

Half-Yearly Report 2017

Jan. 1, 2017 to June 30, 2017
Respiratorius AB (publ)
556552-2652

SUMMARY OF H1 REPORT 2017 (GROUP)

First half year (Jan. 1, 2017 – June 30, 2017)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 2,489 (loss: 2,327) thousand.
- Earnings per share¹ totaled SEK -0.02 (-0.02).
- The equity ratio² as of June 30, 2017 was 87.3%.

Second quarter (April 1, 2017 – June 30, 2017)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 1,242 (loss: 1,247) thousand.
- Earnings per share totaled SEK -0.01 (-0.01).

SIGNIFICANT EVENTS DURING THE SECOND QUARTER OF 2017

- 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.

¹ Earnings per share: Profit/loss for the period divided by 139,708,423 shares as of June 30, 2017

² Equity ratio: Shareholders' equity divided by total capital

- Respiratorius announces that the Patent Office of the Russian Federation issued a Decision to Grant regarding the patent application for the RESP3000 series. Like the other patents in this patent family, the granted patent is in force until December 2031, at which time it may possibly be extended.

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

Comments by the CEO

During the first half of 2017, Respiratorius ensured market exclusivity for the future for several of the company's projects through a number of patent approvals and also received orphan drug designation for VAL001 from the FDA.

The clinical phase I/IIa study of VAL001 and the work prior to continued clinical development are progressing as planned. The ongoing clinical phase IIa study is expected to be completed in the first half of 2018 and will be reported as soon as possible thereafter.

In light of the maturity of VAL001, with solid preliminary results from clinical trials, as well as the orphan drug status and patent approvals, the Company believes it is well positioned to find partners. The Company therefore intends to initiate exit discussions with a number of suitable partners in the near future. Such a discussion may result in a sale of the project or the entire company. To prepare for such a development the Company is conducting activities to enhance the economic value, including a health economics study with a leading participant. The Company will ensure that adequate funding is in place for the exit process.

The collaboration with Cadila Pharmaceuticals Ltd. relating to RESP1000 is proceeding according to plan with preparations for clinical trials. Initiating clinical studies will entail an important milestone for Respiratorius, since COPD and severe asthma are common diseases that lack satisfactory treatment options. The continued successful development of the project will entail great social benefit and market potential.

Patent protection for RESP3000 has been further strengthened with the recent approvals in Japan, the US and Russia. All of these markets are significant with respect to out-licensing of the project.

In H1 2017 the Company achieved good growth in value in all projects. 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 relating to VAL001 as well as to other projects.



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 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. 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/IIa study is expected to be completed and reported during the first half of 2018.

The project 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.

Patents 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. 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 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

- Q3 Interim Report November 7, 2017
- Year-end report 2017 February 6, 2018

Condensed consolidated income statement

(SEK 000s)	Jan. 1, 2017 June 30, 2017 6 months	Jan. 1, 2016 June 30, 2016 Cf. 6 months	April 1, 2017 June 30, 2017 Q2	2016-04-01 June 30, 2016 cf Q2	Jan. 1, 2016 Dec. 31, 2016 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	-1,368	-870	-895	-589	-1,563
Administrative costs	-1,246	-927	-653	-539	-2,275
Other expenses	0	0	0	0	0
Capitalized patent and development costs	1,245	763	866	501	1,566
Operating profit/loss before depreciation, amortization and impairment	-1,369	-1,032	-682	-627	-2,273
Depreciation/Amortization	-1,120	-1,286	-560	-643	-2,572
Operating profit/loss after depreciation, amortization and impairment	-2,489	-2,318	-1,242	-1,270	-4,845
Profit/loss from financial investments	0	-9	0	0	-9
Profit/loss after financial items	-2,489	-2,327	-1,242	-1,270	-4,853
Taxes	0	0	0	0	0
Profit/loss for the year	-2,489	-2,327	-1,242	-1,270	-4,853

Condensed income statement – Parent Company

(SEK 000s)	Jan. 1, 2017 June 30, 2017 6 months	Jan. 1, 2016 June 30, 2016 Cf. 6 months	April 1, 2017 June 30, 2017 Q2	Jan. 1, 2016 Dec. 31, 2016 cf Q2	Jan. 1, 2016 Dec. 31, 2016 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	-797	-504	-490	-342	-1,281
Administrative costs	-1,246	-918	-654	-541	-1,858
Other expenses	0	0	0	0	0
Capitalized patent and development costs	696	401	468	254	932
Operating profit/loss before depreciation, amortization and impairment	-1,347	-1,021	-676	-629	-2,206
Depreciation/Amortization	-623	-821	-311	-410	-1,641
Operating profit/loss after depreciation, amortization and impairment	-1,970	-1,841	-987	-1,039	-3,848
Profit/loss from financial investments	-300	-309	-150	-150	-1,109
Profit/loss after financial items	-2,270	-2,150	-1,137	-1,189	-4,956

