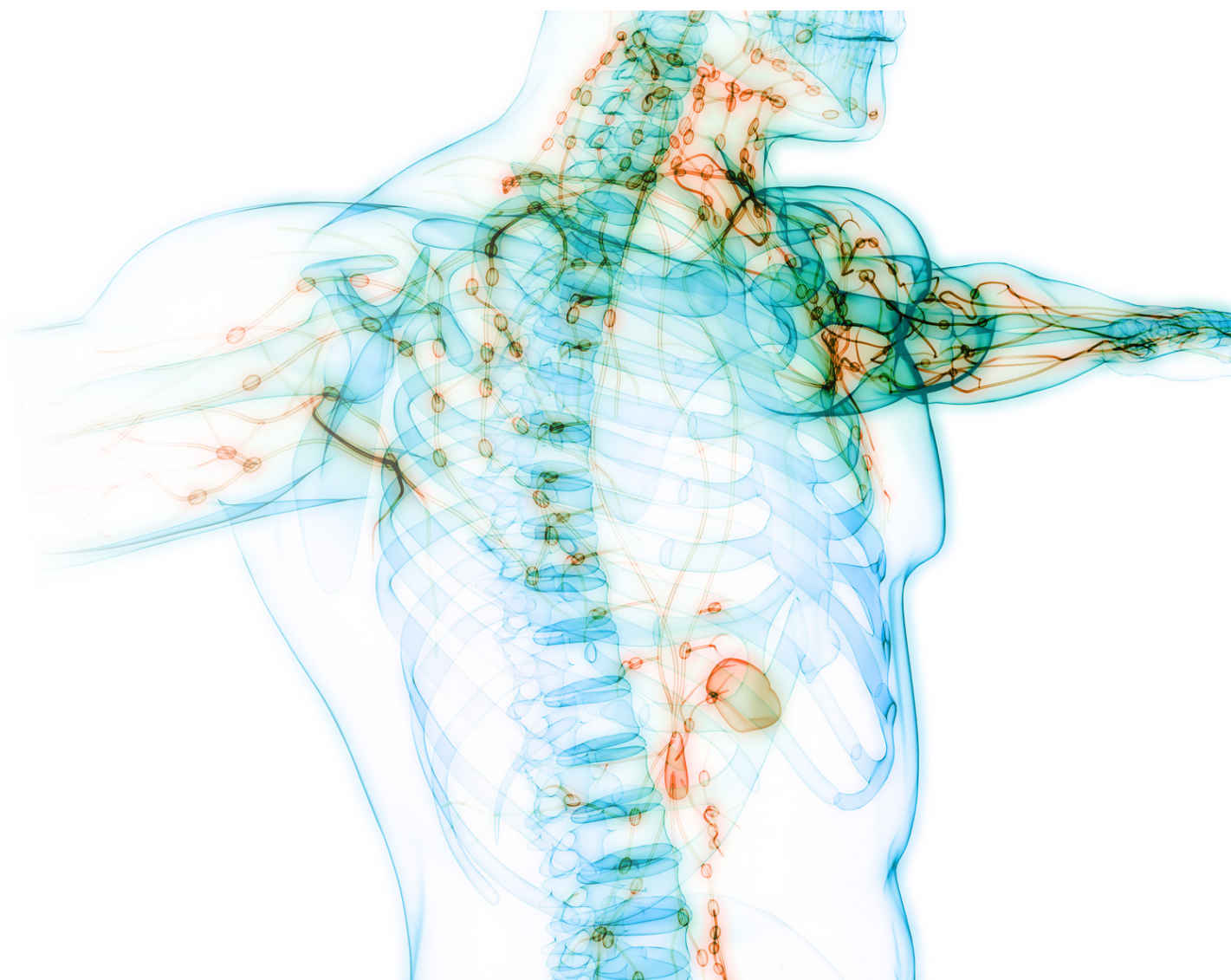


2020



RESPIRATORIUS AB ANNUAL REPORT  
2020





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# The year in brief

## – Develop the Company toward value generating

**At the turn** of the half year, the Company raised capital through a preferential rights issue of units, two (2) newly issued shares and one (1) warrant series 2020/2021, which was about 87.1 percent subscribed, with subscription rights and the remainder, corresponding to about 126.7 percent, without subscription rights. The Company thereby raised about SEK 25.1 million before issue expenses. Share capital may be increased by a maximum of SEK 785,859.85. Each warrant of series 2020/2021 entitles the holder to subscribe for one new share in the Company during the period June 21, 2021 through July 5, 2021 at a subscription price corresponding to 75 percent of the volume-weighted average price for the share during the period from June 7, 2021 through June 18, 2021, though no less than SEK 1.20 and no more than SEK 1.60 per share. If all warrants of series 2020/2021 are exercised to subscribe for shares, the Company can thereby raise an additional capital injection of about SEK 19-25 million before issue expenses, which are estimated at about SEK 0.9-1.3 million.



**In November,** Carl-Magnus Andersson was hired to serve as CMC Director of the Company. Carl-Magnus has extensive experience in drug development with executive positions at a number of pharmaceutical and biotech companies, such as AstraDraco, Acadia Pharmaceuticals, and KaroBio, where his responsibilities included chemistry and pharmacy, and intellectual property strategies.



**In December,** Mia Sandberg Lundblad was hired to serve as Clinical Director. Mia has held executive positions at pharmaceutical companies such as Novo Nordisk and Ferring, where her responsibilities included taking drug candidates from the preclinical phase to early clinical development. Thus she has valuable experience of interaction with drug regulatory authorities.

### VAL001

Work in the project has focused on preparations for a Phase III trial, since the European Medicines Agency (EMA) recommended in a scientific advisory meeting that Respiratorius should do so as the next step in the clinical development of

VAL001. The preparations entail dedicated formulation, where we are now in the final phase. The assessment is that the formulation easily meets the requirements to differentiate VAL001 from other products on the market, which in turn is important from the standpoint of pricing. The formulation is patent pending and we have high hopes for patent approval.

Respiratorius' work with Partner International Inc. to find a company with which to sign an agreement for VAL001 has made progress during the year, resulting in new contacts with interested parties. The assessment is that VAL001 continues to have good potential for divestment or for entering into a partnership, with promising results from the Phase I/IIa clinical trial, as well as a strong patent situation. VAL001 has previously also received Orphan Drug Designation in both Europe and the US. With a unique product, in the form of a dedicated formulation, prospects for a beneficial agreement will likely increase. Patents for VAL001 have now been granted in Europe, the US, Canada, Japan 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 (DLBCL), a form of lymph node cancer.

### RESP9000

The promising results from an airway study in an animal model using the patent-pending candidate compound RES030-085 for treatment of COPD and severe asthma were presented in 2019. These results were an important part of the documentation presented to the Swedish Medical Products Agency at a scientific advisory meeting held in 2020.

Topics discussed at this meeting included Respiratorius' strategy for conducting clinical trials and any additional studies that should be conducted prior to approval. The positive meeting provided clarification and culminated in the initiation of important activities such as production, research and pharmacological studies.

The patent application for RES030-085 has been submitted and reviewed, and the prospects for approval are considered to be favorable.



# Respiratorius in brief

## BUSINESS CONCEPT

Respiratorius develops effective new drugs to treat the common diseases cancer, COPD and severe asthma, as well as improved cardiovascular diagnostics. **The Company bases its operations on patent-pending compounds that have shown superior results in preclinical trials compared with the “gold standard.”**

## VISION

Respiratorius' vision is to help reduce the global burden of disease for the three major diseases cancer, respiratory diseases and cardiovascular diseases.

The Company's goal and driving force is to develop innovative new drugs to improve quality of life and survival time for patients suffering from cancer, chronic obstructive pulmonary disease (COPD) and severe asthma, as well as improved cardiovascular diagnostics. By doing so, the Company will also create long-term shareholder value.

## STRATEGY AND BUSINESS MODEL

Respiratorius will be an attractive partner for academic research groups, biotech companies and global pharmaceutical companies through our unique expertise, with a focus on the early part of the value chain – from academic research to finished product on the market. **Respiratorius searches at an early phase for strategic partners who assume financial and operational responsibility from development to finished product.** This type of partner will have financial resources, experience in large clinical trials and established contacts with regulatory authorities. These partners will also be responsible in the future for manufacturing, marketing and sales of the licensed drugs that may result from the development project. Several large pharmaceutical companies have already shown interest regarding licensing and collaboration on the Company's projects.

A license agreement with a pharmaceutical company is expected to give Respiratorius income in the form of an initial payment followed by milestone payments, as well as royalties. In the event that an agreement is concluded, there is an intention among the major shareholders to distribute approximately half of the advance payment in connection with a license agreement pro rata to all shareholders, provided that the Company's operations remain intact.

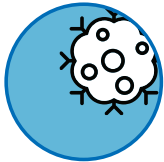
**The timing of signing cooperation agreements with pharmaceutical companies will entail business decisions based on cost, risk, skill requirements and the value that would be added by completing additional steps in-house.** Such cooperation agreements will ensure that the projects receive expertise and resources from pharmaceutical companies at an early stage. With this approach, Respiratorius avoids tying up excessive resources in a single project. It is in the best interest of the Company to work – without compromising on safety, expertise or quality – to minimize time to market for its drugs.

