

Saniona A/S
Baltorpvej 154
2750 Ballerup
Central Business Registration No 34049610

Annual Report 2018

The Annual General Meeting adopted the annual report on

Chairman of the General Meeting



Name: Thomas Feldthus

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Entity details

Saniona A/S

Baltorpvej 154

2750 Ballerup

Central Business Registration No: 34049610

Registered in: Ballerup

Financial year: 01.01.2018 – 31.12.2018

Board of Directors

Joseph Donald deBethizy, Chairman

Claus Tycho Bræstrup

Karl Johan Bertil Sundberg

Anna Helena Constance Ljung

Jørgen Drejer

Executive Board

Jørgen Drejer, CEO

Thomas Feldthus, CFO

Auditors

Deloitte Statsautoriseret Revisionspartnerselskab

Weidekampsgade 6

P.O. Box 1600

0900 Copenhagen C

Statement by Management on the annual report

The Board of Directors and the Executive Board have today considered and approved the annual report of Saniona A/S for the financial year 01.01.2018 - 31.12.2018.

The annual report is presented in accordance with the Danish Financial Statements Act.


In our opinion, the financial statements give a true and fair view of the Entity's financial position at 31.12.2018 and of the results of its operations for the financial year 01.01.2018 - 31.12.2018.

We believe that the management commentary contains a fair review of the affairs and conditions referred to therein.


We recommend the annual report for adoption at the Annual General Meeting.

Ballerup, 30.04.2019

Executive Board




Jørgen Drejer
CEO

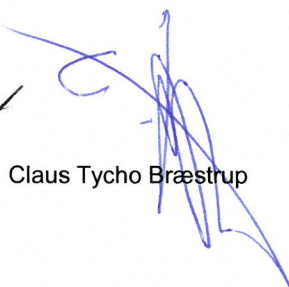


Thomas Feldthus
CFO

Board of Directors



Joseph Donald deBethizy
Chairman



Claus Tycho Bræstrup



Karl Johan Bertil Sundberg



Jørgen Drejer



Anna Helena Constance Ljung

Independent auditor's report

To the shareholders of Saniona A/S

Opinion

We have audited the financial statements of Saniona A/S for the financial year 01.01.2018 - 31.12.2018, which comprise the income statement, balance sheet, statement of changes in equity and notes, including a summary of significant accounting policies. The financial statements are prepared in accordance with the Danish Financial statements Act.

In our opinion, the financial statements give a true and fair view of the Entity's financial position at 31.12.2018 and of the results of its operations and cash flows for the financial year 01.01.2018 - 31.12.2018 in accordance with the Danish Financial statements Act.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs) and additional requirements applicable in Denmark. Our responsibilities under those standards and requirements are further described in the Auditor's responsibilities for the audit of the financial statements section of this auditor's report. We are independent of the Entity in accordance with the International Ethics Standards Board of Accountants' Code of Ethics for Professional Accountants (IESBA Code) and the additional requirements applicable in Denmark, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Management's responsibilities for the financial statements

Management is responsible for the preparation of financial statements that give a true and fair view in accordance with the Danish Financial statements Act, and for such internal control as Management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, Management is responsible for assessing the Entity's ability to continue as a going concern, for disclosing, as applicable, matters related to going concern, and for using the going concern basis of accounting in preparing the financial statements unless Management either intends to liquidate the Entity or to cease operations, or has no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark, we exercise professional judgement and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Entity's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by Management.
- Conclude on the appropriateness of Management's use of the going concern basis of accounting in preparing the financial statements, and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Entity's ability to continue as a going concern.

concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Entity to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures in the notes, and whether the financial statements represent the underlying transactions and events in a manner that gives a true and fair view.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Statement on the management commentary

Management is responsible for the management commentary.

Our opinion on the financial statements does not cover the management commentary, and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the management commentary and, in doing so, consider whether the management commentary is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

Moreover, it is our responsibility to consider whether the management commentary provides the information required under the Danish Financial statements Act.

