Half-Yearly Report 2019

Jan. 1, 2019 – June 30, 2019
Respiratorius AB (publ)
556552-2652

SUMMARY OF H1 REPORT 2019 (GROUP)

First half year 2019 (Jan. 1, 2019 – June 30, 2019)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 2,857 (loss: 2,584) thousand.
- Earnings per share[1] totaled SEK -0.02 (-0.02).
- The equity ratio[2] as of June 30, 2019 was 91.3% (91.2).

Second quarter (April 1, 2019 – June 30, 2019)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 1,311 (loss: 1,430) thousand.
- Earnings per share[1] totaled SEK -0.01 (-0.01).

SIGNIFICANT EVENTS DURING THE SECOND QUARTER OF 2019

At the beginning of the second quarter 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, with the aim of signing an advantageous contract as soon as possible.

Since the exit process for VAL001 was initiated, the offering has been considerably improved through favorable results in the completed clinical study and additional patents granted in Europe, the US, Japan and Korea. Moreover, the European Medicines Agency (EMA) on scientific counseling determined that VAL001 is immediately ready for phase III, as the only study considered to be necessary to obtain marketing authorization. In addition, VAL001 has also previously received *Orphan Drug Designation* in both Europe and the US.

At the end of May, favorable results were presented for the first time from an in vivo study of airways using Respiratorius' substances, with the candidate RES030-085, which belongs to the RES9000

[1] Earnings per share: Profit/loss for the period divided by 157,171,975 shares as of June 30, 2019 (number of shares as of June 30, 2018 was 157,171,975)

[2] Equity ratio: Shareholders' equity divided by total capital

compound series for which a patent application has been submitted for the treatment of COPD and severe asthma.

The study was conducted by an internationally renowned contract laboratory using an established animal model (rats) in which the animals were exposed to a bronchoconstricting substance, carbamylcholine, after which the bronchodilatory effect of the test substances were assessed through airway resistance measurements. The properties of RES030-085 have been compared with controls and with RES022-125 (from the RES1000 series).

Summary of the study results:

- RES030-085 shows a clear and statistically significant bronchodilatory effect on rats when compared with a control group.
- No measured or observed adverse reactions were noted at the effective dose of RES030-085.
- RES030-085 is assessed to have good prospects for being formulated as a drug suitable for inhalation.

Comments by the CEO

During the first half of 2019 the exit process for VAL001 gained momentum. Part of the increased interest is likely because of the development of the project, in which the EMA's Scientific Advice Working Party (SAWP) assessed that VAL001 is immediately qualified for a phase III study, as the only remaining study required to apply for marketing authorization.

The company has therefore decided to allocate additional resources to the exit process by entering into a contract with Partner International, which is well-known for its ability to facilitate transactions for life science projects. During the months that they have been active the number of companies that have expressed interest increased dramatically, and currently there is interest from about 20 companies from all over the world.

The agreement with Partner International and the expansion of the stakeholder base that has been achieved is promising, since the timing for the exit of VAL001 is not time-critical, but rather is governed by obtaining maximum payment in a licensing or sales deal. Development is also proceeding according to plan, which increases the value of the project and simplifies the process for future takers.

In addition, it is rewarding to note the favorable results that a Respiratorius substance (RES030-085 from the compound series for RES9000) demonstrated in an in vivo airway study, which was carried out by an internationally renowned contract laboratory. The study was conducted in an established animal model for substances developed for treatment of COPD and severe asthma.

In the study, the experimental animals (rats) were exposed to a bronchoconstrictor (carbamylcholine), after which the bronchodilatory effect of the test substances was assessed through airway resistance measurements. The bronchodilatory properties of RES030-085 (RES9000 series) have been compared with controls and with RES022-125 from the RES1000 series.

Summary of the study results

- RES030-085 shows a clear and statistically significant bronchodilatory effect on rats when compared with a control group and with RES022-125 (RES1000 series).
- The experiments did not result in any measured or observed adverse reactions at the effective dose of RES030-085.
- RES030-085 is assessed to have good prospects for being formulated as a drug suitable for inhalation.