## ORGANIZATION

The Company has operated for several years based on a virtual model, without any employees, since the need for resources and talent varies during product development and is contracted as needed. **At the end of 2020, the establishment of a small but efficient organization was initiated.** The assessment is that the company is now in a phase, with several promising projects, that requires an organization. This new organization continues to focus on value-generating project development.



## RESPIRATORIUS' PROJECT PORTFOLIO



### VAL001

The product is being developed primarily for the treatment of diffuse large B-cell lymphoma (DLBCL), an aggressive form of lymph node cancer, which is the most common type of Non-Hodgkin's Lymphoma (NHL). Each year, 60,000 people in the US and Europe are diagnosed with DLBCL. The five-year survival rate with standard treatment is estimated at 60–70 percent. The occurrence of DLBCL is increasing, which is also expected to generate increased demand for new, more effective treatments and result in substantial market growth.



### RESP9000/1000

RESP9000 refers to a medication under development for treatment of chronic obstructive lung disease (COPD), which is one of the most common and rapidly growing diseases in the world. COPD is an inflammatory disease of the airways and lungs characterized by a gradual increase in congestion of the airways, which affects patient quality of life.



### RESP2000

RESP2000 is a series of new chemical compounds that differ from the RESP1000 series. Results from preclinical trials conducted on RESP2000 in the US suggest that the effects of the medicinal compound on large and small airways is due to its action upon the muscle cell mitochondria, a type of cell organelle that plays an important role in cell metabolism as energy sources for the cell.



### 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.



### VAL001

The product is being developed primarily for the treatment of diffuse large B-cell lymphoma (DLBCL), an aggressive form of lymph node cancer, which is the most common type of Non-Hodgkin's Lymphoma (NHL). Each year, 60,000 people in the US and Europe are diagnosed with DLBCL. The five-year survival rate with standard treatment is estimated at 60–70 percent. The occurrence of DLBCL is increasing, which is also expected to generate increased demand for new, more effective treatments and result in substantial market growth.

**Treatment of diffuse large B-cell lymphoma** The market within Non-Hodgkins Lymphoma, which includes DLBCL, is defined by therapies with well-established medications. The global population is continually growing because people are living longer, a trend that is expected to continue and to lead to market growth. 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, routine treatment of DLBCL**, which is globally available, entails immunotherapy with R-CHOP, which includes chemotherapy and the antibody-based drug Rituxan (rituximab).

Other drugs for the indication are being developed at a rapid pace, 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 first-line treatment with R-CHOP.

### OBJECTIVES VAL001

**In 2020, preparatory work** prior to a Phase III clinical trial continued, based on the scientific advisory meeting with the European Medicines Agency. The conclusion at the meeting was that the next step in clinical development was a Phase III trial prior to marketing approval.

**VAL001 had already** been 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. There is also a patent application for the formulation that is the basis of the Company's development work, with a dedicated formulation for pretreatment prior to treatment with R-CHOP. Taken together, these achievements provide a solid foundation for a strong intellectual property position.

**The strong intellectual property** position is important in the exit process that has continued during the year, where potential global partners continue to be identified and evaluated prior to the continued development. As previously, the objective is to conclude a cooperation agreement as soon as possible, though this is not time-critical prior to a decision regarding initiating Phase III studies. At the same time as the exit process, preparations for continued clinical development of VAL001 are underway, including production of VAL001 and work related to regulatory documentation.

### RESP9000

RESP9000 refers to a medication under development for treatment of chronic obstructive lung disease (COPD), which is one of the most common and rapidly growing diseases in the world. COPD is an inflammatory disease of the airways and lungs characterized by a gradual increase in congestion of the airways, which affects patient quality of life. It is estimated that the prevalence was 251 million cases in 2016 and that over 3 million people lost their lives as a result of the disease, which corresponds to about 5 percent of all deaths worldwide.

Today COPD is the fourth most common cause of death worldwide. Without preventive measures such as reduced smoking and improved air quality, the total number of COPD-related deaths is expected to increase by 30 percent by 2020, when it is expected to be the third most common cause of death worldwide.

**In global pharmaceutical sales,** medications to treat respiratory conditions account for almost 10 percent of the market, which in 2009 corresponded to more than USD 52 billion. The global market for drugs to treat COPD and severe asthma amounts to more than USD 28 billion and comprises about 55 percent of the entire market for respiratory medications.

**The market for COPD drugs** is expected to grow sharply until 2025. 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 and is expected to increase to USD 14.1 billion by 2025, which corresponds to an annual growth rate of 3.6 percent. The US is already the largest market and in 2025 the market share is expected to be about 78 percent of the total market. Market growth is mainly driven by the increased number of diagnoses and the approval of new drugs.

**In Sweden, an estimated** 500,000 people suffer from the disease and 2,500 to 3,000 people die annually as a result of COPD, which corresponds to about 2.5 to 3 percent of all deaths in that country. COPD is not just a patient problem, but 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

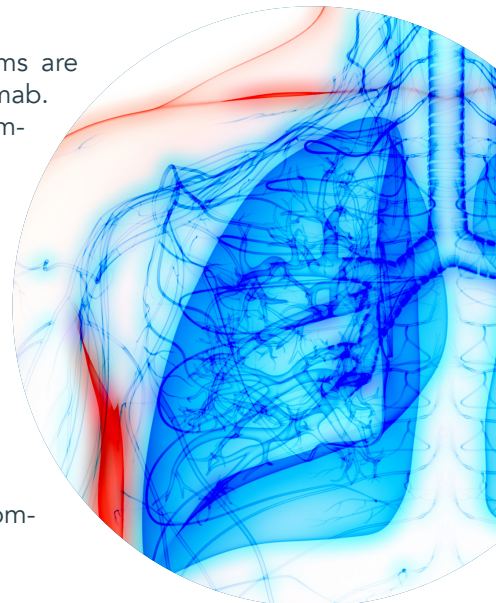
Despite the growing number of new medications, there is a lack of bronchodilators based on new mechanisms for bronchodilation (increasing the diameter in smaller airways). The new medicinal products that have been approved or are undergoing clinical testing are based on fixed-dose combinations of long-acting beta agonists and long-acting muscarinic antagonists (LABA/LAMA), as well as triple combinations with inhaled corticosteroids (ICS), all of which act based on previously known mechanisms. Currently there are no data to clearly support that medications that reduce the number of COPD attacks and provide symptomatic relief actually improve survival and reduce mortality among COPD patients. The need for new anti-inflammatory drugs that are not inhaled corticosteroids is especially large.

**The only medications** with the new anti-inflammatory mechanisms are GlaxoSmithKline's ("GSK") Nucala and AstraZeneca's Benralizumab. These are biopharmaceuticals that target eosinophilic airway inflammation.

#### Objectives RESP9000

During the year, an advisory meeting was held with the Medical Products Agency. The encouraging meeting helped to clarify the continued planning in order to initiate clinical trials as soon as possible. Development of production and formulation for GLP studies of RES030-085 are underway. In addition, supplemental studies are being planned for the preclinical data package required prior to approval of a Phase I trial.

The continued objective is to document the properties of the new compound as part of the preclinical work prior to clinical development.



### 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. The disease can lead to serious complications such as myocardial infarction, stable coronary artery disease and cardiac arrest. Coronary artery disease is caused by narrowing of the coronary arteries which prevents sufficient blood flow to the heart muscle. A common cause is plaque buildup on the inner walls of the arteries, a condition known as atherosclerosis. As a result, the cardiac muscle does not receive sufficient blood and oxygen. Detection and diagnosis of obstructive coronary artery disease at an early stage is therefore extremely important for effective treatment.

**Half of the population of the developed world** becomes sick and dies 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 that could be relevant for RESP3000 is rapidly growing, with an estimated size of USD 4 billion in 2018.

#### Objectives RESP3000

In the RESP3000 project, the Company primarily intends to identify potential partners and stakeholders.



Message from  
Report 2020

“The successful effort to raise capital has resulted in a high level of activity in the projects, allowing us to focus on building an organization to manage the two priority projects VAL001 and RESP9000.”



## Continued progress in our projects

The past year saw the successful development of the projects, with value-generating milestones – we have achieved important results for the two main projects, VAL001 and RESP9000.

According to a recommendation from the European Medicines Agency (EMA), VAL001 has achieved an advanced position and is now ready for Phase III trials. Before such a study can be initiated, efforts are underway to complete a dedicated formulation, adapted for use as pretreatment prior to immunochemotherapy with R-CHOP. Preparatory work also includes the regulatory documentation required to initiate a Phase III trial, which is also the final step before marketing approval.

### Partner process for VAL001

Respiratorius' work with Partner International Inc. to find a company with which to sign an agreement for VAL001 has made progress during the year, with new and further contacts with a number of interested parties. We remain optimistic and determined to complete an exit under conditions that are favorable for the Company. Work on the formulation of VAL001 should be viewed as part of the effort to further strengthen its prospects. We can now see that this work has been successful.

### RESP9000 for the treatment of COPD and severe asthma

Preclinical efforts have intensified after the favorable results of the efficacy study. Development of the formulation and preparations for production are underway prior to the preclinical toxicology program.

