Biolnvent





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## Develops antibodies for the treatment of cancer

BioInvent is a clinical stage company that discovers and develops antibodies for cancer therapies. Based on extensive knowledge in immunology, cancer biology and antibody biology, BioInvent generates innovative immuno-oncological drug candidates.

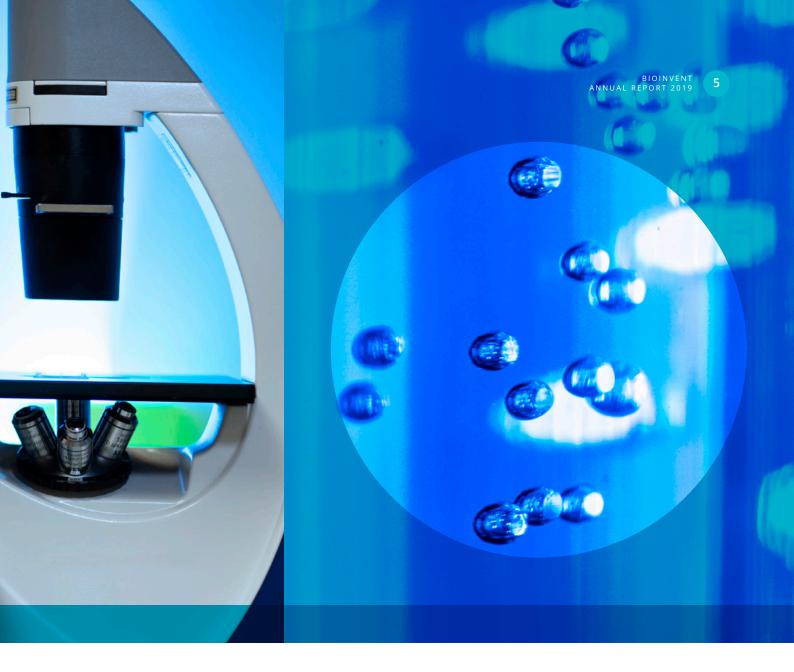
BioInvent discovers and develops novel and first-in-class immuno-modulatory antibodies for cancer therapies, with two ongoing programs in Phase I/II clinical trials for the treatment of hematological cancer and solid tumors, respectively. Two preclinical programs in solid tumors are expected to have entered clinical trials by the end of 2020.

The Company's validated, proprietary F.I.R.S.T™ technology platform simultaneously identifies both targets and the antibodies that bind to them, generating many promising new drug candidates to fuel the Company's own clinical development pipeline or for additional licens-

ing and partnering. The Company generates revenues from research collaborations and license agreements with multiple top-tier pharmaceutical companies, as well as from producing antibodies for third parties in the Company's fully integrated manufacturing unit.

#### **Mission**

BioInvent's primary goal is to develop next generation immuno-oncological drugs with a focus on improving therapeutic results in areas with significant unmet need.



#### **Strategy**

BioInvent's strategy is to leverage its expertise in immunology, cancer biology and antibody biology to develop cancer immunotherapies to improve the quality of life for cancer patients. This is accomplished through collaborations with pharmaceutical companies, academic research groups, networks of clinical specialists and research foundations. The goal is to create value for the Company's shareholders based on successful drug development and subsequent revenue streams from existing and future commercial partners.

#### **Business model**

BioInvent has three main areas for commercialization. The Company's primary value drivers are clinical and preclinical development projects. BioInvent also has research and development collaborations based on the Company's technology platform F.I.R.S.T™ and n-CoDeR®. BioInvent's manufacturing facility provides capacity to produce antibodies for the Company's preclinical studies and clinical trials, which is mandatory for a swift preclinical/clinical development path. The manufacturing facility provides also the opportunity to manufacture antibodies to external parties.

#### **Business focus**

BioInvent's current operational activities are focused on:

- Progressing and expanding the clinical development of its lead antibody BI-1206 for treatment of NHL, and in combination with pembrolizumab (KEYTRUDA®) in advanced solid cancers.
- Developing preclinical first-in-class antibodies targeting tumor associated myeloid cells in collaboration with Pfizer, potential other partners, or alone.
- Advancing three compounds into clinical programs:
  - BI-1808, the Company's most advanced anti-TNFR2 antibody, as a single agent and in combination with an anti-PD1 antibody. A clinical trial application is expected to be submitted in H1 2020.
  - BI-1607 (an anti-FcyRIIB antibody) in combination with a checkpoint inhibitor. A clinical trial application is expected to be submitted in Q1 2021.
  - Developing, in combination with Transgene, oncolytic viruses encoding either a proprietary anti-CTLA-4 antibody sequence, or antibody sequences targeting undisclosed targets for the treatment of solid tumors.
     BT-001, an anti-CTLA-4/oncolytic virus – a clinical trial application was submitted in Q1 2020.



# Progressing through multiple clinical trials and developing a promising preclinical portfolio

#### Clinical and preclinical development

- In January the U.S. Food and Drug Administration granted orphan designation for the antibody BI-1206 for the treatment of mantle cell lymphoma.
- In March, BioInvent announced a broad anti-TNFR2 program to treat solid tumors. Through its unique technology platform, BioInvent has generated a broad panel of highly specific anti-TNFR2 antibodies, including BI-1808
- In June, BioInvent published first clinical data from two parallel phase I/lla clinical trials of its lead product candidate BI-1206 as single agent and/or in combination with rituximab.
- In August, BioInvent announced that a phase I/IIa study in advanced solid tumors will be conducted with BI-1206 in combination with pembrolizumab (Keytruda).
   In December, BioInvent announced that Merck will contribute with the drug Keytruda to the study. In July, BioInvent received authorization from FDA to proceed for an IND application for a phase I/IIa clinical trial.

#### **Development collaborations and license agreements**

In March, BioInvent and Transgene announced an extension of their collaboration to co-develop multi-functional oncolytic viruses for the treatment of solid tumors.

- In April, BioInvent received a €0.75 million milestone payment from Mitsubishi Tanabe Pharma Corporation in connection with enrollment of the first patient in a phase II clinical trial of an antibody identified from BioInvent's proprietary n-CoDeR® antibody library.
- In July, BioInvent received a \$0.5 million milestone payment from XOMA Corporation related to the acceptance by FDA of an IND application for TAK-169.
- In July, BioInvent announced that Pfizer Inc. had selected the first target discovered by BioInvent's technology platform F.I.R.S.T ™, resulting in a \$0.3 million payment to BioInvent.
- In October, BioInvent signed a manufacturing agreement with Cancer Research UK, CRUK, expected to generate approximately SEK 30 million.
- In December, BioInvent and Transgene announced compelling preclinical data for BT-001 in solid tumors.
- In December, BioInvent announced that Pfizer Inc.
  had selected the second target under the companies'
  research collaboration resulting in a \$0.3 million
  payment to BioInvent and that the agreement was
  extended by six months.



 In December, BioInvent's partner Oxurion announced that no further investment will be done in the clinical development of THR-317, which was evaluated for diabetic macular edema. Oxurion carries all costs for the development of THR-317 in non-oncology indications, and BioInvent is entitled to five percent of the project's economic value.

#### **Publications and conferences**

- In March, a review article was published in Frontiers in Immunology, entitled "Targeting the antibody checkpoints to enhance cancer immunotherapy – focus on FcyRIIB" on the mechanisms of resistance to antibody drugs.
- In November, BioInvent held a poster presentation at ASH 2019 with preclinical data on BI-1206 in mantle cell lymphoma.

#### **Financing**

 In April, a rights issue and a private placement were completed, with a Swedish pension fund and a Swedish life science fund, totaling SEK 240.5 million before issue costs.

#### **Extended patent protection**

- In March, BioInvent announced that the United States
   Patent and Trademark Office (USPTO) had issued a
   Notice of Allowance for a patent application relevant to
   its F.I.R.S.™ platform. The patent covers methods for
   differential biopanning.
- In August, USPTO issued a Notice of Allowance for a patent application relating to BI-1206. The patent covers treatment of B cell lymphoma or chronic lym-

phatic leukemia using the Company's drug candidate BI-1206, or one of several other anti-FcyRIIB antibodies, in combination with an anti-CD20 antibody, such as rituximab.

#### Events after the end of the financial year

- BioInvent and Transgene announced in March 2020 that the first clinical trial application for BT-001 was submitted and that the first-in-human trial is expected to start before the end of 2020 in Europe and the US.
- Biolnvent announced in March 2020 that necessary precautions were taken with regard to the coronavirus and that the Company will continue to monitor its spread and associated measures closely. BioInvent has clinical trials in process and clinical trials soon to be initiated. Global measures against the coronavirus and the need to prioritize healthcare resources will likely affect the timelines for these studies. The precise impact is difficult to assess at this stage, given the rapidly developing situation. We may see a delay of the early results from the Phase I open label study with a combination of BI-1206 and rituximab for treatment of Non-Hodgkin Lymphoma (NHL), which, however, are still expected in H2 2020. For the time being, early clinical trial results for BI-1206 in combination with pembrolizumab and clinical trial initiations in other programs remain on track.
- In March 2020, BioInvent announced an agreement with SkylineDx to characterize the gene expression and immunological signatures in tumors of patients preand post-treatment with BI-1206.



## Consistent delivery on our strategic targets

2019 was an eventful year for BioInvent, in which we consistently delivered on our targets. We successfully moved forward in clinical and preclinical development and in our partnerships both with the industry and with academia.

Starting with our clinical development, I want to highlight taking our lead substance, the proprietary antibody BI-1206, into advanced solid tumors and the strong recognition we received from Merck & Co when they decided to sponsor our trial by supplying Keytruda. In recent years, Merck has become more selective in which combination trials to support, so it is a clear demonstration of their belief in BI-1206 and a sign of strength of our clinical development.

We also made good progress in hematological cancer. At the beginning of the year, the U.S. Food and Drug Administration (FDA) granted orphan designation for BI-1206 for the treatment of the hematological cancer form mantle cell lymphoma. Furthermore, we advanced the two parallel clinical studies of BI-1206, in combination with rituximab and as a single agent. In June 2019 Bio-Invent announced the publication of the first data from the two parallel Phase I/IIa clinical trials.

We are leading the way with our BI-1206 project as the only company to have a substance in clinical trials against the promising target FcyRIIB. In preclinical trials, BI-1206 has been shown to selectively block the receptor FcyRIIB. With this mechanism of action, BI-1206 is expected to recover and enhance the activity of rituximab, today's dominant therapy for hematological cancers and as such represents a significant commercial opportunity.

In November, our accomplishments were recognized as we had a poster at the world's most comprehensive annual hematology conference ASH in San Diego, USA, presenting strong preclinical data for BI-1206 in mantel cell lymphoma.

Our preclinical development has also taken important steps during the year. We have generated a broad panel of specific anti-TNFR2 antibodies through our F.I.R.S.T™ platform, and at the beginning of the year we announced a comprehensive anti-TNFR2 program for the treatment of solid tumors. We are excited about TNFR2 as a target and expect the proprietary antibody BI-1808 to be one of the antibodies that we will be able to extract from this promising program. We intend to submit a clinical trial application in H1 2020 to conduct a first-in-human trial with BI-1808.

Part of our preclinical work, such as the anti-TNFR2 program, is carried out on T-regulatory cells (Tregs), and part on tumor associated myeloid cells (TAMs), in collaboration with Pfizer. The work with Pfizer progressed well during the year, and we are very pleased that they have selected two targets within the scope of the agreement. Each resulted in a USD 0.3 million payment. We were also happy to announce that the agreement was extended by six months. Our hope is that Pfizer will also find pro-

mising antibodies from our proprietary n-CoDeR® library, which would be a further validation of our platform and also lead to significant payments.

In December, together with our partner Transgene, we announced that we had obtained convincing preclinical data for BT-001 in solid tumors. BT-001 is a co-developed multifunctional oncolytic virus and if our method of combining oncolytic viruses with antibodies works against the checkpoint inhibitor CTLA4, it could work with a variety of other antibodies. We thus see great potential and have submitted a clinical trial application to conduct a first-inhuman study.

We anticipate several important milestones in 2020 and beyond. This will include early results from the Phase I open label study with a combination of BI-1206 and rituximab in indolent NHL in the second half of the year. We will also be initiating the Phase I/lla study of BI-1206 in combination with pembrolizumab, as mentioned above, with early results from the Phase I study expected in the second half of 2021. We are expecting to advance two compounds into clinical programs in solid cancer: the anti-TNFR2 antibody BI-1808, as single agent and in combination with an anti-PD1 antibody, in 2020; and the anti-FcyRllB antibody BI-1607 in combination with a checkpoint inhibitor in 2021.

As BioInvent continues to bring new programs towards clinical development, financing is of course a priority and we will continue to use a combination of sources for funding. Firstly, we are engaged in several business development discussions with the aim of partnering one or more of the programs in our portfolio. Secondly, the collaboration with Pfizer, which is also a model for other potential collaborations which commercialize our platform. Thirdly, our manufacturing capabilities generate revenue, with the most recent agreement with CRUK expected to generate SEK 30 million. CRUK has the potential to become a long-term strategic partner, as it works with a number of small- to mid-sized companies that need manufacturing support. And our fourth option is to use capital markets for financing. Based on the support from our large institutional investors and increased interest in our programs we feel optimistic that a combination of these four sources will continue to support BioInvent financially. The Board of Directors follows the financing situation and is working on a plan to ensure the Group's continued financing.

I would like to take this opportunity to thank our partners, within academia and in the industry, and our shareholders for the support shown in 2019 and our employees for their dedication to transforming the treatment of cancer to improve the lives of patients. BioInvent is at a truly exciting moment in its history and I look forward to leading our development, and reporting back to you regularly on our journey.

Martin Welschof, CEO



# One of the main breakthroughs of the 21st century

Immunotherapy is a type of treatment that induces and boosts the body's natural defenses in order to combat certain diseases, such as cancer. Immunotherapy represents a paradigm shift in the treatment of cancer and has enabled patients with advanced and metastatic cancer who have no other treatment options to be cured. The field of research relating to cancer within immunotherapy is known as immuno-oncology.

#### **Immunotherapy**

Immunotherapy activates the body's own immune system and teaches it to recognize and attack cancer cells in the body. However, the immune system must not attack healthy tissue and there are therefore a number of "control mechanisms" to prevent it destroying one's own body. It is these control mechanisms that the cancer cells utilize to avoid an attack by the immune system. Immunotherapy can increase the activity of the immune system either by directly activating immune cells (stepping on the accelerator) or by reducing the inhibitory signals that control the immune cells (releasing the brake).

One of the great advantages of immunotherapy is that a part of the immune cells that eliminate the tumor cells continues to live on in the body and have what is known as a tumor-specific immunological memory (the same principle as in vaccinations). This immunological memory both provides protection against recurring cancer and eradicates metastases spread in the body, and is unique to immunotherapy. The cells that provides the immunological memory are called B and T cells. In immuno-oncology it has been shown that it is precisely the generation of cancer-specific T cells that is crucial for a good effect.

## Treatment options within immunotherapy and immuno-oncology

Immuno-oncology aims to improve the function of the immune system, primarily by:

- helping the immune system to recognize and destroy cancer cells, including metastases;
- stopping the cancer from spreading to other parts of thebody; and
- inducing an immunological memory which will prevent the cancer from returning in the future.

To achieve the positive effects of immunotherapy and get the body's immune system to attack the malignant tumor cells, there are a number of different treatment options; where some of the most common are monoclonal antibodies, checkpoint inhibitors, oncolytic virus therapy and T cell therapy (CAR-T). BioInvent is primarily active in monoclonal antibodies such as checkpoint inhibitors, but also in oncolytic virus therapy in collaboration with Transgene.

#### Monoclonal antibodies and checkpoint inhibitors

When the body's immune system discovers something harmful and foreign, it produces antibodies towards it. A monoclonal antibody is an antibody that originates from a single B cell and is therefore the product of a cellular clone. For example, monoclonal antibodies can be used as a targeted treatment to bind to an abnormal protein on a cancer cell. When monoclonal antibodies attach to the tumor cells' specific proteins, the tumor cells are marked and thereby identified and attacked by certain cells of the immune system, e.g. macrophages and other myeloid cells which will ultimately kill them. Another example of immunomodulatory antibodies is T cell-activating antibodies or checkpoint inhibitors. Activation of T cells are essential for an effective immune response against cancer, but in cancerous tissue T cell activation are often inhibited by certain molecules known as checkpoints. By blocking these checkpoints, T cell activation is restored and tumors can be eradicated.

There are checkpoints on the surface of immune cells, which act as a switch for inactivating the immune system. In some cases, cancer cells manipulate these proteins to avoid attacks. For the past few years, immuno-oncology drugs that are capable of blocking the checkpoint receptors PD-1 and CTLA-4 and also the ligand PD-L1 have been used. They have produced good treatment results in certain types of solid tumors and achieved great commercial success, but unfortunately they only help a minority of patients with metastatic cancer. Consequently, intense efforts are underway to develop new drugs that can complement the checkpoint inhibitors.

BioInvent's BI-1206 program in solid tumors is focused on complementing the checkpoint inhibitor PD-1 by counteracting resistance to PD-1 inhibition.

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In January 2020 Anne Ljungars presented her doctorate thesis to the Department of Immunotechnology in the Faculty of Engineering at Lund University (LTH).

Phage display is an established technique with uses that include finding antibodies for various types of targets. BioInvent's screening tool F.I.R.S.T™ was produced by supplementing phage display with new techniques. In her thesis "Phenotypic antibody discovery and mining of complex antibody libraries", Anne Ljungars shows that the technique creates great opportunities for finding many more antibodies than previously.

Antibody drugs are the fastest growing type of drugs and are already used today to treat a range of different diseases, including cancer. However, few new types of antibody drugs are being discovered. One way to find antibodies for drugs is to use phage display to search through a huge library often containing more than 10 billion different antibodies. To then find the individual antibody that works best requires a lot of work.

Traditionally, the work is carried out according to a hypothesis in which first a receptor is found that is believed to be suitable for antibody drugs. The search then begins for antibodies that bind to this receptor. However, by combining new techniques with looking simultaneously for both antibodies and the receptors they bind to, it is possible to find many more functioning antibodies than previously.

"What we do is find antibodies against large amounts of different receptors on the cell and look at these antibodies' function directly. The strategy is to test how the antibodies work without any prior assumptions; for example, whether it can kill a tumor cell. Once we have identified which antibodies work, various tests are carried out to determine which receptor these bind to. By doing this, we have found antibodies that bind to cancer cells but not to normal cells in healthy individuals," says Anne Ljungars.

The process of looking for antibodies and targets simultaneously, rather than first finding a target and then looking for a suitable antibody is central in BioInvents

F.I.R.S.T<sup>™</sup> platform. It is this strategy, combined with new techniques, that is enabling many more antibodies to be found than before.

"This method will be important for the development of future antibody drugs that can be used to treat many different diseases," says Anne Ljungars.



Anne Ljungars has a doctorate in immunotechnology and works at BioInvent. The research was carried out as a collaboration between BioInvent and the Department of Immunotechnology in the Faculty of Engineering at Lund University (LTH), and was financed by BioInvent and the Swedish Foundation for Strategic Research. Anne Ljungars' opponent for the defense of her thesis was Sir Gregory Winter, who was the first to develop phage display to find antibodies.



## Platform for effective drug development

BioInvent has a leading immuno-oncology platform that both generates antibodies and identifies relevant targets. The unique development tool F.I.R.S.T™, where patient material is the foundation throughout the development process, simultaneously identifies the clinically most relevant targets in a disease model and matching antibodies. The proprietary antibody library n-CoDeR® contains antibodies that bind specifically and strongly to their targets.

#### The development tool F.I.R.S.T™

BioInvent has developed a patented screening tool called F.I.R.S.T™, which is an important technical tool for internal drug development as well as for external development partners. The platform is patient-centred and facilitates the development of new antibody therapies, as new drug candidates can be produced without detailed knowledge of the antibodies' target proteins. This unique method has the advantage of simultaneously identifying disease-associated targets and antibodies that bind to them.

The method makes it possible to simultaneously investigate antibody binding to both diseased and healthy tissue in order to select those antibodies and targets that are unique to diseased tissue in terms of binding and expression. Through functional, high-capacity screening, antibodies are then selected on the basis of, for example, their ability to induce cell death of primary cancer cells or improve the immune system's capacity to eliminate tumor cells.

#### The n-CoDeR® antibody library

BioInvent's antibody library n-CoDeR® contains more than 30 billion human antibody genes stored within phages in test tubes. These act as production units for various antibodies, making it possible to search the library to identify precisely those antibodies that bind to a specific target protein. The n-CoDeR® library is searched using an established technology called phage display. To identify an optimal antibody, BioInvent has developed automated processes in which robots carry out the analysis on an industrial scale. The n-CoDeR® library consists of naturally occurring human antibody genes. Every component comes from nature, but the combinations are largely new, making it possible to build an antibody repertoire that is greater than nature's own variability. BioInvent calls this "evolution beyond nature".



## Important targets for BioInvent

BioInvent is developing antibodies specifically targeting regulatory T cells and tumor-associated myeloid cells, both of which are strongly immunosuppressive, and Fcy receptors. All these approaches have synergy effects when combined with the checkpoint inhibitors available today.

#### **Anti-FcyRIIB**

BioInvent has a broad initiative relating to the antibody checkpoint target FcyRIIB. FcyRIIB is a member of the FcyR family and, is the only known inhibitory Fcy receptor. There is preclinical research showing that the activity of many antibodies used in cancer treatment, including all three T cell checkpoint inhibitors currently on the market, anti CTLA-4, PD-1 or PD- L1, are regulated by Fcy interactions. BioInvent has preclinical data suggesting that the effect of such antibodies can be boosted through modulation of FcyRIIB and evaluates this in clinical trials. *BI-1206 and BI-1607 have FcyRIIB as target*.

#### **Tregs**

Cancer-associated regulatory T cells (Tregs) are a subcategory of T cells which modulate the immune system and are of key significance for retaining tolerance of the body's own antigens as well as for preventing autoimmune diseases. Tregs are immunosuppressive and their most important task is to switch off cell-mediated immunity at the end of an immune reaction and to suppress autoreactive T cells. The essential role that regulatory T cells play in controlling the immune system in general, and other T cells more specifically. Since Tregs suppress the effect of the immune system so effectively, unfortunately this also enables a way for the tumor to use these to elude

the body's immune system. There are many publications showing a clear correlation between the number of Tregs in cancer patients and a poor prognosis.

BT-001 and BI-1808 have Tregs as target.

#### **TAMs**

Myeloid cells are a key part of our innate non-specific immune system, but can also be "hijacked" by tumors to support the growth and spread of cancer. The three most important ways in which a tumor-associated myeloid cell (TAM) promote tumor growth are:

- suppression of immune response, among other things by preventing T cell activation
- production of growth factors that promote tumor growth and blood vessel formation
- disintegrating blood vessels and tissue in order to promote metastasis.

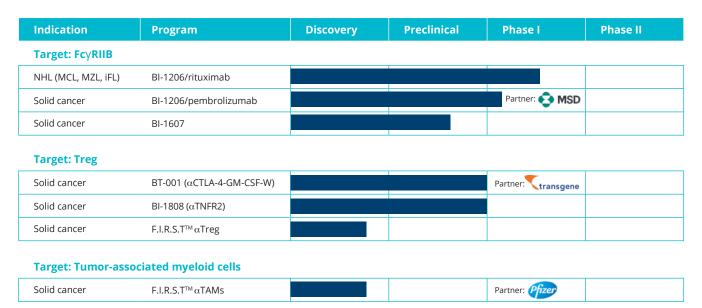
Antibody-mediated "reprogramming" of immunosuppressive TAMs to effector cells that can help to eliminate cancer cells is an attractive therapy concept and is a field of research where BioInvent and its partners are at the forefront. BioInvent is preparing to develop function-modulating antibodies against TAMs.

BioInvent's research collaboration with Pfizer is focused on TAMs.

### **PROJECT PORTFOLIO**

## Broad portfolio increases the chances of success

BioInvent has a portfolio of innovative programs in clinical and preclinical development with the potential to develop into new immuno-oncological drugs for cancer patients.



### Clinical programs

## BI-1206 in non-Hodgkin lymphoma and chronic lymphocytic leukemia

In June 2019 BioInvent announced the publication of the first data from the two parallel Phase I/lla clinical trials. Up to that point, in the UK trial, 10 patients had received single agent therapy with up to 100 mg BI-1206 once weekly for a period of 4 weeks. In the US/EU study, five patients had received up to 100 mg BI-1206 in combination with rituximab. The data were published in the Abstract Book from the 15-ICML International Conference on Malignant Lymphoma.

Receptor occupancy, i.e. the proportion of available FcyRIIB receptors that have bound BI-1206, is dose proportionate and high levels of receptor blockade should be seen at clinically relevant doses of BI-1206. Target-mediated drug disposition has not yet been overcome, and thus, the optimal dose has not yet been reached. Notwithstanding, pharmacodynamic analysis at the current doses showed depletion of peripheral B cells, including circulating mantle cell lymphoma cells during the first week of therapy. Early results from the Phase I open label study in indolent non-Hodgkin lymphoma is expected in H2 2020.

