



## Content

4	BioInvent in 2018
6	BioInvent in brief
8	Comments by the CEO
10	Immunotherapy and immuno-oncology
12	Strategy
<b>15</b>	Project overwiev
19	Market overview
22	The BioInvent share
24	Five-year review
<b>26</b>	The Board and Auditors
<b>27</b>	Senior management
28	Directors' report
33	Consolidated statement of comprehensive income for the Grou
34	Consolidated statement of financial position for the Group
<b>35</b>	Consolidated statement of cash flows for the Group
<b>36</b>	Statement of changes in equity for the Group
<b>37</b>	Income statement for the Parent Company
38	Balance sheet for the Parent Company
<b>39</b>	Statement of cash flows for the Parent Company
40	Statement of changes in equity for the Parent Company
41	Accounting principles and information notes
<b>55</b>	Auditor's Report
<b>58</b>	Corporate governance report
61	Auditor's report on the corporate governance statement
63	Annual General Meeting

## BioInvent in 2018

#### **BioInvent's clinical projects**

- In May, BioInvent received authorization from the Swedish Medical Product Agency to start a Phase I/IIa study of BI-1206 in combination with rituximab in patients with non-Hodgkin lymphoma. In July, the FDA approved an IND application that provides the opportunity to extend the same study to US sites.
- The first patient in the Phase I/IIa study of BI-1206 was dosed in early September.
- In October, BioInvent announced its intention to initiate three new clinical programs in solid cancer, starting in the first half of 2019. In addition to the previously disclosed programs (BI-1206 + rituximab – projected topline results H1 2020; and the Transgene and Pfizer collaborations), and subject to successful preclinical results and sufficient financial resources, BioInvent intends to advance the following programs in solid cancer:
  - An anti-FcγRllB antibody in combination with an anti-PD1 antibody projected start phase I/lla in H1 2019.
  - BI-1607 (an anti-FcγRllB antibody) in combination with a checkpoint inhibitor – projected start phase I proof of concept trial in H2 2019.
  - BI-1808 (anti-TNFR2 antibody), as single agent and in combination with an anti-PD1 antibody
     projected start phase I in H1 2020.

#### **Research and development collaborations**

• In July 2018 BioInvent's partner Oxurion reported Day 150 topline data from a phase I/II study of THR-317 in patients with diabetic macular edema. The study met its primary endpoint of safety for both the 4 mg and 8 mg doses. Whilst the focus of the study was safety, efficacy was also observed. In September 2018 Oxurion enrolled the first patient in a phase II study evaluating THR-317 for treatment of idiopathic MacTel 1.

#### **Publication of scientific data**

- Researchers at University College in London published in March an article in the journal Cancer Cell. In the article, the research group, which is led by BioInvent's collaborator Professor Sergio Quezada, describes data that support the notion that modulation of Fc gamma receptor binding may be an attractive strategy to improve the activity of CTLA-4 antibodies, and potentially also the activity of antibodies directed against additional targets with high relative expression on regulatory T cells.
- In September, a Nature imprint journal published data confirming the power of BioInvent's integrated technology platform for discovery of clinically relevant oncology targets and therapeutic antibodies. The article was written by BioInvent researchers in collaboration with Professor Mats Ohlin's team at Lund University, and clinical researchers at the Hematology and Oncology Departments at Skåne University Hospital.
- BioInvent and Transgene presented two posters at the annual meeting of the Society for Immunotherapy of Cancer Annual in November, with positive data for a new Treg deletion-optimized checkpoint blocking antibody and its targeting oncolytic viral vector.
- The same month, data was published in the leading cancer journal Immunity on the cellular and molecular mechanism of action of antibodies to the co-stimulatory immune checkpoint receptor 4-1BB.

#### **Extended patent protection**

• In January, the Company announced that the European Patent Office had communicated its intention to grant the Copany a patent relevant to the Company's platform, F.I.R.S.T.™, and the patent was then issued in July. The Company announced in July and September receiving similar notices from the patent offices in Japan and the US, respectively, for the corresponding applications in these countries. These two latter patents were issued in July 2018 and January 2019, respectively.

#### **Financing**

 In March, BioInvent completed a directed share issue of SEK 84.6 million before transaction costs to a number of institutions and specialist investors, including Rhenman Healthcare Equity L/S and IMEurope (Institut Mérieux), not previously a shareholder in BioInvent.

#### **Manufacturing agreements**

- In July, BioInvent signed a manufacturing agreement with the Swedish biopharmaceutical Company ITBMed AB, which is expected to generate revenue of at least SEK 17 million in 2018 and 2019.
- In September, BioInvent entered into a licensing and manufacturing agreement with Abcentra (formerly CardioVax) regarding orticumab - previously known as BI-204. The agreement is expected to generate production revenue of approximately USD 3.0 million in the near term. BioInvent is also entitled to royalties on possible future net sales.
- In December, BioInvent entered into a manufacturing agreement with an undisclosed U.S. cell therapy company for the production of cGMP material for their clinical development programs. The manufacturing agreement is expected to generate revenue of approximately USD 1.5 million, mainly in 2019

#### **Change in the executive management**

BioInvent announced in April that Dr Martin Welshof
was appointed new President and CEO. Martin has
broad international experience from executive positions
within the biotech industry and a strong scientific background in the field of antibody technology. He took
office on September 1.

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

- In January 2019, the FDA granted orphan designation for the antibody BI-1206 for the treatment of mantle cell lymphoma.
- In February 2019, BioInvent announced a fully underwritten rights issue of SEK 210 million and a directed issue of SEK 30 million with a Swedish pension fund and a Swedish life science fund. Additionally, the Board of Directors was proposed to be authorized to resolve on an over-allotment option for up to SEK 70 million, that can be exercised if the rights issue is over-subscribed. At the extraordinary general meeting on 20 March 2019, the rights issue and the over-allotment option were approved.
- In March 2019 BioInvent announced that the United States Patent and Trademark Office had issued a Notice of Allowance that a patent application relevant to its F.I.R.S.T.™ platform had been allowed and can proceed to grant. It covers methods for differential biopanning.

SEK million	2018	2017
Net sales	39	45
Loss for the year	-123	-101
Liquid funds	69	134





## BioInvent in brief

BioInvent focuses on research and development of new and first-in-class immunomodulating antibodies for the treatment of cancer. Immuno-oncology drugs are one of the greatest breakthroughs of the 21st century in the field of medicine. In contrast to chemotherapy, which directly targets the tumor cells, immuno-oncology drugs activate important cells in the immune system which can then attack the tumor. BioInvent's drug candidate that has advanced the farthest, BI-1206, is in development to improve the effect of rituximab and overcome rituximab resistance in the treatment of hematological cancer, particularly non-Hodgkin lymphoma (NHL) and chronic lymphocytic leukemia (CLL). The Company's preclinical portfolio is focused on important immunosuppressive cells and pathways in the tumor microenvironment, which include regulatory T cells (Tregs), tumor-associated myeloid cells and mechanisms for resistance to antibody drugs. The Company intends to initiate three clinical programs in solid cancer, subject to successful preclinical results and sufficient financial resources.

#### **Technology Platform**

BioInvent's technology platform consists of the n-CoDeR® antibody library and the unique F.I.R.S.T.™ development tool. From n-CoDeR®, a library developed by BioInvent containing fully human antibodies, drug candidates that bind specifically and firmly to their target structures can be identified. With the help of the unique, function-based F.I.R.S.T.™ screening method, where patient material is the foundation throughout the development process, the most clinically relevant target structures in a disease model and matching antibodies are identified simultaneously.

#### **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 hematological cancers.
- Developing pre-clinical first-in-class antibodies targeting tumor-associated myeloid cells, in collaboration with Pfizer.
- Advancing three compounds into clinical programs in solid cancer: an anti-FcγRllB antibody in combination with an anti-PD1 antibody – projected start phase I/lla in H1 2019; BI-1607 (an anti-FcγRllB antibody) in com-

bination with a checkpoint inhibitor – projected start phase I proof of concept trial in H2 2019; BI-1808 (an anti-TNFR2 antibody), as single agent and in combination with an anti-PD1 antibody – projected start phase I in H1 2020.

- Advancing its preclinical Treg immuno-oncology programs identifying both antibodies to novel targets and novel pathways, as well as differentiated antibodies with new mechanisms of action to validated targets.
- Intensify the collaboration with Transgene to develop oncolytic virus encoding either a validated anti-CTLA-4 antibody sequence, or antibody sequences targeting an undisclosed target aimed at treatment of solid tumors.
- Developing TB-403, in collaboration with Oncurious, as a potential treatment for pediatric brain cancers.

## Comments by the CEO



This is a potentially transformative time for BioInvent. We are accelerating our clinical development programs, and further developing the high-quality preclinical portfolio.

This is underpinned by our efforts in 2018, when BioInvent continued its successful development linked to the immune inhibitory receptor  $Fc\gamma RIIB$ . The first patient was dosed in the beginning of September in an open Phase I/IIa study with the anti- $Fc\gamma RIIB$  antibody BI-1206 in combination with rituximab in patients with indolent relapsed or refractory B-cell non-Hodgkin lymphoma. Topline results from the study are expected in the first half of 2020. In January 2019, the U.S. Food and Drug Administration (FDA) granted orphan designation for the antibody BI-1206 for the treatment of mantle cell lymphoma.

Our ambition is to bring two additional product candidates targeted at  $Fc\gamma RIIB$  into clinical development in 2019, in combination with an anti-PD1 antibody and a checkpoint inhibitor, respectively. Combinations of several different treatment therapies make it possible to attack multiple parts of the tumor to prevent the tumor from escaping the immune system. BioInvent has also identified TNFR2, a member of the so called TNFR superfamily (TNFRS), as a target within the Treg program. We have further identified antibody candidates with various mechanisms of action that show promising preclinical data, the most advanced of which is BI-1808, which is expected to enter clinical trials in the first half of 2020.

Our oncolytic virus collaboration with Transgene has developed well over the past year. An anti-CTLA-4 antibody developed by BioInvent is incorporated into the Transgene vaccinia virus vector, which has shown potential to be administered both intratumorally and systemically. We expect to be able to bring this project into clinical development in 2020 as a potential treatment of solid tumors.



At the same time, we have made further progress in the collaboration with Pfizer, which aims to develop first-in-class antibodies targeting tumor-associated myeloid cells. To date, pools of antibodies have been generated and characterized for functional activity.

This expanded clinical activity requires funding, and BioInvent is now conducting a fully underwritten rights issue of SEK 210 million and a directed issue of SEK 30 million with a Swedish pension fund and a Swedish life science fund. Additionally, the Board of Directors has the possibility to resolve on an over-allotment option for up to SEK 70 million, that can be exercised if the rights issue is over-subscribed. We intend to use the net proceeds mainly to expand the continued clinical development of BI-1206 for treatment of hematological cancers, as well as to advance three compounds into clinical programs in solid cancer. The funds will also be used to continue development of the Company's prioritized preclinical projects, including the collaboration with Transgene.

BioInvent's manufacturing facility, which primarily provides capacity to produce antibodies for the Company's preclinical studies and clinical trials, has also attracted new customers, and in 2018 we have signed new agreements with Abcentra, ITBMed and an undisclosed U.S. cell therapy Company. As well as the advantage of having our own manufacturing facility, it also provides revenue to the Company.

The brief outline above shows clearly what an exciting period this is for BioInvent. The financing enables a potential transformation of BioInvent, by allowing us to accelerate development, further advancing our first-in-class clinical candidates and bringing our high-quality preclinical portfolio into clinical opportunities.

Martin Welschof Chief Executive Officer



## Immunotherapy and immuno-oncology



Immunotherapy is a type of treatment that induces and boosts the body's natural defences 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 number of the immune cells that render the tumor cells harmless live on in the body and have what is known as a tumor-specific immunological memory (the same principle as for ordinary vaccinations against, for example, viruses). This immunological memory both provides protection against recurring cancer and eradicates metastases spread in the body, and is unique to immunotherapy. The cells that can have an 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 recognise and destroy cancer cells, including metastases;
- stopping the cancer from spreading to other parts of the body; 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; the most common are listed below.

#### **Monoclonal antibodies**

When the body's immune system discovers something harmful and foreign, it produces antibodies. 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 block an abnormal protein in a cancer cell. This is done by the monoclonal antibodies attaching to the tumor cells' specific proteins, which means that the tumor cells are marked so that other parts of the immune system, e.g. macrophages and other myeloid cells, can then find and kill them. Another commonly occurring type of antibody is T cell-activating antibodies or checkpoint inhibitors. As mentioned above, T cells are essential for an effective immune response against cancer, but in cancerous tissue they are often inhibited by certain molecules known as checkpoints.



#### **Checkpoint inhibitors**

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

#### **Oncolytic virus therapy**

In oncolytic virus therapy genetically modified viruses are used to kill cancer cells. The physician injects a virus into the tumor and the virus then finds its way into the cancer cells and replicates itself. As a result, the cancer cells rupture and die. When the cancer cells die, they release specific substances, known as antigens, and cause inflammation. The release of antigens and inflammatory substances activates the patient's immune system, making it ready to attack and kill all cancer cells in the body that have the same antigens on their surface. The virus does not attack healthy cells. To increase the effect of the oncolytic virus, the virus can be "loaded" with further immune-stimulating substances.

BioInvent has a partnership with Transgene to co-develop oncolytic viruses that express either an anti-CTLA-4 antibody (one of the checkpoint inhibitors) or an antibody targeting an undisclosed target, aimed at treating solid tumors. This means that infecting the cancer cells with the virus will also lead to local release of an antibody, further reinforcing the anti-cancer effect.

#### T cell therapy

T cells are a type of immune cells that form part of the specific immune system and that fight infection, but also cancer. In T cell therapy, some T cells are removed from the patient's blood or tumor tissue. The cells are then genetically modified in a laboratory to give them specific receptors on their surface that allow the T cells to recognise the cancer cells. The altered T cells are cultivated in large numbers in the laboratory and reintroduced into the patient's body. They then seek out and destroy cancer cells. This type of therapy is known as chimeric antigen receptor (CAR) T cell therapy.

