

SUMMARY OF YEAR-END REPORT (GROUP)

Full year (Jan. 1, 2018 Dec. 31, 2018)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 5,167 (loss: 4,928) thousand.
- Earnings per share totaled SEK -0.03 (-0.04).
- The equity ratio¹ as of Dec. 31, 2018 was 94%.

Fourth quarter (Oct. 1, 2018 – Dec. 31, 2018)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 1,744 (loss: 1,866) thousand.
- Earnings per share² totaled SEK -0.01 (-0.01).

SIGNIFICANT EVENTS IN 2018

VAL001

- At the end of February the Company reported favorable final results from the phase I/IIa clinical studies with VAL001.

The compiled final results are better than the previous interim analysis, which was presented in 2016. Overall survival for 32 patients treated with VAL001 and R-CHOP for 1-year survival is 100%, while 2-year survival is 96.8%. Comparison data in a matched reference population of 330 patients from the Swedish Lymphoma Registry who were treated with R-CHOP alone showed a 1-year survival rate of 89.6% and 2-year survival of 81.7%. These data show a statistically significant survival advantage ($p=0.034$) among patients treated with the combination of VAL001 and R-CHOP compared with patients treated between 2000 and 2015 with R-CHOP alone.

¹ Equity ratio: Shareholders' equity divided by total capital

² Earnings per share: Profit/loss for the period divided by 157,171,975 shares as of March 31, 2018

- The highly esteemed scientific journal American Society of Hematology – Blood Advances, published the scientific article “Valproate in Combination with Rituximab and CHOP as First Line Therapy in Diffuse Large B-cell Lymphoma (VALFRID)” with co-authors including Kristina Drott and Mats Jerkeman.

The publication summarizes the results from the clinical study of VAL001, which was concluded during the first quarter of 2018.

- Respiratorius’ patent application for VAL001, “A Pharmaceutical Composition Comprising an HDAC Inhibitor and a Steroid and the Use thereof,” was approved by both the United States Patent and Trade Office (USPTO) and the Korean Intellectual Property Office (KIPO).

The patent will be issued upon payment of the formal fees, at which time Respiratorius will have market exclusivity in the US and Korea through 2031. Patents were previously granted in Europe and Japan under equivalent conditions.

RESP1000

- A patent application was submitted for a new substance that is the result of research conducted by Respiratorius in the fields of COPD and asthma. The new substance 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 RESP1000 series.

Respiratorius is now focusing on initiating clinical trials as soon as possible with the new substance, which is significantly more attractive with respect to its remaining patent time than RES022-125. Once a patent is granted, market exclusivity is obtained in all countries in which an application has been submitted through 2038.

RESP3000

- At the beginning of 2018 the European Patent Office (EPO) decided to grant a patent for RESP3000 and the Korean Intellectual Property Office (KIPO) announced a similar decision later in the year. Thus, patents have now been granted in Israel, Australia, the US, Japan, South Africa, Russia, Europe and Korea. A strong patent application that several other countries granted is expected to strengthen the Company’s position through market exclusivity in negotiations with potential partners.

Comments by the CEO

In 2018 VAL001 further consolidated its position as a highly promising product candidate. The final results from the clinical study show that 1-year and 2-year survival among patients treated with VAL001 and R-CHOP is about 15 percentage points higher compared with a reference group of patients taken from the Swedish lymphoma registry who were treated with R-CHOP alone. It is worth noting that clinically, patients who do not experience a recurrence of their cancer after two years are considered to be cured.

The patent portfolio for VAL001 was also considerably strengthened during the year as new patents were granted in the US and Korea, complementing previously granted patents in Europe and Japan. The approvals entail market exclusivity on important markets through 2031.

During the year the exit process for VAL001 was initiated, which may entail the sale of the company Valcuria AB, in which all intangible assets related to the project are gathered, a sale of patents, or some form of licensing. The Company believes that the prospects of finding a taker for VAL001 are good and our focus is on this process.

