

# RESPIRATORIUS AB ANNUAL REPORT

# 2021





# Respiratorius in brief

#### **MISSION**

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

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 beneficial results in preclinical trials in the laboratory environment compared with what is currently considered to be standard treatment.







#### **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.

#### 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 Finansin-spektionen (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.



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# The year in brief

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 raised about SEK 25 million before issue expenses for Respiratorius.

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.

#### Our drug candidates

During the year, both of our drug candidates, VAL001 and RCD405, made good progress, with most of the milestones achieved. The results are the culmination of a considerable amount of work and careful planning from a competent organization.

#### VAL001

During the year, production of VAL001 was completed prior to initiating a Phase 1 pharmacokinetic study as part of the preparations for a phase 3 study, as recommended by the European Medicines Agency (EMA) at an earlier scientific advisory meeting. Toward the end of the year, documentation was submitted to the ethics committee and the Swedish Medical Products Agency, and the pharmacokinetic study was approved at the beginning of 2022. The study is expected to be completed in its entirety during the first half of 2022 with preliminary results during the first quarter.

The patent pending novel formulation combines immediate and delayed release of the substance sodium valproate in a capsule. This customized release profile will be evaluated in the pharmacokinetic study in healthy subjects.

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 and a steroid pretreatment before chemotherapy (R-CHOP) for diffuse large B-cell lymphoma.

In addition to this patent, the patent application for the new formulation is being processed in a number of countries and regions. We also expect to extend the patent protection for VAL001 through new applications when the new formulation is evaluated.





#### **RCD405**

The preclinical documentation was completed during the year with promising results, which means that we have now begun the extensive toxicological studies of RCD405 as an inhaled drug. These studies are planned to continue for most of 2022

The single most important results were positive preclinical results from an ex vivo efficacy study with RCD405. 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 and in addition to the bronchodilatory effect, it has also demonstrated anti-inflammatory effect in test tube experiments.

In parallel with the preclinical documentation, work also began on developing a formulation for inhalation of RCD405. This work is being carried out as a collaborative effort with Iconovo AB, which develops complete inhalation products for a global market and has solid expertise in the field of inhalation formulations.

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.



# Project portfolio in brief

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

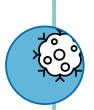
The product is being developed primarily for the treatment of an aggressive form of lymph node cancer known as diffuse large B-cell lymphoma (DLBCL), which is the most common type of Non-Hodgkin's Lymphoma (NHL). Each year, over 60,000 people in the US and Europe are diagnosed with DLBCL. The five-year 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 considerable market growth.



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

#### **RESP3000**

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.







# Comments by the CEO

# We are following the plan, milestones

In 2021, we achieved key milestones in the continued development of VAL001, an extremely promising drug candidate for treatment of lymph node cancer. Within the project for respiratory diseases such as COPD and severe asthma, the drug candidate RCD405 demonstrated promising results in the extensive preclinical investigations that were conducted. We have also been granted a patent in Europe for RCD405 and its compound series.

Production of VAL001 was completed at the end of 2021, which is an important step prior to the pharmacokinetic study in which the new formulation will be evaluated. VALOO1 has a tailored release profile that combines immediate and delayed release of sodium valproate, in the form of small units with the respective release profile combined in one capsule. The formulation is important to distinguish our product from generics and allows us to set the price based on the health-economic value which we believe that VAL001 has. In early 2022 the PK study was approved by the pharmaceutical regulatory authority in the country where the study is being conducted.

For RCD405, comprehensive preclinical trials have been conducted, in part to identify potential safety risks at an early stage, and in part to verify efficacy. So far, 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 substances. RCD405 has also shown an anti-inflammatory effect.

In addition to preclinical trials of RCD405, we have begun to produce and formulate the active substance. The collaboration with Iconovo related to formulation has shown that the compound has favorable properties to serve 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.

We now look forward with confidence to 2022, with important study results and continued development. We recently proposed a division of the projects into two separate companies by distributing and listing one company with the projects related to respiratory diseases, while VAL001 remains in the current company. Such a division would highlight the value of the individual projects. Moreover, we believe that with the current plans, the two projects have different needs for resources moving forward.

Last but not least, a huge thank you to shareholders and investors for

your continued trust and commitment.

Johan Drott,

Chief Executive Officer

# Current drug candidates

The table below shows where Respiratorius' main drug candidates are in the development process.

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Project	Indication	Research preclinical	Phase 0	Phase I	Phase II	Phase III
VAL001	Lymphoma (cancer)					, , , , , , , , , , , , , , , , , , ,
RCD405	COPD and severe asthma		•			

Current drug candidates.

Source: The company's summary



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.



### **VAL001**

The product is under development and has shown clearly promising data for 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, over 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 considerable market growth.

### Treatment of diffuse large B-cell lymphoma

The market within Non-Hodgkin's Lymphoma, which includes DLBCL, consists of well-established medications. The global population is growing because people are living longer. This trend is expected to continue and lead to growth in the value of the market. In addition, new medications that are ready for clinical trials are expected to provide additional market growth and will thereby increase spending for medical and healthcare services.

Currently, standard treatment of DLBCL entails chemotherapy with "R-CHOP," which includes the antibody-based drug Rituxan (rituximab). Other drugs for the indication are undergoing rapid development, with several in late-stage clinical trials. However, many of these new medications are extremely expensive and may cause severe side effects. The majority are also aimed at patients who experience relapse after the first treatment cure with R-CHOP.

#### VAL001 clinical trials

A Phase I clinical trial was successfully completed in 2013. It determined the maximum dose of valproate in combination with standard chemotherapy (R-CHOP). In 2018 the subsequent Phase IIa trial was completed with favorable results. It showed significantly improved one- and two-year survival for patients treated with valproate and R-CHOP, compared with a control group of patients taken from the Swedish lymphoma registry who were treated with R-CHOP alone.

Studies that are intended to result in market approval are currently being prepared. These studies include producing the new capsule formulation containing valproate and documenting its release profile. A unique formulation is crucial for achieving a correct price for the finished product. It is also important in the process of finding a partner.

#### On the way to sales

VAL001 was previously granted orphan drug status in Europe and the US, thereby considerably strengthening the commercial potential of the project. In addition, the Company has a strong patent portfolio with approved patents in the US, Europe, Japan, Canada and Korea. In 2021, Brazil also granted patents. There is also an application for a patent of the formulation that is the basis of the Company's development work, with a dedicated formulation for pretreatment prior to R-CHOP. Taken together, these achievements provide a strong intellectual property position.

The Company is now looking for and evaluating suitable global partners for VAL001. The goal is to conclude a cooperation agreement as soon as possible. As a result, the project, or the subsidiary Valcuria AB, in which all findings and intellectual property rights belonging to VAL001 are gathered, may be sold.



## RCD405

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

In 2016, it was estimated that 251 million people suffered from COPD and that over three million lost their lives as a result of the disease. This corresponds to about five percent of all deaths worldwide. Currently, COPD is the third most common cause of death in the world. Without preventive measures such as reduced smoking and improved air quality, the total number of COPD-related deaths is expected to increase.

#### Market for COPD drugs

The market for COPD drugs is expected to grow sharply. For the eight largest markets (the US, France, Germany, Italy, Spain, the UK, Japan and Australia) the COPD market was estimated to be USD 9.9 billion in 2015. By 2025, it is expected to grow to USD 14.1 billion. The US is the largest market and is expected to be about 78

percent of the total market in 2025. Growth in value is mainly driven by the increased number of patients diagnosed with this condition and the approval of new drugs that enable more patients to be effectively treated.

In Sweden, an estimated 500,000 people suffer from the disease. Each year, 2,500 to 3,000 people in Sweden die as a result of COPD, which corresponds to about 2.5 to 3 percent of all deaths in that country. Not only does COPD cause patients to suffer; it also entails high medical costs for society. The total cost in Sweden for treatment of COPD is estimated at about SEK 9 billion.

#### Treatment of COPD

Although the number of medications is growing, there is a lack of bronchodilators that are based on new modes of action that increase the diameter of smaller airways. The new medicinal products that have been approved or are undergoing clinical testing are all based on previously known modes of action. Currently, there are no data to clearly support the idea that medications which reduce the number of COPD attacks actually reduce mortality among COPD patients. The need for new anti-inflammatory drugs other than inhaled corticosteroids is especially great.

#### Clinical trial a milestone

COPD and severe asthma are common diseases that lack satisfactory treatment options. Initiating a clinical trial in this area represents an important milestone. Consequently, Respiratorius intends to conclude the preclinical program for the new substance RCD405 as soon as possible in order to be able to initiate the first clinical trials. The work is being conducted in collaboration with leading certified toxicological laboratories. Should these studies yield promising results, the project will sharply increase interest among future partners.

In 2018, Respiratorius submitted a patent application for the new substance RCD405. In addition to its bronchodilatory properties, an anti-inflammatory effect has also been demonstrated. It has also been assessed to have a beneficial safety profile.

