

Half-Yearly Report 2021

Jan. 1, 2021 to June 30, 2021
Respiratorius AB (publ)
556552-2652

SUMMARY OF H1 REPORT 2021 (GROUP)

First half 2021 (Jan. 1, 2021 – June 30, 2021)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 4,704 (loss: 3,956) thousand.
- Earnings per share¹ totaled SEK -0.02 (-0.03).
- The equity ratio² as of June 30, 2021 was 95.2% (62.2).

Second quarter (April 1, 2021 – June 30, 2021)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 2,442 (loss: 2,056) thousand.
- Earnings per share¹ totaled SEK -0.01 (-0.01).

SIGNIFICANT EVENTS DURING THE SECOND QUARTER OF 2021

- At the beginning of the second quarter, the Board of Directors of the Company, with the authorization of the Annual General Meeting of May 19, 2020, resolved to carry out a rights issue. The rights issue comprises a total of 13,297,875 new shares where the subscription price was determined through negotiations with the majority of investors and was set at SEK 1.88 per share, which corresponds to a discount of approximately 10 percent in relation to the closing price of the share on April 12, 2021.
The primary use of the issue proceeds will entail an aggressive investment in VAL001. The Company intends to conduct the bridging study between Phase I/IIa and a Phase III study, which is a requirement for the start of Phase III and is likely to increase the value of a contract. The bridging study is a pharmacokinetic (PK) study that is planned to be conducted in healthy volunteers at a contract laboratory, with study start in the second half of 2021.
- In May, Respiratorius AB and Iconovo AB (publ) signed an agreement for the development of

¹ Earnings per share: Profit/loss for the period divided by 201,904,244 shares as of June 30, 2021 (number of shares as of June 30, 2020 was 157,171,975).

² Equity ratio: Shareholders' equity divided by total capital

an inhalation formulation and an inhalation product for phase I studies with Respiratorius' drug candidate RCD405, within the RESP9000 project for treatment of COPD and severe asthma.

Iconovo AB, which develops complete inhalation products for a global market with solid expertise in the field of inhalation formulations, is an ideal partner for Respiratorius' innovative drug candidates for the treatment of COPD and other diseases.

SIGNIFICANT EVENTS FOLLOWING THE END OF THE PERIOD

- In early July, the company raised SEK 14.4 million before issue expenses through the exercise of warrants series 2020/2021 TO1. A total of 11,985,567 warrants of series 2020/2021 TO 1 were exercised for the subscription of 11,985,567 shares, representing an exercise rate of approximately 76 percent.

The majority of the capital injection will be used for RCD405 (RESP9000) and clinical trial preparation.

Comments by the CEO

The first half of 2021 has entailed a high level of activity and important results in the two main projects, RESP9000 and VAL001. The high level of development activity is reflected in the trend for costs and is in line with the budget. During the first half of the year, the company also secured a good financial position through a rights issue, as well as through a good exercise rate of warrants series 2020/2021 TO 1, which expired after the end of the period.

In the VAL001 project, a highly promising drug candidate for a specific form of lymph node cancer, preparations are underway for the start of a clinical pharmacokinetic (PK) study. From a commercial standpoint, the PK study is important for possible differentiation of the Company's product compared with generics, and thereby position VAL001 in terms of pricing to correspond with the predicted health economic value. We believe that approval of the PK study would send an important signal in the partnership process about the Company's confidence in VAL001.

Within the project for new medications for effective treatment of COPD and severe asthma, RESP9000 and the drug candidate RCD405, work is underway to complete the preclinical data package required for submission of application to start the Phase I studies. These efforts have been successful and key risk-mitigating technical milestones have been achieved. Collaboration with Iconovo to establish a formulation for inhalation has begun with promising results, where RCD405 demonstrates promising properties in the formulation.

We have also actively worked on the patent portfolio in the two main projects during the first half of the year, including interaction with patent offices in several countries. We believe we have presented a strong case and have high hopes for future patent approvals.

I confidently look forward to the second half of 2021 and the continued development of our projects in line with our strategic plan and the potential to announce good news. I would also like to take this opportunity to extend a special thank you to the strong and loyal group of shareholders who make the future development of the Company possible.



