BioInvent

2020 Annual Report

Content

BIOINVENT IN BRIEF

BioInvent is translating cancer antibody biology into innovative immuno-oncology therapies

BioInvent International:

Focused on the development of novel, first-in-class immuno-modulatory antibodies for the treatment of cancer. **Four ongoing clinical programs.**

Powerful proprietary discovery engine based on the validated F.I.R.S.T™ technology and n-CoDeR® antibody library, **continuously generating promising new drug candidates.**

In-house, state-of-the art manufacturing facility enabling swift and cost-effective drug candidate development. Manufacturing contracts with clients provide a source of revenue.

Swedish biotechnology company with head office in Lund. 72 employees, 65 of whom work in research and development. **92 percent of the Company's employees have university degrees, including 46 percent with PhDs.**

Listed on Nasdaq Stockholm (Ticker: BINV).

Immuno-oncology drugs are one of the greatest medical breakthroughs of the 21st century, significantly improving cancer survival rates, with the global immuno-oncology market expected to reach USD 133 billion by 2025[1]. Currently available therapies are only able to help a fraction of all cancer patients, leaving a high unmet need for additional novel immuno-oncology treatment options. Our mission is to address this high unmet medical need.

1) I-O Therapy Combinations Spurring Growth of the Global Immuno-oncology Market (researchandmarkets.com).

STRATEGY, FOCUS AND GOAL

Develops antibodies for the treatment of cancer

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

BioInvent discovers and develops novel and first-in-class immuno-modulatory antibodies for cancer therapy, with four ongoing programs in Phase I/II clinical trials for the treatment of hematological cancer and solid tumors.

The Company's validated, proprietary F.I.R.S.T™ technology platform simultaneously identifies both targets and the antibodies that bind to them, generating many promising new drug candidates to fuel the Company's own clinical development pipeline or for additional licensing and partnering. The Company generates revenues from research collaborations and license agreements with multiple top-tier pharmaceutical companies, as well as from producing antibodies for third parties in the Company's fully integrated manufacturing unit.

Mission

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

Strategy

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

Business model

BioInvent has three main areas for commercialization. The Company's primary value drivers are clinical and preclinical development projects. BioInvent also has research and development collaborations based on the Company's technology platform F.I.R.S.T™ and its antibody library 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 and sell antibodies to external parties.

Business focus

BioInvent's current operational activities are focused on:

- Progressing the clinical development of its lead Phase I/II first-in-class anti-FcγRIIB antibody BI-1206 for the treatment of NHL and for the treatment of advanced solid tumors in combination with Keytruda® (pembrolizumab).
- Progressing the clinical development of BI-1808 (anti-TNFR2 antibody), as monotherapy and in combination with Keytruda® for the treatment of solid tumors and CTCL (Cutaneous T-Cell Lymphoma).
- Developing BT-001 (anti-CTLA-4 antibody/oncolytic virus), in partnership with Transgene, for the treatment of solid cancers.
- Advancing BI-1607 (anti-FcγRIIB antibody) in combination with a checkpoint inhibitor, into clinical development for the treatment of solid cancers.
- Continuing development of the Company's prioritized preclinical projects with the aim to generate additional clinical programs, e.g. BI-1910 (anti-TNFR2 antibody).

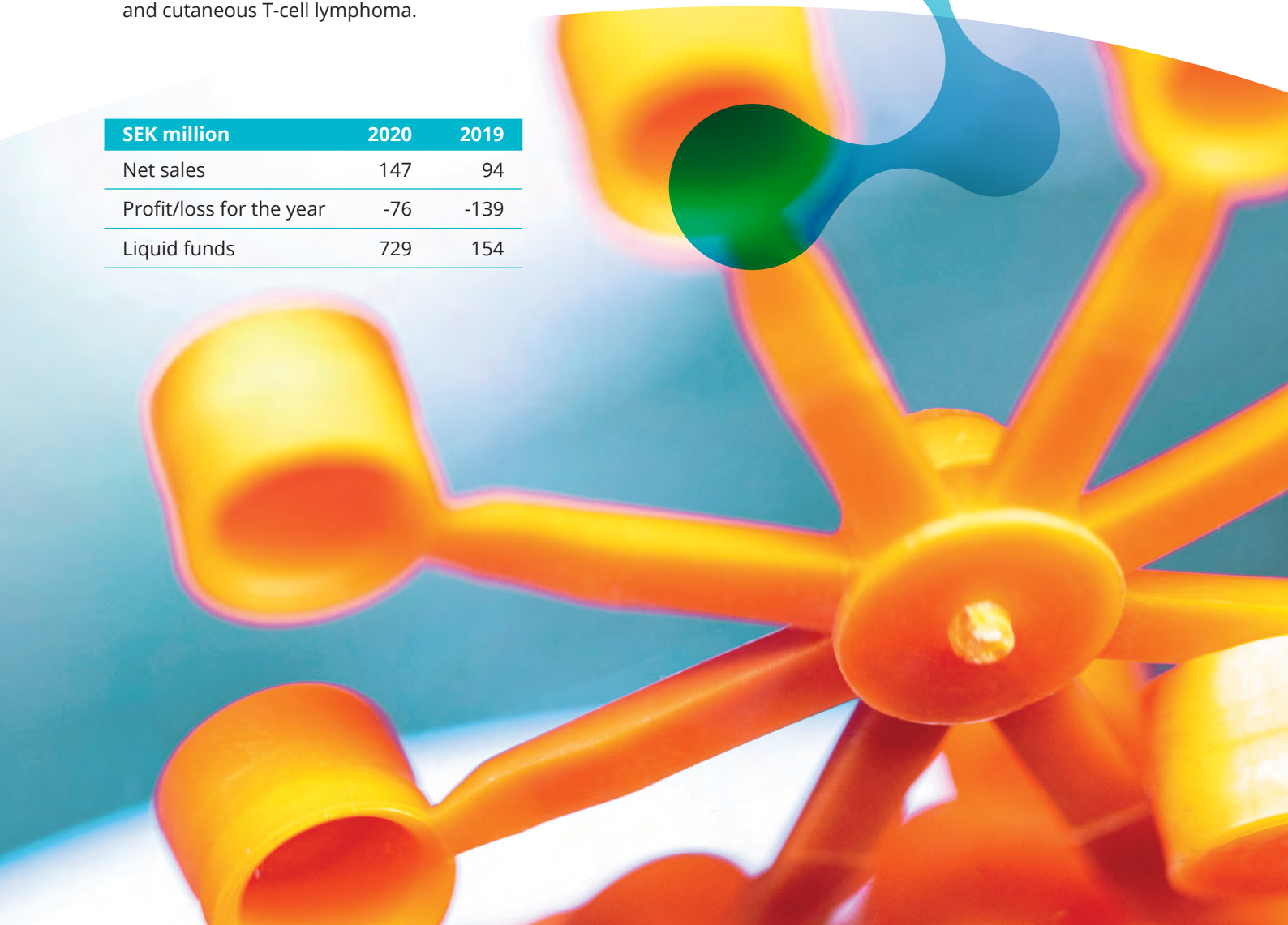
BIOINVENT IN 2020

Expanding our clinical pipeline and new business partnerships

Clinical and preclinical highlights

- Promising progress in the Phase I/IIa trial of lead program BI-1206 in combination with rituximab. Phase I/IIa data suggest that BI-1206 restores activity of rituximab in relapsed non-Hodgkin's lymphoma patients. Responses in 6 out of 9 patients evaluated provide exciting evidence that BI-1206 has the potential to restore activity of rituximab in non-Hodgkin's lymphoma patients who have relapsed after treatment with rituximab. In January 2021, it was reported that two patients achieved a complete response, which continued to be sustained 12 and 24 months later.
- The first patient was enrolled in a second Phase I/IIa clinical trial of BI-1206, this time in combination with anti-PD-1 therapy Keytruda® (pembrolizumab) in patients with solid tumors.
- Approval of a CTA for the Phase I/IIa study of BI-1808, as monotherapy and in combination with the anti-PD-1 therapy Keytruda® for the treatment of solid tumors and cutaneous T-cell lymphoma.
- BioInvent and Transgene received CTA approval for Phase I/IIa trial of oncolytic virus BT-001 in solid tumors.
- High presence at scientific meetings:
  - AACR 2020: BioInvent and Transgene presented preclinical data demonstrating high cure rates in solid tumors of BT-001, an anti-CTLA-4 antibody-encoding oncolytic virus. New proof-of-concept data was presented for the two TNFR2-targeting antibodies BI-1808 and BI-1910. Both candidates have shown significant antitumor activity in several immunocompetent disease models.
  - SITC 2020: New preclinical data on BI-1808 and BT-001.
  - ASH 2020: New promising clinical and preclinical data on BI-1206.

SEK million	2020	2019
Net sales	147	94
Profit/loss for the year	-76	-139
Liquid funds	729	154



Development collaborations and license agreements

- BI-1206 was out-licensed to CASI Pharmaceuticals for the Greater China region. The collaboration accelerates and expands BioInvent's global development plans for BI-1206. BioInvent received $12 million upfront in combination of cash and equity investment and is eligible to receive up to $83 million in milestone payments, plus tiered royalties. The equity investment was approved at an EGM held on November 27.
- A collaboration agreement was signed with the commercial-stage biotech company SkylineDx with expertise in molecular diagnostics, to identify the rights patients and maximize impact of treatment with BI-1206.
- BioInvent's agreement with Pfizer was further extended to permit the companies to further identify and characterize new targets and antibodies binding to these targets. In December, BioInvent received a $3 million milestone payment related to selection of antibodies under the collaboration.
- BioInvent received a €2 million milestone payment under its collaboration with Daiichi Sankyo related to the initiation of a global Phase I clinical trial with a GARP directed antibody.
- BioInvent and Cantargia signed a manufacturing agreement which may generate revenue for BioInvent of up to SEK 30 million Furthermore, a manufacturing agreement was signed with a U.S. cell therapy company.

Financing

- In June, BioInvent successfully completed a directed share issue of approximately SEK 487 million before transaction costs. Investors included new investors such as HBM Healthcare Investments Ltd., Swedbank Robur Medica and Invus Public Equities, L.P. as well as existing shareholders Van Herk Investments B.V., Omega Funds, The Fourth Swedish National Pension Fund and Handelsbanken Healthcare Fund. In August, a repair issue of approximately SEK 139 million before transactions costs, was completed.
- After the end of the year, in February 2021, BioInvent successfully completed a directed share issue of approximately SEK 962 million (USD 116 million) before transaction costs. Investors in the directed share issue included a range of international and Swedish institutional investors, including Redmile Group, LLC., Invus, HBM Healthcare Investments, The Fourth National Swedish Pension Fund, Swedbank Robur Fonder and Van Herk Investments.

COMMENTS BY THE CEO

Solid clinical and business progress sets up exciting 2021

2020 was a year of substantial and exciting clinical and business progress for BioInvent, providing a solid foundation for an important 2021.

We have reported impressive interim data on our lead drug candidate, the novel anti-FcγRIIB antibody BI-1206, for which we also concluded a licensing agreement with CASI Pharmaceuticals in mainland China, Taiwan, Hong Kong and Macau. Our efforts extended well beyond BI-1206, with the expansion of our clinical pipeline to include two further promising products and the raising of significant funds for further development activities.

The data from the Phase I/IIa study of BI-1206, in combination with rituximab in patients with indolent relapsed or refractory B-cell non-Hodgkin's lymphoma (NHL), are very encouraging. The responses in these severely ill patients suggest that BI-1206 may restore the response to rituximab in patients who have few treatment alternatives and the duration of complete response in two patients is particularly impressive. Overall, the data indicate that BI-1206 has the potential to significantly improve the lives of NHL patients who have progressed after previous lines of treatment. We were proud to host a key opinion leader (KOL) event on these results with renowned lymphoma expert Mats Jerkeman, MD, of Lund University and are excited to further evaluate the potential of BI-1206 to bring much needed innovation in this area of significant medical need. We also continue to advance BI-1206 in patients with solid tumors, in a Phase I/IIa trial in combination with anti-PD-1 therapy Keytruda® (pembrolizumab).

Our partnership agreement for BI-1206 with CASI Pharmaceuticals for the development and commercialization of BI-1206 is an important step in the development of this drug candidate. CASI is a proven leader in China and their clinical development and regulatory expertise will be important in generating additional data. The agreement also provides an important source of funding for BioInvent: we received $12 million upfront in combination of cash and equity investment and are eligible to receive up to $83 million in development and commercial milestone payments plus tiered royalties in the high-single to mid-double-digit range on net sales. We have added further flexibility to carry out development and partnering activities with BI-1206 by simplifying and reducing our

> “We have reported impressive interim data on our lead drug candidate, the novel anti-FcγRIIB antibody BI-1206, for which we also concluded a licensing agreement with CASI Pharmaceuticals in mainland China, Taiwan, Hong Kong and Macau.”
>
> **Martin Welschof, CEO**

obligations to Cancer Research UK (CRUK), relating to a clinical development agreement, in exchange for a one-time payment.

An agreement with SkylineDx, a molecular diagnostics company, to characterize the gene expression and immunological signatures in tumors of patients pre- and post-treatment with BI-1206 will help us to identify the right patients who are likely to respond to treatment. This will constitute a major asset in the development of BI-1206 and, along with FcγRIIB expression levels, should support the extension of its use to other malignancies.

Our innovative pipeline is expanding beyond BI-1206 and we now have three products in clinical development, underlining the ability of our n-CoDeR®/F.I.R.S.T™ platforms to produce novel, differentiating drug candidates. In January 2021, we dosed the first patient in a Phase I/IIa first-in-human study of BI-1808, based on a solid preclinical data set. BI-1808 is a first-in-class anti-TNFR2 antibody and is being investigated as monotherapy and in combination with Keytruda® for the treatment of solid tumors and cutaneous T-cell lymphoma (CTCL).

A Phase I/IIa clinical trial of the novel oncolytic vaccinia virus BT-001 in solid tumors was initiated in March 2021, through our collaboration with Transgene. BT-001 combines multiple mechanisms of action and has outstanding potential in a wide range of indications due to its combination of multiple anti-cancer properties.

Our partner Pfizer has selected antibodies directed at a previously selected target, under our agreement covering developing antibodies from the F.I.R.S.T™ drug discovery platform targeting tumor-associated myeloid cells. We may now move forward to develop other antibodies internally or with other partners.

These advances set us up for exciting developments in the coming year. We aim to report early results from the the Phase I open label study with BI-1206 in combination with Keytruda® in solid tumors in H2 2021 and expect further progress in our other trials. We will continue to build up clinical data, with enrolment of more patients in the Phase I/IIa trial of BI-1206 with rituximab in NHL and the two new studies with BI-1808 and BT-001.

Our financial position was reinforced by a successful directed share issue, followed by a repair rights issue which was heavily oversubscribed as well as another successful directed share issue in February 2021. We were pleased to see such strong interest in these share issues and are grateful for the continued support and trust of all our investors. In total these share issues raised approximately SEK 1,550 million before transaction costs, enabling us to broaden and develop our pipeline and are truly transformative for the company. We have also generated funds from our partnerships with CASI, Pfizer and Daiichi Sankyo and various manufacturing agreements. At the end of 2020, BioInvent had SEK 729 million in cash and cash equivalents.

Of course, Covid-19 is continuing to create many uncertainties in the world and healthcare is no exception. As we have previously communicated, BioInvent has taken all the necessary precautions with regards to Covid-19 and we remain on track with our clinical trials and results. As the situation is still evolving, timelines may be impacted in geographic areas most severely affected, and we will provide updates as necessary.

Despite such uncertainties, I am pleased with the substantial advances BioInvent has made in 2020, positioning us for further delivery in 2021. Based on a solid financing position, we will continue to move our exciting pipeline through clinical development in what promises to be a very exciting year for BioInvent.

I would like to take this opportunity to extend my thanks to all our employees, investors and partners for their support of and interest in BioInvent. Together, we are taking the company forward by expanding our clinical pipeline and business partnerships and I look forward to updating you further on our progress through 2021.

Martin Welschof,
CEO

IMMUNO-ONCOLOGY

Immunotherapy – a 21st century transformation of cancer treatment

Immunotherapy encompasses a broad range of treatments that work in synergy with the body's natural immune defenses in order to tackle disease. In cancer, in particular, immunotherapy has already provided a paradigm shift: in a few patients with cancers that continue to grow or spread despite multiple numerous conventional treatments, immunotherapies have stopped tumor growth in its track, or even shrunk the tumor. The aim of the R&D programs at BioInvent now is to improve on those first early steps, developing immunotherapies that not only serve as mainstream treatments for cancer but also push toward the real cures in oncology.

