CombiGene

Year-end report

January – December 2021
CombiGene AB (publ)

CG01: Exclusive collaboration and licensing agreement with Spark Therapeutics

The agreement with Spark has a potential value of USD 328.5 million excluding royalties, with USD 8.5 million upon signing and up to USD 50 million at preclinical and clinical milestones. During the remaining part of the preclinical program, all CG01-related R&D activities that CombiGene is running, internal as well as external, will be agreed upon and approved by Spark, who also assumes all agreed costs.

A stronger organization

In the last year, CombiGene strengthened its organization considerably with the recruitment of a new CFO and by adding new positions within CMC and Research and Development. With these recruitments, CombiGene has expanded its know-how and capacity in a decisive way.

Successful financing of CombiGene's operations

Through a combination of one rights issue, grants from the EU programs Eurostars and Horizon 2020, and the upfront payment from Spark, CombiGene received approximately SEK 149.6 million in 2021, giving the company a strong financial position.

January – December 2021

Period October – December 2021

- Net sales: 84,042 (0) TSEK.
- Other operating revenues: 1,098 (3,171) TSEK.
- Profit from financial items: 57,448 (-10,964) TSEK.
- Earnings per share: 2.90 (-1.22) SEK.

Period January – December 2021

- Net sales: 84,042 (0) TSEK.
- Other operating revenues: 7,478 (12,029) TSEK.
- Profit from financial items: 20,965 (-29,551) TSEK.
- Earnings per share: 1.21 (-3.31) SEK.
- Liquidity as per the end of the reporting period: 136,744 (48,895) TSEK.
- Equity ratio as per the end of the reporting period: 95 (89)%.
- The board proposes that no dividend will be paid for the 2021 financial year.

Events during the year

January – March 2021

- CombiGene's Board of Directors resolves on a fully guaranteed rights issue of approximately SEK 75 million.
- Response from the Swedish and UK pharmaceutical authorities confirm CombiGene's plan for CG01's final preclinical studies.
- The material from the first large-scale production of CG01 is released.
- The CG01 project initiates preclinical biodistribution and toxicology studies.
- CombiGene's lipodystrophy project is awarded EUR 882,500 in development grants by the EU Eurostars program.

April – June 2021

- CombiGene completes a fully guaranteed rights issue providing the company with approximately SEK 75 million before issue costs.
- On May 25, 2021, CombiGene AB held its Annual General Meeting (AGM) in Lund. The AGM resolved all matters in accordance with the proposal of the Board of Directors and the Nomination Committee. The AGM resolved to re-elect Peter Nilsson, Bert Junno, Jonas Ekblom and Per Lundin as Board members

and to elect Gunilla Lundmark as new member of the Board. Bert Junno was also re-elected Chairman of the Board. Mazars AB was re-elected as auditor. The AGM resolved, in accordance with the Nomination Committee's proposal, on board fees and that auditor's fees shall be paid in accordance with approved invoices. The AGM further resolved to merge the company's shares, with twenty (20) existing shares being combined into one (1) new share (aggregation 1:20). The AGM also resolved to amend the Articles of Association in such a way that the Board of Directors shall have its registered office in Stockholm, instead of Lund, Skåne County.

- CombiGene and Neurochase initiate the work of optimizing the administration of CG01 in a preclinical study.
- The plasmids to be used in the GMP production of CG01 are manufactured and subjected to the quality assurance. The plasmids will be used as starting material for the GMP batch.

July – September 2021

- CombiGene initiates GMP production of CG01.
- Patent approved in the U.S. and Russia for CombiGene's gene therapy candidate CG01.
- CombiGene applies for international patent protection for the vectors developed within the CGT2 project.

October – December 2021

- CombiGene and Spark Therapeutics enter exclusive, global licensing agreement for gene therapy candidate CG01. The agreement with Spark has a potential value of USD 328.5 million excluding royalties, with USD 8.5 million upon signing and up to USD 50 million at preclinical and clinical milestones.
- CombiGene's Horizon 2020 project successfully completed with a final payment of approximately EUR 500,000, which means that CombiGene has received the full grant of EUR 3.36 million.
- CombiGene and Spark Therapeutics communicate plan to expand the clinical development program beyond the EU, to also include the U.S. This also expands the preclinical program.

Events after the end of the period

- GMP production of CG01 made available for preclinical studies planned to enable First in Human study.
- CombiGene signs agreement with University of Michigan to evaluate the leading gene therapy candidate within the lipodystrophy project CGT2.

