RESPIRATORIUS

Q1/17

Jan. 1, 2017 to March 31, 2017
Respiratorius AB (publ)
556552-2652

SUMMARY OF Q1 REPORT 2017 (GROUP)

First quarter (Jan. 1, 2017 – March 31, 2017)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 1,247 (loss: 1,310) thousand.
- Earnings per share[1] totaled SEK -0.01 (-0.01).

SIGNIFICANT EVENTS DURING THE FIRST QUARTER OF 2017

- Australian Patent Office grants patent for RESP3000

  The Australian patent office issued a Notice of Acceptance for a patent application for the RESP3000 series, designed for use in cardiovascular diagnostics with PET imaging. The patent priority date dates back to December 2011, which means that the patent is in force until December 2031.

- US Patent Office grants another patent for RESP3000

  The US Patent Office issued a Notice of Allowance for a patent application for the RESP3000 series, designed for use in cardiovascular diagnostics with PET imaging. This granted patent contains requirements for expanded protection and is in force through December 2031.

- Board member Anders Månsson acquires Respiratorius AB shares

  Anders Månsson, who has been a member of the Board of Directors of Respiratorius AB since 2016, and who has not owned any shares to date, acquired 21,517 shares in the Company.

[1] Earnings per share: Profit/loss for the period divided by 139,708,423 shares as of March 31, 2017

SIGNIFICANT EVENTS AFTER THE FIRST QUARTER

- The US Food and Drug Administration (FDA) decides to grant Respiratorius' application for orphan drug designation for valproic acid in the treatment of diffuse large B-cell lymphoma.

  The FDA grants orphan drug designation (ODD) to drugs and biological products intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States. ODD provides certain benefits and incentives, including market exclusivity for 7 years after marketing approval for the designated indication.

- The Japan patent Office issues a "Notice of Allowance" for the patent application for the RESP3000 series, which is designed for use in cardiovascular diagnostics with PET imaging. The granted patent is in force until December 2031.

  Patents were previously granted in the US, Israel, Australia and South Africa. In addition, in March 2017 the US patent office granted a divisional application for RESP3000 relating to specific product requirements.

Comments by the CEO

In the first quarter of 2017, the Company achieved additional value-generating results through patents granted for RESP3000. The Company now possesses a strong patent portfolio with numerous patents granted for all projects.

For VAL001, preparations are underway for continued clinical development, which can begin after the Phase IIa study is reported (expected in the first half of 2018).

After the first quarter ended the FDA granted orphan drug status for valproic acid (VAL001) in the treatment of diffuse large B-cell lymphoma (DLBCL). The decision entails market exclusivity for 7 years after marketing approval for the designated indication. In 2016 VAL001 was granted orphan drug designation in Europe following a decision by the European Commission. In both cases, the decision was preceded by an objective review of clinical results as well as the prospects that VAL001 can be expected to have a significant advantage compared with current treatment of patients diagnosed with DLBCL.

Orphan drug status in the EU and the US combined with patents granted in the EU and Japan probably significantly strengthened the market position and interest in the project among potential partners, which is important both for the continued clinical development and for identifying a potential partner.

The collaboration with Cadila Pharmaceuticals Ltd. relating to RESP1000 is proceeding according to plan with preparations for clinical trials. COPD and severe asthma are major common diseases that still lack satisfactory treatments, which means that the market potential is huge. Initiating clinical studies will probably entail an important milestone for Respiratorius.

Patent protection for RESP3000 has been further strengthened with the recent approvals in Japan and the US. Both of these markets are significant and important in the effort to out-license the project.

In summary, 2017 has begun with continued good growth in value for all projects at Respiratorius. Of course it is particularly gratifying and important that orphan drug status was granted in both the EU and the US, along with additional patent approvals elsewhere.

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

RESP1000 – Drugs 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 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 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 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 March 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.

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

- Half-Yearly Report 2017 August 29, 2017
- Q3 Interim Report 2017 November 7, 2017
- Year-end report 2017 February 6, 2018

Condensed consolidated income statement

(SEK 000s)	Jan. 1, 2017 March 31, 2017 Q1	Jan. 1, 2016 Dec. 31, 2016 Q1	Jan. 1, 2016 Dec. 31, 2016 cf. 12 months	Jan. 1, 2015 Dec. 31, 2015 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	-473	-281	-1,563	-2,499
Administrative costs	-593	-384	-2,275	-2,019
Other expenses	0	0	0	0
Capitalized patent and development costs	379	261	1,566	2,236
Operating profit/loss before depreciation, amortization and impairment	**-687**	**-404**	**-2,273**	**-2,281**
Depreciation/Amortization	-560	-643	-2,572	-3,391
Operating profit/loss after depreciation, amortization and impairment	**-1,247**	**-1,047**	**-4,845**	**-5,672**
Profit/loss from financial investments	0	-9	-9	-12
Profit/loss after financial items	**-1,247**	**-1,056**	**-4,853**	**-5,685**
Taxes	0	0	0	0
Profit/loss for the year	**-1,247**	**-1,056**	**-4,853**	**-5,685**