Principles of immunotherapy

The natural immune system is finely balanced. It defends us against infectious disease and the early manifestations of internal invasions such as cancer. But it also capable of launching attacks on healthy tissue. To maintain the correct balance, the immune system has a number of "control mechanisms" to prevent auto-destruction.

As they evolve, cancer cells can "learn" to avoid immune defenses by co-opting these natural control mechanisms, in effect, telling the immune system to stand down and ignore the threat. Immunotherapy can reverse this subterfuge either by directly activating immune cells (stepping on the accelerator) or by reducing the inhibitory signals that control the immune cells (releasing the brake). Immunotherapies activate the body's existing immune system, teaching it to recognize cancer cells in the body and attack them.

One of the great advantages of immunotherapy is the possibility that treatments can have very long-term effects. Just as vaccinations prime the body to anticipate future infections, immuno-oncology treatments not only stimulate immediate attacks on tumors, they also establish tumor-specific immunological memory. This means that the body is prepared to combat any recurrence of the cancer and to eradicate the spread of cancer (metastases) in the body.

Treatment options within immunotherapy and immuno-oncology

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

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

There are a number of different immunotherapy options that can be used to stimulate the body's immune system into attacking malignant tumor cells, including monoclonal antibodies, checkpoint inhibitors, bispecific T cell engagers, oncolytic virus therapy and cell therapy (CAR T and CAR NK cell therapies). BioInvent is primarily active in monoclonal antibodies such as checkpoint inhibitors, but also in oncolytic virus therapy through a collaboration with Transgene.

Monoclonal antibodies and checkpoint inhibitors

When the body's immune system discovers something it recognizes as harmful and foreign, its first line of defense is the production of antibodies. Monoclonal antibodies originate from a single B cell and are uniform and identical: each of them recognizes and can bind to the same target molecule, such as an abnormal protein on a cancer cell. When bound to tumor proteins, monoclonal antibodies act as labels, marking the tumor cells out for attack by cells of the immune system – such as macrophages and other myeloid cells – which ultimately will kill them.

Monoclonal antibodies can also be used as a general stimulus to anti-cancer immunity. The immune system is dynamic, subject to molecular control mechanisms – check-points - that can down-regulate it or tune it up. In some cases, cancer cells manipulate these proteins to avoid attacks. In cancerous tissue, these check-points are often down-regulated, starving the immune system of the activated T cell that it needs to mount an effective anti-cancer response. Monoclonal antibodies can be designed to block these checkpoints, thereby restoring T cell activation and leading to eradication of the tumors.

Within the past few years, immuno-oncology drugs have been developed that can block the checkpoint receptors PD-1 and CTLA-4 and also the checkpoint ligand PD-L1. They have proved commercially successful and are effective treatments for certain types of solid tumors, especially in a narrow group of patients with metastatic cancer. The challenge now is to develop new drugs that can complement the checkpoint inhibitors and extend effective treatments to a much wider group of cancer patients.

BioInvent has extensive programs for developing immuno-oncology products.

- The antibody BI-1206 is being developed for the treatment of Non-Hodgkin's Lymphoma in combination with rituximab, and in advanced solid tumors in combination with the check-point inhibitor, Keytruda® (pembrolizumab).
- Another BioInvent antibody, BI-1808, is in clinical development both on its own and in combination with Keytruda® to treat solid tumors and cutaneous T-cell lymphoma (CTCL).
- A clinical trial has also been initiated for the oncolytic virus BT-001, developed in partnership with Transgene, to be tested in solid cancer.
- The company expects to apply for permission to start a clinical trial combining another antibody product (BI-1607) in combination with a checkpoint inhibitor in H2 2021.
- We also have an extensive preclinical program to develop first-in-class antibodies targeting tumor-associated myeloid cells.

TECHNOLOGY PLATFORM

Platform for effective drug development

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

The development tool F.I.R.S.T™

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

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

The n-CoDeR® antibody library

BioInvent's antibody library contains more than 30 billion fully human antibody genes stored within bacteria in test tubes. The bacteria act as production units for various antibodies, making it possible to scan the library to precisely identify those antibodies that bind to a specific target protein. The n-CoDeR® library is scanned using the established phage display technology. To identify an optimal antibody, BioInvent has developed automated processes in which robots conduct analysis at scale. The n-CoDeR® library builds on naturally occurring human antibody genes. Every component comes from nature, but the combinations are largely new, making it possible to build an antibody repertoire that is greater than nature's own variability.

TARGETS

Important targets for BioInvent

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

Anti-FcγRIIB

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

BI-1206 and BI-1607 have FcγRIIB as target.

Tregs

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

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

TAMs

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

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

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

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

PROJECT PORTFOLIO

Broad Portfolio with Multiple Shots on Goal

BioInvent's portfolio of next generation immuno-oncology drugs aims to improve therapeutic results in areas with significant unmet need.

Indication	Program	Discovery	Preclinical	Phase I	Phase II
Target: FcγRIIB					
NHL (MCL, MZL, iFL)	BI-1206/rituximab			Partner: CASI	
Solid cancer	BI-1206/pembrolizumab			Partner: MSD	CASI
Solid cancer	BI-1607				
Target: Treg					
Solid cancer	BT-001 (αCTLA-4-GM-CSF-W)			Partner: transgene	
Solid cancer	BI-1808 (αTNFR2)				
Solid cancer	F.I.R.S.T™ αTreg				
Target: Tumor-associated myeloid cells					
Solid cancer	F.I.R.S.T™ αTAMs			Partner: Pfizer	

Clinical programs

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

In January 2021, BioInvent announced that Phase I/IIa data suggest that BI-1206 restores activity of rituximab in relapsed non-Hodgkin's lymphoma patients. Of the 9 patients who completed the induction cycle in the first 4 cohorts, 6 patients showed either complete or partial responses, several of which are still ongoing. Two patients (at dose levels of 30 mg and 70 mg) achieved a complete response, which continued to be sustained 12 and 24 months later. Another patient who had a blastoid form of MCL had achieved a partial response, and a complete depletion of peripheral tumor cells.

In October 2020, BioInvent licensed the anti-FcγRIIB antibody BI-1206 to CASI Pharmaceuticals for Greater China region. The collaboration accelerates and expands BioInvent's global development plans for BI-1206. Under the terms of the agreement, BioInvent and CASI will develop BI-1206 in both liquid and solid cancers, with CASI responsible for commercialization in China and associated markets. BioInvent received $12 million upfront in combination of cash and equity investment and eligible to receive up to $83 million in milestone payments, plus tiered royalties.

In January 2021, BioInvent announced that it had restructured a clinical development agreement with CRUK for BI-1206. In exchange for a one-time payment of £2.5 million, the revised deal simplifies and reduces Bioinvent's obligations to CRUK, which provides Bioinvent with more flexibility to carry out development and partnering activities with BI-1206. The restructured agreement with CRUK releases BioInvent from obligations to pay development or commercial milestones to CRUK on BI-1206 and reduces the royalties due on net sales to low single digit levels.

Background

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

The Phase I/IIa study consists of two parts: i) Phase I, with dose escalation cohorts using a 3+3 dose-escalation design and selection of the recommended Phase IIa dose (RP2D); and ii) Phase IIa, an expansion cohort at the RP2D, enriched with patients with mantle cell lymphoma (MCL). Subjects in each phase receive 1 cycle (4 doses) of induction therapy with BI-1206 in combination with rituximab. Subjects who show clinical benefit at week 6 continue onto maintenance therapy and receive BI-1206 and

rituximab once every 8 weeks for up to 6 maintenance cycles, or up to 1 year from first dose of BI-1206.

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

New promising clinical and preclinical data on BI-1206 was presented at the ASH Annual Meeting in December 2020. The data demonstrate signs of efficacy as first responses observed in lymphoma patients who have relapsed after treatment with rituximab. Preclinical data further reinforce efficacy and tolerability profile, also in ibrutinib-venetoclax resistant mantle-cell lymphoma, both as single agent as well as in combination with rituximab. These data further corroborated the important role of FcγRIIB in establishing resistance to rituximab, and indicate the ability of BI-1206 to overcome this resistance. Together with a high expression in mantle cell lymphoma patient cells, these data indicate the high potential of BI-1206 to address a significant unmet need in the treatment of MCL and other B-cell malignancies such as Follicular lymphoma.

BI-1206 in combination with pembrolizumab in solid tumors

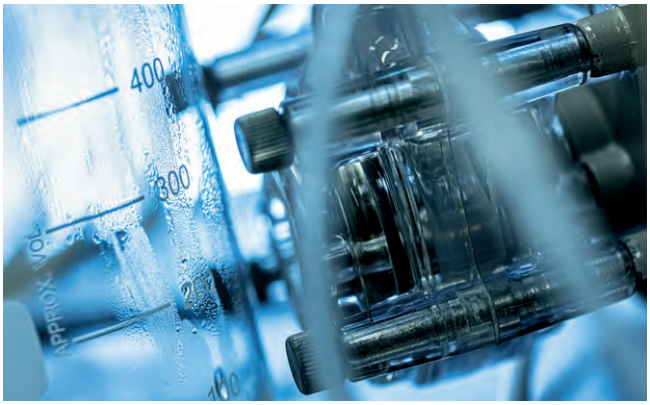
In July 2019 BioInvent received authorization from the FDA to proceed for an IND application for a Phase I/IIa clinical trial of BI-1206 in combination with Keytruda® (pembrolizumab) for the treatment of solid tumors. The first patient was enrolled in June 2020.

Background

The objective of this trial is to explore the safety and tolerability profile of the combination of BI-1206 with Keytruda®, to characterize the pharmacokinetic/pharmacodynamic (PK/PD) profile and to determine the recommended dose of BI-1206 when combined with Keytruda®. It will be conducted in several sites across the US and Europe and will assess potential signs of antitumoral activity, as well as exploring the expression of potential immunological markers that might be associated, and eventually predict clinical responses.

The Phase I/IIa trial is divided into part A, a dose escalation of BI-1206 in combination with the standard dose of Keytruda®, and part B, which will explore the activity of the combination treatment in patients with advanced lung cancer, melanoma and other types of malignancies. Patients will be refractory to or have progressed on previous treatments with anti-PD-1/PD-L1 targeting agents. Early results from the Phase I open label study is expected in H2 2021.

In December 2019 BioInvent entered into a clinical trial collaboration and supply agreement with Merck, to evaluate the combination of BioInvent's BI-1206, one of its proprietary anti-FcγRIIB antibodies and Merck's anti-PD-1 therapy, Keytruda® (pembrolizumab) in a Phase I/IIa clinical trial for patients with solid tumors. The agreement helps BioInvent to expand BI-1206 clinical development to solid tumors in combination with one of the most successful immuno-oncology drugs.



The program is based on BioInvent's preclinical data demonstrating the ability of BI-1206 to address an important mechanism of resistance to PD-1 inhibition, providing a way to enhance anti-tumor immune responses in patients with solid tumors. The Phase I/IIa clinical trial will evaluate the drug combination in patients with advanced solid tumors, who have been previously treated with anti-PD-1 or anti-PD-L1 antibodies, and is a multicenter, dose-finding, consecutive-cohort, open-label trial. The Phase I/IIa trial is planned to be carried out in the U.S. and the EU.

Patent protection BI-1206

Patent applications for the use of antibodies to CD32B, such as BI-1206, in combination with other antibodies, such as rituximab, in the treatment of cancer or inflammatory diseases in certain patient populations have been submitted in several large markets. So far, patents have been granted in the key markets Europe, the US and Japan, as well as in other markets, and a patent application is pending in China. Patent application has also been submitted for a second patent family in Europe, US, Japan and China, as well as other markets, for the treatment of cancer patients who no longer respond to previous antibody therapy. Patent expiry year for the first patent family is 2031 in most markets, including Europe, and 2034 in the US. Patent protection for the second patent family expires in 2035, or possibly at another timepoint in the US.

An international patent application relating to a combination of BI-1206 or similar anti-CD32B antibodies and an anti-PD-1 antibody have also been submitted and the aim is to proceed with the application in several countries.

BI-1808 and BI-1910 (anti-TNFR2 antibody) for the treatment of solid tumors and CTCL

Two different types of TNFR2 targeting antibodies are being developed by BioInvent – BI-1808 in clinical development (a ligand blocker), and BI-1910 (an agonist) in preclinical development.

BioInvent announced, in October 2020, regulatory authority approval of a clinical trial application (CTA) in Denmark for a Phase I/IIa, first-in-human study of BI-1808 for the treatment of solid tumors and CTCL. The first patient was enrolled in January 2021.

Background

BioInvent has identified tumor necrosis factor receptor 2 (TNFR2), a member of the so-called TNFR superfamily (TNFRS) as a target within the Treg program. TNFR2 is particularly upregulated on tumor-associated regulatory T cells (Tregs) and has been shown to be important for their expansion and survival. As a part of its Treg program, BioInvent identified and characterized a wide panel of TNFR2-specific antibodies, generated from its proprietary n-CoDeR® library and unique F.I.R.S.T™ discovery tool, of which BI-1808 and BI-1910 are the lead development candidates.

The Phase I stage is divided into two parts. Part A is a dose escalation study of BI-1808 to assess safety, tolerability, pharmacokinetics/pharmacodynamics, and to determine the recommended dose as a single agent for Phase II trials. Part B will explore the safety, tolerability and recommended dose of BI-1808 in combination with Keytruda®. The Phase IIa stage will consist of expansion cohorts to assess signs of efficacy of BI-1808 as single agent, and in combination with Keytruda® in lung cancer and ovarian cancer patients. Another cohort will explore the activity as single agent in CTCL. The trial will be conducted at several sites across Europe and the U.S. and is expected to enroll approximately 120 patients.

Exciting preclinical data was presented at AACR Virtual Annual Meeting II in June 2020. In vivo studies show that both ligand-blocking (BI-1808 surrogate) and agonistic (BI-1910 surrogate) antibodies regress large established tumors and synergize with anti-PD-1 therapy. Further mode-of-action dissection demonstrate that while the ligand-blocking antibody depleted intratumoral Tregs, the agonist increased intratumoral CD8+ T effector cells. Both antibodies expanded tumor-specific CD8+ T cells and induced long-lasting T cell memory.

New translational data was presented on BI-1808 at the SITC 35th Anniversary Annual Meeting. The data showed that BI-1808 had an expected pharmacokinetic profile and was well tolerated in a toxicology study in doses up to 200 mg/kg.

Patent protection BI-1808

An international patent application for BI-1808 has been submitted. The application includes new anti-TNFR2 antibodies. The aim is to proceed with the application in several countries.

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

BioInvent and Transgene announced in December 2020 that regulatory approval had been received in Belgium for a clinical trial application for a Phase l/lla study of BT-001 in solid tumors. The first patient in a Phase I/IIa study was enrolled in March 2021.

Promising findings was presented both at AACR Virtual Annual Meeting II in June 2020 and at the SITC 35th Anniversary Annual Meeting in November 2020. Cure rates exceeding 70 percent were seen in multiple mouse models, demonstrating the powerful therapeutic effect of BT-001 when used as a single agent, providing a solid basis for BT-001's upcoming clinical development. BT-001 has been designed to combine the killing of cancer cells (oncolysis mediated by the virus), with the production of the anti-CTLA4 antibody and GM-CSF directly in the tumor site to enhance the generation of an efficacious immune response against tumor cells. It was shown that while the anti-CTLA-4 antibody and GM-CSF accumulate in tumors, the systemic exposure is very low. It was shown that a strong tumor-specific response and long-lasting immune memory were developed by BT-001 surrogate treated mice, which prevented establishment of re-implanted tumor cells in mice that had been cured. These data indicate that BT-001 has the potential to make a significant difference in the treatment of solid tumors. In March 2021, the first patient was enrolled to the Phase I/IIa clinical study of BT-001.

Background

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

Transgene is contributing both engineering expertise, as well as its proprietary Vaccinia viruses, designed to directly and selectively destroy cancer cells by intracellular replication of the virus in the cancer cell (oncolysis). Oncolysis induces an immune response against tumors, while the "weaponized" virus allows the expression of genes carried by the viral genome, here an immune modulatory anti-CTLA-4 antibody, which will further boost immune response against the tumor. BioInvent is providing its cancer biology and antibody expertise to the collaboration, as well as anti-CTLA-4 antibody sequences generated through its proprietary n-CoDeR®/-F.I.R.S.T™ platforms.