About CombiGene AB

CombiGene's vision is to provide patients affected by severe life-altering diseases with the prospect of a better life through novel gene therapies. CombiGene's business concept is to develop effective gene therapies for severe life-altering diseases where adequate treatment is currently lacking. Development assets are sourced from an external research network and developed to achieve clinical proof of concept. Drug candidates for common diseases will be co-developed and commercialized through strategic partnerships, while the company may manage this process on its own for drugs targeting niched patient populations.

The Company has an exclusive collaboration and licensing agreement for the CG01 project with Spark Therapeutics.

The company is public and listed on the Swedish marketplace Nasdaq First North Growth Market and the company's Certified Advisor is FNCA Sweden AB, +46 (0)852 80 03 99, info@fnca.se.

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

CombiGene´s project CGT2 is supported by the Eurostars Programme.Project ID: 114714

A rapid transformation into an internationally recognized gene therapy company

The year 2021 was a very successful year, and CombiGene is in a much better position now than twelve months ago. The exclusive global collaboration and licensing deal we signed with Spark Therapeutics in October 2021 transformed CombiGene into an internationally recognized gene therapy company with a strengthened ability to explore new and promising opportunities within the gene therapy field.

CG01 2021: several value creating milestones leading up to the agreement with Spark

The most important event during 2021 is of course the collaboration and licensing deal with Spark, but even before the signing of the agreement CG01 achieved a number of important milestones within manufacturing, preclinical development, and approved patents. Here's a short recap of the terms of agreement and recent developments:

The agreement with Spark. Under the terms of agreement, CombiGene is eligible to receive up to USD 328.5 million excluding royalties, with USD 8.5 million upon signing and up to USD 50 million at preclinical and clinical milestones. CombiGene will also be reimbursed for certain authorized R&D expenses. Upon commercialization, CombiGene is eligible for tiered royalties ranging from the mid-single digits up to low double-digits based on net sales.

Collaboration on the final preclinical parts. We will now continue to run the CG01 project through the final preclinical parts in collaboration with Spark, something we really are looking forward to. When CG01 enters the clinical phase, Spark will take over responsibility for the whole program.

Reimbursement of internal and external R&D expenses. During the remaining part of the preclinical program, all CG01-related R&D activities that CombiGene is running, internal as well as external, will be agreed upon and approved by Spark, who also assumes all agreed costs. As CG01 enters the clinical phase, Spark will take over the responsibility for the continuation of the program and thus also bear all costs during this development phase.

Expanded clinical program. In December 2021, CombiGene and Spark jointly decided to expand CG01's clinical development program to include the U.S. With this decision, the project will find a natural foothold on the world's, by far, largest pharmaceutical market, at the same time as Spark can utilize the company's impressive resources, know-how and networks in an optimal way. In order to prepare CG01 to meet the needs of an extended submission, the remaining preclinical program will be expanded and, in some parts, complemented with additional studies. In practice, this means that the preclinical part supporting initiation of clinical development of CG01 will take longer time to finalize. As previously stated, Spark will assume all costs the remaining part of the preclinical program as well as all costs for the entire clinical program.

GMP production of CG01. In January 2022, the first large scale GMP production of CG01 was made available for preclinical studies planned to enable first-in-human study. Both the production itself and the subsequent testing were performed according to original plans. The data from the analyses will form a central part of future regulatory applications to support proceeding to clinical studies.

Successful financing of our operations

The year 2021 was also successful from a financing point of view. Through a combination of one rights issue, grants from the EU programs Eurostars and Horizon 2020, and the upfront payment from Spark, CombiGene received approximately SEK 149.6 million.

Rights issue. During the first quarter of 2021, CombiGene's financial position was strengthened through a fully guaranteed rights issue of SEK 75 million before issue costs, allowing for an expansion of the company's expertise and capacity regarding production, clinical studies, and gene therapy through three important new recruits.

Eurostars grant. The EU continued to invest in CombiGene in 2021 when the EU financing program Eurostars decided to allocate EUR 882,500 to the development of our lipodystrophy project CGT2. Thanks to the Eurostars grant, we have been able to broaden the international cooperation in this important project to include the University Medical Center Hamburg-Eppendorf and strengthen our collaboration with the CRO company Accelero.

Horizon 2020. In July 2021, CombiGene's Horizon 2020 project was successfully completed and in December 2021 the final payment of approximately EUR 500,000 was received. In total, CombiGene has received EUR 3.36 million in four instalments since 2018.

Upfront payment from Spark. Upon signing the agreement with Spark, CombiGene received USD 8.5 million.

