



RESPIRATORIUS AB

# Annual Report and Consolidated Financial Statements **2017**

RESPIRATORIUS®



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# The Year in Brief

## VAL001

- **FDA granted orphan drug status for VAL001**

In the middle of March the US Food and Drug Administration (FDA) granted orphan drug designation to Respiratorius' product candidate VAL001 for the treatment of diffuse large B-cell lymphoma. VAL001 is a combination of an HDAC inhibitor (valproic acid) and a steroid (prednisolone) and is considered to be a pre-treatment for chemotherapy (R-CHOP) for the treatment of diffuse large B-cell lymphoma (DLBCL), which is an aggressive form of lymph node cancer. The announcement complements the equivalent status granted by the European Medicines Agency (EMA) in 2016. Both of these approvals will reduce time to market and grant market exclusivity for the use of VAL001 for its indication.

- **VINNOVA grants funding for project application**

VINNOVA granted substantial funding for the project "Improved cancer diagnostics and pharmaceutical development" as part of its call for proposals for Challenge-driven Innovation step 3. Research Institutes of Sweden (RISE) is coordinating the project in collaboration with Respiratorius and ten other clinical, industrial and academic participants. The aim of the project is to develop a unique test for use in clinical cancer

diagnostics, personalized cancer therapy and industrial screening of cancer drugs.

## RESP1000

- **Respiratorius presented preliminary results from RESP1000**

As part of the collaboration with Cadila Pharmaceuticals regarding RESP1000, the selected substance RES022-125 demonstrated a disease-modulating effect in an established animal model for the disease COPD. The results will be quantified in detail by Respiratorius before further preclinical development can begin. In connection with this the Company announced that it will assume active leadership in the continued development process and intends to complete toxicology studies and, barring the unforeseen, subsequent phase I or phase I/IIa studies with a focus on Europe.

## RESP3000

- **Patent granted in several countries**

Over the course of the year patents were granted for the RESP3000 series in Russia, Japan and Australia. In the US, a continuation application containing specific product requirements was also granted. All granted patents have priority dates from 2011 and are in force until 2032.



## OTHER

- **Rights issue**

Respiratorius conducted a rights issue in December 2017 that was 120 percent oversubscribed and raised SEK 21 million before issue expenses for the Company. The issue proceeds will primarily be used to fund the promising projects VAL001 and RESP1000.

- **Insider transactions**

Anders Månsson, who has been a Board member since 2016, acquired 21,517 shares in Respiratorius AB. Anders Månsson had no previous holdings in Respiratorius AB.

## SIGNIFICANT EVENTS AFTER THE CLOSE OF THE FINANCIAL YEAR

- **Respiratorius announced encouraging results from clinical phase I/IIa studies of VAL001.**

The clinical phase I/II study was successful. In particular, the study results show an improvement in overall survival among patients treated with VAL001 compared with a control group. Two-year survival (96.8% with a 95% confidence interval) is significantly higher for those patients who were treated with VAL001, compared with the reference population (81.7% with a 95% confidence interval).

It was previously announced that the study results would not be published until the second quarter of 2018, but it was determined that the patient who had not yet completed the final follow-up, 24 months after completion of treatment, will not have any noteworthy effect on the final results. The patient was assessed to be cured just over 20 months following completion of treatment.

- **Patent granted for RESP3000**

The European Patent Office (EPO) announced in February 2018 that the patent application for RESP3000 has been granted. In March 2018, the Mexican Patent Office announced that it had issued a similar decision to grant the patent application. Patents were previously granted in the US, Japan, Israel, Australia, South Africa and Russia. In addition, in 2017 the US patent office granted a divisional application for RESP3000 relating to specific product requirements.



# The Company in Brief

## **BUSINESS CONCEPT**

Respiratorius develops effective new drugs to treat the common diseases cancer, COPD and severe asthma. The Company bases its operations on patent-pending substances that have shown superior results in preclinical studies 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 for patients suffering from cancer, chronic obstructive pulmonary disease (COPD) and severe asthma. 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. Our unique expertise focuses 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 for developing the product. This type of partner will have financial resources, experience in large clinical studies and established contacts with regulatory authorities. These partners will also be responsible in the future for manufacturing, marketing and sales of the licensed drugs that may result from the development project. Several large pharmaceutical companies have already shown interest regarding licensing and collaboration on the Company's projects.

A license agreement with a pharmaceutical company is expected to give Respiratorius income in the form of an initial payment followed by milestone payments, as well as royalties. In the event that a license agreement is 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 operates based on a virtual model, without any employees. Resource and skill requirements vary during project development and are purchased as needed. This organizational model is totally focused on value-generating project development.

#### **RESPIRATORIUS' PATENT PORTFOLIO** **VAL001**

VAL001 is a combination preparation of valproic acid and a steroid. 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-Hodgkins Lymphoma (NHL). These patients comprise 30 percent of patients diagnosed with this type of cancer. Each year, 60,000 people in the US and Europe are diagnosed with NHL, which makes it the seventh most common type of cancer. The five-year survival rate with standard treat-

ment is estimated at only 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 using well-established medications. The global population is continually growing because people are living longer, a trend that is expected to continue, and 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 the most effective treatment for DLBCL, which is accessible worldwide, is the combination therapy 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 late-stage clinical trials underway. Many of these new medications are extremely expensive and may be associated with considerable side effects. The majority are also aimed at patients who experience relapse after first-line treatment with R-CHOP.

### **Objectives VAL001**

During the year, orphan drug status was granted in the US, thereby complementing the equivalent status in Europe and considerably advancing the commercial potential of the project. The Company is identifying and evaluating potential global partners prior to continued development.

The objective for 2018 is to intensify work with a cooperation agreement, to prepare for continued clinical development of VAL001, in part through production of VAL001, and to work on the regulatory documentation.

### **RESP1000**

RESP1000 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, and without preventive measures, 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. 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 9,000 million.

### **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 drugs 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 in addition to inhaled corticosteroids is especially large.

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

#### **Objectives RESP1000**

The collaborative project with Cadila is progressing according to plan and important targets were met during the year for the identified drug candidate from the RESP1000 series, RES022-125. In an established animal model for COPD, RES022-125 demonstrated a disease-modulating effect. The objective for 2018 is to continue under the leadership of Respiratorius with the preparatory preclinical work prior to clinical development.

#### **RESP3000**

RESP3000 is a series of substances 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. It occurs when a coronary artery becomes obstructed, and one common cause is plaque buildup on the inner walls of the arteries. Such buildup is known as atherosclerosis. The condition leads to decreased blood flow through the arteries, which means that 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 cardiovascular diagnostics, specifically for the RESP3000 project, the Company intends to continue development while searching for potential partners and stakeholders. The objective for 2018 is to establish a collaborative effort with a partner for continued clinical development.