In 2019, a successful in vivo efficacy study of the new substance was conducted in rats, indicating clear bronchodilatory properties. These data were later (in 2021) confirmed in tracheal tissue from rat, dog and human (ex vivo). Two separate pharmacokinetic (PK) studies in rats showed that only a very small amount of the RCD405 dose is absorbed into the blood during oral or pulmonary administration. After inhalation, the concentration of RCD405 was one hundred times higher in the lung than in the blood, which is desirable for a substance primarily intended to have a local effect in the lung.

The new substance revitalizes the COPD and severe asthma project through a new patent and the opportunity for market exclusivity. Once a patent is granted, the Company gains market exclusivity in all countries in which an application has been submitted through 2038.

In 2020, an advisory meeting was held with the Swedish Medical Products Agency. The encouraging meeting provided clarification in the run-up to clinical trials. In



In addition to preclinical trials of RCD405, we have begun to produce and formulate the active substance. The collaboration with Iconovo related to formulation has shown that the compound has favorable properties to serve as an inhaled medication.





2021, we continued to develop the production process of the active substance and carried out important parts of the preclinical studies recommended by the Medical Products Agency. As mentioned above, efficacy studies in lung tissue (including human lung tissue) were also carried out, in which the dilating effect was found to be comparable to established bronchodilators.

## **RESP2000**

RESP2000 is a series of chemical compounds that differ from RCD405 and its compound series, as does the RESP1000 series. Results from preclinical trials conducted in the US suggest that the effects of these substances on large and small airways is due to their action on the cell mitochondria, which play an important role in cell metabolism.

However, in order to use the mitochondria to treat a specific disease, the drug must be delivered directly to the right organ and its cells. Otherwise, other cells and organs could be negatively impacted, which could lead to undesirable side effects. It is therefore important that the medicine be inhaled and that, insofar as possible, it should not spread beyond the lungs.

The bronchodilatory properties of RESP2000 could potentially be developed into drugs for treatment of COPD and severe asthma.



#### RESP3000

Coronary Artery Disease (CAD) is the most common type of heart disease and is one of the leading causes of death worldwide. The disease can lead to serious complications such as myocardial infarction, unstable coronary artery disease and cardiac arrest. Coronary artery disease is caused by narrowing of the coronary arteries, which prevents a sufficient amount of blood from reaching the heart. One common cause is plaque buildup on the inner walls of the arteries, which is called atherosclerosis. Detection of obstructive coronary artery disease at an early stage is therefore extremely important to be able to effectively treat the patient.

Half of the population of the developed world sicken and die from cardiovascular disease. Every year, 715,000 people in the US suffer a heart attack and 15 percent of these patients die. The market for PET imaging markers, which could be considered relevant for RESP3000, is rapidly growing with an estimated size of USD 4 billion in 2018.

As a result of the studies of RESP2000, we developed RESP3000, a series of substances for diagnosing cardiovascular diseases using positron emission tomography (PET) imaging. PET imaging provides better resolution, less exposure to radiation and better and more reliable diagnostic information than other methods.

A 2014 proof-of-concept study was undertaken with promising results in which a substance from the RESP3000 series was selected, specifically the substance known as RES3105. Patents have been granted in the US, Japan, Israel, Australia, Russia and South Africa.

# Other research and development

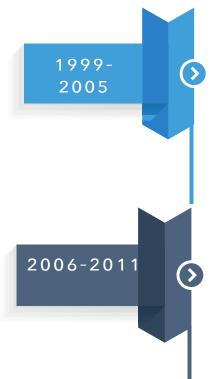
In addition to the development projects mentioned above, we continually evaluate drug candidates that are a strategic fit for Respiratorius. We have also developed a patented technology (R-HSAT) that makes it possible to study smooth muscle in various tissues from both animals and humans. The technology 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.

### Potential for drug candidates

Our aim is to develop existing drug candidates. In the future, we would like to be able to present new effective drugs for the treatment of diffuse large B-cell lymphoma (VAL001), COPD and severe asthma (RCD405), as well as methods for cardiovascular diagnostics (RESP3000). In all of these areas, we believe that Respiratorius has the ability, alone or working with partners, to launch these potential products on large markets. However, it is important to note that both preclinical and clinical trials are required before new drugs can be commercialized. The pharmaceutical industry as such, and clinical trials in particular, are associated with uncertainty regarding both funding and study results.



# **Milestones**



Respiratorius is founded to develop effective drugs to treat COPD and severe asthma, a therapeutic area that still lacks effective drugs.

The Company produces the RESP1000 compound series, which works differently than existing drugs on the market. Tests show that RESP1000 was significantly more effective than existing drugs at countering the underlying medical factors that cause bronchial problems.

RESP1000 is optimized and a substance from the series is chosen for preclinical development and future clinical development.

Another new class of chemical compounds, RESP2000, is discovered. Tests on human lung tissue show that it has a powerful dilatory effect on the trachea at low concentrations.

Over the course of the following years, the bronchodilatory effect of RESP2000 is also confirmed in a live guinea pig study. In addition, the mechanism of action of RESP2000 is mapped in greater detail.

Knowledge of the mechanisms underlying RESP2000 enables Respiratorius to develop RESP3000. This series of compounds can improve diagnosis of cardiovascular disease via PET scan.



Respiratorius acquires the shares in Valcuria AB, along with the VAL001 drug project, which in experiments has shown strong effects on models for lymph node cancer.

The Phase I study for VAL001 is successfully completed.

Excellent results are reported for RESP3000 in a "proof-of-concept" study in biological models. RESP3000 gains patent approval in South Africa and the US.

A Phase lia study is initiated for VAL001.

License and development agreements for RESP1000 are signed with Cadila Pharmaceuticals Ltd.



The Phase IIa study with VAL001 attains full enrollment. Results from an interim analysis of Phase IIa clinical data show a ten-percent increase in 1-year and 2-year survival.

VAL001 receives orphan drug status for Europe.

VAL001 receives orphan drug status for the US.

A clinical trial protocol is developed prior to approval by the European Medicine Agency (EMA). Identification of appropriate partners for a potential sale initiated.

The Company resumes its proactive role in the development of RESP1000, concluding preclinical work prior to an expected Phase I clinical trial in Europe.

VAL001 strengthens its position as a promising drug candidate and a Phase III trial is prepared. At the same time the exit process for VAL001 continues.

Promising results emerge from an airway study in an animal model using the candidate compound RES030-085 (RESP9000 series) for treatment of COPD and severe asthma.

Respiratorius attends an encouraging scientific advice meeting with the Swedish Medical Products Agency concerning planned clinical trials for RESP9000.



Production of VAL001 prior to the pharmacokinetic Phase I study is completed.

Bronchodilatory properties of RCD405 are confirmed in tracheal tissue from rat, dog and human (ex vivo).

The European Patent Office announces that it intends to grant the patent for RCD405 and other compounds in the RESP9000 series.

# **Board of Directors and CEO**



NIKLAS PRAGER, born1970 Chairman of the Board

Niklas Prager holds an MSc from the Stockholm School of Economics and has extensive experience of executive management, board work and investments. He has previously served as CEO of the Swedish division of the pharmaceutical company Pfizer, as well as CEO of several other companies, including Medivir AB.

Holdings: 171,749



JOHAN DROTT, born 1966 CEO

CEO since April 2013. PhD in electronic engineering, with extensive experience in senior positions in medtech and pharmaceutical companies with a focus on research, business development and commercialization of research findings. Founder and CEO of Valcuria AB, which was acquired by Respiratorius AB in 2012. Also CEO of Diaprost AB since March 2015.

Holdings: 11,165,4621



KRISTINA DROTT, born 1971

Board member

Associate professor at the Faculty of Medicine, Lund University. Oncologist at Skåne University Hospital. Founder of Valcuria AB, which was acquired by Respiratorius AB in 2012, and Valcuria Holding AB. Has worked as a consultant at Roche since 2016 to develop a lymphoma education program

Deputy director for Valcuria Holding AB and Valcuria AB.

Holdings: 10, 91,5 4621



INGEMAR KIHLSTRÖM, born 1952 Board member

AB, Emplicure AB and Attana AB.

B.A. in chemistry and biology 1976, PhD in physiology 1982, Associate Professor at Uppsala University 1986. Consultant in bioengineering banking and finance since 2004. Worked with research and development and business development at Astra and Pharmacia 1982–1996, then as a pharmaceutical analyst and corporate adviser in finance including for Swedbank, Aros Securities and ABG Sundal Collier. Chairman of the Board of Miris Holding AB, EQL Pharma AB, Ilya Pharma AB, Spectracure AB and Sensidose AB. Board member of Health Invest Partners AB, Prolight Diagnostics

Holdings: 801,167

<sup>1.</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)



Peter Buhl Jensen, born 1955 Board member

Peter Buhl Jensen has an MD and DMSc from the University of Copenhagen. He has a combination of commercial and medical experience, primarily in the development of cancer drugs. As a serial entrepreneur with extensive experience within the life science industry, Peter is the founder of Topo-Target, Oncology Venture, Medical Prognosis Institute and several other successful companies.

