RESPIRATORIUS

BK/16

Jan. 1, 2016 – Dec. 31, 2016
Respiratorius AB (publ)
556552-2652

SUMMARY OF YEAR-END REPORT (GROUP)

Full year (Jan. 1, 2016 Dec. 31, 2016)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 4,853 (loss: 5,685) thousand.
- Earnings per share totaled SEK -0.01 (-0.05).
- The equity ratio[1] as of Dec. 31, 2016 was 92%.

Fourth quarter (Oct. 1, 2016 – Dec. 31, 2016)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 1,310 (loss: 1,540) thousand.
- Earnings per share[2] totaled SEK -0.01 (-0.01).

SIGNIFICANT EVENTS DURING THE FOURTH QUARTER

- Respiratorius announced in November that the European Commission granted orphan drug status for VAL001.

  Orphan drug status allows ten years of market exclusivity within the EU upon market approval. In addition, free scientific consultancy services are provided when contacting the Swedish Medical Products Agency, which includes support for designing clinical study protocols and reduced costs for regulatory applications prior to commercialization.
- Respiratorius' patent for VAL001 was granted by the European Patent Office (EPO).

  The patent covers a combination of an HDAC inhibitor and a steroid pretreatment before chemotherapy (R-CHOP) for the treatment of diffuse large B-cell lymphoma (DLBCL), a lymphoma that annually affects about 60,000 people in the United States and Europe. DLBCL is the most common type of non-Hodgkin's lymphoma and accounts for 30% of newly diagnosed cases of NHL in the EU.

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1 Equity ratio: Shareholders' equity divided by total capital

2 Earnings per share: Loss for the period divided by 139,708,423 as of Dec. 31, 2016

SIGNIFICANT EVENTS DURING 2016

- During the year Respiratorius announced several patent approvals: in addition to the patent for VAL001, which in November was approved in Europe, an equivalent application in Japan was approved in August. The patent filed for RESP1000 was granted in India and applications for RESP3000 were granted in the US and Israel.

  All patent approvals are expected to strengthen the Company's position through market exclusivity in negotiations with potential partners.

Comments by the CEO

2016 has been an important year for Respiratorius with several significant milestones. We have also been able to report continued favorable development in the project portfolio during the year.

In the first half of the year, we achieved an important goal for VAL001 in the results of the interim analysis of data from the ongoing clinical trial. The results from the analysis showed that 1-year survival of patients treated with VAL001 and R-CHOP was 100% and 2-year survival was 95%. A comparison with a matched reference population of 843 patients from the Swedish Lymphoma Registry treated with R-CHOP alone showed a 1-year survival rate of 90% and 2-year survival of 82%. Despite the limited material, the results were significantly better than the reference material for both 1-year survival (95% level of significance) and 2-year survival (90% level of significance). The goal is to complete the phase I/II study in the last quarter of 2017.

During the second half of the year a patent was granted for VAL001 in both Europe and Japan for the combination of an HDAC inhibitor and a steroid for pretreatment before chemotherapy (R-CHOP) in the treatment of diffuse large B-cell lymphoma (DLBCL). DLBCL is a lymphoma that annually affects about 60,000 people in the US and Europe. Both of these markets are considered important and the patents provide exclusivity until 2031.

VAL001 was also granted orphan drug designation in Europe following a decision by the European Commission. The decision was preceded by an objective review by experts at the European Medicines Agency (EMA) on the basis of clinical results and the prospects that VAL001 can be expected to have a significant advantage compared with current treatment of patients diagnosed with DLBCL. This decision entails market exclusivity in the EU for ten years following marketing approval. An application for orphan drug designation in the US was also submitted to the FDA in connection with the approval in Europe. The official expected processing time at the FDA is 120 days.

For RESP-3000, we were able to announce during the year that patents were granted in the US and Israel, which we consider to be of great significance. The US market is the single most important in size, but it is also important as a frontrunner for the adoption of new clinical technology.