**The past year has been extremely eventful. Most importantly, we can now increase the pace and be more aggressive regarding the RESP1000 and VAL001 projects. Following encouraging results from an efficacy study in the COPD project, Respiratorius can now assume a more proactive role with RESP001 moving forward. The next major steps involve initiating clinical trials. The Company has obtained orphan drug status for VAL001 from the US FDA and preparations are now underway for continued clinical trials. During the year the patent portfolio for RESP3000 was also strengthened with patents granted in several key markets. In summary, Respiratorius has taken several important steps forward in 2017 and is well-positioned for new opportunities in the future.**

#### **ORPHAN DRUG STATUS IN EUROPE AND THE US AND EXIT PROCESS INITIATED FOR VAL001**

The development of VAL001 is progressing according to plan and in 2017 the Company received Orphan Drug Designation in the US for the product for the indication of diffuse large B-cell lymphoma. The European Commission issued a similar decision in 2016 following a review by the European Medicines Agency (EMA). Both of these approvals give VAL001 market exclusivity in Europe and the US, for 10 and 7 years, respectively, following market approval which has material significance for the valuation of the project. These objective reviews by leading drug development experts have strongly increased confidence in the project.

The ongoing clinical development of VAL001 involves completion of the phase IIa study during the first half of 2018. The Company was able to report its results earlier than had previously been announced, and data for one-year and two-year survival were clearly better compared with the previously reported interim analysis (which was conducted in Q2 2016).

In parallel with the conclusion of the clinical study, a phase IIb/III study is being planned to continue the clinical development process. The preparatory work includes development of the clinical trial protocol for approval by the Swedish Medical Products Agency, as well as development and production of the medicine in tablet form.

During the year a health economic study of VAL001 was carried out. An important part of the study is the willingness to pay for one expected quality-adjusted life year (QALY) of SEK 1 million, which is the accepted standard in Sweden. The study compared costs for the current treatment (R-CHOP) in relation to the percentage of patients who are cured for 2 years following treatment with VAL001 and R-CHOP. Given these assumptions, VAL001 is positioned with a maximum price of between SEK 690,000 at 80% survival and SEK 1,380,000 at 90% survival.

An exit process for VAL001 is underway. The results of an exit may involve a sale of the rights to the VAL001 project, or of the subsidiary Valcuria AB, in which all findings and IPR material belonging to VAL001 are gathered.

## Comments by the CEO

# Clearly heading for the market



### **ENCOURAGING RESULTS IN ANIMAL MODELS STRENGTHEN RESP1000**

The collaboration with Cadila relating to RESP1000 has successfully shown that it is possible to produce our product candidate RES022-125 on a large scale at a quality that makes clinical studies possible.

An efficacy study of RES022-125 has demonstrated a disease-modulating effect in an established COPD model based on mice that have been exposed to tobacco smoke in a controlled setting. The study was carried out by Cadila in India and Respiratorius is now assessing the results with the assistance of experts in this type of preclinical trial.

As a result of these promising new findings, the Company intends to assume a clearly active and leading role in the continued development with the goal of initiating clinical trials of RES022-125. Initiating a clinical study aimed at COPD, a common disease that currently lacks satisfactory treatment, would represent an important milestone for Respiratorius.

At the end of 2017, the Company completed a successful and oversubscribed

rights issue which raised approximately SEK 21 million for the Company before issue expenses. The Company's cash on hand is expected to be able to finance operations for 12 to 18 months.

In 2017 Respiratorius made significant advances in all projects. The Company is now entering a new stage of development with two promising projects – VAL001, which is currently in advanced clinical development and for which the Company has now initiated an exit process, and RESP1000, which is approaching the start of clinical development.

Riding the wave of our successes in 2017, we are now entering a new year with strengthened finances and great opportunities. We would like to thank our dedicated shareholders for their steadfast confidence and look forward with great excitement to piloting the Company's projects in a clear direction toward the market.

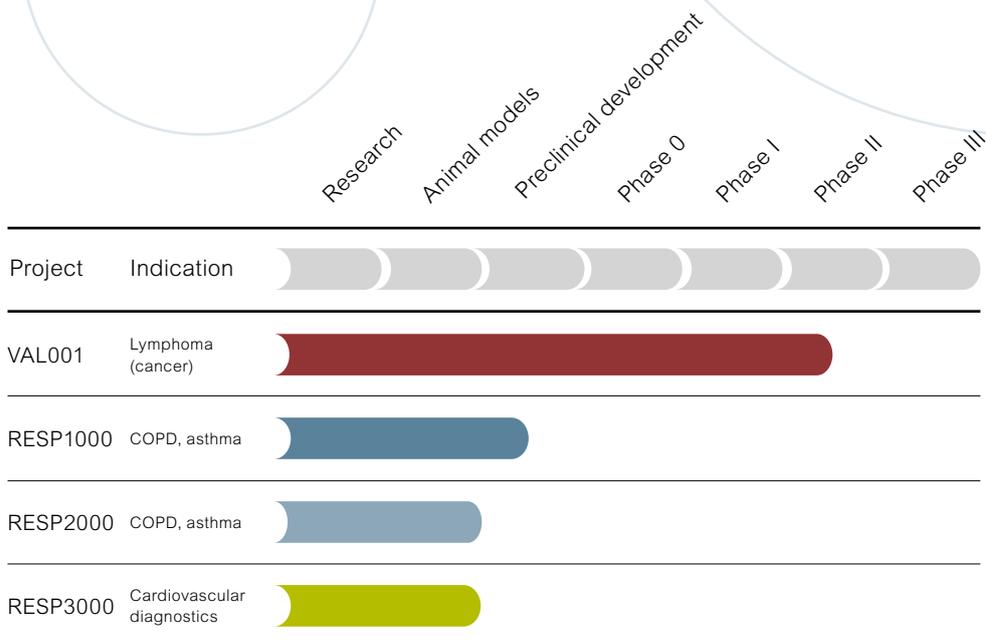
Johan Drott, CEO

# Project portfolio and pipeline

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

## CURRENT DEVELOPMENT PROJECTS

The table below tracks the progress of the major drug candidates that Respiratorius has advanced to the development process.





### **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 clearly shown favorable experimental data for treatment of diseases such as diffuse large B-cell lymphoma, and a phase I clinical trial was successfully completed in 2013. This study determined the maximum tolerated dose in combination with standard chemotherapy (R-CHOP) for treatment of patients with DLBCL. Continued clinical development is underway in a phase IIa study, with full enrollment achieved in 2015. An interim analysis of the data gathered from the ongoing phase I/IIa clinical study was conducted in April 2016. The results shows 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. The final report from the phase I/IIa clinical study will be compiled after the study is completed.

In parallel with the clinical study, preparations are underway for continued clinical development, which will involve a phase IIb/III study. 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 tablet form. This is important to ensure that the project does not lose time to market during the ongoing exit process.

Identification of suitable partners for VAL001 has begun, along with an initiative to sell the VAL001 project, or the subsidiary Valcuria AB, in which all findings and intellectual property rights material belonging to VAL001 are gathered.

### Important events in the near future for VAL001

#### 2018:

- Preparatory work including development of the clinical trial protocol for approval by the EMA, as well as development and production of testing material.
- Identification of appropriate partners for a potential exit process.
- Final report from phase I/IIa clinical study in the first half of 2018.