A stronger organization

In the past year, CombiGene has strengthened its organization considerably with the recruitments of CFO Louise Aspenberg; Project Manager CMC Martin Linhult; Clinical Project Manager Pernilla Fagergren; and Industrial postdoc Esbjörn Melin. With these recruitments, CombiGene has expanded its know-how and capacity in a decisive way.

CGT2: sparse news but positive movements

Sometimes in the development of a project you reach a stage where there is few reportable news. This has been the case for CombiGene's lipodystrophy project CGT2 for a large part of 2021, but this in no way means that there have been no activities within the project. On the contrary, we have been working hard to select the best gene therapy candidate to go forward with. This process is still ongoing, and we recently signed an agreement with Professor Ormond MacDougald at the University of Michigan Medical School to further the development of this project. The agreement comprises one pilot study and one main study in which the most promising gene therapy candidate within the lipodystrophy project CGT2 will be evaluated in an animal model that resembles the disease in humans.

Focus in 2022

In 2022, CombiGene will focus on three areas: the continued preclinical development of CG01 in close collaboration with Spark; bringing the CGT2 project to the stage where we can initiate the important proof-of-concept study; and intensified business development with the ambition of expanding our gene therapy portfolio.

Jan Nilsson,
CEO

On October 12, 2021, the epilepsy project CG01 achieved its most important milestone to date through the collaboration and licensing agreement with Spark Therapeutics.

Since CombiGene and Spark entered an exclusive collaboration and licensing agreement for CG01, the two companies have jointly reviewed the future development of the project to establish the best path forward. In December 2021, the two companies jointly decided to expand the clinical development program to include the U.S. in addition to Europe. The clinical development program for the CG01 project was originally planned to be performed in Europe, CombiGene's home market. Establishing a clinical presence in the U.S. adds much further strength to the CG01 project and enables it to find a natural foothold on the world's largest pharmaceutical market.

In order to prepare CG01 to meet the needs of an extended submission, the remaining preclinical program will be expanded and, in some parts, complemented with additional studies. In practice, this means that the preclinical part of CG01 to support initiation of the First in Human study will take longer time to finalize.

Once the preclinical program is completed, Spark will take full responsibility for the clinical development from the first human study onwards to global commercialization. The work done and know-how acquired by CombiGene regarding the planning of the clinical study has been transferred to Spark.

CG01 Milestones

2016

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

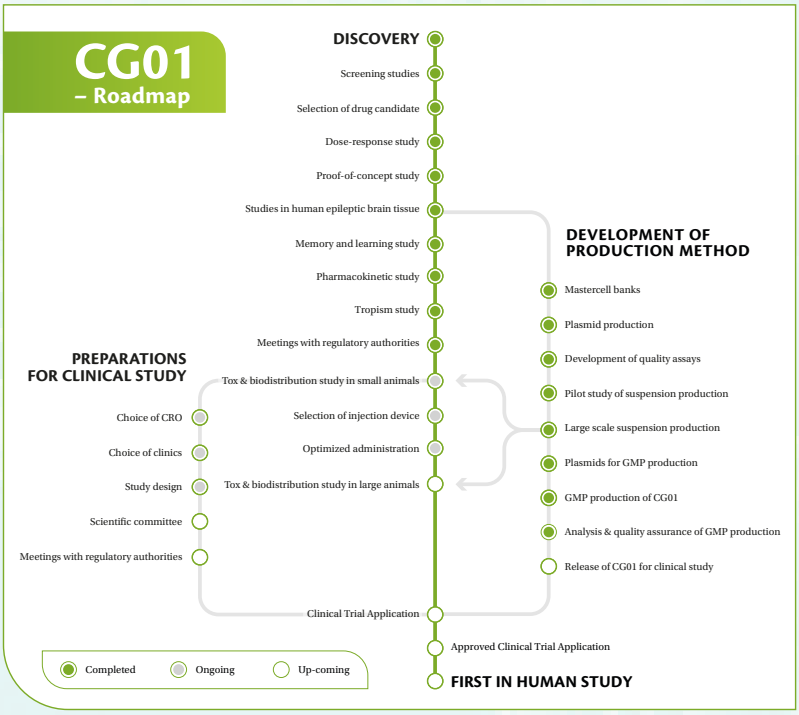
2017

- Data from the dose-response study indicate a dose- dependent anti-epileptic effect.
- The proof-of-concept study in a chronic epilepsy model is initiated.
- Studies in human epileptic brain tissue from patients with pharma-coresistant epilepsy confirm that CG01 is expressed in human cells.