Based on the work we have performed, we conclude that the management commentary is in accordance with the financial statements and has been prepared in accordance with the requirements of the Danish Financial statements Act. We did not identify any material misstatement of the management commentary.

Ballerup, 30.04.2019

Deloitte

Statsautoriseret Revisionspartnerselskab

Central Business Registration No: 33963556



Thomas Hermann

State Authorised Public Accountant

Identification number (MNE) 26740

Management commentary

Primary activities

The object of the company is research and development in the pharmaceutical industry and thus related activity.

Development in activities and finances

Annual results are a natural time to take stock on the events of the past year, and on the many successes that underpin the development of Saniona as a biotech company focused on the treatment of diseases of the central nervous system and eating disorders. We are developing and commercializing treatments for orphan indications such as Prader-Willi syndrome and hypothalamic obesity and are rapidly advancing programs based on our ion channel technology platform, which can also address larger indications. Our aim is to be as capital-efficient as possible - retaining ownership of orphan disease programs, while seeking partnerships for larger disease areas.

A particular highlight of the year is that our partner Medix successfully completed a Phase 3 registration trial for tesofensine in obesity. The results are deeply impressive: 10% average weight loss in 24 weeks, more than half of patients losing more than 10% in weight, and a statistically significant reduction in key obesity-related risk factors. Medix, which owns commercial rights in Mexico and Argentina, will now prepare regulatory filings in those countries, which we expect to be filed in H1 2019 with launch in 2020. As Saniona holds all rights to these data and all other commercial rights to tesofensine in the rest of the world, we believe this program has significant upside.

Seven out of 10 Mexicans are categorized as overweight or obese, more than twice the worldwide average, and eight in 10 deaths are caused by chronic, non-communicable diseases that to a large degree are linked to the overweight and obese population. This trial provides validation of tesofensine as a potentially highly efficacious treatment for obesity and may bring a significant double-digit royalty stream in both Mexico and Argentina to help fund our broad pipeline.

Tesomet development

The strong Phase 3 results also support development of Saniona's wholly-owned Tesomet, a fix-dosed combination of tesofensine and metoprolol in Phase 2 for rare eating disorders. From this and previous studies, we know that the product reduces appetite and provides a significant and clinically meaningful weight loss.

We have obtained proof of concept in the first part of our Phase 2a study of Tesomet in PWS, key opinion leaders strongly support further development, and we are now working to establish the optimal dose. PWS is a significant commercial opportunity, with 20,000 patients in the US and Europe combined, short time to market and potential premium pricing as an orphan drug.

Data showed the clearance of tesofensine is much slower in this patient group than in the general population, and that PWS patients consequently should be given a lower dose to obtain the same blood concentration and effect as seen in normal obese patients. Therefore, in the second part of the study in adolescent PWS patients we initially gave a conservative dose, a quarter of that given to adult PWS patients during the first part of the study. Since this did not result in the required plasma concentration, we are now continuing at a double dose in this dose optimization study (equivalent to half of that given to adult PWS patients).

Based on the strong efficacy on both hyperphagia and weight seen in the first part of the study in adult PWS patients, and the successful Phase 3 trial of tesofensine, the active ingredient in Tesomet, we are confident that Tesomet holds the potential of treating debilitating hyperphagia and significantly reduce weight in this severely underserved population.

Phase 2a in hypothalamic obesity (HO)

In parallel with PWS, we are exploring the potential for Tesomet in HO and have initiated a Phase 2a study in March 2019. This study will include up to 25 patients, who will receive treatment or placebo for 24 weeks followed by an open-label extension, where all patients will receive Tesomet for 24 weeks. We expect results from the double-blind part of the study in Q4 2019 and the full data in H1 2020.

The two rare eating disorders, PWS and HO, have several factors in common, including clinical symptoms, clinical trial design, regulatory advantages from potential orphan drug designation and premium pricing as well as fast time to market due to relative short and small clinical studies.