#### 2019/2020:

- Potential start of clinical phase IIb/III.

### RESP1000

RESP1000 is a compound series of drug candidates with anti-inflammatory and bronchodilatory properties that is currently under development to enable treatment of patients with COPD and severe asthma. In September 2014 Respiratorius signed a license and development agreement for RESP1000 with Cadila Pharmaceuticals Ltd, one of the largest private pharmaceutical companies in India. The project is in the preclinical phase and under the signed license agreement, Cadila Pharmaceuticals Ltd will be responsible for and fund development at its facilities in Ahmedabad, India. Upon completion of clinical phase II, the cooperation agreement will grant Cadila the rights to the Respiratorius patent for the RESP1000 series in a limited territory that includes Africa, the Middle East and Asia (excluding China and Japan). Respiratorius will retain the rights in Europe and the US, as well as in China and Japan. The cooperation agreement also addresses distribution of revenue, if any, in each territory. Respiratorius will receive a percentage in royalties from the future net revenue from all sales in Cadila's markets. Similarly, the parties will share future revenues, such as milestone payments linked to development phases and product sales, as well as royalties, in the Respiratorius territory.

An efficacy study that Cadila carried out in the fall of 2017 showed that the product candidate, RES022-125, has a disease-modulating effect on mice that were induced to regularly inhale tobacco smoke. In the efficacy study, which Cadila conducted in collaboration with Respiratorius, 30 mice were exposed to cigarette smoke for 50 days, after which 15 of the mice inhaled the Respiratorius' substance RES022-125 while they continued to be exposed to cigarette smoke for an additional 41 days. The other 15 mice continued to be exposed to cigarette smoke for 41 more days, but without inhaling RES022-125.

After the trial period, histological studies were carried out on the lung tissue of the mice. Customary established techniques for handling samples were used when analyzing the lung tissue. Preliminary results suggest a clear improvement of pulmonary pathology in the group of animals that inhaled RES022-125 compared with the group that did not inhale RES022-125. The improvement appears to involve the general pulmonary pathology, the degree of infiltration of inflammatory cells, the degree of collagen deposits in pulmonary tissue and the degree of obstructed flow in the pulmonary airways.

As a result of these findings, Respiratorius intends to assume a more proactive leadership role in initiating clinical trials of RES022-125. Initiating a clinical study in the field of COPD and severe asthma, two common diseases that lack satisfactory treatments, represents an important milestone for Respiratorius. In the continuing collaboration with Cadila Pharmaceuticals, Respiratorius intends to carry out toxicological studies of RESP1000 in Europe, in collaboration with leading certified toxicological laboratories. The

Board of Directors considers this to be a strategic step prior to starting clinical trials and it will also probably make the project more attractive to potential partners.

#### Important events in the near future for RESP1000

##### 2017/2018:

- Assume a more proactive leadership role in the development of RESP1000.
- Complete preclinical work
- with RES022-125.

##### 2019/2020:

- Initiate phase I clinical study in Europe.

#### RESP2000

RESP2000 is a series of new chemical substances that differ from the RESP1000 series. Results from preclinical studies conducted on RESP2000 in the US suggest that the effects of the medicinal substance 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. Regulation of the “mitochondrial function” is one area where, according to the Board of Directors, Respiratorius is well-positioned to assume a leading role thanks to its advanced position in research on airway diseases. 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 into the airways 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 substances 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 RESP-2000 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 substances for improving diagnosis of cardiovascular diseases.

The bronchodilatory properties of the RESP2000 substances 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.

#### RESP3000

RESP3000 is a project primarily aimed at diagnosing cardiovascular diseases using PET imaging, which is one of the fastest-growing new technologies for diagnosis of cardiac disease. 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 substance from the RESP3000 series was completed with promising results in 2014, from which RESP3105 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 working with additional drug candidates. However, these drug candidates are currently in a very early stage of development. Development is also underway using the patent-protected substances that Respiratorius has developed as a point of departure, where the Company is testing for new indications. The Board of Directors believes that RESP2000 has a well-defined “mode of action” that can be traced to cellular mitochondria, for which reason the Board also envisions broad potential for uses in areas far removed from the original indications of COPD and asthma.

Respiratorius 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 patients and animals, and to then analyze the impact of various chemical substances 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 substances in human clinical studies 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 substance from the series was chosen for preclinical development aimed at future clinical development.

In 2008 the Company discovered another new class of chemical substances, RESP2000, 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 vivo guinea pig model.

A more detailed study of the mechanism of action of RESP2000 was also carried out.

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 has 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. The VAL001 project

has performed well under the management of Respiratorius and a successful phase I clinical study has been conducted. In 2014 a Phase IIa study was initiated which achieved full enrollment in 2015.

The encouraging results from the phase I/IIa clinical trial were recently presented. The final report from the study will be compiled as soon as possible after study completion.

#### **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 and RESP2000), as well as for diagnosis of cardiovascular diseases (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 drugs on large markets. However, it is important to note that both preclinical and clinical studies are required before new drugs can be commercialized. The pharmaceutical industry as such, and clinical studies in particular, are associated with uncertainty regarding both funding and study results.

# Board of Directors and CEO



**OLOV STERNER**, Born 1953

**Board member**

Professor of Organic Chemistry and Dean of the Faculty of Science, Lund University. Author and co-author of more than 420 publications in scientific journals, as well as 30 patents/patent applications and 5 textbooks. Chairman of the Board of Gedea Biotech AB. Board member of Partners för Utvecklingsinvesteringar inom Life Sciences AB, Glactone AB, and Gabather AB.

**Holdings:** 402,178



**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:** 11,265,462<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, BoMill Holding AB, EQL Pharma AB, Ilya Pharma AB and Spectracure AB. Board member of Health Invest Partners AB, Prolight Diagnostics AB, Emplicure AB and Attana AB.

**Holdings:** 801,167



**JOHAN DROTT**, Born 1966

**CEO**

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

**Holdings:** 11,265,462<sup>1</sup>

<sup>1</sup> Valcuria Holding AB is owned by Kristina Drott (10%), Johan Drott (49.8%) and two external individuals (one natural person and one legal entity)



**CHRISTER FÅHRAEUS**, Born 1965

**Chairman of the Board**

Founder of Respiratorius and Board member or deputy since 1999. MSc in Bioengineering, 4 years as a PhD student in neurophysiology and 3 years of medical school, Lund University, honorary doctor's degree in engineering from Lund University (2002). Founder of Agellis Group AB, Anoto Group AB, Precise Biometrics AB, CellaVision AB, EQL Pharma AB and FlatFrog Laboratories AB.

Chairman of the Board of FlatFrog Laboratories AB and LongBoat Explorers AB. Board member of CellaVision AB, LU Holding AB, and Reccan Diagnostics AB. Deputy director for BioActive Polymers in Lund AB and Wranne Fåhræus design AB. Chief Executive Officer and board member of EQL Pharma AB.

