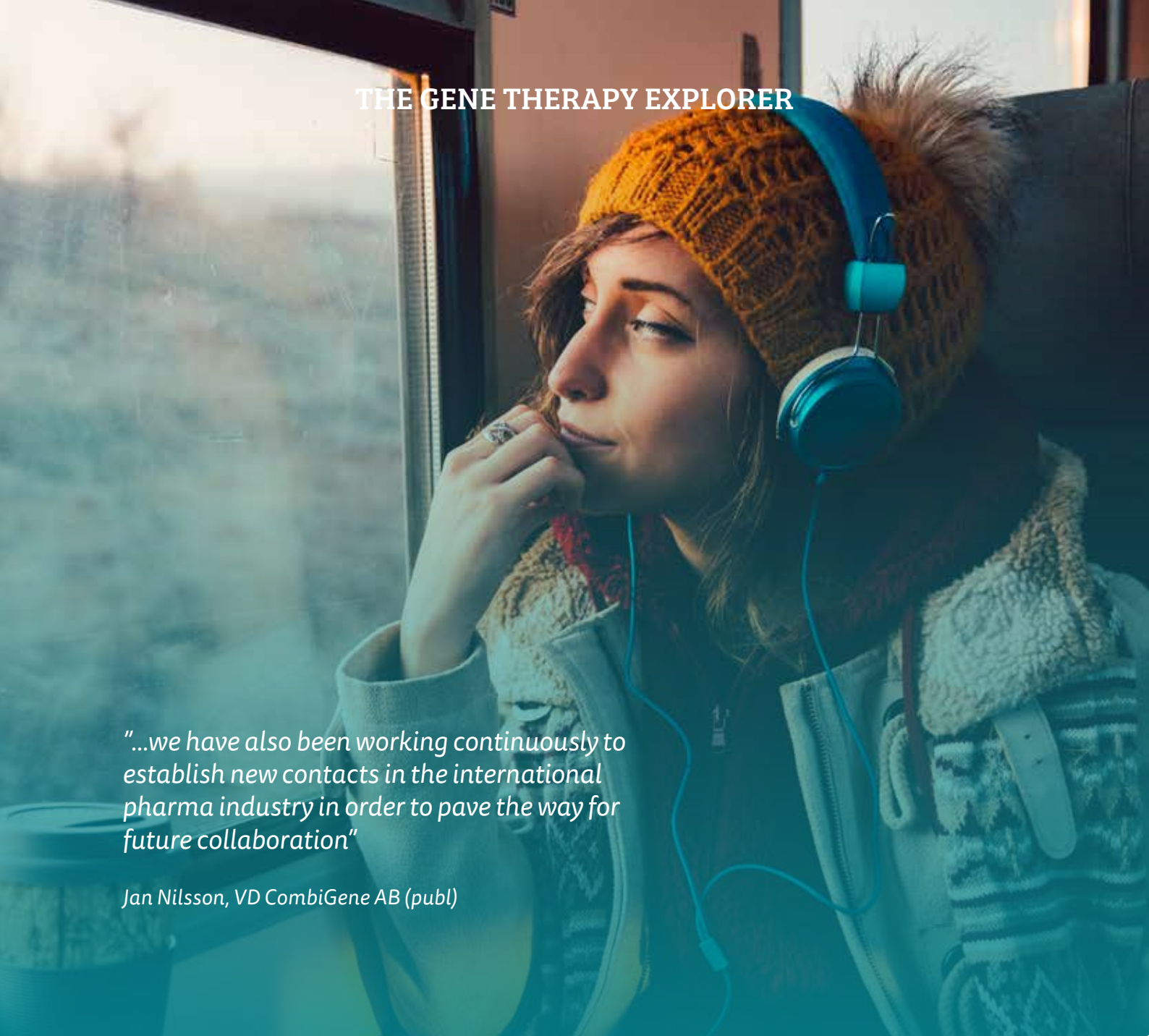
THE GENE THERAPY EXPLORER



"...we have also been working continuously to establish new contacts in the international pharma industry in order to pave the way for future collaboration"

Jan Nilsson, VD CombiGene AB (publ)