The Company is focusing on initiating clinical trials as soon as possible and the work is fully focused on finishing the regulatory documentation required for the compound prior to clinical trials.

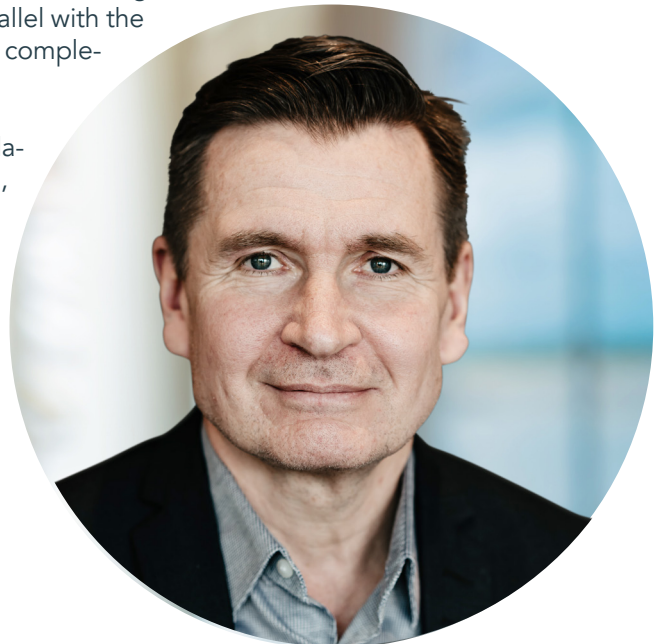
### Strong and important year

In 2020, Respiratorius made great progress, with development of the projects toward value-generating milestones. VAL001 is positioned as a drug candidate ready for Phase III clinical trials. In parallel with the ongoing exit process, important steps are being completed for a Phase III trial.

RESP9000 has shown potential as a drug candidate for the treatment of COPD and severe asthma, an eagerly awaited new project with tremendous market potential.

I would like to thank our committed shareholders for their confidence in Respiratorius. I see 2021 as an important year for the Company with excellent prospects, thanks to the talented organization currently under development.

Johan Drott, Chief Executive Officer








Fotobyrå.com

## Project portfolio and pipeline

The Respiratorius project portfolio includes projects targeting the three major common diseases – cancer, COPD and severe asthma – as well as cardiovascular diseases.

### CURRENT DEVELOPMENT PROJECTS

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

| Project  | Indication                 | Research  | Preclinical  | Phase 0 | Phase I | Phase II | Phase III   |
|----------|----------------------------|---|--|---------|---------|----------|---|
| VAL001   | Lymphoma (cancer)          |   |  |         |         |          |  |
| RESP9000 | COPD and severe asthma     |   |   |         |         |          |   |
| RESP1000 | COPD and severe asthma     |   |  |         |         |          |   |
| RESP2000 | COPD and severe asthma     |  |  |         |         |          |   |
| RESP3000 | Cardiovascular diagnostics |  |  |         |         |          |   |



Message from the  
Report 2020

“The single most important step is the new formulation of VAL001, which has the potential to place the drug in a favorable pricing position. Regulatory requirements must still be met prior to initiating a Phase III trial and marketing approval.”

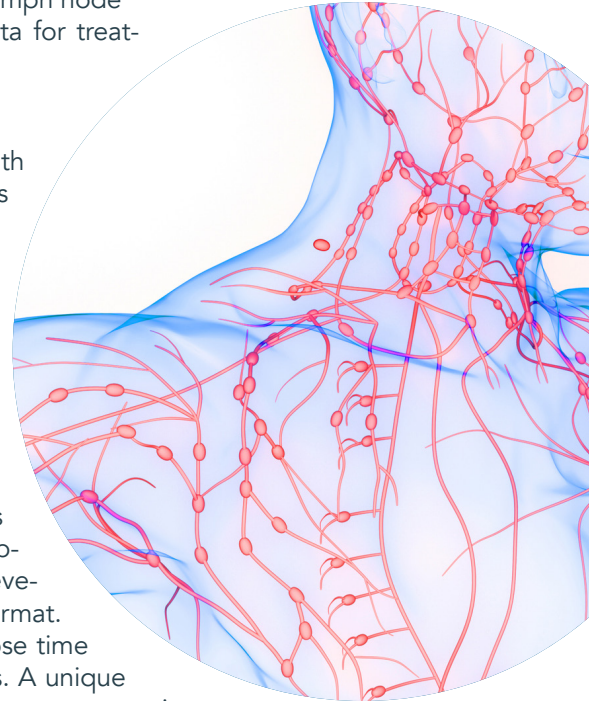
### VAL001

The drug candidate VAL001 is being developed primarily for treatment of diffuse large B-cell lymphoma (DLBCL), the most common form of lymph node cancer. VAL001 has shown clear favorable experimental data for treatment of diseases such as diffuse large B-cell lymphoma.

A Phase I clinical trial was successfully completed in 2013 to determine the maximum tolerated dose in combination with standard chemotherapy (R-CHOP) for treatment of patients with DLBCL. In 2018 the subsequent Phase IIa trial was completed with favorable results. The study results showed significantly improved 1-year and 2-year survival for patients treated with VAL001 and R-CHOP, compared with a matched population from a control group of patients taken from the Swedish lymphoma registry who were treated with R-CHOP alone.

Currently, preparations are underway for continued clinical development, which will involve a Phase III clinical trial. This work includes development of the clinical trial protocol for approval by the European Medicines Agency (EMA), as well as development and production of the test medication in capsule format. This step is important to ensure that the project does not lose time ahead of the market launch during the ongoing exit process. A unique formulation in particular is considered to be essential to ensure correct pricing of the finished product, which is also important for the process of finding a partner.

Identification of suitable partners for VAL001 continues and may entail selling the VAL001 project, or the subsidiary Valcuria AB, in which all findings and intellectual property rights belonging to VAL001 are gathered.



### RESP1000/9000

In 2018 Respiratorius submitted a patent application for a new compound (RES030-085) that was assessed as having a favorable safety profile and equivalent anti-inflammatory and bronchodilatory properties as RES022-125, which is the Respiratorius drug candidate that has come farthest in the RESP1000 series. In 2019, a successful in vivo efficacy study in mice was conducted with the new compound. The bronchodilator effect was evident in the study, as were additional beneficial properties, such as the several hundred-fold higher concentration of RES030-085 measured in the lung compared with in the blood. This indicates that only a small portion is absorbed into the bloodstream and is rapidly metabolized. Experiments have also confirmed the anti-inflammatory properties of RES030-085.

The new compound, which is significantly more attractive with respect to its remaining patent time than RES022-125, allows the Company to revitalize the RESP1000 project as it now focuses on initiating clinical trials as soon as possible. Once a patent is granted, market exclusivity is obtained in all countries in which an application has been submitted through 2038.

Initiating a clinical trial in the field of COPD and severe asthma, two common diseases that lack satisfactory treatments, represents an important milestone. Consequently, Respiratorius intends to conclude the preclinical program, which includes toxicological studies, for the new compound as soon as possible. The work is being conducted in collaboration with leading certified toxicological laboratories. The Board of Directors considers this to be a strategic step prior to initiating clinical trials and it will also probably make the project more attractive to potential partners.



### RESP2000

RESP2000 is a series of new chemical compounds that differ from the RESP1000 series. Results from preclinical trials conducted on RESP2000 in the US suggest that the effects of the medicinal compound on large and small airways is due to its action upon the muscle cell mitochondria, a type of cell organelle that plays an important role in cell metabolism as energy sources for the cell.

The use of mitochondrial function to treat a specific disease, however, requires selective administration to the correct organ and its cells in order to avoid negative effects on other cells and organs, which could result in undesirable side effects. Consequently, it is important to administer the drug via inhalation and to limit further drug dissemination from the lungs when treating pulmonary diseases such as COPD and severe asthma through manipulation of mitochondrial function. Mitochondrial manipulation may necessitate extremely rigorous safety studies before the compounds can be tested in humans. Respiratorius considers it to be a key task to demonstrate clear margins of safety for use of therapeutic doses of RESP2000 as inhalation therapy. The bronchodilatory effect of RESP2000 was confirmed through an in vivo model using guinea pigs. Subsequently a more detailed mapping of the mechanism of action of RESP2000 was conducted that resulted in the development of RESP3000, a series of compounds for improving diagnosis of cardiovascular diseases.

The bronchodilatory properties of the RESP2000 compounds have the potential to be developed into drugs for treatment of COPD and severe asthma. In addition to these indications, some exploratory studies are being carried out in other disease areas for which the mechanism of action indicates potential therapeutic success.

The Board of Directors believes that RESP2000 has a well-defined “mode of action” that can be traced to cellular mitochondria, for which reason the Board also envisions broad potential for uses in areas far removed from the original indications of COPD and severe asthma.

### RESP3000

RESP3000 is a project primarily aimed at diagnosing cardiovascular diseases using PET imaging, which is one of the fastest-growing new technologies in cardiac diagnostics. PET imaging provides better resolution, less exposure to radiation and better and more reliable diagnostic information than other diagnostic methods.