Johan Drott
CEO, Respiratorius AB (publ)

Respiratorius

Operations

Respiratorius AB (publ) develops drug candidates with the goal of launching drugs to treat lymphoma, chronic obstructive pulmonary disease (COPD) and severe asthma.

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 clinical study of VAL001 for treatment of patients with DLBCL is complete with favorable results showing 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.

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 medicinal products 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.

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.

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; the parent has no other shareholdings.

Respiratorius' drug development

Respiratorius focuses its internal development resources on cancer, primarily the development of drugs for the treatment of malignant lymphoma, as well as new drugs for effective treatment of COPD and severe asthma. 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.

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

At a scientific advisory meeting with the EMA's Scientific Advice Working Party (SAWP) regarding clinical strategy, VAL001 was assessed as meeting the criteria to directly begin a phase III study. About 700 patients should be satisfactory for such a study to be able to serve as a basis for marketing approval.

VAL001 for the treatment of DLBCL received orphan drug designation in Europe and the US, and patents were granted in the EU, the US, Japan, Canada and Korea. There is also a patent application for protection of a dedicated formulation.

RESP1000/9000 – 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 compound series, RESP9000, 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 the RES1000 series.

Patents for RESP1000 have been granted in several countries and an application for RESP9000 has been submitted and received a positive review in Europe. The patent application has now moved on for approval in individual countries according to standard procedures.

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 achieved, 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 an external pharmaceutical company 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, now known as Spotlight Stock Market, 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, 2021, the number of shares in the Company was 201,904,244. 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 10
- Year-end report 2021 February 15, 2022

Condensed consolidated income statement

(SEK 000s)	Jan. 1, 2021	Jan. 1, 2020	April 1, 2021	April 1, 2020	Jan. 1, 2020
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020	Dec. 31, 2020
	6 months	Cf 6 months	Q2	Cf 12 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	-5,094	-2,132	-3,010	-1,129	-4,417
Administrative costs	-3,661	-2,045	-1,896	-971	-5,085
Other expenses	0	0	0	0	0
Capitalized patent and development costs	5,564	1,802	3,221	913	4,959
Operating profit/loss before depreciation, amortization and impairment	-3,191	-2,376	-1,685	-1,187	-4,543
Depreciation/Amortization	-1,514	-1,266	-757	-633	-2,531
Operating profit/loss after depreciation, amortization and impairment	-4,704	-3,641	-2,442	-1,820	-7,075
Profit/loss from financial investments	0	-315	0	-236	0
Profit/loss after financial items	-4,704	-3,956	-2,442	-2,056	-7,468
Taxes	0	0	0	0	0
Profit/loss for the year	-4,704	-3,956	-2,442	-2,056	-7,468

Condensed income statement – Parent Company

(SEK 000s)	Jan. 1, 2021	Jan. 1, 2020	April 1, 2021	April 1, 2020	Jan. 1, 2020
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020	Dec. 31, 2020
	6 months	Cf 6 months	Q2	Cf 12 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	-3,228	-1,158	-1,675	-592	-2,873
Administrative costs	-3,276	-2,078	-1,747	-1,155	-4,295
Other expenses	0	0	0	0	0
Capitalized patent and development costs	3,555	1,024	1,784	679	2,904
Operating profit/loss before depreciation, amortization and impairment	-2,949	-2,212	-1,638	-1,068	-4,264
Depreciation/Amortization	-696	-550	-348	-275	-1,101
Operating profit/loss after depreciation, amortization and impairment	-3,645	-2,763	-1,986	-1,343	-5,365
Profit/loss from financial investments	-300	-615	-150	-386	-2,094
Profit/loss after financial items	-3,945	-3,378	-2,136	-1,730	-7,459
Taxes	0	0	0	0	0

Profit/loss for the year	-3,945	-3,378	-2,136	-1,730	-7,459
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Condensed Consolidated Balance Sheet

(SEK 000s)	June 30, 2021	June 30, 2020	Dec. 31, 2020	Dec. 31, 2019
ASSETS				
Intangible assets	22,175	16,233	18,124	15,697
Property, plant and equipment	0	0	0	0
Financial assets	0	0	0	0
Total non-current assets	22,175	16,233	18,124	15,697
Total current assets	28,375	2,915	12,789	1,916
Total assets	50,550	19,148	30,914	17,613
LIABILITIES AND EQUITY				
Total equity	48,104	11,910	29,278	15,866
Non-current liabilities	0	0	0	0
Current liabilities	2,446	7,238	1,635	1,747
TOTAL EQUITY AND LIABILITIES	50,550	19,148	30,914	17,613