Holdings: -



ANNA TÖRNER, born 1963 Board member

Anna Törner has extensive experience in drug development with a focus on regulatory strategies and clinical trials from pharmaceutical companies and government agencies. Pharmacist with a Master's degree in mathematical statistics. PhD in Medical Science from Karolinska Institutet. Founder of SDS Life Science, Business Director SDS MedteQ.

Holdings: -



Respiratorius' strategy is to create strong patent protection for the Company's projects in North America, Europe and Asia, which are all important regions in the pharmaceutical industry. The Company files patents continually for the compounds, drug candidates and methods it develops, and conducts regular searches to identify related patent applications. Respiratorius works strategically with patent attorneys specializing in their respective fields, which ensures both quality and cost effectiveness.

As of December 31, 2020 the patent portfolio includes five patent families, each of which has been granted patents.



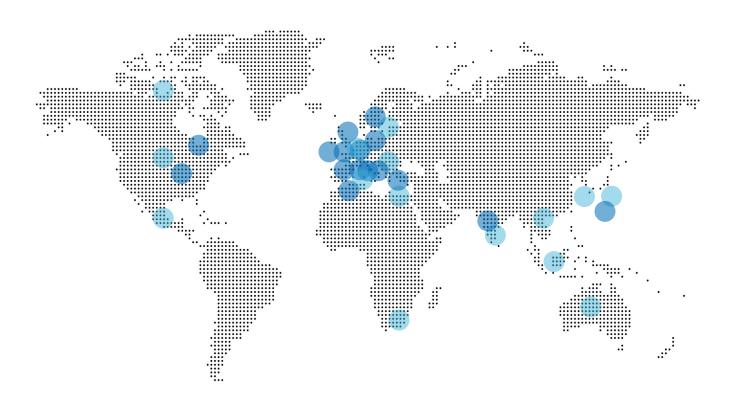
NUMBER	DESCRIPTION	COUNTRY	PRIORITY	EXPIRATION YEAR*
Patent family - VAL00	1			
EP 2688572 B1	A pharmaceutical composition comprising a HDAC inhibitor and a steroid and the use thereof	EPO (BE, CZ, DK, FI, FR, DE, HU, IE, IT, NL, NO, PL, PT, ES, CH/LI, TR, GB, SE)	2011	2032
JP 2014510102 A	A pharmaceutical composition comprising a HDAC inhibitor and a steroid and the use thereof	JP	2011	2032
US10143697	A pharmaceutical composition comprising a HDAC inhibitor and a steroid and the use thereof	US	2011	2032
KR10-1909313	A pharmaceutical composition comprising a HDAC inhibitor and a steroid and the use thereof	KR	2011	2032
CA 2829263	A pharmaceutical composition comprising a HDAC inhibitor and a steroid and the use thereof	CA	2011	2032
BR 112013023970-0	A pharmaceutical composition comprising a HDAC inhibitor and a steroid and the use thereof	BR	2011	2032
Patent familyj - RESP	9000			
EP 3818055***	Novel bronchodilating hetero-linked amides	EPO	2018	2039
Patent family - RESP3				
EP 2793952 B1	Contrast agent for imagining myocardial perfusion	EPO (SE, GB, DE, FR, ES, IT, CH/LI)	2011	2032
AU 2012354223 B2	Contrast agent for imagining myocardial perfusion	AU	2011	2032
IL 233219 A	Contrast agent for imagining myocardial perfusion	IL	2011	2032
JP 6140187 B2	Contrast agent for imagining myocardial perfusion	JP	2011	2032
RU 2629840 C2	Contrast agent for imagining myocardial perfusion	RU	2011	2032
US 9295738 B2	Contrast agent for imagining myocardial perfusion	US	2011	2032
US 9687565 B2	Diagnostic kit avdelad ansökan från 14/367520 (US 9295738 B2)	US	2011	2032
ZA 2014/05199	Contrast agent for imagining myocardial perfusion	ZA	2011	2032
MX 356258	Contrast agent for imagining myocardial perfusion	MX	2011	2032
HK1201459	Contrast agent for imagining myocardial perfusion	НК	2011	2032
IN 317928	Contrast agent for imagining myocardial perfusion	IN	2011	2032
KR 10-1931792	Contrast agent for imagining myocardial perfusion	KR	2011	2032
SG 11201403429Y	Contrast agent for imagining myocardial perfusion	SG	2011	2032



NUMBER	DESCRIPTION	COUNTRY	PRIORITY	EXPIRATION YEAR*
Patent family - RES	P1000			
EP 2181095 B1	Novel bronchodilating alpha, beta-unsaturated isoquinoline amides	FR, IE, IT, LU, MC, NL, CH/ LI, ES, GB, DE	2007	2028
SE531698 C2	Novel bronchodilating alpha, beta-unsaturated amides	SE	2007	2027
US 8318768 B2	Bronchodilating alpha, beta-unsaturated isoquinoline amides	US	2007	2029**
JP 5443348 B2	Novel bronchodilating alpha, beta-unsaturated isoquinoline amides	JP	2007	2028
IN270793B	Novel bronchodilating alpha, beta-unsaturated isoquinoline amides	IN	2007	2028
Patent family - RES	P2000			
US 8415333 B2	Bronchodilating diazaheteroaryls	US	2009	2030
EP2401275B1	Naphthyridine derivatives having bronchodilating activity	CH/LI, DE, ES, FI, FR, GB, IE, LU, NL, SE, TR	2009	2030
Patent familyj - RES	SP-HSAT Measuring equipment)			
SE530473 C2	Device for sorting medicinal products	SE	2006	2026

<sup>\*</sup> Assumes that all annual fees are paid

<sup>\*\*\*</sup> A decision has been issued to grant the patent, effective February 16, 2022.



<sup>\*\*</sup> Expiration year extended by 255 days according to PTA (Patent Term Adjustment)



The Respiratorius share was listed on July 5, 2012 on the Spotlight Stock Market (previously AktieTorget). The share is traded under the ticker symbol RESP and the ISIN code is SE0004550192. On December 31, 2020, 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.

### **SHARE PERFORMANCE IN 2021**

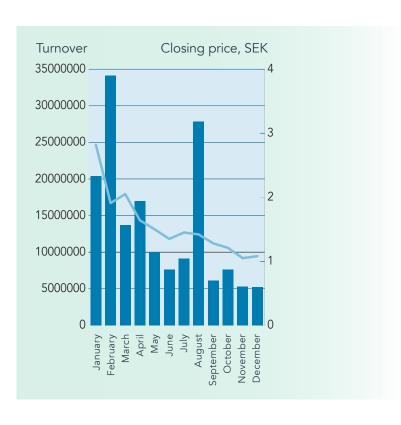
MONTH	CLOSING PRICE	HIGHEST	LOWEST	VOLUME	TURNOVER
January	2.82	3.17	2.76	7,125,586	20,403,280
February	1.91	2.77	1.91	15,453,203	34,113,598
March	2.05	2.15	1.89	6,642,582	13,695,363
April	1.64	2,.14	1.64	9,503,685	16,993,907
May	1,.5	1.64	1.41	6,605,658	9,985,273
June	1.35	1.48	1.27	5,533,195	7,589,327
July	1.45	1.45	1.23	6,714,738	9,129,041
August	1.42	1.70	1.34	18, 992,367	27,825,086
September	1.28	1.48	1.28	4,527,953	6,140,967
October	1.21	1.28	1.16	6,340,800	7,648,821
November	1.05	1.31	1.05	4,512,435	5,260,952
December	1.08	1.11	0.94	5,110,942	5,221,476
Total				97,063,144	164,007,091

#### HISTORICAL SHARE PERFORMANCE

	LOWEST	AVERAGE	HIGHEST	VOLUME OF SHARES
2012	0.23	0.31	0.50	6,760,487
2013	0.27	0.44	0.68	78,859, 373
2014	0.25	0.44	0.71	55,348,448
2015	0.25	0.36	0.69	100,742,020
2016	0.33	0.77	4.04	408,774,754
2017	1.21	1.78	2.99	156,709,862
2018	1.45	1.77	2,.81	65,827,237
2019	1.3	1.69	2.45	59,091,677
2020	0.7	1.74	3.71	198,164,742
2021	0.94	1.61	3.17	97,063,144

# FIVE LARGEST SHAREHOLDERS DEC. 31, 2021

NAME	HOLDINGS (%)
Christer Fåhreus	10.34
Avanza Pension	7.47
Valcuria Holding AB	5.1
Ben Hayes	2.34
Hans Harvig	1.97



The Board of Directors for Respiratorius AB (publ) submit the following annual report and consolidated financial statements for the 2021 financial year. The annual accounts are prepared in Swedish kronor, SEK. Unless otherwise stated, all amounts are presented in whole Swedish kronor (SEK). Information in parentheses refers to the previous year.

# **Administration Report**

#### Information about the business

Respiratorius is a pharmaceutical company engaged in research and development to develop innovative new drugs against cancer, as well as against the respiratory diseases COPD and severe asthma. Based on this research, the Company has also produced new chemical compounds that may primarily improve diagnostics of cardiovascular diseases.