Interim Report

January-March 2019 for CombiGene AB (publ)

CombiGene

Interim Report January-March 2019 for CombiGene AB (publ)

First quarter January - March 2019

- Nets sales: TSEK 0 (0).
- Other operating revenues TSEK 1,635 (50).
- Profit from financial items: TSEK -2,471 (-1,999).
- Earnings per share: SEK -0.05 (-0.12)
- Liquidity as per the end of the reporting period: TSEK 28,228 (4,604)
- Equity/assets ratio as per the end of the reporting period: 58.50 (84.90) %

Operations during the first quarter of 2019

- During the first quarter CombiGene has presented the company on several occasions, among others, at the Stockholm Corporate Finance 11th Life Science Seminar and at Aktiedagen in Lund.
- CombiGene has also received mention in periodicals including Sydsvenskan and BioStock.
- World Epilepsy Day, 11 February, was observed with a lecture by one of CombiGene's scientific founders, Professor Merab Kokaia, and his doctoral student, Esbjörn Melin.
- The Spotlight Stock Market Disciplinary Committee deemed that CombiGene AB (publ) was in breach of its member rules and ordered the company to pay a fine corresponding to one year's annual fee. The breach was due to the company's misinterpretation of the Annual General Meeting's approval of an issue, believing that it referred not only to shares, but also warrants. When the error was noted, the board acted immediately, calling an extraordinary meeting of shareholders, which also approved the issue of warrants. The company incurred no financial loss, as the cost was assumed by an advisor to the company.

Significant events after the end of the reporting period

- CombiGene has submitted a public takeover bid to holders of shares and warrants of series TO1 in Panion Animal Health AB (publ).

CombiGene AB – The Gene Therapy Explorer

CombiGene's business concept is to develop effective gene therapies for treatment of difficult-to-treat diseases for which adequate treatment methods are currently lacking. The company intends to take its candidate drugs through the phases of preclinical development and initial clinical studies under its own management, and subsequently continue development and commercialization under its own management or in collaboration with other partners.

CombiGene's epilepsy project
CombiGene has demonstrated in preclinical studies that the company's candidate drug, CG01, can prevent epileptic seizures. The company is currently focussing on completing the advanced process development for CG01, including the obligatory biodistribution and toxicity studies that are necessary before clinical studies can be initiated.

The treatment method is based on a viral vector that delivers receptors to the brain and on findings from research conducted at Lund University and the University of Copenhagen.

Dynamic research environment
Founded on the basis of scientific discoveries made at Lund University and the University of Copenhagen, CombiGene has offices at Medicon Village in Lund, Sweden.

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A word from the CEO

The first quarter of 2019 involved continued intensive work with our candidate drug, CG01. The focus is now on process development and preparations for the very important toxicology and biodistribution studies. Among other things, this means that we are now approaching selection of the CMO (Contract Manufacturing Organisation) which will produce the GMP-classed (Good Manufacturing Practice) material for coming studies, and the CRO (Contract Research Organisation), which on our behalf will conduct the safety studies in animals which are necessary before clinical trials can begin. After the close of the quarter CombiGene submitted a public takeover bid to holders of shares and warrants of series TO1 in Panion Animal Health AB (publ). The purpose of the offer is to take advantage of the practical and financial synergies in our development processes and partnering.

Public takeover bid presented to holders of shares and warrants in Panion
I am very impressed by Panion's development in recent years and I am convinced that the time for the transaction is optimal, given the potential for practical and financial synergies in our development processes and partnering.

When Panion was distributed to CombiGene's shareholders in 2016 the motive was that a separate and dedicated veterinary medical company would be able to take the product to market faster. Since then, both CombiGene and Panion have gained considerable experience in the gene therapy field via their respective development programmes. This means that we foresee synergies and that the possibilities for success are considerably greater if the projects are managed under one company instead of two. I am also convinced that the proposed transaction will make the company even more attractive in the eyes of a strategic partner.

The most important synergies are in the wholly decisive areas of quality and regulatory issues. Acquisition of Panion will also give us coherent control over our intellectual property rights, which means a very great deal with respect to potential partners.

