RESPIRATORIUS

Q3/21

July 1, 2021 – Sept. 30, 2021
Respiratorius AB (publ)
556552-2652

SUMMARY OF Q3 REPORT 2021 (GROUP)

Third quarter (July 1, 2021 – Sept. 30, 2021)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 2,221 (loss: 1,627) thousand.
- Earnings per share[1] totaled SEK -0.01 (-0.01).
- The equity ratio[2] as of Sept. 30, 2021 was 97.7% (94.1).

SIGNIFICANT EVENTS DURING THE THIRD QUARTER 2021

- 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.
- At the end of August, the European Patent Office (EPO) announced that it intends to grant Respiratorius' patent application for the RESP9000 series, which includes the drug candidate RCD405 (European Patent Application No. 19740090.6 NOVEL BRONCHODILATING HETERO-LINKED AMIDES). The patent will be approved upon payment of the formal fees, at which time Respiratorius will have market exclusivity in Europe through 2039. This is the first approval for the patent family.
- At the end of September, the Brazilian Patent Office announced that it granted a patent for VAL001, which complements previously granted patents in Europe, the US, Japan, Canada and Korea.

  The patent covers a combination of an HDAC inhibitor (valproic acid or valproate) and a 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.

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[1] Earnings per share: Profit/loss for the period divided by 201,904,244 shares as of Sept. 30, 2021

[2] Equity ratio: Shareholders' equity divided by total capital

SIGNIFICANT EVENTS FOLLOWING THE END OF THE PERIOD

- In the middle of October, Respiratorius reported promising preclinical results from an *ex vivo* efficacy study of RCD405.

  The study was carried out at a contract laboratory that specializes in conducting efficacy studies using tissue samples, such as human lung tissue. In this study, RCD405 was evaluated in combination with established bronchodilators in rat, dog and human airway tissue. A concentration-dependent relaxing effect was observed in all experiments when studying the effect of RCD405 after induced contraction. In human lung tissue, the relaxing effect was significant and of the same magnitude as established bronchodilators. The advantage of RCD405 is its multifunctional mode of action, as evidenced by the anti-inflammatory properties demonstrated in LPS-stimulated human peripheral blood mononuclear cells (PBMCs) and in functional enzyme assays.

- In the middle of October, Respiratorius announced the completion of development and initiation of production of the novel formulation of VAL001.

  The patent pending novel formulation, VAL001, combines immediate release and extended release characteristics of sodium valproate contained in a pellet formulation. This tailored release profile will be evaluated in a pharmacokinetic (PK) phase I study in healthy subjects. The process for initiating the PK study is in progress, with applications already submitted to the ethics committee and the Medical Products Agency. Positive evaluation and approvals from the necessary regulatory bodies for the start of the study are expected before the end of 2021.

Comments by the CEO

The Company continued to dedicate intensive efforts to its two lead projects during the third quarter and in mid-October important results were presented for both drug candidates. Production of VAL001 has been initiated in preparation for the start of the PK study, while the bronchodilatory effect of RCD405 has been documented in an efficacy study with lung tissue from different species. Both of these results represent significant milestones. The high level of development activity is reflected in the trend for costs and is in line with the budget.

In the VAL001 project, where the Company has a highly promising drug candidate for a specific form of lymph node cancer, preparations are in the final phase prior to the start of a clinical pharmacokinetic (PK) study. The development of a novel dedicated formulation has now been successfully completed and production has begun. The application for approval to start the study has been submitted to the ethics committee, while the application to the regulatory authority is due to be completed in October. This should result in a study approval by late 2021 or early 2022. The PK study is considered to be important for possible differentiation of the Company's product compared with generics, and an important step for the partnership process for VAL001.

For the drug candidate RCD405, for the treatment of COPD and severe asthma, work is underway to complete the preclinical documentation in preparation for initiating clinical development. These efforts have been successful and key risk-mitigating technical milestones have been achieved. Recently, important promising results were reported from an *ex vivo* efficacy study comparing the bronchodilatory effect of RCD405 with other known bronchodilators in lung tissue from rats, dogs and humans. The collaborative effort with Iconovo to establish a formulation for inhalation has also been successful. RCD405 has demonstrated favorable properties for use as an inhaled drug in a powder formulation.

The European Patent Office announced that it intends to grant the patent application for RCD405 and other compounds in the RESP9000 series, a very gratifying and important announcement. Work on applications for RCD405 and VAL001 is underway in many countries, and the Company is confident that further patent approvals will be forthcoming.

Thanks to our talented organization, the third quarter and the beginning of the fourth quarter have entailed a steady stream of important news. I am also grateful for the loyal group of shareholders who make the future development of the Company possible. I look forward to seeing you all at various events as it becomes possible to attend them in person once again.