A *proof-of-concept* study with the selected compound from the RESP3000 series was completed with promising results in 2014, from which RES3105 was the candidate selected from the compound series. Patents were previously granted in the US, Japan, Israel, Australia, Russia and South Africa.

The objective for the project moving forward is to find a partner for continued clinical development. In preparation for establishing such a collaboration, the Company may complement the current preclinical material with additional limited animal studies.

### OTHER RESEARCH AND DEVELOPMENT

Besides the development projects mentioned above, Respiratorius is continually evaluating drug candidates. However, these drug candidates are currently in a very early stage of development.

Development is also underway using the patent-protected compounds that Respiratorius has developed as a point of departure, where the Company is testing for new indications.

Respiratorius has a patented technology platform (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 purposes, as well as for screening and optimization of drug candidates. Respiratorius intends to out-license the right to use the R-HSAT technology platform.

### BACKGROUND AND HISTORY

Respiratorius was founded in 1999 to develop effective drugs to treat COPD and severe asthma, a therapeutic area still lacking in effective drugs.

A measurement device that can be used for testing (R-HSAT) was developed to study the small airways found in lung tissue in humans and animals, and to then analyze the impact of various chemical compounds on the smooth muscle of the bronchi. Studies have been conducted on isolated human lung tissue samples from over 150 individuals, providing far better support for the positive effects of these compounds in human clinical trials than similar studies conducted on animals.

In 2003, the Company produced the RESP1000 compound series, which has a new mechanism of action compared with existing drugs on the market. RESP1000 appears to be significantly more effective than existing drugs at countering the underlying medical mechanisms that cause bronchial problems. Between 2006 and 2007, RESP1000 was optimized and one compound from the series was chosen for both preclinical and future clinical development.

In 2008 another new class of chemical compounds, RESP2000, was discovered, which shows a potent bronchodilatory effect on human lung tissue at extremely low concentrations. Subsequently, the bronchodilatory effect of RESP2000 was also confirmed by an in vivoguinea pig model. A more detailed study of the mechanism of action of RESP2000 was also conducted.

Knowledge of the RESP2000 mechanism of action enabled the Company to develop RESP3000, a compound series for improving cardiovascular diagnostics using PET imaging. The project made good progress and an assessment of relevant biological models was successfully completed in 2014.





In 2012 Respiratorius acquired the shares in Valcuria AB, along with the VAL001 drug project. The acquisition was conducted on commercial terms based on scientific findings, in which experiments conducted using the VAL001 drug candidate demonstrated strong effects on human lymphoma cell lines (models for lymph node cancer). The strengthening and expansion of the Respiratorius project portfolio with a cancer project was a key component of the commercial foundation to the acquisition.

The VAL001 project has performed well under the management of Respiratorius and a successful Phase I clinical trial has been conducted. In 2014, a Phase IIa trial was initiated, which achieved full enrollment in 2015 and was concluded in 2018.

### POTENTIAL FOR DRUG CANDIDATES

Respiratorius aims to develop the current drug candidates to be able to present new effective drugs in the future for the treatment of diffuse large B-cell lymphoma (VAL001), COPD and severe asthma (RESP1000, RESP2000 and RESP9000), as well as methods for cardiovascular diagnostics (RESP3000). In all of these areas the Board of Directors believes that the Company has the potential, either 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

### 1999-2005

- Respiratorius was founded in 1999 to develop effective drugs to treat COPD and severe asthma, a therapeutic area still lacking in effective drugs.
- The Company produced the RESP1000 compound series, which has a new mechanism of action compared with existing drugs on the market. Tests showed that RESP1000 was significantly more effective than existing drugs at countering the underlying medical mechanisms that cause bronchial problems.

### 2006-2011

- RESP1000 was optimized and a compound from the series was chosen for preclinical development and future clinical development.
- In 2008 the Company discovered another new class of chemical compounds, RESP2000, which shows a potent bronchodilatory effect on human lung tissue at low concentrations.
- During the period the bronchodilatory effect of RESP2000 was also confirmed by an in vivo guinea pig model. A more detailed study of the mechanism of action of RESP2000 was also conducted.
- Knowledge of the RESP2000 mechanism of action enabled the Company to develop RESP3000, a compound series for improving cardiovascular diagnostics using PET imaging.

## 2012-2014

- In 2012 Respiratorius acquired the shares in Valcuria AB, along with the VAL001 drug project. The acquisition was conducted on commercial terms based on scientific findings, in which the VAL001 drug candidate demonstrated strong experimental data on human lymphoma cell lines (models for lymph node cancer).
- In 2013 the Phase I trial for VAL001 was successfully completed. In 2014, a Phase IIa trial was initiated.
- License and development agreement for RESP1000 signed with Cadila Pharmaceuticals Ltd.

## 2015-2020

- Phase IIa trial with VAL001 fully enrolled. The results from the interim analysis of the Phase IIa clinical data show a ten-percent increase in 1-year and 2-year survival. Orphan drug status issued for Europe in 2016 and the US in 2017.
- Excellent results reported from proof-of-concept study in biological models using RESP3000. Patent for RESP3000 granted in South Africa and the US.
- In 2018 preparatory work began, including a clinical trial protocol prior to approval by the Medical Products Agency for VAL001. Efforts to identify appropriate partners for a potential exit process were initiated.
- In 2018 the Company resumed its proactive role in the development of RESP1000 and concluded the preclinical work prior to an expected Phase I clinical trial in Europe in 2018/2019.
- In 2019 VAL001 strengthened its position as a promising drug candidate and preparations for a Phase III trial were accelerated. At the same time the exit process for VAL001 continued.
- In 2019 promising results emerged from an airway study in an animal model using the candidate compound RES030-085 (RESP9000 series) for treatment of COPD and severe asthma.
- In 2020, an encouraging scientific advice meeting was held with the Swedish Medical Products Agency concerning planned clinical trials for RESP9000.



Message from  
Report 2020

“2021 has the potential to be a big year for Respiratorius, with important milestones for the projects. The financial situation allows us to accelerate development and I have high hopes for patent approvals and achievements of milestones of a more technical nature. Of course, we are also focusing on the exit process with the goal of a favorable agreement.”

## Board of Directors and CEO



### **CHRISTER FÅHRAEUS, born 1965**

#### **Chairman of the Board**

MSc in Bioengineering, PhD in Neurophysiology, Bachelor of Medicine, Honorary PhD in Engineering. Founder of Agellis Group AB, Anoto Group AB, Precise Biometrics AB, CellaVision AB, EQL Pharma AB and FlatFrog Laboratories AB. Board member, deputy, or Chairman of the Board since 1999.

Chairman of the Board of Amniotics AB and Umansense AB. Board member of CellaVision AB, Reccan Diagnostics AB, Scandidos AB, Serstech AB and Gasporox AB. CEO and board member of EQL Pharma AB.

Holdings: 20,564,362



### **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. During the second half of 2018 an interim position as CEO of CanimGuide Therapeutics. AB.

Holdings: 11, 165, 462<sup>1</sup>



### **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, 915, 462<sup>1</sup>



### **INGEMAR KIHLSSTRÖM, born 1952**

#### **Board member**

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 AB, Emplicure AB and Attana AB. Holdings: 801,167

801 167

1. 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)



### **OLOV STERNER, born 1953**

#### **Board member**

Professor emeritus of Organic Chemistry at Lund University. Author and co-author of more than 425 publications in scientific journals, as well as 30 patents/patent applications and 5 textbooks.

Chairman of the Board of Gedea Biotech AB. Board member for Gabather AB. Chairman of the Board of Selcis Biopharma AB.

Holdings: 402,178



### **SARAH FREDRIKSSON, born 1968**

#### **Board member**

MSc in bioengineering (1993) and PhD in applied biochemistry (1999), both from Lund University. Professionally, Sarah Fredriksson focuses on business skills and expertise in the Life Sciences, especially in innovation-driven businesses in the fields of bioengineering and biomedical engineering.

CEO of AQLION AB. Chairman of the Board of Genovis AB and Edvance AB, as well as director for LU Holding, SwedeNanoTech AB and SwedenBIO.

Holdings: -



### **ANNA TÖRNER, born 1964**

#### **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.

CEO and board member of Scandinavian Development Services AB.

