RESPIRATORIUS

Q1/19

Jan. 1, 2019 – March 31, 2019
Respiratorius AB (publ)
556552-2652

SUMMARY OF Q1 REPORT 2019 (GROUP)

First quarter (Jan. 1, 2019 – March 31, 2019)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 1,546 (loss: 1,154) thousand.
- Earnings per share[1] totaled SEK -0.01 (-0.01).

SIGNIFICANT EVENTS DURING THE FIRST QUARTER OF 2019

At the close of the first quarter of 2019, Respiratorius announced that the EMA's Scientific Advice Working Party (SAWP) had held a scientific advisory meeting regarding clinical strategy and assessed that VAL001 had met the criteria to directly begin a Phase III study. About 700 patients should be a satisfactory number for such a study to be able to serve as a basis for market approval.

Prior to the start of a Phase III study using the new dedicated formulation, the EMA considers it to be appropriate to conduct a pharmacokinetic study. The purpose is to ensure that dosing with the new formulation is in line with the previously defined maximum tolerated dosage. Realistically, a Phase III study could be expected to start around mid-2020. This timing would allow the Company to complete development and production of VAL001, complete the pharmacokinetic study and obtain all permits and consent forms prior to the start of the study.

SIGNIFICANT EVENTS AFTER THE FIRST QUARTER

Respiratorius announced in late April that a contract was signed with Partner International Inc, to complete the exit of VAL001. Partner International is tasked with working with previously identified candidates and seeking additional stakeholders among pharmaceutical companies in the field of oncology, with the aim of signing a contract as soon as possible.

Since the exit process for VAL001 was initiated the clinical study was completed with favorable results. Additional patents have been granted, thereby strengthening the patent situation, with patents granted in Europe, the US, Japan and Korea.

[1] Earnings per share: Profit/loss for the period divided by 157,171,975 shares as of March 31, 2019

Comments by the CEO

The beginning of 2019 entailed a substantial advance for VAL001 through the recommendation of the EMA's Scientific Advice Working Party (SAWP), which had assessed VAL001 as meeting the criteria for a Phase III study, which is the only remaining study needed to provide a basis for market approval.

In order to carry out the Phase III study, the formulation of the drug must be finalized and scaled up in a GMP-approved process. Respiratorius has already applied for a patent for the formulation and development is under way. Based on the schedule, which includes stability studies, an EMA-recommended pharmacokinetic study and scaling up trials, a Phase III study can begin in the second half of 2020 at the earliest, and more likely toward the end of 2020. From this perspective the timing of the exit of VAL001 is not critical, but rather should be guided by receiving maximum payment in a license or sale deal; the value of the project is still being enhanced without delaying the timeline.

Because of the Company's Phase III status, the prospects of an attractive exit have radically changed and Respiratorius has therefore decided to allocate additional resources to the exit process. Through the agreement with Partner International – which can now present a product candidate ready for Phase III, Orphan Drug Designation – as well as a strong patent situation, we have already substantially increased the number of potential partners and thus the chance to achieve an exit that is attractive for shareholders.

In order for additional partners to be able to come on board and for everyone to have time to go through all of the components in the project, Respiratorius believes that an exit is most likely to occur over the next six to twelve months. From the standpoint of the project, an exit should take place no later than the second half of 2020 to avoid delaying the Phase III start.

Within the project for new medications for effective treatment of COPD and severe asthma, the preclinical process continues to make good progress.

In summary, the first quarter of 2019 has positioned Respiratorius in an interesting relationship with other companies that have clinical Phase III projects. The contract with Partner International, with its solidly established reputation, provides excellent chances for achieving an exit through a contract with a leading pharmaceutical company in the field of oncology, *specialty pharma* or *orphan drugs*.

Johan Drott
CEO, Respiratorius AB (publ)

Respiratorius

Operations

Respiratorius AB (publ) develops drug candidates with the goal of launching drugs to treat common diseases such as cancer, chronic obstructive pulmonary disease (COPD) and severe asthma. The project portfolio also includes a project for improving the diagnosis of certain cardiovascular diseases using PET imaging. The latter project is located outside Respiratorius' main focus, for which reason other strategic options are continually being considered for this project.

The Company's cancer project, VAL001, is based on a combination and reformulation of existing drugs for a new indication, diffuse large B-cell lymphoma (DLBCL). The phase I/IIa clinical study of VAL001 for treatment of patients with DLBCL is complete with favorable results showing significantly increased survival (1-year and 2-year survival) among patients treated with VAL001 prior to treatment with R-CHOP, compared with patients treated with R-CHOP alone.

