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**Half-Yearly Report**

**2020**

**Jan. 1, 2020 – June 30, 2020**

**Respiratorius AB (publ)**  
**556552-2652**

SUMMARY OF H1 REPORT 2020 (GROUP)

**First half year 2020 (Jan. 1, 2020 – June 30, 2020)**

* Net sales totaled SEK 0 (0) thousand.
* Loss after financial items was SEK 3,956 (loss: 2,857) thousand.
* Earnings per share[[1]](#footnote-1) totaled SEK -0.03 (-0.02).
* The equity ratio[[2]](#footnote-2) as of June 30, 2020 was 62.2% (91.3).

**Second quarter (April 1, 2020 – June 30, 2020)**

* Net sales totaled SEK 0 (0) thousand.
* Loss after financial items was SEK 2,056 (loss: 1,311) thousand.
* Earnings per share1 totaled SEK -0.01 (-0.01).

SIGNIFICANT EVENTS DURING THE SECOND QUARTER OF 2020

At the beginning of the second quarter the Board of Directors for Respiratorius resolved to propose that the Annual General Meeting should resolve on a preferential rights issue for units consisting of newly issued shares and warrants. Full subscription of the rights issue will raise around SEK 25.1 million before issue expenses for the Company and if all warrants are exercised, an additional SEK 18.9-25.1 million before issue expenses will be raised.

The rights issue, which closed on June 16, was subscribed for at a rate of about 214 percent, thereby raising a total of SEK 25.1 million for Respiratorius before deductions for issue expenses. Upon full exercise of all 2020/2021 warrants in the Rights Issue, an additional capital injection of about SEK 19-25 million before issue expenses may be raised for the Company.

# Comments by the CEO

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The first half of 2020 has been far from a typical six-month period because of the pandemic, which has resulted in great sacrifices and losses for individuals, private businesses and society at large. Despite the unusual circumstances, business at the Company has essentially progressed according to plan, largely thanks to the analytical and strategic efforts carried out earlier this year to ensure continued development and funding for the Company. This effort resulted in an initial bridge loan in the first quarter, followed by a highly successful effort to raise capital in the second quarter, with a 214 percent subscription rate.

The exit process for VAL001 is continuing according to our plan and from the list of some 20 interested parties, a few have emerged as more interested in the project and more attractive to us than others on the list. Preparations prior to the start of phase III clinical trials for VAL001 are proceeding according to plan, with completion of the study drug, PK study and final study design prior to regulatory approval. The overarching objective is to initiate the phase III study as soon as possible in collaboration with a partner.

Work on the RESP9000 project, a new medication for effective treatment of COPD and severe asthma, is proceeding according to our plan. The sub-project to ensure an optimal formulation for inhalation and production before initiating a toxicology and clinical study program is underway. Preparations have begun for a scientific advisory meeting with a regulatory authority with the aim of confirming the content of the preclinical data package for approval of the clinical program.

The first half of 2020 has entailed good growth in the projects and we are now strong with secured continued funding. We would therefore like to thank our current and new shareholders for the trust and confidence you have shown through our successful rights issue.

![En bild som visar ritning

Automatiskt genererad beskrivning]()

Johan Drott

CEO, Respiratorius AB (publ)

# Respiratorius

## Operations

Respiratorius AB (publ) develops drug candidates with the goal of launching drugs to treat common diseases such as cancer, chronic obstructive pulmonary disease (COPD) and severe asthma. The project portfolio also includes a project for improving the diagnosis of certain cardiovascular diseases using PET imaging. The latter project is located outside Respiratorius’ main focus, for which reason other strategic options are continually being considered for this project.

The Company's cancer project, VAL001, is based on a combination and reformulation of existing drugs for a new indication, diffuse large B-cell lymphoma (DLBCL). The phase I/IIa clinical study of VAL001 for treatment of patients with DLBCL is complete with favorable results showing significantly increased survival (1-year and 2-year survival) among patients treated with VAL001 prior to treatment with R-CHOP, compared with patients treated with R-CHOP alone.