**Holdings:** 24,564,362



**ANDERS MÅNSSON**, Born 1967

**Board member**

Education and experience: Degree in business administration from Lund University (1997) and MBA from the Faculty of Business and Economics, University of Lausanne, Switzerland (2007) Anders has more than 20 years of experience in the pharmaceutical industry, including 15 years of experience in international managerial positions. He has a broad background in business and has held executive positions in areas such as sales and marketing, strategic planning and business development. Chairman of the Board of CanImGuide Therapeutics AB. Industry adviser in Life Science to Ratos AB. CEO and board member of Longboat Explorers AB.

**Holdings:** 47,214



**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 P.U.L.S. Invest AB. Board member of Edvince AB, Nanoecho AB, LU Holding AB, SwedenBio, SwedNanoTech, Bumblefish AB and Sparbankstiftelsens Riskkapitalstiftelse.

**Holdings:** 0

# History

## 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.
- In 2003, 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 substance from the series was chosen for preclinical development aimed at future clinical development.
- In 2008 the Company discovered another new class of chemical substances, 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 carried out.
- 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 experiments conducted using the VAL001 drug candidate demonstrated strong effects on human lymphoma cell lines (models for lymph node cancer).
- In 2013 the phase I study for VAL001 was successfully completed. In 2014, a Phase IIa study was initiated.
- License and development agreement for RESP1000 signed with Cadila Pharmaceuticals Ltd.

## 2015-2019

- Phase IIa study with VAL001 fully enrolled. The results from the interim analysis of the clinical phase IIa 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 including a clinical study protocol prior to approval by the Medical Products Agency for VAL001, as well as identification of appropriate partners for a potential exit process were initiated.
- In 2018 the Company aims to resume its proactive leadership role in the development of RESP1000 and to conclude the preclinical work prior to an expected clinical phase I study in Europe in 2018/2019.



## The share

The Respiratorius share was listed on July 5, 2012 on AktieTorget. The share is traded under the ticker symbol RESP and the ISIN code is SE0004550192. On December 31, 2017, the number of shares in the Company was 139,708,423. As a result of the rights issue conducted in December BTA 171206 (paid subscribed shares) were traded 171206 (SE0010600304), from December 8, 2017 through January 23, 2018. A total of 14,797,585 paid subscribed shares were issued. 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.

## HISTORICAL SHARE PERFORMANCE

	LOWEST	AVERAGE	HIGHEST	VOLUME OF SHARES
2012	0.23	0.31	0.50	6,760,487
2013	0.27	0.44	0.68	78,859,373
2014	0.25	0.44	0.71	55,348,448
2015	0.25	0.36	0.69	100,742,020
2016	0.33	0.77	4.04	408,774,754
2017	1.21	1.78	2.99	156,709,862

## SHARE PERFORMANCE FOR THE YEAR

MONTH	CLOSING PRICE	HIGHEST	LOWEST	VOLUME	TURNOVER
January	2,434	2.99	1.94	42,973,569	108,671,840.30
February	2,463	2.60	1.88	15,735,052	35,771,939.60
March	2,55	2.69	2.11	15,196,863	36,515,079.00
April	1,835	2.85	1.57	24,771,728	52,729,319.50
May	1,372	1.85	1.30	7,258,593	11,119,774.60
June	1,623	1.82	1.21	10,558,706	15,004,494.60
July	1,362	1.62	1.34	4,448,519	6,338,875.20
August	1,777	1.86	1.23	12,084,123	17,903,281.50
September	1,758	1.93	1.55	8,853,264	15,247,787.20
October	1,613	1.78	1.58	3,834,739	6,351,341.80
November	1,575	1.68	1.42	4,486,527	6,930,530.80
December	1.94	2.02	1.38	6,508,179	10,837,577.50

## FIVE LARGEST SHARE-HOLDERS DEC. 31, 2017

NAME	HOLDINGS (%)
Fårö Capital AB	15.6
Valcuria Holding AB	7.7
Avanza Pension	7.1
Hans Harvig	2.5
Hartmut Wiese	1.4



# 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 substances, 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, 2017 the patent portfolio includes five patent families, each of which has been granted patents.

NUMBER	DESCRIPTION	COUNTRY	PRIORITY YEAR	EXPIRATION YEAR*
<b>Patent family – VAL001</b>				
EP 2688572 B1	A pharmaceutical composition comprising an HDAC inhibitor and a steroid and the use thereof	EP, BE, CA, DK, FI, FR, DE, HU, IE, IT, NL, NO, PL, PT, ES, CH/LI, TR, GB	2011	2032
JP 2014510102 A	A pharmaceutical composition comprising an HDAC inhibitor and a steroid and the use thereof	JP	2011	2032
<b>Patent family – RESP3000</b>				
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 divisional application from 14/367520 (US 9295738 B2)	US	2011	2032
2014/05199	Contrast agent for imagining myocardial perfusion	ZA	2011	2032
<b>Patent family – RESP1000</b>				
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 (New bronchodilating alpha, beta-unsaturated amides)	SE	2007	2027
US 8318768 B2	Bronchodilating alpha, beta-unsaturated isoquinoline amides	US	2007	2029**
JP 5443348 B2	Novel bronchodilating alpha, beta-unsaturated isoquinoline amides	JP	2007	2028
IN270793B	Novel bronchodilating alpha, beta-unsaturated isoquinoline amides	IN	2007	2028
<b>Patent family – RESP2000</b>				
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
		Unknown status for: MK		
<b>Patent family - RESP-HSAT (Measuring equipment)</b>				
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).

# Invitation to the Annual General Meeting

## ANNUAL GENERAL MEETING

The Annual General Meeting of shareholders in Respiratorius AB (publ) will be held at 3 p.m. on Tuesday, May 15, 2018, G:a Gästmatsalen Medicon Village, Scheelevägen 2 in Lund.

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

## RIGHT TO PARTICIPATE AND REGISTRATION

Shareholders who are registered in the share register maintained by Euroclear Sweden AB as of May 8, 2018, and who have notified the Company of their intention to participate no later than May 8, 2018, preferably before 4:00 p.m., are entitled to attend the Annual General Meeting.

Notification of participation in the Meeting must be sent in writing, including the shareholder's name, personal or corporate identity no., address, email and phone number, to the address Respiratorius AB, 223 81 LUND, or by email to [info@respiratorius.com](mailto:info@respiratorius.com).

## SHARE REGISTRATION

Shareholders whose shares are registered in the name of a nominee must temporarily have re-registered the shares in their own name at Euroclear Sweden AB to be entitled to participate in the Meeting. Such registration must be effected no later than May 8, 2018 and should be requested well in advance of this date.

## OTHER INFORMATION

Financial reports, 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 reports and press releases and download them from the website or via AktieTorget'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

### FUTURE REPORTING DATES

- First quarter interim report May 15, 2018
- Half-Yearly Report August 28, 2018
- Third quarter interim report November 7, 2018



# 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 2017 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 substances 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 substances 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 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 THE YEAR**

Respiratorius announced in March that the US Federal Drug Administration (FDA) had granted orphan drug status for valproic acid for treatment of diffuse large B-cell lymphoma. Orphan drug status allows seven years of market exclusivity for VAL001 in the US from the time of market approval.

