

Q1/18

Jan. 1, 2018 – March 31, 2018 Respiratorius AB (publ) 556552-2652

SUMMARY OF Q1 REPORT 2018 (GROUP)

First quarter (Jan. 1, 2018 - March 31, 2018)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 1,154 (loss: 1,247) thousand.
- Earnings per share¹ totaled SEK -0.01 (-0.01).

SIGNIFICANT EVENTS DURING THE FIRST QUARTER OF 2018

• At the beginning of February the European Patent Office (EPO) 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 approved in several other countries is expected to strengthen the Company's position through market exclusivity in negotiations with potential partners.

 At the end of February the Company reported encouraging findings from the phase I/IIa clinical studies with VAL001.

The results were even better than those reported in the interim analysis 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 Earnings per share: Profit/loss for the period divided by 157,171,975 shares as of March 31, 2018

SIGNIFICANT EVENTS AFTER THE FIRST QUARTER

Additional patents granted for RESP3000

In early March Respiratorius announced that the Mexican Patent Office intends to grant the patent for the RESP3000 series, which was specifically developed for use in cardiovascular diagnostics using PET imaging. The granted patent will be in force until December 2031. Patents were previously granted in the US, Japan, Israel, Australia, South Africa, Russia and Europe. In addition, in 2017 the US patent office granted a divisional application for RESP3000 relating to specific product requirements.

• Scientific publication of VAL001 clinical trials

In early May Respiratorius announced that the highly esteemed scientific journal American Society of Hematology - Blood Advances, had accepted the manuscript "Valproate in Combination with Rituximab and CHOP as First Line Therapy in Diffuse Large B-cell Lymphoma (VALFRID)" for imminent publication.

Comments by the CEO

The beginning of 2018 has continued to be positive, which along with the successful oversubscribed rights issue offers opportunities to accelerate the pace and to be more aggressive regarding development of the project portfolio.

During the first quarter of 2018 the Company was able to announce promising results earlier than expected from the clinical development of VAL001. Data for 1-year and 2-year survival among patients treated with VAL001 in combination with R-CHOP were just over 10% and 15% higher respectively compared with registry data for patients treated with R-CHOP alone. The results are also clearly better compared with the previously reported interim analysis that was conducted in Q2 2016.

In recent times the project has generated promising clinical findings, along with publication in an acclaimed periodical, orphan drug status in the EU and the US, and patents granted in the EU and Japan. Our assessment is therefore that the market position and interest in the project among potential partners has been considerably strengthened during the ongoing exit process. The objective is to ensure a partner agreement for VAL001 as soon as possible, but no later than within 12 months.

The RESP1000 project is progressing according to plan and an analysis of the study findings is now underway as the preclinical work draws to a conclusion. The Company intends to initiate toxicological studies as soon as possible in preparation for clinical studies with the selected product candidate.

The patent protection for RESP3000 has been further strengthened, which could have great significance for establishing collaboration for continued development.

In summary, 2018 has begun with continued good value development for all projects and with strengthened cash on hand, we can now pilot the company's projects in a clear direction toward the market.

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 earlier interim analysis of the phase I/IIa study indicated promising results, which have now been confirmed. 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, 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. Data 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 patients who were treated between 2010 and 2015.

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 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 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 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, 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.

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

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

Condensed consolidated income statement

(SEK 000s)	Jan. 1, 2018 March 31, 2018 Q1	Jan. 1, 2017 March 31, 2017 Q1	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	-456	-473	-2,429	-1,563
Administrative costs	-564	-583	-2,437	-2,275
Other expenses	0	0	0	0
Capitalized patent and development costs	381	379	2,202	1,566
Operating profit/loss before depreciation, amortization and impairment	-638	-687	-2,664	-2,273
Depreciation/Amortization	-515	-560	-2,240	-2,572
Operating profit/loss after depreciation, amortization and impairment	-1,154	-1,247	-4,904	-4,845
Profit/loss from financial investments	0	0	-24	-9
Profit/loss after financial items	-1,154	-1,247	-4,928	-4,853
Taxes	0	0	0	0
Loss for the year	-1,154	-1,247	-4,928	-4,853

Condensed income statement – Parent Company

(SEK 000s)	Jan. 1, 2018 March 31, 2018 Q1	Jan. 1, 2017 March 31, 2017 cf Q1	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	-128	-307	-1,585	-1,281
Administrative costs	-652	-592	-2,437	-1,858
Other expenses	0	0	0	0
Capitalized patent and development costs	155	228	1,412	932
Operating profit/loss before depreciation, amortization and impairment	-626	-671	-2,610	-2,206
Depreciation/Amortization	-247	-312	-1,246	-1,641
Operating profit/loss after depreciation, amortization and impairment	-873	-983	-3,856	-3,848
Profit/loss from financial investments	-150	-150	-1,324	-1,109
Profit/loss after financial items	-1,023	-1,133	-5,180	-4,956

