

**BK/21** 

Jan. 1, 2021 – Dec. 31, 2021 Respiratorius AB (publ) 556552-2652

## SUMMARY OF YEAR-END REPORT<sup>1</sup>

#### Full year (Jan. 1, 2021 – Dec. 31, 2021)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 9,640 (loss: 7,468) thousand.
- Earnings per share totaled SEK -0.04 (-0.04).
- The equity ratio<sup>2</sup> as of Dec. 31, 2021 was 91.62%.

#### Fourth quarter (Oct. 1, 2021– Dec. 31, 2021)

- Net sales totaled SEK 0 (0) thousand.
- Loss after financial items was SEK 2,715 (loss: 1,885) thousand.
- Earnings per share<sup>3</sup> totaled SEK -0.01 (-0.01).

<sup>1</sup> Unless otherwise stated in this year-end report, all figures refer to the Group. Figures in parentheses refer to outcomes for the corresponding period the previous year.

<sup>2</sup> Equity ratio: Shareholders' equity divided by total capital.

<sup>3</sup> Earnings per share: Profit/loss for the period divided by 213,889,811 shares as of Dec. 31, 2021

#### SIGNIFICANT EVENTS IN 2021

• At the beginning of the second quarter, the Board of Directors, in accordance with the decision of the Annual General Meeting of May 19, 2020, resolved to carry out a rights issue. The rights issue involved a total of 13,297,875 new shares. The subscription price was set through negotiations with several investors 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 rights issue makes it possible to follow an aggressive strategy for VAL001. We intend to conduct a bridging study between Phase I and Phase IIa trials, respectively, and a Phase III trial. This is a requirement prior to starting 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 research organization (CRO), a contract laboratory for clinical trials.

• In May, Respiratorius AB and Iconovo AB (publ) signed an agreement to develop a formulation and product for inhalation in phase I trials with Respiratorius' drug candidate RCD405, for treatment of COPD and severe asthma.

Iconovo AB, which develops complete inhalation products for a global market and has 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.

- In early July, the company raised SEK 14.4 million before issue expenses through the 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 (previously 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. 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. This patent complements the 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) is used for the treatment of diffuse large B-cell lymphoma (DLBCL). This is a cancer of the lymph nodes that annually affects around 60,000 people in the US and Europe.

- 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. In all experiments, a relaxing effect was observed; this effect was higher at high concentrations than in lower concentrations. In human lung tissue, the relaxing effect was significant and of the same magnitude as established bronchodilators. The advantage of using RCD405 is that it acts in several different ways; in addition to the bronchodilatory effect, it has also demonstrated anti-inflammatory effect in test tube experiments.
- In the middle of October, development of the novel formulation of VAL001 and production for the clinical trial were completed.

The patent pending novel formulation combines immediate release and extended release characteristics of the compound sodium valproate in a single pellet. This tailored release profile will be evaluated in a pharmacokinetic (PK) phase I trial in healthy subjects. We

have applied to the ethics committee and the national drug authority for permission to initiate the study.

## SIGNIFICANT EVENTS FOLLOWING THE END OF THE PERIOD

- In early 2022 the PK trial was approved by the pharmaceutical regulatory authority in the country where the trial is being conducted. The ethics committee had already approved the trial, but will now review and approve the minor changes that the pharmaceutical regulatory authority recently requested. The trial and recruitment of subjects will then be able to begin.
- Respiratorius announced on February 9 that it will raise approximately SEK 45 million through a fully guaranteed rights issue of shares and will initiate a process for distribution and special listing of the project within chronic obstructive pulmonary disease (COPD).

The rights issue, subject to the approval of the extraordinary general meeting on March 14, 2022, for shares with preferential rights for existing shareholders will raise approximately SEK 45 million before issue expenses. The rights issue is fully covered by subscription and underwriting commitments from existing shareholders and external investors.