Respiratorius AB (publ) has found, in cooperation with Cadila Pharmaceuticals regarding RESP1000, that our selected substance RES022-125 demonstrated disease-modulating effect on tobacco-smoking rats. The results will be quantified in greater detail at Respiratorius and published as soon as they are completed. Based on these positive preliminary data, Respiratorius intends to carry out toxicology studies and, barring the unforeseen, subsequent phase I or phase I/IIa studies will be carried out with a focus on Europe.

The Company conducted a rights issue in December 2017 that was 120 percent oversubscribed and raised SEK 21 million before issue expenses for the Company. The issue proceeds will primarily be used to fund the prioritized projects VAL001 and RESP1000.

During the year Respiratorius announced several patent approvals for RESP3000. During the year patents were granted in Australia, Japan and Russia. In addition, the US patent office granted a divisional application for RESP3000 relating to specific product requirements. All patent approvals are expected to strengthen the Company's position through market exclusivity in negotiations with potential partners.

#### **SIGNIFICANT EVENTS AFTER THE CLOSE OF THE FINANCIAL YEAR**

At the end of February Respiratorius reported encouraging findings from clinical phase I/IIa studies of VAL001. The assessment is that the clinical studies were successful, especially overall survival among patients treated with VAL001 compared with a control group. The main example (see table 1) is that despite the limited patient material, two-year survival with a 95% confidence interval is significantly higher for those patients who were treated with VAL001, compared with the reference population.

The patent application for RESP3000 was granted in Europe in the mid-January 2018. Patents were previously granted in the US, Japan, Israel, Australia, South Africa and Russia. In addition, the US patent office granted a divisional application for RESP3000 relating to specific product requirements in 2017.

# Financial performance in 2017

## 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
2. the sale of one of its projects, or
3. acquisition involving a legal entity with access to cash, or
4. share issue with or without preferential rights for existing shareholders in favor of financial or strategic investors

## ORGANIZATION AND STAFF

The Company leases appropriate facilities at Medicin Village in Lund. The Medicin 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, nine Board meetings were held focusing primarily on strategy for research, funding and external collaborations, as well as related licensing strategy.

## OUTLOOK

The VAL001 drug project is progressing as planned. The project is currently in phase IIa, with a successful phase I study completed in the third quarter of 2013. In 2016 the Company reported encouraging results from an interim analysis of data from the phase IIa study. 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. Work on a new formulation of the planned product is underway in parallel with clinical development.

Within the field of COPD and asthma, Respi-ratorius and Cadila Pharmaceuticals Ltd. signed a license and development agreement relating to RESP1000 in 2014. Under the agreement Cadila is covering the costs of the development work, which is being carried out in India. In 2017, development work involving synthesis and production of the selected drug candidate was completed. An efficacy study of the drug candidate RES022-125 demonstrated promising results regarding disease modulation.

The Company is open to further collaborations or out-licensing involving RESP2000.

In the RESP3000 project for improved diagnostics of cardiovascular diseases, during the year the Company completed a limited, clear value-generating development process, along with business development initiatives.



# Risk Factors

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

Company's earnings and financial position.

## **OPERATIONAL AND INDUSTRY-RELATED RISK**

### **Clinical development**

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

### Funding and collaborations

There is a risk that in the future, the Company may be unable to raise the necessary capital on the financial markets to run one or more projects until a partner takes over responsibility for continued development. Respiratorius is engaged in discussions with large pharmaceutical companies to establish partnerships under which the 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 substances 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 studies, 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 substances, drug candidates and methods. As with all aspects of drug development, there is a risk that new substances will have side effects that cannot be eliminated by chemical modification or tolerated by patients. In addition, competing businesses could have similar substances under development. The Company's patents, patent applications and a high level of confidentiality cannot guarantee favorable results. Continued development of existing and new substances, drug candidates and methods are of great importance for Respiratorius. If the Company should lose its ability to do so, if future research findings or clinical results do not provide scientific or commercial support for continued drug development, if continued drug development cannot proceed according to

plan for other reasons, if finished products cannot be launched on schedule, or if the market reception is worse than expected, such factors could have a negative impact on Respiratorius' financial performance.

#### Development costs

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

#### Adverse reactions

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

#### Partners

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

#### Key personnel

Respiratorius' key personnel have considerable expertise and extensive experience

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

#### Competitors

There is a risk that other companies could have similar substances under development of which Respiratorius is not aware. There is also a risk that new competitors with a larger resource base of expertise and capital could enter Respiratorius' market and offer better methods and more effective products than Respiratorius. The Company is not aware of any competing companies that are working on development of substances 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 pharmaceuticals 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 substances, 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 substances, drug candidates and methods it develops. However, there is no guarantee that current or future patent applications will be grant-

ed, 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 substances 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 substance. 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 litiga-

tion. 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 studies may be necessary to obtain the relevant approval. There is also a risk that the studies may not be carried out as planned, which could affect their outcome. Such outcomes could delay sales and development, as well as increase the cost of a new product. If Respiratorius fails to obtain, or retain, the permits and approvals that the Company already has, it may adversely affect the Company's business, earnings and financial position.

In certain markets, the success of the Company depends on approval of the Company's method for reimbursement by national insurance systems (private or public) and

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

## SECURITIES-RELATED RISKS

### Share price development

Current and potential investors should note that an investment in Respiratorius involves risk and that there are no guarantees of any increase in the share price. This entails the risk that investors may lose all or part of their invested capital. The share price may fluctuate as a result of circumstances such as variations in earnings in the Company's interim reports, the general economic situation and changes in the stock market interest in the Company and its share.

Limited liquidity in the share could, in turn, help to reinforce such share price fluctuations. Accordingly the share price may be influenced by factors that are in whole or in part beyond the control of the Company. An investment in shares in Respiratorius should therefore be preceded by careful analysis of the Company, its competitors and the business environment, general information about the industry, the general economic situation and other relevant information. It cannot be guaranteed that shares in



Respiratorius can be sold at any time for a price that is acceptable to the shareholder.

#### Marketplace

The Company's share is traded on AktieTorget, a secondary name of ATS Finans AB, which is a securities company under the supervision of Finansinspektionen. AktieTorget operates a trading platform (multilateral trading facility, MTF). Companies whose shares are traded on AktieTorget 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.

#### Dilution

Shareholders who fully or partially choose not to exercise their subscription rights in the Rights Issue will have their share of the Company's share capital diluted, which means that the shareholder's relative voting power at the Annual General Meeting is weakened and that the shareholder's share in the Company's assets and earnings decreases. The dilutive effect for those shareholders who choose not to participate in the Rights Issue will be a maximum of 11.1 percent of votes and capital in the Company.