Drug development in cancer relating to the VAL001 project is based on a combination of proven and well-tolerated drugs used for indications other than cancer. The Company has been able to demonstrate that VAL001 has a clear effect as pretreatment to standard treatment with chemotherapy. Clinical development has begun in this project, including efforts to produce an optimal formulation of the drug.

The Company's scientific and technological platform within the field of COPD and asthma is based on patented and proprietary measurement and testing equipment for biological studies on small human bronchi. The Company has used this platform to develop new patent pending chemical compounds with a strong ability to relax small human bronchi far exceeding the effect of existing drugs. This has been demonstrated in ex-vivo tests on human lung material using Respiratorius' biological measurement equipment.

### Financial overview\*

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(SEK 000S)	2021	2020	2019	2018	2017	2016
Profit/loss after financial items	-9,640	-7,468	- 5,054	-5,167	-4,928	-4,854
Total assets	62,006	30,914	17,613	22,144	31,101	13,725
Equity/assets ratio (%)	91.6	94.7	90.1	94.5	83.9	91.7
Return on equity (%)	neg	neg	neg.	neg.	neg.	neg.

#### PARENT COMPANY

(SEK 000S)	2021	2020	2019	2018	2017	2016
Profit/loss after financial items	-7,798	-7,459	-5,050	-5,178	-5,180	-4,956
Total assets	45,183	30,982	17,771	22,144	31,321	14,182
Equity/assets ratio (%)	95.6	95.1	90.3	95.3	83.9	91.8
Return on equity (%)	neg	neg	neg.	neg.	neg.	neg.

<sup>\*</sup> Definitions of key ratios, see supplementary disclosures

## 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 other operations occur within the parent company, Respiratorius, and the parent has no other shareholdings.

The Company has its registered office in Lund.

## 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. This price corresponds to a discount of approximately 10 percent in relation to the closing price of the share on April 12, 2021.
- 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 develops complete inhalation products for a global market and has solid expertise in the field of inhalation formulations. Iconovo is an ideal partner for Respiratorius' innovative drug candidates for the treatment of diseases such as COPD.
- 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. The advantage of using RCD405 is that it acts in several different ways and 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 and delayed release of the substance sodium valproate in a capsule. 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.

# Financial performance

### Sales and earnings

The Company has not had any net sales for the financial year.

## Liquidity and financial position

The Board of Directors believes that the Company conducts business very cost effectively, with low administrative costs. Research and development of new drugs is associated with costs, which significantly increase in the clinical phase. Consequently, the Board believes that the Company eventually may need to strengthen its liquidity through one of the following options:

- licensing of one of its projects, or
- the sale of one of its projects, or
- · acquisition involving a legal entity with access to cash, or
- share issue with or without preferential rights for existing shareholders in favor of financial or strategic investors

#### Organization and staff

The Company leases appropriate facilities at Medicon Village in Lund. The Medicon Village environment offers close proximity to important skills and interesting business opportunities. Personnel during the year have consisted of a director of clinical development employed by the Company, consultant staffing the position of CEO, and specialists to meet the needs of the individual projects.

### Board work

During the year, eight Board meetings were held, focusing primarily on strategy for research activities, funding and external collaborations, as well as licensing strategy.

# Outlook

The VAL001 drug project is progressing as planned. In 2019, the European Medicines Agency (EMA) conducted a scientific advisory meeting and agreed that Phase III trials should be the next step in clinical development, and would be the only study needed prior to marketing approval. In preparation for continued clinical trials, Respiratorius has developed a formulation for VAL001, which requires the formulation to be documented in a pharmacokinetic study. Production of VAL001 for the pharmacokinetic study was completed in 2021 and applications for the necessary approvals from the ethics committee and regulatory authority were completed and submitted during the year.

The strong patent portfolio was further strengthened through an approval in Brazil, which complements the patents granted earlier in the US, Europe, Japan, Canada and Korea. In 2016 orphan drug status was granted in Europe, which provides 10 years of market exclusivity upon market approval for the product. In 2017 orphan drug status was also granted in the US, providing 7 years of market exclusivity upon market approval for the product. The plan for 2022 is to focus on finding a contract partner for VAL001.

Within COPD and asthma, the focus during the year has been on completing the preclinical development process that was initiated following the scientific advice meeting with the Medical Products Agency that was held in 2020. Since the results were good, the final toxicological studies were initiated and are expected to continue in 2022.

The patent application for RCD405 (RES030-085) was granted during the year in Europe and approvals from other countries can be expected.

In the RESP3000 project for improved diagnostics of cardiovascular diseases, the Company conducted limited business development initiatives during the year.

# **Risk Factors**

Investments in shares are always associated with various types of risks. A number of factors outside the Company's control, as well as a number of factors whose effects Respiratorius can influence, may have a negative impact on the Company's business. Naturally, all risk factors cannot be described without conducting a complete evaluation of the Company along with a general business analysis. The following risk factors, which are described in no particular order and with no claim to be exhaustive, are considered to be the main risks for the Company's business and future development. Additional risks and uncertainties that Respiratorius is not aware of at this time may also develop into important factors that affect the Company's earnings and financial position.

# Operational and industry-related risk

# Clinical development

The success of Respiratorius depends on favorable outcomes from the clinical trials that the Company intends to conduct, as well as approval from regulatory authorities before sales of the drug candidates can begin. There can be no guarantees that Respiratorius' drug candidates will exhibit favorable properties in clinical trials, or that regulatory approval will be obtained. Should such a course of events fail to occur, there is a risk medicines will not be launched in the future, as well as a risk of loss of income.

#### Funding and collaborations

There is a risk that in the future, the Company may be unable to raise the necessary capital on the financial markets to run one or more projects until a partner takes over responsibility for continued development. Respiratorius is engaged in discussions with large pharmaceutical companies to establish partnerships under which the phar-

maceutical company accepts all or part of the financial and operational responsibility, especially when the projects enter the later clinical phases, which are extremely expensive. No assurance can be given that the Company will succeed in establishing such partnerships. Nor can it be assured that new capital can be raised if such needs should arise, or that such capital can be raised on favorable terms. Should the Company be unable to acquire capital, its future development and revenues may be adversely affected, for which reason the Company may need to restructure or significantly reduce the scope of its operations.

### Market growth

Expansion to new countries and regions could entail problems and risks that are difficult to predict. Moreover, delays could occur that would entail a loss of revenue. Respiratorius is in a growth phase, which could mean that the Company will carry out acquisitions of other companies. Synergistic effects that fail to materialize and a less than successful integration process could have an adverse effect on Respiratorius' business and financial performance. Rapid growth could cause problems at the organizational level. It may be difficult to recruit qualified staff and to successfully integrate new staff into the organization. Expansion and aggressive marketing campaigns could also entail increased costs for the Company.

Product development and regulatory approval Pharmacologically active products are manufactured, marketed and distributed on a regulated market for which agencies such as the US Food and Drug Administration (FDA) and the corresponding authority in the EU, the European Medicines Agency (EMA), set rules regarding preclinical and clinical evaluation, approval and quality assessment. If regulatory authorities should impose additional restrictions on Respiratorius' business, or if necessary, future regulatory approvals are not obtained, this could adversely affect the Company commercially and financially. Parts of Respiratorius' product portfolio are in the preclinical stage, which is an early phase in the development of new medications. Even if the Company's preclinical compounds have shown potential to be developed into finished products to date, no assurance can be given that the drug candidate(s) that the Company or a partner select(s) to advance to the next step, clinical trials, will have the intended clinical effect or obtain the required regulatory approvals.

Respiratorius is highly dependent on the continued favorable development of existing and new compounds, drug candidates and methods. As with all aspects of drug development, there is a risk that new compounds will have side effects that cannot be eliminated by chemical modification or tolerated by patients. In addition, competing businesses could have similar compounds under development. The Company's patents, patent applications and a high level of confidentiality cannot guarantee favorable results. Continued development of existing and new compounds, drug candidates and methods are of great importance for Respiratorius. If the Company should lose its ability to do so, if future research findings or clinical results do not provide scientific or commercial support for continued drug development, if continued drug development cannot proceed according to plan for other reasons, if finished products cannot be launched on schedule, or if the market reception is worse than expected, such factors could have a negative impact on Respiratorius' financial performance.

#### **Development costs**

The Company will continue to develop new and existing products in its field. Time and cost aspects of product development may be difficult to accurately determine in advance. Consequently there is a risk that a product may be more expensive to develop than planned.

#### Adverse reactions

When developing new classes of drugs, there is always a risk that the substances may prove to have side effects. In some cases, this can be overcome by chemically modifying substances, but in specific cases, side effects can be intimately associated with the therapeutic effect, thereby precluding their use as medicinal products, which could have a negative impact on Respiratorius' financial performance.