Notice of the Extraordinary General Meeting, for a resolution on the rights issue, has been published in a separate press release. In addition, the Board of Directors of Respiratorius initiated a process to enable the distribution and spin-off of the Company's RCD405 project and other projects related to COPD. The intention is for such a listing to be made possible through distribution to the shareholders of a wholly owned subsidiary. The Board believes that such a distribution could be implemented under the "Lex Asea" rules, which provide an exemption from immediate taxation. The distribution is subject to a resolution at a subsequent Annual General Meeting. The intention is to list the distributed subsidiary on Spotlight in conjunction with the distribution. Distribution and separate listing are expected to be implemented in late June or early July, 2022. To enable distribution in 2022, the Board of Directors proposes that the Extraordinary General Meeting on March 14, 2022, also resolves in favor of a reorganization of the Company's financial year.

• Respiratorius announced on February 14 that the first dosing was carried out in the pharmacokinetic study of VAL001.

Preliminary results are expected during the first quarter and the study will be concluded during the second quarter of 2022.

# Comments by the CEO

In 2021, we achieved key milestones in the continued development of VAL001, an extremely promising drug candidate for a type of lymph node cancer. Within respiratory diseases such as COPD and severe asthma, the drug candidate RCD405 demonstrated promising results in the extensive preclinical investigations that we conducted.

At the end of 2021, production of VAL001 was completed, with a customized release profile. It combines immediate release and extended release characteristics of the compound sodium valproate in a single pellet. This formulation is important to distinguish our product from generics and allows us to set the price based on the health economic value that we believe that VAL001 has. In early 2022, the PK trial, in which the new formulation will be assessed, was approved by the pharmaceutical regulatory authority in the country where the trial is being conducted.

For RCD405, we have conducted comprehensive preclinical trials, in part to identify potential safety risks at an early stage, and in part to verify efficacy. We have not seen any obvious safety risks and most importantly, RCD405 has demonstrated promising results in efficacy studies, where its bronchodilatory action is comparable with established compounds. RCD405 has also shown an anti-inflammatory effect.

In addition to preclinical studies of RCD405, we have begun to produce and formulate the active compound. Our collaboration with Iconovo related to formulation has shown that the compound has favorable properties as an inhaled medication. The work with Iconovo will soon enter the next phase and will run and be completed in parallel with the extensive toxicological study that has begun.

The past year has been intense and successful thanks to the capital that we successfully raised for the company. We now look forward with confidence to important study results and continued development in 2022. Last but not least, a huge thank you to shareholders and investors for your continued trust and commitment.

Johan Drott CEO, Respiratorius AB (publ)

# Respiratorius

#### **BUSINESS CONCEPT**

# To develop candidates for new drugs based on patent-pending compounds that have shown superior results in preclinical studies.

Respiratorius develops candidates for effective novel drugs for the treatment of the common diseases cancer, chronic obstructive pulmonary disease (COPD) and severe asthma, as well as better methods for diagnosing cardiovascular diseases. The Company bases its business on patent-pending compounds that have shown superior results in preclinical studies in the laboratory environment compared with what is currently considered to be the best available treatment, based on the best available diagnostic methods.

#### VISION

# To alleviate human suffering from cancer, respiratory diseases and cardiovascular diseases.

Respiratorius' goal and driving force is to be innovative in developing novel drugs that improve quality of life and prolong the life of patients. By doing so, the Company will also create long-term shareholder value.

# STRATEGY AND BUSINESS MODEL

# To add knowledge and resources from global partners at an early stage in the value chain to minimize the time to product launch.

Respiratorius will be an attractive partner for academic research groups, biotech companies and global pharmaceutical companies. We accomplish this through our unique expertise in the early part of the value chain from academic research.

Respiratorius searches at an early phase for strategic partners who assume financial and operational responsibility to develop a finished product. The type of partner we are looking for will have financial resources, experience in large clinical trials and established contacts with regulatory authorities. These partners will also be able, in the future, to manufacture, market and sell the licensed drugs that may result from the development project. Several major pharmaceutical companies are interested in collaborating with the company and obtaining a license to develop its projects.

A license agreement with a pharmaceutical company will provide Respiratorius with income in the form of an upfront payment, followed by milestone payments and royalties related to product sales. In the event that a license agreement is concluded, the major shareholders intend to distribute approximately half of the upfront payment proportionately to all shareholders, provided that the Company's operations remain intact.