Johan Drott
CEO, Respiratorius AB (publ)

Respiratorius

Operations

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

The Company's drug candidate in oncology, VAL001, is based on a combination and reformulation of existing drugs for a new indication, diffuse large B-cell lymphoma (DLBCL). The phase I/II clinical study for the VAL001 project with DLBC patients demonstrated promising results with significantly increased survival (1-year and 2-year survival) among patients treated with valproate prior to treatment with R-CHOP, compared with patients treated with R-CHOP alone. Following the completion of the study, a custom formulation of valproate was developed to form the drug candidate VAL001.

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 efficacy on human lung tissue was confirmed.

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, in addition to the parent company, also 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 oncology 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 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 results in experimental and clinical trials 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 trial also demonstrate specific effects, such as increased levels of CD20 (an antigen that sits on the surface of B cells and serves as a specific target for rituximab, which is a part of R-CHOP treatment). This effect is thus likely to be favorable in combination treatment with VAL001 and R-CHOP.

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 pivotal phase III study. Normally, at least two pivotal studies are required, but since VAL001 has an approved

application for orphan drug status, it has the advantage that only one pivotal study is required. 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, Brazil and Korea. There is also a patent application for protection of a dedicated formulation.

RCD405 – Drug candidate for the treatment of COPD and severe asthma

During the third quarter of 2018, a new patent application was submitted for the RESP9000 series, which includes RCD405 as the main candidate for a future drug. Compared with RES022-125, Respiratorius' previous drug candidate for treatment of asthma and COPD, RCD405 has demonstrated equivalent anti-inflammatory and bronchodilatory properties, but with a more favorable safety profile.

Patents for RCD405 have now been granted in Europe. The earlier series of compounds in respiratory diseases, RESP1000, is patent-pending in several countries.

RESP2000 – Drug candidates for the treatment of COPD and asthma

RESP2000 is a series of compounds with completely different chemical properties compared with RESP1000, but with bronchodilatory properties that also have the potential to be developed into drugs for the treatment of COPD and severe asthma. The RESP2000 compound series contains substances that affect the mitochondria (cellular energy sources). This project is in the early preclinical phase and no further development work is currently planned.

Patents for RESP2000 have been granted in several countries.

RESP3000 – for diagnosis of 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 preclinical study of RES3105, the selected candidate from the compound series, with promising results. No further development work is currently planned.

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. Respiratorius also 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.

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 related to Respiratorius' 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 related to product sales. 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 the drug candidate.

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 September 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

- Year-end report 2021 February 15, 2022

Condensed consolidated income statement

(SEK 000s)	Jan. 1, 2021 Sept. 30, 2021 9 months	Jan. 1, 2020 Sept. 30, 2020 Cf 9 months	July 1, 2021 Sept. 30, 2021 Q3	July 1, 2020 Sept. 30, 2020 Cf Q3	Jan. 1, 2020 Dec. 31, 2020 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	-7,869	-2,992	-2,775	-860	-4,417
Administrative costs	-5,780	-3,516	-2,119	-1,471	-5,085
Other expenses	0	0	0	0	0
Capitalized patent and development costs	8,994	3,217	3,430	1,416	4,959
Operating profit/loss before depreciation, amortization and impairment	**-4,655**	**-3,291**	**-1,464**	**-915**	**-4,543**
Depreciation/Amortization	-2,271	-1,899	-757	-633	-2,531
Operating profit/loss after depreciation, amortization and impairment	**-6,925**	**-5,190**	**-2,221**	**-1,548**	**-7,075**
Profit/loss from financial investments	0	-394	0	-79	-394
Profit/loss after financial items	**-6,925**	**-5,583**	**-2,221**	**-1,627**	**-7,468**
Taxes	0	0	0	0	0
Profit/loss for the year	**-6,925**	**-5,583**	**-2,221**	**-1,627**	**-7,468**

Condensed income statement – Parent Company

(SEK 000s)	Jan. 1, 2021 Sept. 30, 2021 9 months	Jan. 1, 2020 Sept. 30, 2020 Cf 9 months	July 1, 2021 Sept. 30, 2021 Q3	July 1, 2020 Sept. 30, 2020 Cf Q3	Jan. 1, 2020 Dec. 31, 2020 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	-4,021	-1,649	-793	-491	-2,873
Administrative costs	-5,105	-2,867	-1,829	-789	-4,295
Other expenses	0	0	0	0	0
Capitalized patent and development costs	4,802	1,459	1,247	435	2,904
Operating profit/loss before depreciation, amortization and impairment	**-4,324**	**-3,057**	**-1,375**	**-845**	**-4,264**
Depreciation/Amortization	-1,044	-826	-348	-275	-1,101
Operating profit/loss after depreciation, amortization and impairment	**-5,368**	**-3,883**	**-1,723**	**-1,120**	**-5,365**
Profit/loss from financial investments	-450	-844	-150	-229	-2,094
Profit/loss after financial items	**-5,818**	**-4,727**	**-1,873**	**-1,349**	**-7,459**

