



Interim Report Q3

July 1, 2016 to Sept. 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)

Third quarter (July 1, 2016 – Sept. 30, 2016)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 1,218 (loss: 1,270) thousand.
- Earnings per share¹ totaled SEK -0.01 (-0.01).
- The equity ratio² as of Sept. 30, 2016 was 93.6%.

Nine months (Jan. 1, 2016 – Sept. 30, 2016)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 3,544 (loss: 4,145) thousand.
- Earnings per share¹ totaled SEK -0.03 (-0.03).

SIGNIFICANT EVENTS DURING THE THIRD QUARTER 2016

On August 4 Respiratorius announced that Japan was the first country to grant a patent for VAL001

The patent gives Respiratorius market exclusivity in Japan for a combination of HDAC inhibitors and steroid pretreatment before chemotherapy (R-CHOP) for the treatment of diffuse large B-cell lymphoma (DLBCL), a lymphoma that annually affects about 60,000 people in the United States and Europe. DLBCL is the most common type of non-Hodgkin's lymphoma and accounts for 30% of newly diagnosed cases of NHL in the EU and the US, while the proportion is considerably higher in Japan at 45%.

The priority date of the patent is March 21, 2011, which means that the patent is in force until March 21, 2031. An application may be submitted for an additional 5-year extension.

SIGNIFICANT EVENTS AFTER THE THIRD QUARTER 2016

On October 7 Respiratorius announced that the EMA recommends European orphan drug designation for VAL001 for the treatment of B-cell diffuse large cell lymphoma

The European Medicines Agency's Committee for Orphan Medicinal Products (COMP) informed Respiratorius that it had adopted a positive opinion regarding Respiratorius' application for VAL001 to receive orphan-drug designation in Europe. This means that COMP has determined that the application meets all criteria and recommends that the European Commission formally grant VAL001 Orphan Drug Designation.

On November 4 Respiratorius announced that the European Patent Office (EPO) is granting a patent for VAL001

As with the previous patent in Japan, the patent application applies to a combination of an HDAC inhibitor and a steroid for pretreatment before chemotherapy (R-CHOP) in the treatment of diffuse large B-cell lymphoma (DLBCL). The patent gives Respiratorius market exclusivity in the countries in Europe where Respiratorius completes the application.

¹ Earnings per share: Loss for the period divided by 139,708,423 as of Sept. 30, 2016

² Equity ratio: Shareholders' equity divided by total capital



COMMENTS FROM THE CEO

During the third quarter the application for orphan drug designation for VAL001 has occupied a considerable amount of time. In early October, the European Medicines Agency (EMA) announced orphan drug designation was recommended for VAL001 by the Committee for Orphan Medicinal Products (COMP), which reviews and prepares a report based on which decisions are made regarding orphan drug status. Formal approval is expected in the near future from the European Commission, which issues decisions on orphan drug designation in Europe.

In order for COMP to adopt a positive opinion the orphan drug must be expected to offer a significant therapeutic advantage over existing treatments, which requires clinical data to support such an assumption. In addition, the disease must be classified as rare, which for Europe means that fewer than 5 per 10,000 inhabitants are affected annually.

The Company believes that orphan drug designation for VAL001 will be of great significance for establishing partnerships for the continued development of VAL001. Orphan drug designation is highly valued in the industry, associated with market exclusivity and cost-savings in the further development of the drug. The application also entails an objective and thorough scientific review of the project, which provides additional strength.

The Japanese Patent Office announced that it granted a patent for VAL001 during the third quarter and the European Patent Office (EPO) granted a patent for VAL001 after the third quarter. The application process is making progress in additional countries.

Israel granted a patent for RESP3000 during the third quarter and the US granted a patent earlier in the year. Both of these approvals secure market exclusivity in key markets. In addition to these favorable events, we are continuing with the preparatory work for further clinical development.

The collaboration with Cadila Pharmaceuticals Ltd. relating to RESP1000 is still progressing as planned. The comprehensive preclinical toxicology studies before clinical trials have produced good results to date and the work continues in full swing.

In summary, during the third quarter Respiratorius continued to move forward on all projects, which are all progressing according to plan. The announcements about orphan drug designation are particularly gratifying, as are the important patent approvals.

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 outside 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 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.

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 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. The EMA's Committee for Orphan Medicinal Products (COMP) gave the project a positive opinion and a recommendation for orphan drug designation.

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 – 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 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 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 September 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

Year-end report February 8, 2017

SUBMISSION OF INTERIM REPORT

Lund, November 11, 2016

Respiratorius AB (publ)

Board of Directors

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CONDENSED CONSOLIDATED INCOME STATEMENT

(SEK thousands)	July 1, 2016	July 1, 2015	Jan. 1, 2016	Jan. 1, 2015	Jan. 1, 2015
	Sept. 30, 2016	Sept. 30, 2015	Sept. 30, 2016	Sept. 30, 2015	Dec. 31, 2015
	Q3	cf Q3	9 months	cf 9 months	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	-534	-155	-1,405	-1,609	-2,499
Administrative costs	-440	-371	-1,364	-1,430	-2,019
Other expenses	0	0	0	0	0
Capitalized patent and development costs	400	95	1,163	1,446	2,236
Operating profit/loss before depreciation, amortization and impairment	-575	-430	-1,606	-1,593	-2,281
Depreciation/Amortization	-643	-848	-1,929	-2,543	-3,391
Operating profit/loss after depreciation, amortization and impairment	-1,218	-1,278	-3,535	-4,136	-5,672
Profit/loss from financial investments	0	0	-9	-9	-12
Profit/loss after financial items	-1,218	-1,278	-3,544	-4,145	-5,685
Taxes	0	0	0	0	0
Profit/loss for the year	-1,218	-1,278	-3,544	-4,145	-5,685