Holdings: -

## Patent portfolio

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* |
|--------------------------|--|---|----------|-------------|
| Patent family - VAL001   |  |   |          |             |
| 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     |             |
| Patent family - RESP3000 |  |   |          |             |
| 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  | HK  | 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        |

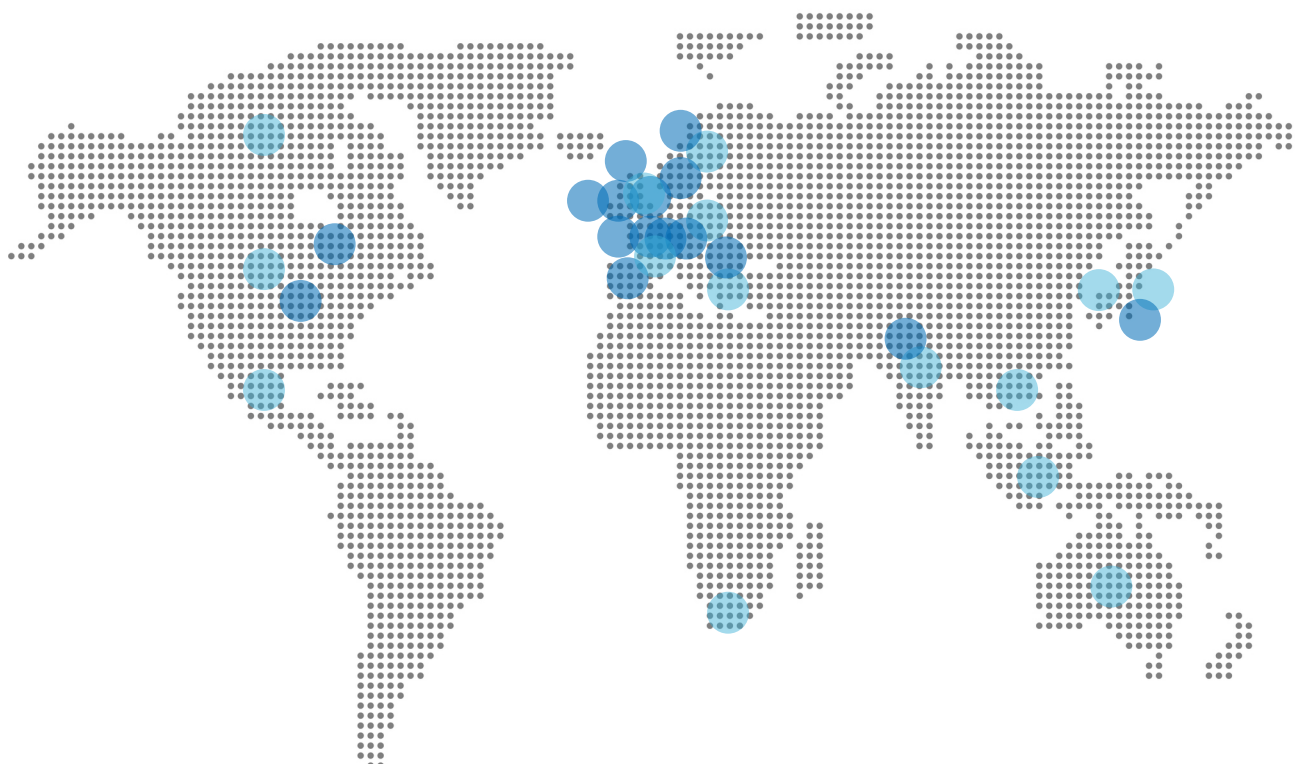




| NUMBER                                  | DESCRIPTION   | COUNTRY                                       | PRIORITY | EXPIRATION* |
|---|---|---|----------|-------------|
| Patent family - RESP1000                |   |   |          |             |
| EP 2181095 B1                           | Novel bronchodilating alpha, beta-unsaturated isoquinoline amides | FR, IE, IT, LU, MC, NL, CH/LI, ES, GB, DE     | 2007     | 2028        |
| SE531698 C2                             | Nya bronkdilaterande a,b-omättade amider                          | 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- RESP2000                 |   |   |          |             |
| 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 family - RESP-HSAT ( Measuring ) |   |   |          |             |
| SE530473 C2                             | Device for sorting medicinal products                             | SE  | 2006     | 2026        |

\* Assumes that all annual fees are paid

\*\* Includes 255 days for "Patent Term Adjustment" (PTA) due to delay in processing of the application by the US Patent and Trademark Office (USPTO).



## The share

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 2020

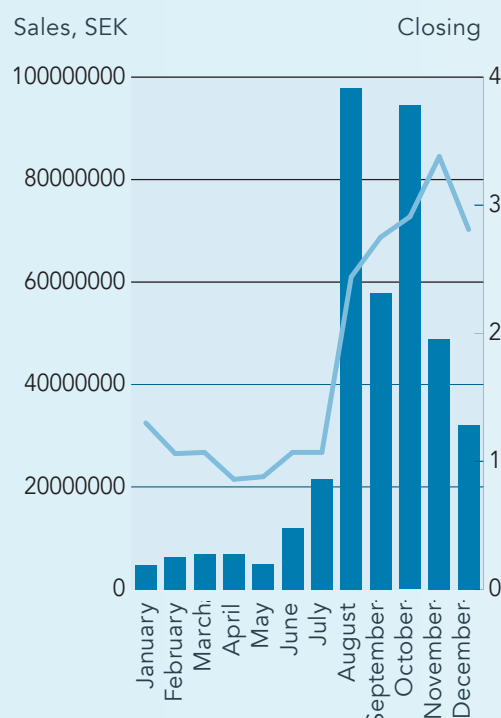
| MONTH     | CLOSING PRICE | HIGHEST | LOWEST | VOLUME      | TURNOVER    |
|-----------|---------------|---------|--------|-------------|-------------|
| January   | 1.30          | 1.46    | 1.28   | 3,620,901   | 4,813,241   |
| February  | 1.06          | 1.39    | 1.06   | 5,092,773   | 6,305,197   |
| March     | 1.07          | 1.18    | 0.70   | 7,488,934   | 6,926,171   |
| April     | 0.86          | 1.25    | 0.84   | 6,979,488   | 6,965,701   |
| May       | 0.88          | 0.98    | 0.84   | 5,532,302   | 4,989,845   |
| June      | 1.07          | 1.12    | 0.85   | 12,500,427  | 12,048,650  |
| July      | 1.07          | 1.25    | 0.99   | 19,373,354  | 21,542,396  |
| August    | 2.44          | 2.44    | 1.24   | 57,033,678  | 97,919,397  |
| September | 2.75          | 2.75    | 2.08   | 24,307,105  | 57,932,266  |
| October   | 2.91          | 3.71    | 2.72   | 29,322,997  | 94,453,716  |
| November  | 3.38          | 3.52    | 2.60   | 16,172,071  | 48,895,842  |
| December  | 2.81          | 3.35    | 2.76   | 10,740,712  | 32,095,688  |
| Total     |               |         |        | 198,164,742 | 394,888,109 |

### HISTORICAL SHARE PERFORMANCE

|      | LOWEST | AVERAGE | HIGHEST | VOLUME 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    |

### FIVE LARGEST SHAREHOLDERS DEC. 31, 2020

| NAME                | HOLDINGS % |
|---------------------|------------|
| Christer Fåhrens    | 11.8       |
| Avanza Pension      | 7.6        |
| Valcuria Holding AB | 5.8        |
| Ben Hayes           | 2.3        |
| Hans Harvig         | 2.1        |



# Administration Report

The Board of Directors and the Chief Executive Officer for Respiratorius AB (publ), corporate identity no. 556552-2652, hereby submit the annual report and consolidated financial statements for the 2020 financial year. The Company is registered in Sweden and has its headquarters in Skåne County, Lund Municipality. The annual accounts are prepared in Swedish kronor, SEK.

## Operations

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.

## 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.

## Significant events during 2020

At the turn of the half year, the Company raised capital through a preferential rights issue of units, two (2) newly issued shares and one (1) warrant series 2020/2021, which was about 87.1 percent subscribed, with subscription rights and the remainder, corresponding to about 126.7 percent, without subscription rights. The Company thereby raised about SEK 25.1 million before issue expenses.

Each warrant of series 2020/2021 entitles the holder to subscribe for one new share in the Company during the period June 21, 2021 through July 5, 2021 at a subscription price corresponding to 75 percent of the volume-weighted average price for the share during the period from June 7, 2021 through June 18, 2021, though no less than SEK 1.20 and no more than SEK 1.60 per share. If all warrants of series 2020/2021 are exercised to subscribe for shares, the Company can thereby raise an additional capital injection of about SEK 19-25 million before issue expenses, which are estimated at about SEK 0.9-1.3 million.

A scientific advice meeting was held in 2020 with the Swedish Medical Products Agency concerning the patent-pending candidate compound RES030-085 for treatment of COPD and severe asthma.

Topics discussed at this meeting included Respiratorius' strategy for conducting clinical trials and any additional studies that should be conducted prior to approval. The positive meeting provided clarification and culminated in the initiation of important activities such as production, research and pharmacological studies.

# Financial performance in 2020

## Sales and earnings

The Company did not have any net sales during 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:

1. licensing of one of its projects, or the sale
2. of one of its projects, or
3. acquisition involving a legal entity with access to cash, or share issue with or
4. 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 consultants staffing the positions of CEO, Director of Research and specialists to meet the needs of the individual projects.

## Board work

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

In 2019, the European Medicines Agency 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 addition, the strong patent portfolio was further strengthened through an approval in Canada, which complements earlier approvals in the US, Europe, Japan and Korea.

## 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 addition, the strong patent portfolio was further strengthened through an approval in Canada, which complements the patents granted earlier in the US, Europe, Japan 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.

In 2019 efforts to identify a suitable partner for VAL001 intensified through a contract with Partner International, while proceeding with preparations for continued clinical development, which include a new formulation of the planned product and regulatory documentation. In 2020, this initiative continued according to the established strategy, with good results.

