

SUMMARY OF Q1 REPORT 2021 (GROUP)**First quarter (Jan. 1, 2021 – March 31, 2021)**

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 2,262 (loss: 1,901) thousand.
- Earnings per share¹ totaled SEK -0.01 (-0.01).

SIGNIFICANT EVENTS DURING THE FIRST QUARTER OF 2021

- No events to report

SIGNIFICANT EVENTS AFTER THE FIRST QUARTER

- 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 issue a total of 13,297,875 new shares. The subscription price 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 issue proceeds will enable the Company to conduct a pharmacokinetic study of VAL001, which is a regulatory requirement to be able to initiate a Phase III study.
- At the end of May, Respiratorius AB and Iconovo AB (publ) presented an agreement for the development of an inhalation formulation and an inhalation product for Phase I studies for Respiratorius' drug candidate RES030-085, within the RESP9000 project for treatment of COPD and severe asthma.

During the spring, several important studies were conducted with good results as part of the preclinical work. Development of a formulation for inhalation together with Iconovo is therefore a natural step in the continued preparations for a Phase I clinical trial within the RESP9000 project.

¹ Earnings per share: Profit/loss for the period divided by 188,606,369 shares as of March 31, 2021

Comments by the CEO

The first quarter of 2021 has entailed a high level of activity in the two main projects, RESP9000 and VAL001, largely as a result of the new organization that reflects both the scope and excellence of our drug development program.

In the VAL001 project, a highly promising drug candidate for a form of lymphoma, work has progressed to the point where the next step, in preparation for a Phase III clinical trial, is to conduct a pharmacokinetic study of the established formulation of VAL001. In commercial terms, the formulation is important to clearly differentiate the Company's product from generics and thereby position the pricing of VAL001 so that it corresponds to the identified health economic value. In addition to providing the data needed before starting a Phase III trial, a pharmacokinetic study also provides the opportunity to differentiate our unique product from generics. The Board of Directors therefore resolved to finance the study through a rights issue aimed primarily at institutional and long-term investors.

Efforts with Partner International Inc. continue unabated, with the aim of concluding an agreement for VAL001. We are currently engaged in interaction with several companies and activity in the Company's virtual data room. As always in such a process, until some form of exclusivity agreement is signed, potential candidates are added, while others drop out. We have declined further negotiations with some interested parties at an early stage, as we recognized that the conditions were not right. We believe that initiating a pharmacokinetic study will send an important signal in the partnership process about our confidence in VAL001.

Within the project for new medications for effective treatment of COPD and severe asthma, RESP9000 and the drug candidate, now known as RCD405, work has been initiated to complete the preclinical data package required for submission of the application to start the Phase I studies. These efforts have been highly successful and key risk-mitigating technical milestones have been achieved.

The beginning of 2021 has been an extremely intensive and successful period for the Company and we confidently look forward to the continued development of our projects. I would also like to take this opportunity to extend a special thank you to our new shareholders, as well as 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.

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 March 31, 2021, the number of shares in the Company was 188,606,369. 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

- Annual General Meeting 2021 June 10, 2021
- Q2 Interim Report August 6, 2021
- Q3 Interim Report November 10, 2021
- Year-end report 2021 February 15, 2022

Condensed consolidated income statement

(SEK 000s)	Jan. 1, 2021 March 31, 2021 Q1	Jan. 1, 2020 March 31, 2020 Cf Q1	Jan. 1, 2020 Dec. 31, 2020 Cf 12 months	Jan. 1, 2019 Dec. 31, 2019 Cf 12 months
Net sales	0	0	0	0
Other operating income	0	0	0	0
Gross profit/loss	0	0	0	0
Research and development costs	-2,084	-1,003	-4,417	-4,286
Administrative costs	-1,765	-1,074	-5,085	-5,036
Other expenses	0	0	0	0
Capitalized patent and development costs	2,344	888	4,959	6,181
Operating profit/loss before depreciation, amortization and impairment	-1,505	-1,189	-4,543	-3,141
Depreciation/Amortization	-757	-633	-2,531	-1,913
Operating profit/loss after depreciation, amortization and impairment	-2,262	-1,822	-7,075	-5,054
Profit/loss from financial investments	0	0	0	0
Profit/loss after financial items	-2,262	-1,901	-7,468	-5,054
Taxes	0	0	0	0
Profit/loss for the year	-2,262	-1,901	-7,468	-5,054