In November 2019 BioInvent had a poster presentation with preclinical data on BI-1206 at the annual American Society of Hematology (ASH) meeting in Orlando. The abstract highlighted a preclinical study of BI-1206 in an ibrutinib-venetoclax dual resistant PDX (patient derived xenograft) model derived from a mantle cell lymphoma (MCL) patient. Single agent BI-1206 had potent anti-MCL activity in the FcyRIIb-expressing MCL PDX model. FcyRIIb was further shown to be highly expressed in 27/27 primary patient MCL samples examined. Along with previously published data demonstrating an important role for FcyRIIB in resistance to rituximab-based cancer immunotherapy, and BI-1206 in boosting rituximab efficacy and overcoming rituximab-resistance, these data indicate the high potential of BI-1206 to address a significant unmet need in MCL and hematologic malignancy.

#### **Background**

BI-1206 is a high-affinity monoclonal antibody that selectivity bind to FcyRIIB (CD32B), the only inhibitory member of the FcyR family. FcyRIIB is overexpressed in several forms of NHL and overexpression has been associated with poor prognosis in difficult-to-treat forms of NHL, such as mantle cell lymphoma. By blocking FcyRIIB, BI-1206 is expected to recover and enhance the activity of

rituximab or other anti-CD20 monoclonal antibodies in the treatment of these diseases. The combination of the two drugs could provide a new and important option for patients suffering from NHL, and represents a substantial commercial opportunity.

In September 2018 BioInvent started a dose escalation, consecutive-cohort, open-label phase I/IIa study of BI-1206. The study will recruit approximately 30 patients across sites in the EU and the U.S. The trial is evaluating BioInvent's proprietary antibody BI-1206 in combination with rituximab in patients with indolent relapsed or refractory Fc NHL. The targeted subindications are mantle cell lymphoma, follicular lymphoma, and marginal zone lymphoma. The study will explore BI-1206's safety and tolerability, and seek to determine a recommended phase II dose (RP2D) when given in combination with rituximab. Expression of biomarkers will be assessed to explore a potential correlation with clinical activity.

This study is run in parallel with the ongoing Phase I/Ila study of BI-1206 in patients with CLL and NHL conducted in the UK by Cancer Research UK. The study is testing single agent activity. Given the overlap with BioInvent's own Phase I/Ila trial of BI-1206 in combination with rituximab in Non-Hodgkin Lymphoma (NHL), and the fact that standard of care for patients with chronic lymphocytic leukemia (CLL) has dramatically evolved over the last few years, recruitment in the UK study has become increasingly challenging in particular since CRUK can only carry out trials in the UK. For these reasons we have agreed to limit the CRUK study to monotherapy, which is almost completed. This will result in a more complementary work and more efficient use of resources.

In January 2019 the U.S. Food and Drug Administration granted orphan designation for BI-1206 for the treatment of mantle cell lymphoma.

#### **Patent protection**

Patent projection for the use of antibodies against CD32B, such as BI-1206, in combination with other antibodies, such as rituximab, in the treatment of cancer or inflammatory diseases in certain patient groups has been applied for in a number of large markets. So far, patents have been granted in the main markets Europe, the US and Japan, as well as other markets. Patent protection has also been sought in a second patent family in the main markets Europe, the US and Japan and other markets, for the treatment of cancer patients who are no longer responding to previous antibody therapy. The first patent family expires in 2031 in most markets, including Europe, and in 2034 in the US. Patents granted in the second patent family will expire in 2035, or possibly later in the US.

## BI-1206 in combination with pembrolizumab in solid tumors

In July 2019 BioInvent received authorization from the FDA to proceed for an IND application for a Phase I/IIa clinical trial of BI-1206 in combination with pembrolizumab for the treatment of solid tumors.



BioInvent entered in December 2019 into a clinical trial collaboration and supply agreement with Merck, to evalu-ate the combination of BioInvent's BI-1206, one of its proprietary anti-FcyRIIB antibodies and Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in a Phase I/ lla clinical trial for patients with solid tumors. The agreement helps BioInvent to expand BI-1206 clinical development to solid tumors in combination with one of the most successful immuno-oncology drugs. Early results from the Phase I open label study is expected in H2 2021.

#### **Background**

The program is based on BioInvent's preclinical data demonstrating the ability of BI-1206 to address an important mechanism of resistance to PD1 inhibition, providing a way to enhance anti-tumor immune responses in patients with solid tumors. The Phase I/IIa clinical trial will evaluate the drug combination in patients with advanced solid tumors, who have been previously treated with anti-PD1 or anti-PD-L1 antibodies, and is a multicenter, dose-finding, consecutive-cohort, open-label trial. The Phase I/IIa trial is planned to be carried out in the U.S. and the EU.

#### **Patent protection**

A patent application relating to the combination of BI-1206 or similar anti-CD32B antibodies and an anti-PD-1 antibody has been filed, and is expected to proceed into a patent family covering several markets.

#### TB-403 in pediatric brain tumors

TB-403 is currently in a Phase I/II study for the treatment of patients with medulloblastoma in cooperation with a US based pediatric oncology network, Beat Childhood Cancer. TB-403 is not within BioInvent's current main focus.

TB-403 has received Orphan Designation for medulloblastoma from the European Medicines Agency (EMA). TB-403 is developed in collaboration with Oncurious, a subsidiary of Oxurion. BioInvent's ownership in TB-403 is 50 percent and it contributes with 50 percent of the development costs.

### Preclinical programs

BioInvent's preclinical research is focused on developing novel immuno-modulatory antibodies for cancer therapy. Such antibodies may significantly improve efficacy of currently available checkpoint inhibitor therapies and/or activate anti-cancer immunity in currently non-responding patients and cancer types.

#### Strategic collaboration with Pfizer - developing antibodies that act on tumor-associated myeloid cells

In partnership with Pfizer Inc. since December 2016, BioInvent works to identify novel oncology targets and therapeutic antibodies that may either reverse the immunosuppressive activity of tumor-associated myeloid cells or reduce the number of tumor-associated myeloid cells in the tumor.

BioInvent announced in July 2019 selection of the first target and in December 2019 the second target discovered by BioInvent's proprietary F.I.R.S.T™ technology platform under the collaboration with Pfizer Inc. The selection of targets triggered two payments from Pfizer to BioInvent of \$0.3 million. Under the terms of the 2016 agreement, potential selection and development of antibodies directed against these targets, as well as potential selection of further targets and development of antibodies directed at them, would allow BioInvent to be eligible for further milestone payments.

In December 2019 BioInvent announced that the research term under its collaboration and license agreement with Pfizer had been extended by six months. The purpose of the research extension is to permit the companies to further identify and characterize new targets and antibodies binding to these targets.

BioInvent is eligible for potential future development milestones in excess of \$500 million (assuming five antibodies are developed through to commercialization). The Company could also receive up to double digit royalties related to product sales. In exchange, Pfizer will have the right to develop and commercialize any antibodies generated from this agreement.

BioInvent received an upfront payment of \$3 million when the agreement was signed in December 2016, and research funding has been received during 2017, 2018 and 2019. Pfizer also made a \$6 million equity investment in new shares of BioInvent when the agreement was signed.

## Developing antibodies that act on regulatory T cells (Tregs) via novel or validated targets

Tregs can substantially inhibit various immune responses, enabling tumor cells to escape detection. BioInvent is utilizing its F.I.R.S.T™ platform to identify and characterize monoclonal antibodies to cancer-associated Treg targets in a function-first, target-agnostic, manner. The company is also pursuing differentiated antibodies to known targets through novel mechanisms and pathways.

#### BI-1808 (anti-TNFR2)

BioInvent has identified TNFR2, a member of the so called TNFR superfamily (TNFRS) as a target within the Treg program. The company has antibody candidates with various mechanisms of action that show promising preclinical data. A clinical trial application is expected to be submitted in H1 2020 for BI-1808.

## BT-001 – Partnership with Transgene – developing next generation oncolytic viruses expressing an anti-CTLA-4 antibody to treat solid tumors

In December 2019 BioInvent and Transgene announced preclinical data for BT-001 in solid tumors. The therapeutic activity was assessed in several immunocompetent preclinical models, showing outstanding antitumoral activity for BT-001 murine surrogate antibody-encoding viruses conferring cures in a majority of mice transplanted with different solid cancer tumors (> 70 % in all tested models). The new preclinical data also confirmed that the anti-CT-LA4 antibody expressed by BT-001 in mouse tumor cells retained biochemical integrity and folding, functionality, and biological activity. In addition, BT-001's biodistribution profile demonstrated higher concentration and prolonged activity of the anti-CTLA4 antibodies in tumors compared to intravenous anti-CTLA-4 antibody therapy. Preclinical data on BT-001 will be presented at scientific meetings in the coming months.

BioInvent and Transgene announced in March 2020 that the first clinical trial application for BT-001 was submitted and that the first-in-human trial is expected to start before the end of 2020 in Europe and the US.

#### **Background**

BioInvent and Transgene collaborate to co-develop oncolytic virus (OV) candidates encoding a validated anti-CTLA-4 antibody sequence – potentially with additional transgenes – aimed at treating solid tumors, with the potential to be significantly more effective than the combination of a virus and an antibody as single agents.

Transgene is contributing both engineering expertise, as well as its proprietary Vaccinia viruses, designed to directly and selectively destroy cancer cells by intracellular replication of the virus in the cancer cell (oncolysis). Oncolysis induces an immune response against tumors, while the "weaponized" virus allows the expression of genes carried by the viral genome, here an immune modulatory anti-CTLA-4 antibody, which will further boost immune response against the tumor.

BioInvent is providing its cancer biology and antibody expertise to the collaboration, as well as anti-CTLA-4 antibody sequences generated through its proprietary n-CoDeR®/F.I.R.S.T<sup>TM</sup> platforms.

In March 2019 BioInvent and Transgene announced an extension of their collaboration to co-develop multifunctional oncolytic viruses encoding antibodies targeting an undisclosed target, which can be used in the treatment of a broad range of solid tumors.

The research and development costs, as well as revenue and royalties from candidates generated from the collaboration, are shared 50:50.





# It now comes down to getting proof in the clinical phase

In our day-to-day work, each new antibody that we see having an effect is exciting – but in the slightly longer term, the proof of our work is when an antibody moves into the clinical phase.

#### What do you do within preclinical at BioInvent?

In principle, we have the same procedure for all preclinical projects. First we screen antibodies from our library and then we test them functionally. We look for the antibody that is best, and then we ask ourselves why it was best. Over a year we must surely investigate hundreds of antibodies and we are always trying to understand how they work. The more we understand about why a particular antibody works well, the better we can design a clinical trial.

#### Does the work always take the same form?

No, that's why it's particularly enjoyable working at Bio-Invent. Our research is not only broad – in other words, we test many different antibodies within different areas – but it also extends from very early research to relatively late research – late for preclinical that is. In early projects, such as our TAM project with Pfizer, we test several hundred antibodies to find a suitable antibody to take further. In a late preclinical project, such as the antibody BI-1808, we have selected a specific antibody and test precisely that one in many different experiments to understand how it works.

#### Why is your preclinical work focused on Tregs?

It has been known for a long time that the adaptive immune system is able to recognize cancer cells as dangerous, but it is only over the past 10 years that it has been possible to show that the body's immune system can actually entirely eliminate large tumors. An immune system that is in balance can quickly be activated to deal with something that could harm us, such as bacteria or a viruses, while at the same time it can quickly be inhibited so as not to attack the body's own cells. In cancer, the cancer cells exploit the inhibiting, or regulatory, mechanisms in order to conceal themselves and avoid being attacked by the immune system, which allows the cancer to grow and

spread. We want to take away one of the key inhibiting mechanisms – the regulatory T cells, or Tregs – so that the immune system can be activated to kill the cancer cells. The regulatory T cells are part of the adaptive immune system and regulate both other T cells and cells such as macrophages (cells that disarm bacteria, for example) to suppress the immune system. By killing Tregs we allow the immune system to work as it should.

#### And how does it work with TAMs?

Tumor-associated myeloid cells, or TAMs, may make up 50 percent of a tumor mass and are therefore extremely important, but they are probably harder to eliminate than Tregs. Instead we believe it is more advantageous to try to reprogram them so that the immune system is activated. Not much research is being carried out in this area yet, because the basic research into TAMs started later than in the case of Tregs. Roche has a substance in clinical phase that acts on TAMs, but there is a great deal left to discover and the track we are on is very exciting.

## Pfizer invested early in the F.I.R.S.T™ TAM project. Why do you think they did that?

Yes, they invested even before we had produced antibodies or identified targets. I think they liked the idea and saw the potential of the platform once they had seen the high quality of our earlier work. The F.I.R.S.T™ methodology is extremely well suited to TAM research. In addition, we have good access to patient cells via our university collaborations, which can provide clearer validation of the results at an earlier stage and thus reduce the risk involved in development.

#### What makes BioInvent unique?

In addition to the F.I.R.S.T<sup>TM</sup> platform and the fact that we have an extremely strong preclinical team, we have good - not to say unique - collaborations with academia, which provides us with access to technology and models and researchers. Things that normally are very difficult to access outside of the academic world. The best example is probably our collaboration with the University of Southampton, which has been ongoing for 10 years. We have very close contact and call each other almost daily. Another important collaboration I would like to highlight is that with Skåne University Hospital, which among other things gives us access to patient samples. Both collaborations are unique and very valuable to us. We do not pay anything for the patient samples, for example, but instead get them because they believe in what we are doing after having worked with us for a long time. We have built up reciprocal trust.

#### What makes the F.I.R.S.T™ tool stand out?

Above all, the fact that we've been working on it for so long. We've been dissecting it and optimizing it for nearly 15 years now. That's a really long time, especially within biotech. The platform is unique in being able to look for antibodies and targets simultaneously, which is possible because we are testing against patient cells.

#### How do you do that?

We start with a patient's cell. It could be a cancer cell or a regulatory T cell that we may have received from Skåne University Hospital. We start with our n-CoDeR® library and from there select a large number of different types of antibodies that bind to the cell. We then test which of the antibodies is best at, say, killing the cell. At the same time, we investigate what the antibody binds to. In this way we find out which out of all the available targets and all the antibodies is best at – in this case – killing the cell we started with.

## What do you think is the most interesting thing in your preclinical program right now?

Personally, I'm very keen to see how things go with Bl-1808. In this project we know a lot about the specific antibody Bl-1808, but we are also gaining a deep understanding of the target – the receptor TNFR2. Another incredibly exciting area is oncolytic viruses. If BT-001, that is the virus loaded with anti-CTLA-4, works then the method – combining an oncolytic virus with antibodies – could also work with a whole load of other antibodies, so there is huge potential. The entire area is in its infancy and there is a great deal going on in this field, but nobody else has come further than us.

## What do you think will be the most exciting thing in 2020?

In our day-to-day work, each new antibody that we see having an effect is exciting – but in the slightly longer term, the proof of our work is when an antibody moves into the clinical stage. Although it means that our primary task in preclinical is at an end, it is only then that we get to see how the antibodies actually behave in humans and that's why it's very exciting to follow the progress of BI-1206, BI-1808 and BT-001. After all the years we have spent testing and understanding them, it then comes down to getting proof in the clinical stage.

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In addition to the F.I.R.S.T™ platform and the fact that we have an extremely strong preclinical team, we have good – not to say unique – collaborations with academia, which provides us with access to technology and models and researchers

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Ingrid Teige, Head of Preclinical Research teamat BioInvent



## A fast growing market

Immuno-oncology drugs constitute one of the main medical breakthroughs of the 21st century, and the first treatments have already increased the possibility of people being cured and surviving, although so far only in limited patient groups. The market is expected to expand as more products in this category are approved. Antibody-based immunotherapies have the potential to be used in the treatment of virtually all kinds of cancer. BioInvent develops antibody-based immunotherapies primarily aimed at treating hematological cancer and solid tumors.

#### The market for immunotherapy

Of the 10 best-selling drugs in the global pharmaceutical market, eight are biological – and seven of these are antibody-based. Oncology is the segment most dominated by antibody-based drugs. 79 therapeutic monoclonal antibodies have been approved in USA, and are currently on the market, including 30 monoclonal antibodies for the treatment of cancer.<sup>1)</sup>

Great progress has been made in immuno-oncology in recent years and the total market for immunotherapy drugs is also expected to grow rapidly in the future. The global immuno-oncology market is expected to reach USD 76 bn by 2022.<sup>2)</sup> The average cost for treatment with existing immunotherapy drugs is currently around USD 150,000 per patient and year. However, there are great differences between geographical regions and types of cancer and total cost depends on a number of factors including insurance coverage, types of cancer and treatment and frequency of treatment.<sup>3)</sup>

#### **Market trends**

The antibody-based drug segment is one of the fastest growing segments in the global pharmaceutical market. Although immuno-oncology therapies still only make up a fraction of the total oncology market, antibodies are a key element in this new approach. The 5 top-selling antibody-based cancer drugs in 2018 were Opdivo® (nivolumab, BMS), Keytruda (pembrolizumab, Merck), Herceptin® (trastuzumab, Roche), Avastin® (bevacizumab, Roche), Rituxan®/MabThera® (rituximab, Roche).

There are several factors that explain the strong market growth for antibody-based drugs and their use in immuno-oncology. Antibodies are the body's natural defence molecules. They are extremely selective and very well tolerated in their natural form; they exert a clear, specific effect and they are well integrated into the immune system, which can modulate their therapeutic effect. These types of biopharmaceuticals are more complex than small molecule drugs, which makes them more difficult to copy.

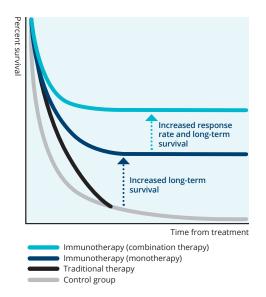
<sup>1)</sup> Development of Therapeutic antibodies for the treatment of diseases, Lu et al Journal of Biomedical science 2020 27:1.

<sup>2)</sup> Global Immuno-Oncology Market Demand Analysis /Opportunity evaluation 2019-2027. Nov 2019 and Global data market analysis 2018.

<sup>3)</sup> Reuters, "The cost of cancer: new drugs show success at a steep price", 3 april 2017.

#### **Combination therapy**

Combined therapy combines two or more therapies and is in the process of developing into an important element of cancer treatment. Combining various different treatment therapies allows multiple parts of the tumor to be attacked, preventing the tumor from eluding the immune system. The combinations may include both traditional treatments such as chemotherapy or radiotherapy and more recent treatments such as immunotherapies. By combining immune-boosting drugs with drugs that block the tumor's immune-inhibiting properties, the survival rate and quality of life of the patients can be substantially improved.



#### **Hematological cancer**

BioInvent's drug candidate that has advanced the farthest, BI-1206, has been developed to improve the effect of rituximab and overcome rituximab resistance in the treatment of hematological cancer, particularly non-Hodgkin lymphoma and chronic lymphocytic leukaemia.

Sales of rituximab (Rituxan®/Mabthera®) amounted to USD 6.6 billion in 2019 with projected sales of USD 5.0 billion in 2020 related mainly to treatment for haematological cancer.<sup>4)</sup>

Focusing on drugs for treatment of the four most prevalent B-cell NHL subtypes FL, MZL, DLBCL and MCL in the 7 major markets comprised of USA, France, Germany, Italy, Spain, UK and Japan sales are expected to reach USD 5.5 billion in 2024.<sup>5)</sup>

The largest actors within hematological cancer are Roche (Rituxan®, rituximab), GSK (Arzerra®, ofatumumab), Cephalon/TEVA (Treanda®, bendamustin) Merck/Keytruda®, BMS/Opdivo®, and Celgene/BMS (Revlimid®, lenalidomid).

#### **Non-Hodgkins lymphoma**

Non-Hodgkin lymphoma is an umbrella term for a group of cancers that develop in the body's lymphatic system. Non-Hodgkin lymphoma can be divided into a number of different sub-indications, of which BioInvent's focus segments comprise patients with mantle cell lymphoma (MCL), follicular lymphoma (FL) and marginal zone lymphoma (MZL). Aggressive lymphomas are usually treated with combinations of various chemotherapeutic agents and monoclonal antibodies such as rituximab (Rituxan®/Mabthera®, Roche). Low-grade lymphomas have a better prognosis and treatment is often only initiated once a patient has disease symptoms.

The Company's addressable market for the three initial main indications is believed to be, according to the Company's estimates, approximately USD 200 million per year in the US alone. In addition to these indications, there is further potential to later expand into other indications within non-Hodgkin lymphoma, including diffuse large-cell B cell lymphoma, Waldenstrom. macroglobulinemia and Burkitt's lymphoma which are the more aggressive sub-indications of non-Hodgkin lymphoma. A prerequisite for further expansion is that good results can be presented for the initial indications.

#### **Chronic lymphocytic leukemia**

Chronic lymphocytic leukemia (CLL) is an incurable lymphoma that is characterised by a large number of B cell lymphocytes in blood. Other lymphoid organs such as bone marrow, spleen and lymph nodes but also the liver are also to a large extent. The large number of white blood cells displace the usual blood cells, which have a key role counteracting infections and foreign antigens. One consequence is that the affected patient's immune system is compromised, making it increasingly difficult to fight infections. The disease mainly affects older individuals and the course of the disease is often slow. Patients are usually treated with chemotherapy in combination with monoclonal antibodies.

The National Cancer Institute estimates that the incidence of chronic lymphocytic leukemia is about 4.9 per 100,000 individuals.<sup>7)</sup> The global market for the treatment of chronic lymphocytic leukemia was estimated to be approximately USD 7.6 billion by 2025 growing at CAGR 6.2 percent over the forecast period.<sup>8)</sup>

#### **Solid tumors**

In addition to BioInvent's ongoing studies with the drug candidate BI-1206 in hematological cancer, all of BioInvent's candidates are focused on the treatment of solid tumors. BI-1206 is evaluated for solid tumors in a Phase I/IIa clinical program in combination with pembrolizumab (Keytruda). BioInvent has not at present made any formal decision on which indications the Company initially will focus on. The Company's assessment is, however, that the drug candidates currently in the company's pipeline that are focused on solid tumors, have the potential to be used for most types of solid tumors, especially those tumors where modification of the immune response has been shown to have a potential therapeutic role.

<sup>4)</sup> Global Data sales and Forecast 2020.

<sup>5)</sup> GBI Research. National Cancer Institute, Nov 2019, and BCell NHL Market 2024, opportunity analysis and forecasts Global data.

<sup>6)</sup> The Company's estimate is based on external reports from Cello Health BioConsulting, 2018 (formerly Defined Health).

<sup>7)</sup> SEER National Cancer Institute, Cancer Stat Facts: Leukemia – Chronic Lympocytic Leukemia (CLL).

<sup>8)</sup> Global Chronic Lymphocytic Leukemia Treatment Market – Dec 2019 iHealthcare Analyst report.

# I highly appreciate the very close collaboration that we have with BioInvent



Mark Cragg, Professor of Experimental Cancer Research within Medicine at the University of Southampton.

## You have been the Chairman for almost a year but have been involved in the SAB for many years, please tell us a bit about the role of the SAB?

Each year we meet to review BioInvent's scientific program. There is tremendous expertise on the board across all aspects of antibody biology and immune-oncology and so we discuss and comment on the programs that BioInvent is running and focus on their scientific and commercial viability.

#### Could you elaborate on how the SAB contributes?

A good example is Tony Tolcher; he runs a lot of clinical trials and is very helpful in understanding what the clinical and commercial markets looks like. If BioInvent was to develop a reagent that was a long way behind the clinical or commercial competitors, he who would be able to point out the difficulties with such a strategy and pinpoint the need to have something significantly different from current drugs that are in the market to be competitive. Similarly, Alexander Rudensky is a world leader in Treg biology and very helpful in providing suggestions on key experiments that will provide new insight.

#### In your view, what is special about BioInvent?

They are rare in that they are very interested in really understanding the biology of a disease which I think is slightly different from some other biotech companies

that might be more interested in just very quickly identifying a reagent and trying it clinically. They do a lot of preclinical modelling, but also use human immune cells to understand whether the preclinical models are really reading out for functions that might be useful in humans. It's about having the whole package. They also have a fantastic phage-display library to identify unique antibodies that are already fully human.

## You are not only on the SAB of BioInvent, you are also a key person in the collaboration between BioInvent and the University of Southampton, could you tell us a bit more about that?

To achieve their goals of understanding the biology of disease, BioInvent has invested in collaborations and I highly appreciate the very close collaboration that we have with them. We have regular meetings and communicate frequently. As academics, we are interested in the biology, but we also want to produce drugs. BioInvent comes from the other end, they want to produce drugs, but they are also interested in the biology. So, we meet in the middle where we can generate really meaningful reagents that allow us to understand the biology and then hopefully go on to treat patients more successfully.

