

Half-Yearly Report 2018

Jan. 1, 2018 – June 30, 2018
Respiratorius AB (publ)
556552-2652

SUMMARY OF H1 REPORT 2018 (GROUP)

First half year (Jan. 1, 2018 – June 30, 2018)

- Net sales totaled SEK 0 (0) thousand
- Loss after financial items was SEK 2,734 (loss: 2,489) thousand
- Earnings per share¹ totaled SEK -0.02 (-0.02)
- The equity ratio² as of June 30, 2018 was 91.2%

Second quarter (April 1, 2018 – June 30, 2018)

- Net sales totaled SEK 0 (0) thousand
- Loss after financial items was SEK 1,580 (loss: 1,242) thousand
- Earnings per share¹ totaled SEK -0.01 (-0.01)

SIGNIFICANT EVENTS DURING THE SECOND QUARTER OF 2018

- The Mexican Patent Office announced that it intends to grant the patent application for the RESP3000 series. The series was specifically developed for use in cardiovascular diagnostics using PET imaging. The granted patent is 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.
- The highly esteemed scientific journal American Society of Hematology – Blood Advances, accepted the manuscript "Valproate in Combination with Rituximab and CHOP as First Line Therapy in Diffuse Large B-cell Lymphoma (VALFRID)" for imminent publication.
The publication summarizes the results from the clinical study of VAL001, which was concluded during the first quarter of 2018.

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

² Equity ratio: Shareholders' equity divided by total capital

- A new patent application for a new substance that is the result of Respiratorius' research in COPD and asthma has been submitted. 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.

SIGNIFICANT EVENTS FOLLOWING THE END OF THE PERIOD

- 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 approved 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.

Comments by the CEO


The major milestone achieved by Respiratorius during first half 2018 was the successful completion of the clinical study for VAL001 with promising results. These promising results, along with the patent approvals announced by both the US and Korea following the end of the period, provide an additional injection for ongoing business discussions. The Company therefore continues to be optimistic in its assessment that prospects are favorable for finding a taker for the project in the near future.

Regardless of exit activities, preparatory work for continued clinical development is making progress, along with development of a new formulation. These activities are important to avoid unnecessarily losing time to market, which has been assessed as a major asset in the project.

During the first half of the year the Company changed its priorities in the RESP1000 project from the previous drug candidate RES022-125, which is Respiratorius' drug candidate in the RES1000 series that has advanced the farthest, to a new drug candidate with equivalent favorable properties. A patent application has been submitted and preclinical development work has begun. Upon approval, the new drug candidate will provide the Company with an important extension of the patent period.

Patent protection for RESP3000 has been further strengthened with a new approval in Mexico and overall, significant market exclusivity at the time of the launch.

In the first half of 2018 the Company achieved good value growth in all projects and we continue to be optimistic regarding our current objectives 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 clearly shown favorable 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/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 second quarter of 2018 a new patent application was submitted for a substance that has been assessed as having a favorable safety profile and equivalent 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 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 Spotlight (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 half-yearly 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

- Q3 Interim Report November 7, 2018

Condensed consolidated income statement

(SEK 000s)	Jan. 1, 2018	Jan. 1, 2017	April 1, 2018	April 1, 2017	Jan. 1, 2017
	June 30, 2018	2017-06-30	June 30, 2018	2017-06-30	2017-12-31
	6 months	Cf 6 months	Q2	Cf Q2	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	-1,126	-1,368	-670	-895	-2,429
Administrative costs	-1,541	-1,246	-977	-653	-2,437
Other expenses	0	0	0	0	0
Capitalized patent and development costs	963	1,245	582	866	2,202
Operating profit/loss before depreciation, amortization and impairment	-1,703	-1,369	-1,065	-682	-2,664
Depreciation/Amortization	-880	-1,120	-365	-560	-2,240
Operating profit/loss after depreciation, amortization and impairment	-2,584	-2,489	-1,430	-1,242	-4,904
Profit/loss from financial investments	0	0	0	0	-24
Profit/loss after financial items	-2,584	-2,489	-1,430	-1,242	-4,928
Taxes	0	0	0	0	0
Loss for the year	-2,584	-2,489	-1,430	-1,242	-4,928