## 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.

#### BioInvent's five focus areas

Five focus areas are deemed essential to BioInvent's continued success:

#### **High-level science**

BioInvent has a Scientific Advisory Board consisting of five world-leading experts in the antibody area and cancer immune-biology. The main task of the Scientific Advisory Board, chaired by Professor Martin Glennie of the University of Southampton, is to provide BioInvent with valuable input during the development of novel antibody treatments for various types of cancer diseases.

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. Additionally, BioInvent works in partnership with leading external researchers, notably Professor Martin Glennie and Professor Mark Cragg, both from the University of Southampton. Their research team is a global leader in the field of antibodies and cancer.

The combination of the knowledge and experience, both within the Company and of external partners, increases the value of the BioInvent's n-CoDeR® and F.I.R.S.T.™ technology platforms. A clear indication of the high-level science of BioInvent's research and drug development is the publication of articles on its research in scientific journals such as Cancer Cell and Immunity.

#### **Professional product development**

BioInvent has a team with long experience of preclinical and clinical drug development, and collaborates with other pharmaceutical companies that can provide valuable support in these processes. The collaboration with Pfizer regarding development of antibodies against tumorassociated myeloid cells is the most obvious example of this.

In addition, BioInvent uses its good relations with internationally leading clinical opinion formers within the medical profession to develop clinical development plans and to build external interest for its projects.

BioInvent's own manufacturing facility gives BioInvent the capacity to independently produce antibodies for preclinical studies and clinical trials, which is mandatory for a swift pre-clinical/clinical development path.

A clear indication of the high-level science of BioInvent's research and drug development is the publication of articles on its research in scientific journals such as Cancer Cell and Immunity.



### BioInvent's Scientific Advisory Board

Martin Glennie, Professor in immunochemistry at the University of Southampton. World-leading scientist in antibody biology. Dr. Glennie's group has pioneered characterisation of molecular mechanisms underlying therapeutic activity of clinically validated antibodies, forming the basis for development of new generations of antibody drugs.

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, specialised in CD4-T cell regulation and homeostasis, and its role in autoimmunity and cancer.

The main task of the Scientific Advisory Board, chaired by Professor Martin Glennie, University of Southampton, is to provide BioInvent with valuable input in its effort to develop new antibody treatments for various forms of cancer diseases.

BioInvent's Chief Scientific Officer, Professor Björn Frendéus, has been appointed Secretary of the Scientific Advisory Board.

#### **Commercial focus**

Demand from global pharmaceutical companies for promising immuno-oncology projects is high, and many large commercial partnerships worth tens of billions of SEK combined have been announced in recent years. BioInvent's intention is to enter into collaboration agreements with global pharmaceutical companies to generate significant revenue flows and to ensure an effective continued development and commercialisation of the Company's projects. The optimal time to sign such agreements varies between different projects and depends on, for example, resource requirements, risk level and commercial potential. In some cases it may be attractive to enter into a partnership as early as the preclinical phase, while in other cases it may be more profitable to invest in proprietary clinical trials.

BioInvent's decisions on investing in new projects, as well as follow-up investments in ongoing projects, are always preceded by structured analysis of the commercial potential. The medical need for new treatment, the project's level of invention, the patentability, the competition situation and anticipated total development costs are examples of parameters that are evaluated in such an analysis.

The Board of Directors and management have extensive experience of negotiations and business transactions with global companies. The appointment of Dr. Martin Welschof as CEO in 2018 is expected to significantly strengthen the commercial focus. The Company has a structured approach to marketing its projects and management spends a significant portion of its time on contacts with prospective partners and licensees around the world.

For projects in certain indications the Company can apply for so-called orphan designation, which has advantages in the form of streamlined approval processes and strengthened exclusivity protection.

#### Sound risk management

Investments in companies that work with drug development can be very profitable, but setbacks in projects are not uncommon and in the worst of cases they can jeopardise the survival of such companies. Consequently, BioInvent attaches great importance to preparing the Company for the risks to which a Company of this type is inevitably exposed.

BioInvent focuses on the development of antibodies for the treatment of cancer. Antibodies generally have a lower development risk than small molecule drug candidates and in this area the Company can leverage the extensive body of knowledge it has accumulated with respect to immunology, cancer biology and antibody biology.

BioInvent uses biological material from relevant cancer patients throughout the preclinical research and drug development process. This makes it possible to recreate disease biology in the laboratory environment already in the early development phase and thereby to get indications of the effect of various substances. This approach



increases the potential for developing competitive drug candidates and reduces the risk of failure in clinical phase.

Another way to manage development risks is to share them with a commercial partner. BioInvent has projects in collaboratons with Pfizer, Transgene and Oncurious, resulting in lower investments and risks for BioInvent than if the projects had been run in-house.

#### **Financing**

The Company aims to have a stable financial situation in order to be able to run drug projects up to the time deemed optimal to enter into income-generating partnership agreements. BioInvent's strategy is to enter into such agreements when it is considered suitable for its projects. Revenue from such partnership agreements usually consists of initial license fees, milestone payments, compensation for development work and future royalties on sales of the drug. An example of this is the agreement with Pfizer that was signed in December 2016. BioInvent received an initial license fee of USD 3 million and has since received research funding in 2017 and 2018.

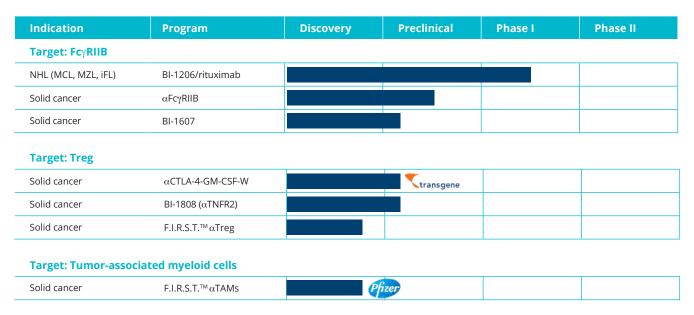
There is also potential for further revenue from contract manufacturing of antibodies at the Company's own GMP certified manufacturing facility and from license agreements based on the n-CoDeR® library.

In some cases BioInvent has been able to limit its share of costs for drug development in the clinical phase through financial and operational support from well-respected research foundations. One example of this is the collaboration with Cancer Research UK, Cancer Research Technology and Leukaemia & Lymphoma Research regarding the Company's BI-1206 antibody.

Good cost control and efficient use of internal resources are integral to BioInvent's working methods. If, for any reason, the Company were to find itself in a situation of having insufficient working capital, the Company may need to choose to defer or reduce costs related to development programs and to other research activities. In such a situation the Company could also be forced to seek additional external financing.

## Project overview

BioInvent has a portfolio of innovative projects with the potential to being developed into new immuno-oncological drugs for cancer patients. In October 2018, the Company announced its ambition to expand its existing pipeline with three new clinical programs within solid tumors.



BioInvent additionally has ownership in anti-PIGF programs TB-403 and THR-317 partnered with Oncurios and Oxurion. Two parallell clinical phase I/II studies ongoing with BI-1206 (BioInvent and CRUK sponsered).

A clinical phase I/II study is under way with the antibody BI-1206 in patients with hematological cancers (non-Hodgkin lymphoma and chronic lymphocytic leukemia) that are resistant to rituximab. In parallel, a further clinical phase I/II study is in progress involving BI-1206, the aim of which is to investigate its effect when combined with rituximab for the sub-indications mantle cell lymphoma, follicular lymphoma and marginal zone lymphoma.

New antibodies against tumor-associated myeloid cells are being developed in cooperation with Pfizer, and an internal project is under way to identify antibodies against regulatory T cells. In 2017, a research project was started in cooperation with Transgene to develop new ways to treat solid tumors based on oncolytic virus candidates and antibodies against CTLA-4.

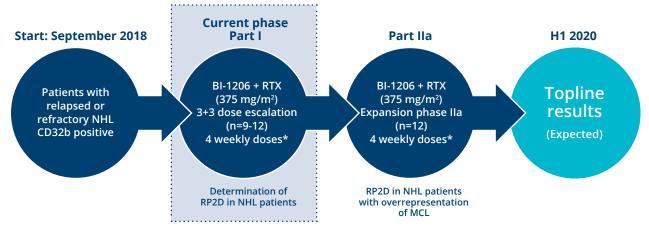
In addition to the programs listed in the table above, BioInvent is also co-owner of the anti-PIGF programs TB-403 and THR-317; projects co-owned with the biotech companies Oncurious and Oxurion, respectively, and aimed at improving treatment options for children with a rare form of brain tumor and for diabetic macular edema.

## Clinical projects

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

BI-1206 is a monoclonal antibody that recognizes with high affinity and selectivity  $Fc\gamma RIIB$  (CD32B), the only inhibitory member of the  $Fc\gamma R$  family.  $Fc\gamma RIIB$  is overexpressed by a number of non-Hodgkin lymphoma tumors, and overexpression has been shown to be associated with poor prognosis in difficult-to-treat forms of non-Hodgkin lymphoma, such as mantle cell lymphoma or follicular lymphoma.

Several preclinical and retrospective clinical data indicate that  $Fc\gamma RIIB$  is involved in the development of resistance to rituximab, which is today's state-of-the-art treatment for non-Hodgkin lymphoma and chronic lymphocytic leukaemia. Also in models for different types of cancer,  $Fc\gamma RIIB$  has been shown to be involved in the development of resistance to treatment with other antibodies. BI-1206 is therefore believed to have a very interesting mechanism of action with potential for use both against non-Hodgkin lymphoma and chronic lymphocytic leukaemia, but also



<sup>\*</sup> The patients are treated with one dose per week during a 4 week period.

against other types of cancer. By using BI-1206 to block the immune-inhibitory effect of  $Fc\gamma RIIB$  the immune system can be stimulated, which can boost and restore the therapeutic effect of both rituximab and other monoclonal antibody drugs.

Combined treatment with BI-1206 and rituximab has shown significantly enhanced anti-tumor effects in clinically relevant animal models using tumor cells from patients with non-Hodgkin lymphoma, compared with monotherapy with rituximab. A series of studies have shown that as many as half of the cancer patients who responded to an initial rituximab treatment are resistant to the drug after relapse, which underscores the need for improved treatment. Combination therapy has the potential to significantly improve the treatment of patients with this disease and represents a substantial commercial opportunity. Moreover, BI-1206 has demonstrated the ability to kill lymphoma cells in preclinical models using tumor cells taken directly from patients.

#### **Project status**

In September 2018 BioInvent started dosing of the first patient in a dose escalation, consecutive-cohort, openlabel phase I/IIa study of BI-1206 after obtaining approval from the Swedish Medical Products Agency and the US Food and Drug Administration (FDA) to initiate patient inclusion. The study will recruit approximately 30 patients across sites in the EU and the US. The study is evaluating BioInvent's antibody BI-1206 in combination with rituximab in patients with indolent relapsed or refractory B cell non-Hodgkin lymphoma. The targeted sub-indications 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, and expression of biomarkers will be assessed to explore potential correlation with activity. Topline results from the study are expected in the first half of 2020.

This study will run in parallel with the ongoing phase I/IIa study of BI-1206 in patients with chronic lymphocytic leukaemia and non-Hodgkin lymphoma conducted in the UK by Cancer Research UK. The ongoing study in the UK is currently testing single agent activity and is open for enrolment of additional patients. In July 2018 BioInvent announced that no dose-limiting toxicity had been reported.

In January 2019, the FDA granted orphan designation for the antibody 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 by the European Patent Office and by the national patent offices in Japan and Australia. The European patent is valid in 24 countries. Corresponding applications are pending in another five countries, including the US. Patent protection has also been sought for the treatment of cancer patients who are no longer responding to previous antibody therapy. Such applications have been filed in eight large markets.

## TB-403 in pediatric brain tumors - developed in collaboration with Oncurious

The antibody TB-403 targets the protein PIGF, which is believed to be involved in the development of a variety of rare but life-threatening tumors that mainly affect children and adolescents. Medulloblastoma is a malignant tumor which almost exclusively affects children. The treatment usually involves surgical removal of the tumor without prior chemotherapy. Up to 75 percent of patients are cured by these treatments, but normal cells important for cognition and memory are also affected. Consequently, the children who survive often suffer life-

long neurological side effects. Preclinical trials indicate that TB-403 has the potential to be developed into a drug that can improve treatment results in patients with medulloblastoma. TB-403 is co-owned with Oncurious, a subsidiary of the Belgian Company Oxurion. In July 2017 BioInvent increased its ownership of TB-403 from 40 to 50 percent after renegotiating the multi-year collaboration agreement signed in 2004. BioInvent continues to contribute 50 percent of the development costs.

#### **Project status**

TB-403 is currently in a phase I/II study for the treatment of patients with medulloblastoma in cooperation with a US-based paediatric oncology network, Beat Childhood Cancer. The study is progressing according to plan and the fourth dose level is currently ongoing. TB-403 has received orphan designation for medulloblastoma from the European Medicines Agency (EMA).

#### **Patent protection**

Patents for TB-403 and similar antibodies have been granted in Europe, the US, Japan and several additional countries, and patent applications are pending in further countries. Patents covering use of antibodies against PIGF, for example for the purpose of treating or preventing cancer, have also been granted, including in the US.

## THR-317 in diabetic macular edema – under development by Oxurion

The drug candidate THR-317, which is based on the same antibody as TB-403, is being developed by Oxurion as a potential new treatment for diabetic macular edema. Macular edema is a condition characterized by fluid retention and swelling of the macula, which can result in significant vision loss. 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 commercial cash flow.