Respiratorius’ work relating to the future treatment of pulmonary diseases and the diagnosis of cardiovascular diseases is based on new proprietary and patent-protected compound series. The Board of Directors believes that these compound series have the potential to be developed into drug candidates and biomarkers. The compounds, which use novel mechanisms, are tested in the Company’s proprietary and patent-protected measuring and test equipment where we have been able to ensure efficacy on human lung tissue.

## Group structure

Respiratorius is the parent company of a Group that includes, in addition to the parent company, the wholly owned subsidiaries Bergdalsten Kemi AB and Valcuria AB. Bergdalsten Kemi AB is a dormant company. Valcuria AB holds the patent rights for Respiratorius’ VAL001 cancer project. All operations occur within the parent company, Respiratorius, and the parent has no other shareholdings.

## Respiratorius’ drug development

Respiratorius focuses its internal development resources on cancer, primarily the development of drugs for the treatment of malignant lymphoma, as well as new drugs for effective treatment of COPD and severe asthma. The project portfolio also includes a project for improving the diagnosis of certain cardiovascular diseases.

## Below is a brief overview of Respiratorius’ primary projects:

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

VAL001 is a drug candidate that has shown clearly promising experimental and clinical data against diseases such as diffuse large B-cell lymphoma, the most common type of non-Hodgkin’s lymphoma. The Company has successfully completed a phase I/IIa study that was conducted at Skåne University Hospital in Lund, Uppsala University Hospital, and Norrland University Hospital in Umeå.

Results from the phase I/IIa study show significantly increased survival (1-year and 2-year survival) among patients treated with VAL001 prior to treatment with R-CHOP, compared with patients treated with R-CHOP alone. Comparative data were taken from the Swedish Lymphoma Registry with a matched reference population of patients who were treated between 2010 and 2015. The results from the phase I/IIa study also demonstrate specific effects through increased levels of CD20, which may likely be beneficial in patients treated with Rituximab.

At a scientific advisory meeting with the EMA’s Scientific Advice Working Party (SAWP) regarding clinical strategy, VAL001 was assessed as meeting the criteria to directly begin a phase III study. About 700 patients should be satisfactory for such a study to be able to serve as a basis for marketing approval.

VAL001 (valproic acid) for the treatment of DLBCL received orphan drug status in Europe and the US, and patents were granted in the EU, the US, Japan, Canada and Korea. There is also a patent application for protection of a dedicated formulation.

### RESP1000/9000 – Drug for the treatment of COPD and asthma

RESP1000 is a compound series of drug candidates with bronchodilatory and anti-inflammatory properties under development to enable treatment of both COPD and asthma. The project is in preclinical phase and in 2014 a license and collaboration agreement was signed with Cadila Pharmaceuticals Ltd. for preclinical and clinical development of selected drug candidates from the RESP1000 series.

During the third quarter of 2018 a new patent application was submitted for a compound series, RESP9000, that has been assessed as having a favorable safety profile and equivalent anti-inflammatory and bronchodilatory properties as RES022-125, which is Respiratorius’ drug candidate that has come the farthest in RES1000 series.

Patents for RESP1000 have been granted in several countries.

### RESP2000 – Drug candidate for the treatment of COPD and asthma

RESP2000 is a series of new chemical substances, completely different from RESP1000, that have bronchodilatory properties and the potential to be developed into drugs for treatment of COPD and severe asthma. The RESP2000 compound series contains substances that affect the mitochondria (in simple terms, the cellular energy sources). In addition, certain exploratory studies will be conducted for other indications. This project is currently in early preclinical phase.

Patents for RESP2000 have been granted in several countries.

### RESP3000 – for diagnosis of conditions such as cardiovascular diseases

RESP3000 is a project aimed at diagnosing conditions such as cardiovascular diseases using PET imaging. The patent-protected RESP3000 compound series represents a further development of the RESP2000 compound series. Respiratorius has completed a study of RES3105, the selected candidate from the compound series, with promising results.