SUMMARY CONSOLIDATED BALANCE SHEET

(SEK thousands)	Sept. 30, 2016	Sept. 30, 2015	Dec. 31, 2015	2014-12-31
Assets				
Intangible assets	11,545	12,368	12,311	13,465
Property, plant and equipment	0	0	0	0
Financial assets	0	0	0	0
Total non-current assets	11,545	12,368	12,311	13,465
Total current assets	3,294	261	7,937	3,401
Total assets	14,839	12,629	20,247	16,866
Liabilities and equity				
	-	-		
Total equity	13,892	11,914	17,436	16,058
Non-current liabilities	0	0	0	0
Current liabilities	947	716	2,812	808
Total equity and liabilities	14,839	12,629	20,247	16,866



CONDENSED CONSOLIDATED CASH FLOW

	July 1, 2016	July 1, 2015	Jan. 1, 2016	Jan. 1, 2015	Jan. 1, 2015
(SEK thousands)	Sept. 30, 2016	Sept. 30, 2015	Sept. 30, 2016	Sept. 30, 2015	Dec. 31, 2015
	Q3	Cf Q3	9 months	cf 9 months	cf 12 months
Cash flow from operations during the period	-574	-430	-1,615	-1,602	-2,294
Changes in working capital	270	104	5,814	-102	-5,665
Cash flow from operations after changes in working capital	-304	-326	4,199	-1,704	-7,959
Cash flow from investing activities	-401	-95	-1,163	-1,446	-2,236
Cash flow from financing activities	0	0	0	0	7,062
Cash flow for the period	-705	-421	3,036	-3,150	-3,133
Cash / cash equivalents at beginning of period	3,758	421	17	3,150	3,150
Cash / cash equivalents at end of period	3,053	0	3,053	0	17



CONDENSED INCOME STATEMENT – PARENT COMPANY

(SEK thousands)	July 1, 2016	July 1, 2015	Jan. 1, 2016	Jan. 1, 2015	Jan. 1, 2015
	Sept. 30, 2016	Sept. 30, 2015	Sept. 30, 2016	Sept. 30, 2015	Dec. 31, 2015
	Q3	Cf Q3	9 months	cf 9 months	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	-354	-140	-858	-447	-885
Administrative costs	-435	-369	-1,353	-1,413	-1,963
Other expenses	0	0	0	0	0
Capitalized patent and development costs	239	81	641	288	642
Operating profit/loss before depreciation, amortization and impairment	-550	-428	-1,571	-1,571	-2,206
Depreciation/Amortization	-410	-655	-1,231	-1,965	-2,619
Operating profit/loss after depreciation, amortization and impairment	-960	-1,083	-2,802	-3,536	-4,825
Profit/loss from financial investments	-150	-150	-459	-459	-612
Profit/loss after financial items	-1,110	-1,233	-3,261	-3,994	-5,438
Taxes	0	0	0	0	0
Profit/loss for the year	-1,110	-1,233	-3,261	-3,994	-5,438



CONDENSED BALANCE SHEET – PARENT COMPANY

(SEK thousands)	Sept. 30, 2016	Sept. 30, 2015	Dec. 31, 2015	2014-12-31
Assets				
Intangible assets	4,808	5,700	5,398	7,376
Property, plant and equipment	0	0	0	0
Financial assets	4,250	4,750	4,700	5,044
Total non-current assets	9,058	10,450	10,098	12,420
Total current assets	6,474	2,746	10,277	4,787
Total assets	15,532	13,196	20,376	17,207
Liabilities and equity				
Total equity	14,715	12,357	17,975	16,351
Non-current liabilities	98	98	98	104
Current liabilities	719	741	2,303	752
Total equity and liabilities	15,532	13,196	20,376	17,207



CASH-FLOW STATEMENT – PARENT COMPANY

	July 1, 2016	July 1, 2015	Jan. 1, 2016	Jan. 1, 2015	Jan. 1, 2015
	Sept. 30, 2016	Sept. 30, 2015	Sept. 30, 2016	Sept. 30, 2015	Dec. 31, 2015
(SEK thousands)	Q3	Cf Q3	9 months	cf 9 months	cf 12 months
Cash flow from operations during the period	-1,000	-428	-2,030	-1,580	-2,218
Changes in working capital	571	251	5,489	-1,066	-7,035
Cash flow from operations after changes in working capital	-429	-178	3,459	-2,645	-9,254
Cash flow from investing activities	-240	-181	-641	-444	-898
Cash flow from financing activities	0	-6	0	-6	7,056
Cash flow for the period	-669	-364	2,819	-3,095	-3,095
Cash / cash equivalents at beginning of period	3,487	364	0	3,095	3,095
Cash / cash equivalents at end of period	2,819	0	2,819	0	0



CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

2016-01-01 - 2016-09-30

(SEK thousands)	Share capital	Restricted re-serves	Non-restricted re-serves	Profit/loss for the year
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		270	-270	
Rights issue				
Issue costs				
Profit/loss for the period				-3,544
Amount at end of period	6,985	21,957	-11,507	-3,544

CONDENSED STATEMENT OF CHANGES IN EQUITY – PARENT COMPANY

2016-01-01 - 2016-09-30

(SEK thousands)	Share capital	Restricted re-serves	Non-restricted re-serves	Profit/loss for the year
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		270	-270	
Rights issue				
Issue costs				
Profit/loss for the period				-3,261
Amount at end of period	6,985	21,957	-10,967	-3,261



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