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

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

Patent protection BT-001

Patent protection for new anti-CTLA-4 antibodies and oncolytic viruses expressing such antibodies, such as BT-001, has been applied for in several major markets.

Preclinical programs

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

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

In partnership with Pfizer Inc. since December 2016, BioInvent works to identify novel oncology targets and therapeutic antibodies that may either reverse the immunosuppressive activity of tumor-associated myeloid cells or reduce the number of tumor-associated myeloid cells in the tumor. In July 2020 BioInvent announced that the research term under its collaboration and license agreement with Pfizer had been further extended until the end of 2020.

In December 2020 BioInvent announced that Pfizer had selected antibodies directed at a previously selected target. The selection of these antibodies triggered a payment from Pfizer to BioInvent of $3 million.

Background

BioInvent announced in July 2019 selection of the first target and in December 2019 the second target discovered by BioInvent's proprietary F.I.R.S.T™ technology platform under the collaboration with Pfizer Inc. The selection of targets triggered two payments from Pfizer to BioInvent of $0.3 million.

BioInvent is eligible for potential future development milestones in excess of $100 million if one antibody is 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 for the period 2017-2020. Pfizer also made a $6 million equity investment in new shares of BioInvent when the agreement was signed.

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

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

MARKET AND INDICATIONS

A fast growing market

Immuno-oncology drugs constitute one of the main medical breakthroughs of the 21st century. The first treatments have already greatly increased the survival time of patients, especially in blood-borne cancers and some well-served segments such as breast cancer. The market is expected to expand as more products in this category are approved. Antibody-based immunotherapies have the potential to be used in the treatment of virtually all kinds of cancer. BioInvent develops antibody-based immuno-therapies primarily aimed at treating hematological cancer and solid tumors.

The market for immunotherapy

Of the 10 best-selling drugs in the global pharmaceutical market, seven are biological – and five of these are anti-body-based.[1)] Oncology is the segment most dominated by antibody-based drugs. 98 therapeutic monoclonal antibodies have been approved in USA, and are currently on the market, including 31 monoclonal antibodies for the treatment of cancer.[2)]

Immuno-oncology R&D has greatly expanded in recent years with 4,720 immuno-oncology drugs in clinical or preclinical development in 2020, up 22 percent from 2019.[3)] Propelled by this R&D effort, the total market for immunotherapy drugs is also expected to grow rapidly in the future. The global immuno-oncology market is expected to reach USD 133 bn by 2025.[4)] The average cost for treatment with existing immunotherapy drugs is currently around USD 100,000 per patient per year.[5)] However, there are great differences between geograph-ical regions and types of cancer and total cost depends on a number of factors including insurance coverage, types of cancer and treatment and frequency of treat-ment.

Market trends

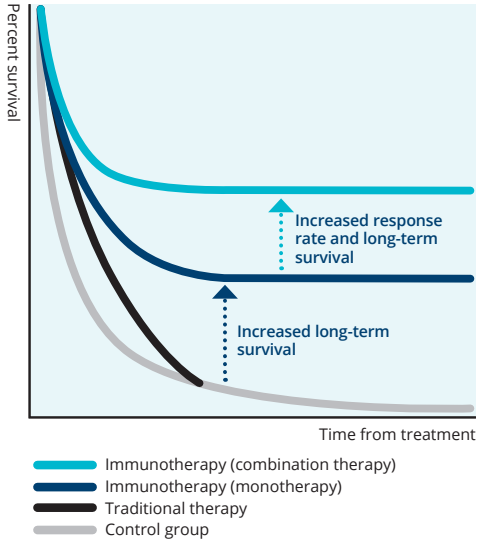
The antibody-based drug segment is one of the fastest growing segments in the global pharmaceutical market. Although immuno-oncology therapies still only make up a fraction of the total oncology market, antibodies are a key element in this new approach. The 5 top-selling anti-body-based cancer drugs in 2019 were Keytruda (pem-brolizumab, Merck), Opdivo® (nivolu-mab, BMS), Her-ceptin® (trastuzumab, Roche), Avastin® (bevacizumab, Roche), Rituxan®/MabThera® (rituximab, Roche).[1)]

Several factors explain the strong market growth for antibody-based drugs and their use in immuno-oncology. Antibodies are the body's natural defence molecules. They are extremely selective and very well tolerated (safe) in their natural form; they exert a clear, specific effect and they are well integrated into the immune system, which can modulate their therapeutic effect. They are also being integrated as adaptable components into more complex therapeutic forms such as antibody-drug conjugates, bispecific T cell engagers and directed T cell therapies. These types of biopharmaceuticals are more complex than small molecule drugs, which makes them more difficult to copy.

1) https://pharmaintelligence.informa.com/~/media/informa-shop-window/pharma/2020/files/reports/top-10-best-selling-drugs-of-2019.pdf
2) The Antibody Society, https://www.antibodysociety.org/resources/approved-antibodies/ Accessed January 31, 2021.
3) Upadhaya, S. et al., Nature Reviews Drug Discovery, 19, 751–752 (2020).
4) I-O Therapy Combinations Spurring Growth of the Global Immuno-oncology Market (researchandmarkets.com).
5) Dranitsaris, G et al. Expert Reviews of Pharmacoeconmics & Outcomes Research 18, 351–357 (2018).

Combination therapy

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



Hematological cancer

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

Sales of rituximab (Rituxan®/Mabthera®) amounted to USD 6.6 billion in 2019 with projected sales of USD 5.0 billion in 2020 related mainly to treatment for haematological cancer.[6)]

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

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

Non-Hodgkins lymphoma

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

The Company's addressable market for the three initial main indications is believed to be, according to the Company's estimates, approximately USD 200 million per year in the US alone.[8)] 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 characterized 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 involved to a large extent. The large number of white blood cells displace the normal 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 5.0 per 100,000 individuals.[9)] The global market for the treatment of chronic lymphocytic leukemia was estimated to be approximately USD 7.6 billion by 2025 growing at CAGR 6.2 percent over the forecast period.[10)]

Solid tumors

In addition to BioInvent's ongoing studies with the drug candidate BI-1206 in hematological cancer, all of BioInvent's candidates are focused on the treatment of solid tumors. BI-1206 is being evaluated for solid tumors in a Phase I/IIa clinical program in combination with pembrolizumab (Keytruda). BioInvent has not yet made any formal decision on which indications it will focus on initially. The Company's assessment is 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.

6) Global Data sales and Forecast 2020.
7) GBI Research. National Cancer Institute, Nov 2019, and BCell NHL Market 2024, opportunity analysis and forecasts Global data.
8) The Company's estimate is based on external reports from Cello Health BioConsulting, 2018 (formerly Defined Health).
9) SEER National Cancer Institute, Cancer Stat Facts: Leukemia – Chronic Lymphocytic Leukemia (CLL): Accessed February 1, 2021
10) Global Chronic Lymphocytic Leukemia Treatment Market – December 2019.

INTERVIEW

Mats Jerkeman, MD, Lund University

Please explain your involvement with BioInvent and its clinical trials?
I've been working with BioInvent for over 10 years, since initial discussions on the preclinical development of BI-1206, a novel immuno-modulatory antibody. During that time, I have been involved in providing patient material such as plasma and cells from patients with lymphoma and in the development of new targets and antibodies against those. We have had discussions about unmet needs in patients with B-cell lymphomas and have worked together in developing treatment protocols for these. More recently, we have been conducting clinical trials and I have enrolled patients in the BI-1206 plus rituximab study in relapsed or refractory Non-Hodgkin's Lymphoma. Having been able to follow the development of BI-1206 from the very start, it is very interesting to see patients now receiving these agents.

As I work in Lund at the University Hospital, it has been really rewarding to work together with a neighboring company in the same city. It is a pleasure working with them and to gain an insight into the development of their treatments, and to have an impact in clinical development.

What are the challenges in treating follicular lymphoma (FCL) and mantle cell lymphoma (MCL)?
For FCL, ideally we need non-toxic treatments for patients who have few symptoms – the disease can be very indolent, so we do not want to give them a treatment that causes severe side effects. It is a challenge to develop a treatment which improves on single agent therapy with rituximab. The ultimate aim of course is to develop a curative treatment.

MCL is typically a more aggressive disease. Usually in younger patients, we try and give very aggressive treatment in the hope of curing them. For elderly patients, we want to develop chemo-free regimens that are effective but much less toxic. For these patients, the treatment challenges are similar to those for FCL.

Both FCL and MCL are both very sensitive to anti-CD20 antibodies like rituximab: however, there are few non-toxic treatment options for patients who either relapse or do not respond to rituximab.

Can you outline the current treatment options?
For FCL, patients initially often receive no treatment (wait and watch). When in need of therapy, patients receive single agent rituximab, rituximab plus chemotherapy or rituximab plus lenalidomide. At relapse, options also include PI3K-inhibitors.

For MCL, younger patients receive an intensive combination chemo-immunotherapy including cytarabine, followed by consolidation with high dose chemotherapy with autologous stem cell transplantation. Elderly patients receive chemo-immunotherapy, often rituximab plus bendamustine. At relapse, BTK-inhibitors, such as ibrutinib, are very active. CAR-T cell therapy is an approved option in US and UK.

What has been your experience treating patients with BioInvent's anti-FcyRIIB antibody, BI-1206?
First of all, I would say that BI-1206 is a relatively non-toxic treatment: this is important where patients are frail and where quality of life is very important. We have encountered some side effects, like infusion related reactions and elevation of liver enzymes, though have learned how to handle these with a premedication protocol. Overall I think the side effects are very manageable and limited in duration and there is no cumulative toxicity.

Then, we have seen interesting efficacy including long-term responses in patients with both FCL and MCL. Although so far there are still very few patients, the early data are encouraging and I am very much looking forward to seeing more.

How does BI-1206 work with rituximab?
Theoretically it enhances the efficacy of rituximab by blocking one of the resistance mechanisms of rituximab resistance. We have not experienced any clash between BI-1206 and rituximab yet. The idea is that these two treatments are synergistic.

What makes it unique?
There are no other antibodies against the same target, so it is a unique mechanism of action. It is targeting a specific Fc receptor in terms of inhibition, which is quite similar to stimulatory Fc receptors. It is difficult to develop antibodies that are specific to the inhibitory receptor rather than the stimulatory receptor, and this goes some way to explaining why BI-1206 is special.

How would you characterize the clinical results with BI-1206 so far?
Overall, we are seeing encouraging signs of response in a heavily pre-treated population.

We have seen responses with long duration. The best example is a patient with FCL who has a complete response that has been ongoing for two years: that doesn't mean 'a cure' but that all their signs of cancer have disappeared in response to treatment. This was achieved at quite a low dose of BI-1206, one that we were not sure was going to be effective. Another patient, with MCL with high risk features, had a partial response and although this was not long lasting, it is still very encouraging.

I have personal experience with these patients and it is unlikely they would have responded so well to rituximab alone, so we think this is the impact of BI-1206. Of course, we must be cautious that this is quite early stage and so we cannot be sure, but it is exciting nevertheless.

If successful in development, how would you expect BI-1206 to fit into the treatment paradigm for FCL and MCL?
BI-1206 is being developed as a potential treatment option for patients after having failed the current standard of care. With its favorable toxicity profile, if we continue to see encouraging response rates, I see potential to move this up into earlier lines of treatment.

I think it would be interesting to combine BI-1206 with rituximab and also to use it as a single agent for the treatment of FCL, in both first and second line. Possibly the next step would be to try BI-1206 as second line treatment for patients who have previously received rituximab as a single agent. The ultimate step would be to try BI-1206 as first line treatment as a single agent versus rituximab.

For MCL, single agent rituximab is not very effective, except when used as a maintenance treatment after chemotherapy. So for MCL, BI-1206 could be used with rituximab as maintenance treatment but it is also an option for elderly patients with MCL in combination with standard therapy. There are very few options for patients with MCL who fail BTK inhibitors and there are some preclinical data that BI-1206 could be effective also in this situation.

SCIENTIFIC ADVISORY BOARD

Leading experts in cancer research

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

Mark Cragg, Chairman, professor of Experimental Cancer Research within Medicine at the University of Southampton and is director of the i4PhD Cancer Immunology Pathway. Dr. Cragg's group is interested in two main areas – anti-bodies and small molecule inhibitors with the aim of understanding how these therapeutics function to delete tumor cells and how they might be augmented.

Stephen Beers, Professor of Immunology and Immunotherapy in the Faculty of Medicine at the University of Southampton. His research group focusses on the mechanisms of action of monoclonal antibodies in the treatment of cancer and the impact of the tumor microenvironment on efficacy.

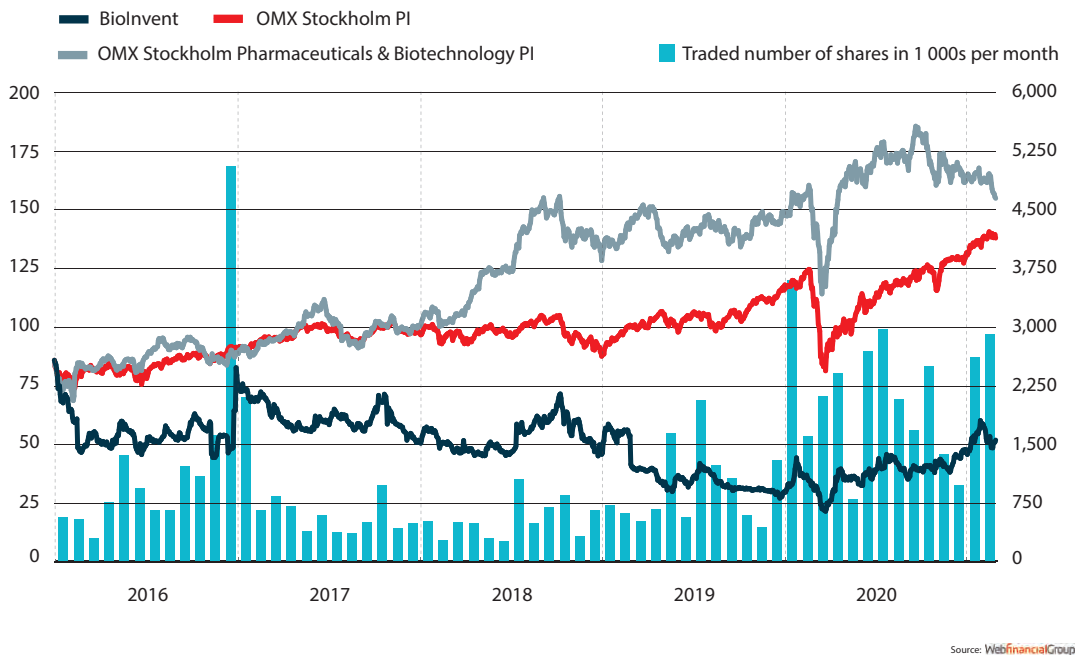
Falk Nimmerjahn, Professor in experimental immunology and immune therapy at the Friedrich-Alexander University Erlangen-Nürnberg. Leading scientist within Fc:FcgR biology and its impact on the therapeutic efficacy and tolerability of antibodies.

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.

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

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.

The BioInvent share



Price trend and trading volume

In 2020, the share price increased 53 percent, from SEK 30.01 (adjusted for the reverse share split) to SEK 45,90. In 2020 the OMX Stockholm_PI increased 13 percent and OMX Stockholm Pharmaceuticals & Biotechnology_PI increased 12 percent. The highest price paid in 2020 was SEK 49.00 and the lowest price was SEK 20.39. BioInvent's market capitalization totaled SEK 1,807 million at the end of 2020.

Average trading volume per trading day was SEK 3.8 million (1.6). Average number of trades per trading day were 442 (210).

Largest shareholders, December 31, 2020

	No. of shares	Percentage of capital and votes
Van Herk Investments B.V.	5,174,492	13.1
Omega Funds, LP	4,148,762	10.5
HBM Healthcare Investments Ltd	2,318,840	5.9
Fjärde AP-fonden	2,239,130	5.7
TSGH (Compagnie Merieux Alliance)	1,515.876	3.8
Avanza Pension	1,461,338	3.7
Swedbank Robur Medica	1,449,275	3.7
CASI Pharmaceuticals, Inc	1,175,763	3.0
Goldman Sachs International Ltd, W8IMY	946,279	2.4
Pfizer	878,943	2.2
Other shareholders	18,067,398	45.9
Total	**39,376,096**	**100.0**

Ownership structure

In 2020, the number of shareholders increased 13 percent, from 10,109 to 11,464. Foreign owners held 52 percent (38) of the share capital and votes. The ten largest shareholders owned 54 percent (47) of the shares.