## What do you as researcher appreciate the most with BioInvent?

As an academic, I really appreciate that they can move very quickly towards the clinic. For us, it can be quite slow. We've had other projects where it has taken a very long time to get to clinical testing. BioInvent has a fantastic production team, an already fully human phage library and their own production facilities, which means they can turn the handle very quickly. Something we researchers highly appreciate.

## Current research within immune oncology is vibrant, what is of most importance for BioInvent?

I would say that BioInvent is very much in the right place with their projects in TNFR2, Tregs and with the BI-1206 and BI-1607 programs blocking the inhibitory receptor FcgRIIB. I think their strategy is good – they are focused at looking at a limited number of targets, but at the same time they are broad enough if not all of those targets pan out.

## When it comes to BioInvent, what do you look most forward to in 2020?

Seeing what happens with BI-1206 both in hematological cancer and in solid tumors is of course extremely exciting. But the TNFR2 program is also really exciting. We have a collaboration with BioInvent on that and it is generating some very exciting data.

#### SCIENTIFIC ADVISORY BOARD

## Leading experts in cancer research

Since 2017, BioInvent has a Scientific Advisory Board consisting of five world-leading experts in the antibody area and cancer immune-biology. The Scientific Advisory Board is one of several tools used by BioInvent in its scientific work, and the Company has built up extensive internal knowledge of the biological aspects of developing antibody-based drug candidates.

Mark Cragg, Professor of Experimental Cancer Research and director of the Cancer Pathway Integrated Postgraduate Program at the University of Southampton, is a leading researcher in antibody biology. Professor Cragg's research group is interested in two main areas – antibodies and small molecule inhibitors with the aim of understanding how these therapeutics function to delete tumor cells and how they might be augmented. Over the last decade, he has investigated many different therapeutic agents such as rituximab, bexxar, imatinib, gefitinib, cetuximab and tarceva and has been involved in the development of next generation antibody reagents such as ofatumumab and obinutuzumab, as well as first in class antibodies such as BI-1206.

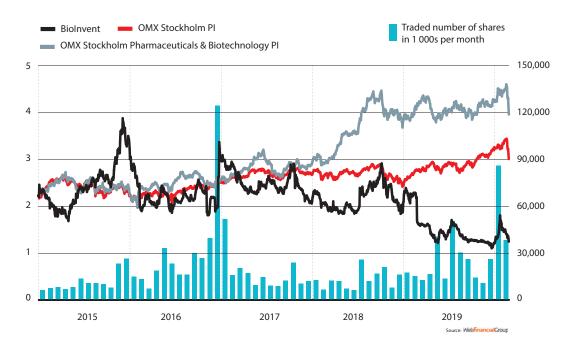
**Falk Nimmerjahn**, Professor in experimental immunology and immune therapy at the Friedrich-Alexander University Erlangen-Nürnberg. Leading scientist within Fc:FcgR biology and its impact on the therapeutic efficacy and tolerability of antibodies.

**Rienk Offringa**, Professor at the German Cancer Research Center. Head of a European consortium engaged in immune stimulating anti-cancer antibodies. Formerly Principal Scientist at Genentech.

**Tony Tolcher**, former Director of Clinical Research at South Texas Accelerated Research Therapeutics (START) and now active in the Company NEXT Oncology. Dr. Tolcher specialises in early phase clinical testing of exploratory anti-cancer drugs.

**Alexander Rudensky**, Chair of the Immunology Program at Sloan Kettering Institute. Dr. Rudensky is a world-leading scientist within the area of regulatory T cells, specialized in CD4-T cell regulation and homeostasis, and its role in autoimmunity and cancer.

## The BioInvent share



#### Price trend and trading volume

In 2019, the share price decreased 36 percent, from SEK 1.90 to SEK 1.22. In 2019 the OMX Stockholm\_PI increased 30 percent and OMX Stockholm Pharmaceuticals & Biotechnology\_PI increased 12 percent. The highest price paid in 2019 was SEK 2.43 and the lowest price was SEK 1.05. BioInvent's market capitalization totaled SEK 613 million at the end of 2019.

During the year 271 million (153) BioInvent shares were traded for a value of SEK 403 million (345). This corresponds to a rate of turnover of 60 percent (47).

Average trading volume per trading day was 1,084,602 (613,682) shares for a value of SEK 1.6 million (1.4). Average number of trades per trading day were 210 (168).

#### **Largest shareholders, 31 December 2019**

	No. of shares	Percentage of capital and votes
Van Herk Investments B.V.	43,301,545	8.6
TSGH (Compagnie Merieux Alliance)	37,896,917	7.6
Avanza Pension Försäkring	31,841,205	6.3
Omega Fund IV, LP	28,356,732	5.7
Pfizer	22,003,478	4.4
Skandinaviska Enskilda Banken	19,426,433	3.9
Nordnet Pensionsförsäkring	18,152,465	3.6
East Bay AB	12,925,000	2.6
Fjärde AP-fonden	12,500,000	2.5
Mexor i Skellefteå AB	9,821,713	2.0
Other shareholders	265,544,408	52.9
Total	501,769,896	100.0

#### **Ownership structure**

In 2019, the number of shareholders increased 16 percent, from 8,685 to 10,109. Foreign owners held 38 percent (41) of the share capital and votes. The ten largest shareholders owned 47 percent (53) of the shares.

#### **Share capital**

The BioInvent share has been listed on NASDAQ Stockholm (BINV) since 2001. The Company's share capital consists of 501,769,896 shares.

If fully exercised, Option Program 2017/2020 will represent a dilution equivalent to around 0.4 percent of the shares in the Company and Option Program 2019/2025 will represent a dilution equivalent to around 1.0 percent of the shares in the Company. The Company's option programs are described on page 51.

There is only one class of stock. Each share carries one vote at the Annual General Meeting and all shares carry equal right to a share in the assets and profits of the Company. The regulations in the Company's Articles of Association contain no restrictions on the transfer of shares.

#### Dividend and dividend policy

The Board of Directors do not recommend payment of any dividend for the 2019 financial year. The Company will continue to focus on research and development of new products. Available financial resources will be used to finance these projects. The Board of Directors therefore do not recommend that any dividend be paid for the next few years.

#### **Distribution of financial reports**

Annual reports will be sent to shareholders upon request and may be ordered at the address: BioInvent international AB, 223 70 Lund, Sweden or by phone +46 (0)46-286 85 50. The annual report is published in Swedish and English.

#### **Analysts covering BioInvent**

Klas Palin - Redeye, Stockholm Sam Slutsky – Life Sci Capital, New York Johan Unnérus - Pareto Securities, Stockholm

#### **Upcoming financial information**

Interim reports: 28 April, 27 August, 29 October 2020.

#### **Share statistics, 31 December 2019**

Size of holdings	No. of shareholders	No. of shareholders %	No. of shares in %
1–500	2,804	27.7 %	0.1 %
501-1,000	1,159	11.5 %	0.3 %
1,001-5,000	2,867	28.4 %	1.9 %
5,001-10,000	1,092	10.8 %	2.0 %
10,001-20,000	791	7.8 %	2.5 %
20,001-50,000	676	6.7 %	4.6 %
50,001-100,000	322	3.2 %	4.7 %
100,001-500,000	308	3.0 %	13.4 %
500,001-1,000,000	45	0.4 %	5.8 %
1,000,001-5,000,000	29	0.3 %	9.7 %
5,000,001-10,000,000	7	0.1 %	9.8 %
10,000,001-50,000,000	9	0.1 %	45.2 %
Total	10,109	100.0 %	100.0 %

#### Changes in the share capital

Year	Transaction	Increase in share capital, SEK	Increase in no. of shares	Share capital, SEK	Share capital, no. of shares	Ratio value
1006	District International AD formula di		•••••••••••••••••••••••••••••••••••••••		10.000	10.00
1996 1997	BioInvent International AB was founded <sup>1)</sup> New share issue	7,140	714	100,000 107,140	10,000 10,714	10.00 10.00
1997	Bonus issue	857,120	85,712	964,260	96,426	10.00
1998	Share split 1:10	037,120	867,834	964,260	964,260	1.00
1998	New share issue <sup>2)</sup>	181,000	181,000	1,145,260	1,145,260	1.00
1999	New share issue <sup>3)</sup>	108,527	108,527	1,253,787	1,253,787	1.00
2000	New share issue <sup>4)</sup>	250,000	250,000	1,503,787	1,503,787	1.00
2000	Warrants exercised	11,013	11,013	1,514,800	1,514,800	1.00
2001	Bonus issue	9,846,200	,	11,361,000	1,514,800	7.50
2001	Share split 1:15	3/0 :0/200	21,207,200	11,361,000	22,722,000	0.50
2001	Warrants exercised	461,152.5	922,305	11,822,152.5	23,644,305	0.50
2001	New share issue <sup>5)</sup>	2,250,000	4,500,000	14,072,152.5	28,144,305	0.50
2002	New share issue <sup>6)</sup>	665,625.5	1,331,251	14,737,778	29,475,556	0.50
2005	New share issue <sup>7)</sup>	8,842,666.5	17,685,333	23,580,444.5	47,160,889	0.50
2007	New share issue <sup>8)</sup>	4,250,000	8,500,000	27,830,444.5	55,660,889	0.50
2010	New share issue <sup>9)</sup>	2,717,400	5,434,800	30,547,844.5	61,095,689	0.50
2011	New share issue <sup>10)</sup>	3,054,784	6,109,568	33,602,628.5	67,205,257	0.50
2012	New share issue <sup>11)</sup>	3,360,263	6,720,525	36,962,891	73,925,782	0.50
2013	Reduction of the share capital	-31,048,828		5,914,063	73,925,782	0.08
2013	New share issue <sup>12)</sup>	887,109	11,088,867	6,801,172	85,014,649	0.08
2014	New share issue <sup>13)</sup>	2,222,032	27,775,401	9,023,204	112,790,050	0.08
2015	New share issue <sup>14)</sup>	4,010,313	50,128,911	13,033,517	162,918,961	0.08
2016	New share issue <sup>15)</sup>	9,584,213	119,802,658	22,617,730	282,721,619	0.08
2016	New share issue <sup>16)</sup>	1,757,888	21,973,594	24,375,617	304,695,213	0.08
2018	New share issue <sup>17)</sup>	3,656,342	45,704,281	28,031,960	350,399,494	0.08
2018	Warrants exercised <sup>18)</sup>	32,038	400,478	28,063,998	350,799,972	0.08
2019	New share issue <sup>19)</sup>	12,023,999	150,299,988	40,087,997	501,099,960	0.08
2019	Warrants exercised <sup>20)</sup>	53,595	669,936	40,141,592	501,769,896	0.08

- 9 BioInvent International AB was established by its managers, Stiftelsen Industrifonden, Pronova a.s. and Aragon Fondkommission.
- In November 1998 the Company issued 181,000 new shares aimed at institutional investors. The issue price was SEK 125 and SEK 22.6 million was raised after deductions of issue costs.
- In November 1999 the Company issued 108,527 new shares aimed at institutional investors. The issue price was SEK 175 and SEK 18.7 million was raised after deductions of issue costs.
- In March 2000, the Company issued 250,000 shares aimed at institutional investors. The issue price was SEK 720 and SEK 169.0 million was raised after deductions of issue costs.
- 9) New share issue in connection with the listing. The issue price was SEK 62 and SEK 261.6 million was raised after deductions of issue costs.
- In March 2002, the Company carried out a directed issue of 1,331,251 new shares for Oxford GlycoSciences. The issue price was SEK 39 and this raised SEK 52.0 million. There were no issue costs
- <sup>7)</sup> In November 2005 the Company carried out a new share issue. The issue price was SEK 9 and SEK 146.2 million was raised after deductions of issue costs.
- <sup>8)</sup> In July 2007 the Company carried out a directed issue. The issue price was SEK 14.75 and SEK 120.0 million was raised after deductions of issue costs.
- 9 In February 2010 the Company carried out a directed issue. The issue price was SEK 27.60 and SEK 144.4 million was raised after deductions of issue costs.
- 10 In June 2011 the Company carried out a directed issue. The issue price was SEK 22.30 and SEK 128.3 million was raised after deductions of issue costs.
- 11) In April 2012 the Company carried out a rights issue. The issue price was SEK 15.60 and SEK 96.5 million was raised after deductions of issue costs.
- 12) In August 2013 the Company carried out a rights issue. The issue price was SEK 2.10 and SEK 19,4 million was raised after deductions of issue costs. 13) In April 2014 the Company carried out a rights issue and a directed issue. The issue price was SEK 2.30 and SEK 57.3 million was raised after deductions of issue costs.
- 14) In May 2015 the Company carried out a rights issue and a directed issue. The issue price was SEK 1.55 and SEK 67.6 million was raised after deductions of issue costs.
- 15) In April 2016 the Company carried out a rights issue and a directed issue. The issue price was SEK 1.95 and SEK 209.5 million was raised after deductions of issue costs.
- 16) In December 2016 the Company carried out a directed issue. The issue price was SEK 2.56 and SEK 53.4 million was raised after deductions of issue costs. 17) In April 2018 the Company carried out a directed issue. The issue price was SEK 1.85 and SEK 80.3 million was raised after deductions of issue costs
- <sup>18)</sup> Warrants exercised in Board Share Program 2017.
- 19) In April 2019 the Company carried out a rights issue and directed issue. The issue price was SEK 1.60 and SEK 220.0 million was raised after deductions of issue costs.
- <sup>20)</sup> Warrants exercised in Board Share Program 2018.

## Five-year review

INCOME STATEMENT, SEK MILLION	2019	2018	2017	2016	2015
Net sales	93.7	38.5	45.0	71.3	15.9
Research and development costs	-207.9	-140.2	-109.7	-99.5	-80.5
Sales and administrative costs	-29.1	-28.0	-39.3	-35.7	-31.6
Other operating revenue and costs	5.4	6.4	3.3	1.0	1.3
	-231.6	-161.8	-145.6	-134.1	-110.9
Operating loss	-137.8	-123.2	-100.6	-62.9	-95.0
Net financial items	-0.8	0.1	0.1	0.3	-0.1
Loss before tax	-138.6	-123.2	-100.5	-62.6	-95.0
Tax	-	-	-	-	4,3
Loss for the year	-138.6	-123.2	-100.5	-62.6	-95.0
BALANCE SHEET, SEK MILLION	2019	2018	2017	2016	2015
Intangible fixed assets	0.0	0.0	0.0	0.0	0.0
Tangible fixed assets	33.0	18.0	19.2	5.6	1.3
Financial fixed assets	-	-	-	-	-
Inventories	5.4	3.0	2.4	1.9	0.5
Current receivables	33.8	30.6	14.7	42.6	12.7
Liquid funds	154.0	68.9	133.8	226.1	40.0
Total assets	226.1	120.4	170.0	276.3	54.4
Shareholders' equity	169.4	87.6	130.2	230.4	29.5
Non-interest-bearing liabilities	41.1	32.8	39.8	45.9	25.0
Interest-bearing liabilities	15.5	-	-	-	-
Total shareholders' equity and liabilities	226.1	120.4	170.0	276.3	54.4
CASH FLOW, SEK MILLION	2019	2018	2017	2016	2015
Operating loss	-137.8	-123.2	-100.6	-62.9	-95.0
Adjustments for depreciation, interest and other items	11.6	5.4	3.3	1.1	6.2
Changes in working capital	0.8	-23.6	21.5	-10.3	16.2
Cash flow from current operations	-125.4	-141.4	-75.9	-72.0	-72.6
Cash flow from investment activities	-3.8	-3.8	-16.5	-5.3	-0.7
Cash flow from current operations and investment activities	-129.3	-145.2	-92.4	-77.4	-73.2
Cash flow from financing activities	214.4	80.3	-	263.5	67.6
Increase/decrease in liquid funds	85.1	-64.9	-92.4	186.1	-5.7

KEY FINANCIAL RATIOS	2019	2018	2017	2016	2015
RET FINANCIAL RATIOS	2019	2016	2017	2016	2015
Net revenue growth, %	143.2	-14.4	-36.9	347.6	-66.1
Net working capital, SEK million	-2.0	0.7	-22.8	-1.3	-11.8
Net working capital/net sales, %	-2.1	1.9	-50.6	-1.9	-74.4
Capital employed, SEK million	185.0	87.6	130.2	230.4	29.5
Capital employed/net sales, %	197.3	227.3	289.3	323.3	185.0
Shareholders' equity, SEK million	169.4	87.6	130.2	230.4	29.5
Return on shareholders' equity, %	-107.9	-113.1	-55.7	-48.2	-232.1
Return on capital employed, %	-101.7	-113.1	-55.7	-48.2	-232.1
Capital turnover, times	0.7	0.4	0.3	0.5	0.4
Equity/assets ratio, %	74.9	72.8	76.6	83.4	54.1
Intangible fixed assets investments, SEK million	-	-	-	-	-
Tangible fixed assets investments, SEK million	3.8	3.8	16.5	5.3	0.7
Average number of employees	68	59	53	46	39
DATA PER SHARE	2019	2018	2017	2016	2015
Earnings per share, SEK					
Before dilution	-0.31	-0.36	-0.33	-0.25	-0.64
After full dilution	-0.31 <sup>1)</sup>	-0.36 <sup>1)</sup>	-0.33 <sup>1)</sup>	-0.25 <sup>1)</sup>	-0.64 <sup>1)</sup>
Shareholders' equity per share, SEK					
Before dilution	0.34	0.25	0.43	0.76	0.18
After full dilution	0.342)	0.252)	0.432)	0.762)	0.182)

The figures in the tables are rounded to one decimal, while the calculations are made using a greater number of decimals. As a result, it may appear that certain tables do not add up.

#### Definitions<sup>3)</sup>

#### **Net working capital**

Cash flow per share, SEK

Before dilution (thousands)

After full dilution (thousands)

Number of shares at end of period Before dilution (thousands)

After full dilution (thousands)

Share price, 31 December, SEK

Average no. of shares

Non-interest-bearing current assets less non-interest-bearing current liabilities.

#### **Capital employed**

The balance sheet total less non-interest-bearing liabilities and non-interest-bearing provisions.

#### Return on shareholders' equity

Loss after financial items as a percentage of the average shareholders' equity.

#### Return on capital employed

Loss after financial items plus financial costs as a percentage of average capital employed.

### 3) Definitions of alternative financial ratios not defined by IFRS.

#### **Capital turnover**

-0.29

453,527

453,527<sup>2)</sup>

501,770

501,7702)

1.22

-0.43

339,470

339,470<sup>2)</sup>

350,800

350,800<sup>2)</sup>

1.90

-0.30

304,695

304,6952)

304,695

304,6952)

2.07

-0.31

247,962

247,9622)

304,695

304,6952)

3.07

-0.51

142,450

142,4502)

162,919

162,9192)

3.59

Net revenue divided by the average capital employed.

#### Equity/assets ratio

Shareholders' equity as a percentage of the balance sheet total.

#### Cash flow per share

Cash flow from current operations and investment activities divided by the average number of shares.

<sup>1)</sup> There is no dilution of earnings per share because the earnings per share before dilution was negative.

<sup>2)</sup> No dilution is present since the subscription price exceeds the average share price.

## The Board and Auditors



**Leonard Kruimer** 

#### Chairman of the Board

Chairman of the Board since 2018. Chairman of the Remuneration Committee and member of the Audit Committee.

MBA, US.CPA. He served as a Board Member in BioInvent between 2016-2017. He was CFO and member of the board of Crucell NV from 1998 to 2011 and has held senior executive positions at Royal Boskalis N.V., GE Capital and Continental Can Company. Born 1958.

#### Other board appointments

Board member in Zealand Pharma A/S, Oncolytics Biotech Inc. and member of the Investment Advisory Council in Karmijn Kapitaal Investments.

#### **Shareholding**



#### **Employee representative**

Member of the Board since 2013. M.Sc. in Molecular and Functional biology. Senior Research Engineer. Born 1959.

#### Other board appointments

Shareholding

20,850 (own and affiliated holdings)



Member of the Board since 2017. Chairman of the Audit Committee.

M.Sc. in Aerospace Engineering and M.Sc. in Business Economics. CEO of SkylineDx and managing director of Exponential B.V. Extensive board experience in life science companies, with previous board assignments in for example Agendia, deVGen, Innate Pharma, Isobionics and Octoplus. Board member of BioInvent during 2013-2016. Currently Fund Manager for Swanbridge Capital. Born 1976.

#### Other board appointments

Board member of DCPrime, Vital-neXt, Ceradis BV and Anemones Hospitality and Hotels.

**Shareholding** 2.802.661



#### **Employee representative**

Member of the Board since 2017. Ph.D. in Immunology. Senior Research Scientist. Born 1979.

#### Other board appointments

Auditors KPMG AB **Auditor in charge** Eva Melzig,

Born in 1961.

Authorised Public Accountant.

Lives in Falsterbo, Sweden. Auditor for BioInvent International AB since 2016.

**Shareholding** 20.625





Member of the Board since 2016. Member of the Remuneration Committee.

M.D. Previously different exec-utive positions in Clinical Development, Medical Affairs, Business **Development and Commercial** within Swedish Orphan Biovitrum, Eli Lilly, Roche, Pharmacia & Upjohn and biotech companies in USA the Netherlands, Switzerland and Sweden. Born 1960.

#### Other board appointments

Board member of Medivir AB, Agendia, Savara Pharmaceutical Inc and PLUS Therapeutics Inc.

**Shareholding** 



Member of the Board since 2016. CFA, Ph.D. Partner NeoMed Management. Former partner in Private Equity Sectoral Asset Management and Omega Funds. Researcher at University of Geneva. Research analyst at Pictet Bank. Born 1968.

#### Other board appointments Board member of Etherna Immunotherapies, FoRx, Immunic and Sophia Genetics.

**Shareholding** 



Member of the Board since 2018. Chairman of the Science Committee, and member of the Remuneration Committee.

Doctor of Medicine and Doctor of Neurobiology. Previous experience as CEO and President of GPC Biotech, **Executive Vice President and Chief** Scientific Officer at Genome Therapeutics Corporation and Vice President of Oncology Drug Discovery and, in parallel, Vice President of Corporate and Academic Alliances, both at Bristol-Myers Squibb. Senior faculty positions at Harvard Medical School, Massachusetts General Hospital, and Princeton University. Born 1956.

#### Other board appointments

Board member and chairman of multiple public and private biotech companies in the United States, Europe, and Canada, including Oxford BioTherapeutics, CryptoMedix Inc., Oncolytics Biotech Inc., Aprea AB and Vaccibody AS. Advisory board member/Senior Advisor to Biotech Venture Capital Funds such as BB Pureos Bioventures and Hadean Ventures

#### **Shareholding**

107,464

## Senior management



#### **Chief Executive Officer**

Ph.D. (Dr.rer.nat.) in recombinant antibody technology. Employed since 2018. He did his postdoctoral training at the German Cancer Research Center, Department for Recombinant Antibody Technology and at the University of Heidelberg, Department of Transplantation Immunology both in Heidelberg, Germany. Martin has a broad international experience from executive positions within the biotech industry, including Director of Technology at Axaron Bioscience AG, Heidelberg, Germany, CEO of Affitech (Nasdaq Copenhagen) and CEO of Opsona Therapeutics, Dublin, Ireland. Member of the Board of APIM Therapeutics AS, Nextera AS and Uni Targeting Research. Born 1961.

#### **Shareholding**

125,000

221,619

#### **Options** Conditional employee options



#### **Chief Scientific Officer**

Doctor of Immunology. Employed since 2001. Graduated from the Swedish Foundation for Strategic Research funded Biomedicine programs within the Infection & Vaccinology program. Visiting Professor at University of Southampton. Born 1973.

#### **Shareholding**

483,083 (own and affiliated holdings)

Conditional employee options 393,852 (own and affiliated holdings)



#### **Chief Financial Officer**

MBA, Lund University. Employed since 1998. Chief Financial Officer since 2016 and has previously served as Director Business Control. Previous experience from the Swedish Tax Agency and as auditor at PricewaterhouseCoopers. Born 1963.

#### **Shareholding**

145,892

Conditional employee options 168.794



#### **Chief Medical Officer**

Doctor in Medicine and Surgery from the Universidad del Rosario (Bogotá), and holds a PhD from the Pasteur Institut/Université Paris. Employed since 2017. He has performed academic work at the Pasteur Institut and the University of California San Francisco on cancer immunotherapy. Andres joins BioInvent from a position as Chief Scientific Officer at Debiopharm, and has previously held senior roles at IDM and BioMérieux/Pierre Fabre. Born 1956.

#### **Shareholding**

**Options** 

Conditional employee options 162,281



Kristoffer Rudenholm Hansson

#### Senior Vice President. **Technical Operations**

Master of Science in Chemical engineering. Employed since 2016 and is responsible for process development and production of antibodies for clinical studies. He has more than 15 years' experience from managing manufacturing of antibodies and other proteins for clinical use. Kristoffer has held a numerous positions within CMC Biologics A/S, DAKO A/S and Symphogen A/S. Born 1974.