#### **Project status**

In July 2018 BioInvent's partner Oxurion reported Day 150 topline data from a phase I/II study of THR-317 in patients with diabetic macular edema. The study met its primary endpoint of safety for both the 4 mg and 8 mg doses. Whilst the focus of the study was safety, efficacy was also observed. In September 2018 Oxurion enrolled the first patient in a phase II study evaluating THR-317 for treatment of idiopathic MacTel 1.

#### **Patent protection**

Patents for the antibody have been granted in Europe, the US, Japan and several additional countries, and patent applications are pending in further countries.



### Preclinical programs

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

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

Regulatory T cells 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. The most advanced candidate is BI-1808 and a first clinical study is scheduled for H1 2020.

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

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.

Transgene is contributing both its OV design and 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 "armed" virus allows the expression of genes carried by the oncolytic viral genome, such as an immune modulatory anti-CTLA-4 antibody, to further boost immune responses against the tumor.

BioInvent is contributing its cancer biology and antibody expertise to the collaboration, as well as anti-CTLA-4 antibody sequences generated through its proprietary  $n\text{-}CoDeR^{\otimes}/F.I.R.S.T.^{\text{TM}}$  platforms.

This novel OV product has the potential to be significantly more effective than the combination of these two products as single agents. Transgene has earlier generated preclinical proof-of-concept data showing that an oncolytic vaccinia virus encoding a checkpoint inhibitor resulted in better overall survival than the corresponding combination of separate single agents.

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.

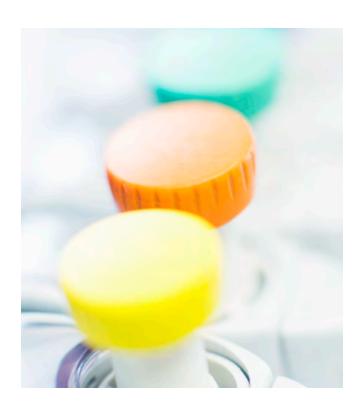
The research and development costs, as well as revenues and royalties from candidates generated from the collaboration, will be shared 50:50.

## Strategic collaboration with Pfizer - development of antibodies targeting tumor-associated myeloid cells

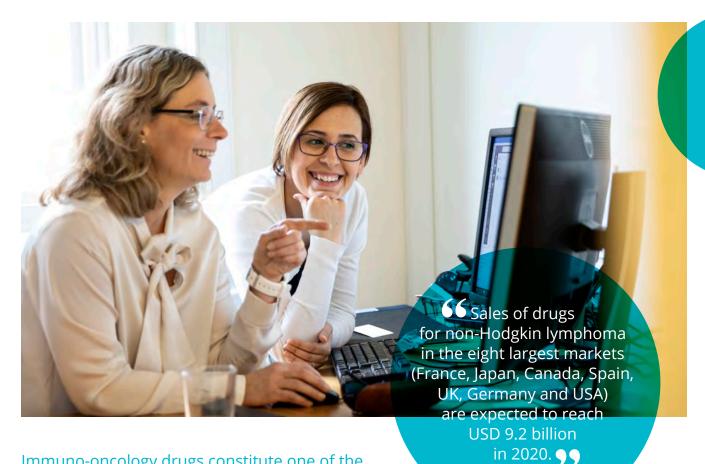
In partnership with Pfizer Inc. since December 2016, BioInvent works to identify novel oncology targets and therapeutic antibodies that may either reverse the immunosuppressive activity of tumor-associated myeloid cells or reduce the number of tumor-associated myeloid cells in the tumor. To date, pools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

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 and 2018. Pfizer also made a \$6 million equity investment in new shares of BioInvent when the agreement was signed.



## Market overview



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 global immuno-oncology market amounted to USD 43 billion in 2016 and is expected to reach USD 97 billion in 2022, representing annual average growth of 14.6 percent<sup>2)</sup>. In recent years global pharmaceutical companies have been entering into multiple collaboration agreements for immuno-oncology drug candidates for a total contract value in the tens of billions of SEK per project.

#### **Hematological cancer**

BioInvent's drug candidate that has advanced the farthest, BI-1206, is in development to improve the effect of rituximab and overcome rituximab resistance in the treatment of hematological cancer, particularly non-Hodgkin lymphoma and chronic lymphocytic leukaemia. In addition, there is also great market potential to use BI-1206 in combination with other CD20 antibodies such as obinutuzumab/ Gazyva® or e.g. rituximab biosimilars. Sales of rituximab

(Rituxan®/Mabthera®) amounted to USD 7.8 billion in 2017 and related mainly to treatment of hematological cancer.<sup>3)</sup> Sales of drugs for non-Hodgkin lymphoma in the eight largest markets (France, Japan, Canada, Spain, UK, Germany and USA) are expected to reach USD 9.2 billion in 2020.<sup>4)</sup> The largest players within hematological cancer are Roche (Rituxan®, rituximab) and Novartis (Arzerra®, ofatumumab).

<sup>2)</sup> Zion Market Research, 2018.

<sup>3)</sup> Company Reports 2017, Roche.

<sup>4)</sup> GBI Research. National Cancer Institute, October 2014.



#### Non-Hodgkin lymphoma

Non-Hodgkin lymphoma (NHL) 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 Com-pany's estimates, approximately USD 200 million per year in the US alone.<sup>5)</sup> 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 4.7 per 100,000 individuals.<sup>6)</sup> The global market for the treatment of chronic lymphocytic leukemia was estimated to be approximately USD 7.9 billion in 2017 and is expected to grow with average annual growth of 19 percent until 2023.<sup>7)</sup>

#### **Solid tumors**

In addition to BioInvent's two ongoing studies with the drug candidate BI-1206, which is aimed at treating hematological cancer, BioInvent is preparing for clinical studies in solid cancer within the  $Fc_{\gamma}RIIB$  program. All of BioInvent's other candidates are focused on the treatment of solid tumors. Other than the indications medulloblastoma and

diabetic macular oedema, 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.

#### Medulloblastoma

The drug candidate TB-403 is being developed for the treatment of medulloblastoma – the most common type of malignant brain tumor in children. Around 80 percent of all patients with medulloblastoma are under 19 years of age, and most contract the disease as early as between the ages of three and seven. The disease is rare and according to CBTRUS, the incidence in the USA between 2009 and 2013, was about 4.0 per 100,000 for individuals between ages 0 and 19 years.<sup>8)</sup>

The standard treatment for medulloblastoma consists of surgery, radiotherapy and chemotherapy. Even if treated successfully, healthy cells are affected, including cells important for cognition and memory. One consequence of this is that children who survive the treatment often have lifelong neurological side effects. If these neurological side effects are to be reduced, targeted tumor-specific treatment options are needed, meaning that the treatment specifically targets the tumor cells thereby minimising damage to the body's healthy cells. BioInvent has an ongoing collaboration with Oncurious to develop drugs within this indication.

#### Diabetic macular edema

Diabetic macular edema is a diabetes-related eye disease. The disease is characterised by fluid retention and swelling of the macula, which can result in significant vision loss. Current treatment options include laser therapy, steroids, anti-VEGF (vascular endothelial growth factor), or a combination of these.

BioInvent has an ongoing collaboration with Oxurion to develop drugs within this indication.



- 5) The Company's estimate is based on external reports from Cello Health BioConsulting, 2018 (formerly Defined Health).
- 6) National Cancer Institute, Cancer Stat Facts: Leukemia Chronic Lympocytic Leukemia (CLL).
- 7) Market Research Future, Chronic Lymphocytic Leukemia Treatment Market Research Report Global Forecast till 2023, 2019.
- 8) CBTRUS Statistical Report: Primary Brain and Other Central Nervous System Tumors Diagnosed in the United States in 2009–2013, Vol 18 October 2016.



#### **Competition situation**

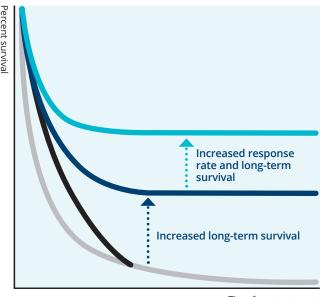
BioInvent's competitors consist of both global and smaller pharmaceutical companies and biotech companies that develop antibody-based drugs. There are numerous such companies developing immuno-oncology cancer therapies, including BMS, Merck, Genentech/Roche, Pfizer and Amgen.

There are a number of pharmaceutical companies that already have commercial products aimed at the same indications (non-Hodgkin lymphoma and chronic lymphocytic leukemia) as BioInvent's drug candidate BI-1206. As far as the Company is aware, no other competing Company is currently targeting the Fc $\gamma$ RIIB receptor for the treatment of these indications. This puts BioInvent and BI-1206 in a unique position among its competitors. Since BioInvent's competitors within the indications mentioned are mainly companies with monotherapies, it is likely that one or more of these could become potential partners in a combination therapy – assuming that the combination BI-1206/rituximab proves to be successful.

#### **Combination therapy**

A clear trend within immunotherapy is the emergence of combination therapy. Combined therapy combines two or more therapies and is in the process of developing into an important element of cancer treatment. Combining several different treatment therapies allows multiple parts of the tumor to be attacked, preventing the tumor from escaping the immune system.<sup>10)</sup> The combinations may include both traditional treatments, such as chemotherapy or radiotherapy, and more recent treatments, such as im-

munotherapies. 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. <sup>11)</sup> The effect of combining therapies is illustrated in the graph below.



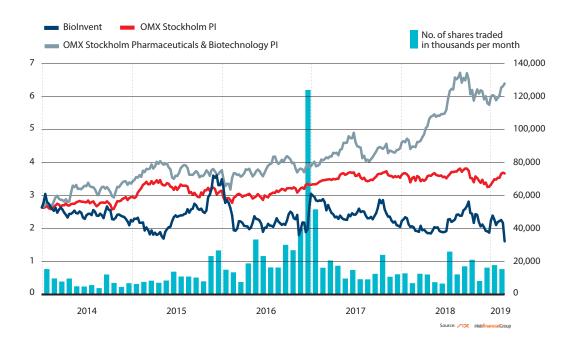
Time from treatment

Immunotherapy (combination therapy)
Immunotherapy (monotherapy)
Traditional therapy
Control group

<sup>10)</sup> Mokhtari R. B., et al., Oncotarget, Combination therapy in combating cancer, June 2017.

<sup>11)</sup> Harris S. J., et al., Cancer Biology & Medicine, Immuno-oncology combinations: raising the tail of the survival curve, June 2016.

## The BioInvent share



#### Price trend and trading volume

In 2018, the share price decreased 8 percent, from SEK 2.07 to SEK 1.90. In 2018 the OMX Stockholm\_PI decreased 8 percent and OMX Stockholm Pharmaceuticals & Biotechnology\_PI increased 30 percent. The highest price paid in 2018 was SEK 2.96 and the lowest price was SEK 1.80. BioInvent's market capitalization totaled SEK 667 million at the end of 2018.

During the year 153 million (203) BioInvent shares were traded for a value of SEK 345 million (532). This corresponds to a rate of turnover of 47 percent (69).

Average trading volume per trading day was 613,682 (807,431) shares for a value of SEK 1.4 million (2.1). Average number of trades per trading day were 168 (221).

#### **Largest shareholders, 31 December 2018**

	No. of shares	Percentage of capital and votes
Van Herk Investments B.V.	29,091,272	8.3
Omega Fund IV, LP	28,352,982	8.1
TSGH (Compagnie Merieux Alliance)	27,561,395	7.9
Avanza Pension Försäkring	24,393,722	7.0
Pfizer	21,973,594	6.3
Skandinaviska Enskilda Banken	14,128,316	4.0
Nordnet Pensionsförsäkring	13,067,730	3.7
Mexor i Skellefteå AB	9,701,713	2.8
East Bay AB	9,400,000	2.7
Peter Hoglin	7,689,173	2.2
Staffan Rasjö	7,444,985	2.1
Other shareholders	157,995,090	45.0
Total	350,799,972	100.0

#### **Ownership structure**

In 2018, the number of shareholders increased 3 percent, from 8,393 to 8,685. Foreign owners held 41 percent (36) of the share capital and votes. The ten largest shareholders owned 53 percent (49) of the shares.

#### **Share capital**

The BioInvent share has been listed on NASDAQ Stockholm (BINV) since 2001. The Company's share capital consists of 350,799,972 shares.

If fully exercised, Subscription Warrants Program 2016/2019 will represent a dilution equivalent to around 0.3 percent of the shares in the Company, Board Share Program 2018 will represent a dilution equivalent to around 0.6 percent of the shares in the Company and Option Program 2017/2020 will represent a dilution equivalent to around 2.0 percent of the shares in the Company. The Company's option programs are described on page 47.

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 2018 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, SE-223 70 Lund, Sweden, or by fax +46 (0)46-211 08 06, or telephone +46 (0)46-286 85 50, or by e-mail info@bioinvent.com.

The annual report is published in Swedish and English.

#### **Analysts covering BioInvent**

Klas Palin – Redeye, Stockholm Sam Slutsky – Life Sci Capital, New York Peter Östling – Pareto Securities, Stockholm

#### **Upcoming financial information**

Interim reports: 22 May, 23 July, 24 October 2019.

#### **Share statistics, 31 December 2018**

Size of holdings	No. of shareholders	No. of shareholders %	No. of shares in %
1–500	2,702	31.1 %	0.1 %
501-1,000	1,079	12.4 %	0.3 %
1,001-5,000	2,440	28.1 %	1.9 %
5,001-10,000	886	10.2 %	2.0 %
10,001-20,000	580	6.7 %	2.5 %
20,001-50,000	494	5.7 %	4.6 %
50,001-100,000	224	2.6 %	4.7 %
100,001-500,000	225	2.6 %	13.4 %
500,001-1,000,000	30	0.3 %	5.8 %
1,000,001-5,000,000	14	0.2 %	9.7 %
5,000,001-10,000,000	4	0.0 %	9.8 %
10,000,001-50,000,000	7	0.1 %	45.2 %
Total	8.685	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
1996	BioInvent International AB was founded <sup>1)</sup>	•	•••••••••••••••••••••••••••••••••••••••	100,000	10,000	10.00
1990	New share issue	7.140	714	107,140	10,714	10.00
1997	Bonus issue	857,120	85,712	964,260	96,426	10.00
1997		037,120	•	,	•	
	Share split 1:10	101.000	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		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

- 1) Biolnvent International AB was established by its managers, Stiftelsen Industrifonden, Pronova a.s. and Aragon Fondkommission.
- <sup>2</sup> 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.
- <sup>3)</sup> 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.
- 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.
- 6 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.
- 🤌 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.
- <sup>17)</sup> 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.