Taxes	0	0	0	0	0
Profit/loss for the year	-2,270	-2,150	-1,137	-1,189	-4,956

Summary Consolidated Balance Sheet

(SEK 000s)	June 30, 2017	June 30, 2016	Dec. 31, 2016	Dec. 31, 2015
ASSETS				
Intangible non-current assets	11,430	11,788	11,305	12,311
Property, plant and equipment	0	0	0	0
Financial assets	0	0	0	0
Total non-current assets	11,430	11,788	11,305	12,311
Total current assets	132	4,094	2,421	7,937
Total assets	11,562	15,882	13,726	20,247
LIABILITIES AND EQUITY				
Total equity	10,093	15,109	12,582	17,436
Non-current liabilities	0	0	0	0
Current liabilities	1,469	772	1,143	2,812
TOTAL EQUITY AND LIABILITIES	11,562	15,882	13,726	20,247

Condensed balance sheet – Parent Company

(SEK 000s)	June 30, 2017	June 30, 2016	Dec. 31, 2016	Dec. 31, 2015
ASSETS				
Intangible non-current assets	4,762	4,979	4,689	5,398
Property, plant and equipment	0	0	0	0
Financial assets	3,800	4,400	4,100	4,700
Total non-current assets	8,562	9,379	8,789	10,098
Total current assets	3,420	7,250	5,393	10,277
Total assets	11,982	16,629	14,182	20,376
LIABILITIES AND EQUITY				
Total equity	10,748	15,825	13,019	17,975
Non-current liabilities	93	98	93	98
Current liabilities	1,141	706	1,071	2,303
TOTAL EQUITY AND LIABILITIES	11,982	16,629	14,182	20,376

Summary Consolidated Statement of Cash Flows

(SEK 000s)	Jan. 1, 2017 June 30, 2017 6 months	Jan. 1, 2016 June 30, 2016 Cf. 6 months	April 1, 2017 June 30, 2017 Q2	2016-04-01 June 30, 2016 Cf Q2	Jan. 1, 2016 Dec. 31, 2016 Cf. 12 months
Cash flow from operations during the period	-1,369	-1,041	-682	-628	-2,282
Changes in working capital	134	-5,544	102	33	6,016
Cash flow from operations after changes in working capital	-1,235	-4,504	-580	-595	3,734
Cash flow from investing activities	-1,245	-763	-866	-501	-1,566
Cash flow from financing activities	0	0	0	0	0
Cash flow for the period	-2,480	3,741	-1,466	-1,096	2,168
Cash/cash equivalents at beginning of period	2,185	17	1,151	4,854	17
Cash/cash equivalents at end of period	-295	3,758	-295	3,758	2,185

Summary Statement of Cash Flows - Parent Company

(SEK 000s)	Jan. 1, 2017 June 30, 2017 6 months	Jan. 1, 2016 June 30, 2016 Cf. 6 months	April 1, 2017 June 30, 2017 Q2	2016-04-01 June 30, 2016 Cf Q2	Jan. 1, 2016 Dec. 31, 2016 Cf. 12 months
Cash flow from operations during the period	-1,647	-1,030	-205	-629	-2,215
Changes in working capital	-278	4,918	-2,267	-422	5,309
Cash flow from operations after changes in working capital	-1,925	3,888	-2,472	-1,051	3,094
Cash flow from investing activities	-696	-401	-149	-254	-932
Cash flow from financing activities	0	0	0	0	0
Cash flow for the period	-2,621	3,487	-2,621	-1,305	2,162
Cash/cash equivalents at beginning of period	2,162	0	2,162	4,792	0
Cash/cash equivalents at end of period	-459	3,487	-459	3,487	2,162

Condensed statement of changes in equity – Consolidated Jan. 1, 2017 – June 30, 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		120	-120	
Issue of new shares				
Issue costs				
Profit/loss for the period				-2,489
Amount at end of period	6,985	22,137	-16,540	-2,489

Condensed statement of changes in equity – parent company Jan. 1, 2017 – June 30, 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		120	-120	
Issue of new shares				
Issue costs				
Profit/loss for the period				-2,270
Amount at end of period	6,985	22,137	-16,103	-2,270

Submission of Half Yearly Report

Lund, August 29, 2017
 Respiratorius AB (publ)
 Board of Directors

For additional information, please contact:

Johan Drott
 CEO, Respiratorius AB (publ)
 Telephone: +46 (0)709-22 41 40