RESPIRATORIUS

BK/19

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

SUMMARY OF YEAR-END REPORT [1]

Full year (Jan. 1, 2019 – Dec. 31, 2019)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 5,054 (loss: 5,167) thousand.
- Earnings per share totaled SEK -0.03 (-0.03).
- The equity ratio[2] as of Dec. 31, 2019 was 90%.

Fourth quarter (Oct. 1, 2019 – Dec. 31, 2019)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 861 (loss: 1,226) thousand.
- Earnings per share[3] totaled SEK -0.01 (-0.01).

1 Unless otherwise stated in this year-end report, all figures refer to the Group. Figures in parentheses refer to outcomes for the corresponding period the previous year.
[2] Equity ratio: Shareholders' equity divided by total capital.
[3] Earnings per share: Profit/loss for the period divided by 157,171,975 shares as of Dec. 31, 2019.

SIGNIFICANT EVENTS IN 2019

- In March, 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. In addition, according to the EMA about 700 patients should be a satisfactory number for such a study to be able to serve as a basis for market approval.
- In April, Respiratorius signed a contract with Partner International Inc. with the aim of completing the exit of VAL001. Partner International Inc. is tasked with continuing the discussion with previously identified candidates and seeking additional stakeholders, with the objective of signing an advantageous contract.

- In June, Respiratorius reported promising results from an airway study in an animal model using the patent-pending candidate substance RES030-085, in the RESP9000 series, for treatment of COPD and severe asthma.

- In November, the Canadian Intellectual Property Office (CIPO) announced that it intends to approve Respiratorius' patent application for VAL001, "A Pharmaceutical Composition Comprising an HDAC Inhibitor and a Steroid and the Use thereof."

SIGNIFICANT EVENTS FOLLOWING THE END OF THE PERIOD

- No events to report

Comments by the CEO

In 2019, VAL001 continued to strengthen its position as an extremely promising drug candidate for a type of lymph node cancer. We are pleased to report that the same applies to Respiratorius' new product candidate in respiratory diseases, RESP9000.

At a scientific advisory meeting with the EMA regarding clinical strategy, VAL001 was assessed as meeting the criteria for a Phase III study, which should be able to serve as a basis for marketing approval. Meeting the criteria for a Phase III study significantly advances the VAL001 project forward in time and reduces time to market.

Since VAL001 is now poised for a Phase III study, the exit process was intensified as the Company entered into an agreement with Partner International Inc., which has an excellent reputation and global representation in corporate and business development in the life science industry. Partner International Inc. is tasked with completing the exit process for VAL001, which may entail the sale of the company Valcuria AB, in which all intangible assets related to the project are gathered, a sale of intangible assets, or some form of licensing.

I would like to clarify that the timing of the exit of VAL001 is not critical, but rather is guided by receiving maximum payment in a license or sale deal, since the value of the project is still being enhanced without delaying the timeline.

Within the project for new medications for effective treatment of COPD and severe asthma, RESP9000, an airway study in an animal model was conducted using the patent-pending candidate substance RES030-085. The preclinical study showed that RES030-085 has a clear and statistically significant bronchodilatory effect compared with a control group. Moreover, no measured or observed adverse reactions were demonstrated at the effective dose of RES030-085.

This is the first time that any Respiratorius substance has demonstrated a bronchodilatory effect in an in vivo model. Prior assessments of efficacy are mainly based on ex vivo experiments on tissue samples (bronchioles) from humans and rats. These experiments showed that the bronchodilatory substances from Respiratorius chemical series are 100 times less sensitive for rats compared with humans. Consequently, it was not a given that it would be possible to demonstrate in vivo efficacy in rats.

Overall, 2019 entailed continued value growth in our projects. The clinical significance of VAL001 has been clearly demonstrated and the Company remains optimistic regarding the objective of finding an exit partner for VAL001 prior to starting a Phase III study. The results from the in vivo study with RESP9000 make the project extremely promising and increase its market potential.

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 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.

Brief overview of Respiratorius' project portfolio:

<u>VAL001 – Drug candidate for the treatment of diffuse large B-cell lymphoma</u>

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. According to discussions with the European Medicines Agency (EMA), a pivotal Phase II study should be sufficient to meet the documentation requirements for a marketing authorization application.

Prior to the start of a Phase III study using the new dedicated formulation, the EMA also considers that it would 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.

VAL001 received orphan drug status in Europe and the US, and patents were granted in the EU, the US, Japan, Canada 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.