The collaboration with Cadila Pharmaceuticals Ltd. relating to RESP1000 is still progressing as planned. The extensive preclinical toxicology program before the start of clinical trials is underway and the results to date have been satisfactory. The global market for effective new drugs for the treatment of COPD and asthma is huge and for COPD in particular there is a significant medical need for effective treatment. Being able to initiate clinical studies with RESP1000 will probably entail an important milestone for Respiratorius.

In summary, Respiratorius continued to move forward on all projects in 2016. The announcements about orphan drug designation are particularly gratifying. We look forward to similar announcements from additional regions.

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 IIa study of VAL001 for treatment of 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.

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, as well as 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/II study is expected to be completed during the fourth quarter of 2017.

The project has received orphan drug designation in Europe and an application for orphan drug designation in the US is currently being processed by the FDA.

RESP1000 – Drug candidate 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.

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.

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 RESP3000 with promising results.

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 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, 2016, 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, 2016 to Dec. 31, 2016.

Holdings of insiders

Natural/Legal entity	Position at Respiratorius	Shares as of Dec. 31, 2016
Johan Drott, Valcuria Holding AB[3]	CEO	5,380,560
Kristina Drott, Valcuria Holding AB	Board member	1,080,000
Christer Fåhraeus, Fårö Capital AB	Chairman of the Board	21,926,100
Ingemar Kihlström, Ingemar Kihlström AB	Board member	801,167
Olov Sterner	Board member	402,178
Sarah Fredriksson	Board member	0
Anders Månsson	Board member	0

Annual Report

Respiratorius' annual report for the 2016 financial year will be published on the respective websites of the Company (www.respiratorius.se) and AktieTorget (www.aktietorget.se) in April 2017. The Annual General Meeting of shareholders in Respiratorius will be held on May 2, 2017. The complete annual report will be presented not later than in connection with the invitation to the AGM.

Audit

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

Principles for preparation of the year-end report

This year-end report has been prepared in accordance with the Swedish Annual Accounts Act and BFNAR 2012:1 Annual Report and consolidated financial statements (K3). Transition to K3 has not led to any changes in accounting principles. Respiratorius only capitalizes development costs for projects that have entered clinical phase as well as for patent costs.

Calendar

- Q1 Interim Report May 2, 2017
- Annual General Meeting May 2, 2017
- Half-Yearly Report August 29, 2017
- Q3 Interim Report November 7, 2017
- Year-end report 2017 February 6, 2018

[3] 1 Valcuria Holding AB is owned by Kristina Drott, Johan Drott and two external people (one natural person and one legal entity)

Condensed consolidated income statement

(SEK 000s)	2016-10-01 2016-12-31 Q4	2015-10-01 2015-12-31 Q4	2016-01-01 2016-12-31 cf 12 months	2015-01-01 2015-12-31 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	-159	-889	-1,563	-2,499
Administrative costs	-911	-589	-2,275	-2,019
Other expenses	0	0	0	0
Capitalized patent and development costs	403	790	1,566	2,236
Operating profit/loss before depreciation, amortization and impairment	**-667**	**-688**	**-2,273**	**-2,281**
Depreciation/Amortization	-643	-848	-2,572	-3,391
Operating profit/loss after depreciation, amortization and impairment	**-1,310**	**-1,536**	**-4,845**	**-5,672**
Profit/loss from financial investments	0	-4	-9	-12
Profit/loss after financial items	**-1,310**	**-1,540**	**-4,853**	**-5,685**
Income tax expense	0	0	0	0
Profit/loss for the year	**-1,310**	**-1,540**	**-4,853**	**-5,685**

Condensed income statement – Parent Company

(SEK 000s)	2016-10-01 2016-12-31 Q4	2015-10-01 2015-12-31 Q4	2016-01-01 2016-12-31 cf 12 months	2015-01-01 2015-12-31 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	-422	-438	-181	-885
Administrative costs	-505	-550	-1,858	-1,963
Other expenses	0	0	0	0
Capitalized patent and development costs	292	353	932	642
Operating profit/loss before depreciation, amortization and impairment	**-636**	**-635**	**-2,206**	**-2,206**
Depreciation/Amortization	-410	-655	-1,641	-2,619
Operating profit/loss after depreciation, amortization and impairment	**-1,046**	**-1,290**	**-3,848**	**-4,825**
Profit/loss from financial investments	-650	-154	-1,109	-612
Profit/loss after financial items	**-1,696**	**-1,444**	**-4,956**	**-5,438**
Income tax expense	0	0	0	0