Condensed income statement – Parent Company

(SEK 000s)	Jan. 1, 2021 March 31, 2021 Q1	Jan. 1, 2020 March 31, 2020 Cf Q1	Jan. 1, 2020 Dec. 31, 2020 Cf 12 months	Jan. 1, 2019 Dec. 31, 2019 Cf 12 months
Net sales	0	0	0	0
Other operating income	0	0	0	0
Gross profit/loss	0	0	0	0
Research and development costs	-1,553	-566	-2,873	-3,101
Administrative costs	-1,529	-923	-4,295	-3,560
Other expenses	0	0	0	0
Capitalized patent and development costs	1,772	345	2,904	3,720
Operating profit/loss before depreciation, amortization and impairment	-1,311	-1,144	-4,264	-2,941
Depreciation/Amortization	-348	-275	-1,101	-729
Operating profit/loss after depreciation, amortization and impairment	-1,659	-1,420	-5,365	-3,670
Profit/loss from financial investments	-150	-229	-2,094	-1,380

Profit/loss after financial items	-1,809	-1,648	-7,459	-5,050
Taxes	0	0	0	0
Profit/loss for the year	-1,809	-1,648	-7,459	-5,050

Condensed Consolidated Balance Sheet

(SEK 000s)	March 31, 2021	March 31, 2020	Dec. 31, 2020	Dec. 31, 2019
ASSETS				
Intangible assets	19,711	15,953	18,124	15,697
Property, plant and equipment	0	0	0	0
Financial assets	0	0	0	0
Total non-current assets	19,711	15,953	18,124	15,697
Total current assets	9,281	5,474	12,789	1,916
Total assets	28,992	21,427	30,914	17,613
LIABILITIES AND EQUITY				
Total equity	27,016	13,966	29,278	15,866
Non-current liabilities	0	0	0	0
Current liabilities	1,976	7,461	1,635	1,747
TOTAL EQUITY AND LIABILITIES	28,992	21,427	30,914	17,613

Condensed balance sheet – Parent Company

(SEK 000s)	March 31, 2021	March 31, 2020	Dec. 31, 2020	Dec. 31, 2019
ASSETS				
Intangible assets	11,195	8,038	9,771	7,969
Property, plant and equipment	0	0	0	0
Financial assets	9,302	8,702	8,952	8,152
Total non-current assets	20,497	16,740	18,723	16,121
Total current assets	8,861	5,121	12,258	1,650
Total assets	29,358	21,861	30,982	17,771
LIABILITIES AND EQUITY				
Total equity	27,657	14,397	29,466	16,045
Non-current liabilities	70	76	70	76
Current liabilities	1,631	7,388	1,445	1,650
TOTAL EQUITY AND LIABILITIES	29,358	21,861	30,982	17,771

Summary Consolidated Statement of Cash Flows

(SEK 000s)	Jan. 1, 2021 March 31, 2021 Q1	Jan. 1, 2020 March 31, 2020 Cf Q1	Jan. 1, 2020 Dec. 31, 2020 Cf 12 months	Jan. 1, 2019 Dec. 31, 2019 Cf 12 months
Cash flow from operations during the period	-1,505	-1,268	-4,937	-3,141
Changes in working capital	566	497	-858	677
Cash flow from operations after change in working capital	-939	-771	-5,795	-2,464
Cash flow from investing activities	-2,344	-888	-4,959	-6,181
Cash flow from financing activities	0	5,000	20,880	0
Cash flow for the period	-3,283	3,340	10,127	-8,645
Cash/cash equivalents at beginning of period	11,747	1,621	1,621	10,266
Cash/cash equivalents at end of period	8,465	4,961	11,747	1,621

Condensed Statement of Cash Flows - Parent Company

(SEK 000s)	Jan. 1, 2021 March 31, 2021 Q1	Jan. 1, 2020 March 31, 2020 Cf Q1	Jan. 1, 2020 Dec. 31, 2020 Cf 12 months	Jan. 1, 2019 Dec. 31, 2019 Cf 12 months
Cash flow from operations during the period	-2,157	-1,924	-8,560	-4,321
Changes in working capital	84	-47	-2,334	-1,253
Cash flow from operations after change in working capital	-2,073	-1,971	-10,894	-5,575
Cash flow from investing activities	-926	356	-102	-3,125
Cash flow from financing activities	0	5,000	20,875	0
Cash flow for the period	-2,999	3,385	-9,879	-8,700
Cash/cash equivalents at beginning of period	11,245	1,367	1,367	10,067
Cash/cash equivalents at end of period	8,247	4,751	11,245	1,367

Condensed consolidated statement of changes in equity Jan. 1, 2021 – March 31, 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		128	-128	
Profit/loss for the period				-2,262
Amount at end of period	9,430	23,343	-3,495	-2,262

Condensed statement of changes in equity – Parent Company Jan. 1, 2021 – March 31, 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		128	-128	
Profit/loss for the period				-1,809
Amount at end of period	9,430	23,344	-3,308	-1,809

Submission of interim report

Lund, May 27, 2021
Respiratorius AB (publ)
Board of Directors

For additional information, please contact:

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