



Half-Yearly Report

Jan. 1, 2016 to June 30, 2016

Respiratorius AB (publ)
556552-2652

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 (biomarker for PET)



INTERIM REPORT SUMMARY (GROUP)

First half year (Jan. 1, 2016 – June 30, 2016)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 2,327 (loss: 2,867) thousand.
- Earnings per share¹ totaled SEK -0.02 (-0.02).
- The equity ratio² as of June 30, 2016 was 95.1%.

Second quarter (April 1, 2016 – June 30, 2016)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 1,270 (loss: 1,454) thousand.
- Earnings per share¹ totaled SEK -0.01 (-0.01).

SIGNIFICANT EVENTS DURING SECOND QUARTER 2016

April 29: Respiratorius announces promising findings resulting from the interim analysis of clinical phase I/IIa studies of VAL001

Interim analysis of overall survival for patients treated with VAL001 and R-CHOP showed that 1-year survival was 100% and 2-year survival was 95%. Median follow-up was 648 days. Comparison with a matched reference population of 843 patients from the Swedish Lymphoma Registry treated with R-CHOP alone showed a 1-year survival rate of 90% and 2-year survival of 82%. Despite the limited material, the results were significantly better than the reference material for both 1-year survival (95% level of significance) and 2-year survival (90% level of significance).

May 2: Respiratorius announces that its new formulation of VAL001 had been successful

Respiratorius' research and development relating to a new formulation of VAL001 has been successful. Consequently, the Company was able to file a patent application for its new formulation and broaden the intellectual property protection for the cancer project.

May 31: Respiratorius announces that the RESP3000 project would be presented at a leading conference in the US

A scientific abstract on Respiratorius' RESP3000 development project for improved diagnosis of cardiovascular diseases and other ailments was accepted for presentation at the SNMMI 2016 Annual Meeting in San Diego, California in June 2016. The SNMMI is a leading international scientific conference in nuclear medicine and molecular imaging.

¹ Earnings per share: Profit/loss for the period divided by 139,708,423 as of June 30, 2016

² Equity ratio: Shareholders' equity divided by total capital



COMMENTS FROM THE CEO

With several promising findings, the first half of 2016 has been successful for the Company. The single most important achievement is the positive outcome of an interim analysis of the phase I/IIa study of VAL001, the Company's drug candidate for the treatment of diffuse large B-cell lymphoma, which is the most common type of lymphoma. The analysis shows significantly better overall survival among study patients treated with VAL001 and R-CHOP both at one year (1-year survival) and two years (2-year survival), compared with a reference group that did not receive treatment with VAL001. The phase I/IIa study showed 1-year survival of 100% and 2-year survival of 95%. Comparative data from a matched reference population of 843 patients from the Swedish Lymphoma Registry who were treated with R-CHOP alone showed a 1-year survival rate of 90% and 2-year survival of 82%. Although it must be kept in mind that relatively few patients were included in the phase I/IIa study, the difference in survival between patients treated with VAL001 and the matched reference population clearly demonstrates its potential, which is reason for optimism regarding the continued positive development of the project.

For the Company, these promising findings mean that continued clinical development may involve fewer patients and thereby lower costs. Fewer patients also mean faster enrollment.

The presentation of RESP3000 at the SNMMI 2016 Annual Meeting in San Diego, California was an important step in the marketing of Respiratorius' scientific advances. However, it is too early to draw conclusions about what concrete role the networking and discussions may have in the continued commercialization and development process.

Currently the focus is on positioning RESP3000 in relation to competing diagnostic methods. The next phase of the project, which is still in the planning stage, will be governed by the selection of the first clinical indication, such as coronary artery disease and myocardial infarction, which affect a large number of patients.

The collaboration with Cadila Pharmaceuticals Ltd. relating to RESP1000 is progressing as planned through regular contact and briefings. We are extremely satisfied with the expertise at Cadila, as well as the meticulous approach to development shown by their personnel.

In summary, the first half of 2016 has resulted in continued favorable development and many promising outcomes throughout Respiratorius' project portfolio. I therefore remain optimistic about the continued development within the Company.

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. The latter project is located at the periphery of Respiratorius' main focus, for which reason other strategic options are still 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 patients with DLBCL is fully enrolled and 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 diagnosis of cardiovascular diseases is based on new in-house developed 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 in-house developed and patent-protected measuring and test equipment where we have been able to ensure efficacy using samples of 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. Samples 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.

RESP1000 – Drug candidate 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.

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.



RESP3000 – Project 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 RESP3000 with promising results.

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 wide 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 collaborating 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 payments upon achievement of milestones, as well as royalties. In the event that a license agreement is concluded, there is a shareholders' agreement among the major shareholders according to which they will act to ensure that half the advance payment in connection with a license agreement will be distributed pro rata to all shareholders.

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 June 30, 2016, 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

Interim Report Q3	November 11, 2016
Year-end report	February 8, 2017

SUBMISSION OF INTERIM REPORT

Lund, August 1, 2016

Respiratorius AB (publ)

Board of Directors

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CONDENSED CONSOLIDATED INCOME STATEMENT

(SEK 000s)	Jan. 1, 2016	Jan. 1, 2015	April 1, 2016	April 1, 2015	Jan. 1, 2015
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015	Dec. 31, 2015
	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	-870	-1,455	-589	-315	-2,499
Administrative costs	-924	-1,059	-539	-522	-2,019
Other expenses	0	0	0	0	0
Capitalized patent and development costs	763	1,351	501	240	2,236
Operating profit/loss before depreciation, amortization and impairment	-1,032	-1,163	-627	-597	-2,281
Depreciation/Amortization	-1,286	-1,695	-643	-848	-3,391
Operating profit/loss after depreciation, amortization and impairment	-2,318	-2,858	-1,270	-1,445	-5,672
Profit/loss from financial investments	-9	-9	0	-9	-12
Profit/loss after financial items	-2,327	-2,867	-1,270	-1,454	-5,685
Taxes	0	0	0	0	0
Profit/loss for the year	-2,327	-2,867	-1,270	-1,454	-5,685