Share capital

The BioInvent share has been listed on Nasdaq Stockholm (BINV) since 2001. The Company's share capital consists of 58,471,096 shares at the time this annual report was presented (April 2021).

If fully exercised, Option Programme 2019/2025 will represent a dilution equivalent to around 0.3 percent of the shares in the Company. The Company's option programmes are described on page 49.

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 2020 financial year. The Company will continue to focus on research and development of new products. Available financial resources will be used to finance these projects. The Board of Directors therefore do not recommend that any dividend be paid for the next few years.

Distribution of financial reports

Annual reports will be sent to shareholders upon request and may be ordered at the address BioInvent international AB, 223 62 Lund or by phone +46 (0)46-286 85 50. The annual report is published in Swedish and English.

Analysts covering BioInvent

Dan Akschuti – Pareto Securities, Stockholm
Niklas Elmhammer – Redeye, Stockholm
Sebastiaan van der Schoot – Kempen, Amsterdam

Upcoming financial information

Interim reports: April 28, August 26, October 28, 2021.

Increase/decrease in no. of shares

Year	Transaction	Increase/decrease in share capital, SEK	Increase/decrease in no. of shares	Share capital, SEK	Share capital, no. of shares	Ratio value
1996	BioInvent International AB was founded[1]			100,000	10,000	10.00
1997	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
1998	Share split 1:10		867,834	964,260	964,260	1.00
1998	New share issue[2]	181,000	181,000	1,145,260	1,145,260	1.00
1999	New share issue[3]	108,527	108,527	1,253,787	1,253,787	1.00
2000	New share issue[4]	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[5]	2,250,000	4,500,000	14,072,152.5	28,144,305	0.50
2002	New share issue[6]	665,625.5	1,331,251	14,737,778	29,475,556	0.50
2005	New share issue[7]	8,842,666.5	17,685,333	23,580,444.5	47,160,889	0.50
2007	New share issue[8]	4,250,000	8,500,000	27,830,444.5	55,660,889	0.50
2010	New share issue[9]	2,717,400	5,434,800	30,547,844.5	61,095,689	0.50
2011	New share issue[10]	3,054,784	6,109,568	33,602,628.5	67,205,257	0.50
2012	New share issue[11]	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[12]	887,109	11,088,867	6,801,172	85,014,649	0.08
2014	New share issue[13]	2,222,032	27,775,401	9,023,204	112,790,050	0.08
2015	New share issue[14]	4,010,313	50,128,911	13,033,517	162,918,961	0.08
2016	New share issue[15]	9,584,213	119,802,658	22,617,730	282,721,619	0.08
2016	New share issue[16]	1,757,888	21,973,594	24,375,617	304,695,213	0.08
2018	New share issue[17]	3,656,342	45,704,281	28,031,960	350,399,494	0.08
2018	Warrants exercised[18]	32,038	400,478	28,063,998	350,799,972	0.08
2019	New share issue[19]	12,023,999	150,299,988	40,087,997	501,099,960	0.08
2019	Warrants exercised[20]	53,595	669,936	40,141,592	501,769,896	0.08
2020	New share issues[21]	36,258,976	453,237,200	76,400,568	955,007,096	0.08
2020	New share issues[22]	2,351,625	29,395,311	78,752,193	984,402,407	0.08
2020	Reverse share split	-1	-945,026,311	78,752,192	39,376,096	2,00

1) BioInvent International AB was established by its managers, Stiftelsen Industrifonden, Pronova a.s. and Aragon Fondkommission.
2) 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.
3) 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.
4) 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.
5) 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.
7) 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.
8) In July 2007 the Company carried out a directed issue. The issue price was SEK 14.75 and SEK 120.0 million was raised after deductions of issue costs.
9) In February 2010 the Company carried out a directed issue. The issue price was SEK 27.60 and SEK 144.4 million was raised after deductions of issue costs.
10) In June 2011 the Company carried out a directed issue. The issue price was SEK 22.30 and SEK 128.3 million was raised after deductions of issue costs.
11) In April 2012 the Company carried out a rights issue. The issue price was SEK 15.60 and SEK 96.5 million was raised after deductions of issue costs.
12) In August 2013 the Company carried out a rights issue. The issue price was SEK 2.10 and SEK 19,4 million was raised after deductions of issue costs.
13) In April 2014 the Company carried out a rights issue and a directed issue. The issue price was SEK 2.30 and SEK 57.3 million was raised after deductions of issue costs.
14) In May 2015 the Company carried out a rights issue and a directed issue. The issue price was SEK 1.55 and SEK 67.6 million was raised after deductions of issue costs.
15) In April 2016 the Company carried out a rights issue and a directed issue. The issue price was SEK 1.95 and SEK 209.5 million was raised after deductions of issue costs.
16) In December 2016 the Company carried out a directed issue. The issue price was SEK 2.56 and SEK 53.4 million was raised after deductions of issue costs.
17) In April 2018 the Company carried out a directed issue. The issue price was SEK 1.85 and SEK 80.3 million was raised after deductions of issue costs.
18) Warrants exercised in Board Share Program 2017.
19) In April 2019 the Company carried out a rights issue and directed issue. The issue price was SEK 1.60 and SEK 220.0 million was raised after deductions of issue costs.
20) Warrants exercised in Board Share Program 2018.
21) During the summer 2020 the Company carried out a directed issue and a repair rights issue. The issue price was SEK 1.38 and SEK 589.4 million was raised after deductions of issue costs.
22) In December 2020 the Company carried out a directed issue. The issue price was SEK 2.09 and SEK 61.1 million was raised after deductions of issue costs.

Five-year review

INCOME STATEMENT, SEK MILLION	2020	2019	2018	2017	2016
Net sales	147.4	93.7	38.5	45.0	71.3
Research and development costs	-191.4	-207.9	-140.2	-109.7	-99.5
Sales and administrative costs	-32.2	-29.1	-28.0	-39.3	-35.7
Other operating revenue and costs	0.7	5.4	6.4	3.3	1.0
	-222.8	-231.6	-161.8	-145.6	-134.1
Operating loss	**-75.5**	**-137.8**	**-123.2**	**-100.6**	**-62.9**
Net financial items	-0.9	-0.8	0.1	0.1	0.3
Loss before tax	**-76.3**	**-138.6**	**-123.2**	**-100.5**	**-62.6**
Tax	-	–	–	–	–
Loss for the year	**-76.3**	**-138.6**	**-123.2**	**-100.5**	**-62.6**

BALANCE SHEET, SEK MILLION	2020	2019	2018	2017	2016
Intangible fixed assets	0.0	0.0	0.0	0.0	0.0
Tangible fixed assets	29.6	33.0	18.0	19.2	5.6
Financial fixed assets	–	–	–	–	–
Inventories	4.1	5.4	3.0	2.4	1.9
Current receivables	39.7	33.8	30.6	14.7	42.6
Liquid funds	729.3	154.0	68.9	133.8	226.1
Total assets	**802.6**	**226.1**	**120.4**	**170.0**	**276.3**
Shareholders' equity	743.5	169.4	87.6	130.2	230.4
Non-interest-bearing liabilities	47.5	41.1	32.8	39.8	45.9
Interest-bearing liabilities	11.6	15.5	–	–	–
Total shareholders' equity and liabilities	**802.6**	**226.1**	**120.4**	**170.0**	**276.3**

CASH FLOW, SEK MILLION	2020	2019	2018	2017	2016
Operating loss	-75.5	-137.8	-123.2	-100.6	-62.9
Adjustments for depreciation, interest and other items	11.7	11.6	5.4	3.3	1.1
Changes in working capital	1.2	0.8	-23.6	21.5	-10.3
Cash flow from current operations	**-62.6**	**-125.4**	**-141.4**	**-75.9**	**-72.0**
Cash flow from investment activities	-6.7	-3.8	-3.8	-16.5	-5.3
Cash flow from current operations and investment activities	**-69.3**	**-129.3**	**-145.2**	**-92.4**	**-77.4**
Cash flow from financing activities	644.6	214.4	80.3	–	263.5
Increase/decrease in liquid funds	**575.3**	**85.1**	**-64.9**	**-92.4**	**186.1**

KEY FINANCIAL RATIOS	2020	2019	2018	2017	2016
Equity/assets ratio, %	92.6	74.9	72.8	76.6	83.4
Average number of employees	72	68	59	53	46

DATA PER SHARE	2020	2019	2018	2017	2016
Earnings per share, SEK					
Before dilution	-2.66	-7.64	-9.07	-8.25	-6.31
After full dilution	-2.66[1)]	-7.64[1)]	-9.07[1)]	-8.25[1)]	-6.31[1)]
Average no. of shares					
Before dilution (thousands)	28,716	18,141	13,579	12,188	9,918
After full dilution (thousands)	28,716[2)]	18,141[2)]	13,579[2)]	12,188[2)]	9,918[2)]

1) There is no dilution of earnings per share because the earnings per share before dilution was negative.
2) No dilution is present since the subscription price exceeds the average share price.

The number of ordinary shares outstanding before the reverse share split has been adjusted for the proportionate change in the number of shares outstanding as if the reverse split had occurred on January 1, 2016.

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[3)]

Equity/assets ratio
Shareholders' equity as a percentage of the balance sheet total.

[3)] Definition of alternative financial ratio not defined by IFRS.

The Board and Auditors

Leonard Kruimer

Chairman of the Board
Chairman of the Board since 2018. Chairman of the Remuneration Committee and member of the Audit Committee.
MBA, US.CPA. He served as a Board Member in BioInvent between 2016–2017. He was CFO and member of the board of Crucell NV from 1998 to 2011 and has held senior executive positions at Royal Boskalis N.V., GE Capital and Continental Can Company. Born 1958.

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

Shareholding
14,288

Vessela Alexieva

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

Other board appointments
-

Shareholding
932 (own and affiliated holdings)

Dharminder Chahal

Member of the Board since 2017. Chairman of the Audit Committee.
M.Sc. in Aerospace Engineering and M.Sc. in Business Economics. CEO of SkylineDx and managing director of Exponential B.V. Extensive board experience in life science companies, with previous board assignments in for example Agendia, deVGen, Innate Pharma, Isobionics and Octoplus. Board member of BioInvent during 2013–2016. Currently Fund Manager for Swanbridge Capital. Born 1976.

Other board appointments
Board member of Immunicum, Medis Medical Imaging, Sensara, VitalneXt, Ceradis BV and Anemones Hospitality and Hotels.

Shareholding
290,000

Anette Mårtensson

Employee representative
Member of the Board since 2020.
Master's degree in protein chemistry. Analytical Engineer. Previously laboratory engineer at Innovagen AB and laboratory assistant at Lund University. Born 1982.

Other board appointments
-

Shareholding
248

Kristoffer Bissessar

Member of the Board since 2020. Chairman of the Audit Committee.
Broad experience from the financial industry, operative in banking and finance between 1989–2012, with experience from asset management, institutional equity sales and investment banking. Previously held senior positions at Svenska Handelsbanken AB, Deutsche Bank AG and Nordea Bank AB and served as board member of the Swedish Securities Dealers Association. Board member of BioInvent during 2018-2019. Born 1968.

Other board appointments
CEO and board member of Evolvere Partners AB

Shareholding
14,000

Thomas Hecht

Member of the Board since 2020.
Doctor of Medicine. Previously experience as Vice President Marketing at Amgen Europe, and has held various positions of increasing responsibility in clinical development, medical affairs and marketing at Amgen between 1989 and 2002. Prior to joining the biopharmaceutical industry, Thomas Hecht was certified in internal medicine and served as Co-Head of the Program for Bone Marrow Transplantation at the University of Freiburg, Germany. Currently Managing Partner at HHC Healthcare Consulting. Born 1951.

Other board appointments
Chairman of the board of Orion Biotechnology Ltd., Affimed N.V., and Aelix Therapeutics S.L. and board member of Kuur Therapeutics Ldt.

Shareholding
-

Bernd Seizinger

Member of the Board since 2018. Chairman of the Science Committee, and member of the Remuneration Committee.
Doctor of Medicine and Doctor of Neurobiology. Previous experience as CEO and President of GPC Biotech, Executive Vice President and Chief Scientific Officer at Genome Therapeutics Corporation and Vice President of Oncology Drug Discovery and, in parallel, Vice President of Corporate and Academic Alliances, both at Bristol-Myers Squibb. Senior faculty positions at Harvard Medical School, Massachusetts General Hospital, and Princeton University. Born 1956.

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

Shareholding
4,298

Auditors KPMG AB

Auditor in charge
Linda Bengtsson, Authorized Public Accountant.
Born 1974.
Auditor for BioInvent International AB since 2020.

Senior management

Martin Welschof

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

Shareholding
10,000

Options
Conditional employee options
517,111

Björn Frendéus

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

Shareholding
23,089 (own and affiliated holdings)

Options
Conditional employee options
221,619

Stefan Ericsson

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

Shareholding
8,000

Options
Conditional employee options
115,685

Andres McAllister

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

Shareholding
3,009

Options
Conditional employee options
257,592

Kristoffer Rudenholm Hansson

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

Shareholding
22,303 (whereof 7,177 in endowment insurance)

Options
Conditional employee options
117,753

Information on the holdings of shares and other financial instruments in BioInvent by Directors and Group management refers to conditions as of April 8, 2021, 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 January 1–December 31, 2020. The Company is registered in Sweden and is located in the Lund municipality. The visiting address is Ideongatan 1, Lund and the postal address is 223 70 Lund. The descriptions below of the status of BioInvent's projects are current at the time this annual report was presented.

Clinical projects

BI-1206 in non-Hodgkin lymphoma

In January 2021, BioInvent announced that Phase I/IIa data suggest that BI-1206 restores activity of rituximab in relapsed non-Hodgkin's lymphoma patients. Of the 9 patients who completed the induction cycle in the first 4 cohorts, 6 patients showed either complete or partial responses, several of which are still ongoing. Two patients (at dose levels of 30 mg and 70 mg) achieved a complete response, which continued to be sustained 12 and 24 months later. Another patient who had a blastoid form of MCL had achieved a partial response, and a complete depletion of peripheral tumor cells.

In October 2020, BioInvent licensed the anti-FcγRIIB antibody BI-1206 to CASI Pharmaceuticals for Greater China region. The collaboration accelerates and expands BioInvent's global development plans for BI-1206. Under the terms of the agreement, BioInvent and CASI will develop BI-1206 in both hematological and solid cancers, with CASI responsible for commercialization in China and associated markets. BioInvent received $12 million upfront in combination of cash and equity investment and eligible to receive up to $83 million in milestone payments, plus tiered royalties.

In January 2021, BioInvent announced that it had restructured a clinical development agreement with CRUK for BI-1206. In exchange for a one-time payment of £2.5 million, the revised deal simplifies and reduces BioInvent's obligations to CRUK, which provides BioInvent with more flexibility to carry out development and partnering activities with BI-1206. The restructured agreement with CRUK releases BioInvent from obligations to pay development or commercial milestones to CRUK on BI-1206 and reduces the royalties due on net sales to low single digit levels.

Background

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

The Phase I/IIa study consists of two parts: i) Phase I, with dose escalation cohorts using a 3+3 dose-escalation design and selection of the recommended Phase IIa dose (RP2D); and ii) Phase IIa, an expansion cohort at the RP2D, enriched with patients with mantle cell lymphoma (MCL). Subjects in each phase receive 1 cycle (4 doses) of induction therapy with BI-1206 in combination with rituximab. Subjects who show clinical benefit at week 6 continue onto maintenance therapy and receive BI-1206 and rituximab once every 8 weeks for up to 6 maintenance cycles, or up to 1 year from first dose of BI-1206.

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

These data further corroborated the important role of FcγRIIB in establishing resistance to rituximab, and indicate the ability of BI-1206 to overcome this resistance. Together with a high expression in mantle cell lymphoma patient cells, these data indicate the high potential of BI-1206 to address a significant unmet need in the treatment of MCL and other B-cell malignancies such as follicular lymphoma.

BI-1206 in combination with pembrolizumab in solid tumors

In July 2019 BioInvent received authorization from the FDA to proceed with a Phase I/IIa clinical trial of BI-1206 in combination with Keytruda® (pembrolizumab) for the treatment of solid tumors. The first patient was enrolled in June 2020.