## Five-year review

INCOME STATEMENT, SEK MILLION	2018	2017	2016	2015	2014
Net sales	38.5	45.0	71.3	15.9	46.9
Research and development costs	-140.2	-109.7	-99.5	-80.5	-73.4
Sales and administrative costs	-28.0	-39.3	-35.7	-31.6	-31.9
Other operating revenue and costs	6.4	3.3	1.0	1.3	3.4
	-161.8	-145.6	-134.1	-110.9	-101.9
Operating loss	-123.2	-100.6	-62.9	-95.0	-54.9
Net financial items	0.1	0.1	0.3	-0.1	0.9
Loss before tax	-123.2	-100.5	-62.6	-95.0	-54.0
Tax	-	-	-	4,3	-
Loss for the year	-123.2	-100.5	-62.6	-95.0	-54.0
BALANCE SHEET, SEK MILLION	2018	2017	2016	2015	2014
Intangible fixed assets	0.0	0.0	0.0	0.0	0.0
Tangible fixed assets	18.0	19.2	5.6	1.3	2.3
Financial fixed assets	_	-	-	-	4,5
Inventories	3.0	2.4	1.9	0.5	0.1
Current receivables	30.6	14.7	42.6	12.7	21.6
Liquid funds	68.9	133.8	226.1	40.0	45.6
Total assets	120.4	170.0	276.3	54.4	74.1
Shareholders' equity	87.6	130.2	230.4	29.5	52.4
Non-interest-bearing liabilities	32.8	39.8	45.9	25.0	21.7
Interest-bearing liabilities	-	-	-	-	_
Total shareholders' equity and liabilities	120.4	170.0	276.3	54.4	74.1
CASH FLOW, SEK MILLION	2018	2017	2016	2015	2014
Operating loss	-123.2	-100.6	-62.9	-95.0	-54.9
Adjustments for depreciation, interest and other items	5.4	3.3	1.1	6.2	2.7
Changes in working capital	-23.6	21.5	-10.3	16.2	-23.8
Cash flow from current operations	-141.4	-75.9	-72.0	-72.6	-76.0
Cash flow from investment activities	-3.8	-16.5	-5.3	-0.7	-0.4
Cash flow from current operations and investment activities	-145.2	-92.4	-77.4	-73.2	-76.4
Cash flow from financing activities	80.3	-	263.5	67.6	57.3
Increase/decrease in liquid funds	-64.9	-92.4	186.1	-5.7	-19.1

KEY FINANCIAL RATIOS	2018	2017	2016	2015	2014
Net revenue growth, %	-14.4	-36.9	347.6	-66.1	-42.6
Net working capital, SEK million	0.7	-22.8	-1.3	-11.8	0.0
Net working capital/net sales, %	1.9	-50.6	-1.9	-74.4	0.0
Capital employed, SEK million	87.6	130.2	230.4	29.5	52.4
Capital employed/net sales, %	227.3	289.3	323.3	185.0	111.7
Shareholders' equity, SEK million	87.6	130.2	230.4	29.5	52.4
Return on shareholders' equity, %	-113.1	-55.7	-48.2	-232.1	-106.4
Return on capital employed, %	-113.1	-55.7	-48.2	-232.1	-106.4
Capital turnover, times	0.4	0.3	0.5	0.4	0.9
Equity/assets ratio, %	72.8	76.6	83.4	54.1	70.7
Intangible fixed assets investments, SEK million	-	-	-	-	-
Tangible fixed assets investments, SEK million	3.8	16.5	5.3	0.7	0.4
Average number of employees	59	53	46	39	38
DATA PER SHARE	2018	2017	2016	2015	2014
Earnings per share, SEK		••••••••••	••••••		••••••••••••
Before dilution	-0.36	-0.33	-0.25	-0.64	-0.53
After full dilution	-0.36 <sup>1)</sup>	-0.331)	-0.251)	-0.641)	-0.53 <sup>1)</sup>
Shareholders' equity per share, SEK					
Before dilution	0.25	0.43	0.76	0.18	0.46
After full dilution	0.252)	0.432)	0.762)	0.182)	0.462)
Cash flow per share, SEK	-0.43	-0.30	-0.31	-0.51	-0.75
cash now per share, ser	01.15				
Average no. of shares	05				
•	339,470	304,695	247,962	142,450	101,989
Average no. of shares		304,695 304,695 <sup>2)</sup>	247,962 247,962 <sup>2)</sup>	142,450 142,450 <sup>2)</sup>	101,989 101,989 <sup>2)</sup>

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

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

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

Before dilution (thousands)

Share price, 31 December, SEK

After full dilution (thousands)

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**

339 470

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

1.90

Net revenue divided by the average capital employed.

304,695

304,6952)

2.07

#### **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.

304,695

304,6952)

3.07

162,919

162,919<sup>2)</sup>

3.59

112,790

112,7902)

2.28

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

## The Board and Auditors



#### Chairman of the Board MBA. Born 1958.

Lives near Amsterdam, Netherlands. Provides presently interim management solutions and consulting to companies. He served as a Board Member in BioInvent between 2016–2017. Between 1998-2011, he served as CFO and member of the board of Crucell NV, and he has also held senior executive positions at ProFibrix B.V., Royal Boskalis Westminister N.V., TIP GE Capital, McKinsey & Company and Continental Can Company, Inc. Chairman of the Board since 2018. Chairman of the Remuneration Committee and member of the Audit Committee.

#### Other board appointments

Member of the Board of Karmijn Kapitaal Investments.

#### **Shareholding**



#### **Employee representative** MSc in Molecular and Functional

biology. Born 1959. Lives in Lund, Sweden. Research Engineer. Member of the Board since 2013.

#### Other board appointments

#### Shareholding

20,850 (own and affiliated holdings)



Consultant. Born 1968. Lives in Stockholm. Extensive experience from financial markets, active within the financial industry between 1989-2012 with experience in asset management, institutional equities and investment banking. Has previously held different managerial positions within Handelsbanken, Deutsche Bank and Nordea. Has previously served on the Board of the Swedish Securities Dealers Association. Member of the Board since 2018. Chairman of the Audit Committee.

#### Other board appointments

Member of the Board of Evolvere Partners AB.

#### **Shareholding**

820,000 (whereof 120,000 in Sw. kapitalförsäkring)



**Dharminder Chahal** 

M.Sc. in Aerospace Engineering and M.Sc. in Business Economics. Born 1976.

Lives in the Netherlands. CEO of SkylineDx since 2013. He is also currently the CEO of Quorics, Managing Director at Exponential BV, and Fund Manager at Swanbridge Capital. Extensive board experience within life science, in current and previous board roles at Agendia, Bioinvent (2013-2016), deVGen, Innate Pharma, and OctoPlus. Member of the Board since 2017. Member of the Audit Committee.

### Other board appointments Chairman of the Board of DCPrime.

Member of the Boards of Isobionics, VitalneXt and Ceradis BV.

#### **Shareholding**

305,360



#### **Employee representative**

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

#### Other board appointments

**Shareholding** 15,000



#### An van Es Johansson

M.D. Born 1960. Lives in Stockholm, Sweden. Previously different executive 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. Member of the BioInvent Board since 2016. Member of the Remuneration Committee.

#### Other board appointments

Member of the Board of AlzeCure and van Es Consulting.

**Shareholding** 55,360



#### CFA, Ph.D. Born 1968. Lives in Commugny, Switzerland.

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

#### Other board appointments

Member of the Boards of Andrew Alliance, Etherna Immunotherapies, Immunic and Sophia Genetics.

#### **Shareholding**



Doctor of Medicine and Doctor of Neurobiology. Born 1956. Lives Stockton, New Jersey, USA. Serves currently as chairman and board member in a number of biotech companies in the U.S., Europe and Canada. Previously President & CEO of GPC Biotech, Executive Vice President and Chief Scientific Officer of Genome Therapeutics Corporation and Vice President of Oncology Drug Discovery and - in parallel - Vice President of Corporate and Academic Alliances at Bristol-Myers Squibb. Member of the BioInvent Board since 2018. Member of the Remuneration Committee.

#### Other board appointments

Chairman of the board in Oxford BioTherapeutics, Board member and acting CEO in CryptoMedix. Board member and Chairman of the Scientific and Clinical Advisory Board in Opsona, board member and Co-Chair of the Scientific Advisory Board of Oncolytics and board member of Aprea and Vaccibody.

#### **Shareholding**

#### **Auditors KPMG AB**

#### **Auditor in charge**

Eva Melzig, Authorised Public Accountant. Born in 1961. Lives in Falsterbo. Sweden. Auditor for BioInvent International AB since 2016.

## Senior management



**Chief Executive Officer** 

Ph.D. (Dr.rer.nat.) in recombinant antibody technology. He did his postdoctoral training at the German Can-cer Research Center, Department for Recombinant Antibody Technology and at the University of Heidelberg, Department of Transplantation Immunology both in Heidelberg, Germany. Born 1961. Lives in Oslo, Norway. Employed since 2018. 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, Nextera and Uni Targeting Research.



**Options** 



**Chief Medical Officer** 

from the Universidad del Rosario (Bogotá), and holds a PhD from the Pasteur Institut/Université Paris. Born 1956. Lives in Geneva, Switzerland. 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

Doctor in Medicine and Surgery

#### **Shareholding**

**Options** 

#### Conditional employee options



#### **Chief Scientific Officer**

Doctor of Immunology. Born 1973. Lives in Lund, Sweden. 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.

#### Shareholding

483,083 (own and affiliated holdings)

#### **Options**

Conditional employee options 270,258



#### **Chief Financial Officer**

MBA, Lund University. Born 1963. Lives in Lund, Sweden. Employed since 1998. Chief Financial Officer since 2016 and has previously served as Director Business Control. He was employed by the Swedish Tax Authority 1996–1997. Previously he worked as an auditor at PricewaterhouseCoopers 1990–1995.

#### **Shareholding**

114,641

#### **Options**

Conditional employee options 115,825



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

Master of Science in Chemical engineering. Born 1974. Lives in Malmö Sweden. 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.

491,628 (whereof 148,176 in Sw. kapitalförsäkring)

#### **Options**

Subscription Warrants 50,000 and conditional employee options

Information on the holdings of shares and other financial instruments in BioInvent by Directors and Group management refers to conditions as of 3 April 2019, 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, 2018. The Company is registered in Sweden and is located in the Lund municipality. The visiting address is Sölvegatan 41, 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

BI-1206 is a monoclonal antibody that recognizes with high affinity and selectivity Fc $\gamma$ RIIB (CD32B), the only inhibitory member of the Fc $\gamma$ R family. CD32B is overexpressed by a number of NHL tumors, and overexpression has been shown to be associated with poor prognosis in difficult-to-treat forms of NHL, such as mantle cell lymphoma or follicular lymphoma. By blocking Fc $\gamma$ RIIB, BI-1206 is expected to recover and enhance the activity of rituximab or other anti-CD20 monoclonal antibodies. 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 dosing of the first patient in a dose escalation, consecutive-cohort, open-label phase I/IIa study of BI-1206 after obtaining approval from the Swedish Medical Product Agency and the U.S. Food and Drug Administration (FDA) to initiate patient enrollment. 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 non-Hodgkin lymphoma. 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. Topline results from the study are expected in the first half of 2020.

This study will 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 ongoing study is currently testing single agent activity and is open for enrollment of additional patients.

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

## TB-403 in pediatric brain tumors – development in collaboration with Oncurious

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. The study progresses according to plan, and the fourth dose level is ongoing.

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 (formerly known as ThromboGenics). BioInvent's ownership in TB-403 is 50 percent and it contributes with 50 percent of the development costs.

## THR-317 in diabetic macular edema – under development by Oxurion

In July 2018 BioInvent's partner Oxurion reported Day 150 topline data from a phase I/II study of THR-317 in patients with Diabetic Macular Edema. The study met its primary endpoint of safety for both the 4 mg and 8 mg doses. Whilst the focus of the study was safety, efficacy was also observed. In September 2018 Oxurion enrolled the first patient in a phase II study evaluating THR-317 for the treatment of idiopathic MacTel 1.

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.

#### **Pre-clinical 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.

## 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. The most advanced candidate is BI-1808 and a first clinical study is scheduled for H1 2020.

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

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.

Transgene is contributing both its OV design and 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 oncolytic viral genome, such as an immune modulatory anti-CTLA-4 antibody, to 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

This novel OV product has the potential to be significantly more effective than the combination of single agents. Transgene has generated preclinical proof-of-concept data showing that an oncolytic vaccinia virus encoded with a checkpoint inhibitor resulted in better overall survival than the corresponding combination of separate single agents.

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, will be shared 50:50

## 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. To date, pools of antibodies have been generated and are being characterized for functional activity.

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 and 2018. Pfizer also made a \$6 million equity investment in new shares of BioInvent when the agreement was signed.

#### **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 know-how, 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. bioessays and biomarkers, new indications and combination partner 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 2018 BioInvent had 62 (56) employees, 56 (49) of whom work in research and development. 92 percent of the Company's employees have university degrees, including 42 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 environ-

mental 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. Selfmonitoring 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 authorisations 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. Bio-Invent uses genetically modified micro-organisms (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 con-tracted 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 38.5 million (45.0). Revenue for the period are mainly derived from production of antibodies for clinical studies, revenue from research funding and revenue from partners using the n-CoDeR® antibody library. Revenue in 2017 included a €0.5 million milestone payment received under the collaboration with Mitsubishi Tanabe Pharma in connection with the approval of starting a Phase I study.