There are no valid data about prevalence in HO, which most often occurs following surgical removal of craniopharyngioma, a benign brain tumor, with a reported incidence of 1/50,000. The number of patients is probably

half those with PWS, since not all patients with craniopharyngioma develop hyperphagia and associated obesity, but this is still an interesting market due to potential premium pricing under orphan drug status.

The objective is to prepare Tesomet for pivotal Phase 2b/3 studies in at least one of the two indications, PWS and HO, during 2019 and start such pivotal studies in 2020.

We have also successfully completed two Phase 1 studies and an additional preclinical toxicology study for Tesomet. The results from these trials, together with the long-term toxicology studies, provide more flexibility in designing clinical studies (extension of ongoing PWS study and 6-12 months studies in HO) and pave the way for pivotal Phase 2b/3 trials.

Progress in early pipeline

The early-stage pipeline is progressing rapidly into the clinic and our partnerships are proving fruitful, both in the long- and short-term, providing important non-dilutive funding for our own programs.

SAN711, a new and potentially game-changing treatment of neuropathic pain and itching, which comes from our advanced ion channel platform, has successfully completed preclinical development. Preparations for Phase 1 clinical trials are underway and may start during summer 2019, either internally or together with a potential partner. Preclinical data for SAN711 are very compelling and we believe it has the potential to become a first-line treatment in patients suffering from severe untreatable itching conditions and neuropathic pain disorders. There is a significant unmet medical need and a significant commercial opportunity in rare itching disorders for which we may potentially pursue accelerated development, for example in Brachioradial pruritus.

We received a €4 million milestone payment from Boehringer Ingelheim following selection of a clinical candidate for schizophrenia, bringing the total Saniona has received from this agreement to €9 million. Boehringer Ingelheim is conducting IND-enabling studies to initiate clinical studies.

Cadent Therapeutics raised \$40 million to support the development of their lead compound, CAD-1883, which comes from a collaboration with Saniona. Cadent initiated a Phase 1 study in Q1 2018, have already started a Phase 2a study for in essential tremor, and expects to start another Phase 2a study for Ataxia in H2 2020. Saniona holds an ownership stake in Cadent of 3.4% and will receive royalties on CAD-1883 if it reaches the market.

The IK program has also made significant progress during the year and we hope to soon be able to present a clinical candidate for IND enabling studies. This is a new concept in inflammatory and autoimmune diseases, and we have strong data in models for Crohn's disease and ulcerative colitis, the indications in which we are most likely to develop it in collaboration with a partner. The concept may also be developed for rare diseases, potentially internally. Overall, we believe it represents an important asset for Saniona.

Finally, we have been granted SEK 1.4 million by the Danish Innovation Fund (DIF) for the development of our Kv-7 program, which could lead to a potential new treatment within urinary incontinence, pain and epilepsy, including rare types of epilepsy where there is a genetic link to Kv-7 channels and where there are currently no good treatment options.

As you can see from the above, Saniona is developing rapidly. We are at the cusp of the approval of our first major product – tesofensine, and moving a large number of promising products through value inflection points. I am deeply grateful for the efforts and commitment of our team, shareholders and partners who are supporting our efforts. This year has been a very exciting one, and I am very much looking forward to continuing our journey through 2019 and beyond.

In 2018, the company reported revenues of DKK 39,538 thousand and net loss before tax of DKK 33,342 thousand.

The company had negative equity of DKK 63,607 thousand at the end of 2018. The company is financed through loans from the parent company and collaboration agreements.

At 31 December 2018, the group had SEK -63,607 thousand in equity and SEK 29,973 thousand in cash and cash equivalents.

Group relations

The company became part of a group on 30 January 2014, where the parent company, Saniona AB, acquired 100 % of the shares in the company. Saniona AB does not have any business other than owning shares in the company. The group is listed on Nasdaq Stockholm First North Premier. The group's share is traded under the ISIN code SE0005794617. The group is a research and development company focused on drugs for diseases of the central nervous system, autoimmune diseases, metabolic diseases and treatment of pain.