Background

The objective of this trial is to explore the safety and tolerability profile of the combination of BI-1206 with Keytruda®, to characterize the pharmacokinetic/pharmacodynamic (PK/PD) profile and to determine the recommended dose of BI-1206 when combined with Keytruda®. It will be conducted in several sites across the US and Europe and will assess potential signs of antitumoral activity, as well as exploring the expression of potential immunological markers that might be associated, and eventually predict clinical responses.

The Phase I/IIa trial is divided into part A, a dose escalation of BI-1206 in combination with the standard dose of Keytruda®, and part B, which will explore the activity of the combination treatment in patients with advanced lung cancer, melanoma and other types of malignancies. Patients will be refractory to or have progressed on previous treatments with anti-PD-1/PD-L1 targeting agents. Early results from the Phase I open label study is expected in H2 2021.

In December 2019 BioInvent entered into a clinical trial collaboration and supply agreement with Merck, to evaluate the combination of BioInvent's BI-1206 and Merck's anti-PD-1 therapy, Keytruda® in a Phase I/IIa clinical trial for patients with solid tumors. The agreement helps BioInvent to expand BI-1206 clinical development to solid tumors in combination with one of the most successful immuno-oncology drugs.

The program is based on BioInvent's preclinical data demonstrating the ability of BI-1206 to address an important mechanism of resistance to PD-1 inhibition, providing a way to enhance antitumor immune responses in patients with solid tumors. The Phase I/IIa clinical trial will evaluate the drug combination in patients with advanced solid tumors, who have been previously treated with anti-PD-1 or anti-PD-L1 antibodies, and is a multicenter, dose-finding, consecutive-cohort, open-label trial. The Phase I/IIa trial is planned to be carried out in the U.S. and the EU.

BI-1808 and BI-1910 (anti-TNFR2 antibodies) for the treatment of solid tumors and CTCL

Two different types of TNFR2 targeting antibodies are being developed by BioInvent – BI-1808 in clinical development (a ligand blocker), and BI-1910 (an agonist) in preclinical development.

BioInvent announced, in December 2020, regulatory authority approval of a clinical trial application (CTA) in Denmark for a Phase I/IIa, first-in-human study of BI-1808 for the treatment of solid tumors and CTCL. The first patient was enrolled in January 2021.

Background
BioInvent has identified tumor necrosis factor receptor 2 (TNFR2), a member of the so-called TNFR superfamily (TNFRS) as a target within the Treg program. TNFR2 is particularly upregulated on tumor-associated regulatory T cells (Tregs) and has been shown to be important for their expansion and survival. As a part of its Treg program, BioInvent identified and characterized a wide panel of TNFR2-specific antibodies, generated from its proprietary n-CoDeR® library and unique F.I.R.S.T™ discovery tool, of which BI-1808 and BI-1910 are the lead development candidates.

The Phase I stage is divided into two parts. Part A is a dose escalation study of BI-1808 to assess safety, tolerability, pharmacokinetics/pharmacodynamics, and to determine the recommended dose as a single agent for Phase II trials. Part B will explore the safety, tolerability and recommended dose of BI-1808 in combination with Keytruda®. The Phase IIa stage will consist of expansion cohorts to assess signs of efficacy of BI-1808 as single agent, and in combination with Keytruda® in lung cancer and ovarian cancer patients. Another cohort will explore the activity as single agent in CTCL. The trial will be conducted at several sites across Europe and the U.S. and is expected to enroll approximately 120 patients.

Exciting preclinical data was presented at AACR Annual Meeting II in June 2020. In vivo studies show that both ligand-blocking (BI-1808 surrogate) and agonistic (BI-1910 surrogate) antibodies regress large established tumors and synergize with anti-PD-1 therapy. Further mode-of-action dissection demonstrate that while the ligand-blocking antibody depleted intratumoral Tregs, the agonist increased intratumoral CD8+ T effector cells. Both antibodies expanded tumor-specific CD8+ T cells and induced long-lasting T cell memory.

New translational data was presented on BI-1808 at the SITC 35th Annual Meeting in November 2020. The data showed that BI-1808 had an expected pharmacokinetic profile and was well tolerated in a toxicology study in doses up to 200 mg/kg.

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

BioInvent and Transgene announced in December 2020 that regulatory approval had been received in Belgium for a clinical trial application for a Phase I/IIa study of BT-001 in solid tumors.

Promising findings was presented both at AACR Annual Meeting II in June 2020 and at the SITC 35th Annual Meeting in November 2020. Cure rates exceeding 70 percent were seen in multiple mouse models, demonstrating the powerful therapeutic effect of BT-001 when used as a single agent, providing a solid basis for BT-001's upcoming clinical development. BT-001 has been designed to combine the killing of cancer cells (oncolysis mediated by the virus), with the production of the anti-CTLA-4 antibody and GM-CSF directly in the tumor site to enhance the generation of an efficacious immune response against tumor cells. It was shown that while the anti-CTLA-4 antibody and GM-CSF accumulate in tumors, the systemic exposure is very low. It was shown that a strong tumor-specific response and long-lasting immune memory were developed by BT-001 surrogate treated mice, which prevented establishment of re-implanted tumor cells in mice that had been cured. These data indicate that BT-001 has the potential to make a significant difference in the treatment of solid tumors.

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

Transgene is contributing both engineering expertise, as well as its proprietary oncolytic virus (OV) platform Invir.IO™, designed to directly and selectively destroy cancer cells by intracellular replication of the virus in the cancer cell (oncolysis). Oncolysis induces an immune response against tumors, while the "weaponized" virus allows the expression of genes carried by the viral genome, here an immune modulatory anti-CTLA-4 antibody, which will further boost immune response against the tumor. BioInvent is providing its cancer biology and antibody expertise to the collaboration, as well as anti-CTLA-4 antibody sequences generated through its proprietary n-CoDeR®/F.I.R.S.T™ platforms.

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

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

Preclinical programs

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

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

In partnership with Pfizer Inc. since December 2016, BioInvent works to identify novel oncology targets and therapeutic antibodies that may either reverse the immunosuppressive activity of tumor-associated myeloid cells or reduce the number of tumor-associated myeloid cells in the tumor. In July 2020 BioInvent announced that the research term under its collaboration and license agreement with Pfizer had been further extended until the end of 2020.

In December 2020 BioInvent announced that Pfizer had selected antibodies directed at a previously selected target. The selection of these antibodies triggered a payment from Pfizer to BioInvent of $3 million.

Background
BioInvent announced in July 2019 selection of the first target and in December 2019 the second target discovered by BioInvent's proprietary F.I.R.S.T™ technology platform under the collaboration with Pfizer Inc. The selection of targets triggered two payments from Pfizer to BioInvent of $0.3 million.

BioInvent is eligible for potential future development milestones in excess of $100 million if one antibody is 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 for the period 2017-2020. Pfizer also made a $6 million equity investment in new shares of BioInvent when the agreement was signed.

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

Tregs can substantially inhibit various immune responses, enabling tumor cells to escape detection. BioInvent is utilizing its F.I.R.S.T™ platform to identify and characterize monoclonal

antibodies to cancer-associated Treg targets in a function-first, target-agnostic, manner. The company is also pursuing differentiated antibodies to known targets through novel mechanisms and pathways.

Personnel and organization

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

The research department works with BioInvent's technology platforms, F.I.R.S.T™ and n-CoDeR® and develops antibodies for the Company's preclinical projects. The research department further supports clinical development programs with important mechanism-of-action and translational data e.g. bioassays and biomarkers, new indications and combination data. The research activities are organized in a project-based, cross-functional 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 December 31, 2020 BioInvent had 72 (72) employees, 65 (66) of whom work in research and development. 92 percent of the Company's employees have university degrees, including 46 percent with PhDs.

Environment

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

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

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

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

Quality and regulatory approval

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

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

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

Revenue and result

Net sales amounted to SEK 147.4 million (93.7). Revenues for the period were mainly derived from upfront payment of $5 million in connection with licensing of BI-1206 to CASI Pharmaceuticals for the Greater China region, a $3 million milestone payment related to selection of antibodies under the collaboration with Pfizer, a €2 million milestone payment under the collaboration with Daiichi Sankyo related to the initiation of a Phase I clinical trial, and also revenues from production of antibodies for clinical studies and revenues from research funding.

Revenues for the corresponding period 2019 were mainly derived from production of antibodies for clinical studies, revenues from research funding and also two $0.3 million milestone payment from Pfizer Inc. in connection with selection of the first and second target discovered by BioInvent, a €0.75 million milestone payment received from Mitsubishi Tanabe Pharma Corporation in connection with enrollment of the first patient in a Phase II clinical trial and a $0.5 million milestone payment from XOMA Corporation related to the acceptance by FDA of an IND application.

The Company's total costs amounted to SEK 223.6 million (237.0). Operating costs are divided between external costs of SEK 144.0 million (158.7), personnel costs of SEK 67.6 million (66.7) and depreciation of SEK 12.0 million (11.6).

Research and development costs amounted to SEK 191.4 million (207.9). Sales and administrative costs amounted to SEK 32.2 million (29.1).

Loss after tax amounted to SEK -76.3 million (-138.6). The net financial items amounted to SEK -0.9 million (-0.8). Loss per share before and after dilution amounted to SEK -2.66 (-7,64). Loss per share in 2019 has been adjusted as if the reverse split in 2020 had been completed January 1, 2019.

Financial position and cash flow

In June and July 2020, BioInvent successfully completed a directed share issue of approximately SEK 487 million before transaction costs. Investors included new investors such as HBM Healthcare

Investments, Swedbank Robur Fonder and Invus as well as existing shareholders Van Herk Investments, Omega Funds, The Fourth Swedish National Pension Fund and Handelsbanken Healthcare Fund. In July 2020, BioInvent's Board of Directors resolved on a repair rights issue of a maximum of approximately SEK 139 million. It was completed in August and was heavily oversubscribed.

In October 2020, BioInvent licensed BI-1206 to CASI Pharmaceuticals for the Greater China region. Under the terms of the Agreement, as part of the upfront payment, CASI has made a $7 million investment (SEK 61.4 million) in 29,395,311 new shares in BioInvent at a subscription price of SEK 2.09 per share, which corresponds to 130 % of the average volume weighted price for the share during the ten trading days prior to October 27, 2020, and 14,697,655 new warrants (at no separate option premium), each warrant with a right to subscribe for an equal number of new shares in BioInvent within a period of five years and at a subscription price of SEK 3.14 per share (0.04 new shares for each warrant and at a subscription price SEK 78.50 after the reverse share split). The equity investment was approved at an EGM held on November 27, 2020.

The EGM held on November 27, 2020 approved the proposal on a reverse share split 1:25, a reduction of the share capital to adjust the share capital to the Company's operations (the reduction was registered by the Swedish Companies Registration Office on February 11, 2021), and an updated authorization for the Board to decide on a new issue of shares comprising 109,378,025 new shares (corresponding to 4,375,121 shares after the reverse share split).

On February 23, 2021, BioInvent successfully completed a directed share issue of approximately SEK 962 million before transaction costs. Investors in the directed share issue are a range of international and Swedish investors, including Redmile Group, LLC., Invus, HBM Healthcare Investments, The Fourth National Swedish Pension Fund, Swedbank Robur Fonder and Van Herk Investments. 2,834,399 new shares were issued based on the authorization granted by the EGM on November 27, 2020, and 16,260,601 new shares were issued after approval at an EGM held on March 23, 2021.

After the share issues and the reverse share split, the share capital consists of 58,471,096 shares.

As of December 31, 2020, the Group's liquid funds amounted to SEK 729.3 million (154.0). The cash flow from operating activities and investment activities amounted to SEK -69.3 million (-129.3).

The shareholders' equity amounted to SEK 743.5 million (169.4) at the end of the period. The Company's share capital was SEK 78.8 million. The equity/assets ratio at the end of the period was 93 (75) percent. Shareholders' equity per share amounted to SEK 18.88 (8.44). Shareholders' equity per share in 2019 has been adjusted as if the reverse split in 2020 had been completed January 1, 2019.

The five-year review is described on page 24.

Investments

Investments for the period in tangible fixed assets amounted to SEK 6.7 million (3.8).

Parent Company

The BioInvent Group consists of the Parent Company, BioInvent International AB, and the subsidiary BioInvent Finans AB. Net sales amounted to SEK 147.4 million (93.7). Loss after tax amounted to SEK -76.2 million (-138.4). The cash flow from operating activities and investment activities amounted to SEK -75.1 million (-134.9). All operations of the Group are conducted by the Parent Company. Except for financial leases, the Group's and the Parent Company's financial statements coincide in every material way.

The share

The BioInvent share has been listed on Nasdaq Stockholm (BINV) since 2001. The Company's share capital consists of 58,471,096 shares.

If fully exercised, Option Program 2019/2025 will represent a dilution equivalent to around 0.3 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 2020 authorized the Board of Directors to resolve on the issue of new shares, on one or several occasions during the period up to the next annual general meeting. The number of shares to be issued by virtue of the authorization shall not entail a dilution effect of more than 20 per cent of the registered share capital after completed issue. The Extraordinary General Meeting in BioInvent on November 27, 2020 resolved to authorize the Board of Directors to, on one or several occasions during the period up to the next Annual General Meeting, resolve on the issue of a maximum of 109,378,025 shares (corresponding to 4,375,121 shares after the reverse share split). The Annual General Meeting has not authorized the Board of Directors to take decisions on acquisition of shares by the Company.

Corporate governance report

Based on the Annual Accounts Act, chapter 6, § 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 significant revenue streams are generated for the Company from licensing or sales, and to assist international pharmaceutical companies in their drug development and thereby generate revenue that contributes to finance the Company's costs.

Risks and risk management

Pharmaceutical development

BioInvent is a clinical stage company that discovers and develops novel and first-in-class immuno-modulatory antibodies for cancer therapies, with four programs in clinical development.

Pharmaceutical development is generally associated with a very high risk, and since BioInvent's project portfolio is relatively limited and contains early phase projects, this applies to a great extent also to BioInvent. As BioInvent's project portfolio are developed, the Company's knowledge and experience in important areas will grow and a larger project portfolio could over time make the Company less dependent on the success of an individual project. Antibodies also have a beneficial risk profile and a larger percentage of projects in the antibody area reach the market today compared to traditional pharmaceuticals. The probability that a drug candidate will reach the market also increases as the project is advanced through the development

chain. Development of pharmaceuticals is thus capital demanding, and since only a small number of the pharmaceutical products which are subject to preclinical and clinical development will result in an approved and commercialized product, there is a risk that the research and development costs that are invested never result in an approved pharmaceutical.

BioInvent's development of pharmaceuticals is also associated with risks that include, for example, development work being delayed or more expensive in relation to established schedules or not funded at all. Further, some or all of the Company's product candidates at preclinical or clinical trials may prove to be ineffective, have side effects or in another way not meet the applicable requirements or receive the necessary market approvals, or prove to be difficult to license successfully or develop into commercially viable products.

Clinical trials and product responsibility

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

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

Partners and commercialization

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

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

Competition

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

Intellectual property protection

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

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

Compensation for pharmaceutical sales

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

Qualified personnel and key individuals

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

Additional financing requirements

BioInvent's overall objectives are to build a portfolio of clinical development projects within cancer where 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 53.

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 2020 Annual General Meeting adopted guidelines for remuneration to the CEO and other senior executives. There has been no deviations from these guidelines.

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

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

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

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

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

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

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

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

Senior executives shall be employed for an indefinite period of time. For the CEO, the termination pay and the severance pay may together not exceed an amount equivalent to 24 months fixed cash base salary and for other senior executives may the termination pay and the severance pay not exceed an amount equivalent to 12 months fixed cash base salary. Severance pay shall not be paid when termination is made by the senior executive. Senior executives may be reimbursed for non-compete undertakings after termination of the employment, however, only to the extent that severance pay is not paid for the corresponding period of time. Such remuneration shall intend to compensate the senior executive for the difference between the fixed cash base salary at the time of termination of the employment and the (lower) income obtained, or could be obtained, through a new employment, assignment or own business. The remuneration shall be paid during the time the

[1] The pensionable salary also includes variable cash salary as well as certain other remuneration.

non-compete undertaking applies, however not for more than 12 months following termination of employment.