Within the field of COPD and asthma, an in vivo efficacy study was conducted in 2019 and yielded favorable results for the drug candidate RES030-085 from the RESP9000 series, for which a patent was submitted in 2018. RES030-085 is assessed as having a favorable safety profile and anti-inflammatory and bronchodilatory properties equivalent to those of the drug candidate RES022-125 from the RESP1000 series.

The results from the in vivo study were an important part of the documentation presented to the Swedish Medical Products Agency at a scientific advisory meeting held in 2020.

Topics discussed at this meeting included Respiratorius' strategy for conducting clinical trials and any additional studies that should be conducted prior to approval. The positive meeting provided clarification and culminated in the initiation of important activities such as production, research and pharmacological studies.

The patent application for RES030-085 has been submitted and reviewed, and the prospects for approval are considered to be favorable.

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 that 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 pharmaceutical 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 drug candidates, there is always a risk that the compounds may prove to have side effects. In some cases, this can be overcome by chemically modifying compounds, 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. More-

over, 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 compounds 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 appli-

cations 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 insuran-

ce 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 risk

### 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



## Financial overview\*

### GROUP

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

### PARENT

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

\* Definitions of key ratios, see supplementary

## Appropriation

### Proposal for treatment of the Company's

|  |             |
|--|-------------|
| At the disposal of the Annual General Meeting:     |             |
| loss brought forward                               | -37,223,368 |
| Share premium reserve                              | 41,448,994  |
| Loss for the year                                  | -7,458,866  |
|  | -3,233,239  |
| The Board of Directors proposes that the following |             |
| be carried forward to new account                  | -3,233,239  |
|  | -3,233,239  |

Regarding the Company's financial performance and position in general, please refer to the following income statements and balance sheets with accompanying supplementary disclosures.



## Statement of change in equity

| GROUP                    | SHARE CAPITAL | OTHER CAPITAL CONTRIBUTIONS | OTHER EQUITY INCLUDING LOSS FOR THE YEAR | TOTAL EQUITY |
|--------------------------|---------------|-----------------------------|--|--------------|
| Amount, Jan. 1           | 7,858,599     | 39,577,813                  | -31,569,989                              | 15,866,423   |
| Issue of new shares      | 1,571,719     | 23,575,796                  |  | 25,147,515   |
| Issue expenses           |               | -4,267,220                  |  | -4,267,220   |
| Profit/loss for the year |               |                             | -7,468,314                               | -7,468,314   |
| Amount, Dec. 31          | 9,430,318     | 58,886,389                  | -39,038,303                              | 29,278,404   |

| PARENT   | SHARE CAPITAL | OTHER RESTRICTED EQUITY | OTHER UN-RESTRICTED CAPITAL | LOSS FOR THE YEAR | TOTAL UN-RESTRICTED EQUITY |
|--|---------------|-------------------------|-----------------------------|-------------------|----------------------------|
| Amount, Jan. 1   | 7,858,599     | 22,939,289              | -9,702,478                  | -5,050,471        | -14,752,949                |
| Issue of new shares  | 1,571,719     |                         | 23,575,796                  |                   | 23,575,796                 |
| Fund for development costs   |               | 33,000                  | -330,000                    |                   | -330,000                   |
| Issue expenses   |               |                         | -4,267,220                  |                   | -4,267,220                 |
| Allocation of loss for the year according to resolution of the Annual General Meeting: |               |                         | -5,050,471                  | 5,050,471         | 0                          |
| Profit/loss for the year   |               |                         |                             | -7,458,866        | -7,458,866                 |
| Amount, Dec. 31  | 9,430,318     | 23,269,289              | 4,225,627                   | -7,458,866        | -3,233,239                 |

# Income statement

|   | NOTE | GROUP                       |                             | PARENT                      |                             |
|---|------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
|   |      | JAN 1, 2020<br>DEC 31, 2020 | JAN 1, 2019<br>DEC 31, 2019 | JAN 1, 2020<br>DEC 31, 2020 | JAN 1, 2019<br>DEC 31, 2019 |
| <b>Operating revenue, etc.</b>  |      |                             |                             |                             |                             |
| Other operating income  |      | 0                           | 0                           | 0                           | 0                           |
|   |      | 0                           | 0                           | 0                           | 0                           |
| <b>Operating expenses</b>   |      |                             |                             |                             |                             |
| Raw material and consumables  |      | -4,086,817                  | -5,285,603                  | -2,242,500                  | -3,100,989                  |
| Other external costs  | 1    | -4,742,912                  | -3,358,201                  | -4,253,127                  | -2,882,628                  |
| Personnel costs   | 2    | -672,276                    | -677,648                    | -672,276                    | -677,648                    |
| Depreciation, amortization and impairment of plant, property, and equipment and intangible assets |      | -2,531,489                  | -1,913,401                  | -1,100,976                  | -728,994                    |
| Capitalized work for own account  |      | 4,958,934                   | 6,180,891                   | 2,903,767                   | 3,719,821                   |
|   |      | -7,074,560                  | -5,053,963                  | -5,365,112                  | -3,670,438                  |
| <b>Operating loss</b>   |      | -7,074,560                  | -5,053,963                  | -5,365,112                  | -3,670,438                  |
| <b>Profit/loss from financial items</b>   |      |                             |                             |                             |                             |
| 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  |      | -393,755                    | -33                         | -393,755                    | -33                         |
|   |      | -393,755                    | -33                         | -993,755                    | -600,637                    |
| <b>Profit/loss after financial items</b>  |      | -7,468,314                  | -5,053,996                  | -6,358,866                  | -4,270,471                  |
| <b>Appropriations</b>   |      |                             |                             |                             |                             |
| Group contributions paid  |      | 0                           | 0                           | -1,100,000                  | -780,000                    |
|   |      | 0                           | 0                           | -1,100,000                  | -780,000                    |
| <b>Profit/loss for the year</b>   |      | <b>-7,468,314</b>           | <b>-5,053,996</b>           | <b>-7,458,866</b>           | <b>-5,050,471</b>           |
| Attributable to:  |      |                             |                             |                             |                             |
| Equity holders of the parent company  |      | -7,468,314                  | -5,053,996                  |                             |                             |

# Balance sheet

|  |      | GROUP             |                   | PARENT            |                   |
|--|------|-------------------|-------------------|-------------------|-------------------|
|  | NOTE | DEC 31, 2020      | DEC 31, 2019      | DEC 31, 2020      | DEC 31, 2019      |
| <b>NON-CURRENT ASSETS</b>                  |      |                   |                   |                   |                   |
| <b>Intangible assets</b>                   |      |                   |                   |                   |                   |
| Capitalized expenditure for research, etc. | 5    | 13,719,860        | 10,577,084        | 8,130,245         | 6,269,589         |
| Patents                                    | 6    | 4,404,519         | 5,119,851         | 1,641,193         | 1,699,058         |
|  |      | 18,124,379        | 15,696,935        | 9,771,438         | 7,968,647         |
| <b>Financial assets</b>                    |      |                   |                   |                   |                   |
| Participations in Group companies          | 7    | 0                 | 0                 | 1,700,000         | 2,300,000         |
|  |      | 0                 | 0                 | 1,700,000         | 2,300,000         |
| <b>Total non-current assets</b>            |      | 18,124,379        | 15,696,935        | 11,471,438        | 10,268,647        |
| <b>CURRENT ASSETS</b>                      |      |                   |                   |                   |                   |
| <b>Current receivables</b>                 |      |                   |                   |                   |                   |
| Receivables from Group companies           |      | 0                 | 0                 | 7,251,901         | 5,851,901         |
| Other receivables                          |      | 775,574           | 126,076           | 746,446           | 114,184           |
| Prepaid expenses and accrued income        |      | 266,391           | 169,387           | 266,391           | 169,387           |
|  |      | 1,041,965         | 295,463           | 8,264,738         | 6,135,472         |
| <b>Cash and bank balances</b>              |      |                   |                   |                   |                   |
| Cash and bank balances                     |      | 11,747,427        | 1,620,678         | 11,245,475        | 1,366,548         |
|  |      | 12,789,392        | 1,620,678         | 11,245,475        | 1,366,548         |
| <b>Total current assets</b>                |      | 12,789,392        | 1,916,141         | 12,258,312        | 1,650,119         |
| <b>TOTAL ASSETS</b>                        |      | <b>30,913,772</b> | <b>17,613,076</b> | <b>30,981,651</b> | <b>17,770,667</b> |