Since Panion's shareholders are offered shares in CombiGene in exchange, the shareholders will benefit from all synergies resulting from the transaction. The bid will potentially result in greater long-term value for all shareholders.

CombiGene's business development
CombiGene's business development strategy is twofold. While we are actively seeking interesting new gene therapy projects that match CombiGene's business, for several years we have also been working continuously to establish new contacts in the international pharma industry in order to pave the way for future collaboration. These discussions are ongoing, above all, at various types of conferences and congresses. We recently participated in the Cell & Gene Meeting on the Med conference in Barcelona, Spain, and later this spring CombiGene will take part in the 4th Biotech Hanse Forum in Stockholm and the BIO International Convention in Philadelphia.

During 2018 we identified several academic groups that are working with gene therapy solutions which, in the long term, could prove interesting for us. However, it is too soon to say with any certainty exactly when any possible collaboration will be initiated.

Jan Nilsson, CEO

Comments from our Chief Research and Development Officer

CG01 – update
The level of activity in the CG01 project remains high. Here are a few of the most important activities conducted during the quarter:

- Work at CGT Catapult was ramped up during the quarter. In addition to work with the ongoing development of analysis methods, CGT Catapult has also begun process development for manufacturing of CG01.
- Focus has also been placed on assessing several of the CMOs (Contract Manufacturing Organisations), one of which will produce the GMP-classed (Good Manufacturing Practice) material for coming safety studies in animals and the first clinical study.
- Our new colleague Annika Ericsson has assumed responsibly from day one and done a fantastic job with detailed planning of the coming safety study in animals, as well as assessing an appropriate CRO (Contract Research Organisation) for conducting the study. This work is vitally important, since this study is mandatory before we can begin our first clinical study.
- Tentative preparations for the initial clinical study have begun, since we hired a British consultant to arrange a meeting with clinics in the UK in order to gain an understanding of the situation for therapy-resistant epilepsy patients in the UK. The consultant has considerable experience of clinical studies and gene therapy projects, having worked with both large pharmaceutical companies and biotech firms. Together with our consultant, we planned and held the first meeting with epilepsy specialist physicians and neurosurgeons in the UK in early April.

Karin Agerman
Chief Research and Development Officer

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The CG01 project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 823282

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Gene therapy attracts great interest

Gene therapy is currently one of the most exciting areas of pharmaceutical development. At the start of Q4 2018, 362 clinical studies were under way, of which 32 had reached phase III, the final clinical phase before market approval. The focus of the clinical studies is on oncological diseases, cardiovascular diseases and diseases related to the central nervous system. Investment in gene therapy amounted during 2018 to USD 9.7 billion.

The great interest in gene therapy on the part of both researchers and investors is explained by the unique advantages that gene therapy offers. First of all, gene therapy can potentially treat diseases for which adequate treatment methods are currently lacking. Secondly, after only one or a few treatments, gene therapy can have a long-term and, possibly, lifelong effect, as compared to conventional drugs, which often must be taken several times daily for the rest of the patient's life.

That gene therapy is one of the most interesting areas of pharmaceutical development is also confirmed by successes in recent years in the USA. On August 30th 2017 the US Food and Drug Administration (FDA) approved the first gene-therapeutic drug for the US market. Since then, other gene therapies have also been approved. The FDA has also demonstrated great confidence in gene therapy by simplifying the regulatory framework for this type of drug. CombiGene is of the view that the number of approved gene therapies will grow quickly in the coming years to become established treatment alternatives in a range of areas.

Epilepsy – a global problem
Epilepsy is a global problem. The disease affects an estimated 0.6 to 0.8 percent of the world's population. In 2016 there were 5.7 million diagnosed epilepsy patients in the USA, the EU5 and Japan. About one-third of these patients do not respond to conventional medical treatment. It is these epilepsy patients CombiGene intends to help with its candidate drug, CG01.

Enormous potential for CombiGene
In the USA alone some 14,000 patients are diagnosed with drug-resistant focal epilepsy each year, patients who could be candidates for surgery. CombiGene estimates that, realistically, 10–20 percent of these patients could be treated with the company's candidate drug, CG01. Assuming that the treatment cost per patient could amount to USD 200,000, sales could be as much as between 280 and 560 million euros. Globally, the corresponding figure is between 0.9 and 1.8 billion euros.

