

THE GENE THERAPY EXPLORER

"Among the major milestones reached during the year are, above all, our collaboration with British CGT Catapult, the capital contribution from Horizon 2020 and the successful rights issue conducted during the autumn of 2018"

Jan Nilsson, CEO CombiGene AB (publ)

Year-end statement

January-December 2018 for CombiGene AB (publ)

Year-end statement January-December 2018 for CombiGene AB (publ)

Fourth quarter October - December 2018

- Nets sales: TSEK 0 (0).
- Profit from financial items: TSEK -3,159 (-3,294).
- Earnings per share: SEK -0.06 (-0.20)

Period January to December 2018

- Nets sales: TSEK 8 (3,000).
- Profit from financial items: TSEK -13,146 (-8,958)
- Earnings per share: SEK -0.25 (-0.54)
- Liquidity as per the end of the reporting period:
TSEK 31,806 (4,918)
- Equity/assets ratio as per the end of the reporting
period: 58 (80) %

Operations during the fourth quarter of 2018

- An extraordinary meeting of shareholders approves
terms for the preference issue.
- CombiGene is approved for listing on Nasdaq First
North Stockholm, with the first day of trading set to
19 December 2018.
- CombiGene is recognized in an article in Nature,
one of the world's foremost scientific periodicals.

Significant events after the end of the reporting period

- CombiGene strengthens its management team
Anna Jönsson appointed CFO

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.

The company is public and listed on the Swedish marketplace Nasdaq First North.

The board proposes that no dividend will be paid for the 2018 financial year.

Certified Advisor

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A word from the CEO

In summarizing the events of the past year we are pleased to report that 2018 was a very successful year for CombiGene. Among the major milestones reached during the year are, above all, our collaboration with British CGT Catapult, the capital contribution from Horizon 2020 and the successful rights issue conducted during the autumn of 2018. Funding from Horizon 2020 and proceeds from the preference issue have made it possible for CombiGene to enter a new and more offensive phase.

Strong financial position – a stronger company

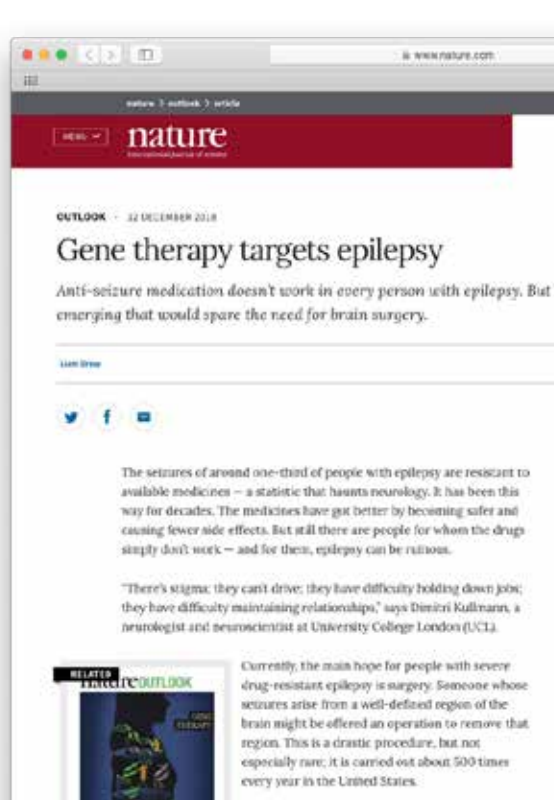
Funding from Horizon 2020 amounting to €3.36 million, and the preferential rights issue, which raised 31 million kronor in issue capital before issuing expenses, mean that CombiGene can proceed on the offensive as never before. Two important recruitments were made during the year: Karin Agerman, who is our Chief Research and Development Officer, and Annika Ericsson, Senior Project Manager. Anna Jönsson was employed as CombiGene's Chief Financial Officer in early 2019. With these recruitments, we have created a platform upon which we have both the resources and the expertise to drive our important CG01 epilepsy project with full forces while at the same time pursuing expansive business development with the long-term ambition of broadening our business with additional gene therapy projects.

International recognition necessitates a new trading platform

CombiGene is active in one of the most dynamic fields of global pharmaceutical development and the company's epilepsy project is now in a very interesting phase of development. As our epilepsy project has advanced, international interest in CombiGene has increased. Very clear confirmation of this was given by the article on gene therapy and CombiGene's operations that was published in the very highly regarded scientific periodical Nature. What pleases me most about the article in Nature is that it shows how great an interest there is in gene therapy and – not least – what an impact CombiGene and our research have started to make internationally. The growing international interest in CombiGene is also the reason we have changed the trading platform for our share during the quarter from SPOTLIGHT to Nasdaq First North, which is an internationally more well-known marketplace.