**Shareholding** 522,882 (whereof 179,430 in endowment insurance)

#### Options

Conditional employee options 167,028

Information on the holdings of shares and other financial instruments in BioInvent by Directors and Group management refers to conditions as of 8 April 2020, and includes personal holdings and holdings of related parties, as well as holdings of legal entities that are directly or indirectly controlled by the person or a related party. For the CEO information is also provided about any significant shareholdings and ownership in companies with which BioInvent has significant business relationships.

## Directors' report

The Board of Directors and the CEO of BioInvent International AB (publ), co. reg. no. 556537-7263, listed on the NASDAQ Stockholm (BINV), hereby present the annual accounts and consolidated accounts for the financial year 1 January–31 December, 2019. The Company is registered in Sweden and is located in the Lund municipality. The visiting address is Ideongatan 1, Lund and the postal address is 223 70 Lund. The descriptions below of the status of BioInvent's projects are current at the time this annual report was presented.

#### **Clinical Projects**

## BI-1206 in non-Hodgkin lymphoma and chronic lymphocytic leukemia

In June 2019 BioInvent announced the publication of the first data from the two parallel Phase I/lla clinical trials. Up to that point, in the UK trial, 10 patients had received single agent therapy with up to 100 mg BI-1206 once weekly for a period of 4 weeks. In the US/EU study, five patients had received up to 100 mg BI-1206 in combination with rituximab. The data were published in the Abstract Book from the 15-ICML International Conference on Malignant Lymphoma.

Receptor occupancy, i.e. the proportion of available FcyRIIB receptors that have bound BI-1206, is dose proportionate and high levels of receptor blockade should be seen at clinically relevant doses of BI-1206. Target-mediated drug disposition has not yet been overcome, and thus, the optimal dose has not yet been reached. Notwithstanding, pharmacodynamic analysis at the current doses showed depletion of peripheral B cells, including circulating mantle cell lymphoma cells during the first week of therapy. Early results from the Phase I open label study in indolent non-Hodgkin lymphoma is expected in H2 2020.

In November 2019 BioInvent had a poster presentation with preclinical data on BI-1206 at the annual American Society of Hematology (ASH) meeting in Orlando. The abstract highlighted a preclinical study of BI-1206 in an ibrutinib-venetoclax dual resistant PDX (patient derived xenograft) model derived from a mantle cell lymphoma (MCL) patient. Single agent BI-1206 had potent anti-MCL activity in the FcyRIIb-expressing MCL PDX model. FcyRIIb was further shown to be highly expressed in 27/27 primary patient MCL samples examined. Along with previously published data demonstrating an important role for FcyRIIB in resistance to rituximab-based cancer immunotherapy, and BI-1206 in boosting rituximab efficacy and overcoming rituximab-resistance, these data indicate the high potential of BI-1206 to address a significant unmet need in MCL and hematologic malignancy.

#### Background

BI-1206 is a high-affinity monoclonal antibody that selectivity bind to FcyRIIB (CD32B), the only inhibitory member of the FcyR family. FcyRIIB is overexpressed in several forms of NHL and overexpression has been associated with poor prognosis in difficult-to-treat forms of NHL, such as mantle cell lymphoma. By blocking FcyRIIB, BI-1206 is expected to recover and enhance the activity of rituximab or other anti-CD20 monoclonal antibodies in the treatment of these diseases. The combination of the two drugs could provide a new and important option for patients suffering from NHL, and represents a substantial commercial opportunity.

In September 2018 BioInvent started a dose escalation, consecutive-cohort, open-label phase I/IIa study of BI-1206. The study will recruit approximately 30 patients across sites in the

EU and the U.S. The trial is evaluating BioInvent's proprietary antibody BI-1206 in combination with rituximab in patients with indolent relapsed or refractory B-cell NHL. The targeted subindications are mantle cell lymphoma, follicular lymphoma, and marginal zone lymphoma. The study will explore BI-1206's safety and tolerability, and seek to determine a recommended phase II dose (RP2D) when given in combination with rituximab. Expression of biomarkers will be assessed to explore a potential correlation with clinical activity.

This study is run in parallel with the ongoing Phase I/Ila study of BI-1206 in patients with CLL and NHL conducted in the UK by Cancer Research UK. The study is testing single agent activity. Given the overlap with BioInvent's own Phase I/Ila trial of BI-1206 in combination with rituximab in Non-Hodgkin Lymphoma (NHL), and the fact that standard of care for patients with chronic lymphocytic leukemia (CLL) has dramatically evolved over the last few years, recruitment in the UK study has become increasingly challenging in particular since CRUK can only carry out trials in the UK. For these reasons we have agreed to limit the CRUK study to monotherapy, which is almost completed. This will result in a more complementary work and more efficient use of resources.

In January 2019 the U.S. Food and Drug Administration granted orphan designation for BI-1206 for the treatment of mantle cell lymphoma.

#### BI-1206 in combination with pembrolizumab in solid tumors

In July 2019 BioInvent received authorization from the FDA to proceed for an IND application for a Phase I/IIa clinical trial of BI-1206 in combination with pembrolizumab for the treatment of solid tumors.

BioInvent entered in December 2019 into a clinical trial collaboration and supply agreement with Merck, to evaluate the combination of BioInvent's BI-1206, one of its proprietary anti-FcyRIIB antibodies and Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in a Phase I/IIa clinical trial for patients with solid tumors. The agreement helps BioInvent to expand BI-1206 clinical development to solid tumors in combination with one of the most successful immuno-oncology drugs. Early results from the Phase I open label study is expected in H2 2021.

#### **Background**

The program is based on BioInvent's preclinical data demonstrating the ability of BI-1206 to address an important mechanism of resistance to PD1 inhibition, providing a way to enhance antitumor immune responses in patients with solid tumors. The Phase I/IIa clinical trial will evaluate the drug combination in patients with advanced solid tumors, who have been previously treated with anti-PD1 or anti-PD-L1 antibodies, and is a multicenter, dose-finding, consecutive-cohort, open-label trial. The Phase I/IIa trial is planned to be carried out in the U.S. and the EU.

#### TB-403 in pediatric brain tumors

TB-403 is currently in a Phase I/II study for the treatment of patients with medulloblastoma in cooperation with a US based pediatric oncology network, Beat Childhood Cancer. TB-403 is not within BioInvent's current main focus.

TB-403 has received Orphan Designation for medulloblastoma from the European Medicines Agency (EMA). TB-403 is developed in collaboration with Oncurious, a subsidiary of Oxurion. BioInvent's ownership in TB-403 is 50 percent and it contributes with 50 percent of the development costs.

#### **Preclinical programs**

BioInvent's preclinical research is focused on developing novel immuno-modulatory antibodies for cancer therapy. Such antibodies may significantly improve efficacy of currently available checkpoint inhibitor therapies and/or activate anti-cancer immunity in currently non-responding patients and cancer types.

## Strategic collaboration with Pfizer – developing antibodies that act on tumor-associated myeloid cells

In partnership with Pfizer Inc. since December 2016, BioInvent works to identify novel oncology targets and therapeutic antibodies that may either reverse the immunosuppressive activity of tumor-associated myeloid cells or reduce the number of tumor-associated myeloid cells in the tumor.

BioInvent announced in July 2019 selection of the first target and in December 2019 the second target discovered by Bio-Invent's proprietary F.I.R.S.T™ technology platform under the collaboration with Pfizer Inc. The selection of targets triggered two payments from Pfizer to BioInvent of \$0.3 million. Under the terms of the 2016 agreement, potential selection and development of antibodies directed against these targets, as well as potential selection of further targets and development of antibodies directed at them, would allow BioInvent to be eligible for further milestone payments.

In December 2019 BioInvent announced that the research term under its collaboration and license agreement with Pfizer had been extended by six months. The purpose of the research extension is to permit the companies to further identify and characterize new targets and antibodies binding to these targets.

BioInvent is eligible for potential future development milestones in excess of \$500 million (assuming five antibodies are developed through to commercialization). The Company could also receive up to double digit royalties related to product sales. In exchange, Pfizer will have the right to develop and commercialize any antibodies generated from this agreement.

BioInvent received an upfront payment of \$3 million when the agreement was signed in December 2016, and research funding has been received during 2017, 2018 and 2019. Pfizer also made a \$6 million equity investment in new shares of BioInvent when the agreement was signed.

## Developing antibodies that act on regulatory T cells (Tregs) via novel or validated targets

Tregs can substantially inhibit various immune responses, enabling tumor cells to escape detection. BioInvent is utilizing its F.I.R.S.T™ platform to identify and characterize monoclonal antibodies to cancer-associated Treg targets in a function-first, target-agnostic, manner. The company is also pursuing differentiated antibodies to known targets through novel mechanisms and pathways.

#### BI-1808 (anti-TNFR2)

BioInvent has identified TNFR2, a member of the so called TNFR superfamily (TNFRS) as a target within the Treg program. The company has antibody candidates with various mechanisms of action that show promising preclinical data. A clinical trial application is expected to be submitted in H1 2020 for BI-1808.

## BT-001 - Partnership with Transgene - developing next generation oncolytic viruses expressing an anti-CTLA-4 antibody to treat solid tumors

In December 2019 BioInvent and Transgene announced preclinical data for BT-001 in solid tumors. The therapeutic activity was assessed in several immunocompetent preclinical models, showing outstanding antitumoral activity for BT-001 murine surrogate antibody-encoding viruses conferring cures in a majority of mice transplanted with different solid cancer tumors (> 70%

in all tested models). The new preclinical data also confirmed that the anti-CTLA4 antibody expressed by BT-001 in mouse tumor cells retained biochemical integrity and folding, functionality, and biological activity. In addition, BT-001's bio-distribution profile demonstrated higher concentration and prolonged activity of the anti-CTLA4 antibodies in tumors compared to intra-venous anti-CTLA-4 antibody therapy. Preclinical data on BT-001 will be presented at scientific meetings in the coming months.

BioInvent and Transgene announced in March 2020 that the first clinical trial application for BT-001 was submitted and that the first-in-human trial is expected to start before the end of 2020 in Europe and the US.

#### **Background**

BioInvent and Transgene collaborate to co-develop oncolytic virus (OV) candidates encoding a validated anti-CTLA-4 antibody sequence – potentially with additional transgenes – aimed at treating solid tumors, with the potential to be significantly more effective than the combination of a virus and an antibody as single agents.

Transgene is contributing both engineering expertise, as well as its proprietary Vaccinia viruses, designed to directly and selectively destroy cancer cells by intracellular replication of the virus in the cancer cell (oncolysis). Oncolysis induces an immune response against tumors, while the "weaponized" virus allows the expression of genes carried by the viral genome, here an immune modulatory anti-CTLA-4 antibody, which will further boost immune response against the tumor.

BioInvent is providing its cancer biology and antibody expertise to the collaboration, as well as anti-CTLA-4 antibody sequences generated through its proprietary n-CoDeR®/F.I.R.S.T™ platforms.

In March 2019 BioInvent and Transgene announced an extension of their collaboration to co-develop multi-functional oncolytic viruses encoding antibodies targeting an undisclosed target, which can be used in the treatment of a broad range of solid tumors

The research and development costs, as well as revenue and royalties from candidates generated from the collaboration, are shared 50:50.

#### **Personnel and organization**

BioInvent's operations consist of Clinical Development, Preclinical Development and Technical Operations where work is done in an integrated way to create the best possible conditions for the various projects. This enables the Company to benefit from the accumulated immunology, cancer biology and antibody biology knowhow, ensuring that prioritised projects have the resources they need for their development.

The research department works with BioInvent's technology platforms, F.I.R.S.T™ and n-CoDeR® and develops antibodies for the Company's preclinical projects. The research department further supports clinical development programs with important mechanism-of-action and translational data e.g. bioassays and biomarkers, new indications and combination data. The research activities are organized in a project-based, crossfunctional manner. Technical Operations consists of three functions, one responsible for producing antibodies for clinical studies, one working with quality assurance and quality control, and the Protein & Analytical Chemistry support team.

In addition to the line functions referred to above, the Company's quality assurance department and the Company's own patent department are directly involved in research and development. The organization's support functions include business development, HR, accounting and finance and IT.

As of 31 December 2019 BioInvent had 72 (62) employees, 66 (56) of whom work in research and development. 92 percent of the Company's employees have university degrees, including 46 percent with PhDs.

#### **Environment**

BioInvent places great importance on environmental work which is an integrated part of the daily routines. BioInvent works actively with environmental issues and the principles under the general rules of consideration in the Swedish Environmental Code are observed in the Company's ongoing operations. The Company consistently endeavours to reduce the use of substances that may be harmful to the environment and ensure that environmental impact is kept to a minimum. The aim is to assess the possibility early on in the value chain of replacing a substance that is harmful to the environment with a less harmful one. Another goal is to continuously improve the use of chemical substances and other resources so that the Company's environmental impact is minimised in this respect as well. Proactive environmental efforts reduce the risk of harming the environment and health and put the Company in a better position to handle future environmental legislation and societal requirements.

BioInvent's operations require permits according to the Swedish Environmental Code. The Group has a permit in accordance with the Swedish Environmental Code for manufacturing of biological pharmaceutical substances, and reports are required to be submitted to Lund municipality. Lund municipality carries out annual environmental inspections of the Company. Self-monitoring is carried out to monitor the Company's operations on an ongoing basis to counteract and prevent negative environmental impact. As part of this self-monitoring process, the Company has introduced a description of environmental consequences and a plan for the self-monitoring process. In accordance with the plan, periodic inspections are carried out to check compliance with authorizations and current legislations.

The Company has limited emissions from its laboratories and production facility. The emissions consist of commonly found salts and easily biodegradable organic substances. Waste is sorted and separated, and special procedures are applied for handling environmentally hazardous waste.

The Company also has a permit to import and export cell lines in accordance with the European Parliament's regulation. BioInvent uses genetically modified microorganisms (GMM) in its research and development work and has permits for the so called contained use of such organisms according to the Swedish Work Environment Authority's directions.

#### **Quality and regulatory approval**

The Company has a permit under the EU rules on producing investigational pharmaceutical products for clinical trials according to Good Manufacturing Practice (GMP). This permit is issued by the Swedish Medical Products Agency which conducts regular inspections to verify that production maintains the approved level of quality. BioInvent is also involved in auditing activity to ensure the quality of internal work, raw materials and that contracted services maintain a high standard. The Company conducts regular internal inspections and audits of external suppliers to ensure that GMP regulations are met.

BioInvent's preclinical studies to evaluate the safety of products are carried out through contract research organizations (CROs) in accordance with Good Laboratory Practice (GLP). Clinical trials are conducted according to Good Clinical Practice (GCP). In cases where tests are carried out on animals, they are conducted in laboratories that strictly adhere to the applicable regulations.

BioInvent has many years' experience of quality work, and endeavors to constantly improve the quality of all of its work.

#### **Revenue and result**

Net sales amounted to SEK 93.7 million (38.5). Revenues for the period are mainly derived from production of antibodies for clinical studies, revenues from research funding and also two \$0.3 million milestone payment from Pfizer Inc. in connection with selection of the first and second target discovered by BioInvent, a  $\leq$  0.75 million milestone payment received from

Mitsubishi Tanabe Pharma Corporation in connection with enrollment of the first patient in a Phase II clinical trial and a \$0.5 million milestone payment from XOMA Corporation related to the acceptance by FDA of an IND application.

The Company's total costs amounted to SEK 237.0 million (168.1). The increase of costs is mainly due to that projects are advancing and moving towards clinical phase. Operating costs are divided between external costs of SEK 158.7 million (103.2), personnel costs of SEK 66.7 million (59.8) and depreciation of SEK 11.6 million (5.1). During the period, the transition to IFRS 16 affected the operating result by 5.9 SEK million in increased depreciation and SEK 6.2 million in reduced external costs, and thus had no material effect on the operating result.

Research and development costs amounted to SEK 207.9 million (140.2).

Loss after tax amounted to SEK -138.6 million (-123.2). The net financial items amounted to SEK -0.8 million (0.1). Loss per share before and after dilution amounted to SEK -0.31 (-0.36).

#### Financial position and cash flow

The Board of Directors of BioInvent resolved in February 2019 on a fully underwritten rights issue of SEK 210.5 million (prior to issue costs) and a directed issue of SEK 30.0 million (prior to issue costs) with a Swedish pension fund and a Swedish life science fund. The rights issue and the directed issue were completed in April 2019 and 46.9 percent of the rights issue was subscribed for with subscription rights. 0.7 percent was subscribed for without subscription rights and 52.4 percent was subscribed for by guarantors.

In June 2019, 669,936 shares were subscribed for to secure the fulfilment of the Company's obligations under the Board Share Program 2018. The subscription price per share amounted to the share's quota value (0.08).

After the share issues the share capital consists of 501,769,896 shares.

As of 31 December, 2019, the Group's liquid funds amounted to SEK 154.0 million (68.9). The cash flow from operating activities and investment activities for the January-December period amounted to SEK -129.3 million (-145.2).

The shareholders' equity amounted to SEK 169.4 million (87.6) at the end of the period. The Company's share capital at the end of the period was SEK 40.1 million. The equity/assets ratio at the end of the period was 75 (73) percent. As an effect of the transition to IFRS 16, the Group's total assets have increased. As of 31 December, 2019 lease assets amounted to 7 percent of total assets, which had a negative impact on the key financial ratio equity/assets ratio. Shareholders' equity per share amounted to SEK 0.34 (0.25).

The five-year review is described on page 26.

#### **Investments**

Investments for the period in tangible fixed assets amounted to SEK 3.8 million (3.8).

#### **Parent Company**

The BioInvent Group consists of the Parent Company, BioInvent International AB, and the subsidiary BioInvent Finans AB. Net sales amounted to SEK 93.7 million (38.5). Loss after tax amounted to SEK -138.4 million (-123.2). The cash flow from operating activities and investment activities amounted to SEK -134.9 million (-145.2). All operations of the Group are conducted by the Parent Company. Except for financial leases, the Group's and the Parent Company's financial statements coincide in every material way.

#### The share

The BioInvent share has been listed on NASDAQ Stockholm (BINV) since 2001. The Company's share capital consists of 501,769,896 shares.

If fully exercised, Option Program 2017/2020 will represent a dilution equivalent to around 0.4 percent of the shares in the Company and Option Program 2019/2025 will represent a dilution equivalent to around 1.0 percent of the shares in the Company.

There is only one class of stock. Each share carries one vote at the Annual General Meeting and all shares carry equal right to a share in the assets and profits of the Company. The regulations in the Company's Articles of Association contain no restrictions on the transfer of shares. The Company is not aware of any agreements between shareholders that would restrict the right to transfer shares. Nor are there any agreements, in which the Company is a party, that may go into force, be amended or go out of force if control of the Company is changed as a result of a public purchase offer.

According to the Articles of Association, members of the Board of Directors are elected annually by the Annual General Meeting. The Articles of Association do not contain any restrictions regarding appointment or dismissal of Board members or changes in the Articles of Association.

The Annual General Meeting 2019 authorized the Board of Directors to resolve on the issue of new shares on one or several occasions during the period up to the next annual general meeting. The number of shares to be issued by virtue of the authorization shall not exceed 20 percent of the registered share capital (as per the date of the resolution on the issue of new shares). The Annual General Meeting has not authorized the Board of Directors to take decisions on acquisition of shares by the Company.

#### **Corporate governance report**

Based on the Annual Accounts Act, chapter 6,  $\S$  8, BioInvent has decided to produce a Corporate Governance Report that is separate from the Annual Report.

#### **Future prospects**

BioInvent's overall objective is to build a portfolio of clinical development projects within cancer where risk is balanced and significant revenue streams are generated for the Company from licensing or sales, and to assist international pharmaceutical companies in their drug development and thereby generate revenue that contributes to finance the Company's costs.

#### Risks and risk management Pharmaceutical development

BioInvent is a clinical stage company that discovers and develops novel and first-in-class immuno-modulatory antibodies for cancer therapies. BioInvent's project portfolio currently consists of preclinical and clinical oncology projects whereof two are in clinical phase I/IIa trials

Pharmaceutical development is generally associated with a very high risk, and since BioInvent's project port-folio is relatively limited and contains early phase projects, this applies to a great extent also to BioInvent. As BioInvent's project portfolio are developed, the Company's knowledge and experience in important areas will grow and a larger project portfolio could over time make the Company less dependent on the success of an individual project. Antibodies also have a beneficial risk profile and a larger percentage of projects in the antibody area reach the market today compared to traditional pharmaceuticals. The probability that a drug candidate will reach the market also increases as the project is advanced through the development chain. Development of pharmaceuticals is thus capital demanding, and since only a small number of the pharmaceutical products which are subject to preclinical and clinical development will result in an approved and commercialized product, there is a risk that the research and development costs that are invested never result in an approved pharmaceutical.

BioInvent's development of pharmaceuticals is also associated with risks that include, for example, development work being

delayed or more expensive in relation to established schedules or not funded at all. Further, some or all of the Company's product candidates at preclinical or clinical trials may prove to be ineffective, have side effects or in another way not meet the applicable requirements or receive the necessary market approvals, or prove to be difficult to license successfully or develop into commercially viable products.

#### Clinical trials and product responsibility

All of BioInvent's potential product candidates require additional, extensive research and development before they can result in commercialization and ultimately, steady revenues. Preclinical and clinical trials proceed from hypotheses regarding mechanisms of action which, in validating trials, may turn out to be insufficient, ineffective or cause unacceptable side effects, and a clinical study may be halted at any time. It is hard to predict the outcome of clinical trials and earlier positive results may also prove to be unrepresentative of the results obtained in later trials, for example when the drug candidate is tested with humans. BioInvent endeavors to advance its projects through the value chain. To receive approval from the authorities for commercial sales of the Company's product candidates, the Company or its partners must demonstrate the safety and efficacy of each potential product for human use for each stated indication.

The Company's operations are associated to risks relating to product liability, which is inevitable connected to research and development, preclinical and clinical studies, production, marketing and potential future sales of pharmaceutical products. Product liability could lead to claims for damages being lodged against the Company if its pharmaceutical candidates cause illness, physical injury, death or damage to property. The Company has a commercial insurance policy that provides coverage in the geographic markets in which BioInvent currently is active. Although the Company considers its insurance coverage to be adequate, the scope and amount of the insurance coverage are limited and there is a risk that applicable insurance policies do not provide sufficient coverage in the event of a potential claim.

#### **Partners and commercialization**

BioInvent is dependent on agreements with partners, such as large pharmaceutical companies, to be able to conduct sufficient clinical trials, especially in late development phases, as well as sale of possible future pharmaceutical products. The optimal time to sign such agreements varies between different projects and depends on, for example, resource requirements, risk level and commercial potential. In the absence of adequate partnerships, BioInvent may not be able to realize the full value of a product candidate. BioInvent lacks organizational prerequisites to be able to complete the development of and/or to commercialize a product candidate on its own. It would require extensive financial resources to build such an organization, and BioInvent is therefore currently dependent on external co-operations to be able to take a product all the way to the market.

There is also a risk that any future product launches by Bio-Invent will not be well received on the market or become commercial successes. The market acceptance of the Company's and its partners potential future products from doctors, patients and care payers depends on a number of factors, such as the clinical indications for which the product is approved, to which extent the product constitute a safe and effective treatment, the existence and the severity of harmful side effects, the cost for treatment in relation to alternative treatments as well as the access to adequate remuneration systems and subsidies.

#### Competition

BioInvent is subject to competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide that develop antibody-based drugs. In addition to existing treatments for the indications that the Company is targeting with its research and product candidates,

the Company may also face competition from other research and other product candidates under development by other companies. There is a number of approved pharmaceutical products on the market for treatment of cancer (oncology), and a large number of pharmaceutical and biotechnology companies operate in the field of research and development of pharmaceuticals for use in treatment of cancer. These companies include various large, well-financed and experienced pharmaceutical and biotechnology companies as well as companies that have partnered with such companies, which may give them advantages in relation to BioInvent with regards to financing, development, regulatory matters and market establishment.

#### Intellectual property protection

BioInvent's future success largely depends on the Company's ability to obtain and retain patent protection for potential products and for its own, patented technologies. The patents relate both to the Company's core technology for antibody drug development and various aspects thereof, as well as different antibody products under development and their use as drugs. The patent rights status of pharmaceutical and biotechnology companies is in general uncertain and involves complex medical and legal assessments. Therefore, BioInvent is thus dependent on its ability to keep its own and its partners' research that is not patented, protected to the relevant extent, so that BioInvent thereby can prevent others from using BioInvent's technologies, research and confidential information.

There is also a risk that granted patents will not make Bio-Invent's future products competitive or that competitors will be able to circumvent the Company's patent protection. If in its research or development, BioInvent uses substances, methods or technologies that are patented or that will be granted patents or are protected by other rights, the owner of these patents or other rights could claim that BioInvent is infringing on those rights. BioInvent monitors and evaluates the activities, patents and patent applications of competitors on an ongoing basis for the purpose of identifying activities that are covered by the Company's intellectual property and patents that could cover parts of the Company's sphere of activity. It may also be necessary to initiate legal proceedings to defend the Company's current or future patents, and to determine the extent and validity of patents that belong to a third party.