## Balance sheet, cont'd

|  |      | GROUP        |              | PARENT       |              |
|--|------|--------------|--------------|--------------|--------------|
|  | NOTE | DEC 31, 2020 | DEC 31, 2019 | DEC 31, 2020 | DEC 31, 2019 |
| EQUITY AND LIABILITIES                           |      |              |              |              |              |
| Restricted equity, Group                         |      |              |              |              |              |
| Share capital                                    | 8    | 9,430,318    | 7,858,599    |              |              |
| Other paid-in capital                            |      | 5,886,389    | 39,577,813   |              |              |
| Other equity, including profit/loss for the year |      | -39,038,303  | -31,569,989  |              |              |
|  |      | 29,278,404   | 15,866,423   |              |              |
| Restricted equity, parent company                |      |              |              |              |              |
| Share capital                                    | 8    |              |              | 9,430,318    | 7,858,599    |
| Share capital, not registered                    |      |              |              | 0            | 0            |
| Restricted reserves                              |      |              |              | 23,269,289   | 22,939,289   |
|  |      |              |              | 32,699,607   | 30,797,887   |
| Unrestricted equity                              |      |              |              |              |              |
| Unrestricted reserves                            |      |              |              | -            | -            |
| Share premium reserve                            |      |              |              | 41,448,994   | 22,470,419   |
| Retained earnings                                |      |              |              | -37,223,367  | -32,172,896  |
| Profit/loss for the year                         |      |              |              | -7,458,866   | -5,050,471   |
|  |      |              |              | -3,233,239   | -14,752,948  |
| Total equity                                     |      | 29,278,404   | 15,866,423   | 29,466,368   | 16,044,939   |
| Non-current liabilities                          |      |              |              |              |              |
| Liabilities to Group companies                   | 9    | 0            | 0            | 70,037       | 75,662       |
| Total non-current liabilities                    |      | 0            | 0            | 70,037       | 75,662       |
| Current liabilities                              |      |              |              |              |              |
| Accounts payable                                 |      | 1,000,175    | 1,041,189    | 850,553      | 985,102      |
| Other liabilities                                |      | 0            | 0            | 0            | 0            |
| Accrued expenses and deferred income             | 10   | 635,193      | 705,464      | 594,693      | 664,964      |
| Total current liabilities                        |      | 1,635,368    | 1,746,653    | 1,445,246    | 1,650,066    |
| TOTAL EQUITY AND LIABILITIES                     |      | 30,913,772   | 17,613,076   | 30,981,651   | 17,770,667   |

## Statement of cash

|  | NOTE | GROUP             |                  | PARENT            |                  |
|--|------|-------------------|------------------|-------------------|------------------|
|  |      | DEC 31, 2020      | DEC 31, 2019     | DEC 31, 2020      | DEC 31, 2019     |
| <b>Operating activities</b>  |      |                   |                  |                   |                  |
| Profit/loss after financial items  |      | -7,468,314        | -5,053,996       | -6,358,867        | -4,270,471       |
| Adjustments for non-cash items, depreciation/amortization                    |      | 2,531,489         | 1,913,401        | 1,100,976         | 728,994          |
| Impairment losses  |      | 0                 | 0                | 600,000           | 600,000          |
| <b>CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL</b> |      | -4,936,825        | -3,140,595       | -4,657,891        | -2,941,477       |
| Cash flow from changes in working capital                                    |      |                   |                  |                   |                  |
| Reduction(+)/increase (-) for receivables                                    |      | -746,502          | 153,073          | -2,129,266        | -1,936,364       |
| Reduction (-)/increase(+) of current liabilities                             |      | -111,285          | 523,534          | -204,820          | 682,915          |
| <b>CASH FLOW FROM OPERATING ACTIVITIES</b>                                   |      | -5,794,612        | -2,463,988       | -6,991,977        | -4,194,926       |
| <b>Investing activities</b>  |      |                   |                  |                   |                  |
| Investments in intangible assets   | 4,5  | -4,958,934        | -6,180,891       | -2,903,767        | -3,719,821       |
| Group contributions paid   | 7    | 0                 | 0                | -1,100,000        | -780,000         |
| <b>CASH FLOW FROM INVESTING ACTIVITIES</b>                                   |      | -4 958 934        | -6 180 891       | -4,003,767        | -4,499,821       |
| <b>Financing activities</b>  |      |                   |                  |                   |                  |
| Rights issue for the year  |      | 20,880,295        | 0                | 20,880,295        | 0                |
| Reduction (-)/increase(+) of non-current liabilities                         |      | 0                 | 0                | -5,625            | -5,625           |
| <b>CASH FLOW FROM FINANCING ACTIVITIES</b>                                   |      | 20,880,295        | 0                | 20,874,670        | -5,625           |
| Change in cash and cash equivalents  |      | 10,126,749        | -8,644,879       | 9,878,926         | -8,700,372       |
| Cash and cash equivalents, Jan. 1  |      | 1,620,677         | 10,265,556       | 1,366,548         | 10,066,920       |
| <b>CASH AND CASH EQUIVALENTS, DEC. 31</b>                                    |      | <b>11,747,426</b> | <b>1,620,678</b> | <b>11,245,474</b> | <b>1,366,548</b> |



# Supplementary

## 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

#### Capitalization model

All expenditures incurred during the research phase are expensed as incurred. All expenditure incurred during the development phase is 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 complete 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 costs**

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.

## NOTES TO FINANCIAL STATEMENTS

### Note 1 Remuneration to auditors

|                   | GROUP   |         | PARENT  |         |
|-------------------|---------|---------|---------|---------|
|                   | 2020    | 2019    | 2020    | 2019    |
| Crowe Osborne AB  |         |         |         |         |
| Audit assignments | 143,040 | 139,323 | 113,340 | 110,050 |
| Other services    | 0       | 0       | 0       | 0       |
|                   | 143,040 | 139,323 | 113,340 | 110,050 |

Audit assignments refer to the auditor's work for the statutory audit and audit services relating to various types of quality assurance services. Other services are those that are not included in the audit assignment, audit services or tax advice.

### Note 2 Personnel

|  | GROUP   |         | PARENT  |         |
|--|---------|---------|---------|---------|
|  | 2020    | 2019    | 2020    | 2019    |
| Average number of employees  |         |         |         |         |
| The average number of employees is based on the number of hours worked for which the company paid in relation to normal working hours. |         |         |         |         |
| Average number of employees  | 0.00    | 0.00    | 0.00    | 0.00    |
| Salaries, benefits   |         |         |         |         |
| Salaries, benefits, social security expenses and pension costs have been paid as follows:  |         |         |         |         |
| Board of Directors and CEO:  |         |         |         |         |
| Salaries, benefits   | 530,000 | 530,000 | 530,000 | 530,000 |
|  | 530,000 | 530,000 | 530,000 | 530,000 |
| Social security expenses   | 154,478 | 154,478 | 154,478 | 166,526 |
| Total Board of Directors and others  | 684,478 | 684,478 | 684,478 | 696,526 |

In 2020 Chairman of the Board Christer Fåhræus was paid SEK 130,000 and other Board members were paid SEK 80,000 for serving on the Board of Directors.

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 675,820 were paid (previous year SEK 691,377).

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

|            | GROUP |      | PARENT   |          |
|------------|-------|------|----------|----------|
|            | 2020  | 2019 | 2020     | 2019     |
| Impairment | 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

|  | 2020       | 2019       |
|--|------------|------------|
| Effective tax reconciliation           |            |            |
| Profit/loss before taxes               | -7,468,314 | -5,053,996 |
| Tax liability 21.4% (21.4%)            | 1,598,219  | 1,081,555  |
| Tax effects of:                        |            |            |
| Non-deductible expenses                | 0          | 0          |
| Non-taxable revenues                   | 0          | 7          |
| Consolidated depreciation/amortization | -128,400   | -128,400   |
| Loss carryforward for the year         | -1,469,819 | -935,162   |
| Total                                  | 0          | 0          |

### PARENT

|                                    | 2020       | 2019       |
|------------------------------------|------------|------------|
| Effective tax reconciliation       |            |            |
| Profit/loss before taxes           | -7,458,866 | -5,050,471 |
| Tax liability 21.4% (21.4%)        | 1,596,197  | 1,080,801  |
| Tax effects of:                    |            |            |
| Non-deductible expenses            | 0          | 0          |
| Non-taxable revenues               | 0          | 7          |
| Impairment of shares in subsidiary | -128,400   | -128,400   |
| Loss carryforward for the year     | -1,467,797 | -952,408   |
| Total                              | 0          | 0          |

## Note 5 Capitalized expenditure for research, etc.

|   | GROUP        |              | PARENT       |              |
|---|--------------|--------------|--------------|--------------|
|   | DEC 31, 2020 | DEC 31, 2019 | DEC 31, 2020 | DEC 31, 2019 |
| Opening cost                                  | 38,707,336   | 33,106,733   | 33,085,364   | 29,669,375   |
| Purchases                                     | 4,528,664    | 5,600,603    | 2,684,347    | 3,415,989    |
| Closing accumulated cost                      | 43,236,000   | 38,707,336   | 35,769,711   | 33,085,364   |
| Opening depreciation/amortization             | -28,130,252  | -27,304,424  | -26,815,775  | -26,333,683  |
| Depreciation/amortization for the year        | -1,385,888   | -825,828     | -823,691     | -482,092     |
| Closing accumulated depreciation/amortization | -29,516,140  | -28,130,252  | -27,639,466  | -26,815,775  |
| Closing carrying amount                       | 13,719,860   | 10,577,084   | 8,130,245    | 6,269,589    |



