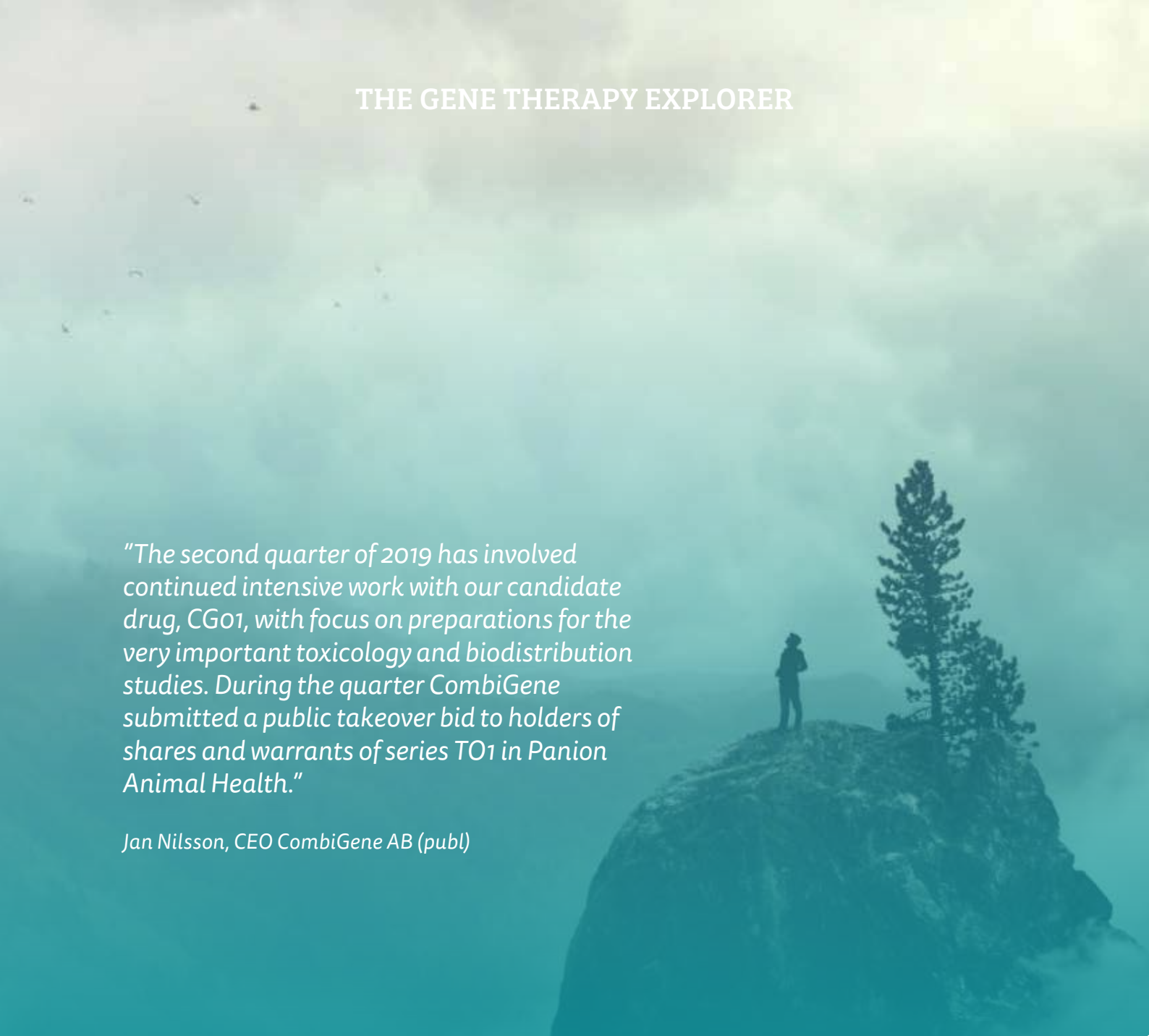
THE GENE THERAPY EXPLORER



"The second quarter of 2019 has involved continued intensive work with our candidate drug, CG01, with focus on preparations for the very important toxicology and biodistribution studies. During the quarter CombiGene submitted a public takeover bid to holders of shares and warrants of series TO1 in Panion Animal Health."