Remuneration to board members and deputy board members is, according to law, resolved by the general meeting to the extent the remuneration is related to the board assignment. If a board member is employed by the company, the renumeration to such board member shall be paid in accordance with these guidelines. Board members employed by the company shall not receive additional remuneration for a board assignment in the company or in a group company. If a board member performs work for the company that is not board related, market-based remuneration, taking into account the nature of the work and the work effort, shall be paid. Such remuneration shall be resolved by the Board of Directors (or, if follows from the Swedish Companies Act, the general meeting). The Board of Directors' Remuneration Committee prepares and formulates proposals for the Board of Directors to resolve on remuneration for the CEO. The Board of Directors' Remuneration Committee prepares, in consultation with the CEO, and resolves on matters regarding remuneration to other senior executives. The assessment of whether the criteria for variable cash salary have been fulfilled shall be made by the Board of Directors and the Remuneration Committee, respectively, in a substantially non-discretionary way. The CEO and other members of the executive management do not participate in the Board of Directors' processing of and resolutions regarding remuneration related matters in so far as they are affected by such matters.

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

The Board of Directors shall have the right to derogate from these guidelines if justified by particular circumstances in individual cases and a derogation is necessary to serve the company's long-term interests, including its sustainability, or to ensure the company's financial viability. In such case, the Board of Directors shall in its decision sate in which part derogation from the guidelines have been made, the specific reasons that justify the derogation and also report any derogation and the reasons in the Board of Directors annual report on the Remuneration Committee´s evaluation of remuneration to senior management. The Board of Directors shall prepare a proposal for new guidelines when there is a need for changes in these guidelines, but no later than at the annual general meeting 2024.

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

Events after the end of the financial year

In January 2021, BioInvent announced that it had restructured a clinical development agreement with Cancer Research UK (CRUK) for BI-1206. In exchange for a one-time payment of £2.5 million, the revised deal simplifies and reduces Bioinvent's obligations to CRUK.

BioInvent announced in January 2021, enrollment of the first patient in a Phase I/IIa study of BI-1808.

In January 2021, BioInvent announced that An van Es-Johansson would resign as a director of the board effective as of February 15, 2021, due to personal reasons.

In January 2021, BioInvent announced that Phase I/IIa data suggest that BI-1206 restores activity of rituximab in relapsed non-Hodgkin's lymphoma patients. Responses in 6 out of 9 patients evaluated provide exciting evidence that BI-1206 has the potential to restore activity of rituximab in non-Hodgkin's lymphoma patients who have relapsed after treatment with rituximab. Two patients (30 mg and 70 mg dose) achieved a complete response which continued to be sustained 12 and 24 months later.

On February 23, 2021, BioInvent successfully completed a directed share issue of approximately SEK 962 million before transaction costs. Investors in the directed share issue are a range of international and Swedish investors, including Redmile Group, LLC., Invus, HBM Healthcare Investments, The Fourth National Swedish Pension Fund, Swedbank Robur Fonder and Van Herk Investments. 2,834,399 new shares were issued based on the authorization granted by the EGM on November 27, 2020, and the issue of 16,260,601 new shares were issued after approval at an EGM held on March 23, 2021.

BioInvent announced in March 2021, enrollment of the first patient in a Phase I/IIa study of BT-001.

In March 2021, BioInvent announced that proof-of-concept data on the anti-FcyRIIB antibody BI-1607 should be presented at the AACR Annual Meeting 2021.

In early April 2021, BioInvent announced an IND approval from the FDA regarding the Phase I/IIa clinical trial of the anti-TNFR2 antibody BI-1808 as single agent and in combination with pembrolizumab in solid tumors and CTCL.

Proposed appropriation of profits

At the disposal of the Annual General Meeting: Share premium reserve of SEK 713,690,799, retained earnings of SEK -41,000 and loss for the year of SEK -76,249,566. The Board of Directors propose that profits at the disposal of SEK 637,400,233 is carried forward. Thus, it is proposed that no dividend be given for the financial year 2020.

Consolidated statement of comprehensive income for the Group

SEK thousand	Note	2020	2019
Net sales	3	147,372	93,740
Operating costs	4–8		
Research and development costs		-191,421	-207,896
Sales and administrative costs		-32,155	-29,094
Other operating revenue	9	1,862	6,519
Other operating costs	9	-1,132	-1,117
		-222,846	-231,588
Operating profit/loss		**-75,474**	**-137,848**
Financial income	10	625	186
Financial expenses	11	-1,484	-971
Net financial items		**-859**	**-785**
Profit/loss before tax		**-76,333**	**-138,633**
Tax	12	-	-
Profit/loss for the year		**-76,333**	**-138,633**
Other comprehensive income			
Items that have been or may be reclassified subsequently to profit or loss		-	-
Comprehensive income for the year		**-76,333**	**-138,633**
Other comprehensive income for the year attributable to the parent company's shareholders		-76,333	-138,633
Earnings per share, SEK	13		
Before dilution		-2.66	-7.64
After dilution		-2.66	-7.64

Consolidated statement of financial position for the Group

SEK thousand	Note	2020	2019
ASSETS			
Acquired intangible fixed assets	14	0	0
Right of use assets	22	12,834	16,842
Equipment	15	16,182	14,823
Investments in rented premises	15	580	1,340
Total fixed assets		**29,596**	**33,005**
Inventories		4,079	5,380
Accounts receivable	21	29,920	12,708
Other receivables	21	5,545	17,145
Prepaid expenses and accrued income	17	4,230	3,898
Liquid funds	21	729,270	153,975
Total current assets		**773,044**	**193,106**
Total assets		**802,640**	**226,111**

SEK thousand	Note	2020	2019
SHAREHOLDERS' EQUITY	19		
Share capital		78,752	40,142
Other allocated capital		2,482,063	1,870,236
Reserves		1	1
Accumulated loss		-1,817,317	-1,740,943
Total shareholders' equity		**743,499**	**169,436**
Shareholder's equity pertaining to the Parent Company's shareholders		743,499	169,436
LIABILITIES			
Lease liabilities	22	5,632	9,472
Total long term liabilities		**5,632**	**9,472**
Lease liabilities	22	5,972	6,057
Accounts payable	21	16,913	14,361
Other liabilities	21	8,016	9,536
Accrued expenses and deferred income	20	22,608	17,249
Total short term liabilities		**53,509**	**47,203**
Total shareholders' equity and liabilities		**802,640**	**226,111**

Consolidated statement of cash flows for the Group

SEK thousand	2020	2019
Current operations		
Operating profit/loss	-75,474	-137,848
Depreciation	12,004	11,612
Adjustments for other non-cash items	-41	379
Interest received	28	65
Interest paid	-335	-479
Cash flow from current operations before changes in working capital	**-63,818**	**-126,271**
Changes in working capital		
Changes in inventories	1,301	-2,430
Changes in current receivables	-5,944	-3,185
Changes in short term liabilities	5,839	6,459
	1,196	**844**
Cash flow from current operations	**-62,622**	**-125,427**
Investment activities		
Acquisition of tangible fixed assets	-6,700	-3,839
Cash flow from investment activities	**-6,700**	**-3,839**
Cash flow from current operations and investment activities	**-69,322**	**-129,266**
Financing activities		
Directed share issues and rights issue	589,383	
Directed share issue	61,054	
Directed share issue, Board Share Program 2018		54
Rights issue and directed share issue		220,015
Amortization of lease liability	-5,820	-5,679
Cash flow from financing activities	**644,617**	**214,390**
Change in liquid funds	**575,295**	**85,124**
Opening liquid funds	153,975	68,851
Liquid funds at year-end	**729,270**	**153,975**
Liquid funds, specification:		
Current investments	-	-
Cash and bank	729,270	153,975
	729,270	**153,975**

Statement of changes in equity for the Group

SEK thousand	Share-capital	Other allocated capital	Reserves	Accumulated loss	Total
Shareholders' equity December 31, 2018	**28,064**	**1,662,245**	**1**	**-1,602,689**	**87,621**
Comprehensive income for the year					
Profit/loss for the year				-138,633	-138,633
Comprehensive other income for the year			-		-
Total comprehensive income for the year			-	**-138,633**	**-138,633**
Total, excluding transactions with equity holders of the Company	**28,064**	**1,662,245**	**1**	**-1,741,322**	**-51,012**
Transactions with equity holders of the Company					
Effect of employee incentive programs				379	379
Rights issue and directed share issue	12,024	207,991			220,015
Directed new share issue, Board Share Program 2018	54				54
Shareholders' equity December 31, 2019	**40,142**	**1,870,236**	**1**	**-1,740,943**	**169,436**
Comprehensive income for the year					
Profit/loss for the year				-76,333	-76,333
Comprehensive other income for the year			-		-
Total comprehensive income for the year			**-**	**-76,333**	**-76,333**
Total, excluding transactions with equity holders of the Company	**40,142**	**1,870,236**	**1**	**-1,817,276**	**93,103**
Transactions with equity holders of the Company					
Effect of employee incentive program				-41	-41
Directed share issues and rights issue	36,259	553,124			589,383
Directed share issue	2,351	58,703			61,054
Shareholders' equity December 31, 2020	**78,752**	**2,482,063**	**1**	**-1,817,317**	**743,499**

The share capital as of December 31, 2020 consists of 39,376,096 shares and the share's ratio value was 2.00. The directed share issues were completed in July 2020 and the repair rights issue was completed in August 2020. These amounted to in total approximately SEK 625.5 million before issue expenses and approximately SEK 589.4 million after issue expenses. The directed new share issue carried out in December 2020 raised approximately SEK 61.4 million before issue expenses and approximately SEK 61.1 million after issue expenses.

Consolidated income statement for the Parent Company

SEK thousand	Note	2020	2019
Net sales	3	147,372	93,740
Operating costs	4–8		
Research and development costs		-191,649	-208,124
Sales and administrative costs		-32,175	-29,114
Other operating revenues	9	1,862	6,519
Other operating costs	9	-1,132	-1,117
		-223,094	-231,836
Operating profit/loss		**-75,722**	**-138,096**
Interest income and similar items	10	625	186
Interest costs and similar items	11	-1,153	-498
Profit/loss after financial items		**-76,250**	**-138,408**
Tax	12	-	-
Profit/loss for the year		**-76,250**	**-138,408**
Other comprehensive income		-	-
Comprehensive income for the year		**-76,250**	**-138,408**

Consolidated balance sheet for the Parent Company

SEK thousand	Note	2020	2019
ASSETS			
Fixed assets			
Intangible fixed assets			
Acquired intangible fixed assets	14	0	0
Tangible fixed assets			
Equipment	15	16,182	14,823
Investments in rented premises	15	580	1,340
		16,762	16,163
Financial fixed assets			
Shares in subsidiaries	16	687	687
		687	687
Total fixed assets		**17,449**	**16,850**
Current assets			
Inventories		4,079	5,380
Current receivables			
Accounts receivable		29,920	12,708
Other receivables		5,545	17,145
Prepaid expenses and accrued income	17	5,768	5,436
		41,233	35,289
Liquid funds			
Current investments		-	-
Cash and bank		729,270	153,975
		729,270	153,975
Total current assets		**774,582**	**194,644**
Total assets		**792,031**	**211,494**

SEK thousand	Note	2020	2019
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Restricted equity			
Share capital		78,752	40,142
Statutory reserve		27,693	27,693
		106,445	67,835
Non-restricted equity			
Share premium reserve		713,691	239,893
Retained earnings		-41	379
Profit/loss for the year		-76,250	-138,408
		637,400	101,864
Total shareholders' equity		**743,845**	**169,699**
Short term liabilities			
Accounts payable		16,913	14,361
Liabilities to subsidiaries		687	687
Other liabilities		7,978	9,498
Accrued expenses and deferred income	20	22,608	17,249
Total short term liabilities		**48,186**	**41,795**
Total shareholders' equity and liabilities		**792,031**	**211,494**

Consolidated statement of cash flows for the Parent Company

SEK thousand	2020	2019
Current operations		
Operating profit/loss	-75,722	-138,096
Depreciation	6,101	5,709
Adjustments for other non-cash items	-41	379
Interest received	28	65
Interest paid	-4	-6
Cash flow from current operations before changes in working capital	**-69,638**	**-131,949**
Changes in working capital		
Changes in inventories	1,301	-2,430
Changes in current receivables	-5,944	-4,723
Changes in short term liabilities	5,839	7,996
	1,196	**843**
Cash flow from current operations	**-68,442**	**-131,106**
Investment activities		
Acquisition of tangible fixed assets	-6,700	-3,839
Cash flow from investment activities	**-6,700**	**-3,839**
Cash flow from current operations and investment activities	**-75,142**	**-134,945**
Financing activities		
Directed share issues and rights issue	589,383	
Directed share issue	61,054	
Directed share issue, Board Share Program 2018		54
Rights issue and directed share issue		220,015
Cash flow from financing activities	**650,437**	**220,069**
Change in liquid funds	**575,295**	**85,124**
Opening liquid funds	153,975	68,851
Liquid funds at year-end	**729,270**	**153,975**
Liquid funds, specification		
Current investments	-	-
Cash and bank	729,270	153,975
	729,270	**153,975**

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 December 31, 2018	**28,064**	**27,693**	**154,838**	**-122,936**	**87,659**
Appropriation of profit/loss			-122,936	122,936	0
Comprehensive income for the year					
Profit/loss for the year				-138,408	-138,408
Comprehensive other income for the year				-	-
Total, comprehensive income for the year				**-138,408**	**-138,408**
Total, excluding transactions with equity holders of the Company	**28,064**	**27,693**	**31,902**	**-138,408**	**-50,749**
Transactions with equity holders of the Company					
Effect of employee incentive program				379	379
Rights issue and directed share issue	12,024		207,991		220,015
Directed new share issue, Board Share Program 2018	54				54
Shareholders' equity December 31, 2019	**40,142**	**27,693**	**239,893**	**-138,029**	**169,699**
Appropriation of profit/loss			-138,029	-138,029	0
Comprehensive income for the year					
Profit/loss for the year				-76,250	-76,250
Comprehensive other income for the year				-	-
Total, comprehensive income for the year				**-76,250**	**-76,250**
Total, excluding transactions with equity holders of the Company	**40,142**	**27,693**	**101,864**	**-76,250**	**93,449**
Transactions with equity holders of the Company					
Effect of employee incentive program				-41	-41
Directed share issue and rights issue	36,259		553,124		589,383
Directed share issue	2,351		58,703		61,054
Shareholders' equity December 31, 2020	**78,752**	**27,693**	**713,691**	**-76,291**	**743,845**

The share capital as of December 31, 2020 consists of 39,376,096 shares and the share's ratio value was 2.00. The directed share issues were completed in July 2020 and the repair rights issue was completed in August 2020. These amounted to in total approximately SEK 625.5 million before issue expenses and approximately SEK 589.4 million after issue expenses. The directed new share issue carried out in December 2020 raised approximately SEK 61.4 million before issue expenses and approximately SEK 61.1 million after issue expenses.

Accounting principles and information notes

Note 1 Accounting principles

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

Parent Company's accounting principles
The Parent Company's annual accounts have been prepared in compliance with the Annual Accounts Act and applying the Swedish Financial Reporting Board's recommendation RFR 2, Reporting for Legal Entities. The Parent Company's accounting principles are consistent with the Group's accounting principles, except that the new principles for financial leases, in accordance with IFRS 16, are not applied by the parent company. The Parent Company's accounting principles for 2020 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.

New IFRSs that the Company has not yet started to apply
New and amended IFRS standards with future application dates are not expected to have a material impact on the Group's financial statements.

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

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

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

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

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

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

Revenue from collaboration agreements associated with outlicensing of proprietary projects
These revenues consist of initial license fees, milestone payments and remuneration for development work as well as future royalties on sales of the medication.

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

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

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

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

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

Research and development costs
Research costs are expensed as they occur. Costs for development of new products are not capitalized, unless the criteria in IAS 38 have been met. Since the Company's drug projects are quite a long time away from being registered as products that can be sold and thereby generate a financial gain for the Company, no costs for development of products are capitalized, i.e. no intangible assets developed by 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 2020 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 1,9 million (2020: 2.0). 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 2020 Alecta's surplus in the form of the collective consolidation level was 148 percent (148).