Taxes	0	0	0	0	0
Profit/loss for the year	**-5,818**	**-4,727**	**-1,873**	**-1,349**	**-7,459**

Condensed Consolidated Balance Sheet

(SEK 000s)	Sept. 30, 2021	Sept. 30, 2020	Dec. 31, 2020	Dec. 31, 2019
ASSETS				
Intangible assets	24,848	17,016	18,124	15,697
Property, plant and equipment	0	0	0	0
Financial assets	0	0	0	0
Total non-current assets	**24,848**	**17,016**	**18,124**	**15,697**
Total current assets	**36,049**	**15,599**	**12,789**	**1,916**
Total assets	**60,897**	**32,614**	**30,914**	**17,613**
LIABILITIES AND EQUITY				
Total equity	**59,526**	**30,692**	**29,278**	**15,866**
Non-current liabilities	0	0	0	0
Current liabilities	1,371	1,922	1,635	1,747
TOTAL EQUITY AND LIABILITIES	**60,897**	**32,614**	**30,914**	**17,613**

Condensed balance sheet – Parent Company

(SEK 000s)	Sept. 30, 2021	Sept. 30, 2020	Dec. 31, 2020	Dec. 31, 2019
ASSETS				
Intangible assets	13,530	8,602	9,771	7,969
Property, plant and equipment	0	0	0	0
Financial assets	13,008	9,202	8,952	8,152
Total non-current assets	**26,538**	**17,804**	**18,723**	**16,121**
Total current assets	**35,222**	**15,124**	**12,258**	**1,650**
Total assets	**61,760**	**32,929**	**30,982**	**17,771**
LIABILITIES AND EQUITY				
Total equity	**60,821**	**31,727**	**29,466**	**16,045**
Non-current liabilities	70	70	70	76
Current liabilities	869	1,131	1,445	1,650
TOTAL EQUITY AND LIABILITIES	**61,760**	**32,929**	**30,982**	**17,771**

Summary Consolidated Statement of Cash Flows

(SEK 000s)	Jan. 1, 2021 Sept. 30, 2021 9 months	Jan. 1, 2020 Sept. 30, 2020 Cf 9 months	July 1, 2021 Sept. 30, 2021 Q3	July 1, 2020 Sept. 30, 2020 Cf Q3	Jan. 1, 2020 Dec. 31, 2020 Cf 12 months
Cash flow from operations during the period	-4,655	-3,685	-1,464	-994	-4,937
Changes in working capital	28	-95	-705	699	-858
Cash flow from operations after change in working capital	**-4,627**	**-3,779**	**-2,169**	**-295**	**-5,795**
Cash flow from investing activities	-8,994	-3,217	-3,430	-1,416	-4,959
Cash flow from financing activities	37,172	20,409	13,643	15,409	20,880
Cash flow for the period	**23,551**	**13,412**	**8,044**	**13,698**	**10,127**
Cash/cash equivalents at beginning of period	11,747	1,621	27,254	1,334	1,621
Cash/cash equivalents at end of period	**35,298**	**15,033**	**35,298**	**15,033**	**11,747**

Condensed Statement of Cash Flows – Parent Company

(SEK 000s)	Jan. 1, 2021 Sept. 30, 2021 9 months	Jan. 1, 2020 Sept. 30, 2020 Cf 9 months	July 1, 2021 Sept. 30, 2021 Q3	July 1, 2020 Sept. 30, 2020 Cf Q3	Jan. 1, 2020 Dec. 31, 2020 Cf 12 months
Cash flow from operations during the period	-6,862	-5,552	-2,221	-1,624	-8,560
Changes in working capital	-4,582	-2,239	-3,018	-743	-2,334
Cash flow from operations after change in working capital	**-11,444**	**-7,792**	**-5,239**	**-2,367**	**-10,894**
Cash flow from investing activities	-2,265	642	-401	265	-102
Cash flow from financing activities	37,174	20,403	16,344	15,403	20,875
Cash flow for the period	**23,465**	**13,254**	**10,704**	**13,301**	**9,879**
Cash/cash equivalents at beginning of period	11,245	1,367	26,706	1,319	1,367
Cash/cash equivalents at end of period	**34,710**	**14,620**	**37,410**	**14,620**	**11,245**

Condensed consolidated statement of changes in equity – Jan. 1, 2021 – Sept. 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		427	-427	
Rights issue	665		37,978	
Issue expenses			-1,470	
Profit/loss for the period				-6,925
Amount at end of period	**10,095**	**23,642**	**32,714**	**-6,925**

Condensed statement of changes in equity – Parent Company Jan. 1, 2021 – Sept. 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		427	-427	
Issue of new shares	665		37,978	
Issue expenses			-1,470	
Profit/loss for the period				-5,818
Amount at end of period	**10,095**	**23,643**	**32,901**	**-5,818**

Submission of report

Lund, November 10, 2021
Respiratorius AB (publ)
Board of Directors

For additional information, please contact:

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