Jan Nilsson, CEO CombiGene AB (publ)

Interim Report

January – June 2019 for CombiGene AB (publ)

CombiGene

Interim Report January – June 2019 for CombiGene AB (publ)

Second Quarter April - June 2019

- Nets sales: TSEK 0 (0)
- Other operating revenues TSEK 3,137 (0)
- Profit from financial items: TSEK -2,814 (-2,159)
- Earnings per share: SEK -0,05 (-0.13)

Period January - June 2019

- Nets sales: TSEK 0 (0)
- Other operating revenues TSEK 4,772 (50)
- Profit from financial items: TSEK -5,285 (-4,158)
- Earnings per share: SEK -0.10 (-0.24)
- Liquidity as per the end of the reporting period: TSEK 21,839 (3,561)
- Equity/assets ratio as per the end of the reporting period: 59,35 (77.07) %

Operations during the second quarter of 2019

- CombiGene has submitted a public offering to holders of shares and warrants of series TO1 in Panion Animal Health AB (publ).
- CombiGene has held a meeting with a clinical advisory board in the UK to elucidate how CG01 can be used in practice in health care.

Significant events after the end of the reporting period

- CombiGene extends the acceptance period for holders of shares and warrants in Panion.
- CombiGene completes the offer to holders of shares and warrants in Panion, concludes the acceptance period and decides to introduce a non-cash issue. After completion of the offer CombiGene controls 21,959,690 shares and 3,847,594 warrants, corresponding to 88.35 percent of the total number of shares and votes in Panion and about 84.91 percent of the total number of the outstanding warrants.

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 genes 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 second quarter of 2019 has involved continued intensive work with our candidate drug, CG01, with focus on preparations for the very important toxicology and biodistribution studies. During the quarter CombiGene submitted a public takeover bid to holders of shares and warrants of series TO1 in Panion Animal Health AB (publ). Among other things, the purpose of the offer was to take advantage of the practical and financial synergies in both companies' development processes and partnering. As of the close of July we hold 88.35 percent of the total number of shares and votes in Panion and about 84.91 percent of the total number of the outstanding warrants. Based on this fundamentally positive outcome, CombiGene decided to complete the offering.

Continued high level of activity in the CG01 project
Progress on CG01 has continues during the first half of the year. We expect to complete final selection of the CMO and CRO companies (Contract Manufacturing Organisation and Contract Research Organisation) during 2019. On our behalf, the CMO and CRO companies will produce CG01 and conduct the safety studies which are necessary before clinical trials can begin.

CombiGene completes the offering to Panion's shareholders
In April CombiGene submitted a public takeover bid to holders of shares and warrants of series TO1 in Panion Animal Health AB (publ). In late June we extended the acceptance period until July 10th. As of the close of the acceptance period it was apparent that we ha gained control of 88.35 percent of the total number of shares and votes in Panion and about 84.91 percent of the total number of the outstanding warrants. CombiGene has thereby completed the offering to Panion. The acquisition will be financed via the recently announced non-cash issue.

Naturally, it would have been more gratifying if we had acquired at least 90 percent of the shares and warrants. At the same time it is very pleasing to note that so many wish to be shareholders in CombiGene. However, we will control more than 88 percent of the shares and nearly 85 percent of the warrants, which means that we will reach all of our original objectives with respect to the acquisition of Panion. Among the most important of these are the practical and financial synergies synergies to be realized in the development process and, not least, in our efforts to find interesting partners. We also gain full control over our intangible assets, which is particularly important with respect to our relations with future strategic partners.

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 and maintain good 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. During 2019 we have also been asked by pharmaceutical companies with whom we have not had previous contact to present CG01. This is something of a new situation for us; previously, CombiGene has always taken the initial contact.

In early June CombiGene's chairman, Arne Ferstad, and I took part in the BIO International Convention in Philadelphia, USA. The BIO International Convention, the world's largest partnering event in the field of life sciences, is an excellent opportunity to meet players of potential interest. CombiGene has participated in this gathering several times and has established many valuable contacts among CRO/CMO companies, institutional investors and major pharma companies.