Patents have been granted in several countries.

### Other research and development

Using the patent-protected substances that Respiratorius has developed as a point of departure, the Company is testing new indications. 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 constantly evaluates projects relating to additional drug candidates that are a good strategic fit for the Company. Projects in early development phase are given priority.

Respiratorius has a patented technology platform (R-HSAT) for the study of smooth muscle in various tissues of both animals and humans. The technology platform 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 this technology.

## Business model

Respiratorius looks for strategic partners who assume the financial and operational responsibility for developing the final product. Such partners have financial resources, experience in large clinical studies and established contacts with regulatory authorities. These partners will also be responsible in the future for manufacturing, marketing and sales of the licensed drugs that may result from the development project. Several large pharmaceutical companies have already shown interest regarding licensing and collaboration 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 business remains intact.

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

## The share

The Respiratorius share was listed on July 5, 2012, on AktieTorget, now known as Spotlight Stock Market, a securities firm that is under the supervision of Finansinspektionen (the Swedish Financial Supervisory Authority) and operates a Multilateral Trading Facility (MTF) trading platform.

On June 30, 2020, the number of shares in the Company was 157,171,975. There is one class of shares, where each share carries equal rights to the Company’s assets and earnings, and entitles the holder to one vote at the Annual General Meeting.

## Audit

The Interim Report has not been reviewed by the Company’s auditor.

## Principles for preparation of the interim report

This interim report has been prepared in accordance with the Swedish Annual Accounts Act and the Swedish Accounting Standards Board’s general guidelines. In the event that there are no general guidelines, guidance is sought where applicable from the recommendations of the Swedish Financial Accounting Standards Council. The same accounting policies and methods were used in the interim report as in the Company’s most recent annual report. Respiratorius only capitalizes development costs for projects that have entered clinical phase as well as for patent costs.

## Calendar

* Q3 Interim Report November 4, 2020
* Year-end report February 3, 2021

## Condensed consolidated income statement

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| (SEK 000s) | Jan. 1, 2020  June 30, 2020  6 months | Jan. 1, 2019  June 30, 2019  Cf 6 months | April 1, 2020  June 30, 2020  Q2 | April 1, 2019  June 30, 2019  Q2 | Jan. 1, 2019  Dec. 31, 2019  Cf 12 months |
| Net sales | 0 | 0 | 0 | 0 | 0 |
| Other operating income | 0 | 0 | 0 | 0 | 0 |
| **Gross profit/loss** | **0** | **0** | **0** | **0** | **0** |
| Research and development costs | -2,132 | -1,239 | -1,127 | -556 | -4,286 |
| Administrative costs | -2,045 | -3,553 | -971 | -2,277 | -5,036 |
| Other expenses | 0 | 0 | 0 | 0 | 0 |
| Capitalized patent and development costs | 1,802 | 3,043 | 913 | 2,076 | 6,181 |
| **Operating profit/loss before depreciation, amortization and impairment** | **-2,376** | **-1,749** | **-1,187** | **-757** | **-3,141** |
| Depreciation/Amortization | -1,266 | -1,108 | -633 | -554 | -1,913 |
| **Operating profit/loss after depreciation, amortization and impairment** | **-3,641** | **-2,857** | **-1,820** | **-1,311** | **-5,054** |
| Profit/loss from financial investments | -315 | 0 | -236 | 0 | 0 |
| **Profit/loss after financial items** | **-3,956** | **-2,857** | **-2,056** | **-1,311** | **-5,054** |
| Taxes | 0 | 0 | 0 | 0 | 0 |
| **Loss for the year** | **-3,956** | **-2,857** | **-2,056** | **-1,311** | **-5,054** |

