

Q3/18

July 1, 2018 – Sept. 30, 2018 Respiratorius AB (publ) 556552-2652

SUMMARY OF Q3 REPORT 2018 (GROUP)

Third quarter (July 1, 2018 – Sept. 30, 2018)

- Net sales totaled SEK 0 (0) thousand
- Loss after financial items was SEK 1,208 (loss: 1,164) thousand
- Earnings per share¹ totaled SEK -0.03 (-0.03)
- The equity ratio² as of Sept. 30, 2018 was 90.8%

SIGNIFICANT EVENTS DURING THE THIRD QUARTER 2018

 The United States Patent and Trade Office (USPTO) and the Korean Intellectual Property Office (KIPO) announced that they intend to approve Respiratorius' patent application for VAL001, "A Pharmaceutical Composition Comprising an HDAC Inhibitor and a Steroid and the Use thereof."

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.

• A patent application has been submitted for a new substance that is the result of Respiratorius' research in 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 RES1000 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.

¹ Earnings per share: Profit/loss for the period divided by 157,171,975 shares as of Sept. 30, 2018

² Equity ratio: Shareholders' equity divided by total capital

Comments by the CEO

On the same day at the beginning of the third quarter the respective patent offices in the US and Korea announced that they granted the basic patent for VAL001. These approvals provide market exclusivity through the end of 2031 and complement previous approvals in Europe and Japan. The timing of the new approvals is excellent and an additional injection into ongoing business discussions.

The Company continues to believe that the prospects of finding a taker for VAL001 are good and there are already several interested parties. As was previously mentioned, the somewhat broad "exit" concept can entail the sale of the company Valcuria AB, through which all intangible assets related to VAL001 are handled, a sale of patents, or some form of licensing.

Meanwhile, the preparatory work for continued clinical development of VAL001 is progressing as planned. These activities are important to avoid unnecessarily losing time to market, since this has been assessed as one of the assets in the project.

Pre-clinical work is underway regarding the new substance in the area of COPD and asthma for which a patent application has been submitted. The objective is to initiate toxicological studies as soon as possible prior to the "First Time in Man" study, which will be an important step for the project.

In summary, the third quarter of 2018 has entailed continued robust value growth in all projects and the Company remains optimistic regarding the objective of finding a 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 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 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, 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 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 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.

The results from the phase I/IIa study demonstrate specific effects through increased levels of CD20, which may likely be beneficial in patients treated with Rituximab. Results from the study also 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.

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 the Spotlight Stock Market (formerly 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 July 30, 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

Dates for future reports will be published shortly.

Condensed consolidated income statement

(SEK 000s)	Jan. 1, 2018 Sept. 30, 2018 9 months	Jan. 1, 2017 Sept. 30, 2017 Cf 9 months	July 1, 2018 Sept. 30, 2018 Q3	2017-07-01 Sept. 30, 2017 Cf Q3	Jan. 1, 2017 2017-12-31 Cf 12 months
Net sales	0	0	0	0	0
Other operating income	0	0	0	0	0
Gross profit/loss	0	0	0	0	0
Research and development costs	-2,065	-1,765	-939	-397	-2,429
Administrative costs	-2,006	-1,773	-616	-527	-2,437
Other expenses	0	0	0	0	0
Capitalized patent and development costs	1,675	1,565	712	320	2,202
Operating profit/loss before depreciation, amortization and impairment	-2,396	-1,973	-843	-604	-2,664
Depreciation/Amortization	-1,546	-1,680	-515	-560	-2,240
Operating profit/loss after depreciation, amortization and impairment	-3,942	-3,653	-1,358	-1,164	-4,904
Profit/loss from financial investments	0	0	0	0	-24
Profit/loss after financial items	-3,942	-3,653	-1,358	-1,164	-4,928
Taxes	0	0	0	0	0
Loss for the year	-3,942	-3,653	-1,358	-1,164	-4,928

Condensed income statement – Parent Company

(SEK 000s)	Jan. 1, 2018 Sept. 30, 2018 9 months	Jan. 1, 2017 Sept. 30, 2017 Cf 9 months	July 1, 2018 Sept. 30, 2018 Q3	2017-07-01 2017-09-31 Cf Q3	Jan. 1, 2017 2017-12-31 Cf 12 months
Net sales	0	0	0	0	0
Other operating income	0	0	0	0	0
Gross profit/loss	0	0	0	0	0
Research and development costs	-1,229	-1,086	-563	-289	-1,585
Administrative costs	-1,978	-1,772	-353	-526	-2,437
Other expenses	0	0	0	0	0
Capitalized patent and development costs	964	929	359	233	1,412
Operating profit/loss before depreciation, amortization and impairment	-2,243	-1,929	-557	-582	-2,610
Depreciation/Amortization	-741	-935	-247	-312	-1,246
Operating profit/loss after depreciation, amortization and impairment	-2,984	-2,864	-804	-894	-3,856
Profit/loss from financial investments	-450	-450	-150	-150	-1,324
Profit/loss after financial items	-3,434	-3,314	-954	-1,044	-5,180