2018

- Final data from the preclinical proof-of-concept study confirm positive treatment results in the form of significantly fewer and shorter epileptic seizures.
- CombiGene enters into collaboration with British Cell and Gene Therapy Catapult to develop a GMP manufacturing method for CG01.
- Horizon 2020, the EU frame-work program for research and development, allocates EUR 3.36 million for the development and commercialization of CG01.

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



The agreement with Spark

The agreement provides Spark with the exclusive world-wide license to develop, manufacture and commercialize CG01. CombiGene will continue to execute certain aspects of the preclinical program in collaboration with Spark. Under the terms of agreement, CombiGene is eligible to receive up to USD 328.5 million excluding royalties, with USD 8.5 million upon signing and up to USD 50 million at preclinical and clinical milestones. CombiGene will also be reimbursed for certain authorized R&D expenses. Upon commercialization, CombiGene is eligible for tiered royalties ranging from the mid-single digits up to low double-digits based on net sales.

2019

- Acquisition of Panion Animal Health gives CombiGene full control over the company's intangible assets in the CG01 project.
- Agreement with CRO Northern Biomedical Research (NBR), which specializes in preclinical studies in the central nervous system (CNS). The agreement covers assessment of the candidate drug, CG01, in a smaller pilot study, a biodistribution study and a safety study, a so-called toxicity study.
- CombiGene signs an agreement with the CDMO, Cobra Biologics, regarding production of plasmids for GMP manufacturing of CG01.

2020

- Preclinical pharmacokinetic study completed with positive results. The study confirms that CG01 creates long-term expression of the active substances NPY and Y2.
- The preclinical learning and memory study shows that NPY and Y2 have no significant negative effect on cognitive functions.
- Delivery of all three plasmids needed to produce CG01.
- Delivery of GMP master cell banks for the three plasmids.
- Successful pilot study performed with suspension production method.
- Positive results in tropism study.
- Agreement on GMP production with Cobra for plasmids for CG01.
- Delivery of analytical methods for quality control of the production of CG01 developed in collaboration with CGT Catapult.
- Manufacturing agreement with Viralgen for the production of CG01.
- Agreement with the British company Neurochase regarding the development of optimized administration of CG01.
- First large-scale production of CG01 at the Spanish gene therapy manufacturer Viralgen.

2021

- The material from the first large-scale production of CG01 released for use in the final parts of the preclinical program.
- The CG01 project initiates preclinical biodistribution and toxicology studies in small animals.
- GMP-produced plasmids (starting material for the production of CG01) released for GMP production of CG01.
- First GMP production of CG01 initiated.
- CG01 patent is approved in the U.S. and Russia.
- Global and exclusive collaboration and licensing agreement with Spark Therapeutics.
- CombiGene's Horizon 2020 project successfully completed.

CGT2, CombiGene's project to develop a gene therapy treatment for partial lipodystrophy, is in early preclinical development. Since the project was in-licensed from Lipigon in 2019, the pace to validate the project has accelerated. The first step in designing gene therapy vectors and testing them in vitro (tests on different liver cells) has been carried out with good results. Since then, several in vivo studies have been performed to evaluate efficacy and narrow down the potential gene therapy candidates.

CombiGene signs agreement to evaluate the leading gene therapy candidate within the lipodystrophy project CGT2

The evaluation of possible drug candidates is ongoing, and the number of potential candidates has decreased gradually. In January 2022, CombiGene signed an important agreement with Professor Ormond MacDougald at the University of Michigan Medical School in the U.S. The agreement comprises one pilot study and one main study in which CombiGene's most promising gene therapy candidate within the lipodystrophy project CGT2 will be tried and evaluated.

Professor Ormond MacDougald's new experimental model has large resemblances with partial lipodystrophy in humans, the disorder that CombiGene aims to treat. Professor MacDougald has an entire team working within the lipodystrophy field, the team has acquired extensive knowledge that will benefit CombiGene's CGT2 project.

"I'm very happy that CombiGene has signed this agreement with Professor MacDougald," said Annika Ericsson, Preclinical Project Manager at CombiGene. "Professor MacDougald and his team has exactly the know-how and experimental model that we need to evaluate our leading candidate in the lipodystrophy project."

Grants from the EU's Eurostars international funding program

In February 2021, the Lipodystrophy project was awarded EUR 882,500 in project grants by EU's Eurostars international funding program. Thanks to this funding, CombiGene has been able to initiate a collaboration with the University Medical Center Hamburg-Eppendorf, which has a research group with experts in lipid research. Through the Eurostars grant, CombiGene has also strengthened its collaboration with Accelero, a German CRO company that will work on developing analytical methods to measure the efficacy of the CGT2 therapy.