Taxes 0 0 0 0 0 0 Loss for the year -1,023 -1,133 -5,180 -4,956

Condensed Consolidated Balance Sheet

(SEK 000s)	March 31, 2018	March 31, Dec. 31, 2017		Dec. 31, 2016	
ASSETS					
Intangible assets	11,132	11,124	11,267	11,305	
Property, plant and equipment	0	0	0	0	
Financial assets	0	0	0	0	
Total non-current assets	11,132	11,124	11,267	11,305	
Total current assets	16,503	1,450	19,835	2,421	
Total assets	27,635	12,574	31,101	13,726	
LIABILITIES AND EQUITY					
Total equity	24,934	11,334	26,088	12,582	
Non-current liabilities	0	0	0	0	
Current liabilities	2,701	1,240	5,013	1,143	
TOTAL EQUITY AND LIABILITIES	27,635	12,574	31,101	13,726	

Condensed balance sheet – Parent Company

(SEK 000s)	March 31, 2018	March 31, 2017	Dec. 31, 2017	Dec. 31, 2016
ASSETS				
Intangible assets	4,763	4,606	4,855	4,689
Property, plant and equipment	0	0	0	0
Financial assets	3,350	3,950	6,672	4,100
Total non-current assets	8,113	8,556	11,527	8,789
Total current assets	19,768	4,601	19,794	5,393
Total assets	27,881	13,157	31,321	14,182
LIABILITIES AND EQUITY				
Total equity	25,251	11,886	26,273	13,019
Non-current liabilities	87	93	87	93
Current liabilities	2,543	1,178	4,961	1,071
TOTAL EQUITY AND LIABILITIES	27,881	13,157	31,321	14,182

Summary Consolidated Statement of Cash Flows

(SEK 000s)	Jan. 1, 2018 March 31, 2018 Q1	Jan. 1, 2017 March 31, 2017 cf Q1	Jan. 1, 2017 2017-12-10 cf 12 months	Jan. 1, 2016 Dec. 31, 2016 Cf. 12 months
Cash flow from operations during the period	-639	-687	-2,688	-2,282
Changes in working capital	17,111	32	-15,695	-6,016
Cash flow from operations after changes in working capital	16,472	-655	-18,383	-3,734
Cash flow from investing activities	-381	-379	-2,202	-1,566
Cash flow from financing activities	0	0	18,434	0
Cash flow for the period	16,091	-1,034	-2,151	-2,168
Cash/cash equivalents at beginning of period	34	2,185	2,185	17
Cash/cash equivalents at end of period	16,125	1,151	34	2,185

Summary Statement of Cash Flows - Parent Company

(SEK 000s)	Jan. 1, 2018 March 31, 2018 Q1	Jan. 1, 2017 March 31, 2017 cf Q1	Jan. 1, 2017 2017-12-10 cf 12 months	Jan. 1, 2016 Dec. 31, 2016 Cf. 12 months
Cash flow from operations during the period	-776	-821	-3,934	-2,215
Changes in working capital	16,540	-310	-15,845	-5,309
Cash flow from operations after changes in working capital	15,764	-1,131	-19,779	-3,094
Cash flow from investing activities	-5	-228	-812	-932
Cash flow from financing activities	0	0	18,429	0
Cash flow for the period	15,759	-1,359	-2,162	-2,162
Cash/cash equivalents at beginning of period	0	2,162	2,162	0
Cash/cash equivalents at end of period	15,759	803	0	2,162

Condensed statement of changes in equity – Consolidated Jan. 1, 2018 – March 31, 2018

(SEK 000s)	Share capital	Restricted reserves	Unrestricted reserves	Profit/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		83	-83	
Issue of new shares	873			
Issue costs				
Profit/loss for the period				-1,154
Amount at end of period	7,858	22,378	-4,148	-1,154

Condensed statement of changes in equity – parent company Jan. 1, 2018 – March 31, 2018

(SEK 000s)	Share capital	Restricted reserves	Unrestricted reserves	Profit/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		83	-83	
Issue of new shares	873			
Issue costs				
Profit/loss for the period				-1,023
Amount at end of period	7,858	22,378	-3,963	-1,023

Submission of Interim Report

Lund, May 15, 2018 Respiratorius AB (publ) Board of Directors

For additional information, please contact:

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