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 can 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 during the quarter:

- The activity level at CGT Catapult remains high. Several key analysis methods and process development for production of CG01 are in full swing.
- Evaluation of the CMO (Contract Manufacturing Organisation) that will produce GMP-classed (Good Manufacturing Practice) material for the coming safety studies in animals and for the initial clinical studies is in the final stages and is expected to reach completion this autumn.
- Concurrently with evaluation of the CMO we are also assessing the CRO (Contract Research Organisation) that will conduct the coming safety studies in animals.
- A couple of preclinical studies, the results of which are necessary for initiating the important safety studies, have begun during the spring/summer. These studies are mandatory before we can begin our first clinical study.
- To aid in planning the clinical study a Swedish consultant has been engaged part time to identify which CRO company we will use and in which country the first clinical trial will be conducted.

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

Gene therapy attracts great interest

Gene therapy is currently one of the most exciting areas of pharmaceuticals 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 4,772 (50), of which TSEK4,410 (0) refers to part of the contribution from Horizon 2020. Operating profit/loss for the period amounts to TSEK -5,285 (-4,158). The principal costs during the period are mainly attributable to research and development, and fees to consultants and personnel costs.

Cash flow and financial position

Cash flow for the period January - June amounts to TSEK -9,966. Cash and bank balances at the close of the period amount to TSEK 21,839. The equity/assets ratio was 59,35% 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 2019. 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 (2) are women. In addition, an administrator acted as a consultant. In addition, there was an administrative resource and a Chief Financial Officer who was hired as 2 (1) consultants of which 2 (1) were women.

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 14 November 2019 for the period January-September 2019.

Lund, 21 August 2019, CombiGene AB (publ)

Arne Ferstad
Chairman

Lars Thunberg
Board member

Susana Ayesa Alvarez
Board member

Hilde Furberg
Board member

Peter Nilsson
Board member

Jan Nilsson
CEO

For further information, please contact:

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Group income statement in summary

Figures in TSEK	2019 April-June	2018 April-June	2019 Jan-June	2018 Jan-June	2018 Jan-Dec
Nets sales	0	0	0	0	8
Other operating revenues	3 137	0	4 772	50	3 728
Operating expenses					
Other external expenses	-4 515	-1 525	-7 155	-3 297	-15 052
Personnel expenses	-1 436	-634	-2 902	-911	-1 865
Operating profit/loss	**-2 814**	**-2 159**	**-5 285**	**-4 158**	**-13 181**
Net financial income/expense	0	0	0	0	35
Income after net financial items	**-2 814**	**-2 159**	**-5 285**	**-4 158**	**-13 146**
Tax	0	0	0	0	0
Net profit/loss for the period	**-2 814**	**-2 159**	**-5 285**	**-4 158**	**-13 146**
Earnings per share, before dilution	-0,05	-0,13	-0,10	-0,24	-0,25
Earnings per share, after dilution	-0,05	-0,13	-0,10	-0,24	-0,25
Average number of shares before dilution	51 593 476	17 197 826	51 593 476	16 976 381	26 889 024
Average number of shares after dilution	51 593 476	17 197 826	51 593 476	16 976 381	26 889 024
Total outstanding shares	*51 593 476*	*17 197 826*	*51 593 476*	*17 197 826*	*51 593 476*

Group balance sheet in summary

Figures in TSEK	2019 30 June	2018 30 June	2018 31 Dec
ASSETS			
Intangible assets	1 842	1 224	1 654
Total fixed assets	**1 842**	**1 224**	**1 654**
Current assets			
Other receivables	1 939	903	1 657
Cash and bank balances	21 839	3 561	31 805
Total current assets	**23 778**	**4 464**	**33 462**
Total assets	**25 619**	**5 688**	**35 116**
LIABILITIES AND SHAREHOLDERS' EQUITY			
Share capital	5 159	1 720	5 159
Other capital contribution	54 590	32 970	54 590
Other shareholders' equity	-39 295	-26 148	-26 149
Profit/loss for the year	-5 285	-4 158	-13 146
Total shareholders' equity	**15 170**	**4 384**	**20 455**
Liabilities			
Current liabilities	10 450	1 304	14 661
Total liabilities	**10 450**	**1 304**	**14 661**
Total shareholders' equity and liabilities	**25 619**	**5 688**	**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	**5 159**	**54 590**	**-39 294**	**20 455**
Net profit/loss for the period			-5 285	-5 285
Amount as per the end of the reporting period	**5 159**	**54 590**	**-44 579**	**15 170**

