable effects as well as the undesirable effects.

Pharmacokinetics (PK)

Pharmacokinetics is the study of how the body affects a drug including the relationship between the dosed amount of a drug and the obtained blood concentration of the drug.

Prader-Willi syndrome (PWS)

Prader-Willi syndrome is a complex genetic condition that affects many parts of the body. In infancy, this condition is characterized by weak muscle tone (hypotonia), feeding difficulties, poor growth, and delayed development. Affected individuals develop an insatiable appetite, which leads to chronic overeating (hyperphagia) and obesity. Some people with Prader-Willi syndrome, particularly those with obesity, also develop type 2 diabetes.

SAN711

SAN711 is a selective GABAA $\alpha 3$ modulator (PAM), which increases the activity of the GABAA receptor protein in the vertebrate central nervous system. It is derived from Saniona's advanced ion channel platform and has demonstrated strong efficacy in rodent itching and pain models. SAN711 is ready for Phase 1 clinical testing.

SAN903

SAN903 is a selective IK channel modulator, which inhibits the potassium outflux from cells through the IK channels, which are expressed by immune cells and believed to be key mediator of inflammation in auto inflammatory diseases such as inflammatory bowel diseases.

Schizophrenia

A mental disorder often characterized by abnormal social behavior and failure to recognize what is real. Common symptoms include false beliefs, unclear or confused thinking, auditory hallucinations, reduced social engagement and emotional expression, and lack of motivation.

Tesofensine

A triple monoamine reuptake inhibitor, which is positioned for obesity and type 2 diabetes, two of the major global health problems. Tesofensine has been evaluated in Phase 1 and Phase 2 human clinical studies with the aim of investigating treatment potential with regards to obesity, Alzheimer's disease and Parkinson's disease. Tesofensine demonstrated strong weight reducing effects in Phase 2 clinical studies in obese patients.

TRC

The University of Pennsylvania Treatment Research Center.

Type 2 diabetes

A metabolic disorder that is characterized by hyperglycemia (high blood sugar) in the context of insulin resistance and relative lack of insulin. This contrasts with diabetes mellitus type 1, in which there is an absolute lack of insulin due to breakdown of islet cells in the pancreas. The classic symptoms are excess thirst, frequent urination, and constant hunger. Type 2 diabetes makes up about 90% of cases of diabetes, with the other 10% due primarily to diabetes mellitus type 1 and gestational diabetes. Obesity is thought to be the primary cause of type 2 diabetes in people who are genetically predisposed to the disease.

Urinary incontinence (UI)

UI, or the loss of bladder control, is a common and often embarrassing problem. It is not a disease, but rather a symptom of many conditions. Many factors increase risk, for example aging, pregnancy, prostate problems and obesity.

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