The timing of signing an agreement with a pharmaceutical company is a business decision that will be based on cost, risk, skill requirements and the value that would be added by completing additional steps in-house. A cooperation agreement will ensure that the projects receive expertise and resources at an early stage.

This strategy will enable Respiratorius to avoid tying up excessive resources in a single project. At the same time, it is in the best interest of the Company to ensure – without compromising on safety, expertise or quality – that the time to market for its drugs is as short as possible.

# ORGANIZATION

For many years, the Company has worked with just a few employees, since resource and skill requirements vary during project development and are purchased as needed. The Company is now in a phase with several promising projects and has therefore begun to build a small but efficient organization.

# **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 cancer project. The parent company has no other shareholdings. All operations occur within the parent company, Respiratorius.

# PROJECT PORTFOLIO IN BRIEF

# VAL001 - Drug candidate for the treatment of diffuse large B-cell lymphoma

VAL001 is a drug candidate that has shown clearly promising results in the treatment of an aggressive type of lymph node cancer, known as diffuse large B-cell lymphoma (DLBCL) DLBCL is the most common form of non-Hodgkin lymphoma (NHL). Each year, 60,000 people in the US and Europe are diagnosed with DLBCL. The five-year survival rate with standard treatment is estimated at 60–70 percent. DLBCL is becoming increasingly common, which is also expected to increase demand for new and more effective treatments, which will result in market growth.

# RCD405 - drug candidate for the treatment of COPD and severe asthma

RCD405 is a drug candidate under development for treatment of chronic obstructive lung disease (COPD), one of the most common and rapidly growing diseases in the world. COPD is an inflammatory disease of the airways and lungs characterized by a gradual increase in congestion of the airways, which affects patient quality of life.

Patents for RCD405 and the RESP9000 compound series have been granted in Europe. Patents have been granted for the earlier series of compounds in respiratory diseases, RESP1000, in several countries.

# RESP2000 - drug candidates for the treatment of COPD and asthma

RESP2000 is a series of novel chemical compounds that differ from RCD405. Results from preclinical trials in the US suggest that the effects of the compound on large and small airways is due to its action upon the muscle cell mitochondria, a type of cell organelle that plays an important role in cell metabolism as energy sources for the cell. This project is in the early preclinical phase and no further development work is currently planned. Patents for the RESP2000 compound series have been granted in several countries.

# RESP3000 - for diagnosis of cardiovascular diseases

RESP3000 is a series of compounds developed for cardiovascular diagnostics. Coronary Artery Disease (CAD) is the most common type of heart disease and is one of the leading causes of death worldwide. No further development is planned at this time, as we actively search for parties interested in this project.

Patents have been granted in several countries.

# Other research and development

Besides the development projects mentioned above, Respiratorius is continually evaluating drug candidates that are a strategic fit for the company. We are also developing our patent-protected compounds and testing efficacy in other diseases and conditions.

Respiratorius has also developed a patented technology (R-HSAT) that makes it possible to study smooth muscle in various tissues from both animals and humans. The technology can be used for research and screening, as well as for optimization of drug candidates. Respiratorius intends to out-license the right to use the R-HSAT technology platform.

## ANNUAL REPORT AND ANNUAL GENERAL MEETING

Respiratorius' annual report for the 2021 financial year will be published on the Company's website (www.respiratorius.com) and the Spotlight website (www.spotlightstockmarket.se) no later than three weeks ahead of the Annual General Meeting.

The 2022 AGM will be held on May 2 in Lund. The time and location of the AGM will be published in conjunction with the invitation to the AGM.

#### NOMINATION COMMITTEE

In accordance with the decision taken at the 2021 Annual General Meeting, the Nomination Committee was appointed and announced prior to the AGM. The Nomination Committee consists of: Emanuel Eriksson, Chairman of the Nomination Committee, Fårö Capital AB, Johan Drott, Valcuria Holding AB and Ben Hayes.

#### PROPOSED APPROPRIATION OF PROFIT OR LOSS

The Board of Directors proposes that no dividend be paid for the 2021 financial year.

#### THE SHARE

The Respiratorius share (nickname: RESP) was listed in 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 December 31, 2021, the number of shares in the Company was 213,889,811. 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.

