

## **BK/17**

Jan. 1, 2017– Dec. 31, 2017 Respiratorius AB (publ) 556552-2652

#### SUMMARY OF YEAR-END REPORT (GROUP)

#### Full year (Jan. 1, 2017 Dec. 31, 2017)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 4,928 (loss: 4,853) thousand.
- Earnings per share totaled SEK -0.04 (-0.03).
- The equity ratio<sup>1</sup> as of Dec. 31, 2017 was 83%.

#### Fourth quarter (Oct. 1, 2017 – Dec. 31, 2017)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 1,866 (loss: 1,164) thousand.
- Earnings per share<sup>2</sup> totaled SEK -0.01 (-0.03).

#### SIGNIFICANT EVENTS DURING THE FOURTH QUARTER

- Respiratorius has found, in collaboration with Cadila, regarding RESP1000, that the product candidate RES022-125 demonstrates a disease-modulating effect in an established animal model for the disease COPD. Based on these positive preliminary data, Respiratorius intends to carry out GLP toxicology studies and, barring the unforeseen, subsequent phase I or phase I/IIa with a focus on Europe.
- Respiratorius announced that the Company is taking important steps prior to initiating
  phase IIb/III studies for VAL001, and preparing clinical trials of RESP1000 in Europe. To
  finance the studies and working capital, the Company's Board of Directors decided to
  conduct a rights issue, which raised about SEK 21 million before issue expenses.
- Respiratorius announced that VINNOVA, as part of its call for proposals for Challengedriven Innovation step 3, granted substantial funding for the project "Improved cancer diagnostics and pharmaceutical development." RISE is coordinating the project in which Respiratorius and 10 other clinical, industrial and academic parties are participating.

<sup>&</sup>lt;sup>1</sup> Equity ratio: Shareholders' equity divided by total capital

<sup>&</sup>lt;sup>2</sup> Earnings per share: Profit/loss for the period divided by 139,708,423 shares as of Dec. 31, 2017

#### SIGNIFICANT EVENTS IN 2017

- During the first half of the year the US Food and Drug Administration (FDA) granted orphan
  drug status for VAL001. The decision applies to valproic acid, which is one of the active
  ingredients in VAL001, for the treatment of diffuse large B-cell lymphoma. The European
  Commission issued a similar decision in 2016 following a review by the European
  Medicines Agency (EMA).
- During the year Respiratorius announced several patent approvals for RESP3000.
   Australia, the US, Japan, and Russia were added during the year.

#### SIGNIFICANT EVENTS AFTER THE BALANCE SHEET DATE 2017

At the beginning of 2018 the European Patent Office (EPO) also announced that it had
issued a decision to grant a patent for RESP3000. Thus, patents have now been granted
in Israel, Australia, USA, Japan, South Africa, Russia and Europe. A strong patent
application with approvals in several other countries is expected to strengthen the
Company's position through market exclusivity in negotiations with potential partners.

# Comments by the CEO

Respiratorius continued to make progress in 2017, especially in the RESP1000 and VAL001 projects.

The collaboration with Cadila Pharmaceuticals Ltd. relating to RESP1000 is progressing and has successfully shown that it is possible to synthesize and produce our product candidate RES022-125 on a large scale.

An efficacy study of RES022-125 has demonstrated a disease-modulating effect in an established COPD model based on mice that have been induced to regularly inhale tobacco smoke. The study was carried out by Cadila in India and Respiratorius is now reviewing the results with the assistance of experts in this type of preclinical trial.

As a result of these promising new findings, the Company intends to assume a clear active and leading role in the continued development with the goal of initiating clinical trials of RES022-125. Initiating a clinical study aimed at COPD, a common disease that currently lacks satisfactory treatment, would represent an important milestone for Respiratorius.

With a leading role in the continuing collaboration with Cadila, Respiratorius intends to carry out toxicological studies of RES022-125 in Europe, in collaboration with prominent certified toxicological laboratories. This approach will speed up and simplify preparations for starting clinical trials in Europe, which will probably make the project more attractive to potential partners. There are no additional changes relating to the collaboration with Cadila for the development of RESP1000 at this time, but the contract may be renegotiated to reflect Respiratorius' investment in the development process.

The development of VAL001 is progressing according to plan and in 2017 the Company received Orphan Drug Designation in the US for Valproat for the treatment of diffuse large B-cell lymphoma. In 2016 the European Commission issued a similar decision, after a review conducted by the European Medicines Agency (EMA), to grant equivalent status for the project in the EU.

The ongoing clinical development consists of the phase IIa study, which is expected to be completed in the first half of 2018 and will be reported as soon as possible thereafter. While this clinical trial is in progress, a phase IIb/III study is being planned to continue the clinical development process. The preparatory work includes development of the clinical trial protocol for approval by the Swedish Medical Products Agency, as well as development and production of the medicine in tablet form.