#### **Partners**

Respiratorius has collaborations with a number of partners. It cannot be ruled out that one or more of them could choose to terminate their collaboration with the Company, which could have a negative impact on the business. In addition, it cannot be guaranteed that Respiratorius' partners will fully meet the quality standards set by the Company. Moreover, it could be more expensive and/or take longer than expected for the Company to establish new partnerships, which could have a negative impact on Respiratorius' financial performance.

### Key personnel

Respiratorius' key personnel have considerable expertise and extensive experience within the Company's business areas. A loss of one or more key individuals could therefore adversely affect the Company's operations and there is a risk that the Company would be unable to recruit skilled personnel should the need arise. Moreover, it is impossible to fully protect the Company against former employees disseminating information to other parties, which entails a risk that competitors could learn about and benefit from the know-how developed by Respiratorius, which could harm the Company.

#### Competitors

There is a risk that other companies could have similar substances under development of which Respiratorius is not aware. There is also a risk that new competitors with a larger resource base of expertise and capital could enter Respiratorius' market and offer better methods and more effective products than Respiratorius. The Company is not aware of any competing companies that are working on development of compounds that interact with or use the mechanisms of action that the Company has identified. However, this should not be interpreted to mean that the Company has no competitors now or in the future. Established pharmaceutical companies are usually extremely cautious about publicizing preclinical research programs. There may be companies working with similar technology and objectives. An extensive investment and product development by a competitor could entail risk for lower future earnings. Increased competition could have a negative impact on sales and financial performance for the Company in the future.

# Economic conditions and currency risk

External factors such as inflation, currency and interest rate fluctuations, supply and demand, as well as booms and recessions could have an impact on operating costs, selling prices and valuation of shares. These factors, which are beyond the Company's control, could have a negative impact on Respiratorius' future revenues and valuation of shares. A portion of sales revenues could be received in international currencies. Exchange rates could fluctuate considerably.

#### Political risk

Respiratorius is a Swedish company. The business could become internationalized as it expands, directly or indirectly through partners. Risks could arise from changes in laws, taxes, duties, exchange rates and other conditions for foreign companies. The Company could also be affected by political and economic uncertainties in other countries. The above may be associated with negative consequences for the Company's business and results of operations.

#### Confidentiality

The success of Respiratorius depends on confidentiality and expertise in the Company's research. No assurance can be given that the Company's employees, consultants, advisers or other individuals will not violate the confidentiality agreements they have signed. Moreover, there is no assurance that confidential information will not be disclosed in some other way, and therefore could be used by competitors.

### Patents and rights

Respiratorius has several approved patents as well as patent applications. The success of Respiratorius depends in part on whether patent protection can be obtained and maintained for the Company's compounds, drug candidates and methods, and that the business can be run without encroaching on technological areas protected by someone else's patent. The Company files patents continually for the compounds, drug candidates and methods it develops. However, there is no guarantee that current or future patent applications will be granted, or that granted patents will provide adequate protection against competitors. Moreover, there is always a risk that disputes concerning infringement of patents and other intellectual property rights could be initiated against or by the Company. Disputes of this type are usually expensive and if a dispute should arise, it could have a significant negative impact on the Company.

There is also no guarantee that patents will bring a competitive advantage, or that competitors will not be able to bypass Respiratorius' patents. If Respiratorius is forced to defend its intellectual property against a competitor, considerable costs could be involved, which in turn could have a negative impact on the Company's financial position. If Respiratorius uses compounds or methods in research that are patented or will be granted patents, the holders of these patents could claim that Respiratorius infringed on their patent. A third party's patent could prevent one of the Company's future licensees from freely using a licensed compound. The uncertainty associated with patents makes it difficult to predict the outcome of such disputes. In addition, the costs of such disputes, even one that has a favorable outcome for Respiratorius, could be considerable and would therefore have a negative impact on Respiratorius' financial position.

# Disputes, claims, investigations and proceedings

The Company could become involved in disputes within the context of normal business operations, and be subject to civil claims in legal proceedings concerning agreements, product liability or alleged deficiencies regarding delivery of goods and services. Such claims could involve large amounts and considerable legal costs. The Company (or the Company's executives, directors, employees or related parties) could become subject to criminal investigations and litigation. Such disputes, claims, investigations and proceedings can be time-consuming, disrupt normal operations, involve substantial damages, and result in significant costs. In addition, it may be difficult to predict the outcome of complex disputes, claims, investigations and proceedings. Future disputes, claims, investigations and proceedings may have a material adverse effect on the Company's business, prospects, earnings and financial position.



#### Taxes

Respiratorius expects to have sales in several markets outside Sweden in the future. Tax legislation in each country can change over time. If changes occur, they could affect the Company's business, earnings and financial position.

## Regulatory approval

Respiratorius is dependent on approval of the Company's products and methods through clinical trials and decisions by public authorities. There is a risk that the outcome of such trials may not be advantageous for the Company, or that such decisions may grant approval for a more limited indication than expected, or the application may be completely rejected. In such cases, additional clinical trials may be necessary to obtain the relevant approval. There is also a risk that the studies may not be carried out as planned, which could affect their outcome. Such outcomes could delay sales and development, as well as increase the cost of a new product. If Respiratorius fails to obtain, or retain, the permits and approvals that the Company already has, it may adversely affect the Company's business, earnings and financial position.

In certain markets, the success of the Company depends on approval of the Company's method for reimbursement by national insurance systems (private or public) and the method must be implemented under national clinical treatment guidelines for use alone or in combination with other therapy. Respiratorius is working to integrate the methods into current markets, but there is a risk that the Company's drug candidates will not be able to meet or continue to meet the reimbursement requirements from national insurance systems in the markets where the Company is active. Moreover, there is a risk that these national insurance systems will not pay adequate reimbursement and that the systems will not pay such reimbursement within a certain period of time. If, in certain markets, the insurance systems do not approve reimbursement and if clinical acceptance of the drugs is not obtained, it will have a significant negative impact on future sales growth and thereby the Company's business, earnings and financial position.

### Securities-related risks

## Share price development

Current and potential investors should note that an investment in Respiratorius involves risk and that there are no guarantees of any increase in the share price. This entails the risk that investors may lose all or part of their invested capital. The share price may fluctuate as a result of circumstances such as variations in earnings in the Company's interim reports, the general economic situation and changes in the stock market interest in the Company and its share. Limited liquidity in the share could, in turn, help to reinforce such share price fluctuations. Accordingly the share price may be influenced by factors that are in whole or in part beyond the control of the Company. An investment in shares in Respiratorius should therefore be preceded by careful analysis of the Company, its competitors and the business environment, general information about the industry, the general economic situation and other relevant information. It cannot be guaranteed that shares in Respiratorius can be sold at any time for a price that is acceptable to the shareholder.

#### Marketplace

The Company's share is traded on Spotlight Stock Market (previously AktieTorget), a secondary name of ATS Finans AB, which is a securities company under the supervision of Finansinspektionen. Spotlight Stock Market operates a trading platform (multilateral trading facility, MTF). Companies whose shares are traded on Spotlight Stock Market are not subject to all legislation applicable to a company listed on a so-called regulated market. Investors should be aware that trading in shares listed on an MTF may be associated with more risk than trading on a regulated market.

## Owners with significant influence

A few shareholders own a significant proportion of the Company's total outstanding shares. Consequently, these shareholders, individually or together, have the opportunity to exert significant influence on matters requiring approval by the shareholders, including appointment and removal of directors and any proposed mergers, consolidation or sale of assets, as well as other corporate transactions. This concentration of ownership may be a disadvantage for other shareholders, whose interests may not be the same as those of the majority shareholders.

### Liquidity in the share and equity-related securities

Shares in Respiratorius are traded on Spotlight Stock Market (previously AktieTorget). It cannot be guaranteed that the liquidity of the shares will be satisfactory, which means there is a risk that these securities will not be traded daily and that the gap between the purchase and the selling price may be large, which in turn may affect the price level of the Respiratorius share. If liquidity is limited, this may entail difficulties for holders of these securities to change their holdings.

## Future dividend

The Company has not paid any dividends to shareholders since it was founded. The management intends to use any profits generated over the next few years to develop the Company's business and to consolidate its position in the market. Any future dividends, and their amount, depend on factors such as the Company's future earnings, financial position, working capital requirements and liquidity. Any decisions regarding dividends will be taken by the Annual General Meeting following a proposal from the Board of Directors. There is a risk that Respiratorius will not issue any dividend in the future.

# FINANCIAL STATEMENTS

# Statement of change in equity

Amount, Dec. 31	10,694,490	94,794,790	-48.678.721	56,810,559
Profit/loss for the year			-9,640,418	-9,640,418
Issue expenses		-2,210,112		-2,210,112
Issue of new shares	1,264,172	38,118,513		39,382,685
Amount, Jan. 1	9,430,318	58,886,389	-39,038,303	29,278,404
GROUP	SHARE CAPITAL	OTHER PAID- IN CAPITAL	OTHER EQUITY, INCLUDING PROFIT/LOSS FOR THE YEAR	TOTAL

# Proposed appropriation of profits

The Board of Directors proposes that the earnings available for distribution (SEK):

Accumulated loss SEK	-3,810,739
Share premium reserve SEK	35,908,401
Loss for the year SEK	-9,638,410
	22,459,252
The Board of Directors proposes that the	
following be carried forward to new account	22,459,252
	22,459 ,52

The financial performance and position of the Group and parent company in general can be seen in the following income statements and balance sheets with accompanying supplementary disclosures.