	Position at	Shares as of Dec. 31,
Natural/Legal entity	Respiratorius	2021
Niklas Prager	Chairman of the Board	171,749
Kristina Drott, Valcuria Holding AB <sup>4</sup>	Board member	10,915,462
Peter Buhl	Board member	0
Ingemar Kihlström, Ingemar Kihlström AB	Board member	801,167
Anna Törner	Board member	0
Johan Drott, Valcuria Holding AB, Drott	CEO	11,290,462
Development AB <sup>4</sup>		

#### HOLDINGS OF INSIDERS

<sup>&</sup>lt;sup>4</sup> Valcuria Holding AB is owned by Kristina Drott (9.6%), Johan Drott (49.8%) and two external individuals (one natural person and one legal entity). In addition to the holding through Valcuria Holding AB, Johan Drott owns 375,000 shares in Respiratorius through Drott Development AB.

## PRINCIPLES FOR PREPARATION OF THE YEAR-END REPORT

This year-end 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.

#### **AUDIT**

The year-end report has not been reviewed by the Company's auditor.

#### CALENDAR 2022

•	Extraordinary General Meeting	March 14
•	Annual General Meeting 2022	May 2

Annual General Meeting 2022

Since the Company plans to change the financial year, which will be decided at the Extraordinary General Meeting on March 14, the dates for other reports cannot be presented at this time.

## SUBMISSION OF 2021 YEAR-END REPORT

The Board of Directors and the Chief Executive Officer hereby certify that this year-end report for the period January – December 2021 provides a true and fair overview of operations at Respiratorius AB.

Lund, February 15, 2022

Respiratorius AB (publ)

Board of Directors and Chief Executive Officer

#### FOR ADDITIONAL INFORMATION, PLEASE CONTACT:

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## CONDENSED CONSOLIDATED INCOME STATEMENT

(SEK 000s)	2021-10-01 Dec. 31, 2021 Q4	Oct. 1, 2020 Dec. 31, 2020 Q4	Jan. 1, 2021 Dec. 31, 2021 Cf 12 months	Jan. 1, 2020 Dec. 31, 2020 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	-9,495	-1,425	-17,364	-4,417
Administrative costs	-1,706	-1,569	-7,485	-5,085
Other expenses	0	0	0	0
Capitalized patent and development costs	9,332	1,742	18,326	4,959
Operating profit/loss before depreciation, amortization and impairment	-1,869	-1,252	-6,523	-4,543
Depreciation/Amortization	-756	-633	-3,027	-2,531
Operating profit/loss after depreciation, amortization and impairment	-2,625	-1,885	-9,550	-7,075
Profit/loss from financial investments	-90	0	-90	-394
Profit/loss after financial items	-2,715	-1,885	-9,640	-7,468
Taxes	0	0	0	0
Profit/loss for the year	-2,715	-1,885	-9,640	-7,468

# CONDENSED INCOME STATEMENT – PARENT COMPANY

(SEK 000s)	2021-10-01 Dec. 31, 2021 Q4	Oct. 1, 2020 Dec. 31, 2020 Q4	Jan. 1, 2021 Dec. 31, 2021 Cf 12 months	Jan. 1, 2020 Dec. 31, 2020 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	-3,223	-1,223	-7,244	-2,873
Administrative costs	-1,236	-1,428	-6,341	-4,295
Other expenses	0	0	0	0
Capitalized patent and development costs	2,926	1,444	7,728	2,904
Operating profit/loss before depreciation, amortization and impairment	-1,533	-1,207	-5,857	-4,264
Depreciation/Amortization	-347	-275	-1,391	-1,101
Operating profit/loss after depreciation, amortization and impairment	-1,880	-1,482	-7,248	-5,365
Profit/loss from financial investments	-1,940	-1,250	-2,390	-2,094
Profit/loss after financial items	-3,820	-2,732	-9,638	-7,459
Taxes	0	0	0	0
Profit/loss for the year	-3,820	-2,732	-9,638	-7,459