Group cash flow statement in summary

Figures in TSEK	2019 Jan-June	2018 Jan-June	2018 Jan-Dec
Cash flow from operating activities	-9 778	-3 387	228
Cash flow from investing activities	-188	0	-430
Cash flow from financing activities	0	2 030	27 089
Cash flow for the period	**-9 966**	**-1 357**	**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	**21 839**	**3 561**	**31 805**

Parent Company income statement in summary

Figures in TSEK	2019 April-June	2018 April-June	2019 Jan-June	2018 Jan-June	2018 Jan-Dec
Nets sales	0	0	0	0	8
Other operating revenues	3 137	0	4 772	50	3 728
Operating expenses					
Other external expenses	-4 508	-1 525	-7 139	-3 297	-15 034
Personnel expenses	-1 435	-634	-2 902	-911	-1 864
Operating profit/loss	**-2 806**	**-2 159**	**-5 269**	**-4 158**	**-13 162**
Net financial income/expense	0	0	0	0	35
Income after net financial items	**-2 806**	**-2 159**	**-5 269**	**-4 158**	**-13 127**
Tax	0	0	0	0	0
Net profit/loss for the period	**-2 806**	**-2 159**	**-5 269**	**-4 158**	**-13 127**

Parent Company balance sheet in summary

Figures in TSEK	2019 30 June	2018 30 June	2018 31 Dec
ASSETS			
Intangible assets	1 842	1 224	1 654
Financial assets	167	166	167
Total fixed assets	**2 009**	**1 390**	**1 821**
Current assets			
Other receivables	1 970	903	1 674
Cash and bank balances	21 660	3 380	31 625
Total current assets	**23 660**	**4 283**	**33 299**
Total assets	**25 639**	**5 673**	**35 120**
LIABILITIES AND SHAREHOLDERS' EQUITY			
Restricted equity			
Share capital	5 159	1 720	5 159
Statutory reserve	4	4	4
Reserve for development expenses	695	77	508
Non-restricted equity			
Share premium reserve	34 501	12 882	34 501
Accumulated loss including profit/loss for the year	-25 154	-10 299	-19 697
Total shareholders' equity	**15 205**	**4 384**	**20 474**
Liabilities			
Current liabilities	10 435	1 289	14 646
Total liabilities	**10 435**	**1 289**	**14 646**
Total shareholders' equity and liabilities	**25 639**	**5 673**	**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			188		-188	
New share issue *Issuing expenses*						
Net profit/loss for the period					-5 269	-5 269
Amount as per the end of the reporting period	**5 159**	**4**	**695**	**34 501**	**-25 154**	**15 205**

Parent Company cash flow statement in summary

Figures in TSEK	2019	2018	2018
	Jan-June	Jan-June	Jan-Dec
Cash flow from operating activities	-9 777	-3 387	230
Cash flow from investing activities	-188	0	-431
Cash flow from financing activities	0	2 030	27 089
Cash flow for the period	**-9 965**	**-1 357**	**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	**21 660**	**3 380**	**31 625**

Group financial key ratios

Figures in TSEK	2019 Jan-June	2018 Jan-June	2018 Jan-Dec
Earnings per share, before dilution, SEK	-0,10	-0,24	-0,25
Earnings per share, after dilution, SEK	-0,10	-0,24	-0,25
Shareholders' equity per share, SEK	0,29	0,25	0,39
Equity/assets ratio, %	59,35	77,07	58,27
Average number of shares before dilution	51 593 476	16 976 381	26 889 024
Average number of shares after dilution	51 593 476	16 976 381	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 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 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.

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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

The content of this report reflects only the Companys view. The Commission are not responsible for any use that may be made of the information.


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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