# Income statement

		GROUP		PARENT COMPANY	
	JAN. 1, 2021	JAN. 1, 2020	JAN. 1, 2021	JAN. 1, 2020	
NOT	DEC. 31, 2021	DEC. 31, 2020	DEC. 31, 2021	DEC. 31, 2020	
Operating revenue, etc.					
Other operating income	0	0	0	0	
	0	0	0	0	
Operating expenses					
Raw material and consumables	-16,778,408	-4,086,817	-6,658,194	-2,242,500	
Other external costs	-5,886,898	-4,742,912	-4,742,872	-4,253,127	
Personnel costs	-2,184,419	-672,276	-2,184,419	-672,276	
Depreciation, amortization and impairment of plant, property, and equipment and intangible assets	-3,027,383	-2,531,489	-1,391,353	-1,100,976	
Capitalized work for own account	18,326,501	4,958,934	7,728,427	2,903,767	
	-9,550,607	-7,074,560	-7,248,410	-5,365,112	
Operating profit/loss		-7,074,560		-5,365,112	
Profit/loss from financial items					
Profit/loss from participations in Group companies	3 0	0	-600,000	-600,000	
Other interest income and similar profit/loss items	0	0	0	0	
Interest expense and similar profit/loss items	-89,811	-393,755	0	-393,755	
Profit/loss after financial items	-9,640,418	-7,468,314	-600,000	-993,755	
				-	
Appropriations Group contributions paid	0	0	- 1,790,000	-1,100,000	
	0	0	-1 790 000	1 100 000	
Profit/loss for the year	-9,640,418	-7,468,314	-9,638,410	-7,458,866	
Attributable to:					
Equity holders of the parent compan	-9,640,418	-7,468,314			

# **Balance sheet**

	GROUP		PARENT COMPANY	
NOTE	DEC. 31, 2021	DEC. 31, 2020	DEC. 31, 2021	DEC. 31, 2020
NON-CURRENT ASSETS				
Intangible assets				
Capitalized expenditure for research, etc. 5	29,199,672	13,719,860	14,236,476	8,130,245
Patents 6	4,223,825	4,404,519	1,872,036	1,641,193
	33,423,497	18,124,379	16,108,512	9,771,438
Financial assets				
Participations in Group companies 7	0	0	1,100,000	1,700,000
	0	0	1,100,000	1,700,000
Total non-current assets	33,423,497	18,124,379	17,208,512	11,471,438
CURRENT ASSETS				
Current receivables				
Receivables from Group companies	0	0	14,461,901	7,251,901
Other receivables	618,813	775,574	490,185	746,446
Prepaid expenses and accrued income	271,432	266,391	192,815	266,391
	890,245	1,041,965	15,144,901	8,264,738
Cash and bank balances				
Cash and bank balances	27,692,582	11,747,427	27,290,994	11,245,475
	27,692,582	11,747,427	27,290,994	11,245,475
Total current assets	28,582,827	12,789,392	42,435,895	19,510,213
TOTAL ASSETS	62,006,324	30,913,772	59,644,407	30,981,651

# Balance sheet, cont'd

	GROUP		PARENT COMPANY	
NOTE	DEC. 31, 2021	DEC. 31, 2020	DEC. 31, 2021	DEC. 31, 2020
EQUITY AND LIABILITIES				
Restricted equity, Group				
Share capital 8	10,694,491	9,430,318		
Other paid-in capital	59,755,190	58,886,389		
Other equity, including profit/loss for the year	-13,639,121	-39,038,303		
Total equity attribu- table to parent com- pany shareholders	56,810,560	29,278,404		
Restricted equity, parent companyt				
Share capital 8			10,694,491	9,430,318
Share capital, not registered			0	0
Restricted reserves			23,846,788	23,269,289
			34,541,279	32,699,607
Unrestricted equity				
Unrestricted reserves			-	-
Share premium reserve			35,908,401	41,448,994
Retained earnings			-3,810,739	-37,223,367
Profit/loss for the year			-9,638,410	-7,458,866
			22,495,252	-3,233,239
Total equity	56,810,560	29,278,404	57,000,531	29,466,368
Non-current liabilities 9				
Liabilities to Group companies	0	0	71,124	70,037
Total non-current liabilities	0	0	71,124	70,037
Current liabilities				
Accounts payable	4,368,796	1,000,175	1,792,782	850,553
Other liabilities	312,092	0	312,092	0
Accrued expenses and deferred income 10	514,876	635,193	467,878	594,693
Total current liabilities	5,195,764	1,635,368	2,572,752	1,445,246
TOTAL EQUITY AND LIABILITIES	62,006,324	30,913,772	59,644,407	30,981,651

# Statement of cash flows

	GROUP		PARENT COMPANY	
NOTE	DEC. 31, 2021	DEC. 31, 2020	DEC. 31, 2021	DEC. 31, 2020
Operating activities				
Profit/loss after financial items	-9,640,418	-7,468,314	-7,848,410	-6,358,867
Adjustments for non-cash items, depreciation/amortization	3,027,383	2,531,489	1,391,353	1,100,976
Impairment losses	0	0	600,000	600,000
CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL	-6,613,035	-4,936,825	-5,857,057	-4,657,891
Cash flow from chang- es in working capital				
Reduction(+)/increase (-) for receivables	151,721	-746,502	-6,880,163	-2,129,266
Reduction (-)/increase(+) of current liabilities	3,560,396	-111,285	1,127,507	-204,820
CASH FLOW FROM OPERATING ACTIVITIES	-2,900,918	-5,794,612	-11,609,713	-6,991,977
Investing activities				
Investments in intangible assets 4,5	- 18,326,501	-4,958,934	-7,728,427	-2,903,767
Group contributions paid 7	0	0	-1,790,000	-1,100,000
CASH FLOW FROM INVESTING ACTIVITIES	-18,326,501	-4,958,934	-9,518,427	-4,003,767
Financing activities				
Rights issue for the year	37,172,572	20,880,295	37,172,572	20,880,295
Reduction (-)/increase(+) of non-current liabilities	0	0	1,087	-5,625
CASH FLOW FROM FINANCING ACTIVITIES	37,172,572	20,880,295	37,173,659	20,874,670
Change in cash and cash equivalents	15,945,153	10,126,749	16,045,519	9,878,926
Cash and cash equivalents, Jan. 1	11,747,427	1,620,677	11,245,475	1,366,548
CASH AND CASH EQUI- VALENTS, DEC. 31	27,692,580	11,747,426	27,290,994	11,245,474

## Supplementary disclosures

### GENERAL DISCLOSURES

## **ACCOUNTING POLICIES**

This annual report has been prepared in accordance with the Annual Accounts Act and BFNAR 2012:1 Annual Reports and Consolidated Financial Statements. The policies are unchanged compared with the previous year.

### VALUATION PRINCIPLES

#### Receivables

Receivables are reported at the amounts expected to be received.

## Other assets, provisions and liabilities

Other assets, provisions and liabilities have been valued at cost unless otherwise stated below.

## Property, plant and equipment

Property, plant and equipment are recognized at cost, less accumulated depreciation and any impairment losses. The assets are depreciated over their estimated useful lives except for land, which is not depreciated. The useful life is reviewed at each reporting date. The following useful lives are applied:

## Number of years

Machinery and other technical installations 5
Equipment, tools and machinery 5

## Intangible assets

Intangible assets, consisting of patents and capitalized development costs, are recognized at cost less accumulated depreciation and impairment losses. The assets are depreciated on a straight-line basis over their estimated useful lives. The following useful lives are applied:

## Number of years

Capitalized expenditure for research and development and similar work 10 Patents 10

Research costs are expensed as incurred. Development costs for future products are expensed in the research phase. Expenditure thereafter and until commercialization is capitalized, to the extent that it is probable that the product is commercially viable.

# CAPITALIZATION OF INTERNALLY GENERATED INTANGIBLE ASSETS NON-CURRENT ASSETS

### Capitalization model

All expenditures incurred during the research phase are expensed as incurred. All expenditure incurred during the development phase are capitalized when the following conditions are met: the Company intends to complete the intangible asset and use or sell it and now has the ability to use or sell the asset, it is technically possible for the Company to com-

plete the intangible asset so that it can be used or sold, and the availability of adequate technical, financial and other resources to complete the development and to use or sell the asset, it is probable that the intangible asset will generate future economic benefits and the Company can reliably calculate the expenditure attributable to the asset during its development. Cost includes personnel costs incurred in the process of development along with an appropriate portion of relevant overheads and borrowing costs.

### Tax on income

Current tax is calculated on the taxable profit for the period and the part of income for the previous financial year, on which income tax has not yet been reported.