#### 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 AktieTorget. In addition to trading in shares, subscription rights and paid subscribed shares will be traded for a limited period in connection with the Rights Issue. It cannot be guaranteed that the liquidity of the shares, subscription rights and paid subscribed 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 overview\*

## GROUP

SEK THOUSAND	2017	2016	2015	2014	2013
Profit/loss after financial items	-4,928	-4,854	-5,685	-5,275	-5,097
Total assets	31,101	13,725	20,247	16,866	15,419
Equity/assets ratio (%)	83.9	91.7	89.0	95.2	80.2
Return on equity (%)	neg.	neg.	neg.	neg.	neg.

## PARENT COMPANY

(SEK 000S)	2017	2016	2015	2014	2013
Profit/loss after financial items	-5,180	-4,956	-5,438	-5,385	-4,995
Total assets	31,321	14,182	20,376	17,207	15,802
Equity/assets ratio (%)	83.9	91.8	88.2	95.0	80.8
Return on equity (%)	neg.	neg.	neg.	neg.	neg.

\* Definitions of key ratios, see supplementary disclosures

# Appropriation

Proposal for treatment of the Company's loss

At the disposal of the Annual General Meeting:

loss brought forward SEK	-15,983,403
share premium reserve SEK	17,283,495
loss for the year SEK	<u>-5,179,693</u>
	-3,879,601

The Board of Directors proposes:

carry forward to new account SEK	<u>-3,879,601</u>
	-3,879,601

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 changes in equity

GROUP	SHARE CAPITAL	SHARE CAPITAL, NOT REGISTERED	ADDITIONAL PAID-IN CAPITAL	OTHER EQUITY, INCLUDING PROFIT/LOSS FOR THE YEAR	TOTAL EQUITY
Amount, Jan. 1	6,985,421		22,016,818	-16,420,909	12,581,330
Ongoing rights issue		873,178	20,083,085		20,956,263
Issue costs			-2,522,090		-2,522,090
Loss for the year				-4,927,643	-4,927,643
<b>Amount, Dec. 31</b>	<b>6,985,421</b>	<b>873,178</b>	<b>39,577,813</b>	<b>-21,348,552</b>	<b>26,087,860</b>

PARENT COMPANY	SHARE CAPITAL	SHARE CAPITAL, NOT REGISTERED	OTHER RESTRICTED EQUITY	OTHER UNRESTRICTED EQUITY	PROFIT/LOSS FOR THE YEAR	TOTAL UNRESTRICTED EQUITY
Amount, Jan. 1	6,985,421		22,016,789	-11,027,144	-4,956,259	-15,983,403
Ongoing rights issue		873,178		20,083,085		20,083,085
Fund for development costs			277,500	-277,500		-277,500
Issue costs				-2,522,090		-2,522,090
Allocation of loss for the year according to resolution of the Annual General Meeting:				-4,956,259	4,956,259	
Loss for the year					-5,179,693	-5,179,693
<b>Amount, Dec. 31</b>	<b>6,985,421</b>	<b>873,178</b>	<b>22,294,289</b>	<b>1,300,092</b>	<b>-5,179,693</b>	<b>-3,879,601</b>

# Income statement

	NOTE	GROUP		PARENT COMPANY	
		2017-01-01 DEC. 31, 2017	2016-01-01 DEC. 31, 2016	2017-01-01 DEC. 31, 2017	2016-01-01 DEC. 31, 2016
<b>Operating revenue, etc.</b>					
Other operating income		0	0	0	0
		<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Operating expenses</b>					
Raw material and consumables		-975,889	-591,814	-737,111	-313,431
Other external costs	1	-3,191,682	-2,587,637	-2,586,769	-2,170,616
Personnel costs	2	-697,905	-660,280	-697,905	-654,655
Depreciation, amortization and impairment of plant, property, and equipment and intangible assets		-2,240,117	-2,571,793	-1,246,050	-1,641,092
Capitalized work for own account		2,201,764	1,565,895	1,411,839	932,230
		<b>-4,903,829</b>	<b>-4,845,629</b>	<b>-3,855,996</b>	<b>-3,847,564</b>
<b>Operating loss</b>		<b>-4,903,829</b>	<b>-4,845,629</b>	<b>-3,855,996</b>	<b>-3,847,564</b>
<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		51	266	51	250
Interest expense and similar profit/loss items		-23,865	-8,945	-23,748	-8,945
		<b>-23,814</b>	<b>-8,679</b>	<b>-623,697</b>	<b>-608,695</b>
<b>Profit/loss after financial items</b>		<b>-4,927,643</b>	<b>-4,854,308</b>	<b>-4,479,693</b>	<b>-4,456,259</b>
<b>Appropriations</b>					
Group contributions paid		0	0	-700,000	-500,000
		<b>0</b>	<b>0</b>	<b>-700,000</b>	<b>-500,000</b>
<b>Loss for the year</b>		<b>-4,927,643</b>	<b>-4,854,308</b>	<b>-5,179,693</b>	<b>-4,956,259</b>
Attributable to:					
Equity holders of the parent company		-4,927,643	-4,854,308		

# Balance sheet

	NOTE	GROUP		PARENT COMPANY	
		DEC. 31, 2017	DEC. 31, 2016	DEC. 31, 2017	DEC. 31, 2016
<b>NON-CURRENT ASSETS</b>					
<b>Intangible assets</b>					
Capitalized expenditure for research, etc.	5	5,447,805	5,368,485	3,210,475	3,102,168
Patents	6	5,818,726	5,936,400	1,644,844	1,587,362
		<b>11,266,531</b>	<b>11,304,885</b>	<b>4,855,319</b>	<b>4,689,530</b>
<b>Financial assets</b>					
Participations in Group companies	7	0	0	3,500,000	4,100,000
		<b>0</b>	<b>0</b>	<b>3,500,000</b>	<b>4,100,000</b>
<b>Total non-current assets</b>		<b>11,266,531</b>	<b>11,304,885</b>	<b>8,355,319</b>	<b>8,789,530</b>
<b>CURRENT ASSETS</b>					
<b>Current receivables</b>					
Receivables from Group companies		0	0	3,171,901	3,020,901
Other receivables		19,667,319	131,420	19,660,600	105,748
Prepaid expenses and accrued income		132,900	103,900	132,900	103,900
		<b>19,800,219</b>	<b>235,320</b>	<b>22,965,401</b>	<b>3,230,549</b>
<b>Cash and bank balances</b>					
Cash and bank balances		34,324	2,184,532	0	2,162,256
		<b>34,324</b>	<b>2,184,532</b>	<b>0</b>	<b>2,162,256</b>
<b>Total current assets</b>		<b>19,834,534</b>	<b>2,419,852</b>	<b>22,965,401</b>	<b>5,392,805</b>
<b>TOTAL ASSETS</b>		<b>31,101,074</b>	<b>13,724,737</b>	<b>31,320,720</b>	<b>14,182,335</b>