An in vivo efficacy study was conducted by an internationally renowned contract laboratory in an established animal model with good results. In the study, the experimental animals were exposed to a bronchoconstrictor (carbamylcholine) and 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.

The patent application for RESP9000 has been 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 severe 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 approved 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 can proceed according to plan.

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.

Annual Report and Annual General Meeting

Respiratorius' annual report for the 2019 financial year will be published on the Company's website (www.respiratorius.com) and the Spotlight website (www.spotlightstockmarket.se) no later than three weeks prior to the Annual General Meeting.

The 2020 Annual General Meeting will be held on May 19 in Lund. The time and location of the Annual General Meeting will be published in conjunction with the invitation to the AGM.

Nomination Committee

In accordance with the decision taken at the 2019 Annual General Meeting, the Nomination Committee was appointed and announced prior to the AGM. The Nomination Committee consists of Christer Fåhraeus, Chairman of the Nomination Committee, Fårö Capital AB, Johan Drott, Valcuria Holding AB and Hans Harvig.

Proposed appropriation of profit or loss

The Board of Directors proposes that no dividend be paid for the 2019 financial year.

The share

The Respiratorius share (nickname: RESP) was listed in 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 December 31, 2019, the number of shares in Respiratorius AB 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.

Holdings of insiders

Natural/Legal entity	Position at Respiratorius	Shares as of Dec. 31, 2019
Christer Fåhraeus, Fårö Capital AB	Chairman of the Board	20,564,362
Kristina Drott, Valcuria Holding AB[3]	Board member	11,265,462
Sarah Fredriksson	Board member	0
Ingemar Kihlström, Ingemar Kihlström AB	Board member	801,167
Olov Sterner	Board member	402,178
Anna Törner	Board member	0
Johan Drott, Valcuria Holding AB[1]	CEO	11,265,462

Principles for preparation of the year-end report

This year-end 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.

[1] Valcuria Holding AB is owned by Kristina Drott (9.6%), Johan Drott (49.8%) and two external individuals (one natural person and one legal entity)

Audit

The year-end report has not been reviewed by the Company's auditor.

Calendar 2020/2021

- Interim report for the period Jan-March 2020 May 19, 2020
- Annual General Meeting 2020 May 19, 2020
- Half-Yearly Report for the period Jan-June 2020 August 25, 2020
- Interim Report for the period Jan.-Oct. 2020 November 4, 2020
- Year-end report 2020 February 3, 2021

Submission of 2019 Year-end Report

The Board of Directors and the Chief Executive Officer hereby certify that this year-end report for the period January – December 2019 provides a true and fair overview of operations at Respiratorius AB.

Lund, February 4, 2020

Respiratorius AB (publ)

Board of Directors and Chief Executive Officer

Condensed consolidated income statement

(SEK 000s)	2019-10-01 Dec. 31, 2019 Q4	Oct. 1, 2018 Dec. 31, 2018 Q4	Jan. 1, 2019 Dec. 31, 2019 Cf 12 months	Jan. 1, 2018 Dec. 31, 2018 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	-1,802	-420	-4,286	-2,485
Administrative costs	-1,006	-838	-5,036	-2,844
Other expenses	0	0	0	0
Capitalized patent and development costs	2,198	550	6,181	2,225
Operating profit/loss before depreciation, amortization and impairment	**-610**	**-708**	**-3,141**	**-3,104**
Depreciation/Amortization	-251	-516	-1,913	-2,062
Operating profit/loss after depreciation, amortization and impairment	**-861**	**-1,224**	**-5,054**	**-5,166**
Profit/loss from financial investments	0	-1	0	-1
Profit/loss after financial items	**-861**	**-1,225**	**-5,054**	**-5,167**
Taxes	0	0	0	0
Loss for the year	**-861**	**-1,225**	**-5,054**	**-5,167**

Condensed income statement – Parent Company

(SEK 000s)	Oct. 1, 2019 Dec. 31, 2019 Q4	Oct. 1, 2018 Dec. 31, 2018 Q4	Jan. 1, 2019 Dec. 31, 2019 Cf 12 months	Jan. 1, 2018 Dec. 31, 2018 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	-1,614	-119	-3,101	-1,348
Administrative costs	-968	-734	-3,560	-2,712
Other expenses	0	0	0	0
Capitalized patent and development costs	2,022	147	3,720	1,111
Operating profit/loss before depreciation, amortization and impairment	**-560**	**-706**	**-2,941**	**-2,949**
Depreciation/Amortization	45	-248	-729	-989
Operating profit/loss after depreciation, amortization and impairment	**-515**	**-954**	**-3,670**	**-3,937**
Profit/loss from financial investments	-930	-791	-1,380	-1,241
Profit/loss after financial items	**-1,445**	**-1,745**	**-5,050**	**-5,178**
Taxes	0	0	0	0
Loss for the year	**-1,445**	**-1,745**	**-5,050**	**-5,178**