Events after the balance sheet date

- In January, Saniona initiated an open label extension study in the second part of its Phase 2a study of Tesomet comprising nine adolescent patients with PWS. The treatment with a dose of 0.125 mg/day appeared to be well tolerated but did not achieve sufficient plasma levels known to be efficacious in previous Phase 2 and Phase 3 studies. Saniona has now filed and received approval to increase the dose to 0.25 mg/day in the Czech Republic; approval in Hungary is pending. The first patients are expected to be switched to the 0.25 mg dose in March and the study is scheduled to continue until the end of June.
- Saniona's partner University of Pennsylvania Treatment Research Center plans to continue the investigator-initiated study with NS2359 for cocaine addiction at a higher dose following their interim analysis.
- Saniona successfully completed a full regulatory toxicological program for its first in class compound, SAN711, which offers a new treatment paradigm for itching and neuropathic pain. Saniona has scaled-up the manufacturing process, produced the material for clinical studies and the program is now ready for Phase 1 studies.
- Saniona recruited the first patients in a Phase 2 clinical study of Tesomet to treat the rare eating disorder hypothalamic obesity. The trial comprises a total of up to 25 patients and is conducted at Rigshospitalet in Copenhagen, Denmark.

Income statement for 2018

DKK	Notes	2018	2017
Revenue		39,537,696	16,005,672
Costs of raw materials and consumables		(2,773,928)	(2,356,718)
Other external expenses		(54,538,910)	(34,207,017)
Gross profit/loss		(17,775,142)	(20,558,063)
Staff costs	1	(15,954,064)	(16,530,956)
Depreciation, amortization and impairment losses		(461,162)	(432,560)
Operating profit/loss		(34,190,368)	(37,521,579)
Other financial income		2,318,678	980,172
Other financial expenses		(1,469,947)	(941,920)
Profit/loss before tax		(33,341,637)	(37,483,327)
Tax on profit/loss for the year	2	5,366,810	5,489,603
Profit/loss for the year		(27,974,827)	(31,993,724)
Proposed distribution of profit/loss			
Retained earnings		(27,974,827)	(31,993,724)
		(27,974,827)	(31,993,724)

Balance sheet at 31.12.2018

DKK	Notes	2018	2017
Other fixtures and fittings, tools and equipment		1,313,300	958,262
Leasehold improvements		24,589	74,645
Property, plant and equipment	3	1,337,889	1,032,907
Other receivables		2,906,072	4,550,391
Deferred tax		44,809	67,415
Fixed asset investments		2,950,881	4,617,806
Fixed assets		4,288,770	5,650,713
Trade receivables		1,521,282	5,427,433
Other receivables		3,195,157	2,373,208
Income tax receivable		5,500,000	5,500,000
Prepayments		507,669	336,125
Receivables		10,724,108	13,636,766
Cash		29,973,070	3,925,841
Current assets		40,697,178	17,562,607
Assets		44,985,948	23,213,320

Balance sheet at 31.18.2018

DKK	Notes	2018	2017
Contributed capital		501,000	501,000
Other reserves		1,623,265	524,288
Retained earnings		(65,731,740)	(37,756,912)
Equity		(63,607,475)	(36,731,624)
Payables to group enterprises		81,702,997	52,207,046
Non-current liabilities other than provision		81,702,997	52,207,046
Trade payables		5,263,829	3,937,499
Income tax payable		0	0
Other payables		2,772,397	3,343,910
Deferred income		18,854,200	456,489
Current liabilities other than provisions		26,890,426	7,737,898
Liabilities other than provisions		108,593,423	59,944,944
Equity and liabilities		44,985,948	23,213,320
Unrecognized rental and lease commitments	4		
Contingent liabilities	5		
Related parties with controlling interest	6		

Statement of changes in equity for 2018

DKK	Contributed capital	Other reserves	Retained earnings	Total
Equity beginning of year	501,000	524,288	(37,756,912)	(36,731,624)
Other equity postings	-	1,098,976	-	1,098,976
Profit/loss of the year	-	-	(27,974,827)	(27,974,827)
Equity end of year	501,000	1,623,264	(65,731,739)	(64,607,475)