The Company's total costs amounted to SEK 168.1 million (149.0). Operating costs are divided between external costs of SEK 103.2 million (87.2), personnel costs of SEK 59.8 million (58.9) and depreciation of SEK 5.1 million (2.9). Personnel costs for the

fourth quarter 2017 included a provision of SEK 3.0 million for dismissal and severance payments to the former CEO.

Research and development costs amounted to SEK 140.2 million (109.7).

During the period financial support from the EU's framework program etc. was reported for early research projects. The grant amounted to SEK 6.5 million (1.6) and has been reported in the income statement under "Other operating revenue".

Loss after tax amounted to SEK -123.2 million (-100.5). The net financial items amounted to SEK 0.1 million (0.1). Loss per share before and after dilution amounted to SEK -0.36 (-0.33).

#### Financial position and cash flow

In March 2018 a directed share issue of SEK 84.6 million before transaction costs was completed. The board of directors resolved, based on the authorization granted by the annual general meeting 2017, on a directed share issue of 45,704,281 new shares at a price of SEK 1.85 per share. The issue generated significant interest from institutions and sector specialist funds, including Rhenman Healthcare Equity L/S and IMEurope (Institut Mérieux) who was the largest participant in the issue and became one of the largest shareholders of the Company.

In May 2018, 400,478 shares were subscribed for to secure the fulfilment of the Company's obligations under the Board Share Program 2017. The subscription price per share amounted to the share's quota value (0.08).

After the share issues the share capital consists of 350,799,972 shares.

As of December 31, 2018, the Group's liquid funds amounted to SEK 68.9 million (133.8). The cash flow from operating activities and investment activities amounted to SEK -145.2 million (-92.4).

The shareholders' equity amounted to SEK 87.6 million (130.2) at the end of the period. The Company's share capital at the end of the period was SEK 28.1 million. The equity/assets ratio at the end of the period was 73 (77) per cent. Shareholders' equity per share amounted to SEK 0.25 (0.43). The Group had no interest-bearing liabilities.

The five-year review is described on page 24.

#### Investments

Investments for the January - December period in tangible fixed assets amounted to SEK 3.8 million (16.5).

#### **Parent Company**

The BioInvent Group consists of the Parent Company, BioInvent International AB, and the subsidiary BioInvent Finans AB. Net sales amounted to SEK 38.5 million (45.0). Loss after tax amounted to SEK -123.2 million (-100.5). The cash flow from operating activities and investment activities amounted to SEK -145.2 million (-92.4). The Parent Company coincides in every material way with the Group.

#### The share

The BioInvent share has been listed on NASDAQ Stockholm (BINV) since 2001. The Company's share capital consists of 350.799.972 shares.

If fully exercised, Subscription Warrants Program 2016/2019 will represent a dilution equivalent to around 0.3 percent of the shares in the Company, Board Share Program 2018 will represent a dilution equivalent to around 0.6 percent of the shares in the Company and Option Program 2017/2020 will represent a dilution equivalent to around 2.0 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 2018 authorised 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 15 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 authorised 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, § 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

Pharmaceutical development is generally associated with very high risk and this applies to BioInvent's projects as well. However, antibodies 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 increases as the project is advanced through the development chain. The same applies to the costs which increase sharply in the later clinical phases.

BioInvent's operations are subject to the usual risks associated with pharmaceutical development, including the risk that BioInvent or partners using BioInvent's technology through technology licences will not succeed in developing new product candidates, that development work will be delayed, that some or all of the Company's product candidates will prove ineffective, have side effects or in another way not meet the applicable requirements or receive the necessary market approval, or prove to be difficult to license successfully or develop into commercially viable products.

As BioInvent and the Company's project portfolio are developed, the Company's knowledge and experience in important areas will grow. A larger project portfolio could over time make the Company less dependent on the success of an individual project. However, BioInvent's project portfolio is relatively limited and contains early phase projects, which means that a setback in an individual project could have a significantly negative impact on the Company. There is also a risk that development work will be delayed in relation to established schedules, which could also have a negative impact on BioInvent.

#### Clinical trials and product responsibility

BioInvent endeavours to advance its projects through the value chain, which will mean increased expenses for clinical trials and relevant market approval. 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. There is a risk that clinical trials performed by the Company or its partners are unable to show that the intended products are sufficiently safe and effective to obtain the necessary authorization from authorities, or that the Company's projects will not result in competitive products, which may mean that the intended products cannot be launched on the market.

The possibility cannot be excluded that the use of the Company's products in clinical trials could lead to claims for damages being lodged against the Company in the event that such product should cause illness, physical injury, death or damage to property. BioInvent's activities are exposed to potential liability risks, which are a normal aspect of research, development and manufacture of biopharmaceutical products. 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 policy are limited and there is a risk that coverage will not be adequate in the event of a legal claim.

#### **Commercialisation and partners**

None of BioInvent's product candidates have yet been commercialized and may never be commercialised. There is a risk that the products launched on the market will not be well received or become commercial successes. The market acceptance of the Company's potential future products will depend on a number of factors, such as the clinical indications for which the product is approved, in which extent the product constitute a safe and effective treatment as well as the cost for treatment in relation to alternative treatments.

From time to time BioInvent enters agreements with partners for the development and commercialisation of potential products. Even if the Company tries to develop and strengthen such partnerships there is a risk that the collaboration will not result in a successful product launch. There is always the risk that the partner could change its focus and priorities, which in turn could have a negative effect on the collaboration. There is a risk that BioInvent will not succeed in entering into such agreements on satisfactory terms. In the absence of partnership agreements, BioInvent may not be able to realise the full value of a product candidate.

#### **Competition and fast technological development**

The development and commercialization of new pharmaceutical products is highly competitive, and BioInvent is subject to, and will onwards be subject to, competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. In addition to existing treatments for the indications that the Company is targeting with its research and product candidate, the Company may also face competition from other research and other product candidates under development by other companies. Many of the competitors have far greater resources than BioInvent. There is always a risk that the Company's product concept will be subject to competition from similar products or that entirely new product concepts will prove superior.

#### **Biotechnology and patent risk**

BioInvent's potential future success depends in part also on the Company's ability to obtain and retain patent protection for potential products and to keep its own and its partners' research confidential so that BioInvent can prevent others from using BioInvent's discoveries and protected information.

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 biotech companies is in general uncertain and involves complex medical and legal assessments. There is a risk that the Company's products and processes will not be able to be patented, that they will be deemed to infringe competitors' rights, that patents granted will not provide adequate protection or that patents granted will be attacked or disputed by competitors.

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 success depends in part also on the extent to which the Company's products will qualify for subsidies from publicly or privately 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 is dependent on the Company's senior executives and other key individuals. Losing any of these key employees could delay or disrupt research programs or development, outlicensing or commercialisation of the Company's product candidates. The Company's ability to attract and retain qualified personnel is crucial for its future successes. Even if BioInvent believes that the Company will be able to both attract and retain qualified personnel, there is a risk that this will not be able to occur on satisfactory terms in relation to the competition from other pharmaceutical and biotech companies, universities and other institutions.

#### **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.

See also financial risks at page 52.

## 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 2018 Annual General Meeting adopted guidelines for remuneration to the CEO and other senior executives. There has been no deviations from these guidelines. The Board proposes that the guidelines for remuneration to the CEO and other senior executives remain unchanged and apply from the 2019 Annual General Meeting, aside from raising the maximum variable remuneration from 30 percent to 40 percent of the fixed salary.

These guidelines will apply to those persons who during the period that the guidelines are in effect, belong to executive management and to other department heads who are directly subordinate to the CEO, referred to below as "senior executives". BioInvent will 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. Senior executives will receive a fixed salary. In addition, variable compensation may also be paid to reward clearly target related accomplishments in a simple and transParent way. Senior management's variable compensation will 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. Such targets will not be related to developments of the Company's share. Senior management's variable compensation will not exceed 40 percent of the fixed salary. Such remuneration can be pensionable.

The maximum result of variable compensation shall not entail costs for the Company in excess of a total of SEK 3.3 million (excluding social security costs), calculated based on the number of persons currently included in executive management (such costs may change proportionately if the number of persons in management should change).

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.

Each year the Board of Directors will consider whether or not to propose a share-based incentive scheme to the Annual General Meeting. Issuance and transfer of ownership of securities resolved by the Annual General Meeting in accordance with the rules of chapter 16 of the Swedish Companies Act or the old "Leo" Act, are not covered by these guidelines to the extent that the Annual General Meeting has taken or will take such decisions.

Executive management's 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 collective value of these benefits must comprise a smaller portion of total compensation.

Senior executives have the right to retire with pension at the earliest from the date the individual reaches the age of 65. Senior executives will be covered by the prevailing ITP plan or a defined contribution occupational pension that does not exceed 35 percent of pensionable salary. 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.

The total of dismissal and severance pay for members of senior management will not exceed 24 monthly salaries for the CEO and 12 monthly salaries for others senior executives.

According to Swedish law, the Annual General Meeting resolves on remuneration to board members and deputy board members to the extent such remuneration is for board related duties. If a board member is employed by the Company, remuneration is paid to such board members in accordance with these guidelines. Board members who are employed by the Company will not receive separate compensation for board duties in the Company or Group companies. If a board member carries out duties for the Company that are not board duties, compensation will be paid that is market-based and with consideration taken to the nature and performance of the assignment.

The Board's Remuneration Committee prepares and formulates proposals for the Board to resolve with respect to remuneration for the CEO. The Board of Directors Remuneration Committee prepares, in consultation with the CEO, and decides on questions involving remuneration to other senior executives. The Board decides on issues relating to remuneration for board members for duties not included in the duties of the board, provided that this can be accomplished with the necessary majority, otherwise the Annual General Meeting decides on such matters.

The Board of Directors will have the right to depart from these guidelines if justified by particular circumstances in individual cases, provided that this is subsequently reported and explained.

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

In January 2019, BioInvent announced that the U.S. Food and Drug Administration had granted the Company orphan designation for its proprietary antibody BI-1206 for the treatment of mantle cell lymphoma.

In February 2019 BioInvent resolved on a fully underwritten rights issue of SEK 210 million and a directed issue of SEK 30 million with a Swedish pension fund and a Swedish life science fund. Additionally, it is proposed that the board of directors is authorized to resolve on an over-allotment option for up to SEK 70 million, that can be exercised if the rights issue is over-subscribed. The rights issue and the over-allotment option were approved by an extraordinary general meeting held on 20 March 2019.

In March 2019 BioInvent announced that the United States Patent and Trademark Office had issued a Notice of Allowance that a patent application relevant to its F.I.R.S.T.™ platform had been allowed and can proceed to grant. It covers methods for differential biopanning.

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

At the disposal of the Annual General Meeting: Share premium reserve of SEK 154,838,988, retained earnings of SEK 227,000 and loss for the year of SEK -123,163,171. The Board of Directors propose that profits at the disposal of SEK 31,902,817 is carried forward. Thus, it is proposed that no dividend be given for the financial year 2018.

# Consolidated statement of comprehensive income for the Group

SEK thousand	Note	2018	2017
Net sales	3	38,548	45,014
Operating costs	4-9		
Research and development costs		-140,182	-109,723
Sales and administrative costs		-27,955	-39,263
Other operating revenue	10	6,697	3,490
Other operating costs	10	-340	-150
	•••••••••••••••••••••••••••••••••••••••	-161,780	-145,646
Operating loss		-123,232	-100,632
Financial income	11	151	156
Financial expenses	12	-82	- 52
Net financial items	••••••••••	69	104
Loss before tax		-123,163	-100,528
Tax	13	-	-
Loss for the year		-123,163	-100,528
Other comprehensive income			
Items that have been or may be reclassified subsequently to profit or loss		-	-
Comprehensive income for the year		-123,163	-100,528
Other comprehensive income for the year attributable to the Parent Company's shareholders		-123,163	-100,528
Lors pershave CEV	1.4	•••••	•
Loss per share, SEK  Before dilution	14	-0.36	-0.33
After dilution		-0.36	-0.33
Aitel dilution		-0.30	-0.33

# Consolidated statement of financial position for the Group

SEK thousand	Note	2018	2017
ASSETS	•	•	
Acquired intangible fixed assets	15	0	0
Equipment	16	15,934	16,387
Investments in rented premises	16	2,099	2,859
Total fixed assets	3	18,033	19,246
Inventories		2,950	2,386
Accounts receivable	22	8,881	1,404
Other receivables	22	15,030	7,462
Prepaid expenses and accrued income	18	6,655	5,789
Liquid funds	22	68,851	133,760
Total current assets		102,367	150,801
Total assets		120,400	170,047
SEK thousand	Note	2018	2017
SEK thousand SHAREHOLDERS' EQUITY	Note 20	2018	2017
		<b>2018</b> 28,064	<b>2017</b> 24,376
SHAREHOLDERS' EQUITY			
SHAREHOLDERS' EQUITY Share capital		28,064	24,376
SHAREHOLDERS' EQUITY  Share capital Other allocated capital		28,064 1,662,245	24,376 1,585,601
SHAREHOLDERS' EQUITY  Share capital Other allocated capital Reserves		28,064 1,662,245 1	24,376 1,585,601 1
SHAREHOLDERS' EQUITY  Share capital Other allocated capital Reserves Accumulated loss		28,064 1,662,245 1 -1,602,689	24,376 1,585,601 1 -1,479,753
SHAREHOLDERS' EQUITY  Share capital Other allocated capital Reserves Accumulated loss  Total shareholders' equity		28,064 1,662,245 1 -1,602,689 <b>87,621</b>	24,376 1,585,601 1 -1,479,753
SHAREHOLDERS' EQUITY  Share capital Other allocated capital Reserves Accumulated loss  Total shareholders' equity Shareholder's equity pertaining to the Parent Company's shareholders		28,064 1,662,245 1 -1,602,689 <b>87,621</b>	24,376 1,585,601 1 -1,479,753 <b>130,225</b> 130,225
SHAREHOLDERS' EQUITY  Share capital Other allocated capital Reserves Accumulated loss  Total shareholders' equity Shareholder's equity pertaining to the Parent Company's shareholders  LIABILITIES Accounts payable Other liabilities	20 22 22	28,064 1,662,245 1 -1,602,689 <b>87,621</b> 87,621	24,376 1,585,601 1 -1,479,753 <b>130,225</b> 130,225 14,171 2,667
SHAREHOLDERS' EQUITY  Share capital Other allocated capital Reserves Accumulated loss  Total shareholders' equity Shareholder's equity pertaining to the Parent Company's shareholders  LIABILITIES Accounts payable	20	28,064 1,662,245 1 -1,602,689 <b>87,621</b> 87,621	24,376 1,585,601 1 -1,479,753 <b>130,225</b> 130,225
SHAREHOLDERS' EQUITY  Share capital Other allocated capital Reserves Accumulated loss  Total shareholders' equity Shareholder's equity pertaining to the Parent Company's shareholders  LIABILITIES Accounts payable Other liabilities	20 22 22	28,064 1,662,245 1 -1,602,689 <b>87,621</b> 87,621 10,821 5,364	24,376 1,585,601 1 -1,479,753 <b>130,225</b> 130,225 14,171 2,667