Intensive process development in the epilepsy project

I was very pleased when we signed the agreement with CGT Catapult and our collaboration has proceeded exactly as I had hoped it would. Catapult is a British organization that has amassed a considerable amount of international talent. This international expertise is very valuable, since it



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means that we in the project team gain access not only to the very best scientific quality, but also that the team has very considerable international contacts and experience. The project is now in a very intensive phase of process development and is making preparations for the toxicology and biodistribution studies.

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 dialogues are ongoing and take place at different types of conferences; for example, at BIO-Europe in Copenhagen in November last year, where we held several partnering meetings.

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.

Looking ahead

Our development of a manufacturing method in collaboration with CGT Catapult is a time-consuming process, but we will reach several definitive milestones in the project during 2019, among others, the biodistribution and toxicity studies that we plan to initiate later in the year. We will not be able to present project milestones as frequently as we have during 2017/2018, but that by no means implies that the pace of development is slowing down. On the contrary; with capital from the preference issue and Horizon 2020, CombiGene is very well equipped to pursue the project with full force.

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:

- Panion held a pre-submission meeting with the FDA in which CombiGene participated. Panion is the veterinary medicine company that uses the same technology as CombiGene.
- Partnering meetings were held at the BIO-Europe conference in Copenhagen, 5-7 November.
- A meeting was held with CombiGene’s Scientific Advisory Board.
- The recruitment of Annika Ericsson to the position of Senior Project Manager makes CombiGene even stronger.
- The process for selection of a CMO (Contract Manufacturing Organization) for production and a CRO (Contract Research Organization) for the coming toxicology and biodistribution studies commenced during the quarter.
- Work at CGT Catapult proceeds. CGT Catapult is now setting up a large series of new complementary analyses that are adapted for future GMP production.

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

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

Gene therapy attracts great interest

Gene therapy is currently one of the most exciting areas of pharmaceuticals development. At the start of Q3 2018, 351 clinical studies were under way, of which 33 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 the first three quarters of 2018 to USD 7.8 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 EU 5 and Japan. About one-third of these patients do not respond to conventional medical treatment. The majority suffer from a form of focal epilepsy and it is these 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. Com-

biGene 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 clearly 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.

Financial Information

Income and profit/loss

The Group has had revenue amounting to TSEK 8 (3,000) during the period January-December. The previous year's revenue of TSEK 3,000 is income from outlicensing whereby the buyer has acquired the right to use the company's technology within the veterinary medicine area. Other operating income amounts to TSEK 3,728 (450), of which TSEK 3,628 (0) refers to part of the contribution from Horizon 2020. Operating profit/loss for the period amounts to TSEK -13,181 (-8,958). 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 - December amounts to TSEK 26,888. Cash and bank balances at the close of the period amount to TSEK 31,806. The equity/assets ratio was 58% at the end of the reporting period.

Liquidity and financing

The board is of the opinion that the capital raised via the preference share issue completed in September 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 26,889,024. 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 (1) person, of which 2 (1) are women. In addition, an administrator acted as a consultant.

Lund, February 13 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

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 year-end statement

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.

Proposed distribution of profit

The board proposes that no dividend will be paid for the 2018 financial year.

AGM and Annual Report

The Annual General Meeting of Shareholders for 2019 will be held in Lund on 16 May. The Annual Report will be available to the public at the company's office in Lund and will be published on Nasdaq's website no later than 3 weeks prior to the AGM.

Review by auditors

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

Future reporting date

Interim Report for Q1 2019, 17 May 2019.

For further information, please contact:

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Group income statement in summary

Figures in TSEK	2018 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
Net sales	0	0	8	3 000
Other operating revenues	1 549	0	3 728	450
Operating expenses				
Other external expenses	-4 241	-2 805	-15 053	-10 105
Personnel expenses	-397	-489	-1 864	-2 303
Operating profit/loss	-3 089	-3 294	-13 181	-8 958
Net financial income/expense	-70	0	35	0
Profit/loss after financial items	-3 159	-3 294	-13 146	-8 958
Tax	0	0	0	0
Net profit/loss for the period	-3 159	-3 294	-13 146	-8 958
Earnings per share, before dilution	-0,06	-0,20	-0,25	-0,54
Earnings per share, after dilution	-0,06	-0,20	-0,25	-0,54
Average number of shares, before dilution	51 593 476	16 522 230	26 889 024	15 853 473
Average number of shares, after dilution	51 593 476	16 522 230	26 889 024	15 853 473
Total outstanding shares	51 593 476	16 522 230	51 593 476	16 522 230