An exit process for VAL001 has begun. The results of such an exit discussion may involve a sale of the rights to the VAL001 project, or of the subsidiary Valcuria AB, in which all findings and IPR material belonging to VAL001 are gathered.

Implementing these aggressive plans for RESP1000 and VAL001 requires new funding. At the end of 2017, the Company completed a successful and oversubscribed rights issue, with a subscription rate of 120%, which raised approximately SEK 21 million for the Company before issue expenses.

With funding that is now considered to be sufficient for 12 to 18 months, the Company is now entering a new stage of development with two promising projects – VAL001, which is in advanced clinical development and is initiating the exit process, and RESP1000, which is about to begin clinical development.

Johan Drott

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 study of VAL001 for treatment of patients with DLBCL is fully enrolled and all patients have undergone treatment. An interim analysis of the phase I/IIa study showed promising results. The initiative to find an optimal formulation directly adapted for the indication was successful and a new patent application has been filed for this formulation.

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 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 is increasingly focusing its internal development resources on cancer, primarily the development of drugs for the treatment of malignant lymphoma. Development work relating to COPD and asthma is conducted in cooperation with Cadila Pharmaceuticals Ltd., India, through a licensing and collaboration agreement. 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 clearly shown positive experimental 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 study and the now fully enrolled phase IIa study is being conducted at Skåne University Hospital in Lund, Uppsala University Hospital, and Norrland University Hospital in Umeå. The results from the phase I study demonstrate specific effects, such as increased levels of CD20, which may likely be beneficial in patients treated with Rituximab. An

interim analysis from the phase I/IIa study shows 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 843 patients. This clinical phase I/IIa study is expected to be completed and reported during the first half of 2018. VAL001 (valproic acid) for the treatment of DLBCL received orphan drug status in Europe and the US, and patents were granted in the EU and Japan.

#### RESP1000 - Drugs for 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.

In 2017 an efficacy study of the product candidate RES022-125 was carried out with promising results. The goal is to initiate toxicological studies as soon as possible prior to beginning clinical phase I studies in Europe.

Patents protecting the entire RESP1000 series have been granted in several countries.

#### RESP2000 - Drug candidate for 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 protecting the entire RESP2000 series 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. 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 protecting the entire RESP3000 series 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, 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, 2017, the number of shares in the Company was 139,708,423. 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, 2017 to Dec. 31, 2017.

#### Holdings of insiders

Natural/Legal entity	Position at Respiratorius	Shares as of Dec. 31, 2017	Paid subscribed shares as of Dec. 31, 2017
Johan Drott, Valcuria Holding AB <sup>3</sup>	CEO	10,800,000	465,462
Kristina Drott, Valcuria Holding AB <sup>3</sup>	Board member	10,800,000	465,462
Christer Fåhraeus, Fårö Capital AB	Chairman of the Board	21,835,100	2,729,262
Ingemar Kihlström, Ingemar Kihlström AB	Board member	801,167	
Olov Sterner	Board member	402,178	
Sarah Fredriksson	Board member	0	
Anders Månsson	Board member	21,517	

#### **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 15, 2018
 Annual General Meeting May 15, 2018
 Half-Yearly Report August 28, 2018
 Q3 Interim Report November 7, 2018

<sup>&</sup>lt;sup>3</sup> Valcuria Holding AB is owned by Kristina Drott (10%), Johan Drott (49.8%) and two external individuals (one natural person and one legal entity)

#### Condensed consolidated income statement

(SEK 000s)	Oct. 1, 2017 Dec. 31, 2017 Q4	Oct. 1, 2016 Dec. 31, 2016 Q4	Jan. 1, 2017 Dec. 31, 2017 cf 12 months	Jan. 1, 2016 Dec. 31, 2016 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	-664	-159	-2,429	-1,563
Administrative costs	-664	-911	-2,437	-2,275
Other expenses	0	0	0	0
Capitalized patent and development costs	637	403	2,202	1,566
Operating profit/loss before depreciation, amortization and impairment	-691	-667	-2,664	-2,273
Depreciation/Amortization	-560	-643	-2,240	-2,572
Operating profit/loss after depreciation, amortization and impairment	-1,251	-1,310	-4,904	-4,845
Profit/loss from financial investments	-24	0	-24	-9
Profit/loss after financial items	-1,275	-1,310	-4,928	-4,853
Taxes	0	0	0	0
Profit/loss for the year	-1,275	-1,310	-4,928	-4,853

#### Condensed income statement – Parent Company

(SEK 000s)	Oct. 1, 2017 Dec. 31, 2017 Q4	Oct. 1, 2016 Dec. 31, 2016 Q4	Jan. 1, 2017 Dec. 31, 2017 cf 12 months	Jan. 1, 2016 Dec. 31, 2016 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	-499	-422	-1,585	-1,281
Administrative costs	-665	-505	-2,437	-1,858
Other expenses	0	0	0	0
Capitalized patent and development costs	483	292	1,412	932
Operating profit/loss before depreciation, amortization and impairment	-681	-636	-2,610	-2,206
Depreciation/Amortization	-311	-410	-1,246	-1,641
Operating profit/loss after depreciation, amortization and impairment	-992	-1,046	-3,856	-3,848
Profit/loss from financial investments	-874	-650	-1,324	-1,109
Profit/loss after financial items	-1,866	-1,696	-5,180	-4,956
Taxes	0	0	0	0