## Condensed income statement – Parent Company

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| (SEK 000s) | Jan. 1, 2020  June 30, 2020  6 months | Jan. 1, 2019  June 30, 2019  Cf 6 months | April 1, 2020  June 30, 2020  Q2 | April 1, 2019  June 30, 2019  Cf Q2 | Jan. 1, 2019  Dec. 31, 2019  Cf 12 months |
| Net sales | 0 | 0 | 0 | 0 | 0 |
| Other operating income | 0 | 0 | 0 | 0 | 0 |
| **Gross profit/loss** | **0** | **0** | **0** | **0** | **0** |
| Research and development costs | -1,158 | -972 | -592 | -553 | -3,101 |
| Administrative costs | -2,078 | -1,976 | -1,155 | -1,036 | -3,560 |
| Other expenses | 0 | 0 | 0 | 0 | 0 |
| Capitalized patent and development costs | 1,024 | 1,277 | 679 | 710 | 3,720 |
| **Operating profit/loss before depreciation, amortization and impairment** | **-2,212** | **-1,672** | **-1,068** | **-880** | **-2,941** |
| Depreciation/Amortization | -550 | -516 | -275 | -258 | -729 |
| **Operating profit/loss after depreciation, amortization and impairment** | **-2,763** | **-2,188** | **-1,343** | **-1,138** | **-3,670** |
| Profit/loss from financial investments | -615 | -300 | -386 | -150 | -1,380 |
| **Profit/loss after financial items** | **-3,378** | **-2,488** | **-1,730** | **-1,288** | **-5,050** |
| Taxes | 0 | 0 | 0 | 0 | 0 |
| **Loss for the year** | **-3,378** | **-2,488** | **-1,730** | **-1,288** | **-5,050** |

## Condensed Consolidated Balance Sheet

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| (SEK 000s) | **June 30, 2020** | **June 30, 2019** | **Dec. 31, 2019** | **Dec. 31, 2018** |
| ASSETS |  |  |  |  |
| Intangible assets | 16,233 | 13,364 | 15,697 | 11,429 |
| Property, plant and equipment | 0 | 0 | 0 | 0 |
| Financial assets | 0 | 0 | 0 | 0 |
| **Total non-current assets** | **16,233** | **13,364** | **15,697** | **11,429** |
| **Total current assets** | **2,915** | **6,404** | **1,916** | **10,714** |
| **Total assets** | **19,148** | **19,768** | **17,613** | **22,144** |
| LIABILITIES AND EQUITY |  |  |  |  |
| **Total equity** | **11,910** | **18,063** | **15,866** | **20,920** |
| Non-current liabilities | 0 | 0 | 0 | 0 |
| Current liabilities | 7,238 | 1,705 | 1,747 | 1,223 |
| **TOTAL EQUITY AND LIABILITIES** | **19,148** | **19,768** | **17,613** | **22,144** |

## Condensed balance sheet – Parent Company

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| (SEK 000s) | **June 30, 2020** | **June 30, 2019** | **Dec. 31, 2019** | **Dec. 31, 2018** |
| ASSETS |  |  |  |  |
| Intangible assets | 8,442 | 5,738 | 7,969 | 4,978 |
| Property, plant and equipment | 0 | 0 | 0 | 0 |
| Financial assets | 8,552 | 7,832 | 8,152 | 6,832 |
| **Total non-current assets** | **16,994** | **13,570** | **16,121** | **11,810** |
| **Total current assets** | **2,829** | **6,192** | **1,650** | **10,334** |
| **Total assets** | **19,823** | **19,762** | **17,771** | **22,144** |
| LIABILITIES AND EQUITY |  |  |  |  |
| **Total equity** | **12,667** | **18,607** | **16,045** | **21,095** |
| Non-current liabilities | 76 | 81 | 76 | 81 |
| Current liabilities | 7,080 | 1,073 | 1,650 | 967 |
| **TOTAL EQUITY AND LIABILITIES** | **19,823** | **19,762** | **17,771** | **22,144** |