# Consolidated statement of cash flows for the Group

SEK thousand	2018	2017
Current operations	••••••••••••	•••••••••••••••••••••••••••••••••••••••
Operating loss	-123,232	-100,632
Depreciation	5,061	2,880
Adjustments for other non-cash items	227	316
Interest received	131	103
Interest paid	-2	-1
Cash flow from current operations before changes in working capital	-117,815	-97,334
Changes in working capital		
Changes in inventories	-564	-468
Changes in current receivables	-15,911	27,963
Changes in short term liabilities	-7,104	-6,037
	-23,579	21,458
Cash flow from current operations	-141,394	-75,876
Investment activities		
Acquisition of tangible fixed assets	-3,847	-16,478
Cash flow from investment activities	-3,847	-16,478
Cash flow from current operations and investment activities	-145,241	-92,354
Financing activities		
Directed new share issue	80,300	
Directed new share issue, Board Share Programe 2017	32	
Cash flow from financing activities	80,332	-
Change in liquid funds	-64,909	-92,354
Opening liquid funds	133,760	226,114
Liquid funds at year-end	68,851	133,760
Liquid funds, specification:		
Short-term investments		30,060
Cash and bank	68,851	103,700
	68,851	133,760

# Statement of changes in equity for the Group

SEK thousand	Share- capital	Other allocated capital	Reserves	Accumulated loss	Total
Shareholders' equity 31 December 2016	24,376	1,585,601	1	-1,379,541	230,437
Comprehensive income for the year					
Loss for the year				-100,528	-100,528
Comprehensive other income for the year			-		-
Total comprehensive income for the year			-	-100,528	-100,528
Total, excluding transactions with equity holders of the Company	24,376	1,585,601	1	-1,480,069	129,909
Transactions with equity holders of the Company					
Effect of employee incentive programs				316	316
Shareholders' equity 31 December 2017	24,376	1,585,601	1	-1,479,753	130,225
Comprehensive income for the year					
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

The share capital as of December 31, 2018 consists of 350,799,972 shares and the share's ratio value is 0.08. The directed new share issue carried out in April 2018 raised SEK 80,300 thousand after issue expenses of SEK 4,253 thousand.

# Income statement for the Parent Company

CEI(c)			
SEK thousand	Note	2018	2017
Net sales	3	38,548	45,014
Operating costs	4-9		
Research and development costs		-140,182	-109,723
Sales and administrative costs		-27,955	-39,263
Other operating revenue	10	6,697	3,490
Other operating costs	10	-340	-150
	•••••••••••••••••••••••••••••••••••••••	-161,780	-145,646
Operating loss		-123,232	-100,632
Operating loss		-123,232	-100,032
Interest income and similar items	11	151	156
Interest costs and similar items	12	- 82	- 52
Loss after financial items	•••••••••••••••••••••••••••••••••••••••	-123,163	-100,528
Tax	13	-	-
Loss for the year	•••••••••••••••••••••••••••••••••••••••	-123,163	-100,528
Other comprehensive income			-
Comprehensive income for the year	•••••••••••••••••••••••••••••••••••••••	-123,163	-100,528

# Balance sheet for the Parent Company

SEK thousand Note	2018	2017
ASSETS	••••••	
Fixed assets		
Intangible fixed assets Acquired intangible fixed assets 15	0	0
	0	0
Tangible fixed assets	15.024	16 207
Equipment 16 Investments in rented premises 16	15,934 2,099	16,387 2,859
3	18,033	19,246
Financial fixed assets	. 5,000	,
Shares in subsidiaries 17	687	687
	687	687
Total fixed assets	18,720	19,933
Current assets		
Inventories	2,950	2,386
Current receivables		
Accounts receivable Other receivables	8,881 15,030	1,404 7,462
Prepaid expenses and accrued income 18	6,655	5,789
	30,566	14,655
Liquid funds		
Short-term investments Cash and bank	- 60 051	30,060
Casii aliu balik	68,851	103,700
	68,851	133,760
Total current assets	102,367	150,801
Total current assets Total assets	102,367 121,087	150,801 170,734
		·
Total assets  SEK thousand  Note	121,087	170,734
Total assets  SEK thousand Note  SHAREHOLDERS' EQUITY AND LIABILITIES	121,087	170,734
Total assets  SEK thousand  Note  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity	121,087	170,734
Total assets  SEK thousand Note  SHAREHOLDERS' EQUITY AND LIABILITIES	121,087	170,734
Total assets  SEK thousand  Note  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity	121,087 2018	170,734 2017
Total assets  SEK thousand  Note  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital	<b>2018</b> 28,064	<b>2017</b> 24,376
SEK thousand  Note  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve	28,064 27,693	24,376 27,693
SEK thousand  Note  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings	28,064 27,693 55,757 154,838 227	24,376 27,693 52,069 178,406 316
SEK thousand  Note  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve	28,064 27,693 55,757 154,838 227 -123,163	24,376 27,693 52,069 178,406 316 -100,528
SEK thousand Note  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings Loss for the year	28,064 27,693 55,757 154,838 227	24,376 27,693 52,069 178,406 316
SEK thousand  Note  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings	28,064 27,693 55,757 154,838 227 -123,163	24,376 27,693 52,069 178,406 316 -100,528
SEK thousand Note  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings Loss for the year  Total shareholders' equity Short term liabilities	28,064 27,693 55,757 154,838 227 -123,163 31,902 87,659	24,376 27,693 52,069 178,406 316 -100,528 78,194 130,263
SEK thousand Note  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings Loss for the year  Total shareholders' equity	28,064 27,693 55,757 154,838 227 -123,163 31,902	24,376 27,693 52,069 178,406 316 -100,528 78,194
SEK thousand Note  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings Loss for the year  Total shareholders' equity Short term liabilities Accounts payable Liabilities to subsidiaries Other liabilities	28,064 27,693 55,757 154,838 227 -123,163 31,902 87,659	24,376 27,693 52,069 178,406 316 -100,528 78,194 130,263
SEK thousand Note  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings Loss for the year  Total shareholders' equity Short term liabilities Accounts payable Liabilities to subsidiaries	28,064 27,693 55,757 154,838 227 -123,163 31,902 87,659	24,376 27,693 52,069 178,406 316 -100,528 78,194 130,263
SEK thousand Note  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings Loss for the year  Total shareholders' equity Short term liabilities Accounts payable Liabilities to subsidiaries Other liabilities	28,064 27,693 55,757 154,838 227 -123,163 31,902 87,659 10,821 687 5,326	24,376 27,693 52,069 178,406 316 -100,528 78,194 130,263 14,171 687 2,629
SEK thousand Note  SHAREHOLDERS' EQUITY AND LIABILITIES Shareholders' equity Restricted equity Share capital Statutory reserve  Non-restricted equity Share premium reserve Retained earnings Loss for the year  Total shareholders' equity  Short term liabilities Accounts payable Liabilities to subsidiaries Other liabilities Accrued expenses and deferred income 21	28,064 27,693 55,757 154,838 227 -123,163 31,902 <b>87,659</b> 10,821 687 5,326 16,594	170,734  24,376 27,693 52,069 178,406 316 -100,528 78,194 130,263 14,171 687 2,629 22,984

# Statement of cash flows for the Parent Company

SEK thousand	2018	2017
Current operations	•	
Operating loss	-123,232	-100,632
Depreciation	5,061	2,880
Adjustments for other non-cash items	227	316
Interest received	131	103
Interest paid	-2	-1
Cash flow from current operations before changes in working capital	-117,815	-97,334
Changes in working capital		
Changes in inventories	-564	-468
Changes in current receivables	-15,911	27,963
Changes in short term liabilities	-7,104	-6,037
	-23,579	21,458
Cash flow from current operations	-141,394	-75,876
Investment activities		
Acquisition of tangible fixed assets	-3,847	-16,478
Cash flow from investment activities	-3,847	-16,478
Cash flow from current operations and investment activities	-145,241	-92,354
Financing activities		
Directed new share issue	80,300	
Directed new share issue, Board Share Program 2017	32	
Cash flow from financing activities	80,332	-
Change in liquid funds	-64,909	-92,354
Opening liquid funds	133,760	226,114
Liquid funds at year-end	68,851	133,760
Liquid funds, specification		
Short-term investments	-	30,060
Cash and bank	68,851	103,700
	68,851	133,760



# Statement of changes in equity for the Parent Company

	Restricted equity Non-restricted equitys				
SEK thousand	Share capital	Statutory reserve	Share premium reserve	Accumulated loss	Total
Shareholders' equity 31 December 2016	24,376	27,693	240,935	-62,529	230,475
Appropriation of loss			-62,529	62,529	0
Comprehensive income for the year Loss for the year Comprehensive other income for the year				-100,528	-100,528
Total, comprehensive income for the year				-100,528	-100,528
Total, excluding transactions with equity holders of the Company	24,376	27,693	178,406	-100,528	129,947
Transactions with equity holders of the Company  Effect of employee incentive programs				316	316
Shareholders' equity 31 December 2017	24,376	27,693	178,406	-100,212	130,263
Appropriation of loss			-100,212	100,212	0
Comprehensive income for the year Loss for the year				-123,163	-123,163
Comprehensive other income for the year  Total, comprehensive income for the year				- -126,163	-123,163
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

The share capital as of December 31, 2018 consists of 350,799,972 shares and the share's ratio value is 0.08. The directed new share issue carried out in April 2018 raised SEK 80,300 thousand after issue expenses of SEK 4,253 thousand.

# 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. The Parent Company's accounting principles for 2018 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 is applying IFRS 15 and IFRS 9 for the first time with effect from 1 January 2018.

# **IFRS 9 Financial Instruments**

IFRS 9 establishes principles for the recognition and measurement of assets, financial liabilities and certain contracts for the purchase and sale of non-financial instruments. This standard has replaced IAS 39 Financial Instruments: Recognition and Measurement. The standard has had no impact on the carrying amounts of financial assets or liabilities since, in the Company's analysis, the new impairment model based on expected future credit losses did not result in any change in the assessment of impairment losses; moreover, the Company does not apply hedge accounting and therefore these parts of IFRS 9 have had no impact.

The table below explains the original measurement categories according to IAS 39 and the new measurement categories according to IFRS 9 for each type of the Group's financial assets and liabilities as of 1 January 2018.

# **IFRS 15 Revenue from Contracts with Customers**

IFRS 15 is a comprehensive standard for determining how and when revenue is to be recognised. It replaces IAS 18 *Revenue*, IAS 11 *Construction Contracts* and associated interpretations. Under IFRS 15 the revenue is

recognised when control over the goods or services transfers to the customer. The introduction of IFRS 15 has had no impact on the consolidated statement of financial position, the statement of comprehensive income or the statement of cash flows.

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

A number of new or revised IFRS standards will not become effective until future financial years and were not applied in advance in the preparation of these financial statements.

### **IFRS 16 Leases**

The Group will apply IFRS 16 Leases with effect from 1 January 2019. IFRS 16 introduces a uniform lease recognition model for lessees. A lessee recognises 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 will recognise new assets and liabilities for operating leases relating to laboratory, production and office facilities. The cost of these leases will change, since the Group will recognise depreciation on right-of-use assets and interest expense on lease liabilities. Given the current level of leases it is anticipated that the Group's assets and liabilities may increase by approximately SEK 23 million.

The Group plans to apply the modified retrospective approach of 1 January 2019 without restating comparative information.

Low-value leases (assets with a value of less than around SEK 50 thousand when new) will not be included in the lease liability, but instead will continue 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.

No other new or amended IFRS standards with future application dates are 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.

Financial assets	Original classification according to IAS 39	New classification according to IFRS 9
Accounts receivable	Loans and receivables	Amortised cost
Other receivables	Loans and receivables	Amortised cost
Short-term investments	Loans and receivables	Amortised cost
Cash and cash equivalents	Loans and receivables	Amortised cost
Currency forward contracts	Financial assets at fair value through profit or loss	Mandatorily at fair value through profit or loss

Financial liabilities	Original classification according to IAS 39	New classification according to IFRS 9
Accounts payable	Other financial liabilities	Other financial liabilities
Other liabilities	Other financial liabilities	Other financial liabilities
Accrued expenses	Other financial liabilities	Other financial liabilities
Currency forward contracts	Financial liabilities at fair value through profit or loss	Mandatorily at fair value through profit or loss

### 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 antibodybased 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 originate 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**

BioInvent's net revenue consist of:

- revenue from collaboration agreements associated with outlicensing of proprietary projects
- revenue from technology licenses and
- revenue from external development projects.