Taxes	0	0	0	0	0
Loss for the year	-3,434	-3,314	-954	-1,044	-5,180

Condensed Consolidated Balance Sheet

(SEK 000s)	2018-09-30	2017-09-30	2017-12-31	2016-12-31
ASSETS				
Intangible assets	11,395	11,189	11,267	11,305
Property, plant and equipment	0	0	0	0
Financial assets	0	0	0	0
Total non-current assets	11,395	11,189	11,267	11,305
Total current assets	13,000	-333	19,835	2,421
Total assets	24,395	10,856	31,101	13,726
LIABILITIES AND EQUITY				
Total equity	22,146	8,928	26,088	12,582
Non-current liabilities	0	0	0	0
Current liabilities	2,249	1,928	5,013	1,143
TOTAL EQUITY AND LIABILITIES	24,395	10,856	31,101	13,726

Condensed balance sheet – Parent Company

(SEK 000s)	2018-09-30	2017-09-30	2017-12-31	2016-12-31
ASSETS				
Intangible assets	5,078	4,684	4,855	4,689
Property, plant and equipment	0	0	0	0
Financial assets	7,222	3,650	6,672	4,100
Total non-current assets	12,300	8,334	11,527	8,789
Total current assets	12,506	3,163	19,794	5,393
Total assets	24,806	11,497	31,321	14,182
LIABILITIES AND EQUITY				
Total equity	22,840	9,705	26,273	13,019
Non-current liabilities	81	93	87	93
Current liabilities	1,885	1,699	4,961	1,071
TOTAL EQUITY AND LIABILITIES	24,806	11,497	31,321	14,182

Summary Consolidated Statement of Cash Flows

(SEK 000s)	Jan. 1, 2018 Sept. 30, 2018 9 months	Jan. 1, 2017 Sept. 30, 2017 Cf 9 months	July 1, 2018 Sept. 30, 2018 Q3	2017-07-01 Sept. 30, 2017 Cf Q3	Jan. 1, 2017 2017-12-31 Cf 12 months
Cash flow from operations during the period	-2,395	-1,973	-692	-753	-2,688
Changes in working capital	16,672	720	144	734	-15,695
Cash flow from operations after changes in working capital	14,277	-1,253	-548	-19	-18,383
Cash flow from investing activities	-1,675	-1,565	-711	-319	-2,202
Cash flow from financing activities	0	0	0	0	18,434
Cash flow for the period	12,602	2,818	-1,259	-338	-2,151
Cash/cash equivalents at beginning of period	34	2,185	13,895	-295	2,185
Cash/cash equivalents at end of period	12,636	-633	12,636	-633	34

Summary Statement of Cash Flows - Parent Company

(SEK 000s)	Jan. 1, 2018 Sept. 30, 2018 9 months	Jan. 1, 2017 Sept. 30, 2017 Cf 9 months	July 1, 2018 Sept. 30, 2018 Q3	2017-07-01 2017-09-30 Cf Q3	Jan. 1, 2017 2017-12-31 Cf 12 months
Cash flow from operations during the period	-2,692	-2,379	-707	-731	-3,934
Changes in working capital	15,436	506	-548	783	-15,845
Cash flow from operations after changes in working capital	12,744	-1,873	-1,255	52	-19,779
Cash flow from investing activities	-514	-929	-210	-233	-812
Cash flow from financing activities	0	0	0	0	18,429
Cash flow for the period	12,230	-2,802	-1,465	-181	-2,162
Cash/cash equivalents at beginning of period	0	2,162	13,695	-459	2,162
Cash/cash equivalents at end of period	12,230	-640	12,230	-640	0

Condensed statement of changes in equity - Consolidated Jan. 1, 2018 - Sept. 30, 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		193	-193	
Issue of new shares	873			
Issue costs				
Profit/loss for the period				-3,942
Amount at end of period	7,858	22,488	-4,258	-3,942

Condensed statement of changes in equity – Parent Company Jan. 1, 2018 – Sept. 30, 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		193	-193	
Issue of new shares	873			
Issue costs				
Profit/loss for the period				-3,434
Amount at end of period	7,858	22,488	-4,073	-3,434

Submission of report

Lund, November 7, 2018 Respiratorius AB (publ) Board of Directors

For additional information, please contact:

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