In summary, the first half of 2019 entailed brisk activity in the exit process for VAL001 through collaboration with Partner International, along with promising results from value-enhancing studies of RESP9000. In addition to continued preclinical development of RESP9000 during the upcoming six-month period, the exit process for VAL001 will be further intensified.

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 (DLBCL), 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.

As part of the scientific advisory process 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. Inclusion of about 700 patients should be satisfactory for such a study to be able to serve as a basis when applying for marketing authorization.

VAL001 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.

RESP9000 – Drug for the treatment of COPD and asthma

RESP9000, a compound series with a favorable safety profile for which a patent application was recently submitted, has anti-inflammatory and bronchodilatory properties equivalent to those of RESP1000 and RESP2000, but is completely outside these compound series with respect to patents. The project is in a preclinical phase and is the company's prioritized project for development of new medications for treatment of COPD and severe asthma.

The patent application for RESP9000 was recently submitted and has a priority date from 2018.

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.

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 June 30, 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

- Q3 Interim Report November 7, 2019
- Year-end report February 4, 2020

Condensed consolidated income statement

(SEK 000s)	Jan. 1, 2019 June 30, 2019 6 months	Jan. 1, 2018 June 30, 2018 Cf 6 months	April 1, 2019 June 30, 2019 Q2	April 1, 2018 June 30, 2018 Cf Q2	Jan. 1, 2018 Dec 31, 2018 Cf 12 months
Net sales	0	0	0	0	0
Other operating income	0	0	0	0	0
Gross profit/loss	**0**	**0**	**0**	**0**	**0**
Research and development costs	-1,239	-1,126	-556	-670	-2,485
Administrative costs	-3,553	-1,541	-2,277	-977	-2,844
Other expenses	0	0	0	0	0
Capitalized patent and development costs	3,043	963	2,076	582	2,225
Operating profit/loss before depreciation, amortization and impairment	**-1,749**	**-1,703**	**-757**	**-1,065**	**-3,104**
Depreciation/Amortization	-1,108	-880	-554	-365	-2,062
Operating profit/loss after depreciation, amortization and impairment	**-2,857**	**-2,584**	**-1,311**	**-1,430**	**-5,166**
Profit/loss from financial investments	0	0	0	0	-1
Profit/loss after financial items	**-2,857**	**-2,584**	**-1,311**	**-1,430**	**-5,167**
Taxes	0	0	0	0	0
Loss for the year	**-2,857**	**-2,584**	**-1,311**	**-1,430**	**-5,167**

Condensed income statement – Parent Company

(SEK 000s)	Jan. 1, 2019 June 30, 2019 6 months	Jan. 1, 2018 June 30, 2018 Cf 6 months	April 1, 2019 June 30, 2019 Q2	April 1, 2018 June 30, 2018 Cf Q2	Jan. 1, 2018 Dec 31, 2018 Cf 12 months
Net sales	0	0	0	0	0
Other operating income	0	0	0	0	0
Gross profit/loss	**0**	**0**	**0**	**0**	**0**
Research and development costs	-972	-666	-553	-538	-1,348
Administrative costs	-1,976	-1,623	-1,036	-972	-2,712
Other expenses	0	0	0	0	0
Capitalized patent and development costs	1,277	605	710	450	1,111
Operating profit/loss before depreciation, amortization and impairment	**-1,672**	**-1,685**	**-880**	**-1,060**	**-2,949**
Depreciation/Amortization	-516	-494	-258	-247	-989
Operating profit/loss after depreciation, amortization and impairment	**-2,188**	**-2,179**	**-1,138**	**-1,307**	**-3,937**
Profit/loss from financial investments	-300	-300	-150	-150	-1,241
Profit/loss after financial items	**-2,488**	**-2,479**	**-1,288**	**-1,457**	**-5,178**
Taxes	0	0	0	0	0