#### **Compensation for pharmaceutical sales**

BioInvent's potential future revenues are partially dependent on to what extent the Company's potential future products will qualify for subsidies from private or publicly financed healthcare programs. A significant portion of the Company's potential future income is likely to be dependent on subsidies from third parties, such as public authorities, public health providers or private health insurance providers. Certain countries require that products must first undergo a lengthy review before public subsidies may be considered. Many of the countries in which the Company's future products could be commercialized have measures to curb rising healthcare costs. Such measures may be expected to continue and could result in stricter rules for both reimbursement levels and the medications covered.

#### Qualified personnel and key individuals

BioInvent's operations is organized in Clinical Development, Preclinical Development and Technical Operations, which requires the Company to hire employees with relevant skills within, for example, strategic design and implementation of clinical trial, immunology, cancer biology, antibody biology and manufacturing. However, in a business environment characterized by strong competition and rapid technological change with continuous enhancement and improved industrial know-how, it may be challenging to attract and retain employees possessing the right skills, experience and values. The competition for qualified employees may also lead to increased remuneration levels. Conversely, if BioInvent were to offer excessively low remuneration

levels, this might lead to employees choosing to terminate their employments, which would affect BioInvent's competitiveness and operations. If the Company would lose a key individual, potentially valuable know-how and experience could also be lost.

#### **Additional financing requirements**

BioInvent's overall objectives are to build a portfolio of clinical development projects within cancer where risk is balanced and significant revenue streams are generated for the Company from licensing or sales, and to assist pharmaceutical companies in their drug development and thereby generate revenue that contributes to finance the Company's costs. Based on the fact that future, new clinical studies are expected to involve considerable cost, BioInvent's activities relating to these studies are expected to continue cause negative cash flows to accrue until the Company generates annual revenue on an ongoing basis from products on the market. The capital requirement is financed through (i) revenue from collaboration agreements associated with outlicensing of proprietary projects, (ii) revenue from technology licenses, (iii) revenue from external development projects and, (iv) shareholders' equity. Failure to secure such financing could negatively affect the Company's business, financial position and operating income. Revenue expected to be received from outlicensing existing or new product candidates may fluctuate considerably. Payment from partners will typically be contingent upon projects reaching agreed development and regulatory approval milestones. An inability to achieve such milestones or adhere to schedules could seriously harm the Company's future financial position.

The Board of Directors follows the financing situation and is working on a plan to ensure the Group's continued financing. See also financial risks at page 56.

## Principles of remuneration to Directors, the CEO and other senior executives

Remuneration of Directors, the CEO and other senior executives is described in note 4. The 2019 Annual General Meeting adopted guidelines for remuneration to the CEO and other senior executives. There has been no deviations from these guidelines.

The Board of Director's proposal for guidelines for remuneration to management shall apply to those persons who, during the period the guidelines are in effect, belong to the executive management, hereinafter referred to as "senior executives".

BioInvent shall offer compensation and terms of employment deemed necessary to recruit and retain qualified executives who are capable of achieving established goals. The overarching principle is to offer market-based salaries and other remuneration to senior executives at BioInvent.

In addition to fixed cash base salary, remuneration may be paid in the form of variable cash salary, pension benefits and other benefits. Additionally, the general meeting may resolve on share-related incentive programs. Incentive programs resolved by the general meeting are excluded from these guidelines, subject to what is stated below regarding the content of the Board of Directors' proposal.

The fixed cash base salary shall be based on the individual senior executives area of responsibility, authority, competence, experience and performance.

The variable cash salary shall reward clearly target related accomplishments in an simple and transparent way. The senior executives' variable remuneration shall depend on the extent to which previously established targets are met within the frame of the Company's operation, mainly technical and commercial milestones within proprietary drug projects. By rewarding clear and measurable progress in the Company's own drug projects as well as commercial progress, the criteria contribute to support and motivate employees to achieve the Company's established business strategy and long-term value creation. The senior executives' annual variable cash salary may amount to not more than 40 percent of the fixed cash base salary. The variable cash salary shall qualify for pension benefits. The Board of Directors

shall have the possibility to, in accordance with general legal principles, reclaim variable cash salary.

In addition to the fixed cash base salary and variable cash salary, the company may pay a stay-on bonus (deferred fixed remuneration), which for a three year period may amount to a maximum of 100 percent of the fixed cash base salary for one year, and in the case of new recruitment, a guaranteed fixed bonus which may amount to a maximum of 100 percent of the fixed cash base salary.

Each year, the Board of Directors shall consider whether a share-based incentive program should be proposed for the annual general meeting. If the general meeting is proposed to resolve on share-based remuneration, the Board of Directors' proposal for the general meeting shall include information about acquiring periods and, if applicable, information about the share-based remuneration expected share of total remuneration, the obligation to retain shares for a certain period after acquisition and an explanation of how the share-based remuneration promote the Company's business strategy, long-term interests and sustainability.

The senior executives' non-monetary benefits, such as company cars, computers, mobile phones, extra health insurance, or occupational health care, may be provided to the extent that such benefits are deemed market-based for senior executives in equivalent positions in the market where the company is active. The total amount of such benefits shall be to less than 10 percent of the fixed cash base salary.

Senior executives shall be covered by the prevailing ITP plan or defined contribution occupational pension that does not exceed 35 percent of the pensionable salary<sup>1)</sup>. Senior executive who reside outside Sweden or are foreign nationals and have their main pension in a country other than Sweden, may be offered other pension solutions that are reasonable in the relevant country. Such solutions must be defined contribution plans and not exceed 35 per of the salary base.

Senior executives shall be employed for an indefinite period of time. For the CEO, the termination pay and the severance pay may together not exceed an amount equivalent to 24 months fixed cash base salary and for other senior executives may the termination pay and the severance pay not exceed an amount equivalent to 12 months fixed cash base salary. Severance pay shall not be paid when termination is made by the senior executive.

Senior executives may be reimbursed for non-compete undertakings after termination of the employment, however, only to the extent that severance pay is not paid for the corresponding period of time. Such remuneration shall intend to compensate the senior executive for the difference between the fixed cash base salary at the time of termination of the employment and the (lower) income obtained, or could be obtained, through a new employment, assignment or own business. The remuneration shall be paid during the time the non-compete undertaking applies, however not for more than 12 months following termination of employment.

Remuneration to board members and deputy board members is, according to law, resolved by the general meeting to the extent the remuneration is related to the board assignment. If a board member is employed by the company, the renumeration to such board member shall be paid in accordance with these guidelines. Board members employed by the company shall not receive additional remuneration for a board assignment in the company or in a group company. If a board member performs work for the company that is not board related, market-based remuneration, taking into account the nature of the work and the work effort, shall be paid. Such remuneration shall be resolved by the Board of Directors (or, if follows from the Swedish Companies Act, the general meeting).

The Board of Directors' Remuneration Committee prepares and formulates proposals for the Board of Directors to resolve on remuneration for the CEO. The Board of Directors' Remune-

ration Committee prepares, in consultation with the CEO, and resolves on matters regarding remuneration to other senior executives. The assessment of whether the criteria for variable cash salary have been fulfilled shall be made by the Board of Directors and the Remuneration Committee, respectively, in a substantially non-discretionary way. The CEO and other members of the executive management do not participate in the Board of Directors' processing of and resolutions regarding remuneration-related matters in so far as they are affected by such matters.

These guidelines promotes the company's business strategy, long-term interests and sustainability in the way stated above regarding the criteria for variable remuneration and contribute to the company's ability to attract and retain important people to the operation in the long term. In the preparation of the Board of Directors' proposal for these remuneration guidelines, salary and employment conditions for employees of the company have been taken into account by including information on the employees' total income, the components of the remuneration and increase and growth rate over time, in the Remuneration Committee's and the Board of Directors' basis of decision when evaluating whether the guidelines and the limitations set out herein are reasonable.

The Board of Directors shall have the right to derogate from these guidelines if justified by particular circumstances in individual cases and a derogation is necessary to serve the company's long-term interests, including its sustainability, or to ensure the company's financial viability. In such case, the Board of Directors shall in its decision sate in which part derogation from the guidelines have been made, the specific reasons that justify the derogation and also report any derogation and the reasons in the Board of Directors annual report on the Remuneration Committee's evaluation of remuneration to senor management.

The Board of Directors shall prepare a proposal for new guidelines when there is a need for changes in these guidelines, but no later than at the annual general meeting 2024.

Information on remuneration to senior executives during previous fiscal years is presented in the company's annual report, including any previously remuneration resolved by not yet due.

#### Events after the end of the financial year

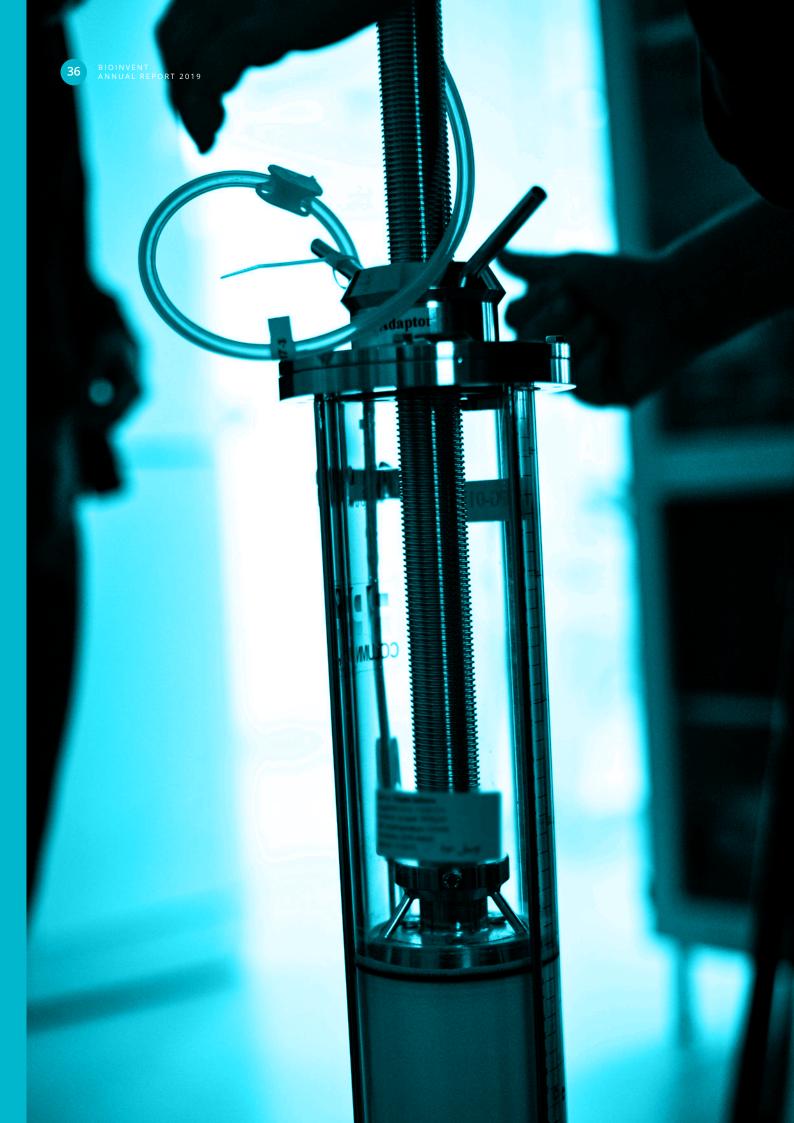
BioInvent and Transgene announced in March 2020 that the first clinical trial application for BT-001 was submitted and that the first-in-human trial is expected to start before the end of 2020 in Europe and the US.

BioInvent announced in March 2020 that necessary precautions were taken with regard to the coronavirus and that the Company will continue to monitor its spread and associated measures closely. BioInvent has clinical trials in process and clinical trials soon to be initiated. Global measures against the coronavirus and the need to prioritize healthcare resources will likely affect the timelines for these studies. The precise impact is difficult to assess at this stage, given the rapidly developing situation. We may see a delay of the early results from the Phase I open label study with a combination of BI-1206 and rituximab for treatment of Non-Hodgkin Lymphoma (NHL), which, however, are still expected in H2 2020. For the time being, early clinical trial results for BI-1206 in combination with pembrolizumab and clinical trial initiations in other programs remain on track.

In March 2020, BioInvent announced an agreement with SkylineDx to characterize the gene expression and immunological signatures in tumors of patients pre- and post-treatment with BI-1206.

#### **Proposed appropriation of profits**

At the disposal of the Annual General Meeting: Share premium reserve of SEK 239,893,829, retained earnings of SEK 379,000 and loss for the year of SEK -138,408,288. The Board of Directors propose that profits at the disposal of SEK 101,864,541 is carried forward. Thus, it is proposed that no dividend be given for the financial year 2019.



# Consolidated statement of comprehensive income for the Group

SEK thousand	Note	2019	2018
Net sales	3	93,740	38,548
Operating costs	4-8		
Research and development costs		-207,896	-140,182
Sales and administrative costs		-29,094	-27,955
Other operating revenue	9	6,519	6,697
Other operating costs	9	-1,117	-340
	•••••••••	-231,588	-161,780
Operating profit/lloss		-137,848	-123,232
Financial income	10	186	151
Financial expenses	11	-971	-82
Net financial items	••••••••••	-785	69
Profit/loss before tax		-138,633	-123,163
Tax	12	-	-
Profit/loss for the year		-138,633	-123,163
Other comprehensive income			
Items that have been or may be reclassified subsequently to profit or loss		-	-
Comprehensive income for the year		-138,633	-123,163
Other comprehensive income for the year attributable to the parent company's shareholders		-138,633	-123,163
Loss per share, SEK	13		
Before dilution		-0,31	-0.36
After dilution		-0,31	-0.36

# Consolidated statement of financial position for the Group

SEK thousand No.	ote	2019	2018
ASSETS	•		
Acquired intangible fixed assets	14	0	0
Right of use assets	22	16,842	
Equipment	15	14,823	15,934
Investments in rented premises	15	1,340	2,099
Total fixed assets	3	33,005	18,033
Inventories		5,380	2,950
Accounts receivable	21	12,708	8,881
Other receivables	21	17,145	15,030
Prepaid expenses and accrued income	17	3,898	6,655
Liquid funds	21	153,975	68,851
Total current assets	•	193,106	102,367
Total assets		226,111	120,400
SEK thousand No.	ote	2019	2018
SHAREHOLDERS' EQUITY	19	•	
Share capital		40,142	28,064
Other allocated capital		1,870,236	1,662,245
Reserves		1	1
Accumulated loss		-1,740,943	-1,602,689
Total shareholders' equity		169,436	87,621
Shareholder's equity pertaining to the Parent Company's shareholders		169,436	87,621
LIABILITIES			
Lease liabilities	22	9,472	
Total long term liabilities		9,472	
Lease liabilities	22	6,057	
Accounts payable	21	14,361	10,821
Other liabilities	21	9,536	5,364
Accrued expenses and deferred income	20	17,249	16,594
Total short term liabilities		47,203	32,779
Total shareholders' equity and liabilities		226,111	120,400

# Consolidated statement of cash flows for the Group

SEK thousand	2019	2018
Current operations		
Operating loss	-137,848	-123,232
Depreciation	11,612	5,061
Adjustments for other non-cash items	379	227
Interest received	65	131
Interest paid	-479	-2
Cash flow from current operations before changes in working capital	-126,271	-117,815
Changes in working capital		
Changes in inventories	-2,430	-564
Changes in current receivables	-3,185	15,911
Changes in short term liabilities	6,459	-7,104
	844	-23,579
Cash flow from current operations	-125,427	-141,394
Investment activities		
Acquisition of tangible fixed assets	-3,839	-3,847
Cash flow from investment activities	-3,839	-3,847
Cash flow from current operations and investment activities	-129,266	-145,241
Financing activities		
Directed share issue		80,300
Directed share issue, Board Share Program 2017		32
Directed share issue, Board Share Program 2018	54	
Rights issue and directed share issue	220,015	
Amortization of lease liability	-5,679	
Cash flow from financing activities	214,390	80,332
Change in liquid funds	85,124	-64,909
Opening liquid funds	68,851	133,760
Liquid funds at year-end	153,975	68,851
Liquid funds, specification:		
Current investments	_	_
Cash and bank	153,975	68,851
	153,975	68,851



# Statement of changes in equity for the Group

SEK thousand	Share- capital	Other allocated capital	Reserves	Accumulated loss	Total
Shareholders' equity 31 December 2017	24,376	1,585,601	1	-1,479,753	130,225
Comprehensive income for the year					
Profit/loss for the year				-123,163	-123,163
Comprehensive other income for the year			-		-
Total comprehensive income for the year			-	-123,163	-123,163
Total, excluding transactions with equity holders of the Company	24,376	1,585,601	1	-1,602,916	7,062
Transactions with equity holders of the Company					
Effect of employee incentive programs				227	227
Directed new share issue	3,656	76,644			80,300
Directed new share issue, Board Share Program 2017	32				32
Shareholders' equity 31 December 2018	28,064	1,662,245	1	-1,602,689	87,621
Comprehensive income for the year					
Profit/loss for the year				-138,633	-138,633
Comprehensive other income for the year			-		-
Total comprehensive income for the year			-	-138,633	-138,633
Total, excluding transactions with equity holders of the Company	28,064	1,662,245	1	-1,741,322	-51,012
Transactions with equity holders of the Company					
Effect of employee incentive program				379	379
Rights issue and directed share issue	12,024	207,991			220,015
Directed new share issue, Board Share Program 2018	54				54
Shareholders' equity 31 December 2019	40,142	1,870,236	1	-1,740,943	169,436

The share capital as of 31 December, 2019 consists of 501,769,896 shares and the share's ratio value is 0.08. The rights issue and directed issue completed in April 2019, amounted to in total SEK 220,015 thousand after issue expenses of SEK 20,465 thousand.

# Consolidated income statement for the Parent Company

SEK thousand	Note	2019	2018
Net sales	3	93,740	38,548
Operating costs	4-8		
Research and development costs		-208,124	-140,182
Sales and administrative costs		-29,114	-27,955
Other operating revenues	9	6,519	6,697
Other operating costs	9	-1,117	-340
	•	-231,836	-161,780
Operating profit/loss		-138,096	-123,232
Interest income and similar items	10	186	151
Interest costs and similar items	11	-498	- 82
Profit/loss after financial items	•••••••••••••••••••••••••••••••••••••••	-138,408	-123,163
Tax	12	-	-
Profit/loss for the year	•••••••••••	-138,408	-123,163
Other comprehensive income		-	-
Comprehensive income for the year	•••••••••••••••••••••••••••••••••••••••	-138,408	-123,163

# Consolidated balance sheet for the Parent Company

	Note	2019	2018
ASSETS	•••••••••••••••••••••••••••••••••••••••	•••••••••••	
Fixed assets			
Intangible fixed assets			
Acquired intangible fixed assets	14	0	0
Tangible fixed assets			
Equipment	15 15	14,823	15,934
Investments in rented premises	15	1,340	2,099
Financial fixed assets		16,163	18,033
Shares in subsidiaries	16	687	687
		687	687
Total fixed assets		16,850	18,720
Current assets			
Inventories		5,380	2,950
Current receivables			
Accounts receivable		12,708	8,881
Other receivables		17,145	15,030
Prepaid expenses and accrued income	17	5,436	6,655
		35,289	30,566
Liquid funds Current investments			
Cash and bank		153,975	68,851
	•••••••••••••••••••••••••••••••••••••••	153,975	68,851
Total suggests			
Total current assets		194,644	102,367
Total current assets Total assets			
	Note	194,644	102,367
<b>Total assets</b> SEK thousand	Note	194,644 211,494	102,367 121,087
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES	Note	194,644 211,494	102,367 121,087
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES	Note	194,644 211,494	102,367 121,087
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital	Note	194,644 211,494 2019	102,367 121,087 2018
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES  Shareholders' equity  Restricted equity	Note	194,644 211,494 2019	102,367 121,087 2018
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES  Shareholders' equity  Restricted equity  Share capital  Statutory reserve	Note	194,644 211,494 2019	102,367 121,087 2018 28,064
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity  Restricted equity  Share capital	Note	194,644 211,494 2019 40,142 27,693	102,367 121,087 2018 28,064 27,693
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve	Note	194,644 211,494 2019 40,142 27,693 67,835	102,367 121,087 2018 28,064 27,693 55,757
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve	Note	194,644 211,494 2019 40,142 27,693 67,835 239,893	102,367 121,087 2018 28,064 27,693 55,757 154,838
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings	Note	194,644 211,494 2019 40,142 27,693 67,835 239,893 379	102,367 121,087 2018 28,064 27,693 55,757 154,838 227
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings Profit/loss for the year	Note	194,644 211,494 2019 40,142 27,693 67,835 239,893 379 -138,408 101,864	28,064 27,693 55,757 154,838 227 -123,163 31,902
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings Profit/loss for the year  Total shareholders' equity	Note	194,644 211,494 2019 40,142 27,693 67,835 239,893 379 -138,408	102,367 121,087 2018 28,064 27,693 55,757 154,838 227 -123,163
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings Profit/loss for the year  Total shareholders' equity Short term liabilities Accounts payable	Note	194,644 211,494 2019 40,142 27,693 67,835 239,893 379 -138,408 101,864	28,064 27,693 55,757 154,838 227 -123,163 31,902
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings Profit/loss for the year  Total shareholders' equity Short term liabilities Accounts payable Liabilities to subsidiaries	Note	194,644 211,494 2019 40,142 27,693 67,835 239,893 379 -138,408 101,864 169,699 14,361 687	102,367 121,087 2018 28,064 27,693 55,757 154,838 227 -123,163 31,902 87,659 10,821 687
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings Profit/loss for the year  Total shareholders' equity Short term liabilities Accounts payable Liabilities to subsidiaries Other liabilities		194,644 211,494 2019 40,142 27,693 67,835 239,893 379 -138,408 101,864 169,699 14,361 687 9,498	102,367 121,087 2018 28,064 27,693 55,757 154,838 227 -123,163 31,902 87,659 10,821 687 5,326
SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings Profit/loss for the year  Total shareholders' equity Short term liabilities Accounts payable Liabilities to subsidiaries Other liabilities Accrued expenses and deferred income	Note 20	194,644 211,494 2019 40,142 27,693 67,835 239,893 379 -138,408 101,864 169,699 14,361 687	102,367 121,087 2018 28,064 27,693 55,757 154,838 227 -123,163 31,902 87,659 10,821 687
Total assets  SEK thousand  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings Profit/loss for the year  Total shareholders' equity Short term liabilities Accounts payable Liabilities to subsidiaries Other liabilities		194,644 211,494 2019 40,142 27,693 67,835 239,893 379 -138,408 101,864 169,699 14,361 687 9,498	102,367 121,087 2018 28,064 27,693 55,757 154,838 227 -123,163 31,902 87,659 10,821 687 5,326

# Consolidated statement of cash flows for the Parent Company

SEK thousand	2019	2018
Current operations		
Operating profit/loss	-138,096	-123,232
Depreciation	5,709	5,061
Adjustments for other non-cash items	379	227
Interest received	65	131
Interest paid	-6	-2
Cash flow from current operations before changes in working capital	-131,949	-117,815
Changes in working capital		
Changes in inventories	-2,430	-564
Changes in current receivables	-4,723	-15,911
Changes in short term liabilities	7,996	-7,104
	843	-23,579
Cash flow from current operations	-131,106	-141,394
Investment activities		
Acquisition of tangible fixed assets	-3,839	-3,847
Cash flow from investment activities	-3,839	-3,847
Cash flow from current operations and investment activities	-134,945	-145,241
Financing activities		
Directed new share issue	0	80,300
Directed share issue, Board Share Program 2017		32
Directed share issue, Board Share Program 2018	54	
Rights issue and directed share issue	220,015	
Cash flow from financing activities	220,069	80,332
Change in liquid funds	85,124	-64,909
Opening liquid funds	68,851	133,760
Liquid funds at year-end	153,975	68,851
Liquid funds, specification		
Current investments	-	-
Cash and bank	153,975	68,851
	153,975	68,851

# Statement of changes in equity for the Parent Company

	Restricted equity		Non-resti	ricted equitys	
SEK thousand	Share capital	Statutory reserve	Share premium reserve	Accumulated loss	Total
Shareholders' equity 31 December 2017	24,376	27,693	178,406	-100,212	130,263
Appropriation of profit/loss			-100,212	100,212	0
Comprehensive income for the year					
Profit/loss for the year				-123,163	-123,163
Comprehensive other income for the year				-	-
Total, comprehensive income for the year				-126,163	-126,163
Total, excluding transactions with equity holders of the Company	24,376	27,693	78,194	-123,163	7,100
Transactions with equity holders of the Company					
Effect of employee incentive program				227	227
Directed new share issue	3,656		76,644		80,300
Directed new share issue, Board Share Program 2017	32				32
Shareholders' equity 31 December 2018	28,064	27,693	154,838	-122,936	87,659
Appropriation of loss			-122,936	122,936	0
Comprehensive income for the year					
Profit/loss for the year				-138,408	-138,408
Comprehensive other income for the year				-	-
Total, comprehensive income for the year				-138,408	-138,408
Total, excluding transactions with equity holders of the Company	28,064	27,693	31,902	-138,408	-50,749
Transactions with equity holders of the Company					
Effect of employee incentive program				379	379
Rights issue and directed share issue	12,024		207,991		220,015
Directed new share issue, Board Share Program 2018	54				54
Shareholders' equity 31 December 2019	40,142	27,693	239,893	-138,029	169,699

The share capital as of 31 December, 2019 consists of 501,769,896 shares and the share's ratio value is 0.08. The rights issue and directed issue completed in April 2019, amounted to in total SEK 220,015 thousand after issue expenses of SEK 20,465 thousand.