CGT2 Milestones

2019

- In-licensing of the project from Lipigon.

2020

- Design of expression plasmids, which are a starting material for gene-therapeutic vectors CombiGene intends to develop for treatment of partial lipodystrophy.
- In vitro studies (tests on liver cells) show proper protein expression.
- Priority-based patent application filed with the UK Patent Office.
- In vivo studies initiated for evaluation of the different gene therapy vectors.

PCT application

In August 2021, CombiGene submitted a so-called PCT application to protect the vectors developed within the CGT2 project. The Patent Cooperation Treaty (PCT) is an international agreement that allows companies to seek patent protection internationally for their innovations in about 150 countries. Within the framework of the PCT, a preliminary assessment of patentability is made before the application proceeds to the national phase where national patent applications are submitted. PCT applications are handled by the World Intellectual Property Organization (WIPO), a self-funding body within the United Nations.

The now submitted PCT application builds on the UK patent application filed in 2020 and is a natural next step in ensuring adequate patent protection for the lipodystrophy project CGT2.

2021

- The lipodystrophy project receives EUR 882,500 in development grants from the EU Eurostars program.
- PCT application submitted.

2022

- CombiGene signs agreement with University of Michigan to evaluate the leading gene therapy candidate within the lipodystrophy project CGT2.

CombiGene´s project CGT2 is supported by the Eurostars Programme.Project ID: 114714

Value-creating business development through development of gene therapy assets and international partnering

CombiGene has for several years worked long-term to establish the company as an interesting player in the international pharmaceutical market and has gradually built up an extensive network of partners with specific competences within gene therapy. Overall, CombiGene's business development spans three areas: In-licensing new projects with high commercial potential, value adding of in-licensed projects through successful preclinical development, and out-licensing of projects that target significant patient populations in late preclinical/early clinical phase. In the case of drug candidates targeting limited patient populations, CombiGene may drive development and commercialization under its own management.

So far, CombiGene's business development has resulted in the in-licensing of the CGT2 lipodystrophy project from Lipigon, establishing collaboration with a number of CRO and CDMO companies within the CG01 and CGT2 projects, and out-licensing of the CG01 epilepsy project to Spark Therapeutics in an agreement with a potential value of USD 328.5 million excluding royalties.

Focus on in-licensing new projects

The agreement with Spark Therapeutics meant that CombiGene in one stroke strengthened its cash position by USD 8.5 million and is eligible to receive up to USD 50 million during CG01's preclinical and clinical development. The agreement also means that Spark will take over the full responsibility of running the CG01 development once the preclinical phase is completed. All in all, this means that CombiGene is now well placed to take the next step in the company's development and the in-licensing of additional gene therapy projects will be in focus.

CombiGene will primarily seek AAV-based projects because it is within this technology platform that the company has established knowledge in a number of key areas such as vector design (design of drug candidate), safety aspects and production. Similarly, the areas of disease that are in focus are those where CombiGene has built up a solid knowledge, i.e., diseases of the central nervous system and metabolic diseases.

Having said that, CombiGene will at the same time have an open attitude towards all possible projects and evaluate each opportunity on its own merits. CombiGene regularly participates in important partnering conferences and the company has continuous dialogues with interesting actors in both academia and industry to identify interesting projects.

Income and earnings

The Group has a total net sale of SEK 84,042 (0) thousand during the period January-December. The revenue relates to the license agreement with Spark Therapeutics, signed in October 2021. Other operating revenues amounts to SEK 7,478 (12,029) thousand, of which SEK 5,671 (10,731) thousand refers to the revenue-earned portion of the grant received from Horizon 2020 and SEK 1,406 (0) thousand refers to the revenue-earned portion of the grant received from Eurostars. Operating profit for the period amounted to SEK 20,965 (-28,159) thousand. The main costs during the period have been related to research & development, fees for consultants and personnel costs.

Cash flow and financial position

Cash flow for the period January-December amounts to SEK 87,849 thousand. Liquidity at the end of the period amounts to 136,744 thousand. The equity ratio is 95,5%.

Liquidity and financing

The total Horizon 2020 grant amounts to EUR 3,36 million. The final payment of approximately EUR 0,5 million was received in October after the final report of the project was approved. The EU's Eurostars program, which is aimed at small and medium-sized enterprises wishing to collaborate on research and development projects, has allocated development grants to the CGT2 project. The total grant for CombiGene amounts to SEK 5 million, of which SEK 1 million has so far been paid out.