Group balance sheet in summary

Figures in TSEK	31 Dec 2018	31 Dec 2017
ASSETS		
Intangible assets	1 654	1 224
Total fixed assets	1 654	1 224
Current assets		
Other receivables	1 644	1 997
Cash and bank balances	31 805	4 918
Total current assets	33 449	6 915
Total assets	35 103	8 139
SHAREHOLDERS' EQUITY AND LIABILITIES		
Share capital	5 159	1 652
Other capital contribution	54 589	31 008
Other shareholders' equity	-26 147	-17 190
Profit/loss for the year	-13 146	-8 958
Total shareholders' equity	20 455	6 512
Liabilities		
Current liabilities	14 648	1 627
Total liabilities	14 648	1 627
Total shareholders' equity and liabilities	35 103	8 139

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	2018	2017	2018	2017
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Cash flow from operating activities	-9 723	-2 759	230	-9 527
Cash flow from investing activities	-98	0	-431	0
Cash flow from financing activities	25 058	0	27 089	11 391
Cash flow for the period	15 237	-2 759	26 888	1 863
Liquid assets at the start of the reporting period	16 569	7 677	4 918	3 055
Liquid assets at the end of the reporting period	31 806	4 918	31 806	4 918

Parent Company income statement in summary

Figures in TSEK	2018	2017	2018	2017
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Net sales	0	0	8	3 000
Other operating revenues	1 549	0	3 728	450
Operating expenses				
Other external expenses	-4 222	-2 800	-15 034	-10 086
Personnel expenses	-397	-489	-1 864	-2 303
Operating profit/loss	-3 070	-3 289	-13 162	-8 939
Net financial income/expense	-70	-27	35	-24
Profit/loss after financial items	-3 140	-3 316	-13 127	-8 963
Tax	0	0	0	0
Net profit/loss for the period	-3 140	-3 316	-13 127	-8 963

Parent Company balance sheet in summary

Figures in TSEK	31 Dec 2018	31 Dec 2017
ASSETS		
Intangible assets	1 654	1 224
Financial assets	167	166
Total fixed assets	1 821	1 390
Current assets		
Other receivables	1 661	1 997
Cash and bank balances	31 625	4 737
Total current assets	33 286	6 734
Total assets	35 107	8 124
SHAREHOLDERS' EQUITY AND LIABILITIES		
Restricted equity		
Share capital	5 159	1 652
Statutory reserve	4	4
Reserve for development expenses	508	77
Non-restricted equity		
Share premium reserve	34 501	10 919
Accumulated loss including profit/loss for the year	-19 697	-6 140
Total shareholders' equity	20 474	6 512
Liabilities		
Current liabilities	14 633	1 612
Total liabilities	14 633	1 612
Total shareholders' equity and liabilities	35 107	8 124

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

Figures in TSEK	Share Capital	Statutory reserve	Reserve for development expenses	Share premium reserve	Accumulated profit/loss including profit/loss for the period	Total shareholders' equity
Balance brought forward	1 652	4	77	10 919	-6 140	6 512
Reserve for development expenses			430		-430	
New share issue	3 507			29 745		33 253
Issuing expenses				-6 164		-6 164
Net profit/loss for the period					-13 127	-13 127
Amount as per the end of the reporting period	5 159	4	507	34 501	-19 697	20 474

Parent Company cash flow statement in summary

Figures in TSEK	2018	2017	2018	2017
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Cash flow from operating activities	-9 723	-2 759	230	-9 514
Cash flow from investing activities	-98	0	-431	0
Cash flow from financing activities	25 058	0	27 089	11 391
Cash flow for the period	15 237	-2 759	26 888	1 877
Liquid assets at the start of the reporting period	16 388	7 496	4 737	2 860
Liquid assets at the end of the reporting period	31 625	4 737	31 625	4 737

Group financial key ratios

Figures in TSEK	2018	2017	2018	2017
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Earnings per share, before dilution, SEK	-0,62	-0,20	-0,25	-0,54
Earnings per share, after dilution, SEK	-0,62	-0,20	-0,25	-0,54
Shareholders' equity per share, SEK	0,39	0,39	0,39	0,39
Equity/assets ratio, %	58,27	80,00	58,27	80,00
Average number of shares before dilution	51 593 476	16 522 230	26 889 024	15 853 473
Average number of shares after dilution	51 593 476	16 522 230	26 889 024	15 853 473
Total outstanding shares	51 593 476	16 522 230	51 593 476	16 522 230

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 close of the reporting 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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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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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.

GombiGene – the gene therapy explorer

 **combiGene**

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