Notes

1. Staff costs

DKK	2018	2017
Wages and salaries	14,284,376	14,912,415
Pension costs	1,247,276	1,217,861
Other social security costs	44,507	32,227
Other staff costs	377,905	368,453
	15,954,064	16,530,956
Number of employees at balance sheet date	25	26

Share based payments

Share-based compensation expenses for the full year of 2018 totaled DKK 1,518 (359) thousand. 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 granted in 2015	Options granted in 2017	Options granted in 2018	Total
Share-based payment				
Outstanding at 1 January 2018	64,000	38,292	-	102,292
Granted during the period	-	-	331,016	331,016
Forfeited during the period	-	-	-	-
Outstanding at 31 December 2018	64,000	38,292	331,016	433,308

According to the table below, the Group had 433,308 options outstanding as of December 31, 2018. If all issued warrants are exercised for subscription of new shares, the Parent Company's will issue a total of 433,308 new shares corresponding to a dilution of approximately 1.82%.

Incentive program	2015	2017	2018:1	2018:2	2018:3
Allotted options	64,000	38,750	286,003	34,500	10,513
Fair value per option (SEK)	13.13	29.48	12.67	18.89	18.89
Share price for underlying shares (SEK)	19.90	45.50	26.95	33.85	33.85
Subscription price (SEK)	20.72	41.13	33.60	30.08	30.08
Vesting period	4 years	4 years	3 years	4 years	3 years
Estimated life of the option	4.50 years	5.50 years	6.25 years	5.5 years	4 years
Risk-free interest rate during the life of the option	0.2257%	-0.0584%	0.2389%	-0.0713%	-0.0713%
Assumed volatility*	91.29%	76.75%	57.41%	63.58%	63.58%
Expected dividends	0	0	0	0	0

* In 2015 and 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, the volatility equals a twelve-month period.

A detailed description of the warrant program in 2015 and 2017 can be found in the annual report 2017.

2018:1 On January 19, 2018, the extraordinary shareholders' meeting voted in favour of establishing an incentive program involving the allotment of a maximum of 217,625 options free of charge to the chairman of the board of directors, J. Donald deBethizy. Allotment of 217,625 options took place in March 2018. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 33.60. 25% of the options vested on January 19, 2018, when the holder was elected as chairman of the Board of Directors. The balance of the options is earned with 25% on each anniversary of the election as chairman of the Board of Directors over a period of 3 years. The holder can take advantage of assigned and earned stock options during 30 days from the day following the publication of the Group's quarterly reports, or in the case of full-year, the year-end report, the first time after publication of the quarterly report for the first quarter of 2021 and last time after publication of the quarterly report for the first quarter of 2024. In order to enable the Parent Company's delivery of shares under the option program and to secure social security charges which may arise in connection with the Option Program, the extraordinary shareholders' meeting resolved to issue a maximum of 286,003 warrants to a wholly owned subsidiary in the Group.

2018:2 The 2018 Annual General Meeting voted in favour of establishing an employee incentive program involving the allotment of a maximum of 34,500 options free of charge to certain employees and consultants of the Group. Allotment of 34,500 options took place in July 2018. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 30.08. The options are earned gradually over a period of 48 months. Holders can take advantage of assigned and earned stock options during 30 days from the day following the publication of the Group's quarterly reports, or in the case of full-year, the year-end report, the first time after publication of the quarterly report for the first quarter of 2022 and last time after publication of the quarterly report for the third quarter of 2023.