**IAS 17** 

# Accounting principles and information notes

# **Note 1 Accounting principles**

# Statement of compliance with the applicable rules

The consolidated accounts have been prepared in accordance with International Financial Reporting Standards (IFRS). Since the Parent Company is an enterprise within the EU, only EU-approved IFRS will be applied. Moreover, the consolidated accounts are prepared in compliance with the Annual Accounts Act through the application of the Swedish Financial Reporting Board's recommendation RFR 1, Supplementary Accounting Regulations for Groups.

# **Parent Company's accounting principles**

The Parent Company's annual accounts have been prepared in compliance with the Annual Accounts Act and applying the Swedish Financial Reporting Board's recommendation RFR 2, Reporting for Legal Entities. The Parent Company's accounting principles are consistent with the Group's accounting principles, except that the new principles for financial leases, in accordance with IFRS 16, are not applied by the parent company. The Parent Company's accounting principles for 2019 are unchanged from the previous year.

# **Accounting principles**

Other than the exceptions detailed, the accounting principles set out below have been applied consistently to all periods presented in the consolidated financial statements.

# Changes in accounting principles

The Group applies IFRS 16 Leases with effect from 1 January 2019. IFRS 16 introduces a uniform lease recognition model for lessees. A lessee recognizes a right-of-use asset, representing a right to use the underlying asset, and a lease liability, representing an obligation to make future lease payments. Leases with a short term or where the underlying asset is of low value are exempted. The Group recognizes new assets and liabilities for operating leases relating to laboratory, production and office facilities. The cost of these leases changes, since the Group recognizes depreciation on lease assets and interest expense on lease liabilities. The Group applies the modified retrospective approach of 1 January 2019 without restating comparative information. In accordance with the transitional rules, the value of the asset has been set at the same amount as the liability as of 1 January, 2019 (with adjustment for prepaid lease charges reported in the balance sheet as of 31 December, 2018). A discount rate of 2.5 percent has been applied. Low-value leases (assets with a value of less than around SEK 50 thousand when new) are not included in the lease liability, but instead continued to be expensed on a straight line basis over the term of the lease. It is assessed that the Group does not have any significant volume of leases with a term of less than 12 months, known as short-term leases.

At the transition to IFRS 16, the Group reported right-of-use assets of SEK 22,745 thousand and lease liabilities of SEK 21,207 thousand, of which SEK 6,057 thousand was short-term lease liabilities. Adjustment of prepaid lease fees amounted to SEK 1,538 thousand. The reported rightof-use assets as of 1 January 2019 are entirely attributable to properties.

# Reconciliation between operating lease commitments as of 31 December, 2018 and opening acquisition value of lease liability

SEK million	2019
Operating lease commitments as of 31 December, 2018, according to the annual report 2018, note 7	29.8
Deduction of operating costs and property taxes	-6.0
Discounting	-1.1
Prepaid lease	-1.5
Opening acquisition value of lease liability as of January 1, 2019	21.2

# Comparative figures as if IAS 17 had been applied for 2019.

Excerpt from the statement of comprehensive income for the Group

	IFRS 16	IAS 17	IAS 17
SEK thousand	2019	2019	2018
Operating profit/loss	-137,848	-138,096	-123,232
Financial expenses	-971	-498	-82
Net financial items	-785	-312	69
Profit/loss before tax	-138,633	-138,408	-123,163
Tax	-	-	-
Profit/loss for the year	-138,633	-138,408	-123,163

### Excerpt from the consolidated statement of financial position for the Group **IAS 17**

**IFRS 16** 

	11/1/2 10	IA3 17	IAS I7
SEK thousand	2019	2019	2018
ASSETS			
Right of use assets	16,842		
Total fixed assets	33,005	16,163	18,033
Prepaid expenses and accrued income	3,898	5,436	6,655
Total current assets	193,106	194,644	102,367
Total assets	226,111	210,807	120,400
SHAREHOLDERS' EQUITY			
Accumulated loss	-1,740,943	-1,740,718	-1,602,689
Total shareholders' equity	169,436	169,661	87,621
LIABILITIES			
Lease liabilities	9,472		
Total long term liabilities	9,472		
Lease liabilities	6,057		
Total short term liabilities	47,203	41,146	32,779
Total shareholders' equity and liabilities	226.111	210.807	120.400

# Excerpt from the consolidated statement of cash flows for the Group

	IFRS 16	IAS 17	IAS 17
SEK thousand	2019	2019	2018
Current operations			
Interest paid	-479	-7	-2
Cash flow from current operations before changes in working capital	-126,271	-131,950	-117,815
Changes in working capital	844	844	-23,579
Cash flow from current operations	-125,427	-131,106	-141,394
Cash flow from investment activities	-3,839	-3,839	-3,847
Cash flow from current operations and investment activities	-129,266	-134,945	-145,241
Financing activities			
Amortization of lease liability	-5,679		
Cash flow from financing activities	214,390	220,069	80,332
Change in liquid funds	85,124	85,124	-64,909

# New IFRSs that the Company has not yet started to apply

New and amended IFRS standards with future application dates are not expected to have a material impact on the Group's financial statements.

### Classification

Non-current assets primarily comprise amounts that are expected to be recovered or settled subsequent to 12 months from the reporting date while current assets primarily comprise amounts that are expected to be recovered or settled within 12 months of the reporting date. Noncurrent liabilities consist primarily of amounts that the Company as of the reporting period have an unconditional right to choose to pay more than twelve months after the reporting period. If the Company does not have such a right at the end of the reporting period – or if the liability is held for trading or the liability is expected to be settled within the normal operating cycle – the liability is reported as a current liability.

### Basis for preparation of the accounts

The consolidated accounts are based on historical acquisition values, with the exception of some financial assets which are carried at fair value (available-for-sale financial assets and financial assets and liabilities carried at fair value through profit or loss for the year).

The BioInvent Group consists of the Parent Company, BioInvent International AB, and the wholly owned subsidiary BioInvent Finans AB. The consolidated financial statements are prepared using the acquisition method. Accordingly, shareholders' equity in the subsidiary is entirely eliminated upon acquisition. The Group's equity consists of the equity in the Parent Company and the equity in the subsidiary accrued after the acquisition.

# Segment reporting

BioInvent's executive officers, Board and management team monitor and manage the Company's operations based on the financial results and position at the consolidated level without dividing the business into segments. BioInvent develops antibody-based drugs. The Company's risks and opportunities are mainly affected by the progress of the projects. The Company engages in integrated activities, in which the projects are considered to carry similar risks and opportunities, and there is there therefore only one business segment, which is apparent in the consolidated income statement, balance sheet, cash flow statement and the notes associated with these.

The Company's revenue originates from different geographic areas; however, the Company's risks and opportunities in these geographic areas are similar. All sales take place through the Company's own sales organization in Sweden.

# **Revenue recognition**

Revenue is reported at the actual value of what has been received or will be received. Revenue are recognized to the extent that it is likely that financial benefits will arise for the Company, and revenue can be calculated reliably.

# Revenue from collaboration agreements associated with outlicensing of proprietary projects

These revenues consist of initial license fees, milestone payments and remuneration for development work as well as future royalties on sales of the medication.

- Initial license fees (upfront payments) are received at the time of signing
  of the agreement. These payments are recognized as revenue in their
  entirety when the collaboration agreement is signed provided that
  BioInvent have met all obligations in accordance with the agreement.
- Milestone payments are received when the outlicensed drug project
  passes essential steps in the development process, such as the start of
  different clinical phases. Milestone payments are recognized as revenue
  when all terms and conditions of the agreement are met.
- Payment for development work in conjunction with collaboration agreements is recognized as revenue as the work is completed.
- Future royalty revenue are recognized based on the economic substance of the agreements.

# Revenue from technology licenses

These revenues refer to outlicensing of the Company's technology platform n-CoDeR® and include access fees, milestone payments when predefined goals are reached, and future royalties on the sale of products developed under the license. Access fees for technology are recognized as revenue when all obligations of the agreement are met.

# External development

BioInvent also carries out external development projects such as process development and antibody manufacturing to external parties. In such agreements BioInvent receives ongoing compensation for work carried out. Revenue and expenses as well as profit and loss are reported in the accounting period during which the work is carried out. If a risk of loss is deemed to exist, individual provisions are performed on an ongoing basis.

### **Government grants**

These grants are recognized as accrued income when it is reasonable to assume that the grant will be received and that the criteria associated with the grant will be met. Grants are recognized as revenue through profit/loss for the year under "Other operating revenue" against the incurred project costs for which the grant was received.

### Interest income

Interest income is recognized in the period to which it relates based on the effective interest method. Effective interest is the interest that results in the present value of all future payments during the fixed interest term being equivalent to the carrying amount of the asset. Interest income is reported as financial income, see note 10.

# Research and development costs

Research costs are expensed as they occur. Costs for development of new products are not capitalized, unless the criteria in IAS 38 have been met. Since the Company's drug projects are quite a long time away from being registered as products that can be sold and thereby generate a financial gain for the Company, no costs for development of products are capitalized, i.e. no intangible assets developed by Biolnvent have been capitalized.

### Remuneration to employees

### Short-term remuneration

The Company reports short-term remuneration to employees as a cost during the period that the employee carries out the work for which he/ she is being compensated.

### Compensation after end of employment

For employees in Sweden the ITP 2 plan's defined benefit pension commitment for retirement and family pension is insured through Alecta. According to a statement issued by the Swedish Financial Reporting Board, "UFR 3 Classification of ITP plans financed by insurance in Alecta," this is a defined benefit plan that covers several employers. For the 2019 financial year, the Company did not have access to the information necessary to report this proportional portion of the plan's commitments, plan assets and costs, and as a result it was not possible to report this as a defined benefit plan. The ITP 2 pension plan secured by an Alecta insurance is therefore reported as a defined contribution plan. The premiums for defined benefit retirement and family pension plans is individually calculated and depends, among other things, on salary, pension earned previously and the anticipated remaining term of service. The anticipated premiums for the next reporting period for the ITP 2 pension plans covered by Alecta amount to SEK 2.0 million (2019: 2.2). The Group has determined that this portion of the total premiums for the plan and the Group's portion of the total number of active members in the plan are insignificant.

The collective consolidation level consists of the market value of Alecta's assets expressed as a percentage of insurance commitments calculated according to Alecta's actuarial methods and assumptions, which do not correspond with IAS 19. The collective consolidation level should normally be permitted to vary between 125 and 155 percent. If Alecta's collective consolidation level is less than 125 percent or exceeds 155 percent, steps are to be taken to create the necessary conditions for the consolidation level to return to the normal interval. In the case of low consolidation, one possible measure would be to raise the agreed price for taking out a new policy and increasing existing benefits. In the case of high consolidation, one possible measure would be to introduce premium deductions. At the end of 2019 Alecta's surplus in the form of the collective consolidation level was 148 percent (142).

# Compensation in connection with notice of termination

Compensation in connection with termination of employment is reported as a cost where the Company is obliged to prematurely terminate an employee's employment.

# **Share-related compensation**

A share option program allows the employees to acquire shares in the Company. The fair value of options allotted is recognized as a personnel cost, with a corresponding increase in equity. The fair value is calculated at the time of allotment and distributed over the vesting period.

The cost reported corresponds to the fair value of an estimate of the number of options expected to vest, taking into consideration terms of service, performance and market conditions. This cost is adjusted in subsequent periods so that it finally reflects the actual number of options vested. However, it is not adjusted when forfeiture is due only to the conditions relating to the market not being fulfilled.

Social security charges relating to equity-related instruments are expensed over the vesting periods for the options. The provision for social security charges is based on the fair value of the options on the reporting date.

# Disclosure of related party transactions

For information about benefits to senior executives, see note 4. Otherwise there are no transactions with related parties, in accordance with IAS 24, to report.

### Leases

# Principles applied with effect from 1 January 2019

When an agreement is entered into, the Group assesses whether the agreement is – or includes – a lease. An agreement is, or includes, a lease if the agreement conveys a right to use an identified asset for a period of time in exchange for consideration.

The Group reports a right of use asset and a lease liability when the lease begins. The right of use asset is measured initially at acquisition value, consisting of the initial value of the lease liability plus lease payments that are made on or before the start date as well as any initial direct expenses. The right of use asset is depreciated on a straight line basis from the start date until the end of the asset's useful life or the end of the lease term, whichever is the earlier. In the Group's case, this is normally the end of the lease term.

The lease liability, which is divided into a non-current and a current portion, is measured initially at the present value of the remaining lease payments over the assessed term of the lease. The term of the lease is the non-cancellable period plus additional periods in the lease if, at the time the lease commences, it is considered reasonably certain that such options will be exercised.

The lease payments are normally discounted using the Group's incremental borrowing rate, which in addition to the Group's credit risk reflects the term and currency of the lease in question as well as the quality of the underlying asset intended as security. The lease liability encompasses the present value of fixed payments, index- or price-linked variable lease payments, any residual value guarantees that are expected to be paid and penalties for termination of the lease.

The lease liability for the Group's premises where the rent is indexlinked is calculated as the rent that applies at the end of the reporting period in question. On this date the liability is adjusted, with corresponding adjustment of the carrying amount of the right of use asset. Similarly, the values of the liability and asset are adjusted in conjunction with reassessment of the lease term.

The Group presents right of use assets and lease liabilities on separate lines in the statement of financial position. No right of use asset or lease liability is recognised for leases with a term of 12 months or less, or where the underlying asset is of low value (less than SEK 50,000). Lease payments for these are expensed on a straight line basis over the term of the lease.

# Principles applied up to and including 31 December 2018

The Group's leases were assessed to be operating leases. The lease payments were expensed in the income statement and distributed over the term of the lease based on use.

# Taxes

Deferred tax shall be reported in the balance sheet, which means that deferred tax is calculated for all identified temporary differences between, on the one hand, the fiscal value of assets and liabilities, and on the other hand, their reported value.

# Intangible fixed assets

Externally acquired technology licenses that can be used broadly in the operation have been capitalized. These technology licenses supplement the proprietary technology platform where they are expected to offer competitive advantages. Cash payment for the acquisitions is capitalized taking into account the fact that a market value exists since the price was arrived at through negotiation between two independent parties. Intangible assets have a finite useful life and are stated at cost less accumulated amortization and impairment losses, if any. Such intangible assets are amortized over their estimated useful lives. The useful life assigned to an asset is evaluated on an ongoing basis and changed if necessary. However, the Company is conservative in its estimate of the usage period of acquired intangible assets, taking into account the constant, rapid development within the biotech industry. Such assets are therefore amortized over a period of up to 5 years.

# **Tangible fixed assets**

# Owned assets

Tangible fixed assets are valued at the acquisition value less accumulated depreciation. Tangible fixed assets are depreciated or amortised according to the straightline method over the expected useful life of the assets. The useful life assigned to an asset is evaluated on an ongoing basis and changed if necessary.

Depreciation/amortisation according to plan is as follows: Equipment 5 years
Investments in rented premises 5–10 years

# Inventories

Inventories are valued according to the lowest value principle and the first in, first out (FIFO) method. This means that the inventories are reported at the lowest of the acquisition value according to the FIFO method and the actual value.

### **Impairment**

The carrying amounts of the Group's assets are tested for impairment if there is indication of impairment.

# Impairment test of tangible and intangible assets and shares in subsidiaries, etc.

If there is any indication of impairment, the asset's recoverable value is calculated according to IAS 36 (see below). The estimated recoverable amount is assessed annually for intangible assets with an indefinite useful life and intangible assets that are not yet ready for use. If it is not possible to establish material independent cash flows for an individual asset, when assessing these assets the impairment requirement will be grouped at the lowest level at which it is possible to identify material independent cash flows (a so-called cash generating unit). Taking into account the specific nature of the business, BioInvent regards the entire business as one cash generating unit.

A significant portion of the reported assets is used to generate the Company's total cash flow. Accordingly, if an asset cannot be assessed separately, it will be assessed with all assets included in the cash-generating unit. Impairment is indicated when the reported value of an asset or cash-generating unit (group of units) exceeds the recovery value. An impairment loss is recognized in the income statement.

The recoverable amount is the higher of fair value less selling expenses and value in use. When calculating value in use, the future cash flow is discounted by a discounting factor which takes into consideration risk free interest and the risk associated with the specific asset.

### Impairment of financial assets

Reserves for expected credit losses are calculated and recognized for the financial assets measured at amortized cost. Reserves for credit losses are initially calculated and recognized based on 12 months' expected credit losses. If there has been a material increase in credit risk since the financial asset was first recognized, reserves for credit losses are calculated and recognized based on expected credit losses for the full remaining term of the asset. For accounts receivable that include a significant financing component a simplified method is applied, and reserves for credit losses are calculated and recognized based on expected credit losses for the full remaining term irrespective of whether there has been a material increase in risk. The calculation of expected credit losses is based mainly on information concerning historical losses for similar receivables and counterparties. The historical information is evaluated and adjusted continually based on the current situation and the Group's expectation of future events.

# Reversal of impairment losses

An impairment loss is reversed if there is an indication that the need for impairment no longer exists and there has been a change in the estimates used to determine the asset's recoverable amount.

An impairment loss is only reversed if the asset's reported value after reversal does not exceed the reported value that the asset would have had if the impairment loss had not been made.

# **Provisions**

A provision differs from other liabilities in that there is uncertainty concerning the time of payment or the sum required for settlement. A provision is recognized in the statement of financial position when there is an existing legal or constructive obligation as a result of a past event, it is probable that an outflow of economic resources will be required to settle the obligation and a reliable estimate of the amount can be made.

Provisions are made in the amount that represents the best estimate of funds needed to settle the existing obligation on the closing day. Where the effect of when a payment is made is significant, provisions are calculated by means of discounting the anticipated future cash flow at an interest rate before tax which reflects current market assessments of the time value of money and, where applicable, the risks linked with the liability.

# Restructuring

A provision for restructuring is recognised where there is an established detailed and formal restructuring plan, and the restructuring has either commenced or has been announced publicly. Future operating costs are not provided for.

# Transactions in foreign currencies

The consolidated financial statements are presented in Swedish kronor, which is the Company's functional and reporting currency. Transactions in foreign currencies are translated when they are entered in the accounts into the reporting currency, according to the spot rate on the transaction day. Receivables and liabilities in foreign currencies have been translated at the closing day exchange rate. Exchange rate gains and losses on operating receivables and liabilities are charged to the operating loss. Gains and losses on financial receivables and liabilities are reported as financial items.

### **Financial Instruments**

A financial instrument is any contract that gives rise to a financial asset, a financial liability or an equity instrument in another Company. For Bio-Invent this encompasses cash and cash equivalents, short-term investments, accounts receivable, other receivables, accounts payable, other liabilities, accrued expenses and derivative instruments. Cash and cash equivalents consist of cash and bank balances as well as short-term investments with a maturity of less than three months. Short-term investments comprise investments with a maturity of more than three months but less than 12 months.

### Recognition and measurement at initial recognition

A financial asset or a financial liability is recognized in the balance sheet when the Company becomes a party to the contractual provisions of the instrument. Accounts receivable are recognized in the balance sheet when an invoice has been sent. A liability is recognized when the counterparty has performed and the Company is contractually obliged to pay, even if an invoice has not yet been received. Accounts payable are recognized when an invoice has been received. A financial asset is derecognized from the balance sheet when the rights in the contract have been realized, expire or when the Company loses control over them. The same applies to a portion of a financial asset. A financial liability is derecognized from the balance sheet when the obligation specified in the contract is discharged or otherwise expires. The same applies to a portion of a financial liability. Acquisition and disposal of financial assets are recognized on the trade date, which is the date on which the Company undertakes to acquire or dispose of the asset.

At initial recognition financial instruments are measured at fair value

plus or minus transaction costs, except in the case of instruments measured on an ongoing basis at fair value through profit or loss, for which transaction costs are instead expensed as they arise. Accounts receivable (without a significant financing component) are initially recognized at the transaction price established in accordance with IFRS 15.

# Classification and subsequent measurement of financial assets

All the Group's financial assets, with the exception of derivative instruments, are recognized at amortized cost. This is because they are held within the framework of a business model where the purpose is to collect contractual cash flows which consist only of payments of principal and interest. Derivatives which are assets are recognized at fair value through profit or loss.

### Classification and subsequent measurement of financial liabilities

All the Group's financial liabilities, with the exception of derivative instruments, are recognised at amortised cost. Derivatives which are liabilities are recognised at fair value through profit or loss.

# **Hedge accounting**

Currency forward contracts are used to hedge receivables or liabilities against exchange rate risk. Both the underlying receivable or liability and the currency forward contract are reported at the exchange rate on the balance sheet date and exchange rate differences are recognized through profit or loss for the year. There is therefore no need for any special hedge accounting in the financial statements to reflect the financing hedging. Exchange rate differences on receivables and liabilities relating to operations are recognized in "Operating loss," while exchange rate differences on financial receivables and liabilities are recognized in "Net financial items".

# Note 2 Judgements and estimates in the financial statements

Preparing financial reports according to IFRS requires that management makes judgements and estimates as well as assumptions that affect the application of the accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual outcomes may differ from these judgements and estimates. Estimates and assumptions are reviewed periodically. Changes to estimates are recognized in the period when the change is made if the change only affected that period. If the change affects current and future periods, it is recognized in the period when the change is made and in future periods.

Critical estimates and judgments made in applying the Company's accounting policies are described below.

# Financing

Based on the fact that future, new clinical studies are expected to involve considerable cost, BioInvent's activities relating to these studies are expected to continue cause negative cash flows to accrue until the Company

generates annual revenue on an ongoing basis from products on the market. The capital requirement is financed through (i) revenue from collaboration agreements associated with outlicensing of proprietary projects, (ii) revenue from technology licenses, (iii) revenue from external development projects and, (iv) shareholders' equity. Failure to secure such financing could negatively affect the Company's business, financial position and operating income. The Board of Directors and Senior Management regularly assess the Company's capital requirements.

# **Recognition of revenue**

The Company's recognition of revenue require judgments by management whether important contract terms have been met when milestone payments are received, the timing of revenue recognition of license fees and external development and manufacturing services, as well as possibilities to receive payment of invoiced receivables.

# Note 3 Net revenues, fixed assets and investment activities

Revenue reported under *Net sales* consists entirely of revenue from contracts with collaboration partners. *Other operating income* includes financial support received from the EU's framework programs as well as exchange gains.

		roup	Parent Company	
SEK thousand	2019	2018	2019	2018
Revenue by geographical region	••••••••	•	•	••••••••••
Sweden	23,990	17,544	23,990	17,544
Europe	1,091	411	1,091	411
USA	60,551	20,593	60,551	20,593
Other countries	8,108	-	8,108	-
Total	93,740	38,548	93,740	38,548
Revenue consists of				
Revenues from collaboration agreements associated with outlicensing of proprietary projects	21,834	11,196	21,834	11,196
Revenues from technology licenses	12,717	2,222	12,717	2,222
Revenues from external development projects	59,189	25,130	59,189	25,130
Total	93,740	38,548	93,740	38,548
Fixed assets				
Sweden	33,005	18,033	16,163	18,033
Investment activities				
Sweden	3,839	3,847	3,839	3,847

# Note 4 Salaries, other remuneration and social security etc

		2019		2018		
SEK thousand	Salaries and other remuneration	Social security costs (of which pension costs)	Salaries and other remuneration	Social security costs (of which pension costs)		
Parent Company Subsidiaries	45,583 -	19,828 (8,103) -	40,864 -	17,051 (6,455) -		
Group total	45,583	19,828 (8,103)	40,864	17,051 (6,455)		

# Salaries and other remuneration distributed between the Board of Directors, the CEO and other employees

	20	)19	2018		
SEK thousand	Board and CEO <sup>1)</sup>	Other employees	Board and CEO <sup>1)</sup>	Other employees	
Parent Company	5,363 (828)	40,220	4,131 (638)	36,733	
Subsidiaries	-	-	-	-	
Group total	5,363	40,220	4,131	36,733	

<sup>1)</sup> Whereof variable remuneration incl. retention bonus.

# Pension costs distributed between the Board of Directors, the CEO and other employees

	20	119	2018		
SEK thousand	Board and CEO	Other employees	Board and CEO	Other employees	
Parent Company	721	7,382	608	5,847	
Subsidiaries	-	-	-	-	
Group total	721	7,382	608	5,847	

# **Benefits for senior executives**

# Principles

The Annual General Meeting resolves on remuneration for Board Members, including remuneration for committee work, based on the proposal from the Nominating Committee.