Respiratorius' work relating to the future treatment of pulmonary diseases and the diagnosis of cardiovascular diseases is based on new proprietary and patent-protected compound series. The Board of Directors believes that these compound series have the potential to be developed into drug candidates and biomarkers. The compounds, which use novel mechanisms, are tested in the Company's proprietary and patent-protected measuring and test equipment where we have been able to ensure efficacy on human lung tissue.

Group structure

Respiratorius is the parent company of a Group that includes, in addition to the parent company, the wholly owned subsidiaries Bergdalsten Kemi AB and Valcuria AB. Bergdalsten Kemi AB is a dormant company. Valcuria AB holds the patent rights for Respiratorius' VAL001 cancer project. All operations occur within the parent company, Respiratorius, and the parent has no other shareholdings.

Respiratorius' drug development

Respiratorius focuses its internal development resources on cancer, primarily the development of drugs for the treatment of malignant lymphoma, as well as new drugs for effective treatment of COPD and severe asthma. The project portfolio also includes a project for improving the diagnosis of certain cardiovascular diseases.

Below is a brief overview of Respiratorius' primary projects:

VAL001 – Drug candidate for the treatment of diffuse large B-cell lymphoma

VAL001 is a drug candidate that has shown clearly promising experimental and clinical data against diseases such as diffuse large B-cell lymphoma, the most common type of non-Hodgkin's lymphoma. The Company has successfully completed a phase I/IIa study that was conducted at Skåne University Hospital in Lund, Uppsala University Hospital, and Norrland University Hospital in Umeå.

Results from the phase I/IIa study show significantly increased survival (1-year and 2-year survival) among patients treated with VAL001 prior to treatment with R-CHOP, compared with patients treated with R-CHOP alone. Comparative data were taken from the Swedish Lymphoma Registry with a matched reference population of patients who were treated between 2010 and 2015. The results from the phase I/IIa study also demonstrate specific effects through increased levels of CD20, which may likely be beneficial in patients treated with Rituximab.

At a scientific advisory meeting with the EMA's Scientific Advice Working Party (SAWP) regarding clinical strategy, VAL001 was assessed as meeting the criteria to directly begin a Phase III study. About 700 patients should be satisfactory for such a study to be able to serve as a basis for market approval.

VAL001 (valproic acid) for the treatment of DLBCL received orphan drug status in Europe and the US, and patents were granted in the EU, the US, Japan and Korea. There is also a patent application for protection of a dedicated formulation.

RESP1000 – Drug for the treatment of COPD and asthma

RESP1000 is a compound series of drug candidates with bronchodilatory and anti-inflammatory properties under development to enable treatment of both COPD and asthma. The project is in preclinical phase and in 2014 a license and collaboration agreement was signed with Cadila Pharmaceuticals Ltd. for preclinical and clinical development of selected drug candidates from the RESP1000 series.

During the third quarter of 2018 a new patent application was submitted for a substance that has been assessed as having a favorable safety profile and equivalent anti-inflammatory and bronchodilatory properties as RES022-125, which is Respiratorius' drug candidate that has come the farthest in RES1000 series.

Patents for RESP1000 have been granted in several countries.

RESP2000 – Drug candidate for the treatment of COPD and asthma

RESP2000 is a series of new chemical substances, completely different from RESP1000, that have bronchodilatory properties and the potential to be developed into drugs for treatment of COPD and severe asthma. The RESP2000 compound series contains substances that affect the mitochondria (in simple terms, the cellular energy sources). In addition, certain exploratory studies will be conducted for other indications. This project is currently in early preclinical phase.

Patents for RESP2000 have been granted in several countries.

RESP3000 – for diagnosis of conditions such as cardiovascular diseases

RESP3000 is a project aimed at diagnosing conditions such as cardiovascular diseases using PET imaging. The patent-protected RESP3000 compound series represents a further development of the RESP2000 compound series. Respiratorius has completed a study of RES3105, the selected candidate from the compound series, with promising results.

Patents have been granted in several countries.

Other research and development

Using the patent-protected substances that Respiratorius has developed as a point of departure, the Company is testing new indications. The Board of Directors believes that RESP2000 has a well-defined "mode of action" that can be traced to cellular mitochondria, for which reason the Board also envisions broad potential for uses in areas far removed from the original indications of COPD and asthma.

Respiratorius constantly evaluates projects relating to additional drug candidates that are a good strategic fit for the Company. Projects in early development phase are given priority.

Respiratorius has a patented technology platform (R-HSAT) for the study of smooth muscle in various tissues of both animals and humans. The technology platform can be used for research purposes, as well as for screening and optimization of drug candidates. Respiratorius intends to out-license the right to use this technology.