In March / April 2021, a guaranteed rights issue of shares was carried out. The rights issue provided the company with approximately SEK 75 million before issue costs. The company's share capital increased by SEK 16,674,692.6, from SEK 22,927,702.4 to SEK 39,602,395. The number of shares increased by 166,746,926 shares, from 229,277,024 shares to 396,023,950 shares.

The board and company management continuously evaluate alternatives to ensure the company's financing in the short and medium term.

The share

At the Annual General Meeting of CombiGene on 25 May 2021 a reverse share split was resolved upon, whereby twenty (20) existing shares were consolidated into one (1) new share. Through the reverse share split, the number of shares in CombiGene decreased from 396,023,950 to 19,801,197, with a quota value of approximately SEK 2 per share until August 6 when the reduction of the share capital was executed, after which each share has a quota value of SEK 0.05. The average number of shares for the period is 17,311,414. All shares are of the same type and have the same voting rights. For comparability, a retroactive adjustment has been made to the number of shares.

Employees

The number of employees in the Group at the end of the period was 8 (5), of whom 5 (3) are women. In addition, there was an administrative resource who was hired as 1 (1) consultant, of whom 1 (1) was woman.

Risks and uncertainties

A drug development company of CombiGene's type is characterized by a high operational and financial risk. The Company is dependent on current and future licensing, collaboration, and other agreements with experienced partners for the development and successful commercialization of existing and future drug candidates. The most significant example of this is CombiGene's exclusive global collaboration and licensing agreement with Spark Therapeutics, which has a potential total value of USD 328.5 million excluding royalties. The agreement with Spark is thus of great importance for CombiGene's future operations, earnings, and financial position. Other factors that may negatively affect the likelihood of commercial success include, among other things, the risk that CombiGene's gene therapies are not deemed safe or not effective, and the risk that the business may not receive the necessary funding.

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.

Proposed distribution of profits

The board proposes that no dividend will be paid for the 2021 financial year.

AGM and Annual Report

The Annual General Meeting for 2022 will be held on 19 May. More information regarding this will be published later. The Annual Report will be available to the public at the Company's office in Lidingö and will be published on the Companys website no later than three weeks before the AGM.

Review by auditors

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

Future reporting date

Interim report January – March 2022, 12 May 2022.

For further information, please contact:

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Stockholm, 17 February 2022, CombiGene AB (publ)

Bert Junno *Chairman*	Peter Nilsson *Board member*	Jonas Ekblom *Board member*
Per Lundin *Board member*	Gunilla Lundmark *Board member*	

Group income statement in summary

Figures in TSEK	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Net sales	84,042	0	84,042	0
Other operating revenues	1,098	3,171	7,478	12,029
Operating expenses				
Other external expenses	-21,538	-11,104	-54,591	-29,640
Personnel expenses	-4,778	-2,382	-11,692	-7,185
Other operating expenses	-727	0	-1,677	-869
Profit/loss before depreciation	**58,097**	**-10,315**	**23,560**	**-25,665**
Depreciation	-649	-649	-2,595	-2,495
Profit/loss after depreciation	**57,448**	**-10,964**	**20,965**	**-28,159**
Net financial income/expense	0	0	0	-1,392
Income after net financial items	**57,448**	**-10,964**	**20,965**	**-29,551**
Tax	0	0	0	0
Net profit/loss for the period	**57,448**	**-10,964**	**20,965**	**-29,551**
Attributable to				
Parent company shareholders	57,448	-10,964	20,965	-29,383
Non-controlling interests	0	0	0	-169
Earnings per share before dilution	2.90	-1.22	1.21	-3.31
Earnings per share after dilution	2.90	-1.22	1.21	-3.31
Average number of shares before dilution	19,801,197	9,022,098	17,311,414	8,939,008
Average number of shares after dilution	19,801,197	9,022,098	17,311,414	8,939,008
Total outstanding shares	*19,801,197*	*11,463,851*	*19,801,197*	*11,463,851*

Group balance sheet in summary

Figures in TSEK	2021 31 Dec	2020 31 Dec
ASSETS		
Intangible assets	21,599	24,046
Total fixed assets	**21,599**	**24,046**
Current assets		
Inventories	0	824
Other receivables	7,472	5,649
Cash and bank balances	136,744	48,895
Total current assets	**144,216**	**55,368**
Total assets	**165,815**	**79,414**
SHAREHOLDERS' EQUITY AND LIABILITIES		
Share capital	990	22,928
Other capital contribution	224,124	136,305
Other shareholders' equity	-87,800	-58,417
Profit/loss for the year	20,965	-29,383
Equity attributable to parent company shareholders	**158,279**	**71,433**
Minority interest	**0**	**0**
Total shareholders' equity	**158,279**	**71,433**
Liabilities		
Current liabilities	7,536	7,981
Total liabilities	**7,536**	**7,981**
Total shareholders' equity and liabilities	**165,815**	**79,414**