Benefits for CEO and other senior executives were determined in accordance with the 2019 Annual General Meeting. The Board determines the fixed salary of the CEO annually. The Board's Remuneration Committee determines the fixed salary of other senior executives annually. In addition to a fixed salary, variable remuneration may be payable according to the incentive scheme described below.

BioInvent's program for variable remuneration for the CEO and other senior executives is performance-related and can amount to 0–40 percent of the fixed annual cash salary. The performance related components

in the current program, for the period 1 January – 31 December 2020, are based primarily on high expectations for technical and commercial milestones in proprietary drug projects. The Board of Directors resolved in January 2020 to pay SEK 720 thousand to CEO Martin Welschof and SEK 1,516 thousand to other senior executives for the period 1 January – 31 December 2018. Variable remuneration is pensionable income.

The Company has provided a retention bonus to the CEO for the period 1 September 2018 to 31 August 2021. The retention bonus amounts to SEK 200 thousand (net after income tax) and will be paid out after the bonus period. Receipt of the retention bonus required the corresponding acquisition of BioInvent shares in 2019 to be held during the three-year period. The Cost in 2019 amounted to SEK 108 thousand.

In addition, other senior executives are covered by employee stock option incentive programs, described on page 51.

# Remuneration and other benefits in 2019

SEK thousand	Fixed salary/ fees	Board and committee fees	Variable remuneration incl. retention bonus	Other benefits	Salary exchange	Pension costs	Total
Board and CEO							
Leonard Kruimer, Chairman		682					682
Dharminder Chahal, member		363					363
An van Es Johansson, member		306					306
Vincent Ossipow, member		306					306
Bernd Seizinger, member		363					363
Martin Welschof, CEO	2,400		828	115		721	4,064
	2,400	2,020	828	115	•	721	6,084
Other senior executives (4 individuals)	6,489		1,516	342	555	1,343	10,245
Total	8,889	2,020	2,344	457	555	2,064	16,329

### Remuneration and other benefits in 2018

SEK thousand	Fixed salary/ fees	Board and committee fees	Variable remuneration incl. retention bonus	Other benefits	Salary exchange	Pension costs	Total
Board and CEO							
Leonard Kruimer, Chairman		341					341
Kristoffer Bissessar, member		242					242
Dharminder Chahal, member		46					46
An van Es Johansson, member		153					153
Vincent Ossipow, member		184					184
Bernd Seizinger, member		153					153
Björn Frendéus, acting CEO	1,424		470	90		369	2,353
Martin Welschof, CEO	800		168	60		240	1,268
	2,224	1,119	638	150	•	609	4,740
Other senior executives							
(5 individuals)	4,414		1,011	233	199	1,073	6,930
Total	6,638	1,119	1,649	383	199	1,682	11,670

### **Benefits for the Board and CEO**

The AGM resolved that the Board's fee shall amount to SEK 682,500 to the Chairman of the Board and SEK 305,500 to each of the other Board members, who are not employed by the company. In addition hereto, the AGM resolved on fees for committee work of SEK 57,500 to the Chairman of the Audit Committee, SEK 46,000 to each of the other members of the Audit Committee and SEK 57,500 to the Chairman of the newly established Scientific Committee and that no fee for work in the Remuneration Committee shall be paid. Fee for committee work shall not be paid to the Chairman of the Board.

Martin Welschof, CEO has received a fixed gross cash salary of SEK 2,400 thousand and SEK 828 thousand in variable remuneration (including retention bonus SEK 108 thousand), as well as SEK 115 thousand in other benefits. The total cost for pension benefits amounted to SEK 721 thousand. He is covered by pension benefits of 30 percent of the fixed annual cash salary. Retirement age is 65. The CEO and the Company have a mutual period of notice of six months. If notice is given by the Company, the CEO is entitled to redundancy pay equivalent to 12 monthly salaries. Redundancy pay is not deducted from other income. If the CEO resigns, no redundancy pay is payable. The CEO received an allotment of 221,619 options in February 2020.

### Benefits for other senior executives

Other senior executives are the individuals who, in addition to the CEO, are part of senior management. The retirement age for these senior executives is 65 and they are covered by the prevailing ITP plan. Employees residing outside Sweden, or who are foreign nationals and have their main pension in a country other than Sweden, may be offered other pension solutions that are reasonable in the relevant country, provided that the solution is a defined contribution pension plan. The Company and the other senior executives have a mutual period of notice of six months. Other senior executives are not entitled to redundancy pay over and above the payment of salaries during the period of notice.

Other senior executives received a fixed gross cash salary in 2019 of SEK 6,489 thousand. SEK 555 thousand has been exchanged from gross cash salary to pension costs. SEK 1,516 thousand was received in variable remuneration, as well as SEK 342 thousand in other benefits. The total pension costs relating to other senior executives amounted to SEK 1,343 thousand. Other senior executives received an allotment of 247,188 options in February 2020.

# Average number of employees

	2019		2018	
	Number of employees	Of which women	Number of employees	Of which women
Parent Company	68	67 %	59	64 %
Subsidiaries	-	-	-	-
Group total	68	67 %	59	64 %

# Percentage of women/men on the Board and in senior positions

•	2019		2018	
		Of which		Of which
	Number <sup>1)</sup>	women	Number <sup>1)</sup>	women
Board and CEO	8	37 %	9	33 %
Other senior executives	4	0 %	4	0 %

1) Number on 31 December.

# **Subscription Warrants Program 2016/2019**

The 2016 Annual General Meeting resolved to adopt an incentive program for the Company's employees in the form of a subscription warrants program. Under the program 957,571 subscription warrants have been transferred. The program includes all employees except the CEO and other senior executives comprised by the retention bonus program implemented in 2015. The last date to exercise was December 1, 2019. No subscription warrants were called for redemption.

# Option Program 2017/2020

The 2017 Annual General Meeting resolved to adopt a long-term incentive program in the form of an option program comprising management and other key persons. Each option entitles the holder to subscribe for one new share in BioInvent during the period from the day of release of the Company's year-end report for the financial year 2019 up to and including 15 December 2020. The subscription price per share shall be SEK 3.00. The program includes currently 10 persons. During the course of the program, 1,422,832 options have been allotted. No further allotments are due. The program, including costs for potential social security charges, is hedged by 1,900,000 warrants held by BioInvent Finans AB.

Employees will vest 50 percent of the options based on performance during each of the financial years 2017, 2018 and 2019, and 50 percent based on the Company's long-term value growth during the term of the program. The performance criteria for the participants shall be based on the same criteria as for the annual bonus, which principally are based on fixed technical milepost- criteria in projects, criteria for development of the project portfolio and other pre-determined criteria attributable to the business. The outcome criteria for the Company's long-term value growth are that the Company's market cap shall be at least three times as large during the period 1 July – 31 December 2019, calculated as an average in the same manner as the Subscription Price, in comparison with the market cap during the measure period for determination of the Subscription Price, calculated correspondingly. Allotment shall be proportional in relation to the period of employment during the year in question.

Vesting for other key persons shall amount to one third for each of the financial years 2017–2019 and be based on the assessment by the Board as to whether and to what extent the relevant person has contributed positively to the fulfilment of goals to be achieved by the relevant person and to the general development of the Company during the respective financial year.

The fair value of the options was determined using the Black & Scholes valuation model in relation to the performance criteria and the Monte Carlo model in relation to the value growth criteria. These measurement models are considered to provide a fair representation of the value for the options. The data below has been used for the calculation.

Option Program 2017/2020	2019	2018	2017
Allotted options	368,307	462,766	591,759
Fair value per option (SEK), Black & Scholes-model	0.11	0.26	0.58
Fair value per option (SEK), Monte Carlo-model	0.25	0.25	0.25
Share price for underlying shares (SEK)	1.90	2.07	2.30
Subscription price (SEK)	3.00	3.00	3.00
Estimated life of the option	1.54 year	2.54 year	3.13 year
Risk-free interest rate during the life of the option	-0.45 %	-0.42 %	-0.52 %
Assumed volatility	40 %	40 %	50 %
Expected dividends	-	-	-
Wage costs (SEK thousand)	-119	227	360

The program expenses refer to both the estimated cost of the value of the employees' service during the period, valued at market value at the time of the allocation, and the portion of the estimated social security fees earned during the period. BioInvent will pay social security fees on the gain that may result from the exercise of the employee options, estimated as the difference between the subscription price of the employee stock option and the market value of the shares.

# Option Program 2019/2025

The 2019 Annual General Meeting resolved to adopt a long-term incentive program in the form of an option program comprising the management group. The option program comprise a maximum of 3,971,000 stock options and the participants may be allotted options free of charge based on performance and continued employment. Each option entitles the holder to subscribe for one new share in BioInvent during the period from the day of release of the company's year-end report for the financial year 2022 up to and including 15 December 2025. The subscription price per share shall be SEK 3.16, corresponding to 140 percent the volume-weighted average price paid for the company's share on the Nasdaq Stockholm during ten trading days before 25 February 2019.

The CEO will vest 1/4 of the options during each of the financial years 2019, 2020, 2021 and 2022, based on performance and continued employment. Other members of the management group will vest 1/3 of the options during each of the financial years 2020, 2021 and 2022, based on performance and continued employment. The performance criteria for the participants will be based on the same criteria as for the annual bonus, which principally are based on fixed technical milepost-criteria in projects, criteria for development of the project portfolio and other pre-determined criteria attributable to the business. The gross benefit under the program is capped to MSEK 15 for the CEO and MSEK 10 for other participants.

To enable the company's delivery of shares pursuant to the option program and to secure costs connected therewith, primarily social security charges, the AGM resolved on a directed issue of maximum of 5,040,000 warrants (corresponding to approximately 1.0 percent of the total number of shares and votes in the company) and approval of transfer of warrants. Allotment of 221,619 took place in February 2020.

The fair value of the options was determined using the Black & Scholes valuation model in relation to the performance criteria. This measurement model is considered to provide a fair representation of the value for the options. The data below has been used for the calculation.

Option Program 2019/2025	2019
Allotted options	221,619
Fair value per option (SEK), Black & Scholes-model	0.65
Share price for underlying shares (SEK)	2.26
Subscription price (SEK)	3.16
Estimated life of the option	5.12 år
Risk-free interest rate during the life of the option	-0.07 %
Assumed volatility	45 %
Expected dividends	-
Wage costs (SEK thousand	498

The program expenses refer to both the estimated cost of the value of the employees' service during the period, valued at market value at the time of the allocation, and the portion of the estimated social security fees earned during the period. BioInvent will pay social security fees on the gain that may result from the exercise of the employee options, estimated as the difference between the subscription price of the employee stock option and the market value of the shares.

# Note 5 Information about auditors' fees

	G	roup	Parent Company	
SEK thousand	2019	2018	2019	2018
KPMG				
Audit	295	295	295	295
Other auditing activities besides the audit	282	25	282	25
Tax consultations	-	-	-	-
Other services	185	56	185	56
Total	762	376	762	376

Audit refers to the statutory audit of the financial statements, the accounting records and the administration of the business by the Board of Directors and the Chief Executive Officer, and auditing and other review procedures performed in accordance with agreements or contracts. This includes other procedures required to be performed by the Company's auditors as well as other services caused by observations during the performance of such examination and other procedures.

# Note 6 Depreciation and impairment losses according to plan of intangible and tangible fixed assets

	Gr	Parent Company		
SEK thousand	2019	2018	2019	2018
Research and development costs	11,094	5,040	5,663	5,040
Sales and administrative costs	518	21	46	21
Total	11,612	5,061	5,709	5,061

Depreciation of intangible and tangible assets is included in the items in the income statement as indicated above. Depreciation of intangible fixed assets amounted to SEK - thousand (-) and impairment losses amounted to SEK - thousand (-).

# Note 7 Income statement classified according to type of cost

	G	roup	Parent	t Company
SEK thousand	2019	2018	2019	2018
External costs	158,715	103,251	164,866	103,251
Personnel costs	66,663	59,825	66,663	59,825
Depreciation	11,612	5,061	5,709	5,061
Total	236.990	168.137	237.238	168.137

# Note 8 Exchange rate differences that affected profit/loss for the period

	Gro	oup	Parent (	Company
SEK thousand	2019	2018	2019	2018
Exchange rate differences that affected the operating loss	-845	-144	-845	-144
Financial exchange rate differences	-371	-32	-371	-32
Total	-1,216	-176	-1,216	-176

# Note 9 Other operating revenues and costs

	Gı	Group		Parent Company	
SEK thousand	2019	2018	2019	2018	
Other operating revenue				•	
Financial support from EU's framework program	6,249	6,504	6,249	6,504	
Insurance compensation	-	1	-	1	
Exchange rate gains	270	192	270	192	
	6,519	6 ,697	6,519	6,697	
Other operating costs					
Interest costs	-3	-4	-3	-4	
Exchange rate losses	-1,114	-336	-1,114	-336	
	-1,117	-340	-1,117	-340	
Total	5,402	6,357	5,402	6,357	

 $In 2018 \ and \ 2019 \ financial \ support \ from \ the \ EU's \ framework \ program \ was \ reported \ for \ early \ research \ projects.$ 

# **Note 10 Financial revenues**

	Gr	oup	Parent (	Company
SEK thousand	2019	2018	2019	2018
Interest income	65	103	65	103
Exchange rate differences	121	48	121	48
Total	186	151	186	151

# **Note 11 Financial costs**

	Gr	oup	Parent	Company
SEK thousand	2019	2018	2019	2018
Interest costs	-6	-2	-6	-2
Interest costs - leases	-473			
Exchange rate differences	-492	-80	-492	-80
Total	-971	-82	-498	-82

# Note 12 Tax on profit for the year

Tax on profit for the year	Gro	oup	Parent	Company
SEK thousand	2019	2018	2019	2018
Current tax on profit for the year	0	0	0	0
Deferred taxes relating to temporary differences	0	0	0	0
Reported tax on profit for the year	0	0	0	0

Reconciliation of effective tax		Group Parent Compan			
SEK thousand	2019	2018	2019	2018	
RReported profit/loss before tax	-138,633	-123,163	-138,408	-123,163	
Tax according to the applicable tax rate, 21,4 % (22 %)	29,667	27,096	29,619	27,096	
Tax effect of costs that are not deductible	-454	-209	-454	-209	
Tax effect of loss carry forward for which the deferred tax claim has not been/shall be considered	-29,213	-26,887	-29,165	-26,887	
Reported tax on profit/loss for the year	0	0	0	0	

There are no substantial deferred taxes that relate to temporary differences as of 31 December 2019. Deferred tax assets relating to unutilized loss carry-forwards and deductible temporary differences are only reported if it is likely that they will be utilized against future taxable earnings. The Group's accumulated unutilized loss carry-forwards amounted to SEK 1,772 million as of 31 December 2019. It is unclear when these loss carry-forwards will be utilized for deduction against taxable earnings. Deferred income tax recoverable relating to loss carry-forward is therefore not reported at any value.

# Note 13 Earnings per share

# Earnings per share before dilution

SEK thousand	2019	2018
Profit/loss for the period	-138,633	-123,163
Average number of outstanding shares (thousand)	453,527	339,470
Earnings per share before dilution, SEK	-0.31	-0.36
Earnings per share after dilution	2019	2018
Earnings per share after dilution  Profit/loss for the period	<b>2019</b> -138,633	<b>2018</b> -123,163

Diluted earnings per share is based on profit/loss for the year attributable to Parent Company shareholders and a weighted average of the number of outstanding shares plus the dilutive effects for potential shares. Option Program 2017/2020 entitles the holder to acquire one new share in Bio-Invent for a subscription price of SEK 3.00. Option Program 2019/2025 entitles the holder to acquire one new share in BioInvent for a subscription price of SEK 3.16. An average share price of SEK 1.49 per share was

used to determine whether a dilution effect exists for 2019. Option Program 2017/2020 and Option Program 2019/2025 have no dilution effect and are therefore excluded from the earnings per share after dilution calculation. The Company reported a loss for the period and accordingly there is no dilution effect. If in the future the share price exceeds the subscription price and the Company reports a profit, these options may lead to dilution.

# Note 14 Intangible fixed assets

Acquired intangible fixed assets	G	roup	Parent	Company
SEK thousand	2019	2018	2019	2018
Opening acquisition value	21,062	21,062	21,062	21,062
Acquisitions	-	-	-	-
Disposals	-	-	-	-
Closing accumulated acquisition value	21,062	21,062	21,062	21,062
Opening depreciation	-21,062	-21,062	-21,062	-21,062
Disposals	-	-	-	-
Depreciation for the year	-	-	-	-
Closing accumulated depreciation and Impairment losses	-21,062	-21,062	-21,062	-21,062
Closing residual value according to plan	0	0	0	0

# **Note 15 Tangible fixed assets**

Equipment	G	roup	Parent	Company
SEK thousand	2019	2018	2019	2018
Opening acquisition value	69,106	71,816	69,106	71,816
Acquisitions	3,839	3,848	3,839	3,848
Disposals	-1,864	-6,558	-1,864	-6,558
Closing accumulated acquisition value	71,081	69,106	71,081	69,106
Opening depreciation	-53,172	-55,429	-53,172	-55,429
Disposals	1,864	6,558	1,864	6,558
Depreciation for the year	-4,950	-4,301	-4,950	-4,301
Closing accumulated depreciation	-56,258	-53,172	-56,258	-53,172
Closing residual value according to plan	14,823	15,934	14,823	15,934

Investments in rented premises	Group		Parent Company	
SEK thousand	2019	2018	2019	2018
Opening acquisition value	15,569	15,569	15,569	15,569
Acquisitions	-	-	-	-
Closing accumulated acquisition value	15,569	15,569	15,569	15,569
Opening depreciation	-13,470	-12,710	-13,470	-12,710
Depreciation for the year	-759	-760	-759	-760
Closing accumulated depreciation	-14,229	-13,470	-14,229	-13,470
Closing residual value according to plan	1,340	2,099	1,340	2,099

Tangible fixed assets are primarily equipment used in research and development. Investments in rented premises are primarily investments in rented production facilities.

# Note 16 Shares in subsidiaries

			Share of	Share of	Book
	Co. reg. no.	Reg. office	equity	votes	value
Biolnvent Finans AB	556605-9571	Lund	100 %	100 %	687

BioInvent Finans AB administers warrants issued by BioInvent International AB.

	Parent C	ompany
SEK thousand	2019	2018
Opening acquisition value	687	687
Closing acquisition value	687	687

# Note 17 Prepaid expenses and accrued income

	Group		Parent Company	
SEK thousand	2019	2018	2019	2018
Prepaid rent	452	1,797	1,990	1,797
Other items	3,446	4,858	3,446	4,858
Total	3,898	6,655	5,436	6,655

# **Note 18 Financial risks**

Responsibility for the Group's financial transactions and risks is managed by the Company's financial function. The objective is to provide cost-effective financing and to minimise negative effects on the Group's performance arising from market risks.

### **Currency risks**

Bioinvent's currency exposure increases as development projects are moved forward in the value chain. Costs of services such as toxicological studies and clinical trials increase. These services are often carried out abroad and are paid for in foreign currencies.

Currency flows in conjunction with the purchase and sale of goods and services in currencies other than SEK generate transaction exposure. Currency exposure is primarily eliminated by matching flows in the same currency. When matching of underlying receivables and liabilities is not possible, the currency exposure is eliminated through forward contracts.

In 2019 49 percent (51) of revenues were invoiced in foreign currencies, mainly USD. Around 43 percent (39) of costs in 2019 were invoiced in foreign currencies, mainly in GBP and EUR. Realised forward contracts for flows in 2019 had an effect on the operating income in the amount of SEK 0.5 (0.4) million. A sensitivity analysis shows that the Company's operating profit/loss in 2019 before hedging transactions would have been affected in the amount of SEK -0.3 million if the Swedish krona had weakened by 1 percent compared with GBP and in the amount of SEK -0.4 million if the Swedish krona had weakened by 1 percent compared with EUR.

### Interest risk

BioInvent's exposure to market risk for changes in interest levels is related to bank balances and corporate and bank certificates. To reduce the effect of the fluctuation in market interest rates, the excess liquidity is invested with different maturities so that the investments mature on a regular basis over the subsequent twelve-month period.

The average interest rate in 2019 was 0.0 percent (0.1). A change in the interest rate of 1 percent in 2019 would have affected the net interest income by SEK 1.3 million.

# Liquidity and credit risk

Liquidity risk is the risk of the Company experiencing difficulties, in future, in fulfilling its obligations associated with financial liabilities. The financial function provides the Board of Directors and management with ongoing liquidity forecasts.

Liquidity risk is minimized by liquidity planning and investment in financial instruments that can be redeemed at short notice. Only investments in interest bearing securities with low credit risk and high liquidity are permitted. There are also limitations in the amount that can be invested with an individual counterparty to avoid concentration of credit risk.

In accordance with the Company's financial policy excess liquidity is placed in bank accounts and invested in corporate and bank certificates with a K1 rating or equivalent. Corporate and bank certificates carry fixed interest rates and may have terms of up to one year.

BioInvent works with established and creditworthy counterparties. A credit assessment is carried out for all partners who will receive some form of credit. In addition, BioInvent monitors receivables on a constant basis. The Company's exposure to doubtful receivables has historically been very low.

# Note 19 Shareholders' equity

# Share capital

	Ordin	ary snares
Thousands of shares	2019	2018
Issued as of 1 January	350,800	304,695
Directed new share issue		45,704
Directed new share issue, Board Share Program 2017		401
Rights issue and directed share issue	150,300	
Directed new share issue, Board Share Program 2018	670	
Issued as of 31 December	501,770	350,800

The share capital as of 31 December 2019 consists of 501,769,896 shares and the share's ratio value is 0.08. Shareholders holding ordinary shares are entitled to dividends. Each share carries one vote at the Annual General Meeting.

# Other allocated capital

Refers to shareholders' equity contributed by the shareholders over and above share capital.

# Fair value reserve

The fair value reserve includes the accumulated net change in fair value of available-for-sale financial assets until such time as the assets are derecognised from the statement of financial position.

# Retained earnings including profit/loss for the year

Retained earnings including profit/loss for the year includes the accumulated profit/loss of the Parent Company and subsidiary.

# **Proposed appropriation of profits**

At the disposal of the Annual General Meeting: Share premium reserve of SEK 239,893,829, retained earnings of SEK 379,000 and loss for the year of SEK -138,408,288. The Board of Directors propose that profits at the disposal of SEK 101,864,541 is carried forward. Thus, it is proposed that no dividend be given for the financial year 2019.

# **Capital management**

According to the Board's policy, the Group's financial goal is to have a strong capital structure and financial stability enabling the Company to retain the trust of investors and credit issuers in the market, and to have a foundation for continued business growth. Capital is defined as total shareholders' equity. Bearing in mind the Company's focus, no specific debt/equity ratio target is defined.

# Note 20 Accrued expenses and deferred income

	Group		Parent Company	
SEK thousand	2019	2018	2019	2018
Payroll liabilities	8,343	8,570	8,343	8,570
Social security fees	3,031	2,973	3,031	2,973
Other items	5,875	5,051	5,875	5,051
Total	17,249	16,594	17,249	16,594

# Note 21 Financial assets and liabilities

# **Group 2019**

SEK thousand		Book value			Fair value
	Mandatorily measured at fair value through profit or loss	Financial assets measured at amortised cost	Other liabilities	Total	Level 2¹)
Financial assets measured at fair value	•	•	•••••••••••••••••••••••••••••••••••••••	•	
Currency forward contracts	25			25	25
	25			25	25
Financial assets not measured at fair value					
Accounts receivable		12,708		12,708	
Other receivables		17,120		17,120	
Current investments		-		-	
Cash and bank		153,975		153,975	
		183,803	•••••••••••••••••••••••••••••••••••••••	183,803	
Financial liabilities measured at fair value					
Currency forward contracts	-5			-5	-5
	-5			-5	-5
Financial liabilities not measured at fair value					
Accounts payable			14,361	14,361	
Other liabilities			-9,531	-9,531	
			-23,892	-23,892	
Group 2018					
SEK thousand		Book value	•••••	•	Fair value
	Mandatorily measured at fair value through profit or loss	Financial assets measured at amortised cost	Other liabilities	Total	Level 2¹)
Financial assets measured at fair value	•	•••	•••••••••••	•	
Currency forward contracts	13			13	13
	13			13	13
Financial assets not measured at fair value					
Accounts receivable		8,881		8,881	
Other receivables		15,017		15,017	
Current investments		-		-	
Cash and bank		68,851		68,851	
		92,749		92,749	

-25

-25

-10,821

-5,339 -16,160 -25

-25

-25

-10,821 -5,339

-16,160

# Maturity structure of financial liabilities - undiscounted cash flows

Currency forward contracts -25

Financial liabilities measured at fair value

Accounts payable

Other liabilities

Financial liabilities not measured at fair value

Remaining term, 31 Dec. 2018 Financial liabilities	-32.779			-32.779
	-42,684	-4,614	-9,947	-57,245
Currency forward contracts	-5			-5
Accrued expenses	-17,249			-17,249
Other liabilities	-9,531			-9,531
Accounts payables	-14,361			-14,361
Lease liabilities	-1,538	-4,614	-9,947	-16,099
SEK thousand Remaining term, 31 Dec. 2019	< 3 months	3–12 months	1–5 year	Total

<sup>1)</sup> Instruments at level 2 were measured at fair value based on prices quoted by brokers. Similar contracts are traded on an active market and the prices reflect actual transactions involving comparable instruments.