Compensation in connection with notice of termination

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

Share-related compensation

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

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

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

Disclosure of related party transactions

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

Leases

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

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

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

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

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

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

Taxes

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

Intangible fixed assets

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

Tangible fixed assets

Owned assets

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

Depreciation/amortisation according to plan is as follows:

Equipment	5 years
Investments in rented premises	5–10 years

Inventories

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

Impairment

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Note 2 Judgements and estimates in the financial statements

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

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

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

Note 3 Net revenues, fixed assets and investment activities

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

	Group		Parent Company	
SEK thousand	**2020**	**2019**	**2020**	**2019**
Revenue by geographical region				
Sweden	2,747	23,990	2,747	23,990
Europe	34,269	1,091	34,269	1,091
USA	89,689	60,551	89,689	60,551
Japan	20,667	8,108	20,667	8,108
Other countries	-	-	-	-
Total	**147,372**	**93,740**	**147,372**	**93,740**
Revenue consists of				
Revenues from collaboration agreements associated with outlicensing of proprietary projects	76,713	21,834	76,713	21,834
Revenues from technology licenses	20,667	12,717	20,667	12,717
Revenues from external development projects	49,992	59,189	49,992	59,189
Total	**147,372**	**93,740**	**147,372**	**93,740**
Fixed assets				
Sweden	29,596	33,005	16,762	16,163
Investment activities				
Sweden	6,700	3,839	6,700	3,839

Note 4 Salaries, other remuneration and social security etc

	2020		2019	
SEK thousand	Salaries and other remuneration	Social security costs (of which pension costs)	Salaries and other remuneration	Social security costs (of which pension costs)
Parent Company	49,970	16,263 (6,889)	45,583	19,828 (8,103)
Subsidiaries	-	-	-	-
Group total	**49,970**	**16,263 (6,889)**	**45,583**	**19,828 (8,103)**

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

	2020		2019	
SEK thousand	Board and CEO[1)]	Other employees	Board and CEO[1)]	Other employees
Parent Company	6,307 (1,224)	43,663	5,363 (828)	40,220
Subsidiaries	-	-	-	-
Group total	**6,307**	**43,663**	**5,363**	**40,220**

1) Whereof variable remuneration incl. retention bonus.

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

	2020		2019	
SEK thousand	Board and CEO	Other employees	Board and CEO	Other employees
Parent Company	810	6,079	721	7,382
Subsidiaries	-	-	-	-
Group total	**810**	**6,079**	**721**	**7,382**

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 2020 Annual General Meeting. The Board determines the fixed salary of the CEO annually. The Board's Remuneration Committee determines the fixed salary of other senior executives annually. In addition to a fixed salary, variable remuneration may be payable according to the incentive scheme described below.

BioInvent's program for variable remuneration for the CEO and other senior executives is performance-related and can amount to 0–40 percent of the fixed annual cash salary. The performance related components in the current program, for the period January 1– December 31, 2021, are based primarily on high expectations for technical and commercial milestones in proprietary drug projects. The Board of Directors resolved in February 2021 to pay SEK 1,080 thousand to CEO Martin Welschof and SEK 2,123 thousand to other senior executives for the period January 1– December 31, 2020. Variable remuneration is pensionable income.

The Company has provided a retention bonus to the CEO for the period September 1, 2018 to August 31, 2021. The retention bonus amounts to SEK 200 thousand (net after income tax) and will be paid out after the bonus period. Receipt of the retention bonus required the corresponding acquisition of BioInvent shares in 2019 to be held during the three-year period. The cost in 2020 amounted to SEK 144 thousand.

In addition, other senior executives are covered by employee stock option incentive programs, described on page 49.

Remuneration and other benefits in 2020

SEK thousand	Fixed salary/ fees	Board and committee fees	Variable remuneration incl. retention bonus	Other benefits	Salary exchange	Pension costs	Total
Board and CEO							
Leonard Kruimer, Chairman		682					**682**
Kristoffer Bissessar, member		363					**363**
Dharminder Chahal, member		352					**352**
An van Es-Johansson, member		306					**306**
Thomas Hecht, member		280					**280**
Bernd Seizinger, member		363					**363**
Martin Welschof, CEO	2,700		1,224	37		810	**4,771**
	2,700	**2,346**	**1,224**	**37**		**810**	**7,117**
Other senior executives (4 individuals)	6,042		2,123	276	15	1,500	9,956
Total	**8,742**	**2,346**	**3,347**	**313**	**15**	**2,310**	**17,073**

Remuneration and other benefits in 2019

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

Benefits for the Board and CEO

The AGM 2020 resolved that the Board's fee shall amount to SEK 682.5 thousand to the Chairman of the Board and SEK 305.5 thousand to each of the other Board members, who are not employed by the company. In addition hereto, the AGM resolved on fees for committee work of SEK 57.5 thousand to the Chairman of the Audit Committee, SEK 46 thousand to each of the other members of the Audit Committee and SEK 57.5 thousand to the Chairman of the Scientific Committee and that no fee for work in the Remuneration Committee shall be paid. Fee for committee work shall not be paid to the Chairman of the Board.

Martin Welschof, CEO has received a fixed gross cash salary of SEK 2,700 thousand and SEK 1,224 thousand in variable remuneration (including retention bonus of SEK 144 thousand), as well as SEK 37 thousand in other benefits. The total cost for pension benefits amounted to SEK 810 thousand. He is covered by pension benefits of 30 percent of the fixed annual cash salary. Retirement age is 65. The CEO and the Company have a mutual period of notice of six months. If notice is given by the Company, the CEO is entitled to redundancy pay equivalent to 12 monthly salaries. Redundancy pay is not deducted from other income. If the CEO resigns, no redundancy pay is payable. The CEO vested 295,492 options in 2020.

Benefits for other senior executives

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

Other senior executives received a fixed gross cash salary in 2020 of SEK 6,042 thousand. SEK 15 thousand has been exchanged from gross cash salary to pension costs. SEK 2,123 thousand was received in variable remuneration, as well as SEK 276 thousand in other benefits. The total pension costs relating to other senior executives amounted to SEK 1,500 thousand. Other senior executives vested 712,649 options in 2020.

Average number of employees

	2020		2019	
	Number of employees	Of which women	Number of employees	Of which women
Parent Company	72	69 %	68	67 %
Subsidiaries	-	-	-	-
Group total	72	69 %	68	67 %

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

	2020		2019	
	Number[1)]	Of which women	Number[1)]	Of which women
Board and CEO	9	33 %	8	37 %
Other senior executives	4	0 %	4	0 %

1) Number on December 31.

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. During the course of the program 1,422,832 options have vested. The last date to exercise was December 15, 2020. No subscription warrants were called for redemption.

Option Program 2019/2025
The 2019 Annual General Meeting resolved to adopt a long-term incentive program in the form of an option program comprising the management group. The option program comprise a maximum of 3,971,000 stock options and the participants may vest options free of charge based on performance and continued employment. Each option entitles the holder to subscribe for 0.04 new share in BioInvent during the period from the day of release of the company's year-end report for the financial year 2022 up to and including December 15, 2025. The subscription price per share shall be SEK 77.25. Subscription price and number of shares that each option entitles to are recalculated pursuant to the rights issue and reverse share split carried out in 2020.

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

To enable the company's delivery of shares pursuant to the option program and to secure costs connected therewith, primarily social security charges, the 2019 AGM resolved on a directed issue of maximum of 5,040,000 warrants and approval of transfer of warrants. If fully exercised, Option Program 2019/2025 will represent a dilution of 0.3 percent of the shares in the Company. Vesting in 2019 amounted to 221,619 options and 1,008,141 in 2020. As of December 31, 2020, 3,680,086 stock options were outstanding, of which 2,450,326 can be vested in 2021 and 2022.

Fair value per option was valued at the time the options were granted. The data below was used in the calculation, which consists of the input data that applied before the rights issue and reverse share split carried out in 2020 (when each option entitled to subscription of one new share).

Option Program 2019/2025	
Fair value per option (SEK), Black & Scholes-model when granted in 2019	0.65
Share price for underlying shares (SEK)	2.26
Subscription price (SEK)	3.16
Estimated life of the option	5.12 year
Risk-free interest rate during the life of the option	-0.07 %
Assumed volatility	45 %
Expected dividends	-

The costs for the program amounted to SEK -41 thousand (498), and 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

	Group		Parent Company	
SEK thousand	**2020**	**2019**	**2020**	**2019**
KPMG				
Audit assignment	333	285	333	285
Other auditing activities besides the audit	202	351	202	351
Tax consultations	-	-	-	-
Other services	7	126	7	126
Total	**542**	**762**	**542**	**762**

Audit assignment 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

	Group		Parent Company	
SEK thousand	**2020**	**2019**	**2020**	**2019**
Research and development costs	11,488	11,094	6,057	5,663
Sales and administrative costs	516	518	44	46
Total	**12,004**	**11,612**	**6,101**	**5,709**

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

Note 7 Income statement classified according to type of cost

	Group		Parent Company	
SEK thousand	2020	2019	2020	2019
External costs	144,013	158,715	150,164	164,866
Personnel costs	67,559	66,663	67,559	66,663
Depreciation	12,004	11,612	6,101	5,709
Total	**223,576**	**236,990**	**223,824**	**237,238**

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

	Group		Parent Company	
SEK thousand	2020	2019	2020	2019
Exchange rate differences that affected the operating profit/loss	-516	-845	-516	-845
Financial exchange rate differences	-552	-371	-552	-371
Total	**-1,068**	**-1,216**	**-1,068**	**-1,216**

Note 9 Other operating revenues and costs

	Group		Parent Company	
SEK thousand	2020	2019	2020	2019
Other operating revenues				
Swedish grants and financial support from EU's framework program	1,247	6,249	1,247	6,249
Exchange rate gains	615	270	615	270
	1,862	**6,519**	**1,862**	**6,519**
Other operating costs				
Interest costs	-1	-3	-1	-3
Exchange rate losses	-1,131	-1,114	-1,131	-1,114
	-1,132	**-1,117**	**-1,132**	**-1,117**
Total	**730**	**5,402**	**730**	**5,402**

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

Note 10 Financial revenues

	Group		Parent Company	
SEK thousand	2020	2019	2020	2019
Interest income	28	65	28	65
Exchange rate differences	597	121	597	121
Total	**625**	**186**	**625**	**186**

Note 11 Financial costs

	Group		Parent Company	
SEK thousand	2020	2019	2020	2019
Interest costs	-4	-6	-4	-6
Interest costs - leases	-331	-473		
Exchange rate differences	-1,149	-492	-1 149	-492
Total	**-1,484**	**-971**	**-1 153**	**-498**

Note 12 Tax on profit for the year

Tax on profit for the year	Group		Parent Company	
SEK thousand	2020	2019	2020	2019
Current tax on profit for the year	0	0	0	0
Deferred taxes relating to temporary differences	0	0	0	0
Reported tax on profit for the year	**0**	**0**	**0**	**0**

Reconciliation of effective tax	Group		Parent Company	
SEK thousand	2020	2019	2020	2019
Reported profit/loss before tax	-76,333	-138,633	-76,250	-138,408
Tax according to the applicable tax rate, 21,4 % (21.4 %)	16,335	29,667	16,318	29,619
Tax effect of costs that are not deductible	-196	-454	-196	-454
Tax effect of loss carry forward for which the deferred tax claim has not been/shall be considered	-16,139	-29,213	-16,122	-29,165
Reported tax on profit/loss for the year	**0**	**0**	**0**	**0**

There are no substantial deferred taxes that relate to temporary differences as of December 31, 2020. 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 carryforwards amounted to SEK 1,848 million as of December 31, 2020. It is unclear when these loss carry-forwards will be utilized for deduction against taxable earnings. Deferred income tax recoverable relating to loss carry-forward is therefore not reported at any value.

Note 13 Earnings per share

Earnings per share before dilution		
SEK thousand	2020	2019
Profit/loss for the period	-76,333	-138,633
Average number of outstanding shares (thousand)	28,716	18,141
Earnings per share before dilution, SEK	**-2.66**	**-7.64**

Earnings per share after dilution	2020	2019
Profit/loss for the period	-76,333	138,633
Average number of outstanding shares (thousand)	28,716	18,141
Earnings per share after dilution, SEK	**-2.66**	**-7.64**

Earnings per share before dilution is based on profit/loss for the year attributable to Parent Company shareholders and a weighted average of the number of outstanding shares. The number of ordinary shares outstanding before the reverse share split has been adjusted for the proportionate change in the number of shares outstanding as if the reverse split had occurred on January 1, 2019.

Diluted earnings per share is based on profit/loss for the year attributable to Parent Company shareholders and a weighted average of the number of outstanding shares plus the dilutive effects for potential shares. Option Program 2019/2025 entitles the holder to acquire 0.04 new share in BioInvent for a subscription price of SEK 77.25.

An average share price of SEK 38.18 per share was used to determine whether a dilution effect exists for 2020. Option Program 2019/2025 has no dilution effect and are therefore excluded from the earnings per share after dilution calculation. The Company reported a loss for the period and accordingly there is no dilution effect. If in the future the share price exceeds the subscription price and the Company reports a profit, these options may lead to dilution.

Note 14 Intangible fixed assets

Acquired intangible fixed assets	Group		Parent Company	
SEK thousand	2020	2019	2020	2019
Opening acquisition value	21,062	21,062	21,062	21,062
Acquisitions	-	-	-	-
Disposals	-	-	-	-
Closing accumulated acquisition value	**21,062**	**21,062**	**21,062**	**21,062**
Opening depreciation	-21,062	-21,062	-21,062	-21,062
Disposals	-	-	-	-
Depreciation for the year	-	-	-	-
Closing accumulated depreciation and Impairment losses	**-21,062**	**-21,062**	**-21,062**	**-21,062**
Closing residual value according to plan	**0**	**0**	**0**	**0**

Note 15 Tangible fixed assets

Equipment	Group		Parent Company	
SEK thousand	2020	2019	2020	2019
Opening acquisition value	71,081	69,106	71,081	69,106
Acquisitions	6,700	3,839	6,700	3,839
Disposals	-403	-1,864	-403	-1,864
Closing accumulated acquisition value	**77,378**	**71,081**	**77,378**	**71,081**
Opening depreciation	-56,258	-53,172	-56,258	-53,172
Disposals	403	1,864	403	1,864
Depreciation for the year	-5,341	-4,950	-5,341	-4,950
Closing accumulated depreciation	**-61,196**	**-56,258**	**-61,196**	**-56,258**
Closing residual value according to plan	**16,182**	**14,823**	**16,182**	**14,823**

Investments in rented premises	Group		Parent Company	
SEK thousand	2020	2019	2020	2019
Opening acquisition value	15,569	15,569	15,569	15,569
Acquisitions	-	-	-	-
Closing accumulated acquisition value	**15,569**	**15,569**	**15,569**	**15,569**
Opening depreciation	14,229	-13,470	14,229	-13,470
Depreciation for the year	-760	-759	-760	-759
Closing accumulated depreciation	**-14,989**	**-14,229**	**-14,989**	**-14,229**
Closing residual value according to plan	**580**	**1,340**	**580**	**1,340**

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

Note 16 Shares in subsidiaries

	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 International AB.

	Parent Company	
SEK thousand	2020	2019
Opening acquisition value	687	687
Closing acquisition value	**687**	**687**

Note 17 Prepaid expenses and accrued income

	Group		Parent Company	
SEK thousand	2020	2019	2020	2019
Prepaid rent	464	452	2,002	1,990
Other items	3,766	3,446	3,766	3,446
Total	**4,230**	**3,898**	**5,768**	**5,436**

Note 18 Financial risks

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

Currency risks

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

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

In 2020 68 percent (49) of revenues were invoiced in foreign currencies, mainly USD. Around 46 percent (43) of costs in 2020 were invoiced in foreign currencies, mainly in GBP and EUR. Realised forward contracts for flows in 2020 had an effect on the operating income in the amount of SEK -0.7 (0.5) million. A sensitivity analysis shows that the Company's operating profit/loss in 2020 before hedging transactions would have been affected in the amount of SEK +0.7 million if the Swedish krona had weakened by 1 percent compared with USD and in the amount of SEK -0.4 million if the Swedish krona had weakened by 1 percent compared with EUR.

Interest risk

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

The average interest rate in 2020 was 0.0 percent (0.0). A change in the interest rate of 1 percent in 2020 would have affected the net interest income by SEK 3.6 million.

Liquidity and credit risk

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

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

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

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

Note 19 Shareholders' equity

Share capital

	Ordinary shares	
Thousands of shares	**2020**	**2019**
Issued as of January 1	501,770	350,800
Rights issue and directed share issue		150,300
Directed new share issue, Board Share Program 2018		670
Directed share issues and rights issue	453,237	
Directed share issue	29,395	
Reverse share split	-945,026	
Issued as of December 31	**39,376**	**501,770**

The share capital as of December 31, 2020 consists of 39,376,096 shares and the share's ratio value is 2.00. Shareholders holding ordinary shares are entitled to dividends. Each share carries one vote at the Annual General Meeting.