Business model

Respiratorius looks for strategic partners who assume the financial and operational responsibility for developing the final product. Such partners have financial resources, experience in large clinical studies and established contacts with regulatory authorities. These partners will also be responsible in the future for manufacturing, marketing and sales of the licensed drugs that may result from the development project. Several large pharmaceutical companies have already shown interest regarding licensing and collaboration on the Company's projects.

A license agreement with a pharmaceutical company is expected to give Respiratorius income in the form of an initial payment followed by milestone payments, as well as royalties. In the event that a license agreement is concluded, there is an intention among the major shareholders to distribute approximately half of the advance payment in connection with a license agreement pro rata to all shareholders, provided that the business remains intact.

The timing of signing collaboration agreements with pharmaceutical companies will entail business decisions based on cost, risk, skill requirements and the value that would be added by completing additional steps in-house. Such collaboration agreements will ensure that the projects receive expertise and resources from pharmaceutical companies at an early stage, while Respiratorius avoids tying up excessive resources in a single project. It is in the best interest of the Company to work – without compromising safety – to minimize time-to-market for its drugs.

The share

The Respiratorius share was listed on July 5, 2012, on AktieTorget, now known as Spotlight Stock Market, a securities firm that is under the supervision of Finansinspektionen (the Swedish Financial Supervisory Authority) and operates a Multilateral Trading Facility (MTF) trading platform.

On March 31, 2019, the number of shares in the Company was 157,171,975. There is one class of shares, where each share carries equal rights to the Company's assets and earnings, and entitles the holder to one vote at the Annual General Meeting.

Audit

The Interim Report has not been reviewed by the Company's auditor.

Principles for preparation of the interim report

This interim report has been prepared in accordance with the Swedish Annual Accounts Act and the Swedish Accounting Standards Board's general guidelines. In the event that there are no general guidelines, guidance is sought where applicable from the recommendations of the Swedish Financial Accounting Standards Council. The same accounting policies and methods were used in the interim report as in the Company's most recent annual report. Respiratorius only capitalizes development costs for projects that have entered clinical phase as well as for patent costs.

Calendar

- Annual General Meeting May 28, 2019
- Half-Yearly Report August 30, 2019
- Q3 Interim Report November 7, 2019
- Year-end report February 4, 2020

Condensed consolidated income statement

(SEK 000s)	Jan. 1, 2019 March 31, 2019 Q1	Jan. 1, 2018 March 31, 2018 Cf Q1	Jan. 1, 2018 Dec 31, 2018 Cf 12 months	2017-01-01 Dec. 31, 2017 Cf 12 months
Net sales	0	0	0	0
Other operating income	0	0	0	0
Gross profit/loss	**0**	**0**	**0**	**0**
Research and development costs	-683	-456	-2,485	-2,429
Administrative costs	-1,276	-564	-2,844	-2,437
Other expenses	0	0	0	0
Capitalized patent and development costs	967	381	2,225	2,202
Operating profit/loss before depreciation, amortization and impairment	**-992**	**-638**	**-3,104**	**-2,664**
Depreciation/Amortization	-554	-515	-2,062	-2,240
Operating profit/loss after depreciation, amortization and impairment	**-1,546**	**-1,154**	**-5,166**	**-4,904**
Profit/loss from financial investments	0	0	-1	-24
Profit/loss after financial items	**-1,546**	**-1,154**	**-5,167**	**-4,928**
Taxes	0	0	0	0
Loss for the year	**-1,546**	**-1,154**	**-5,167**	**-4,928**

Condensed income statement – Parent Company

(SEK 000s)	Jan. 1, 2019 March 31, 2019 Q1	Jan. 1, 2018 March 31, 2018 Cf Q1	Jan. 1, 2018 Dec 31, 2018 Cf 12 months	2017-01-01 Dec. 31, 2017 Cf 12 months
Net sales	0	0	0	0
Other operating income	0	0	0	0
Gross profit/loss	**0**	**0**	**0**	**0**
Research and development costs	-419	-128	-1,348	-1,585
Administrative costs	-940	-652	-2,712	-2,437
Other expenses	0	0	0	0
Capitalized patent and development costs	567	155	1,111	1,412
Operating profit/loss before depreciation, amortization and impairment	**-792**	**-626**	**-2,949**	**-2,610**
Depreciation/Amortization	-258	-247	-989	-1,246
Operating profit/loss after depreciation, amortization and impairment	**-1,050**	**-873**	**-3,937**	**-3,856**
Profit/loss from financial investments	-150	-150	-1,241	-1,324

Profit/loss after financial items	**-1,200**	**-1,023**	**-5,178**	**-5,180**
Taxes	0	0	0	0
Loss for the year	**-1,200**	**-1,023**	**-5,178**	**-5,180**