CONDENSED CONSOLIDATED BALANCE SHEET

(SEK 000s)	June 30, 2016	June 30, 2015	Dec. 31, 2015
Assets			
Intangible assets	11,788	13,121	12,311
Property, plant and equipment	0	0	0
Financial fixed assets	0	0	0
Total non-current assets	11,788	13,121	12,311
Total current assets	4,094	720	7,937
Total assets	15,882	13,841	20,247
Liabilities and equity			
Total equity	15,109	13,192	17,436
Non-current liabilities	0	0	0
Current liabilities	772	649	2,812
Total equity and liabilities	15,882	13,841	20,247



CONDENSED CONSOLIDATED CASH FLOW

(SEK 000s)	Jan. 1, 2016	Jan. 1, 2015	April 1, 2016	April 1, 2015	Jan. 1, 2015
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015	Dec. 31, 2015
	6 months	Cf 6 months	Q2	Cf Q2	Cf 12 months
Cash flow from operations during the period	-1,041	-1,171	-628	-606	-2,294
Changes in working capital	5,544	-206	33	-13	-5,665
Cash flow from operations after changes in working capital	4,504	-1,378	-595	-619	-7,959
Cash flow from investing activities	-763	-1,351	-501	-240	-2,236
Cash flow from financing activities	0	0	0	0	7,062
Cash flow for the period	3,741	-2,729	-1,096	-859	-3,133
Cash / cash equivalents at beginning of period	17	3,150	4,854	1,280	3,150
Cash / cash equivalents at end of period	3,758	421	3,758	421	17

CONDENSED INCOME STATEMENT – PARENT COMPANY

(SEK 000s)	Jan. 1, 2016	Jan. 1, 2015	April 1, 2016	April 1, 2015	Jan. 1, 2015
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015	Dec. 31, 2015
	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	-504	-307	-342	-137	-885
Administrative costs	-918	-1,043	-541	-511	-1,963
Other expenses	0	0	0	0	0
Capitalized patent and development costs	401	208	254	61	642
Operating profit/loss before depreciation, amortization and impairment	-1,021	-1,143	-629	-586	-2,206
Depreciation/Amortization	-821	-1,310	-410	-655	-2,619
Operating profit/loss after depreciation, amortization and impairment	-1,841	-2,452	-1,039	-1,241	-4,825
Profit/loss from financial investments	-309	-309	-150	-159	-612
Profit/loss after financial items	-2,150	-2,761	-1,189	-1,400	-5,438
Taxes	0	0	0	0	0
Profit/loss for the year	-2,150	-2,761	-1,189	-1,400	-5,438





CONDENSED BALANCE SHEET – PARENT COMPANY

(SEK 000s)	June 30, 2016	June 30, 2015	Dec. 31, 2015
Assets			
Intangible assets	4,979	6,274	5,398
Property, plant and equipment	0	0	0
Financial fixed assets	4,400	4,800	4,700
Total non-current assets	9,379	11,074	10,098
Total current assets	7,250	3,210	10,277
Total assets	16,629	14,284	20,376
Liabilities and equity			
Total equity	15,825	13,590	17,975
Non-current liabilities	98	104	98
Current liabilities	706	590	2,303
Total equity and liabilities	16,629	14,284	20,376

CASH-FLOW STATEMENT – PARENT COMPANY

(SEK 000s)	Jan. 1, 2016	Jan. 1, 2015	April 1, 2016	April 1, 2015	Jan. 1, 2015
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015	Dec. 31, 2015
	6 months	Cf 6 months	Q2	Cf Q2	Cf 12 months
Cash flow from operations during the period	-1,030	-1,151	-629	-595	-2,218
Changes in working capital	4,918	-1,316	-422	-18	-7,035
Cash flow from operations after changes in working capital	3,888	-2,468	-1,051	-613	-9,254
Cash flow from investing activities	-401	-264	-254	-61	-898
Cash flow from financing activities	0	0	0	0	7,056
Cash flow for the period	3,487	-2,731	-1,305	-674	-3,095
Cash / cash equivalents at beginning of period	0	3,095	4,792	1,038	3,095
Cash / cash equivalents at end of period	3,487	364	3,487	364	0



CONSOLIDATED STATEMENT OF CHANGES IN EQUITY JAN. 1, 2016 – JUNE 30, 2016

(SEK 000s)	Share capital	Restricted re- serves	Non-restricted reserves	Profit/loss for the period
Amount at start of period	6,985	21,687	-5,552	-5,685
Transfer of profit/loss			-5,685	5,685
Fund for development expenses		150	-150	
Rights issue				
Issue costs				
Profit/loss for the period				
Amount at end of period	6,985	21,837	-11,387	-2,326

CONDENSED STATEMENT OF CHANGES IN EQUITY – PARENT COM- PANY JAN. 1, 2016 – JUNE 30, 2016

(SEK 000s)	Share capital	Restricted re- serves	Non-restricted reserves	Profit/loss for the period
Amount at start of period	6,985	21,687	-5,259	-5,438
Transfer of profit/loss			-5,438	5,438
Fund for development costs		150	-150	
Rights issue				
Issue costs				
Profit/loss for the period				-2,150
Amount at end of period	6,985	21,837	-10,847	-2,150