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

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

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

Proposed appropriation of profits
At the disposal of the Annual General Meeting: Share premium reserve of SEK 713,690,799, retained earnings of SEK -41,000 and loss for the year of SEK -76 249 566. The Board of Directors propose that profits at the disposal of SEK 637,400,233 is carried forward. Thus, it is proposed that no dividend be given for the financial year 2020.

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

Note 20 Accrued expenses and deferred income

	Group		Parent Company	
SEK thousand	**2020**	**2019**	**2020**	**2019**
Payroll liabilities	11,249	8,343	11,249	8,343
Social security fees	3,143	3,031	3,143	3,031
Other items	8,216	5,875	8,216	5,875
Total	**22,608**	**17,249**	**22,608**	**17,249**

Note 21 Financial assets and liabilities

Group 2020

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 2[1)]**
Financial assets measured at fair value					
Currency forward contracts	93			**93**	93
	93			**93**	**93**
Financial assets not measured at fair value					
Accounts receivable		29,920		**29,920**	
Other receivables		5,452		**5,452**	
Current investments		-		**-**	
Cash and bank		729,270		**729,270**	
		764,642		**764,642**	
Financial liabilities measured at fair value					
Currency forward contracts	-336			**-336**	-336
	-336			**-336**	**-336**
Financial liabilities not measured at fair value					
Accounts payable			-16,913	**-16,913**	
Other liabilities			-7,681	**-7,681**	
			-24,594	**-24,594**	

1) 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..

Group 2019

SEK thousand	Book value				Fair value
	Mandatorily measured at fair value through profit or loss	**Financial assets measured at amortised cost**	**Other liabilities**	**Total**	**Level 2[1)]**
Financial assets measured at fair value					
Currency forward contracts	25			**25**	25
	25			**25**	**25**
Financial assets not measured at fair value					
Accounts receivable		12,708		**12,708**	
Other receivables		17,120		**17,120**	
Current investments		-		**-**	
Cash and bank		153,975		**153,975**	
		183,803		**183,803**	
Financial liabilities measured at fair value					
Currency forward contracts	-5			**-5**	-5
	-5			**-5**	**-5**
Financial liabilities not measured at fair value					
Accounts payable			14,361	**14,361**	
Other liabilities			-9,531	**-9,531**	
			-23,892	**-23,892**	

1) 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. 2020**	**< 3 months**	**3–12 months**	**1–5 year**	**Total**
Lease liabilities	-1,478	-4,494	-5,632	**-11,604**
Accounts payables	-16,913			**-16,913**
Other liabilities	-7,681			**-7,681**
Accrued expenses	-22,608			**-22,608**
Currency forward contracts	-382			**-382**
	-49,062	**-4,494**	**-5,632**	**-59,188**
Remaining term, 31 Dec. 2019				
Financial liabilities	**-42,684**	**-4,614**	**-9,947**	**-57,245**

Note 22 Leases

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

SEK thousand	**2020**	**2019**
Owned tangible fixed assets	16,762	16,163
Right of use assets	12,834	16,842
Total	**29,596**	**33,005**

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

Right of use assets

SEK thousand	**2020**	**2019**
Opening acquisition value	16,842	22,745
Additions (non-cash flow affecting)	1,895	-
Depreciation	-5,903	-5,903
Closing residual value according to plan	**12,834**	**16,842**

Lease liabilities

SEK thousand	**2020**	**2019**
Opening acquisition value	15,529	9,472
Additions (non-cash flow affecting)	1,895	-
Amortization, (cash flow affecting)	-5,820	-5,679
Lease liabilities included in statement of financial position for the Group	**11,604**	**15,529**

Lease liabilities

SEK thousand	**2020**	**2019**
Long term	5,632	9,472
Short term	5,972	6,057
Lease liabilities included in statement of financial position for the Group	**11,604**	**15,529**

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

Amounts reported in the statement of comprehensive income for the Group

SEK thousand	**2020**	**2019**
Depreciation of rights of use assets	-5,903	-5,903
Interest costs, leases	-331	-473
Costs of low value leases	-205	-225
Total	**-6,439**	**-6,601**

Amounts reported in the statement of cash flows for the Group

SEK thousand	**2020**	**2019**
Total cash flows attributable to leases	-6,356	-6,377

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

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

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

Note 23 Events after the end of the reporting period

In January 2021, BioInvent announced that it had restructured a clinical development agreement with Cancer Research UK (CRUK) for BI-1206. In exchange for a one-time payment of £2.5 million, the revised deal simplifies and reduces Bioinvent's obligations to CRUK.

BioInvent announced in January 2021, enrollment of the first patient in a Phase I/IIa study of BI-1808.

In January 2021, BioInvent announced that An van Es-Johansson would resign as a director of the board effective as of February 15, 2021, due to personal reasons.

In January 2021, BioInvent announced that Phase I/IIa data suggest that BI-1206 restores activity of rituximab in relapsed non-Hodgkin's lymphoma patients. Responses in 6 out of 9 patients evaluated provide exciting evidence that BI-1206 has the potential to restore activity of rituximab in non-Hodgkin's lymphoma patients who have relapsed after treatment with rituximab. Two patients (30 mg and 70 mg dose) achived a complete response which continued to be sustained 12 and 24 months later.

On February 23, 2021, BioInvent successfully completed a directed share issue of approximately SEK 962 million before transaction costs. Investors in the directed share issue are a range of international and Swedish investors, including Redmile Group, LLC., Invus, HBM Healthcare Investments, The Fourth National Swedish Pension Fund, Swedbank Robur Fonder and Van Herk Investments. 2,834,399 new shares were issued based on the authorization granted by the EGM on November 27, 2020, and the issue of 16,260,601 new shares were approved at an EGM held on March 23, 2021.

BioInvent announced in March 2021, enrollment of the first patient in a Phase I/IIa study of BT-001.

In March 2021, BioInvent announced that proof-of-concept data on the anti-FcyRIIB antibody BI-1607 should be presented att the AACR Annual Meeting 2021.

In early April 2021, BioInvent announced an IND approval from the FDA regarding the Phase I/IIa clinical trial of the anti-TNFR2 antibody BI-1808 as single agent and in combination with pembrolizumab in solid tumors and CTCL.

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 Ideongatan 1, Lund and the postal address is SE-223 70 Lund. The consolidated accounts consist 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 April 8, 2021.

Leonard Kruimer Chairman of the Board	Vessela Alexieva Board member	Kristoffer Bissessar Board member	Dharminder Chahal Board member
Thomas Hecht Board member	Anette Mårtensson Board member	Bernd Seizinger Board member	Martin Welschof CEO

Our audit report was submitted on April 8, 2021.
KPMG AB

Linda Bengtsson
Authorized 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 2020. The annual accounts and consolidated accounts of the company are included on pages 28-56 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 December 31, 2020 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 December 31, 2020 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.

Accounting of revenue

See Note 2, page 46, and accounting principles on page 43 in the annual account and consolidated accounts for detailed information and description of the matter.

Description of key audit matter

The revenues of the Company consist of:

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

The structure and terms of these agreements and partnerships vary, and revenue is accounted for both at one point in time and over time. As these agreements contain several components, there is a risk that revenues will be recognized in the wrong period.

Response in the audit

Accounting of revenue from agreements with customers has been a focus are for our audit. Our assessment of revenue recognition focuses on the following critical assessment made by executive management:

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

In addition to having taken part of management's assessment above, we have also verified revenue items on a sample basis against underlying agreements, the internal project accounting of the Company and/or supporting documents for payments verifying that the Company has received the revenue.

Milestone payments recognised as revenue have been confirmed against confirmation from the counterparty that the milestone has been reached or by verifying that the counterparty has paid the milestone fee.

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 other information comprises also of the remuneration report which we obtained prior to the date of this auditor's report.The Board of Directors and the Managing Director are responsible for this other information.

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

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

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

Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- 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, measures that have been taken to eliminate the threats or 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 2020 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 the May 28, 2020. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2012.

Malmö April 8, 2021
KPMG AB

Linda Bengtsson
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.

General Meetings

The Annual General Meeting ("AGM"), or as applicable, the Extraordinary General Meeting, is the supreme decisionmaking 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.

The AGM 2020 was held on May 28 and the minutes are available on the BioInvent website. Extraordinary General Meetings were held on July 3, 2020 and November 27, 2020 and the minutes of these meetings are available on the BioInvent website. The AGM 2021 will be held on April 29. The EGM will be held only through advance voting (postal voting) in accordance with temporary legislation.

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: Stefan Ericsson, 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 August 31 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 2020 consisted of Mattias Cramby (Mexor i Skellefteå AB), Erik Esveld (Van Herk Investments B.V.), Vincent Ossipow (Omega Fund IV, LP) and the Chairman of the Board Leonard Kruimer. The Nominating Committee formulated proposals regarding the Chairman of the General Meeting, the composition of the Board of Directors, remuneration of the Board of Directors, as well as election of auditors and auditors fees. The Nominating Committee had four meetings, of which three were by telephone. The committee members also had additional telephone contacts. No fees have been paid to the members of the Nomination Committee.

Pursuant to the Nomination Committees reasoned statement the Nomination Committee has, when preparing its proposal for Board members, applied Section 4.1 of the Code as diversity policy. The goal of the policy is that the Board of Directors shall have a composition appropriate to the Company's operations, phase of development and other relevant circumstances, characterised of diversity and breadth of qualifications, experience and background and that the Company shall strive for gender balance. The AGM 2020 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 2020, five Board members were elected, whereof one woman and four men.

The composition of the Nominating Committee for the AGM 2021 was presented on BioInvent's website on December 9, 2020. According to the Code, the Company must post the names of the Nominating Committee's members on the Company's website six months prior to the AGM and, where applicable, information on which shareholder the Committee member represent. Due to the fact that it has taken longer than anticipated to appoint the Nominating Committee, BioInvent has deviated from the above-mentioned requirement. The Nominating Committee for the AGM 2021 consists of Erik Esveld, appointed by van Herk Investments B.V., Chairman of the Nomination Committee, Vincent Ossipow, appointed by Omega Funds, LP, Jannis Kitsakis, appointed by the Fourth National Swedish Pension Fund, and Leonard Kruimer, Chairman of the Board. No fees have been paid to the members of the Nomination Committee.

Redmile Group, LLC. has since March 29, 2021 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 2020 discharged the Board members and the CEO from liability and re-elected the Board members Dharminder Chahal, An van Es-Johansson, Leonard Kruimer and Bernd Seizinger, and elected Kristoffer Bissessar as new Board member. Leonard Kruimer was elected Chairman of the Board.

The EGM on July 3, 2020 resolved, in accordance with the Nomination Committee's and major shareholders' proposal, to increase the Board of Directors with one member through new election of Dr. Thomas Hecht as a Board member. On January 18, 2021, BioInvent announced that An van Es-Johansson would resign as a director of the board effective as of February 15, 2021, due to personal reasons.

The Board of Directors consists of six directors elected by the General Meeting, as well as the employee representatives Vessela Alexieva and Anette Mårtensson.

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 2020 resolved that the Board's fee shall amount to SEK 682,500 to the Chairman of the Board and SEK 305,500 to each of the other Board members, who are not employed by the company. In addition hereto, the AGM resolved on fees for committee work of SEK 57,500 to the Chairman of the Audit Committee, SEK 46,000 to each of the other members of the Audit Committee and SEK 57,500 to the Chairman of the Scientific Committee and that no fee for work in the Remuneration Committee shall be paid. Fee for committee work shall not be paid to the Chairman of the Board.

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

In 2020 the Board of Directors held six ordinary meetings and nine 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.

The Board has conducted the annual structured Board evaluation and the results of this have been shared with the Nominating Committee.

Board member	Attendance
Leonard Kruimer (Chairman)	15 (15)
Vessela Alexieva	14 (15)
Kristoffer Bissessar[2)]	9 (9)
Dharminder Chahal	15 (15)
Elin Jaensson Gyllenbäck[1)]	5 (6)
Thomas Hecht[3)]	6 (6)
An van Es-Johansson	14 (15)
Anette Mårtensson[2)]	9 (9)
Vincent Ossipow[1)]	6 (6)
Bernd Seizinger	15 (15)

1) Resigned on May 28, 2020 in conjunction with the AGM.
2) Elected on May 28, 2020 in conjunction with the AGM.
3) Elected on July 3, 2020 in conjunction with the EGM.

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

Remuneration Committee

The Board of Directors has appointed a Remuneration Committee consisting of Leonard Kruimer (Chairman), An van Es-Johansson and Bernd Seizinger. All members are independent in relation to the Company and the senior executives. The work is regulated in the instructions that comprise part of the rules of procedure for the Board of Directors and include to consider and to resolve on issues pertaining to remuneration and benefits to senior executives. The work includes preparation of other remuneration issues of greater importance, such as incentive programs. Added to this are assignments to monitor and evaluate ongoing and completed programs for variable remuneration to senior executives, monitor and evaluate implementation of the guidelines for remuneration to senior executives applicable for the year, as well as applicable remuneration structures and levels within the Company. The Remuneration Committee reports to the Board of Directors. The committee held one meeting in 2020.

Member of the Remuneration Committee	Attendance
Leonard Kruimer (Chairman)	1 (1)
An van Es-Johansson	1 (1)
Bernd Seizinger	1 (1)

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 2020; before then Leonard Kruimer (Chairman) and Dharminder Chahal). 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 eight meetings in 2020.

Member of the Audit Committee	Attendance
Kristoffer Bissessar (Chairman after May 28, 2020)[1)]	5 (5)
Dharminder Chahal (Chairman until May 28, 2020)	8 (8)
Leonard Kruimer	8 (8)

1) Elected on May 28, 2020 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 2020 elected KPMG AB to serve as the Company's auditors for a two-year mandate. Linda Bengtsson, 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. Once a year the Board of Directors evaluates the work of the CEO. No member of the senior management is present at this meeting. The CEO and the senior management are presented on page 27.

Remuneration to senior executives
The AGM 2020 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 pages 33-34.

The Company's systems for internal control and risk management with respect to financial reporting for the 2020 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 organization 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, organizational 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 authorization 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 computerized 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 April 8, 2021
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 2020 on pages 60-62 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 April 8, 2021
KPMG AB

Linda Bengtsson
Authorized Public Accountant

BioInvent's Annual Report is produced in cooperation with ID kommunikation.
Photo: Andreas Offesson.

Annual General Meeting

The Annual General Meeting will be held on Thursday April 29, 2021. The AGM will be held only through advance voting (postal voting) in accordance with temporary legislation.

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 April 21, 2021, and notify the company of their intention to participate in the AGM no later than Wednesday April 28, 2021, by submitting their advance votes.

Shareholders whose shares are nominee-registered must temporarily re-register their shares in their own name in the shareholders' register maintained by Euroclear in order to participate in the AGM (so called "voting rights registration"). The shareholders' registers as of the record date on Wednesday April 21, 2021 will include voting rights registrations made not later than Friday April 23, 2021. Therefore, shareholders must, in accordance with the respective nominee's routines, in due time before said date request their nominee to carry out such voting rights registration.

A special form shall be used for advance voting. The form is available on the company's website, www.bioinvent.com. The advance voting form is considered as the notification of participation at the AGM.

The completed and signed voting form must be received by BioInvent International AB no later than Wednesday April 28, 2021, kindly before 4.00 pm. CET. The completed and signed form shall be sent to BioInvent by e-mail to stefan.ericsson@bioinvent.com or by regular mail to BioInvent International AB, Ideongatan 1, SE-223 70 Lund, Sweden, att: Stefan Ericsson. If the shareholder votes in advance by proxy, a power of attorney shall be enclosed with the form. Proxy form is available upon request and on the company's website www.bioinvent.com. If the shareholder is a legal entity, a copy of the registration certificate or, if such document does not exist, a similar document of authorization is to be attached.

Upcoming financial reports
BioInvent will present the following financial reports:
• Interim reports April 28, August 26, October 28, 2021

Investor Relations
Cecilia Hofvander
Senior Director Investor Relations +46 (0)46 286 85 50
cecilia.hofvander@bioinvent.com

Financial reports are also available at www.bioinvent.com

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

BioInvent

BioInvent International AB (publ)
Corp. ID 556537-7263
Address: Ideongatan 1
Postal address: SE-223 70 Lund, Sweden
Tel: +46 (0)46-286 85 50
www.bioinvent.com