2018:3 The 2018 Annual General Meeting voted in favour of establishing an employee incentive program involving the allotment of a maximum of 8,000 options free of charge to certain members of the board of directors of the Group. Allotment of 8,000 options took place in July 2018. Each option entitles the holder to acquire one new share in Saniona for a subscription price of SEK 30.08. 1/3 of the options are vested when the annual shareholders' meeting takes place in 2019. Additional 1/3 of the options are vested when the annual shareholders' meeting takes place in 2020 and the last 1/3 of the options are vested when the annual shareholders' meeting takes place in 2021. The holder can take advantage of assigned and earned stock options during 30 days from the day following the publication of the Group's quarterly reports, or in the case of full-year, the year-end report, the first time after publication of the quarterly report for the first quarter of 2021 and last time after publication of the quarterly report for the first quarter of 2022. To enable the Parent Company's delivery of shares under the option program and to secure social security charges which may arise in connection with the Option Program, the extraordinary shareholders' meeting resolved to issue a maximum of 10,513 warrants to a wholly owned subsidiary in the Group.

The Board of Directors and Executive Management options in the Company as of December 31, 2018.

	Beginning	Granted	Total
Share-based payment			
Joseph Donald deBethizy, chairman of the board	-	217,625	217,625
Anna Helena Constance Ljung, board member	-	4,000	4,000
Karl Johan Bertil Sundberg, board member	-	4,000	4,000
Social security charges	-	70,891	70,891
Outstanding at 31 December 2018	0	296,516	296,516

2. Tax on profit/loss for the year

DKK	2018	2017
Tax on current year taxable income	(5,500,000)	(5,500,000)
Correction joined taxation	110,584	-
Change in deferred tax for the year	22,606	10,397
	(5,366,810)	(5,489,603)

3. Property, plant and equipment

DKK	Other fixtures and fittings, tools and equipment	Leasehold improvements
Costa beginning of year	3,128,635	250,276
Additions	766,143	0
Cost end of year	3,894,778	250,276
Depreciation and impairment losses beginning of the year	(2,170,373)	(175,631)
Depreciation for the year	(411,105)	(50,056)
Depreciation and impairment losses end of the year	(2,581,478)	(225,687)
Carrying amount end of year	1,313,300	24,589

4. Unrecognised rental and lease commitments

DKK	2018	2017
Hereof liabilities under rental or lease agreements until maturity in total	830,286	888,990

5. Contingent liabilities

DKK	2018	2017
Recourse and non-recourse guarantee commitments	39,000	39,000
Contingent liabilities in total	39,000	39,000

A bank guarantee of DKK 39 thousand has been issued to a third party.

The Entity serves as an administration company in a Danish joint taxation arrangement. According to the joint taxation provisions of the Danish Corporation Tax Act, the Entity is therefore liable from the financial year 2013 for income taxes etc. for the jointly taxed entities and from 1 July 2012 also for obligations, if any, relating to the withholding of tax on interest, royalties and dividends for these entities.

6. Related parties with controlling interest

The Company has registered the following shareholder to have the controlling interest of the company:

Saniona AB, Sverige, 100 %.

Accounting policies

Reporting class

This annual report has been presented in accordance with the provisions of the Danish Financial Statements Act governing reporting class B enterprises.

The accounting policies applied to these financial statements are consistent with those applied last year.

Recognition and measurement

Assets are recognized in the balance sheet when it is probable as a result of a prior event that future economic benefits will flow to the Entity, and the value of the asset can be measured reliably.

Liabilities are recognized in the balance sheet when the Entity has a legal or constructive obligation as a result of a prior event, and it is probable that future economic benefits will flow out of the Entity, and the value of the liability can be measured reliably.

On initial recognition, assets and liabilities are measured at cost. Measurement subsequent to initial recognition is effected as described below for each financial statement item.

Anticipated risks and losses that arise before the time of presentation of the annual report and that confirm or invalidate affairs and conditions existing at the balance sheet date are considered at recognition and measurement.

Income is recognized in the income statement when earned, whereas costs are recognized by the amounts attributable to this financial year.

Foreign currency translation

On initial recognition, foreign currency transactions are translated applying the exchange rate at the transaction date. Receivables, payables and other monetary items denominated in foreign currencies that have not been settled at the balance sheet date are translated using the exchange rate at the balance sheet date. Exchange differences that arise between the rate at the transaction date and the rate in effect at the payment date, or the rate at the balance sheet date are recognized in the income statement as financial income or financial expenses.