Condensed income statement – Parent Company

(SEK 000s)	Jan. 1, 2018	Jan. 1, 2017	April 1, 2018	April 1, 2017	Jan. 1, 2017
	June 30, 2018	2017-06-30	June 30, 2018	2017-06-30	2017-12-31
	6 months	Cf 6 months	Q2	Cf Q2	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	-666	-797	-538	-490	-1,585
Administrative costs	-1,623	-1,246	-972	-654	-2,437
Other expenses	0	0	0	0	0
Capitalized patent and development costs	605	696	450	468	1,412
Operating profit/loss before depreciation, amortization and impairment	-1,685	-1,347	-1,060	-676	-2,610
Depreciation/Amortization	-494	-623	-247	-311	-1,246
Operating profit/loss after depreciation, amortization and impairment	-2,179	-1,970	-1,307	-987	-3,856
Profit/loss from financial investments	-300	-300	-150	-150	-1,324
Profit/loss after financial items	-2,479	-2,270	-1,457	-1,137	-5,180
Taxes	0	0	0	0	0

Loss for the year -2,479 -2,270 -1,457 -1,137 -5,180

Condensed Consolidated Balance Sheet

(SEK 000s)	June 30, 2018	2017-06-30	2017-12-31	2016-12-31
ASSETS				
Intangible assets	11,199	11,430	11,267	11,305
Property, plant and equipment	0	0	0	0
Financial assets	0	0	0	0
Total non-current assets	11,199	11,430	11,267	11,305
Total current assets	14,414	132	19,835	2,421
Total assets	25,613	11,562	31,101	13,726
LIABILITIES AND EQUITY				
Total equity	23,354	10,093	26,088	12,582
Non-current liabilities	0	0	0	0
Current liabilities	2,259	1,469	5,013	1,143
TOTAL EQUITY AND LIABILITIES	25,613	11,562	31,101	13,726

Condensed balance sheet – Parent Company

(SEK 000s)	June 30, 2018	2017-06-30	2017-12-31	2016-12-31
ASSETS				
Intangible assets	4,966	4,762	4,855	4,689
Property, plant and equipment	0	0	0	0
Financial assets	6,872	3,800	6,672	4,100
Total non-current assets	11,838	8,562	11,527	8,789
Total current assets	14,197	3,420	19,794	5,393
Total assets	26,035	11,982	31,321	14,182
LIABILITIES AND EQUITY				
Total equity	23,794	10,748	26,273	13,019
Non-current liabilities	87	93	87	93
Current liabilities	2,154	1,141	4,961	1,071
TOTAL EQUITY AND LIABILITIES	26,035	11,982	31,321	14,182

Summary Consolidated Statement of Cash Flows

(SEK 000s)	Jan. 1, 2018 June 30, 2018 6 months	Jan. 1, 2017 2017-06-30 Cf 6 months	April 1, 2018 June 30, 2018 Q2	April 1, 2017 2017-06-30 Cf Q2	Jan. 1, 2017 2017-12-10 Cf 12 months
Cash flow from operations during the period	-1,702	-1,369	-1,065	-682	-2,688
Changes in working capital	16,527	134	-583	102	-15,695
Cash flow from operations after changes in working capital	14,825	-1,235	-1,648	-580	-18,383
Cash flow from investing activities	-964	-1,245	-582	-866	-2,202
Cash flow from financing activities	0	0	0	0	18,434
Cash flow for the period	13,861	-2,480	-2,230	-1,466	-2,151
Cash/cash equivalents at beginning of period	34	2,185	16,125	1,151	2,185
Cash/cash equivalents at end of period	13,895	-295	13,895	-295	34

Summary Statement of Cash Flows - Parent Company

(SEK 000s)	Jan. 1, 2018 June 30, 2018 6 months	Jan. 1, 2017 2017-06-30 Cf 6 months	April 1, 2017 2017-06-30 Q2	April 1, 2017 2017-06-30 Cf Q2	Jan. 1, 2017 2017-12-10 Cf 12 months
Cash flow from operations during the period	-1,984	-1,647	-1,209	-205	-3,934
Changes in working capital	15,984	-278	-555	-2,267	-15,845
Cash flow from operations after changes in working capital	14,000	-1,925	-1,764	-2,472	-19,779
Cash flow from investing activities	-305	-696	-300	-149	-812
Cash flow from financing activities	0	0	0	0	18,429
Cash flow for the period	13,695	-2,621	-2,064	-2,621	-2,162
Cash/cash equivalents at beginning of period	0	2,162	15,759	2,162	2,162
Cash/cash equivalents at end of period	13,695	-459	13,695	-459	0

Condensed statement of changes in equity – Consolidated Jan. 1, 2018 – June 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		165	-165	
Issue of new shares	873			
Issue costs				
Profit/loss for the period				-2,734
Amount at end of period	7,858	22,460	-4,230	-2,734

Condensed statement of changes in equity – Parent Company Jan. 1, 2018 – June 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		165	-165	
Issue of new shares	873			
Issue costs				
Profit/loss for the period				-2,479
Amount at end of period	7,858	22,460	-4,045	-2,479

Submission of report

Lund, August 28, 2018
Respiratorius AB (publ)
Board of Directors

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