Condensed balance sheet – Parent Company

(SEK 000s)	June 30, 2021	June 30, 2020	Dec. 31, 2020	Dec. 31, 2019
ASSETS				
Intangible assets	12,631	8,442	9,771	7,969
Property, plant and equipment	0	0	0	0
Financial assets	10,652	8,552	8,952	8,152
Total non-current assets	23,283	16,994	18,723	16,121
Total current assets	27,531	2,829	12,258	1,650
Total assets	50,814	19,823	30,982	17,771
LIABILITIES AND EQUITY				
Total equity	49,051	12,667	29,466	16,045
Non-current liabilities	70	76	70	76
Current liabilities	1,694	7,080	1,445	1,650
TOTAL EQUITY AND LIABILITIES	50,814	19,823	30,982	17,771

Summary Consolidated Statement of Cash Flows

(SEK 000s)	Jan. 1, 2021 June 30, 2021 6 months	Jan. 1, 2020 June 30, 2020 Cf 6 months	April 1, 2021 June 30, 2021 Q2	April 1, 2020 June 30, 2020 Cf 12 months	Jan. 1, 2020 Dec. 31, 2020 Cf 12 months
Cash flow from operations during the period	-3,191	-2,691	-1,685	-1,423	-4,937
Changes in working capital	732	-794	166	-1,291	-858
Cash flow from operations after change in working capital	-2,458	-3,485	-1,519	-2,714	-5,795
Cash flow from investing activities	-5,564	-1,802	-3,221	-913	-4,959
Cash flow from financing activities	23,530	5,000	23,530	0	20,880
Cash flow for the period	15,507	-286	18,790	-3,627	10,127
Cash/cash equivalents at beginning of period	11,747	1,621	8,465	4,961	1,621
Cash/cash equivalents at end of period	27,254	1,334	27,254	1,334	11,747

Condensed Statement of Cash Flows - Parent Company

(SEK 000s)	Jan. 1, 2021 June 30, 2021 6 months	Jan. 1, 2020 June 30, 2020 Cf 6 months	April 1, 2021 June 30, 2021 Q2	April 1, 2020 June 30, 2020 Cf 12 months	Jan. 1, 2020 Dec. 31, 2020 Cf 12 months
Cash flow from operations during the period	-4,641	-3,928	-2,484	-2,005	-8,560
Changes in working capital	-1,564	-1,496	-1,648	-1,448	-2,334
Cash flow from operations after change in working capital	-6,205	-5,424	-4,132	-3,453	-10,894
Cash flow from investing activities	-1,864	377	-938	21	-102
Cash flow from financing activities	23,530	5,000	23,530	0	20,875
Cash flow for the period	15,461	-47	18,460	-3,432	9,879
Cash/cash equivalents at beginning of period	11,245	1,367	8,247	4,751	1,367
Cash/cash equivalents at end of period	26,706	1,319	26,706	1,319	11,245

Condensed consolidated statement of changes in equity – Jan. 1, 2021 – June 30, 2021

(SEK 000s)	Share capital	Restricted reserves	Unrestricted reserves	Profit/loss for the year
Amount at start of period	9,430	23,215	4,101	-7,468
Transfer of profit/loss			-7,468	7,468
Fund for development costs		278	-278	
Rights issue	665		24,335	
Issue expenses			-1,470	
Profit/loss for the period				-4,704
Amount at end of period	10,095	23,493	19,220	-4,704

Condensed statement of changes in equity – Parent Company Jan. 1, 2021 – June 30, 2021

(SEK 000s)	Share capital	Restricted reserves	Unrestricted reserves	Profit/loss for the year
Amount at start of period	9,430	23,216	4,279	-7,459
Transfer of profit/loss			-7,459	7,459
Fund for development costs		278	-278	
Issue of new shares	665		24,335	
Issue expenses			-1,470	
Profit/loss for the period				-3,945
Amount at end of period	10,095	23,494	19,408	-3,945

Submission of report

Lund, August 6, 2021
Respiratorius AB (publ)
Board of Directors

For additional information, please contact:

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