Condensed income statement – Parent Company

(SEK 000s)	Oct. 1, 2016 Dec. 31, 2016 Q4	Oct. 1, 2015 Dec. 31, 2015 cf. Q4	Jan. 1, 2016 Dec. 31, 2016 cf. 12 months	Jan. 1, 2015 Dec. 31, 2015 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	-307	-162	-181	-885
Administrative costs	-592	-377	-1,858	-1,963
Other expenses	0	-0	0	0
Capitalized patent and development costs	228	147	932	642
Operating profit/loss before depreciation, amortization and impairment	**-671**	**-392**	**-2,206**	**-2,206**
Depreciation/Amortization	-312	-410	-1,641	-2,619
Operating profit/loss after depreciation, amortization and impairment	**-983**	-802	**-3,848**	**-4,825**
Profit/loss from financial investments	-150	-159	-1,109	-612
Profit/loss after financial items	**-1,133**	**-961**	**-4,956**	**-5,438**

Taxes	0	0	0	0
Profit/loss for the year	**-1,133**	**-961**	**-4,956**	**-5,438**

Summary Consolidated Balance Sheet

(SEK 000s)	March 31, 2017	March 31, 2016	Dec. 31, 2016	Dec. 31, 2015
ASSETS				
Intangible non-current assets	11,124	11,929	11,305	12,311
Property, plant and equipment	0	0	0	0
Financial assets	0	0	0	0
Total non-current assets	**11,124**	**11,929**	**11,305**	**12,311**
Total current assets	**1,450**	**5,101**	**2,421**	**7,937**
Total assets	**12,574**	**17,031**	**13,726**	**20,247**
LIABILITIES AND EQUITY				
Total equity	**11,334**	16,380	**12,582**	**17,436**
Non-current liabilities	0	0	0	0
Current liabilities	1,240	651	1,143	2,812
TOTAL EQUITY AND LIABILITIES	**12,574**	**17,031**	**13,726**	**20,247**

Condensed balance sheet – Parent Company

(SEK 000s)	March 31, 2017	March 31, 2016	Dec. 31, 2016	Dec. 31, 2015
ASSETS				
Intangible non-current assets	4,606	5,135	4,689	5,398
Property, plant and equipment	0	0	0	0
Financial assets	3,950	4,550	4,100	4,700
Total non-current assets	**8,556**	**9,685**	**8,789**	**10,098**
Total current assets	**4,601**	**7,981**	**5,393**	**10,277**
Total assets	**13,157**	**17,667**	**14,182**	**20,376**
LIABILITIES AND EQUITY				
Total equity	**11,886**	**17,014**	**13,019**	**17,975**
Non-current liabilities	93	98	93	98
Current liabilities	1,178	555	1,071	2,303
TOTAL EQUITY AND LIABILITIES	**13,157**	**17,667**	**14,182**	**20,376**

Summary Consolidated Statement of Cash Flows

(SEK 000s)	Jan. 1, 2017 March 31, 2017 Q1	Jan. 1, 2016 March 31, 2016 cf. Q1	Jan. 1, 2016 Dec. 10, 2016 cf. 12 months	Jan. 1, 2015 Dec. 31, 2015 Cf. 12 months
Cash flow from operations during the period	-687	-413	-2,282	-2,294
Changes in working capital	32	-5,512	-6,016	-5,665
Cash flow from operations after changes in working capital	**-655**	**-5,099**	**-3,734**	**-7,959**
Cash flow from investing activities	-379	-261	-1,566	-2,236
Cash flow from financing activities	0	0	0	7,062
Cash flow for the period	**-1,034**	**4,837**	**-2,168**	**-3,133**
Cash/cash equivalents at beginning of period	2,185	17	17	3,150
Cash/cash equivalents at end of period	**1,151**	**4,854**	**2,185**	**17**

Summary Statement of Cash Flows - Parent Company

(SEK 000s)	Jan. 1, 2017 March 31, 2017 Q1	Jan. 1, 2016 March 31, 2016 cf. Q1	Jan. 1, 2016 Dec. 10, 2016 cf. 12 months	Jan. 1, 2015 Dec. 31, 2016 Cf. 12 months
Cash flow from operations during the period	-821	-401	-2,215	-2,218
Changes in working capital	-310	5,340	-5,309	-7,035
Cash flow from operations after changes in working capital	**-1,131**	**4,939**	**-3,094**	**-9,254**
Cash flow from investing activities	-228	-147	-932	-898
Cash flow from financing activities	0	0	0	7,056
Cash flow for the period	**-1,359**	**4,792**	**-2,162**	**3,095**
Cash/cash equivalents at beginning of period	2,162	0	0	3,095
Cash/cash equivalents at end of period	**803**	**4,792**	**2,162**	**0**

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

(SEK 000s)	Share capital	Restricted reserves	Unrestricted 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		60	-60	
Issue of new shares				
Issue costs				
Profit/loss for the period				-1,247
Amount at end of period	**6,985**	**22,077**	**-16,480**	**-1,247**

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

(SEK 000s)	Share capital	Restricted reserves	Unrestricted reserves	Profit/loss for the year
Amount at start of period	**6,985**	**22,017**	**-11,567**	**-4,956**
Transfer of profit/loss			-4,956	4,956
Fund for development costs		60	-60	
Issue of new shares				
Issue costs				
Profit/loss for the period				-1,133
Amount at end of period	**6,985**	**22,077**	**-16,043**	**-1,133**

Submission of First Quarter Report

Lund, May 2, 2017
Respiratorius AB (publ)
Board of Directors

For additional information, please contact:

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