# Not 22 Leases

The impact of the transition to IFRS 16 on the Group's leases is described in Note 1 Accounting principles. The transition method that the Group has chosen to apply in the transition to IFRS 16 means that the comparative information has not been recalculated to reflect the new requirements.

The Group's tangible fixed assets comprise both owned and leased assets.

SEK thousand	2019
Owned tangible fixed assets Right of use assets	16,163 16,842
Total	33,005

The Group's lease assets consist of laboratory, production and office premises. No leases contain covenants or other restrictions apart from the security in the leased asset.

### Right of use assets

SEK thousand

Opening acquisition value as of 1 January, 2019 Depreciation for the year	22,745 -5.903
Closing residual value according to plan	16,842
Lease liabilities	
SEK thousand	2019
l and tarm	0.472

# Long term 9,472 Short term 6,057 Lease liabilities included in statement of financial position for the Group 15,529

For maturity analysis of lease liabilities, see Note 21 Financial assets and liabilities.

# Amounts reported in the statement of comprehensive income for the Group

SEK thousand	2019
Depreciation of rights of use assets	-5,903
Interest costs, leases	-473
Costs of low value leases	-225
Total	-6,601

# IAS 17 Non-cancellable lease payments as of 31 December, 2018 amounted to:

SEK thousand	Group 2018	Parent company 2018
Payments due year 2019	7,854	7,854
Payments due year 2020-2023	21,950	21,950
Payments due year 2024 or later	-	-
Total	29,804	29,804

Lease charges were for laboratory, production and office premises and was primarily included in research and development costs. Expensed fees for operating leases amounted to SEK 7,401 thousand in 2018.

# Amounts reported in the consolidated statement of cash flows for the Group $\,$

SEK thousand	2019
Total cash flows attributable to leases	-6,377

The above cash flow includes both the amounts of leases that are reported as lease liabilities and the amounts of leases of low value.

### **Leases for premises**

2019

The Group's leases for premises have been signed with Wihlborgs Fastigheter. The leases normally have a term of three years. These leases generally include an option to renew the lease for a further three years at the end of the lease period. Usually the lease is automatically extended by three years unless notice to terminate the lease is given in writing at least nine months prior to the end of the lease period.

Leases for premises include lease payments that are based on changes in the rental price index. The leases also require the Group to pay charges relating to property taxes. These amounts are set annually.

# Not 23 Events after the end of the reporting period

BioInvent and Transgene announced in March 2020 that the first clinical trial application for BT-001 was submitted and that the first-in-human trial is expected to start before the end of 2020 in Europe and the US.

BioInvent announced in March 2020 that necessary precautions were taken with regard to the coronavirus and that the Company will continue to monitor its spread and associated measures closely. Bio-Invent has clinical trials in process and clinical trials soon to be initiated. Global measures against the coronavirus and the need to prioritize healthcare resources will likely affect the timelines for these studies. The precise impact is difficult to assess at this stage, given the rapidly developing situation. We may see a delay of the early results from the Phase I open label study with a combination of BI-1206 and rituximab for treatment of Non-Hodgkin Lymphoma (NHL), which, however, are still expected in H2 2020. For the time being, early clinical trial results for BI-1206 in combination with pembrolizumab and clinical trial initiations in other programs remain on track.

In March 2020, BioInvent announced an agreement with SkylineDx to characterize the gene expression and immunological signatures in tumors of patients pre- and post-treatment with BI-1206.

# Not 24 Information about the Parent Company

BioInvent International AB (publ) is a limited liability Company registered in Sweden. The registered office is in the Lund municipality. The visiting address is Sölvegatan 41, Lund and the postal address is SE-223 70 Lund, Sweden. The consolidated accounts cover of the Parent Company BioInvent International AB and the wholly-owned subsidiary BioInvent Finans AB.

The undersigned certify that the consolidated accounts and the annual report have been prepared in accordance with International Financial Reporting Standards (IFRS), as adopted for use in the European Union, and generally accepted accounting principles respectively, and give a true and fair view of the financial positions and results of the Group and the Company, and that the Directors' reports of the Group and the Company give a fair review of the development of the operations, financial positions and results of the Group and the Company and describes substantial risks and uncertainties that the Group companies faces.

The annual report and the consolidated accounts were approved for publication by the Board and the CEO on 8 April 2020.

Leonard Kruimer	Vessela Alexieva	Dharminder Chahal	Elin Jaensson Gyllenbäck
Chairman of the Board	Board member	Board member	Board member
An van Es Johansson	Vincent Ossipow	Bernd Seizinger	Martin Welschof
Board member	Board member	Board member	CEO

Our audit report was submitted on 8 April 2020. KPMG AB

# Auditor's Report

To the general meeting of the shareholders of BioInvent International AB (publ), corp. id 556537-7263

# Report on the annual accounts and consolidated accounts

# **Opinions**

We have audited the annual accounts and consolidated accounts of BioInvent International AB (publ) for the year 2019. The annual accounts and consolidated accounts of the company are included on pages 30–58 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act, and present fairly, in all material respects, the financial position of the parent company as of 31 December 2019 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2019 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and 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 general meeting of shareholders adopts the income statement and balance sheet for the parent company and the statement of comprehensive income and statement of financial position for the group.

Our opinions in this report on the the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

# **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. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

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

# **Key Audit Matters**

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

# **Financing**

See disclosure 2 and the section on risk, page 33, in the annual accounts and the consolidated accounts for detailed information and description of the matter.

# **Description of key audit matter**

The Company is focused on the discovery and development of immuno-regulatory antibodies to treat cancer. Due to the length of time it takes to develop a drug, the Company has significant research and development cost during the development period and is expected to spend more resources in the future until the research and development results can be commercialised.

The revenues of the Company consist of:

- Revenue from collaboration agreements associated with out-licensing of proprietary projects
- · Revenue from technology licenses and
- Revenue from external development projects.

From time to time, the Company also receives infusions of capital from the shareholders to be able to ensure financing of the operations and support the clinical studies.

The Board of Directors follows the financing situation and is working on a plan to ensure the Group's continued financing.

# Response in the audit

We have considered the decision of the Board to apply the going concern principle when preparing the annual accounts and consolidated accounts. We have assessed executive management's forecasts, showing whether or not there is available cash to conduct the business for a period of at least twelve months from the date of the financial reports.

We have considered the reasonableness and support for the assumptions that form the basis for the cash flow forecasts, including the so called sensitivity analysis. We have had discussions with executive management on how the assumptions were made and we have considered this in our assessment.

With respect to significant agreements with partners, we have considered the Group's revenue and cost undertakings, paying particular attention to the terms in the agreements. For agreements that are more assessment-dependent, e.g. milestone payments in product development, we have assessed a range of potential cash flows and the sensitivity of these.

We have had discussions with executive management on the Group's future plans and potential sources of financing, and evaluated these in relation to the information available and our past experience.

# **Accounting of revenue**

See disclosure 2 and accounting principles on page 45 in the annual account and consolidated accounts for detailed information and description of the matter.

# Description of key audit matter

The revenues of the Company consist of:

- Revenue from collaboration agreements associated with out-licensing of proprietary projects
- · Revenue from technology licenses and
- Revenue from external development projects.

The structure and terms of these agreements and partnerships vary, and revenue is accounted for both at one point in time and over time.

As these agreements contain several components, there is a risk that revenues will be recognized in the wrong period.

### Response in the audit

Accounting of revenue from agreements with customers has been a focus are for our audit.

Our assessment of revenue recognition focuses on the following critical assessment made by executive management:

- Assessment of whether important agreement terms have been met when receiving milestone payments
- Timing of revenue recognition of license fees and royalties
- Assessment of timing of revenue recognition for external development and manufacturing assignments
- · Possibilities to receive payments for the invoiced receivables.

Milestone payments recognised as revenue have been confirmed through confirmation from the counterparty that the milestone has been reached. Revenue derived from development assignments and licensing agreements have been verified against the agreement terms and we have assessed whether or not agreement terms have been met in order for revenues to be recognised.

Significant revenue items have been verified against underlying agreements and supporting documents for payments verifying that the Company has received the revenue.

# Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1–29. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is 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 concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

# Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director 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 and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director 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 Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to 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 Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

# **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 issue 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 scepticism throughout the audit. We also:

- dentify 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 our 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 the Managing Director.
- · Conclude on the appropriateness of the Board of Directors' and the Managing Director'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, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our 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

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

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter.

# 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 Managing Director of BioInvent International AB (publ) for the year 2019 and the proposed appropriations of the company's profit or loss.

We recommend to the general 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 Managing Director 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 Managing Director

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

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are neces-sary 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 Managing Director 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 scepticism 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.

KPMG AB, Box 227, 201 22 , Malmö, was appointed auditor of BioInvent International AB (publ) by the general meeting of the shareholders on the 24 April 2018. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2012.

Malmö 8 April 2020 KPMG AB

# Corporate governance report

BioInvent applies the Swedish Corporate Governance Code ("the Code"). In addition to the Code, BioInvent also complies with applicable rules in the Swedish Companies Act, rules and recommendations ensuing from the Company's listing on Nasdaq Stockholm, and good practices on the stock market.

This corporate governance report has been prepared in accordance with the provisions of the Annual Accounts Act and the Code. The corporate governance report has been prepared as a document separate from the Annual Report, and is as such not part of the formal Annual Report documentation. The corporate governance report has been reviewed by the Company's auditor in accordance with the provisions of the Annual Accounts Act. The auditor's statement is attached to the report.

# **Annual General Meeting**

The Annual General Meeting ("AGM"), or as applicable, the Extraordinary General Meeting, is the supreme decision making body of BioInvent in which all shareholders are entitled to participate. The Articles of Association contain no restrictions regarding the number of votes that may be cast by a shareholder at a General Meeting and no special provisions regarding amendments of the Articles of Association.

The AGM addresses the Company's progress and resolves on a number of key issues, such as the adoption of the income statement and balance sheet, allocation of result, discharge from liability for the Board of Directors and the CEO, and the election of Board of Directors until the next AGM. Every second year, an auditor for the Company is elected for a term of two years and the AGM resolves on compensation for the auditor.

At the AGM 2019, the Board of Directors was authorised to resolve on the issue of not more than the number of new shares equivalent to 20 percent of the registered share capital (as per the date of the resolution on the issue of new shares), on one or several occasions during the period up to the next AGM.

The AGM 2019 was held on 25 April and the minutes are available on the BioInvent website. The AGM 2020 will be held in Lund on Thursday 28 May at 4 p.m.

Notification to attend the AGM is published no earlier than six and no later than four weeks before the Meeting. Proposals to the General Meeting should be addressed to BioInvent International AB, attn: Board of Directors, 223 70 Lund and submitted in good time before notification to attend the Meeting is issued, no later than seven weeks before the Meeting.

# **Nominating Committee and shareholders**

In accordance with the resolution of the AGM, the Nominating Committee shall consist of the Chairman of the Board as the convener, and a representative for each of the Company's three largest shareholders as of 31 August each calendar year. The Nominating Committee shall prepare all the elections and proposals of remuneration that come into question from the Nominating Committee has been appointed until a new Nominating Committee is appointed. The Nominating Committee is tasked with preparing proposals to present to the AGM regarding the election of Chairman of the General Meeting, election of Chairman of the Board and other Board members, resolution on remuneration of the Board of Directors, shared among the Chairman, other Board members and possible compensation for committee work and, where applicable, election of auditors and auditor's fees.

The Nominating Committee for the AGM 2019 consisted of

Mattias Cramby (Mexor i Skellefteå AB), Erik Esveld (Van Herk Investments B.V.), Vincent Ossipow (Omega Fund IV, LP) and the Chairman of the Board Leonard Kruimer. The Nominating Committee formulated proposals regarding the Chairman of the General Meeting, the composition of the Board of Directors and remuneration of the Board of Directors. The Nominating Committee had four meetings, of which three were by telephone. The committee members also had additional telephone contacts. No fees have been paid to the members of the Nomination Committee.

Pursuant to the Nomination Committees reasoned statement the Nomination Committee has, when preparing its proposal for Board members, applied Section 4.1 of the Code as diversity policy. The goal of the policy is that the Board of Directors shall have a composition appropriate to the Company's operations, phase of development and other relevant circumstances, characterised of diversity and breadth of qualifications, experience and background and that the Company shall strive for gender balance. The AGM 2019 resolved to elect Board members in accordance with the Nomination Committees' proposal, which resulted in the present Board of Directors. However, when preparing its proposal, the Nomination Committee concluded that the composition of the Board of Directors will not meet the ambition that 40 percent of the Board members shall represent the underrepresented gender, but noted that the two employee representatives appointed to the Board of Directors are women. At the AGM 2019, five Board members were elected, whereof one woman and four men.

The composition of the Nominating Committee for the AGM 2020 was presented on BioInvent's website on 9 January 2020. According to the Code, the Company must post the names of the Nominating Committee's members on the Company's website six months prior to the AGM and, where applicable, information on which shareholder the Committee member represent. Due to the fact that it has taken longer than anticipated to appoint the Nominating Committee, BioInvent has deviated from the abovementioned requirement. The Nominating Committee for the AGM 2020 consists of Mattias Cramby (Mexor i Skellefteå AB), Erik Esveld (Van Herk Investments B.V.), Vincent Ossipow (Omega Fund IV, LP) and the Chairman of the Board Leonard Kruimer. No fees have been paid to the members of the Nomination Committee.

No shareholder holds a stake equal to or greater than 10 percent of the votes of all shares in BioInvent.

# The Board of Directors and its work

BioInvent's Board of Directors is elected annually at the AGM for the period until the next AGM and shall, according to the Articles of Association, consist of no less than five and no more than nine members. The Articles of Association contain no special provisions regarding the election or dismissal of Board members.

The AGM 2019 discharged the Board members and the CEO from liability and re-elected the ordinary Board members Dharminder Chahal, An van Es Johansson, Leonard Kruimer, Vincent Ossipow and Bernd Seizinger. Leonard Kruimer was elected Chairman of the Board. The Board of Directors consists of five directors elected by the General Meeting, as well as the employee representatives Vessela Alexieva and Elin Jaensson Gyllenbäck.

The Board of Directors is presented on page 28. All Board members elected by the General Meeting are independent in relation to the Company, senior executives and major shareholders.

The AGM 2019 resolved that the Board's fee shall amount to SEK 682,500 to the Chairman of the Board and SEK 305,500 to each of the other Board members, who are not employed by the company. In addition hereto, the AGM resolved on fees for committee work of SEK 57,500 to the Chairman of the Audit Committee, SEK 46,000 to each of the other members of the Audit Committee and SEK 57,500 to the Chairman of the newly established Scientific Committee and that no fee for work in the Remuneration Committee shall be paid. Fee for committee work shall not be paid to the Chairman of the Board.

The work of the Board of Directors is governed by rules of procedure which are revised and adopted by the Board of Directors at least once a year. The rules of procedure primarily consist of directions for the Board of Directors work, instructions for the division of duties between the Board of Directors and the CEO and instructions for the financial reporting.

In 2019 the Board of Directors held six ordinary meetings and seven extraordinary meetings. The Board of Directors met with the Company's auditor on two occasions, including one occasion without the presence of the CEO or other persons from the senior management. Attorney Madeleine Rydberger, Mannheimer Swartling Advokatbyrå, has served as the secretary of the Board of Directors during the year. Regular items on the agenda at the meetings included monitoring of the operation in relation to the Company's budget and strategic plan. In addition, the Board of Directors has considered and resolved on issues pertaining to research and development, financing, intellectual property, strategic focus and planning, the budget, essential agreements, audit, financial reporting and compensation related issues.

Board member	Attendance
Leonard Kruimer (Chairman)	13 (13)
Vessela Alexieva	13 (13)
Kristoffer Bissessar <sup>1)</sup>	8 (8)
Dharminder Chahal	11 (13)
Elin Jaensson Gyllenbäck	10 (13)
An van Es Johansson	11 (13)
Vincent Ossipow	12 (13)
Bernd Seizinger	12 (13)

<sup>1)</sup> Resigned on 25 April 2019 in conjunction with the AGM.

Once a year the Board of Directors evaluates its own work and the work of the CEO with a view to develop Board procedures and efficiency. The evaluation takes the form of a questionnaire that the members answer, after which the responses are compiled and presented to the Board of Directors and the Nomination Committee along with the results of the evaluations carried out in the two preceding years.

# **Remuneration Committee**

The Board of Directors has appointed a Remuneration Committee consisting of Leonard Kruimer (Chairman), An van Es-Johansson and Bernd Seizinger. All members are independent in relation to the Company and the senior executives. The work is regulated in the instructions that comprise part of the rules of procedure for the Board of Directors and include to consider and to resolve

on issues pertaining to remuneration and benefits to senior executives. The work includes preparation of other remuneration issues of greater importance, such as incentive programs. Added to this are assignments to monitor and evaluate ongoing and completed programs for variable remuneration to senior executives, monitor and evaluate implementation of the guidelines for remuneration to senior executives applicable for the year, as well as applicable remuneration structures and levels within the Company. The Remuneration Committee reports to the Board of Directors. The committee held two meetings in 2019.

Member of the Remuneration Committee	Attendance
Leonard Kruimer (Chairman)	2 (2)
An van Es Johansson	2 (2)
Bernd Seizinger	2 (2)

# **Audit Committee**

The Board of Directors has appointed an Audit Committee consisting of Leonard Kruimer (Chairman) and Dharminder Chahal (for the period following the AGM in 2019; before then Kristoffer Bissessar (Chairman), Dharminder Chahal and Leonard Kruimer). The Audit Committee's members have the requisite accounting expertise.

The Audit Committee, whose work is regulated in the instructions that serve as part of the rules of procedure for the Board of Directors, is tasked with preparing issues on behalf of the Board of Directors regarding procurement of audit services and remuneration, monitoring the auditors' work and the Company's internal control systems, monitoring the current risk scenario, monitoring external audits and the Company's financial information, adopting the interim reports for quarters 1 and 3, pre-paring the interim report for quarters 2 and 4, as well as the Company's Annual Report, monitoring issues pertaining to financing, and preparing the adoption and revision of financial policy and other issues that the Board of Directors entrusts to the Committee to prepare. The Audit Committee reports to the Board of Directors. The committee held eight meetings in 2019.

Member of the Audit Committee	Attendance
Kristoffer Bissessar (Chairman) <sup>1)</sup>	2 (2)
Dharminder Chahal	8 (8)
Leonard Kruimer (Chairman)	8 (8)

<sup>1)</sup> Resigned on 25 April 2019 in conjunction with the AGM.

# **Auditors**

According to the Articles of Association, BioInvent shall appoint a registered auditing Company for a term of two years. The auditor attends at least one Board meeting a year not attended by the CEO and other members of the Company's senior management. The AGM 2018 elected KPMG AB to serve as the Company's auditors for a two-year mandate. Eva Melzig, authorized public accountant, is principal auditor.

# **Group Management**

According to its guidelines and instructions, the Board of Directors has delegated the day-to-day business to the CEO. The CEO and under his leadership, other members of the management group, are responsible for collective business operations and day-to-day business. The CEO regularly reports to the Board of Directors on the Company's business operations, financial performance and other issues relevant to the Company. At one Board meeting a year the Board of Directors evaluates the work of the CEO. No member of the senior management is present at this meeting. The CEO and the senior management are presented on page 29.

# **Remuneration to senior executives**

The AGM 2019 adopted guidelines for remuneration to senior executives. According to the guidelines, salaries and other terms of employment for senior management are set at market rates. In addition to a fixed base salary senior executives can also receive a variable salary, which will be limited and based mainly on technical and commercial milestones within proprietary drug projects. In addition to such fixed and variable compensation, the Company may grant retention bonuses which for a three year period may amount to a maximum of 100 percent of the fixed salary for a year. Senior executives may also receive remuneration in the form of options or other share-related incentive programs, as decided by the Annual General Meeting of shareholders. The complete guidelines can be seen in the Board of Directors Report on page 49.

# The Company's systems for internal control and risk management with respect to financial reporting for the 2019 financial year

According to the Swedish Companies Act and the Code the Board of Directors is responsible for internal control. This description has been prepared in accordance with the Annual Accounts Act, Chapter 6, Section 6, and describes the Company's systems and procedures for internal control in connection with financial reporting. Internal control and risk management regarding financial reporting is a process designed by the Board of Directors to provide the Board of Directors, senior management and others involved in the organisation a reasonable assurance regarding the reliability of external financial reporting and the extent to which the financial statements are formulated in compliance with generally accepted accounting principles, applicable laws and regulations as well as other requirements for listed companies.

# **Control Environment**

The foundation of the internal control process consists of the overall control environment, including among other things: the Company's ethical values, organisational structure and decision making procedures, as well as the allocation of powers and responsibilities. The most essential components of the control environment at BioInvent are documented in its policies and other governing documents. BioInvent's rules of procedure describe the allocation of responsibilities between the Board of Directors and the CEO, as well as among the Board's committees. Other policies and governing documents include the Company's ethical guidelines, treasury policy and authorisation instructions.

### **Control activities**

Appropriate control activities is a prerequisite to manage essential risks associated with the internal control process. To ensure the efficacy of the internal control procedures, BioInvent has both computerised controls in IT systems to handle authorization and approval authority, as well as manual controls such as inventories and reconciliation procedures. Detailed financial analyses of the Company's performance, as well as follow-up of plans and forecasts, supplement the controls and provide an overall confirmation of the quality of financial reporting.

### Information and communications

BioInvent's most essential policies and other governing documents are updated regularly and communicated to everyone involved through established information channels, in print and/or in electronic format.

# Follow-up

BioInvent follows up and assesses its compliance with internal policies and other governing documents on a regular and annual basis. Suitability and functionality are also evaluated on a regular and annual basis. Inadequacies are reported and remedied in accordance with specific established procedures.

# **Internal audit**

BioInvent has formulated governance and internal control systems with regular follow-up of compliance at various levels within the Company. The Board of Directors therefore does not consider a separate audit function to be necessary in the current situation. This is reconsidered annually by the Board of Directors.

Lund, 8 April 2020 The Board of Directors

# Auditor's report on the corporate governance statement

To the general meeting of the shareholders in BioInvent International AB (publ), corporate identity number 556537-7263

# **Engagement and responsibility**

It is the board of directors who is responsible for the corporate governance statement for the year 2019 on pages 62–64 and that it has been prepared in accordance with the Annual Accounts Act.

# The scope of the audit

Our examination has been conducted in accordance with FAR's auditing standard RevU 16 *The auditor's examination of the corporate governance statement.* This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

# **Opinions**

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2–6 the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Malmö 8 April 2019 KPMG AB

Eva Melzig Authorized Public Accountant



# **Annual General Meeting**

The Annual General Meeting will be held on Thursday 28 May, 2020 at 4 p.m., Elite Hotel Ideon, Scheelevägen 27, Lund, Sweden.

Shareholders who wish to attend the AGM must be recorded in the printout of the share register maintained by Euroclear Sweden AB ("Euroclear"), as of Friday 22 May, 2020; and notify the Company of their intention to attend the meeting at the address: BioInvent, Sölvegatan 41, SE 223 70 Lund, Sweden, att: Stefan Ericsson, by telephone +46 46 286 85 54 or by e-mail stefan.ericsson@bioinvent.com on Friday 22 May, 2020 at the latest, preferably before 4 p.m.

On giving notice of attendance, the shareholder shall state name, personal identity number/registration number, number of shares held, phone number and, if applicable, the name of any representative. Proxy to act on behalf of a shareholder should be sent together with the notice of attendance and the proxy must be presented in original at the latest at the AGM. Representative of a legal person shall hand in a copy of a registration certificate or similar documents of authorisation. Proxy form is available at the Company's website www.bioinvent.se and will be supplied directly to shareholders who so request.

In order to participate in the proceedings at the AGM, share-holders with nominee-registered shares must request their bank or broker to have the shares temporarily owner-registered with Euroclear. Such registration must be made as per Friday 22 May, 2020 and the bank or broker should therefore be notified in due time before said date.

# **Upcoming financial reports**

BioInvent will present the following financial reports:
• Interim reports 28 April, 27 August, 29 October 2020

# **Investor Relations**

Martin Welschof, CEO, +46 (0)46 286 85 50, martin.welschof@bioinvent.com
BioInvent's financial reports are also available at www.bioinvent.com

# **Forward looking information**

This annual report contains statements about the future, consisting of subjective assumptions and forecasts for future scenarios. Predictions for the future only apply as of the date they are made and are, by their very nature, in the same way as research and development work in the biotech segment, associated with risk and uncertainty. With this in mind, the actual outcome may deviate significantly from the scenarios described in this annual report.



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