CG01 – milestones

2016
- First screening study conducted
- Selection of a candidate drug

2017
- Data from the dose-response study indicate a dose-dependent anti-epileptic effect.
- Preclinical proof-of-concept study is initiated.
- Studies in human epileptic brain tissue confirm that human brain tissue takes up the candidate drug CG01.

2018
- Final data from the preclinical proof-of-concept study confirm positive treatment results in the form of fewer and shorter seizures.
- CombiGene enters into collaboration with British CGT Catapult to develop a GMP manufacturing method for CG01.
- Horizon 2020, the EU framework programme for research and development, allocates 3.36 million euros for the development and commercialization of CG01.

CombiGene's vision is to develop a treatment method that can improve the quality of life for millions of people worldwide

Financial information

Income and profit/loss

The Group has had revenue amounting to TSEK 0 (0) during the period January-March. Other operating income amounts to TSEK 1 635 (50), of which TSEK1 527 (0) refers to part of the contribution from Horizon 2020. Operating profit/loss for the period amounts to TSEK-2,472 (-1,999). The principal costs during the period are mainly attributable to research and development, and fees to the CEO and consultants.

Cash flow and financial position

Cash flow for the period January - March amounts to TSEK -3,577. Cash and bank balances at the close of the period amount to TSEK 28 228. The equity/assets ratio was 59% at the end of the reporting period.

Liquidity and financing

The board is of the opinion that the capital raised via the most recent preference share issue, completed in September 2018, and funds from the EU Horizon 2020 programme are sufficient for the coming 12-month period. The total contribution from Horizon 2020 amounts to 3.36 million euros, of which about 1.5 million euros has been paid out to the company. The board and management group are working on an ongoing basis to meet the long-term capital requirement for operations.

The share

The number of shares at the end of the period amount to 51,593,476, with a quotient value of SEK 0.10. The average number of shares for the period amounts to 51,593,476. All shares are of the same class and have the same voting right.

Personnel

The average number of employees in the group amounted during the period to 3 (2) person, of which 2 (1) are women. In addition, an administrator acted as a consultant.

Risks and uncertainty factors

A pharmaceutical development company such as CombiGene is exposed to significant operational and financial risk. Many factors can have a negative impact on the probability of commercial success. The risks to which the Company is exposed in its current phase and which must be given careful consideration are the risk that CombiGene's method is not safe or effective and the risk that the necessary financing cannot be secured. During the quarter no significant changes with respect to these risks or uncertainty factors have arisen.

Principles for preparation of the interim report

CombiGene prepares its financial reports in accordance with the Swedish Annual Accounts Act and BFNAR 2012:1 (K3) Annual Accounts and Consolidated Accounts. The same accounting principles have been applied in this interim report as were applied in the most recent annual report.

Review by auditors

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

Future reporting date

Interim Report 21 August 2019, referring to the period January-June 2019.

For further information, please contact:

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Lund, 17 May 2019, CombiGene AB (publ)

Arne Ferstad
Chairman

Lars Thunberg
Board member

Susana Ayesa Alvarez
Board member

Morten Albrechtsen
Board member

Peter Nilsson
Board member

Jan Nilsson
CEO

Group income statement in summary

Figures in TSEK	2019 Jan-March	2018 Jan-March	2018 Jan-Dec
Nets sales	0	0	8
Other operating revenues	1 635	50	3 728
Operating expenses			
Other external expenses	-2 640	-1 772	-15 052
Personnel expenses	-1 467	-277	-1 865
Operating profit/loss	**-2 471**	**-1 999**	**-13 181**
Net financial income/expense	0	0	35
Income after net financial items	**-2 471**	**-1 999**	**-13 146**
Tax	0	0	0
Net profit/loss for the period	**-2 471**	**-1 999**	**-13 146**
Earnings per share, before dilution	-0,05	-0,12	-0,25
Earnings per share, after dilution	-0,05	-0,12	-0,25
Average number of shares before dilution	51 593 476	16 754 935	26 889 024
Average number of shares after dilution	51 593 476	16 754 935	26 889 024
Total outstanding shares	*51 593 476*	*17 197 826*	*51 593 476*