Profit/loss for the year -1,866 -1,696 -5,180 -4,956

#### Condensed Consolidated Balance Sheet

(SEK 000s)	Dec. 31, 2017	Dec. 31, 2016	Dec. 31, 2015
ASSETS			
Intangible non-current assets	11,267	11,305	12,311
Property, plant and equipment	0	0	0
Financial assets	0	0	0
Total non-current assets	11,267	11,305	12,311
Total current assets	19,835	2,421	7,937
Total assets	31,101	13,726	20,247
LIABILITIES AND EQUITY			
Total equity	26,088	12,582	17,436
Non-current liabilities	0	0	0
Current liabilities	5,013	1,143	2,812
TOTAL EQUITY AND LIABILITIES	31,101	13,726	20,247

#### Condensed balance sheet – Parent Company

(SEK 000s)	Dec. 31, 2017	Dec. 31, 2016	Dec. 31, 2015
ASSETS			
Intangible non-current assets	4,855	4,689	5,398
Property, plant and equipment	0	0	0
Financial assets	6,672	4,100	4,700
Total non-current assets	11,527	8,789	10,098
Total current assets	19,794	5,393	10,277
Total assets	31,321	14,182	20,376
LIABILITIES AND EQUITY			
Total equity	26,273	13,019	17,975
Non-current liabilities	87	93	98
Current liabilities	4,961	1,071	2,303
TOTAL EQUITY AND LIABILITIES	31,321	14,182	20,376

#### Summary Consolidated Statement of Cash Flows

(SEK 000s)	Oct. 1, 2017 Dec. 31, 2017 Q4	Oct. 1, 2016 Dec. 31, 2016 Q4	Jan. 1, 2017 Dec. 31, 2017 cf 12 months	Jan. 1, 2016 Dec. 31, 2016 cf 12 months
Cash flow from operations during the period	-715	-667	-2,688	-2,282
Changes in working capital	-16,415	202	-15,695	6,016
Cash flow from operations after changes in working capital	-17,130	-465	-18,383	3,734
Cash flow from investing activities	-637	-402	-2,202	-1,566
Cash flow from financing activities	18,434	0	18,434	0
Cash flow for the period	667	-867	-2,151	2,168
Cash/cash equivalents at beginning of period	-633	3,053	2,185	17
Cash/cash equivalents at end of period	34	2,185	34	2,185

#### Summary Statement of Cash Flows - Parent Company

(SEK 000s)	Oct. 1, 2017 Dec. 31, 2017 Q4	Oct. 1, 2016 Dec. 31, 2016 Q4	Jan. 1, 2017 Dec. 31, 2017 cf 12 months	Jan. 1, 2016 Dec. 31, 2016 cf 12 months
Cash flow from operations during the period	-1,555	-185	-3,934	-2,215
Changes in working capital	-15,901	-180	-15,845	5,309
Cash flow from operations after changes in working capital	-17,455	-365	-19,779	3,094
Cash flow from investing activities	-334	-291	-812	-932
Cash flow from financing activities	18,429	0	18,429	0
Cash flow for the period	640	-657	-2,162	2,162
Cash/cash equivalents at beginning of period	-640	2,819	2,162	0
Cash/cash equivalents at end of period	0	2,162	0	2,162

#### Condensed statement of changes in equity – Consolidated Jan. 1, 2017 – Dec. 31, 2017

(SEK 000s)	Share capital	Share capital, not registered	Restricted reserves	Non-restricted reserves	Profit/loss for the year
Amount at start of period	6,985		22,017	-11,567	-4,853
Transfer of profit/loss				-4,853	4,853
Fund for development costs			278	-278	
Issue of new shares					
Rights issue		873		20,083	
Issue costs				-2,522	
Profit/loss for the period					-4,928
Amount at end of period	6,985	873	22,295	863	-4,928

#### Condensed statement of changes in equity – parent company Jan. 1, 2017 – Dec. 31, 2017

(SEK 000s)	Share capital	Share capital, not registered	Restricted reserves	Non-restricted reserves	Profit/loss for the year
Amount at start of period	6,985		22,017	-11,027	-4,956
Transfer of profit/loss				-4,956	4,956
Fund for development costs			278	-278	
Issue of new shares				20,083	
Share capital, not registered		873			
Issue costs				-2,522	
Profit/loss for the period					-5,180
Amount at end of period	6,985	873	22,295	1,300	-5,180

#### Submission of Interim Report

Lund, February 6, 2018 Respiratorius AB (publ) Board of Directors

#### For additional information, please contact:

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This is a translation of the Swedish original. In case of discrepancies, the Swedish text shall prevail.