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

Figures in TSEK	Share capital	Other capital contribution	Other share-holders' equity	Accumulated profit/loss	Total share-holders' equity
Balance brought forward	**22,928**	**136,305**	**-58,417**	**-29,383**	**71,433**
Allocation of profit/loss			-29,383	29,383	0
Issue	16,675	58,361			75,036
Issue costs		-9,155			-9,155
Reduction of share capital	-38,612	38,612			0
Net profit/loss for the period				20,965	20,965
Amount as per the end of the reporting period	**990**	**224,124**	**-87,800**	**20,965**	**158,279**

Group cash flow statement in summary

Figures in TSEK	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Cash flow from operating activities	70,657	-11,662	22,115	-38,346
Cash flow from investing activites	0	-1,607	-148	-3,211
Cash flow from financing activities	0	26,919	65,881	75,286
Cash flow for the period	**70,657**	**13,650**	**87,849**	**33,729**
Liquid assets at the beginning of the reporting period	66,087	35,245	48,895	15,166
Liquid assets at the end of the reporting period	**136,744**	**48,895**	**136,744**	**48,895**

Parent Company income statement in summary

Figures in TSEK	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Net sales	84,042	0	84,042	0
Other operating revenues	1,098	3,171	7,478	12,029
Operating expenses				
Other external expenses	-21,528	-11,044	-54,517	-29,136
Personnel expenses	-4,778	-2,382	-11,692	-7,185
Other operating expenses	-727	0	-1,677	-869
Profit/loss before depreciation	**58,107**	**-10,256**	**23,634**	**-25,160**
Depreciation	-75	-75	-300	-200
Profit/loss after depreciation	**58,032**	**-10,331**	**23,334**	**-25,360**
Net financial income/expense	-574	-3,442	-2,295	-4,352
Income after net financial items	**57,458**	**-13,773**	**21,039**	**-29,712**
Tax	0	0	0	0
Net profit/loss for the period	**57,458**	**-13,773**	**21,039**	**-29,712**

Parent Company balance sheet in summary

Figures in TSEK	2021 31 Dec	2020 31 Dec
ASSETS		
Intangible assets	4,387	4,540
Financial assets	20,880	23,175
Total fixed assets	**25,267**	**27,714**
Current assets		
Inventories	0	824
Other receivables	8,157	6,233
Cash and bank balances	136,545	48,703
Total current assets	**144,702**	**55,759**
Total assets	**169,970**	**83,474**
SHAREHOLDERS' EQUITY AND LIABILITIES		
Restricted equity		
Share capital	990	22,928
Statutory reserve	4	4
Reserve for development expenses	760	612
Non-restricted equity		
Share premium reserve	165,826	116,619
Accumulated loss including profit/loss for the year	-5,101	-64,604
Total shareholders' equity	**162,478**	**75,558**
Liabilities		
Current liabilities	7,491	7,916
Total liabilities	**7,491**	**7,916**
Total shareholders' equity and liabilities	**169,970**	**83,474**

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	Profit/ loss for the year	Total shareholders' equity
Balance brought forward	**22,928**	**4**	**612**	**116,619**	**-34,892**	**-29,712**	**75,558**
Allocation of profit/loss					-29,712	29,712	0
Provisions for reserve for development expenses			148		-148		0
Issue	16,675			58,361			75,036
Issue costs				-9,155			-9,155
Reduction of share capital	-38,612				38,612		0
Net profit/loss for the period						21,039	21,039
Amount as per the end of the reporting period	**990**	**4**	**760**	**165,826**	**-26,139**	**21,039**	**162,478**

Parent Company cash flow statement in summary

Figures in TSEK	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Cash flow from operating activities	70,648	-11,451	22,109	-38,284
Cash flow from investing activites	0	1,452	-148	-3,259
Cash flow from financing activities	0	23,646	65,881	75,286
Cash flow for the period	**70,648**	**13,647**	**87,843**	**33,743**
Liquid assets at the beginning of the reporting period	65,897	35,056	48,703	14,959
Liquid assets at the end of the reporting period	**136,545**	**48,703**	**136,545**	**48,703**