Group balance sheet in summary

Figures in TSEK	31 March 2019	31 March 2018	31 dec 2018
ASSETS			
Intangible assets	1 750	1 224	1 654
Total fixed assets	**1 750**	**1 224**	**1 654**
Current assets			
Other receivables	767	1 948	1 657
Cash and bank balances	28 228	4 604	31 805
Total current assets	**28 995**	**6 552**	**33 462**
Total assets	**30 744**	**7 776**	**35 116**
LIABILITIES AND SHAREHOLDERS' EQUITY			
Share capital	5 159	1 652	5 159
Non-registered share capital	0	68	0
Other capital contribution	54 590	33 029	54 590
Other shareholders' equity	-39 295	-26 148	-26 149
Profit/loss for the year	-2 471	-1 999	-13 146
Total shareholders' equity	**17 984**	**6 602**	**20 455**
Liabilities			
Current liabilities	12 760	1 174	14 661
Total liabilities	**12 760**	**1 174**	**14 661**
Total shareholders' equity and liabilities	**30 744**	**7 776**	**35 116**

Summary report of changes in the Group's shareholders' equity

Figures in TSEK	Share capital	Other capital contribution	Accumulated profit/loss	Total shareholders' equity
Balance brought forward	**1 652**	**31 008**	**-26 148**	**6 512**
New share issue	3 507	29 746		33 253
Issuing expenses		-6 164		-6 164
Net profit/loss for the period			-13 146	-13 146
Amount as per the end of the reporting period	**5 159**	**54 590**	**-39 294**	**20 455**

Group cash flow statement in summary

Figures in TSEK	2019 Jan-March	2018 Jan-March	2018 Jan-dec
Cash flow from operating activities	-3 481	-2 403	228
Cash flow from investing activities	-96	0	-430
Cash flow from financing activities	0	2 089	27 089
Cash flow for the period	**-3 577**	**-314**	**26 887**
Liquid assets at the start of the reporting period	31 805	4 918	4 918
Liquid assets at the end of the reporting period	**28 228**	**4 604**	**31 805**

Parent Company income statement in summary

Figures in TSEK	2019 Jan-March	2018 Jan-March	2018 Jan-dec
Nets sales	0	0	8
Other operating revenues	1 635	50	3 728
Operating expenses			
Other external expenses	-2 631	-1 772	-15 034
Personnel expenses	-1 467	-277	-1 864
Operating profit/loss	**-2 462**	**-1 999**	**-13 162**
Net financial income/expense	0	0	35
Income after net financial items	**-2 462**	**-1 999**	**-13 127**
Tax	0	0	0
Net profit/loss for the period	**-2 462**	**-1 999**	**-13 127**

Parent Company balance sheet in summary

Figures in TSEK	31 mar 2019	31 mar 2018	31 dec 2018
ASSETS			
Intangible assets	1 750	1 224	1 654
Financial assets	167	166	167
Total fixed assets	**1 917**	**1 390**	**1 821**
Current assets			
Other receivables	791	1 948	1 674
Cash and bank balances	28 049	4 423	31 625
Total current assets	**30 757**	**6 371**	**33 299**
Total assets	**30 757**	**7 761**	**35 120**
LIABILITIES AND SHAREHOLDERS' EQUITY			
Restricted equity			
Share capital	5 159	1 652	5 159
Non-registered share capital	0	68	0
Statutory reserve	4	4	4
Reserve for development expenses	604	77	508
Non-restricted equity			
Share premium reserve	34 501	12 940	34 501
Accumulated loss including profit/loss for the year	-22 255	-8 139	-19 697
Total shareholders' equity	**18 012**	**6 602**	**20 474**
Liabilities			
Current liabilities	12 745	1 159	14 646
Total liabilities	**12 745**	**1 159**	**14 646**
Total shareholders' equity and liabilities	**30 757**	**7 761**	**35 120**