Income statement

Revenue

Revenue from the sale of manufactured goods and goods for resale is recognized in the income statement when delivery is made and risk has passed to the buyer.

Costs of raw materials and consumables

Costs of raw materials and consumables comprise the consumption of raw materials and consumables for the financial year after adjustment for changes in inventories of these goods from the beginning to the end of the year. This item includes shrinkage, if any, and ordinary writedowns of the relevant inventories.

Other external expenses

Other external expenses include expenses relating to the Entity's ordinary activities, including expenses for premises, stationery and office supplies, marketing costs, etc.

Staff costs

Staff costs comprise salaries and wages as well as social security contributions, pension contributions, etc. for entity staff.

Share-based incentive programmes

Share-based incentive programmes in which the employees are offered to buy shares in the immediate parent company (equity-settled share-based payment transactions) are measured at the fair value of the equity instruments at the time of granting and are recognized in the income statement under staff costs at the time of granting. The related counter entry is recognized directly in equity.

The fair value of the equity instruments is calculated using the Black-Scholes formula including the parameters defined in note 1.

Depreciation, amortization and impairment losses

Amortization, depreciation and impairment losses relating to intangible assets and property, plant and equipment comprise amortization, depreciation and impairment losses for the financial year, calculated on the basis of the residual values and useful lives of the individual assets and impairment testing as well as gains and losses from the sale of intangible assets as well as property, plant and equipment.

Other financial income

Other financial income comprises dividends etc. received on other investments, interest income, including interest income on receivables from group enterprises, net capital gains on securities, payables and transactions in foreign currencies, amortization of financial assets as well as tax relief under the Danish Tax Prepayment Scheme etc.

Other financial expenses

Other financial expenses comprise interest expenses, including interest expenses on payables to group enterprises, net capital losses on securities, payables and transactions in foreign currencies, amortization of financial liabilities as well as tax surcharge under the Danish Tax Prepayment Scheme etc.

Tax on profit/loss for the year

Tax for the year, which consists of current tax for the year and changes in deferred tax, is recognized in the income statement by the portion attributable to the profit for the year and recognized directly in equity by the portion attributable to entries directly in equity.

Balance sheet

Property, plant and equipment

Other fixtures and fittings, tools and equipment are measured at cost less accumulated depreciation and impairment losses.

Cost comprises the acquisition price, costs directly attributable to the acquisition and preparation costs of the asset until the time when it is ready to be put into operation.

The basis of depreciation is cost less estimated residual value after the end of useful life. Straight-line depreciation is made on the basis of the following estimated useful lives of the assets:

Other fixtures and fittings, tools and equipment	1-5 years
Leasehold improvements	5 years

For leasehold improvements and assets subject to finance leases, the depreciation period cannot exceed the contract period.

Items of plant and equipment are written down to the lower of recoverable amount and carrying amount.

Receivables

Receivables are measured at amortized cost, usually equaling nominal value less writedowns for bad and doubtful debts.

Deferred tax

Deferred tax is recognized on all temporary differences between the carrying amount and tax-based value of assets and liabilities, for which the tax-based value of assets is calculated based on the planned use of each asset.

Deferred tax assets, including the tax base of tax loss carryforwards, are recognized in the balance sheet at their estimated realizable value, either as a set-off against deferred tax liabilities or as net tax assets.

Income tax payable or receivable

Current tax payable or receivable is recognized in the balance sheet, stated as tax computed on this year's taxable income, adjusted for prepaid tax.

Prepayments

Prepayments comprise incurred costs relating to subsequent financial years. Prepayments are measured at cost.

Cash

Cash comprises cash in hand and bank deposits.

Other financial liabilities

Other financial liabilities are measured at amortized cost, which usually corresponds to nominal value.

Deferred income

Deferred income comprises income received for recognition in subsequent financial years. Deferred income is measured at cost.