Condensed Consolidated Balance Sheet

(SEK 000s)	Dec. 31, 2019	Dec. 31, 2018	Dec. 31, 2017
ASSETS			
Intangible assets	15,697	11,429	11,267
Property, plant and equipment	0	0	0
Financial assets	0	0	0
Total non-current assets	**15,697**	**11,429**	**11,267**
Total current assets	**1,916**	**10,714**	**19,835**
Total assets	**17,613**	**22,144**	**31,101**
LIABILITIES AND EQUITY			
Total equity	**15,866**	**20,920**	**26,088**
Non-current liabilities	0	0	0
Current liabilities	1,747	1,223	5,013
TOTAL EQUITY AND LIABILITIES	**17,613**	**22,144**	**31,101**

Condensed balance sheet – Parent Company

(SEK 000s)	Dec. 31, 2019	Dec. 31, 2018	Dec. 31, 2017
ASSETS			
Intangible assets	7,969	4,978	4,855
Property, plant and equipment	0	0	0
Financial assets	8,152	6,832	6,672
Total non-current assets	**16,121**	**11,810**	**11,527**
Total current assets	**1,650**	**10,334**	**19,794**
Total assets	**17,771**	**22,144**	**31,321**
LIABILITIES AND EQUITY			
Total equity	**16,045**	**21,095**	**26,273**
Non-current liabilities	76	81	87
Current liabilities	1,650	967	4,961
TOTAL EQUITY AND LIABILITIES	**17,771**	**22,144**	**31,321**

Summary Consolidated Statement of Cash Flows

(SEK 000s)	Oct. 1, 2019 Dec. 31, 2019 Q4	Oct. 1, 2018 Dec. 31, 2018 Q4	Jan. 1, 2019 Dec. 31, 2019 cf 12 months	Jan. 1, 2018 Dec. 31, 2018 cf 12 months
Cash flow from operations during the period	-1,111	-710	-3,141	-3,106
Changes in working capital	905	-1,110	677	15,562
Cash flow from operations after change in working capital	**-206**	**-1,820**	**-2,464**	**12,456**
Cash flow from investing activities	-1,696	-550	-6,181	-2,225
Cash flow from financing activities	0	0	0	0
Cash flow for the period	**-1,902**	**-2,370**	**-8,645**	**10,231**
Cash/cash equivalents at beginning of period	3,523	12,636	10,266	34
Cash/cash equivalents at end of period	**1,621**	**10,266**	**1,621**	**10,266**

Condensed Statement of Cash Flows - Parent Company

(SEK 000s)	Oct. 1, 2019 Dec. 31, 2019 Q4	Oct. 1, 2018 Dec. 31, 2018 Q4	Jan. 1, 2019 Dec. 31, 2019 cf 12 months	Jan. 1, 2018 Dec. 31, 2018 cf 12 months
Cash flow from operations during the period	-1,491	-1,497	-4,321	-4,189
Changes in working capital	1,360	-670	-1,253	14,773
Cash flow from operations after change in working capital	**-131**	**-2,166**	**-5,575**	**10,584**
Cash flow from investing activities	-1,877	3	-3,125	-517
Cash flow from financing activities	0	0	0	0
Cash flow for the period	**-2,008**	**-2,163**	**-8,700**	**10,067**
Cash/cash equivalents at beginning of period	3,375	12,230	10,067	0
Cash/cash equivalents at end of period	**1,367**	**10,067**	**1,367**	**10,067**

Condensed consolidated statement of changes in equity – Jan. 1, 2019 – Dec. 31, 2019

(SEK 000s)	Share capital	Restricted reserves	Non-restricted reserves	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		316	-316	
Profit/loss for the period				- 5,054
Amount at end of period	**7,858**	**22,886**	**-9,823**	**-5,054**

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

(SEK 000s)	Share capital	Restricted reserves	Non-restricted reserves	Loss for the year
Amount at start of period	**7,858**	**22,570**	**-4,155**	**-5,178**
Transfer of profit/loss			-5,178	5,178
Fund for development costs		316	-316	
Profit/loss for the period				-5,050
Amount at end of period	**7,858**	**22,886**	**-9,649**	**-5,050**

For additional information, please contact:

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This information is information that Respiratorius AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, on February 4, 2020.