Preparatory work for continued clinical development of VAL001 is proceeding according to plan, including a scientific advisory meeting at the EMA regarding the continued clinical development process, as well as development of a new formulation of VAL001.

Within the project for new medications for effective treatment of COPD and severe asthma, the preclinical process is ongoing. During the year a patent application was submitted for a new substance, which is assessed as having a favorable safety profile and anti-inflammatory and bronchodilatory properties equivalent to those of previous product candidates. A patent application that is granted is accompanied by considerably longer patent protection compared with earlier product candidates, which is attractive for a taker. The objective is to initiate toxicological studies prior to the "First Time in Man" study, which will be an important step for the project.

Overall, 2018 entailed continued good value growth in our projects. Specifically, the value and clinical significance of VAL001 has clearly been consolidated. The Company thus remains optimistic regarding the objective of finding an exit partner for VAL001.



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 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.

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 December 31, 2018, 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.

Proposed appropriation of profit or loss

The Board of Directors and the CEO propose that no dividend be paid for the financial year Jan. 1, 2018 to Dec. 31, 2018.

Holdings of insiders

Natural/Legal entity	Position at Respiratorius	Shares as of Dec. 31, 2018
Johan Drott, Valcuria Holding AB ³	CEO	11,265,462
Kristina Drott, Valcuria Holding AB ³	Board member	11,265,462
Christer Fähræus, Färö Capital AB	Chairman of the Board	24,564,362
Ingemar Kihlström, Ingemar Kihlström AB	Board member	801,167
Olov Sterner	Board member	402,178
Sarah Fredriksson	Board member	0
Anders Månsson	Board member	47,214

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

- Q1 Interim Report May 28, 2019
- Annual General Meeting May 28, 2019
- Half-Yearly Report August 30, 2019
- Q3 Interim Report November 7, 2019
- Year-end report February 4, 2020

³ 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)

Condensed consolidated income statement

(SEK 000s)	Oct. 1, 2018	Oct. 1, 2017	Jan. 1, 2018	2017-01-01
	Dec. 31, 2018	Dec. 31, 2017	Dec. 31, 2018	Dec. 31, 2017
	Q4	Q4	Cf 12 months	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	-420	-664	-2,485	-2,429
Administrative costs	-838	-664	-2,844	-2,437
Other expenses	0	0	0	0
Capitalized patent and development costs	550	637	2,225	2,202
Operating profit/loss before depreciation, amortization and impairment	-708	-691	-3,104	-2,664
Depreciation/Amortization	-516	-560	-2,062	-2,240
Operating profit/loss after depreciation, amortization and impairment	-1,224	-1,251	-5,166	-4,904
Profit/loss from financial investments	-1	-24	-1	-24
Profit/loss after financial items	-1,225	-1,275	-5,167	-4,928
Taxes	0	0	0	0
Loss for the year	-1,225	-1,275	-5,167	-4,928

Condensed income statement – Parent Company

(SEK 000s)	Oct. 1, 2018	Oct. 1, 2017	Jan. 1, 2018	2017-01-01
	Dec. 31, 2018	Dec. 31, 2017	Dec. 31, 2018	Dec. 31, 2017
	Q4	Q4	Cf 12 months	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	-119	-499	-1,348	-1,585
Administrative costs	-734	-665	-2,712	-2,437
Other expenses	0	0	0	0
Capitalized patent and development costs	147	483	1,111	1,412
Operating profit/loss before depreciation, amortization and impairment	-706	-681	-2,949	-2,610
Depreciation/Amortization	-248	-311	-989	-1,246
Operating profit/loss after depreciation, amortization and impairment	-954	-992	-3,937	-3,856
Profit/loss from financial investments	-791	-874	-1,241	-1,324
Profit/loss after financial items	-1,745	-1,866	-5,178	-5,180
Taxes	0	0	0	0

Loss for the year	-1,745	-1,866	-5,178	-5,180
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Condensed Consolidated Balance Sheet