Summary report of changes in the Parent Company's shareholders' equity

Figures in TSEK	Share-holders' equity	Statutory reserve	Reserve for deve-lopment expenses	Share premium reserve	Accumula-ted profit/ loss	Total share-holders' equity
Balance brought forward	**5 159**	**4**	**507**	**34 501**	**-19 697**	**20 474**
Provisions for reserve for development expenses			96		-96	
Net profit/loss for the period					-2 462	-2 462
Amount as per the end of the reporting period	**5 159**	**4**	**603**	**34 501**	**-22 255**	**18 012**

Parent Company cash flow statement in summary

Figures in TSEK	2019	2018	2018
	Jan-March	Jan-March	Jan-dec
Cash flow from operating activities	-3 480	-2 403	230
Cash flow from investing activities	-96	0	-431
Cash flow from financing activities	0	2 089	27 089
Cash flow for the period	**-3 576**	**-314**	**26 888**
Liquid assets at the start of the reporting period	31 625	4 737	4 737
Liquid assets at the end of the reporting period	**28 049**	**4 423**	**31 625**

Group financial key ratios

Figures in TSEK	2019 Jan-March	2018 Jan-March	2018 Jan-dec
Earnings per share, before dilution, SEK	-0,05	-0,12	-0,25
Earnings per share, after dilution, SEK	-0,05	-0,12	-0,25
Shareholders' equity per share, SEK	0,35	0,38	0,39
Equity/assets ratio, %	58,50	84,90	58,27
Average number of shares before dilution	51 593 476	16 754 935	26 889 024
Average number of shares after dilution	51 593 476	16 754 935	26 889 024
Total outstanding shares	*51 593 476*	*17 197 826*	*51 593 476*

Share capital development

Year	Event	Total shareholders' equity (SEK)	Change (SEK)	Total number of shares	Change in number of shares	Quotient value (SEK)
1990	Company registration	50 000	50 000	500	500	100,00
1997	Bonus issue	100 000	50 000	1 000	500	100,00
2010	New share issue	102 600	2 600	1 026	26	100,00
2013	New share issue	143 600	41 000	1 436	410	100,00
2014	Bonus issue	574 400	430 800	5 744	4 308	100,00
2014	New share issue	604 400	30 000	6 044	300	100,00
2014	Split 1 000:1	604 400	0	6 044 000	6 037 956	0,10
2014	New share issue	884 400	280 000	8 844 000	2 800 000	0,10
2015	New share issue	1 134 400	250 000	11 344 000	2 500 000	0,10
2015	New share issue	1 138 197	3 797	11 381 970	37 970	0,10
2016	New share issue	1 180 159	41 962	11 801 590	419 620	0,10
2017	New share issue	1 652 223	472 064	16 522 230	4 720 637	0,10
2018	New share issue	1 719 783	67 560	1 719 783	675 596	0,10
2018	New share issue	5 159 348	3 439 565	51 593 476	34 395 650	0,10
At the end of the period		**5 159 348**		**51 593 476**		**0,10**

Warrant programme 2016

The company has issued 290,000 warrants via the subsidiary CombiGene Personal AB to senior executives in CombiGene AB (publ). Every warrant allows the holder to subscribe for 1.85 shares in the company at a subscription price of SEK 5.98 and subscriptions may be made during the period as of 7 May 2019 to 21 May 2019. CombiGene Personal AB has in addition the possibility to issue a further 63,760 warrants.
Warrants entail a dilution when the market value of the share exceeds the redemption price of the warrant. There is no dilution effect during the period.

Warrant programme 2018

In connection with the new issue conducted during autumn 2018 the company has issued 6,879,130 subscription warrants, each of which entitles the holder to subscribe for one new share in the company at a subscription price of 70% of the volume-weighted average price of the company's share in the marketplace in which the company's share is traded during the period from 15 August 2019 up to and including 28 August 2019. The subscription price will not be less than 2.00 kronor per share or exceed 2.50 kronor per share.

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For many sufferers,
there is no help – yet.
We hope to change this. We are in the process of developing a world-leading method for treating epilepsy. The potential is enormous, the outlook is good.
For very many people.
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