## Summary Consolidated Statement of Cash Flows

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| (SEK 000s) | Jan. 1, 2020  June 30, 2020  6 months | Jan. 1, 2019  June 30, 2019  Cf 6 months | April 1, 2020  June 30, 2020  Q2 | April 1, 2019  June 30, 2019  Cf Q2 | Jan. 1, 2019  Dec. 31, 2019  Cf 12 months |
| Cash flow from operations during the period | -2,691 | -1,749 | -1,423 | -758 | -3,141 |
| Changes in working capital | -794 | 614 | -1,291 | 4 | 677 |
| **Cash flow from operations after change in working capital** | **-3,485** | **-1,135** | **-2,714** | **-754** | **-2,464** |
| Cash flow from investing activities | -1,802 | -3,043 | -913 | -2,076 | -6,181 |
| Cash flow from financing activities | 5,000 | 0 | 0 | 0 | 0 |
| **Cash flow for the period** | **-286** | **4,178** | **-3,627** | **-2,830** | **-8,645** |
| Cash/cash equivalents at beginning of period | 1,621 | 10,266 | 4,961 | 8,918 | 10,266 |
| **Cash/cash equivalents at end of period** | **1,334** | **6,088** | **1,334** | **6,088** | **1,621** |

## Condensed Statement of Cash Flows - Parent Company

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| (SEK 000s) | Jan. 1, 2020  June 30, 2020  6 months | Jan. 1, 2019  June 30, 2019  Cf 6 months | April 1, 2020  June 30, 2020  Q2 | April 1, 2019  June 30, 2019  Cf Q2 | Jan. 1, 2019  Dec. 31, 2019  Cf 12 months |
| Cash flow from operations during the period | -3,928 | -1,972 | -2,005 | -1,030 | -4,321 |
| Changes in working capital | -1,496 | -1,173 | -1,448 | -1,173 | -1,253 |
| **Cash flow from operations after change in working capital** | **-5,424** | **-3,145** | **-3,453** | **-2,203** | **-5,575** |
| Cash flow from investing activities | 377 | -977 | 21 | -559 | -3,125 |
| Cash flow from financing activities | 5,000 | 0 | 0 | 0 | 0 |
| **Cash flow for the period** | **-47** | **-4,122** | **-3,432** | **-2,762** | **-8,700** |
| Cash/cash equivalents at beginning of period | 1,367 | 10,067 | 4,751 | 8,707 | 10,067 |
| **Cash/cash equivalents at end of period** | **1,319** | **5,945** | **1,319** | **5,945** | **1,367** |

## Condensed consolidated statement of changes in equity – Jan. 1, 2020 – June 30, 2020

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| (SEK 000s) | Share capital | Restricted reserves | Unrestricted reserves | Profit/loss for the year |
| **Amount at start of period** | **7,858** | **22,886** | **-9,823** | **-5,054** |
| Transfer of profit/loss |  |  | -5,054 | 5,054 |
| Fund for development costs |  | 165 | -165 |  |
| Profit/loss for the period |  |  |  | -3,956 |
| **Amount at end of period** | **7,858** | **23,051** | **-15,042** | **-3,956** |

## Condensed statement of changes in equity – Parent Company Jan. 1, 2020 – June 30, 2020

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| (SEK 000s) | Share capital | Restricted reserves | Unrestricted reserves | Profit/loss for the year |
| **Amount at start of period** | **7,858** | **22,886** | **-9,649** | **-5,050** |
| Transfer of profit/loss |  |  | -5,050 | 5,050 |
| Fund for development costs |  | 165 | -165 |  |
| Profit/loss for the period |  |  |  | -3,378 |
| **Amount at end of period** | **7,858** | **23,051** | **-14,864** | **-3,378** |

## Submission of report

Lund, August 25, 2020

Respiratorius AB (publ)

Board of Directors

## For additional information, please contact:

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Telephone: 070-922 41 40

1. Earnings per share: Profit/loss for the period divided by 157,171,975 shares as of June 30, 2020 (number of shares as of June 30, 2019 was 157,171,975). [↑](#footnote-ref-1)
2. Equity ratio: Shareholders’ equity divided by total capital [↑](#footnote-ref-2)