Group financial key ratios

Figures in TSEK	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Earnings per share before dilution, SEK	2.90	-1.22	1.21	-3.31
Earnings per share after dilution, SEK	2.90	-1.22	1.21	-3.31
Shareholders' equity per share, SEK	7.99	6.23	7.99	6.23
Equity ratio, %	95.46	89.95	95.46	89.95
Average number of shares before dilution	19,801,197	9,022,098	17,311,414	8,939,008
Average number of shares after dilution	19,801,197	9,022,098	17,311,414	8,939,008
Total outstanding shares	*19,801,197*	*11,463,851*	*19,801,197*	*11,463,851*

Share capital development

Year	Event	Total share capital (SEK)	Change (SEK)	Total shares	Change shares	Quotient (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	17,197,836	675,596	0.10
2018	New share issue	5,159,348	3,439,565	51,593,476	34,395,650	0.10
2019	New share issue	6,372,384	1,213,036	63,723,836	12,130,360	0.10
2019	New share issue	6,373,090	706	63,730,896	7,060	0.10
2019	New share issue	6,505,365	132,275	65,053,647	1,322,751	0.10
2020	New share issue	11,762,201	5,256,836	117,622,007	52,568,360	0.10
2020	New share issue	12,562,201	800,000	125,622,007	8,000,000	0.10
2020	New share issue	14,721,013	2,158,813	147,210,132	21,588,125	0.10
2020	New share issue	17,666,081	2,945,068	176,660,811	29,450,679	0.10
2020	New share issue	17,822,218	156,137	178,222,176	1,561,365	0.10
2020	New share issue	20,768,890	2,946,672	207,688,899	29,466,723	0.10
2020	New share issue	22,927,702	2,158,813	229,277,024	21,588,125	0.10
2021	New share issue	39,602,395	16,674,693	396,023,950	166,746,926	0.10
2021	Reverse share split (1:20)	39,602,395	0	19,801,197	-376,222,753	2.00
2021	Reduction of share capital	990,059.85	-38,612,335	19,801,197	0	0.05
At the end of the period		**990,059.85**		**19,801,197**		**0.05**

AED

Anti-Epileptic Drug.

Clinical phase I

Phase I refers to the first instance of testing of a candidate drug on humans. Phase I trials are often conducted with a small group of healthy volunteer trial subjects to determine the safety and dosage of an as yet non-approved treatment method.

Clinical phase II

Phase II trials refer to a pharmaceutical product under development that is administered to a small group of patients to study the safety, dosage and efficacy.

Clinical phase III

Phase III studies include a sufficient number of patients to meet regulatory prerequisites for approval. The aim is to determine the statistical significance with respect to the effect of a new candidate drug, without major side effects and under carefully controlled real-world conditions. The new drug is sometimes compared with an established treatment, such as an approved drug.

Clinical studies

Research studies that explore whether a new, as yet non-approved, drug, medical strategy, treatment, or device is safe and effective for humans.

GMP

A Good Manufacturing Practice (GMP) is a system for ensuring that pharmaceutical products are consistently produced and controlled according to quality standards. Permits for GMP are granted by the Food and Drug Administration in the country in question and the process is characterized by extremely rigid and high demands on quality in all respects.

In vitro

A term used in biomedical science to describe a biological process made to occur in a laboratory vessel or other controlled experimental environment rather than within a living organism.

In vivo

A term used in biomedical science to describe an experimental biological process, and observations thereof, made to occur within a living organism.

Neuropeptide

Neuropeptides are small, protein-like molecules (peptides) that are used by neurons to communicate with each other.

NPY

Neuropeptide Y, a neurotransmitter that is widely distributed in the central nervous systems of animals and humans.

Proof of concept

Documented evidence that a potential product or method has the intended effect.

Viral vector

Viral vectors are tools that are used to deliver genetic material to cells. Examples of viral vectors are lentivirus, adeno-associated virus (AAV), retrovirus and adenovirus. AAV vectors are non-hazardous viruses that can infect human cells without causing disease and can be used to deliver genetic material into human cells.

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

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CombiGene

– The gene therapy explorer

CombiGene's vision is to provide patients affected by severe life-altering diseases with the prospect of a better life through novel gene therapies. CombiGene's business concept is to develop effective gene therapies for severe life-altering diseases where adequate treatment is currently lacking. Development assets are sourced from an external research network and developed to achieve clinical proof of concept. Drug candidates for common diseases will be co-developed and commercialized through strategic partnerships, while the company may manage this process on its own for drugs targeting niched patient populations.

The Company has an exclusive collaboration and licensing agreement for the CG01 project with Spark Therapeutics.

The company is public and listed on the Swedish marketplace Nasdaq First North Growth Market and the company's Certified Advisor is FNCA Sweden AB, +46 (0)852 80 03 99, info@fnca.se.

CombiGene

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