Profit/loss for the year	**-1,696**	**-1,444**	**-4,956**	**-5,438**

Summary Consolidated Balance Sheet

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

Condensed balance sheet – Parent Company

(SEK 000s)	2016-12-31	2015-12-31
ASSETS		
Intangible non-current assets	4,689	5,398
Property, plant and equipment	0	0
Financial assets	4,100	4,700
Total non-current assets	**8,789**	**10,098**
Total current assets	**5,393**	**10,277**
Total assets	**14,182**	**20,376**
LIABILITIES AND EQUITY		
Total equity	**13,019**	**17,975**
Non-current liabilities	93	98
Current liabilities	1,071	2,303
TOTAL EQUITY AND LIABILITIES	**14,182**	**20,376**

Summary Consolidated Statement of Cash Flows

(SEK 000s)	2016-10-01 2016-12-31 Q4	2015-10-01 2015-12-31 Q4	2016-01-01 2016-12-10 cf 12 months	2015-01-01 2015-12-31 Cf 12 months
Cash flow from operations during the period	-667	-692	-2,282	-2,294
Changes in working capital	202	-5,563	-6,016	-5,665
Cash flow from operations after changes in working capital	-465	-6,255	-3,734	-7,959
Cash flow from investing activities	-402	-790	-1,566	-2,236
Cash flow from financing activities	0	7062	0	7,062
Cash flow for the period	-867	-17	-2,168	-3,133
Cash/cash equivalents at beginning of period	3,053	0	17	3,150
Cash/cash equivalents at end of period	2,185	17	2,185	17

Summary of the parent company cash and cash equivalents

(SEK 000s)	2016-10-01 2016-12-31 Q4	2015-10-01 2015-12-31 Q4	2016-01-01 2016-12-10 cf 12 months	2015-01-01 2016-12-31 Cf 12 months
Cash flow from operations during the period	-185	-639	-2,215	-2,218
Changes in working capital	-180	-5,970	-5,309	-7,035
Cash flow from operations after changes in working capital	-365	-6,608	-3,094	-9,254
Cash flow from investing activities	-291	-453	-932	-898
Cash flow from financing activities	0	7,062	0	7,056
Cash flow for the period	-657	0	-2,162	3,095
Cash/cash equivalents at beginning of period	2,819	0	0	3095
Cash/cash equivalents at end of period	2,162	0	2,162	0

Condensed statement of changes in equity – Consolidated Jan. 1, 2016 – Dec. 31, 2016

(SEK 000s)	Share capital	Restricted reserves	Non-restricted reserves	Profit/loss for the year
Amount at start of period	**6,985**	**21,687**	**-5,552**	**-5,685**
Transfer of profit/loss			-5,685	5,685
Fund for development costs		330	-330	
Issue of new shares				
Issue costs				
Profit/loss for the period				-4,853
Amount at end of period	**6,985**	**22,017**	**-11,567**	**-4,853**

Condensed statement of changes in equity – parent company Jan. 1, 2016 – Dec. 31, 2016

(SEK 000s)	Share capital	Restricted reserves	Non-restricted reserves	Profit/loss for the year
Amount at start of period	**6,985**	**21,687**	**-5,259**	**-5,438**
Transfer of profit/loss			-5,438	5,438
Fund for development costs		**330**	-330	
Issue of new shares				
Issue costs				
Profit/loss for the period				-4,956
Amount at end of period	**6,985**	**22,017**	**-11,027**	**-4,956**

Submission of Year-end financial report

Lund, February 8, 2017
Respiratorius AB (publ)
Board of Directors

For additional information, please contact:

Johan Drott
CEO, Respiratorius AB (publ)
Telephone: 0709-22 41 40