# Balance sheet, cont'd

	NOTE	GROUP		PARENT COMPANY	
		DEC. 31, 2017	DEC. 31, 2016	DEC. 31, 2017	DEC. 31, 2016
<b>EQUITY AND LIABILITIES</b>					
<b>Restricted equity, Group</b>					
Share capital	8	6,985,421	6,985,421		
Share capital, not registered		873,178			
Additional paid-in capital	1	39,577,813	22,016,789		
Other equity, including profit/loss for the year	2	-21,348,552	-16,420,909		
		<b>26,087,860</b>	<b>12,581,301</b>		
<b>Restricted equity, parent company</b>					
Share capital	8			6,985,421	6,985,421
Share capital, not registered				873,178	0
Restricted reserves				22,294,289	22,016,789
				<b>30,152,888</b>	<b>29,002,210</b>
<b>Unrestricted equity</b>					
Unrestricted reserves				-	-
Share premium reserve				17,283,495	5,831,925
Retained earnings				-15,983,403	-16,859,068
Loss for the year				-5,179,693	-4,956,259
				<b>-3,879,601</b>	<b>-15,983,402</b>
<b>Total equity</b>		<b>26,087,860</b>	<b>12,581,331</b>	<b>26,273,287</b>	<b>13,018,808</b>
<b>Non-current liabilities</b>					
Liabilities to Group companies	9	0	0	86,912	92,537
<b>Total non-current liabilities</b>		<b>0</b>	<b>0</b>	<b>86,912</b>	<b>92,537</b>
<b>Current liabilities</b>					
Bank overdraft facility	10	46,781	0	46,781	0
Accounts payable		1,396,000	361,086	1,368,807	314,170
Other liabilities		1,100,000	10,546	1,100,000	10,546
Accrued expenses and deferred income	11	2,470,433	771,774	2,444,933	746,274
<b>Total current liabilities</b>		<b>5,013,214</b>	<b>1,143,406</b>	<b>4,960,521</b>	<b>1,070,990</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>31,101,074</b>	<b>13,724,737</b>	<b>31,320,720</b>	<b>14,182,335</b>

# Statement of cash flows

NOTE	GROUP		PARENT COMPANY	
	DEC. 31, 2017	DEC. 31, 2016	DEC. 31, 2017	DEC. 31, 2016
<b>Operating activities</b>				
Profit/loss after financial items	-4,927,643	-4,854,308	-4,479,693	-4,456,259
Adjustments for non-cash items, depreciation/amortization	2,240,117	2,571,793	1,246,050	1,641,092
Impairment losses	0	0	600,000	600,000
<b>CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL</b>				
	<b>-2,687,526</b>	<b>-2,282,515</b>	<b>-2,633,643</b>	<b>-2,215,167</b>
<b>Cash flow from changes in working capital</b>				
Reduction(+)/increase(-) for receivables	-19,564,899	7,684,615	-19,734,852	-7,046,903
Reduction (-)/increase(+) of current liabilities	3,869,809	-1,668,377	3,889,531	-1,231,625
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>				
	<b>-18,382,616</b>	<b>3,733,723</b>	<b>-18,478,964</b>	<b>3,600,111</b>
<b>Investing activities</b>				
Investments in intangible assets	4.5 -2,201,764	-1,565,895	-1,411,839	-932,230
Group contributions paid	7 0	0	-700,000	-500,000
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>				
	<b>-2,201,764</b>	<b>-1,565,895</b>	<b>-2,111,839</b>	<b>-1,432,230</b>
<b>Financing activities</b>				
Rights issue for the year	18,434,172	0	18,434,172	0
Reduction (-)/increase(+) of non-current liabilities	0	0	-5,625	-5,625
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>				
	<b>18,434,172</b>	<b>0</b>	<b>18,428,547</b>	<b>-5,625</b>
<b>Change in cash and cash equivalents</b>				
Cash and cash equivalents, Jan. 1	2,184,532	16,704	2,162,256	0
<b>CASH AND CASH EQUIVALENTS, DEC. 31</b>				
	<b>34,324</b>	<b>2,184,532</b>	<b>0</b>	<b>2,162,256</b>

# Supplementary disclosures

## GENERAL DISCLOSURES

### ACCOUNTING POLICIES

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

### VALUATION PRINCIPLES

#### Receivables

Receivables are reported at the amounts expected to be received.

#### Other assets, provisions and liabilities

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

#### Property, plant and equipment

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

	Number of years
Machinery and other technical installations	5
Equipment, tools and machinery	5

#### Intangible assets

Intangible assets, consisting of patents and capitalized development costs, are recognized at cost less accumulated depreciation and impairment losses. The assets are depreciated 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 are capitalized when the following conditions are met: the company intends to complete the intangible asset and use or sell it and now has the ability to use or sell the asset, it is technically possible for the company to 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 value 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 96 million, all relating to Sweden. The nominal value of the

tax amounts to SEK 21.1 million at the 22% tax rate. No part of this receivable has been classified as an asset in the Balance Sheet since the Company and Group still and within budgets carry future development costs that exceed budgeted revenues. The receivable will not be recognized as an asset until the Company and the Group budget for or report stable profits. Deferred tax liabilities attributable to untaxed reserves are not recognized separately, untaxed reserves are reported as a gross amount in the balance sheet.

### SEGMENT REPORTING

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

### RELATED PARTIES TRANSACTIONS

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

### CRITICAL ACCOUNTING ESTIMATES AND ASSUMPTIONS

Preparation of the annual accounts and application of different accounting standards are often based on management's assessments or on assumptions and estimates that are regarded as reasonable under the prevailing circumstances.

These assumptions and estimates are often based on historical experience and other factors, including expectations of future events. For Respiratorius AB the following areas are worth noting:

#### Patents and capitalized development fees

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

### CONSOLIDATED ACCOUNTS

#### Subsidiaries

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

value at the acquisition date. The revenues and expenses, identifiable assets and liabilities and any goodwill or negative goodwill of the acquired company are included in the consolidated financial statements from the acquisition date.

#### Consolidated intangible assets

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

#### 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 COMPANY	
	2017	2016	2017	2016
<b>Crowe Horwath Osborne AB</b>				
Audit assignments	123,600	123,600	100,000	100,000
Other services	0	0	0	0
	<b>123,600</b>	<b>123,600</b>	<b>100,000</b>	<b>100,000</b>

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 COMPANY	
	2017	2016	2017	2016
<b>Average number of employees</b>				
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
<b>Salaries, benefits</b>				
Salaries, benefits, social security expenses and pension costs have been paid as follows:				
Board of Directors and CEO:				
Salaries and benefits	530,000	530,000	530,000	530,000
	<b>530,000</b>	<b>530,000</b>	<b>530,000</b>	<b>530,000</b>
Social security expenses	166,526	166,526	166,526	166,526
<b>Total Board of Directors and others</b>	<b>696,526</b>	<b>696,526</b>	<b>696,526</b>	<b>696,526</b>

In 2017 Chairman of the Board Christer Fähræus 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 631,504 were paid.