## Note 6 Patents

|   | GROUP        |              | PARENT       |              |
|---|--------------|--------------|--------------|--------------|
|   | DEC 31, 2020 | DEC 31, 2019 | DEC 31, 2020 | DEC 31, 2019 |
| Opening cost                                  | 18,437,130   | 17,886,842   | 8,849,826    | 8,545,994    |
| Purchases                                     | 430,270      | 580,288      | 219,420      | 303,832      |
| Closing accumulated cost                      | 18,897,400   | 18,467,130   | 9,069,246    | 8,849,826    |
| Opening depreciation/amortization             | -13,347,279  | -12,259,706  | -7,150,768   | -6,903,866   |
| Depreciation/amortization for the year        | -1,145,602   | -1,087,573   | -277,285     | -246,902     |
| Closing accumulated depreciation/amortization | -14,492,881  | -13 347 279  | -7 428 053   | -7,150,768   |
| Closing carrying amount                       | 4,404,519    | 5 119 851    | 1 641 193    | 1,699,058    |

## Note 7 Participations in Group companies

### PARENT

| COMPANY CORPORATE<br>IDENTITY NUMBER             | REGISTERED<br>OFFICE | NUMBER OF/<br>CAP. PER-<br>CENTAGE % | DEC 31, 2020       | DEC 31, 2020       |
|--|----------------------|--------------------------------------|--------------------|--------------------|
|  |                      |                                      | CARRYING<br>AMOUNT | CARRYING<br>AMOUNT |
| Bergdalsten Kemi AB<br>Corp. Id. No. 556650-7330 | Lund                 | 100                                  | 100,000            | 100,000            |
| Valcuria AB<br>Corp. Id. No. 556871-5196         | Lund                 | 100                                  | 1,600,000          | 2,200,000          |
|  |                      |                                      | 1,700,000          | 2,300,000          |

| INFORMATION ABOUT EQUITY AND PROFIT OR LOSS | EQUITY  | PROFIT/LOSS |
|---|---------|-------------|
| Bergdalsten Kemi AB                         | 66,059  | -5,625      |
| Valcuria AB                                 | 495,976 | -3,823      |

## Note 8 Information about share

|                      | HOLDINGS    | PAR VALUE |
|----------------------|-------------|-----------|
| Number/value, Jan. 1 | 157,171,975 | 0.05      |
| Issue of new shares  | 31,434,394  |           |
| Number/value, Dec 31 | 188,606,369 | 0.05      |

## Note 9 Non-current liabilities

|                            | GROUP        |              | PARENT       |              |
|----------------------------|--------------|--------------|--------------|--------------|
|                            | DEC 31, 2020 | DEC 31, 2019 | DEC 31, 2020 | DEC 31, 2019 |
| Amortization after 5 years | 0            | 0            | 70,037       | 75,662       |
|                            | 0            | 0            | 70,037       | 75,662       |

## Note 10 Accrued expenses and deferred income

|                       | GROUP        |              | PARENT       |              |
|-----------------------|--------------|--------------|--------------|--------------|
|                       | DEC 31, 2020 | DEC 31, 2019 | DEC 31, 2020 | DEC 31, 2019 |
| Accrued fees          | 456,319      | 456,319      | 456,319      | 456,319      |
| Othe accrued expenses | 178,874      | 249,145      | 138,374      | 208,645      |
|                       | 635,193      | 705,464      | 594,693      | 664,964      |

## Note 11 Pledged assets

|                   | GROUP        |              | PARENT       |              |
|-------------------|--------------|--------------|--------------|--------------|
|                   | DEC 31, 2020 | DEC 31, 2019 | DEC 31, 2020 | DEC 31, 2019 |
| 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 14, 2021

Christer Fåhraeus



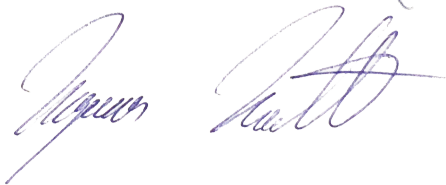
Kristina Drott



Johan Drott  
Executive officer



Ingemar Kihlström



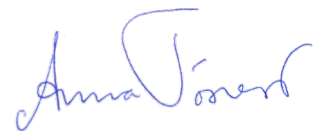
Olov Sterner



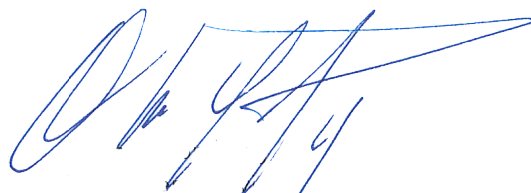
Sarah Fredriksson



Anna Törner



Our Auditor's Report was submitted on April 19, 2021



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 2020. The annual accounts and consolidated accounts of the company are included in the printed version of this document on pages 21-41.

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, 2020 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 1-20 and 42-48 (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 2020 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
- in any 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 19, 2021

Crowe Osborne AB



Olov Strömberg, Authorized public

# Invitation to the Annual General Meeting

## Annual General Meeting

The Annual General Meeting of shareholders in Respiratorius AB will be held on Tuesday, June 10, 2021. In light of the ongoing Covid-19 pandemic and in order to reduce the risk of infection, the Board of Directors has decided that the Annual General Meeting will be held only by advance voting (postal vote) in accordance with temporary legislation. This means that the Annual General Meeting will be conducted without the physical presence of shareholders, proxies or external parties and that shareholders may only exercise their voting rights at the Annual General Meeting by voting in advance as described below.

**The notice to attend the Annual General Meeting** is available on the Respiratorius website ([www.respiratorius.com](http://www.respiratorius.com)).

**Shareholders who wish** to participate in the Annual General Meeting must be registered in the share register maintained by Euroclear Sweden AB as of June 2, 2021. Furthermore, they must also notify the Company no later than Wednesday, June 9, 2021 by submitting their advance votes in accordance with the instructions under the heading "Advance voting" below, so that the advance vote is received by the Company no later than that day.

## Nominee-registered shares

Shareholders whose shares are nominee-registered through a bank or other nominee must, in addition to giving notice of participation by submitting an advance vote, request that their shares be temporarily registered in their own name in the share register kept by Euroclear Sweden AB ("voting right registration") in order to be entitled to participate at the Annual General Meeting. The nominee must complete such voting rights registration no later than Friday, May 21, 2021, which means that shareholders wishing to register their voting rights must notify the nominee well in advance of that date.

## Advance voting

Shareholders may exercise their voting rights at the AGM only by voting in advance, known as postal voting, in accordance with Section 22 of the Swedish Act (2020:198) on temporary exceptions to facilitate the execution of general meetings in companies and other associations. A special form shall be used for advance voting. The form is available on the Respiratorius website ([www.respiratorius.com](http://www.respiratorius.com)). The advance voting form is considered as the notification of participation at the Annual General Meeting. **The Company must receive the completed form no later than Wednesday, June 9, 2021.** The completed form shall be sent to Respiratorius AB (publ), Scheelevägen 2, SE-223 81 Lund, Sweden. The completed form may also be submitted electronically and is then to be sent to [info@respiratorius.com](mailto:info@respiratorius.com). If the shareholder votes in advance by proxy, a written and dated power of attorney signed by the shareholder must be enclosed with the advance voting form. Proxy forms are available on the Company's website ([www.respiratorius.com](http://www.respiratorius.com)). If the shareholder is a legal entity, a certificate of incorporation or other authorization document shall be enclosed with the advance voting form. The shareholder may not provide special instructions or conditions in the advance voting form. If so, the vote is invalid. Further instructions and conditions are included in the form for advance voting.

### Other information

Financial statements, press releases and other information are available on the Respiratorius website [www.respiratorius.com](http://www.respiratorius.com) from the time of publication. Interested parties may subscribe to Respiratorius' financial statements and press releases and download them from the website or via Spotlight's website.

**Respiratorius has decided to** primarily distribute the annual report digitally from the Company's website for both financial and environmental reasons. The printed Annual Report may still be ordered through the Company and mailed to shareholders and other stakeholders who specifically request it.

**For more information please contact** Johan Drott, Chief Executive Officer, [info@respiratorius.com](mailto:info@respiratorius.com).

### Financial calendar

**May 27, 2021: Interim report Q1**

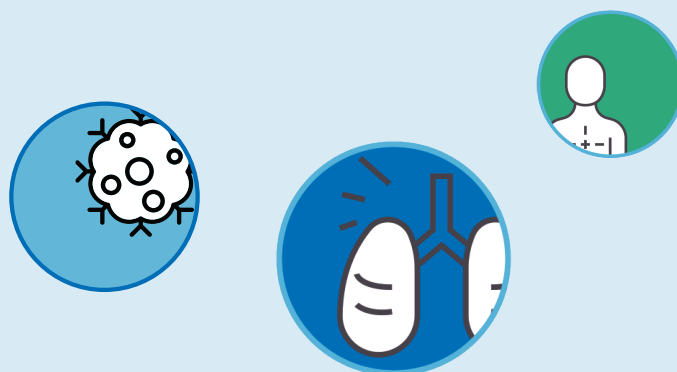
**June 10, 2021: Annual General Meeting**

**Aug. 6, 2021: Interim report Q2**

**Nov. 10, 2021: Interim report Q3**

**Jan. 15, 2022: Year-end report 2021**

2020



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 new drug as a pretreatment to enhance the effects of the standard treatment 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 compound series with a demonstrated bronchodilating effect on human lung tissue.

The Company's project portfolio also contains a compound developed for use in PET imaging, aimed at facilitating the diagnosis of certain cardiovascular diseases.

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