#### CONDENSED CONSOLIDATED BALANCE SHEET

(SEK 000s)	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019
ASSETS			
Intangible assets	33,423	18,124	15,697
Property, plant and equipment	0	0	0
Financial assets	0	0	0
Total non-current assets	33,423	18,124	15,697
Total current assets	28,583	12,789	1,916
Total assets	62,006	30,914	17,613
LIABILITIES AND EQUITY			
Total equity	56,811	29,278	15,866
Non-current liabilities	0	0	0
Current liabilities	5,195	1,635	1,747
TOTAL EQUITY AND LIABILITIES	62,006	30,914	17,613

#### CONDENSED BALANCE SHEET – PARENT COMPANY

(SEK 000s)	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019
ASSETS			
Intangible assets	16,108	9,771	7,969
Property, plant and equipment	0	0	0
Financial assets	15,562	8,952	8,152
Total non-current assets	31,670	18,723	16,121
Total current assets	27,974	12,258	1,650
Total assets	59,644	30,982	17,771
LIABILITIES AND EQUITY			
Total equity	57,001	29,466	16,045
Non-current liabilities	71	70	76
Current liabilities	2,572	1,445	1,650
TOTAL EQUITY AND LIABILITIES	59,644	30,982	17,771

## SUMMARY CONSOLIDATED STATEMENT OF CASH FLOWS

(SEK 000s)	2021-10-01 Dec. 31, 2021 Q4	Oct. 1, 2020 Dec. 31, 2020 Q4	Jan. 1, 2021 Dec. 31, 2021 Cf 12 months	Jan. 1, 2020 Dec. 31, 2020 Cf 12 months
Cash flow from operations during the period	-1,958	-1,252	-6,613	-4,937
Changes in working capital	3,684	-292	3,712	-858
Cash flow from operations after change in working capital	1,726	-1,544	-2,901	-5,795
Cash flow from investing activities	-9,332	-1,742	-18,326	-4,959
Cash flow from financing activities	0	0	37,172	20,880
Cash flow for the period	-7,606	-3,285	15,945	10,127
Cash/cash equivalents at beginning of period	35,298	15,033	11,747	1,621
Cash/cash equivalents at end of period	27,692	11,747	27,692	11,747

# CONDENSED STATEMENT OF CASH FLOWS – PARENT COMPANY

(SEK 000s)	2021-10-01 Dec. 31, 2021 Q4	Oct. 1, 2020 Dec. 31, 2020 Q4	Jan. 1, 2021 Dec. 31, 2021 Cf 12 months	Jan. 1, 2020 Dec. 31, 2020 Cf 12 months
Cash flow from operations during the period	1,005	-3,008	-5,857	-8,560
Changes in working capital	-1,170	377	-5,752	-2,334
Cash flow from operations after change in working capital	-165	-2,631	-11,609	-10,894
Cash flow from investing activities	-7,253	-744	-9,518	-102
Cash flow from financing activities	-2	0	37,172	20,875
Cash flow for the period	-7,420	-3,375	16,045	9,879
Cash/cash equivalents at beginning of period	34,710	14,620	11,245	1,367
Cash/cash equivalents at end of period	27,290	11,245	27,290	11,245

# CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY – JAN. 1, 2021 – DEC. 31, 2021

(SEK 000s)	Share capital	Restricted reserves	Unrestricted reserves	Profit/loss for the year
Amount at start of period	9,430	23,269	4,047	-7,468
Transfer of profit/loss			-7,468	7,468
Fund for development costs		577	-577	
Issue of new shares	1,264		38,118	
Issue expenses			-2,210	
Profit/loss for the period				- 9,640
Amount at end of period	10,694	23,846	31,910	-9,640

# CONDENSED STATEMENT OF CHANGES IN EQUITY – PARENT COMPANY JAN. 1, 2021 – DEC. 31, 2021

(SEK 000s)	Share capital	Restricted reserves	Unrestricted reserves	Profit/loss for the year
Amount at start of period	9,430	23,269	4,226	-7,459
Transfer of profit/loss			-7,459	7,459
Fund for development costs		577	-577	
Issue of new shares	1,264		38,118	
Issue expenses			-2,210	
Profit/loss for the period				-9,638
Amount at end of period	10,694	23,846	32,098	-9,638