Condensed Consolidated Balance Sheet

(SEK 000s)	March 31, 2019	March 31, 2018	Dec 31, 2018	Dec. 31, 2017
ASSETS				
Intangible assets	11,842	11,132	11,429	11,267
Property, plant and equipment	0	0	0	0
Financial assets	0	0	0	0
Total non-current assets	**11,842**	**11,132**	**11,429**	**11,267**
Total current assets	**9,428**	**16,503**	**10,714**	**19,835**
Total assets	**21,270**	**27,635**	**22,144**	**31,101**
LIABILITIES AND EQUITY				
Total equity	**19,375**	**24,934**	**20,920**	**26,088**
Non-current liabilities	0	0	0	0
Current liabilities	1,895	2,701	1,223	5,013
TOTAL EQUITY AND LIABILITIES	**21,270**	**27,635**	**22,144**	**31,101**

Condensed balance sheet – Parent Company

(SEK 000s)	March 31, 2019	March 31, 2018	Dec 31, 2018	Dec. 31, 2017
ASSETS				
Intangible assets	5,287	4,763	4,978	4,855
Property, plant and equipment	0	0	0	0
Financial assets	6,982	3,350	6,832	6,672
Total non-current assets	**12,269**	**8,113**	**11,810**	**11,527**
Total current assets	**9,059**	**19,768**	**10,334**	**19,794**
Total assets	**21,328**	**27,881**	**22,144**	**31,321**
LIABILITIES AND EQUITY				
Total equity	**19,896**	**25,251**	**21,095**	**26,273**
Non-current liabilities	81	87	81	87
Current liabilities	1,351	2,543	967	4,961
TOTAL EQUITY AND LIABILITIES	**21,328**	**27,881**	**22,144**	**31,321**

Summary Consolidated Statement of Cash Flows

(SEK 000s)	Jan. 1, 2019 March 31, 2019 Q1	Jan. 1, 2018 March 31, 2018 Cf Q1	Jan. 1, 2018 2018-12-10 Cf 12 months	2017-01-01 2017-12-10 Cf 12 months
Cash flow from operations during the period	-991	-639	-3,106	-2,688
Changes in working capital	611	17,111	-15,562	-15,695
Cash flow from operations after changes in working capital	**-381**	**16,472**	**12,456**	**-18,383**
Cash flow from investing activities	-967	-381	-2,225	-2,202
Cash flow from financing activities	0	0	0	18,434
Cash flow for the period	**-1,348**	**16,091**	**10,231**	**-2,151**
Cash/cash equivalents at beginning of period	10,266	34	34	2,185
Cash/cash equivalents at end of period	**8,918**	**16,125**	**10,266**	**34**

Summary Statement of Cash Flows - Parent Company

(SEK 000s)	Jan. 1, 2019 March 31, 2019 Q1	Jan. 1, 2018 March 31, 2018 Cf Q1	Jan. 1, 2018 2018-12-10 Cf 12 months	2017-01-01 2017-12-10 Cf 12 months
Cash flow from operations during the period	-953	-776	-4,189	-3,934
Changes in working capital	1	16,540	14,773	-15,845
Cash flow from operations after changes in working capital	**-953**	**15,764**	**10,584**	**-19,779**
Cash flow from investing activities	-406	-5	-517	-812
Cash flow from financing activities	0	0	0	18,429
Cash flow for the period	**-1,360**	**15,759**	**10,067**	**-2,162**
Cash/cash equivalents at beginning of period	10,067	0	0	2,162
Cash/cash equivalents at end of period	**8,707**	**15,759**	**10,067**	**0**

Condensed statement of changes in equity – Consolidated Jan. 1, 2019 – March 31, 2019

(SEK 000s)	Share capital	Restricted reserves	Unrestricted reserves	Profit/loss for the year
Amount at start of period	**7,858**	**22,570**	**4,340**	**-5,167**
Transfer of profit/loss			-5,167	5,167
Fund for development costs		83	-83	
Profit/loss for the period				-1,546
Amount at end of period	**7,858**	**22,653**	**-9,590**	**-1,546**

Condensed statement of changes in equity – Parent Company Jan. 1, 2019 – March 31, 2019

(SEK 000s)	Share capital	Restricted reserves	Unrestricted reserves	Profit/loss for the year
Amount at start of period	**7,858**	**22,570**	**-4,155**	**-5,178**
Transfer of profit/loss			-5,178	5,180
Fund for development costs		83	-83	
Profit/loss for the period				-1,200
Amount at end of period	**7,858**	**22,653**	**-9,416**	**-1,200**

Submission of interim report

Lund, May 28, 2019
Respiratorius AB (publ)
Board of Directors

For additional information, please contact:

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