Current tax is valued at the probable amount according to the tax rates and rules that apply on the balance sheet date.

Deferred tax is the income tax for taxable income relating to future financial years as a result of past transactions or events.

Deferred tax is calculated on temporary differences. A temporary difference exists when the carrying amount of an asset or liability differs from the tax value. Temporary differences are not taken into account in differences relating to investments in subsidiaries, branches, associates or joint ventures if the Company can control the reversal of the temporary differences and it is not clear that the temporary difference will not reverse in the foreseeable future. Differences arising from the initial recognition of goodwill or from the initial recognition of an asset or liability, unless the related transaction is a business combination or affects tax or reported income, are not considered temporary differences.

Deferred tax assets relating to loss carryforwards or other future tax deductions are recognized to the extent that it is probable that the deduction can be offset against future taxable profits within the next three years.

The accumulated losses from business of Group and parent company amount to more than SEK 120.7 million, all relating to Sweden. The nominal value of the tax amounts to SEK 25.8 million at the 21.4% tax rate. No part of this receivable has been classified as an asset in the Balance Sheet since the Company and Group still and within budgets carry future development costs that exceed budgeted revenues. The receivable will not be recognized as an asset until the Company and the Group budget for or report stable profits. Deferred tax liabilities attributable to untaxed reserves are not recognized separately, untaxed reserves are reported as a gross amount in the balance sheet.

### SEGMENT REPORTING

Respiratorius AB operates in only one segment and therefore refers to the income statement and balance sheet concerning reporting of operating segments.

## RELATED PARTIES TRANSACTIONS

Regarding the Company's Board members, there are no transactions other than those described in Note 2.

## CRITICAL ACCOUNTING ESTIMATES AND ASSUMPTIONS

Preparation of the annual accounts and application of different accounting standards are often based on management's assessments or on assumptions and estimates that are regarded as reasonable under the prevailing circumstances. These assumptions and estimates are often based on historical experience and other factors, including expectations of future events.

## For Respiratorius AB the following areas are worth noting: Patents and capitalized development fees

The recoverable amount of capitalized development costs is determined based on economic life and volume. This calculation is based on estimated future cash flows, based on financial forecasts approved by management and covering product life cycles.

## **CONSOLIDATED ACCOUNTS**

#### **Subsidiaries**

Subsidiaries are entities in which the parent company directly or indirectly holds more than 50% of the voting rights or otherwise has a controlling influence. Controlling interest entails the right to determine a company's financial and operative strategies to obtain economic benefits. Accounting for business combinations is based on the entity approach. This means that the acquisition analysis is prepared as of the date when the acquirer gains a controlling influence. From this point the acquirer and the acquiree are viewed as a single accounting unit. Application of the economic entity view entails that all assets (including goodwill) and liabilities as well as revenues and expenses are included in their entirety even for subsidiaries that are not wholly owned. The cost of the subsidiary is calculated as the sum of fair value at the acquisition date for purchased assets with the addition of incurred and assumed liabilities and equity instruments issued, costs directly attributable to the business combination and any additional consideration. The acquisition analysis determines the fair value, with some exceptions, at the acquisition date of acquired identifiable assets, assumed liabilities and any non-controlling interests. Non-controlling interest is measured at fair value at the acquisition date. The revenues and expenses, identifiable assets and liabilities and any goodwill or negative goodwill of the acquired company are included in the consolidated financial statements from the acquisition date.

## Consolidated intangible assets

Group surplus values relate to patents acquired on acquisition of subsidiaries – there is no consolidated goodwill in the consolidated balance sheet – that are recognized when the acquisition of shares in subsidiaries exceeds the value of the identifiable net assets of the acquired company as measured in the acquisition analysis. Patents are recognized at cost, less accumulated depreciation and any impairment losses.

## Elimination of transactions between Group companies and associates

Intra-Group balances, income and expenses and any unrealized gains and losses arising from intra-Group transactions are eliminated in their entirety. Unrealized gains arising from transactions with associates are eliminated to the extent of the Group's interest in the Company. Unrealized losses are eliminated in the same way as unrealized gains, but only to the extent that there is no indication of impairment.

## STATEMENT OF CASH FLOWS

The statement of cash flows has been prepared using the indirect method. Cash and cash equivalents consist of cash and bank deposits.



## **DISCLOSURES REGARDING INDIVIDUAL ITEMS**

### Note 1 Remuneration to auditors

	GROUP		PARENT COMPANY	
	2021	2020	2021	2020
Crowe Osborne AB				
Audit assignments	152,110	143,040	131,172	113,340

## Note 2 Personnel

Note 2 Personnel					
	GRO	UP	PARENT C	OMPANY	
	2021	2020	2021	2020	
Average number of employees The average number of employees is b ber of hours worked for which the Com in relation to normal working hours.		)-			
Average number of employees	1	0	1	0	
women	1	0	1	0	
men	0	0	0	0	
Salaries, benefits  Salaries, benefits, social security expenses and pension costs have been paid as follows:					
Other	781,200	0	781,200	0	
Board of Directors and CEO:	924,359	530,000	924,359	530,000	
	1,705,559	530,000	1,705,559	530,000	
Social security expenses	478,859	154,478	478,859	154,478	
Total Board of Directors and others	2,184,418	684,478	2,184,418	684,478	

In 2021, Christer Fåhraeus, who was Chairman of the Board at the time, and current Chairman of the Board Niklas Prager were paid SEK 480,000 , while the other members of the Board were paid SEK 125,000.

CEO Johan Drott has invoiced for accrued hours worked through Drott Development AB, which is responsible for Johan Drott's salary, social security expenses, pension costs and other expenses. Fees totaling SEK 1,173,516 were paid (previous year SEK 675,820).

## Note 3 Profit/loss from participations in Group companies

	GROUP		PARENT COMPANY	
	2021	2020	2021	2020
Impairment losses	0	0	-600,000	-600,000
	0	0	-600,000	-600,000

An impairment charge of 10% was taken for the shares in a subsidiary because the value of its shares relates to patents.

## Note 4 Tax on profit/loss for the year

## GROUP

Total	0	0
Loss carryforward for the year	-1,857,526	-1,469,819
Consolidated depreciation/amortization	-128,400	-128,400
Tax-exempt income	0	0
Non-deductible expenses	0	0
Tax effects of:		
18X 118UIIILY 21.470 (21.470)	1,703,720	1,570,217
Tax liability 21.4% (21.4%)	1,985,926	1,598,219
Profit/loss before taxes	-9,640,418	-7,468,314
Effective tax reconciliation		
	2021	2020

## PARENT COMPANY

	2021	2020
Effective tax reconciliation		
Profit/loss before taxes	-9,638,410	-7,458,866
Tax liability 21.4% (21.4%)	1,985,512	1,596,197
Tax effects of:		
Non-deductible expenses	0	0
Tax-exempt income	0	0
Impairment of shares in subsidiary	-128 400	-128 400
Loss carryforward for the year	-1 857 112	-1 467 797
Total	0	0

## Note 5 Capitalized expenditure for research, etc.

	GROUP		PARENT CO	MPANY
	DEC. 31, 2021	DEC. 31, 2020	DEC. 31, 2021	DEC. 31, 2020
Opening cost	43,236,000	38,707,336	35,769,711	33,085,364
Purchases	17,318,567	4,528,664	7,198,357	2,684,347
Closing accumulated cost	60,554,567	43,236,000	42,968,068	35,769,711
Opening depreciation/amortization	-29,516,140	-28,130,252	-27,639,466	-26,815,775
Depreciation/amortiztion for the year	-1,838,755	-1,385,888	-1,092,126	-823,691
Closing accumulated depreciation/amortization	-31,354,895	-29,516,140	-28,731,592	-27,639,466
Closing carrying amount	29,199,672	13,719,860	14,236,476	8,130,245



## Not 6 Patents

	GROUP		PARENT CO	OMPANY
	DEC. 31, 2021	DEC. 31, 2020	DEC. 31, 2021	DEC. 31, 2020
Opening cost	18,897,400	18,437,130	9,069,246	8,849,826
Purchases	1,007,934	430,270	530,070	219,420
Closing accumulated cost	19,905,334	18,897,400	9,599,316	9,069,246
Opening depreciation/amortization	-14,492,881	-13,347,279	-7,428,053	-7,150,768
Depreciation/amortiztion for the year	-1,188,628	-1,145,602	-299,227	-277,285
Closing accumulated depreciation/amortization	-15,681,509	-14,492,881	-7,727,280	-7,428,053
Closing carrying amount	4,223,825	4,404,519	1,872,036	1,641,193

## Note 7 Participations in Group companies

## PARENT COMPANY

			DEC. 31, 2021	DEC. 31, 2020
COMPANY CORPORATE IDENTITY NUMBER	REGISTERED OFFICE	NUMBER OF/ SHARE OF CAPITAL %	CARRYING AMOUNT	CARRYING AMOUNT
Bergdalsten Kemi AB Corp. Id. No. 556650-7330	Lund	100	100,000	100,000
Valcuria AB Corp. ID no. 556871-5196	Lund	100	1,000,000	1,600,000
			1,100,000	1.700.000