(SEK 000s)	Dec. 31, 2018	Dec. 31, 2017	Dec. 31, 2016
ASSETS			
Intangible assets	11,429	11,267	11,305
Property, plant and equipment	0	0	0
Financial assets	0	0	0
Total non-current assets	11,429	11,267	11,305
Total current assets	10,414	19,835	2,421
Total assets	22,144	31,101	13,726
LIABILITIES AND EQUITY			
Total equity	20,920	26,088	12,582
Non-current liabilities	0	0	0
Current liabilities	1,223	5,013	1,143
TOTAL EQUITY AND LIABILITIES	22,144	31,101	13,726

Condensed balance sheet – Parent Company

(SEK 000s)	Dec. 31, 2018	Dec. 31, 2017	Dec. 31, 2016
ASSETS			
Intangible assets	4,978	4,855	4,689
Property, plant and equipment	0	0	0
Financial assets	6,832	6,672	4,100
Total non-current assets	11,810	11,527	8,789
Total current assets	10,334	19,794	5,393
Total assets	22,144	31,321	14,182
LIABILITIES AND EQUITY			
Total equity	21,095	26,273	13,019
Non-current liabilities	81	87	93
Current liabilities	967	4,961	1,071
TOTAL EQUITY AND LIABILITIES	22,144	31,321	14,182

Condensed Consolidated Statement of Cash Flows

(SEK 000s)	Oct. 1, 2018 Dec. 31, 2018 Q4	Oct. 1, 2017 Dec. 31, 2017 Q4	Jan. 1, 2018 Dec. 31, 2018 cf 12 months	2017-01-01 Dec. 31, 2017 cf 12 months
Cash flow from operations during the period	-710	-715	-3,106	-2,688
Changes in working capital	-1,110	-16,415	15,562	-15,695
Cash flow from operations after change in working capital	-1,820	-17,130	12,456	-18,383
Cash flow from investing activities	-550	-637	-2,225	-2,202
Cash flow from financing activities	0	18,434	0	18,434
Cash flow for the period	-2,370	667	10,231	-2,151
Cash/cash equivalents at beginning of period	12,636	-633	34	2,185
Cash/cash equivalents at end of period	10,266	34	10,266	34

Condensed Statement of Cash Flows - Parent Company

(SEK 000s)	Oct. 1, 2018 Dec. 31, 2018 Q4	Oct. 1, 2017 Dec. 31, 2017 Q4	Jan. 1, 2018 Dec. 31, 2018 cf 12 months	2017-01-01 Dec. 31, 2017 cf 12 months
Cash flow from operations during the period	-1,497	-1,555	-4,189	-3,934
Changes in working capital	-670	-15,901	14,773	-15,845
Cash flow from operations after change in working capital	-2,166	-17,455	10,584	-19,779
Cash flow from investing activities	3	-334	-517	-812
Cash flow from financing activities	0	18,429	0	18,429
Cash flow for the period	-2,163	640	10,067	-2,162
Cash/cash equivalents at beginning of period	12,230	-640	0	2,162
Cash/cash equivalents at end of period	10,067	0	10,067	0

Condensed consolidated statement of changes in equity – Jan. 1, 2018 – Dec. 31, 2018

(SEK 000s)	Share capital	Restricted reserves	Non-restricted reserves	Loss for the year
Amount at start of period	6,985	22,295	863	-4,928
Transfer of profit/loss			-4,928	4,928
Fund for development costs		275	-275	
Issue of new shares	873			
Issue costs				
Profit/loss for the period				-5,167
Amount at end of period	7,858	22,570	-4,340	-5,167

Condensed statement of changes in equity – Parent Company Jan. 1, 2018 – Dec. 31, 2018

(SEK 000s)	Share capital	Restricted reserves	Non-restricted reserves	Loss for the year
Amount at start of period	6,985	22,295	1,300	-5,180
Transfer of profit/loss			-5,180	5,180
Fund for development costs		275	-275	
Issue of new shares	873			
Issue costs				
Profit/loss for the period				-5,178
Amount at end of period	7,858	22,570	-4,155	-5,178

Submission of Year-end Report

Lund, February 5, 2019
Respiratorius AB (publ)
Board of Directors

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