### NOTE 3 PROFIT/LOSS FROM PARTICIPATIONS IN GROUP COMPANIES

	GROUP		PARENT COMPANY	
	2017	2016	2017	2016
Impairment losses	0	0	-600,000	-600,000
	<b>0</b>	<b>0</b>	<b>-600,000</b>	<b>-600,000</b>

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

	2017	2016
<b>Effective tax reconciliation</b>		
Profit/loss before taxes	-4,927,643	-4,854,308
Tax liability 22.00% (22.00%)	1,084,081	1,067,948
Tax effects of:		
Non-deductible expenses	0	-336
Non-taxable revenues	11	52
Consolidated depreciation/amortization	-132,000	-132,000
Loss carryforward for the year	-952,093	-935,664
<b>Total</b>	<b>0</b>	<b>0</b>

##### PARENT COMPANY

	2016	2015
<b>Effective tax reconciliation</b>		
Profit/loss before taxes	-5,179,693	-4,956,258
Tax liability 22.00% (22.00%)	1,139,532	1,090,377
Tax effects of:		
Non-deductible expenses	0	-3
Non-taxable revenues	11	55
Impairment of shares in subsidiary	-132,000	-132,000
Loss carryforward for the year	-1,007,543	-958,429
<b>Total</b>	<b>0</b>	<b>0</b>

#### NOTE 5 CAPITALIZED EXPENDITURE FOR RESEARCH, ETC.

	GROUP		PARENT COMPANY	
	DEC. 31, 2017	DEC. 31, 2016	DEC. 31, 2017	DEC. 31, 2016
Opening cost	30,504,659	29,582,846	27,827,009	27,183,579
Purchases	1,253,389	921,813	1,014,611	643,430
<b>Closing accumulated cost</b>	<b>31,758,048</b>	<b>30,504,659</b>	<b>28,841,620</b>	<b>27,827,009</b>
Opening depreciation/amortization	-25,136,174	-23,613,851	-24,724,841	-23,442,445
Depreciation/Amortization for the year	-1,174,069	-1,522,323	-906,304	-1,282,396
Closing accumulated depreciation/amortization	-26,310,243	-25,136,174	-25,631,145	-24,724,841
<b>Closing carrying amount</b>	<b>5,447,805</b>	<b>5,368,485</b>	<b>3,210,475</b>	<b>3,102,168</b>

## NOTE 6 PATENTS

	GROUP		PARENT COMPANY	
	DEC. 31, 2017	DEC. 31, 2016	DEC. 31, 2017	DEC. 31, 2016
Opening cost	16,062,562	15,418,481	7,865,403	7,576,603
Purchases	948,375	644,081	397,228	288,800
<b>Closing accumulated cost</b>	<b>17,010,937</b>	<b>16,062,562</b>	<b>8,262,631</b>	<b>7,865,403</b>
Opening depreciation/amortization	-10,126,162	-9,076,693	-6,278,041	-5,919,345
Depreciation/Amortization for the year	-1,066,049	-1,049,469	-339,746	-358,696
Closing accumulated depreciation/amortization	-11,192,211	-10,126,162	-6,617,787	-6,278,041
<b>Closing carrying amount</b>	<b>5,818,726</b>	<b>5,936,400</b>	<b>1,644,844</b>	<b>1,587,362</b>

## NOTE 7 PARTICIPATIONS IN GROUP COMPANIES

### PARENT COMPANY

COMPANY	CORPORATE IDENTITY NUMBER	REGISTERED OFFICE	NUMBER OF/CAP. PERCENT-AGE %	DEC. 31,	DEC. 31,
				2017	2016
				CARRYING AMOUNT	CARRYING AMOUNT
Bergdalsten Kemi AB					
Corp. Id. No. 556650-7330		Lund	100	100,000	100,000
Valcuria AB					
Corp. ID no.556871-5196		Lund	100	3,400,000	4,000,000
				<b>3,500,000</b>	<b>4,100,000</b>

### INFORMATION ABOUT EQUITY AND PROFIT OR LOSS

	EQUITY	PROFIT/LOSS
Bergdalsten Kemi AB	82,934	-5,625
Valcuria AB	481,638	257,675

## NOTE 8 INFORMATION ABOUT SHARE CAPITAL

	HOLDINGS	PAR VALUE
Number/value, Jan. 1	139,708,423	0.05
Rights issue, shares not registered	17,463,552	
<b>Number/value, Dec. 31</b>	<b>157,171,975</b>	<b>0.05</b>

## NOTE 9 NON-CURRENT LIABILITIES

	GROUP		PARENT COMPANY	
	DEC. 31, 2017	DEC. 31, 2016	DEC. 31, 2017	DEC. 31, 2016
Amortization after 5 years	0	0	86,912	92,537
	<b>0</b>	<b>0</b>	<b>86,912</b>	<b>92,537</b>

#### NOTE 10 BANK OVERDRAFT FACILITY

	GROUP		PARENT COMPANY	
	DEC. 31, 2017	DEC. 31, 2016	DEC. 31, 2017	DEC. 31, 2016
Granted overdraft facility amounting to:	0	0	0	0
Credit used on balance sheet date:	0	0	0	0

#### NOTE 11 ACCRUED EXPENSES AND DEFERRED INCOME

	GROUP		PARENT COMPANY	
	DEC. 31, 2017	DEC. 31, 2016	DEC. 31, 2017	DEC. 31, 2016
Accrued fees	753,475	582,629	753,475	582,629
Other accrued expenses	1,716,958	189,145	1,691,458	163,645
	<b>2,470,433</b>	<b>771,774</b>	<b>2,444,933</b>	<b>746,274</b>

#### NOTE 12 LIABILITIES FOR WHICH ASSETS WERE PLEDGED

	GROUP		PARENT COMPANY	
	DEC. 31, 2017	DEC. 31, 2016	DEC. 31, 2017	DEC. 31, 2016
Overdraft facility, amount used	0	0	46,781	0
Granted overdraft facility amounting to:	0	0	0	0

#### NOTE 13 PLEDGED ASSETS

	GROUP		PARENT COMPANY	
	DEC. 31, 2017	DEC. 31, 2016	DEC. 31, 2017	DEC. 31, 2016
Chattel mortgages	2,500,000	2,500,000	2,500,000	2,500,000

#### NOTE 14 DEFINITION OF KEY RATIOS

##### Equity 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 12, 2018



Christer Fåhraeus



Kristina Drott



Johan Drott  
Chief Executive Officer



Ingemar Kihlström



Olov Sterner



Sarah Fredriksson



Anders Månsson

Our Auditor's Report was submitted on April 19, 2018



Olov Strömberg  
Authorized public accountant  
Crowe Horwarth Osborne AB



# 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 2017.

The annual accounts and consolidated accounts of the company are included in the printed version of this document on pages 26 – 48.

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, 2017 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 4 – 25 (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.

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### 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 2017 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

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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 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, 2018

Crowe Horwath Osborne AB



Olov Strömberg  
Authorized public accountant  
Crowe Horwath Osborne AB

# The Company in Brief

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 substance developed for use in PET imaging, aimed at facilitating the diagnosis of certain cardiovascular diseases.