Revenue is reported at the actual value of what has been received or will be received. Revenue are recognised 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 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 recognised 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 refers to access fees for a technology, annual fees for the license, milestone payments and future royalties on the sale of products developed under the license. Access fees for technology are recognised as revenue when all obligations of the agreement are met.

BioInvent also carries out *external development projects* such as process development and antibody manu-facturing. 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 are recognised 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 recognised 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 is recognised 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 11.

### 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 BioInvent 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 2018 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 (2018: 2.1). 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 2018 Alecta's surplus in the form of the collective consolidation level was 142 percent (154).

# 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 recognised 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.

# Leasing

The Group's leasing agreements have been categorized as operational leases. Leasing charges are expensed in the income statement over the period of the lease based on usage.

### **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 amortisation and impairment losses, if any. Such intangible assets are amortised 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 amortised over a period of up to 5 years.

# **Tangible fixed 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 recognised 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 recognised for the financial assets measured at amortised cost. Reserves for credit losses are initially calculated and recognised based on 12 months' expected credit losses. If there has been a material increase in credit risk since the financial asset was first recognised, reserves for credit losses are calculated and recognised 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 recognised 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.

# Impairment of financial assets prior to 1 January 2018

For the comparative period of 2017 the Group assessed at the end of each reporting period whether there was objective evidence that a financial asset or a group of financial assets was impaired.

# **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 recognised 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 BioInvent 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 recognised in the balance sheet when the Company becomes a party to the contractual provisions of the instrument. Accounts receivable are recognised in the balance sheet when an invoice has been sent. A liability is recognised 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 recognised when an invoice has been received. A financial asset is derecognised from the balance sheet when the rights in the contract have

been realised, expire or when the Company loses control over them. The same applies to a portion of a financial asset. A financial liability is derecognised 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 recognised 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 recognised 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 recognised at amortised 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 recognised 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.

# Classification of financial instruments prior to 1 January 2018

Prior to the introduction of IFRS 9 on 1 January 2018 all of the Group's financial assets, other than derivative instruments, were classified as "Loans and receivables". All financial liabilities, with the exception of derivative instruments, were recognised at amortised cost. Derivative instruments were measured 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 recognised 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 recognised in "Operating loss," while exchange rate differences on financial receivables and liabilities are recognised 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 recognised 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 recognised 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 revenue, fixed assets and investment activities

The effect of the transition to IFRS 15 on the Group's revenue from contracts with customers is described in Note 1 Accounting principles. This note also provides a description of where the Group's revenue is generated.

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

	G	roup	Parent Company	
SEK thousand	2018	2017	2018	2017
Revenue by geographical region				•
Sweden	17,544	23,575	17,544	23,575
Europe	411	1,693	411	1,693
Other countries	20,593	19,746	20,593	19,746
Total	38,548	45,014	38,548	45,014
Revenue consists of				
Revenue from collaboration agreements associated with outlicensing of proprietary projects	11,196	8,361	11,196	8,361
Revenue from technology licenses	2,222	4,806	2,222	4,806
Revenue from external development projects	25,130	31,847	21,130	31,837
Total	38,548	45,014	38,548	45,014
Fixed assets				
Sweden	18,033	19,246	18,033	19,246
Investment activities Sweden	3,847	16,478	3,847	16,478
	-/	-7	-7	-,

# Note 4 Salaries, other remuneration and social security etc

		2018		2017			
SEK thousand	Salaries and other remuneration	Social security costs (of which pension costs)	Salaries and other remuneration	ner costs (of which			
Parent Company Subsidiaries	40,864 -	17,051 (6,455) -	39,481 -	17,389 (7,041) -			
Group total	40,864	17,051 (6,455)	39,481	17,389 (7,041)			

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

	2018			2017			
SEK thousand	Board and CEO	Board and CEO	Other employees				
Parent Company	4,131 (638) <sup>1)</sup>	36,733	6,354 (1,077) <sup>1)</sup>	33,127			
Subsidiaries	-	-	-	-			
Group total	4,131	36,733	6,354	33,127			

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

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

	2018			2017		
SEK thousand	Board and CEO	Other employees	Board and CEO	Other employees		
Parent Company	608	5,847	942	6,099		
Subsidiaries	-	-	-	-		
Group total	608	5,847	942	6,099		

# **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 2018 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 0–30 percent of the fixed annual cash salary. The performance related components in the current program, for the period 1 January – 31 December 2019,

are based primarily on high expectations for technical and commercial milestones in proprietary drug projects. The Board of Directors resolved in January 2019 to pay SEK 168 thousand to CEO Martin Welschof, SEK 252 thousand to acting CEO Björn Frendéus and SEK 964 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 for the period 1 July 2015 to 30 June 2018. During the three-year period the maximum bonus can amount to 100 percent of the fixed salary for one year, which has been paid out after the bonus period. Participation in the program required acquisition of BioInvent shares to be held during the three-year period. The cost for the acting CEO Björn Frendéus was SEK 218 thousand for the period 1 January 2018 to 30 June 2018 and the cost for other senior executives was SEK 47 thousand.

In addition, other senior executives are covered by an employee stock option incentive program, described on page 47.

# 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		3412)					341
Kristoffer Bissessar, member		242					242
Dharminder Chahal, member		462)					46
An van Es Johansson, member		1532)					153
Vincent Ossipow, member		184					184
Bernd Seizinger, member		153 <sup>2)</sup>					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 (4 individuals)	4.414		1.011	233	199	1.073	6,930
<u> </u>	<b>.</b>						
Total	6,638	1,119	1,649	383	199	1,682	11,670

### Remuneration and other benefits in 2017

SEK thousand	Fixed salary/ fees	Board and committee fees	Variable remuneration incl. retention bonus	Other benefits	Salary exchange	Pension costs	Total
Board and CEO							
Björn O. Nilsson, Chairman		2891)					289
Dharminder Chahal, member		1691)					169
An van Es Johansson, member		1291)					129
Lars Ingelmark, member		1791)					179
Vincent Ossipow, member		1291)					129
Niklas Prager, member		1691)					169
Michael Oredsson, CEO	4,141		1,077	72		942	6,232
	4,141	1,064	1,077	72	•••••••••••••••••••••••••••••••••••••••	942	7,296
Other senior executives							
(5 individuals)	6,321		1,523	225	515	1,566	10,150
Total	10,462	1,064	2,600	297	515	2,508	17,446

<sup>1)</sup> Participated in Board Share Program 2017.

### Benefits for the Board and CEO

The AGM resolved that the Board's annual basic fees 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 connection hereby it was resolved that the fees to Board members who elect to not participate in the Board share program resolved by the general meeting shall amount to SEK 460,000 to the Chairman of the Board and SEK 184,000 each to the other members of the Board. 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 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.

Björn Frendéus, acting CEO for the period 1 January 2018 to 31 August 2018, has received a fixed gross cash salary of SEK 1,424 thousand and SEK 470 thousand in variable remuneration (including retention bonus for the period 1 January 2018 to 30 June 2018), as well as SEK 90 thousand in other benefits. The total cost for pension benefits amounted to SEK 369 thousand.

Martin Welschof, CEO from 1 September 2018, has received a fixed gross cash salary of SEK 800 thousand and SEK 168 thousand in variable remuneration, as well as SEK 60 thousand in other benefits. The total cost for pension benefits amounted to SEK 240 thousand. He is covered by pension benefits of 30 per cent 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.

### 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 three to 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 2018 of SEK 4,414 thousand. SEK 199 thousand has been exchanged from gross cash salary to pension costs. SEK 1,011 thousand was received in variable remuneration (including retention bonus for the period 1 January 2018 to 30 June 2018), as well as SEK 233 thousand in other benefits. The total pension costs relating to other senior executives amounted to SEK 1,073 thousand. Other senior executives received an allotment of 276,850 options in January 2019.

# Average number of employees

	2018		2017		
	Number of employees	Of which women	Number of employees	Of which women	
Parent Company	59	64 %	53	67 %	
Subsidiaries	-	-	-	-	
Group total	59	64 %	53	67 %	

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

	2018		2017	
		Of which		Of which
	Number <sup>2)</sup>	women	Number <sup>2)</sup>	women
Board and CEO	9	33 %	9	33 %
Other senior executives	4	0 %	4	0 %

<sup>2)</sup> 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 with a maximum dilution effect of approximately 0.3 percent. Subscription Warrants Program 2016/2019 does not constitute an IFRS 2 program.

The program includes all employees except the CEO and other senior executives comprised by the retention bonus program implemented in 2015. The subscription warrants are transferred at market value and each employee may be allotted a maximum of 50,000 subscription warrants. 855,000 subscription warrants were transferred to SEK 0.56 per subscription warrant in the second quarter 2016 and 102,571 subscription warrants were transferred to SEK 1.05 per subscription warrant by the end of December 2016. Subscription of shares by exercise of subscription warrants shall take place during the period from and including 1 July 2019 up to and including 1 December 2019. The subscription price per share shall be SEK 2.81. As part of the incentive program, participants who remain in their employment with the Company as per 1 June 2019 receive a stayon bonus corresponding to two times the amount paid for the acquired subscription warrants, however no more than SEK 60,000.

# **Board Share Program 2018**

The 2018 Annual General Meeting resolved to adopt a Board share program for the members of the Board, whereby the members of the Board who wish to participate in the program are allocated minimum 45 per cent and maximum 100 per cent of the basic fee for the Board assignment in the form of shares in BioInvent to a number that at the time of allocation in terms of value is equivalent to minimum 45 per cent and maximum 100 per cent of the fee. The resolution includes a directed issue of a maximum of 2,000,000 warrants (corresponding to approximately 0.6 per cent of the total number of shares and votes in the Company) and approval of transfer or warrants in order to secure the fulfilment of the Company's obligations under the program. Subscription of shares by virtue of the warrants shall be made no later than 30 July 2019 and the subscription price per share shall amount to the share's quota value (presently SEK 0.08).

# 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, entailing a directed issue of maximum of 7,117,000 warrants (corresponding to approximately 2.0 percent of the total number of shares and votes in the Company) and approval of transfer of warrants to secure the fulfilment of the Company's obligations under the program and social security charges. The program means that the participants may be allotted a maximum of 5,650,000 warrants depending on performance and the Company's long-term value growth. 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.

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 program has been implemented in the third quarter 2017 and includes currently 10 persons. BioInvent has during the third quarter of 2017, under the terms of the program, issued 7,117,000 warrants in BioInvent to the subsidiary BioInvent Finans AB, as security for the Company's fulfillment of the delivery of shares when options are exercised and liquidity for payment of social security contributions. Allotment of 591,759 options took place in January 2018 and 462,766 in January 2019

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.

2018	2017
462,766	591,759
0.26	0,58
0.25	0,25
2.07	2.30
3.00	3.00
2.54 year	3.13 year
-0.42 %	-0.52 %
40 %	50 %
-	-
227	360
	462,766 0.26 0.25 2.07 3.00 2.54 year -0.42 % 40 %

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

	Gr	oup	Parent Company	
SEK thousand	2018	2017	2018	2017
KPMG				
Audit	295	295	295	295
Other auditing activities besides the audit	-	-	-	-
Other services	81	43	81	43
Total	376	338	376	338

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	oup	Parent Company		
SEK thousand	2018	2017	2018	2017	
Research and development costs	5,040	2,871	5,040	2,871	
Sales and administrative costs	21	9	21	9	
Total	5,061	2,880	5,061	2,880	

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 Operational leasing**

Leasing charges are for laboratory, production and office premises and is primarily included in research and development costs. Leasing costs in 2018 and 2017 amounted to SEK 7,401 thousand (7,253) for the Group and the Parent Company. The table below shows the minimum lease payments for non-cancellable operational leasing agreements.

SEK thousand	Group	Parent Company
Payments due:		
Year 2019	7,854	7,854
Year 2020–2023	21,950	21,950
Year 2024 or later	-	-
Total	29,804	29,804

# Note 8 Income statement classified according to type of cost

	G	roup	Parent Company		
SEK thousand	2018	2017	2018	2017	
External costs	103,251	87,171	103,251	87,171	
Personnel costs	59,825	58,935	59,825	58,935	
Depreciation	5,061	2,880	5,061	2,880	
Total	168,137	148,986	168,137	148,986	

# Note 9 Exchange rate differences that affected loss for the period

	Gre	oup	Parent Company		
SEK thousand	2018	2017	2018	2017	
Exchange rate differences that affected the operating loss	-144	-19	-144	-19	
Financial exchange rate differences	-32	-25	-32	-25	
Total	-176	-44	-176	-44	

# Note 10 Other operating revenue and costs

	Group		Parent Company	
SEK thousand	2018	2017	2018	2017
Other operating revenue		•		•
Financial support from the EU's framework program etc.	6,504	1,617	6,504	1,617
Insurance compensation	1	1,745	1	1,745
Exchange rate gains	192	128	192	128
	6,697	3,490	6,697	3,490
Other operating costs				
Interest costs	-4	-3	-4	-3
Exchange rate losses	-336	-147	-336	-147
	-340	-150	-340	-150
Total	6,357	3,340	6,357	3,340

In 2017 and 2018 financial support from the EU's framework program etc. was reported for early research projects.