Loss for the year	**-2,488**	**-2,479**	**-1,288**	**-1,457**	**-5,178**

Condensed Consolidated Balance Sheet

(SEK 000s)	June 30, 2019	June 30, 2018	Dec 31, 2018	Dec. 31, 2017
ASSETS				
Intangible assets	13,364	11,199	11,429	11,267
Property, plant and equipment	0	0	0	0
Financial assets	0	0	0	0
Total non-current assets	**13,364**	**11,199**	**11,429**	**11,267**
Total current assets	**6,404**	**14,414**	**10,714**	**19,835**
Total assets	**19,768**	**25,613**	**22,144**	**31,101**
LIABILITIES AND EQUITY				
Total equity	**18,063**	**23,354**	**20,920**	**26,088**
Non-current liabilities	0	0	0	0
Current liabilities	1,705	2,259	1,223	5,013
TOTAL EQUITY AND LIABILITIES	**19,768**	**25,613**	**22,144**	**31,101**

Condensed balance sheet – Parent Company

(SEK 000s)	June 30, 2019	June 30, 2018	Dec 31, 2018	Dec. 31, 2017
ASSETS				
Intangible assets	5,738	4,966	4,978	4,855
Property, plant and equipment	0	0	0	0
Financial assets	7,832	6,872	6,832	6,672
Total non-current assets	**13,570**	**11,838**	**11,810**	**11,527**
Total current assets	**6,192**	**14,197**	**10,334**	**19,794**
Total assets	**19,762**	**26,035**	**22,144**	**31,321**
LIABILITIES AND EQUITY				
Total equity	**18,607**	**23,794**	**21,095**	**26,273**
Non-current liabilities	81	87	81	87
Current liabilities	1,073	2,154	967	4,961
TOTAL EQUITY AND LIABILITIES	**19,762**	**26,035**	**22,144**	**31,321**

Summary Consolidated Statement of Cash Flows

(SEK 000s)	Jan. 1, 2019 June 30, 2019 6 months	Jan. 1, 2018 June 30, 2018 Cf 6 months	April 1, 2019 June 30, 2019 Q2	April 1, 2018 June 30, 2018 Cf Q2	Jan. 1, 2018 2018-12-10 Cf 12 months
Cash flow from operations during the period	-1,749	-1,702	-758	-1,065	-3,106
Changes in working capital	614	16,527	4	-583	-15,562
Cash flow from operations after change in working capital	**-1,135**	**14,825**	**-754**	**-1,648**	**12,456**
Cash flow from investing activities	-3,043	-964	-2,076	-582	-2,225
Cash flow from financing activities	0	0	0	0	0
Cash flow for the period	**4,178**	**13,861**	**-2,830**	**-2,230**	**10,231**
Cash/cash equivalents at beginning of period	10,266	34	8,918	16,125	34
Cash/cash equivalents at end of period	**6,088**	**13,895**	**6,088**	**13,895**	**10,266**

Condensed Statement of Cash Flows - Parent Company

(SEK 000s)	Jan. 1, 2019 June 30, 2019 6 months	Jan. 1, 2018 June 30, 2018 Cf 6 months	April 1, 2019 June 30, 2019 Q2	April 1, 2018 June 30, 2018 Cf Q2	Jan. 1, 2018 2018-12-10 Cf 12 months
Cash flow from operations during the period	-1,972	-1,984	-1,030	-1,209	-4,189
Changes in working capital	-1,173	15,984	-1,173	-555	14,773
Cash flow from operations after change in working capital	**-3,145**	**14,000**	**-2,203**	**-1,764**	**10,584**
Cash flow from investing activities	-977	-305	-559	-300	-517
Cash flow from financing activities	0	0	0	0	0
Cash flow for the period	**-4,122**	**13,695**	**-2,762**	**-2,064**	**10,067**
Cash/cash equivalents at beginning of period	10,067	0	8,707	15,759	0
Cash/cash equivalents at end of period	**5,945**	**13,695**	**5,945**	**13,695**	**10,067**

Condensed consolidated statement of changes in equity – Jan. 1, 2019 – June 30, 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		165	-165	
Profit/loss for the period				-2,857
Amount at end of period	**7,858**	**22,735**	**-9,672**	**-2,857**

Condensed statement of changes in equity – Parent Company Jan. 1, 2019 – June 30, 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		165	-165	
Profit/loss for the period				-2,857
Amount at end of period	**7,858**	**22,735**	**-9,672**	**-2,857**

Submission of report

Lund, August 30, 2019
Respiratorius AB (publ)
Board of Directors

For additional information, please contact:

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