INFORMATION ABOUT EQUITY AND PROFIT OR LOSS	EQUITY	FINANCIAL PERFORMANCE
Bergdalsten Kemi AB	65,646	-413
Valcuria AB	494,381	-1,595

## Note 8 Information about share capital

Number/value, Dec. 31	213,889,811	0.05
Issue of new shares	25,283,442	
Number/value, Jan. 1	188,606,369	0.05
	NUMBER OF SHARES	PAR VALUE

## Note 9 Non-current liabilities

	GROUP		PARENT COMPANY	
	DEC. 31, 2021	DEC. 31, 2020	DEC. 31, 2021	DEC. 31, 2020
Amortization after 5 years	0	0	71,124	70,037
	0	0	71,124	70,037

## Note 10 Accrued expenses and deferred income

	514,878	635,193	467,878	594,693
Other accrued expenses	202,700	178,874	202,700	138,374
Accrued fees	312,178	456,319	265,178	456,319
	DEC. 31, 2021	DEC. 31, 2020	DEC. 31, 2021	DEC. 31, 2020
	GROUP		PARENT COMPANY	

## Note 11 Pledged assets

	GROUP		PARENT COMPANY	
	DEC. 31, 2021	DEC. 31, 2020	DEC. 31, 2021	DEC. 31, 2020
Chattel mortgages	2,500,000	2,500,000	2,500,000	2,500,000

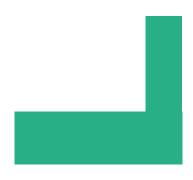
## Note 12 Definition of key ratios

Equity/assets ratio

Adjusted equity as a percentage of total assets

## Return on equity

Profit/loss after financial items as a percentage of average adjusted equity





Lund, April 3, 2022

Niklas Prager Chairman of the Board Kristina Drott Board member

Johan Drott Executive officer

Ingemar Kihlström Board member Peter Buhl Jensen Board member

Anna Törner Board member

> Our Auditor's Report was submitted on April 5, 2022 Authorized public accountant

> > Crowe Osborne AB

Olov Strömberg / Authorized public accountant

## Auditors' report

To the Annual General Meeting of shareholders of Respiratorius AB Corp. ID no.556552-2652

## Report on the annual accounts and consolidated accounts Opinions

We have audited the annual accounts and consolidated accounts of Respiratorius AB for 2021.

The annual accounts and consolidated accounts of the Company are included in the printed version of this document on pages 23–44.

In our opinion, the annual accounts and consolidated accounts have been prepared in accordance with the Swedish Annual Accounts Act and present fairly, in all material respects, the financial position of the parent company and the Group as of Dec. 31, 2021 and of its financial performance and its cash flows for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts. We therefore recommend that the annual meeting of shareholders adopt the income statement and balance sheet for the parent company and the Group.

### Basis for opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the Group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

## Information other than the annual accounts and consolidated accounts

The Board of Directors and the Chief Executive Officer are responsible for this other information. The other information comprises pages 3–22 (but does not include the annual accounts, consolidated financial statements or our audit report regarding them).

Our opinion regarding the annual accounts and consolidated accounts does not cover this information, and we make no statement of assurance regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, it is our responsibility to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure, we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed on this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

## Responsibilities of the Board of Directors and the Chief Executive Officer

The Board of Directors and the Chief Executive Officer are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in

accordance with the Annual Accounts Act. The Board of Directors and the Chief Executive Officer are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, the Board of Directors and the Chief Executive Officer are responsible for the assessment of the ability of the Company and the Group to continue as a going concern. They disclose, as applicable, matters related to the ability to continue as a going concern and using the going concern basis of accounting. The going concern basis of accounting is, however, not applied if the Board of Directors and the Chief Executive Officer intend to liquidate the Company, cease operations or have no realistic alternative but to do so.

## Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to submit an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error, and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the Company's internal control relevant to the audit in order to
  design audit procedures that are appropriate in the circumstances, but not for the purpose
  of expressing an opinion on the effectiveness of the Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and, where applicable, the Chief Executive Officer.
- Conclude on the appropriateness of the Board of Directors' and the Chief Executive Officer's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the Company's and the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, the latter is required to draw attention in the auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify the opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of the auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the
  entities or business activities within the Group to express an opinion on the consolidated
  accounts. We are responsible for the direction, supervision and performance of the Group
  audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform the Board of Directors of significant audit findings during the audit, including any significant deficiencies in internal control that we identified.

## Report on other legal and regulatory requirements Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Chief Executive Officer of Respiratorius AB for the financial year 2021 and the proposed appropriations of the Company's profit or loss.

We recommend to the annual meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Chief Executive Officer be discharged from liability for the financial year.

## Basis for opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the Group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions

## Responsibilities of the Board of Directors and the Chief Executive Officer

The Board of Directors is responsible for the proposal for appropriations of the Company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the Company's and the Group's type of operations, size and risks place on the size of the Parent Company's and the Group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the Company's organization and the administration of the Company's affairs. This includes, among other things, continuous assessment of the Company's and the Group's financial situation and ensuring that the Company's organization is designed so that the accounting, management of assets and the Company's financial affairs otherwise are controlled in a reassuring manner. The Chief Executive Officer shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the Company's accounting in accordance with law and handle the management of assets in a reassuring manner.

## Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Chief Executive Officer in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the Company, or
- other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the Company's profit or loss, and thereby our opinion about this, is to assess with a reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the Company, or that the proposed appropriations of the Company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the Company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the Company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the Company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Lund April 5, 2022

Crowe Osborne AB

Olov Strömberg, Authorized public accountant

Our reports and annual reports contain many industry terms that may be difficult to understand for those who do not work with drug development. We have therefore compiled a small glossary with terms that are specific to our business.

Beta agonists: A class of drugs that cause dilation of the trachea by binding to beta receptors.

Bridging study: Conducted to be able to extrapolate/interpolate results from one study to another.

Ex vivo: Means "outside life" in Latin and refers to studies on materials such as cells, tissue and organs that have been isolated from living organisms.

Pharmacokinetic study: Pharmacokinetics describes what the body does with a drug. A quantitative analysis of the processes related to absorption, distribution, metabolism and elimination of drugs in the body.

Five-year survival: Describes the survival of cancer patients after five years in relation to the expected survival of people who have not been diagnosed with cancer.

Formulation: A formulated product consists of at least two ingredients, often many more, which are selected, processed and combined in a specific way to give the product desired properties. Formulation of a medicine entails determination of what components are to be included and how the medicine is to be delivered to the body.

In vitro: Means "in glass" and refers to studies performed in, for example, test tubes.

In vivo: Means "in the living" and refers to studies done in living animals and humans.

Indication: In medical contexts, the symptoms, specific condition, or similar factors for which a specific treatment is to be used. For example, pain is the indication for a pain-relieving medicine, high blood pressure is an indication for a blood pressure-lowering medicine.

Interim analysis: A statistical analysis that is carried out in the context of a clinical trial prior to the final planned analysis. A planned interim analysis provides an opportunity to see early (before the final analysis) whether the risks associated with a drug are greater or less than expected.

Clinical trial/study: Investigation on healthy people or patients to study the effect of a medication or a treatment method.

Corticosteroids: Often referred to as steroids. A collective name for the synthetically produced hormones that are naturally produced/formed in the adrenal cortex and that have an anti-inflammatory effect. The most common steroid drugs are cortisone and prednisone.

Muscarinic antagonists: A class of drugs that inhibit or block the effects of acetylcholine via muscarinic receptors.

Preclinical study: The next step after basic research. The studies are carried out both in vitro and in vivo. Preclinical work provides knowledge about how the drug candidate affects the organism, the underlying molecular mechanisms and the connection between dose and efficacy. Preclinical research is required before testing on humans.

**Proof of concept**: Preclinical studies are followed by proof of concept, which refers to proof that a concept works, such as effects relating to a unique molecule.

Orphan drug: Drug for treatment of an uncommon disease. Orphan drug status provides a seven-year monopoly on the US market, opportunities for tax deductions for development costs, as well as direct financial research and administrative support.

Toxicological study: Toxicology is the study of the harmful effects of chemical substances on living organisms. Toxicologists study how different substances affect animal and human health, at different exposures.





Respiratorius AB (publ) develops drug candidates with the goal of launching or out-licensing drugs for the treatment of cancer, chronic obstructive pulmonary disease (COPD) and severe asthma.

In the field of oncology, Respiratorius is developing a novel drug as a pretreatment that enhances the effects of the standard therapy currently used for the treatment of diffuse large B-cell lymphoma, the most common type of aggressive lymphoma.



In the field of COPD and asthma, Respiratorius has developed a series of compounds with a demonstrated bronchodilating effect on human lung tissue.



The Company's project portfolio also includes a substance that was developed for use in PET imaging, which more accurately diagnoses certain cardiovascular diseases.



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