# **Note 11 Financial revenue**

	Gr	Group		Parent Company	
SEK thousand	2018	2017	2018	2017	
Interest income	103	130	103	130	
Exchange rate differences	48	26	48	26	
Total	151	156	151	156	

# **Note 12 Financial costs**

	Group		Parent Company	
SEK thousand	2018	2017	2018	2017
Interest costs	-2	-1	-2	-1
Exchange rate differences	-80	-51	-80	-51
Total	-82	-52	-82	-52

# Note 13 Tax on profit for the year

Tax on profit for the year	Group		Parent (	Company
SEK thousand	2018	2017	2018	2017
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	Pare	ent Company
SEK thousand	2018	2017	2018	2017
Reported loss before tax	-123,163	-100,528	-123,163	-100,528
Tax according to the applicable tax rate, 22.0 %	27,096	22,116	27,096	22,116
Tax effect of costs that are not deductible	-209	-207	-209	-207
Tax effect of loss carry forward for which the deferred				
tax claim has not been/shall be considered	-26,887	-21,909	-26,887	-21,909
Reported tax on loss for the year	0	0	0	0

There are no substantial deferred taxes that relate to temporary differences as of 31 December 2018. 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 1,636 million as of 31 December 2018. 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 14 Earnings per share

# Earnings per share before dilution

SEK thousand	2018	2017
Loss for the period	-123,163	-100,528
Average number of outstanding shares (thousand)	339,470	304,695
Earnings per share before dilution, SEK	-0.36	-0.33
Earnings per share after dilution	2018	2017
	· · · · · · · · · · · · · · · · · · ·	
Profit/loss for the period	-123,163	-100,528
Profit/loss for the period  Average number of outstanding shares (thousand)	-123,163 339,470	-100,528 304,695

Earnings per share before dilution is based on loss for the year attributable to Parent Company shareholders and a weighted average of the number of outstanding shares.

Diluted earnings per share is based on 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. Subscription Warrants Program 2016/2019 entitles the holder to acquire one new share in BioInvent for a subscription price of SEK 2.81. Option Program 2017/2020 entitles the holder to acquire one new share in BioInvent for

a subscription price of SEK 3.00. An average share price of SEK 2.25 per share was used to determine whether a dilution effect exists for 2018. Subscription Warrants Program 2016/2019 and Option Program 2017/2020 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 15 Intangible fixed assets

Acquired intangible fixed assets	G	roup	Parent	Company
SEK thousand	2018	2017	2018	2017
Opening acquisition value	21,062	29,291	21,062	29,291
Acquisitions	-	-	-	-
Disposals	-	-8,229	-	-8,229
Closing accumulated acquisition value	21,062	21,062	21,062	21,062
Opening depreciation	21,062	-29,291	21,062	-29,291
Disposals	-	8,229	-	8,229
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 16 Tangible fixed assets**

Equipment	G	roup	Parent Compar		
SEK thousand	2018	2017	2018	2017	
Opening acquisition value	71,816	56,525	71,816	56,525	
Acquisitions	3,848	16,487	3,848	16,487	
Disposals	-6,558	-1,196	-6,558	-1,196	
Closing accumulated acquisition value	69,106	71,816	69,106	71,816	
Opening depreciation	-55,429	-54,505	-55,429	-54,505	
Disposals	6,558	1,196	6,558	1,196	
Depreciation for the year	-4,301	-2,120	-4,301	-2,120	
Closing accumulated depreciation	-53,172	-55,429	-53,172	-55,429	
Closing residual value according to plan	15,934	16,387	15,934	16,387	

Investments in rented premises	G	roup	Parent Company		
SEK thousand	2018	2017	2018	2017	
Opening acquisition value	15,569	15,578	15,569	15,578	
Acquisitions	-	-9	-	-9	
Closing accumulated acquisition value	15,569	15,569	15,569	15,569	
Opening depreciation	-12,710	-11,950	-12,710	-11,950	
Depreciation for the year	-760	-760	-760	-760	
Closing accumulated depreciation	-13,470	-12,710	-13,470	-12,710	
Closing residual value according to plan	2,099	2,859	2,099	2,859	

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

# **Note 17 Shares in subsidiaries**

	Co. reg. no.	Reg. office	Share of equity	Share of votes	Book value
BioInvent Finans AB	556605-9571	Lund	100 %	100 %	687
BioInvent Finans AB administers warrants issued by BioInvent Int	ernational AB.				

	Parent	Ullipally
SEK thousand	2018	2017
Opening acquisition value	687	687
Closing acquisition value	687	687

# Note 18 Prepaid expenses and accrued income

	Gr	Parent Company		
SEK thousand	2018	2017	2018	2017
Prepaid rent	1,797	1,767	1,797	1,767
Other items	4,858	4,022	4,858	4,022
Total	6,655	5,789	6,655	5,789

# **Note 19 Financial risks**

Responsibility for the Group's financial transactions and risks is managed by the Company's financial function. The objective is to provide costeffective 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 2018 51 percent (30) of revenue were invoiced in foreign currencies, mainly USD. Around 39 percent (43) of costs in 2018 were invoiced in foreign currencies, mainly in GBP and EUR. Realised forward contracts for flows in 2018 had an effect on the operating income in the amount of SEK 0.4 (-0.6) million. A sensitivity analysis shows that the Company's operating loss in 2018 before hedging transactions would have been affected in the amount of SEK -0.2 million if the Swedish krona had weakened by 1 percent compared with GBP and in the amount of SEK -0.3 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 2018 was 0.1 percent (0.1). A change in the interest rate of 1 percent in 2018 would have affected the net interest income by SEK 1.1 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.

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# Note 20 Shareholders' equity

# Share capital

	Ordin	ary snares
Thousands of shares	2018	2017
Issued as of 1 January	304,695	304,695
Directed new share issue	45,704	
Directed new share issue, Board Share Program 2017	401	
Issued as of 31 December	350,800	304.695

The share capital as of 31 December 2018 consists of 350,799,972 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 loss for the year

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

# **Proposed appropriation of profits**

At the disposal of the Annual General Meeting: Share premium reserve of SEK 154,838,988, retained earnings of SEK 227,000 and loss for the year of SEK -123,163,171. The Board of Directors propose that profits at the disposal of SEK 31,902,817 is carried forward. Thus, it is proposed that no dividend be given for the financial year 2018.

# **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 21 Accrued expenses and deferred income

	G	roup	Parent Company		
SEK thousand	2018	2017	2018	2017	
Payroll liabilities	8,570	13,898	8,570	13,898	
Social security fees	2,973	4,491	2,973	4,491	
Other items	5,051	4,595	5,051	4,595	
Total	16,594	22,984	16,594	22,984	

# Note 22 Financial assets and liabilities

# **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	
Short-term investments		-		-	
Cash and bank		68,851		68,851	
		92,749		92,749	
Financial liabilities measured at fair value					
Currency forward contracts	-25			-25	-25
	-25	•		-25	-25
Financial liabilities not measured at fair value					
Accounts payable			-10,821	-10,821	
Other liabilities			-5,339	-5,339	
			-16,160	-16,160	

# Group 2017

SEK thousand		Book value			Fair value
	Financial assets/liabilities measured at fair value through profit or loss	Loan receivables and accounts receivables	Other financial liabilities	Total	Level 2¹)
Financial assets measured at fair value	•	•••••••••••••••••••••••••••••••••••••••	•	••••••••••	
Currency forward contracts	44			44	44
	44			44	44
Financial assets not measured at fair value					
Accounts receivable		1,404		1,404	
Other receivables		7,418		7,418	
Short-term investments		30,060		30,060	
Cash and bank		103,700		103,700	
		142,582		142,582	
Financial liabilities measured at fair value					
Currency forward contracts	-7			-7	-7
	-7			-7	-7
Financial liabilities not measured at fair value					
Accounts payable			-14,171	-14,171	
Other liabilities			-2,660	-2,660	
			-16,831	-16,831	

<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.

# Maturity structure of financial liabilities – undiscounted cash flows

SEK thousand Remaining term, 31 Dec. 2018	< 3 monhs	3–12 months	Total
Accounts payable	-10,821	•••••••••••••••••••••••••••••••••••••••	-10,821
Other liabilities	-5,339		-5,339
Accrued expenses	-16,594		-16,594
Currency forward contracts	-25		-25
	-32,779		-32,779
Remaining term, 31 Dec. 2017			
Financial liabilities	- 39,822		-39,822

# Note 23 Important events after the end of the reporting period

In January 2019, BioInvent announced that the U.S. Food and Drug Administration had granted the Company orphan designation for its proprietary antibody BI-1206 for the treatment of mantle cell lymphoma.

In February 2019 BioInvent resolved on a fully underwritten rights issue of SEK 210 million and a directed issue of SEK 30 million with a Swedish pension fund and a Swedish life science fund. Additionally, it is proposed that the board of directors is authorized to resolve on an over-allotment option for up to SEK 70 million, that can be exercised if the rights issue is over-subscribed. The rights issue and the over-allotment option were approved by an extraordinary general meeting held on 20 March 2019.

In March 2019 BioInvent announced that the United States Patent and Trademark Office had issued a Notice of Allowance that a patent application relevant to its F.I.R.S.T.™ platform had been allowed and can proceed to grant. It covers methods for differential biopanning.

# Note 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. 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 3 April 2019.

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

Martin Welschof CEO

Our audit report was submitted on 3 April 2019 KPMG AB

> Eva Melzig Authorised Public Accountant

# 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 2018. The annual accounts and consolidated accounts of the Company are included on pages 28–54 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 2018 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 2018 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 31, 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 outlicensing 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.

In order to receive further financing, the Company decided in February 2019 to implement a capitalization by way of a right issue and a directed issue, expected to raise net proceeds of SEK 219 million.

### 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.

The right issue, decided in March 2019, was a prerequisite for the use of the going concern principle. We have verified that the issue was guaranteed.

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 42 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 area 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 agree-ments 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 1–27. 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 respons-

ible 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:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the Company's internal control relevant to 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 for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform 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 2018 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 necessary to fulfill the Company's accounting in accordance with law and handle the management of assets in a reassuring manner.

# **Auditor's responsibility**

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the 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 24 April 2018. KPMG AB or auditors operating at KPMG AB have been the Company's auditor since 2012.

Malmö 3 April 2019 KPMG AB

Eva Melzig Authorized Public Accountant

# 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 2018, the Board of Directors was authorised to resolve on the issue of not more than the number of new shares equivalent to 15 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 2018 was held on 24 April and the minutes are available on the BioInvent website. The AGM 2019 will be held in Lund on Thursday 25 April 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 2018 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 Björn O. Nilsson. 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 as well as election of auditors and auditors fees. The Nominating Committee had four meetings and a number of telephone calls. 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 2018 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 2018, six Board members were elected, whereof one woman and five men.

The composition of the Nominating Committee for the AGM 2018 was presented on BioInvent's website on 16 January 2019. 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 2019 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 2018 discharged the Board members and the CEO from liability and re-elected the ordinary Board members Dharminder Chahal, An van Es Johansson and Vincent Ossipow and elected Leonard Kruimer, Bernd Seizinger and Kristoffer Bissessar as new Board members. Leonard Kruimer was elected Chairman of the Board. The Board of Directors consists of six 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 26. All Board members elected by the General Meeting are independent in relation to the Company, senior executives and major shareholders.

The AGM 2018 resolved that the Board of Directors basic fees 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 connection hereby it was resolved that the fees to Board members who elect to not participate in the Board share program resolved by the general meeting shall amount to SEK 460,000 to the Chairman of the Board and SEK 184,000 each to the other members of the Board. 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 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 2018 the Board of Directors held six ordinary meetings and eleven 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
Björn O. Nilsson (Chairman) <sup>1)</sup>	9 (9)
Leonard Kruimer (Chairman) <sup>2)</sup>	7 (8)
Vessela Alexieva	17 (17)
Kristoffer Bissessar <sup>2)</sup>	8 (8)
Dharminder Chahal	13 (17)
Elin Jaensson Gyllenbäck	14 (17)
Lars Ingelmark <sup>1)</sup>	7 (9)
An van Es Johansson	14 (17)
Vincent Ossipow	15 (17)
Niklas Prager <sup>1)</sup>	9 (9)
Bernd Seizinger <sup>2)</sup>	7 (8)

- 1) Resigned on 24 April 2018 in conjunction with the AGM.
- 2) Elected on 24 April 2018 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 (for the period following the AGM in 2018; before then Björn O. Nilsson (Chairman), An van Es-Johansson and Vincent Ossipow). 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 three meetings in 2018.

Member of the Remuneration Committee	Attendance
Björn O. Nilsson (Chairman) <sup>1)</sup>	2 (2)
Leonard Kruimer (Chairman) <sup>2)</sup>	1 (1)
An van Es Johansson	3 (3)
Vincent Ossipow <sup>1)</sup>	2 (2)
Bernd Seizinger <sup>2)</sup>	1 (1)

- 1) Resigned on 24 April 2018 in conjunction with the AGM.
- 2) Elected on 24 April 2018 in conjunction with the AGM.

# **Audit Committee**

The Board of Directors has appointed an Audit Committee consisting of Kristoffer Bissessar (Chairman), Dharminder Chahal and Leonard Kruimer (for the period following the AGM in 2018; before then Lars Ingelmark (Chairman), Dharminder Chahal, Björn O. Nilsson and Niklas Prager). 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, preparing 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 four meetings in 2018.

Member of the Audit Committee	Attendance
Lars Ingelmark (Chairman) <sup>1)</sup>	3 (3)
Kristoffer Bissessar (Chairman) <sup>2)</sup>	1 (1)
Dharminder Chahal	4 (4)
Leonard Kruimer <sup>2)</sup>	1 (1)
Björn O. Nilsson <sup>1)</sup>	3 (3)
Niklas Prager <sup>1)</sup>	3 (3)

- 1) Resigned on 24 April 2018 in conjunction with the AGM.
- 2) Elected on 24 April 2018 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 meet-ing. The CEO and the senior management are presented on page 27.

# **Remuneration to senior executives**

The AGM 2018 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 32.

# The Company's systems for internal control and risk management with respect to financial reporting for the 2018 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, 3 April 2019 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 2018 on pages 58–60 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 3 April 2019 KPMG AB

Eva Melzig Authorized Public Accountant



# **Annual General Meeting**

The Annual General Meeting will be held on Thursday 25 April 2019 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 Wednesday 17 April 2019; 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 Wednesday 17 April 2019 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, shareholders 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 Wednesday 17 April 2019 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 22 May, 23 July, 24 October 2019

# **Investor Relations**

Martin Welschof, CEO, +46 (0)46 286 85 50, martin.welschof@bioinvent.com
BioInvent's financial reports are also aviable 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 out-come may deviate significantly from the scenarios described in this annual report.



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