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ANNUAL REPORT

# 14





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# The year in brief

Immuno-oncology is a relatively new and fast-growing medical field where the focus is on developing treatment methods that support the body's own ability to effectively fight tumour cells. In 2014 interest in immuno-oncology drug projects further increased. At the leading annual ASCO cancer congress in the US, 35,000 researchers and oncologists assembled to learn about the latest advances in cancer therapy. After the meeting Asthika Goonewardene, an analyst at Bloomberg Industries, concluded that the extent of the enthusiasm expressed for a class of drug was unprecedented. Meanwhile, BioInvent's immuno-oncology projects made important strides in 2014 and the Company is now looking forward to taking another of its drug candidates into the clinical phase.

In April an oversubscribed rights issue worth around SEK 49 million and a new share issue worth SEK 15 million directed at Rhenman Healthcare Equity L/S and East Bay AB (Peter Thelin family office) were implemented.

In May BioInvent sold the rights to the ADC-1013 product candidate. This transaction has enabled BioInvent to focus on its wholly-owned projects while allowing the value of BioInvent's share in the project to be realised at an early stage.

In June BioInvent was granted broad patent protection in the US for its drug candidate BI-505. This patent is based on the discovery of new functions in known target structures and demonstrates BioInvent's ability to identify competitive antibodies using the Company's F.I.R.S.T.<sup>™</sup> screening platform.

In July BioInvent received two separate payments totalling EUR 1 million from Bayer and Servier for milestones reached within the framework of partnerships with these companies.

In September BioInvent received an additional milestone payment from Bayer in connection with the launch of a phase I study with an antibody identified from the Company's n-CoDeR<sup>®</sup> library. This is the third antibody in the partnership with Bayer to reach phase I studies.

SEK million	2014	2013
Net sales	47	82
Profit/loss for the year	-54	-18
Liquid funds	46	65

# BioInvent in five minutes

## The problem – one in three people will get cancer

One in three people will get cancer and, although treatments have improved, mortality in many forms of cancer is high and drug side effects severe. The body's immune system is one of the most effective weapons to fight cancer and development of immuno-oncology drugs aimed at immune defence against cancer is expected to revolutionise the treatment of cancers. Researchers and pharmaceutical companies all around the world are now working intensely to find antibodies that can affect the target structures on tumour cells and in the immune system that inhibit or promote tumour development. If antibodies can be identified that are effective yet do not obstruct the normal functions of cells in the rest of the body, patients will survive longer and their quality of life will be improved.

## The solution – a unique platform for developing immuno-oncology drugs

BioInvent's unique technology platform consists of two parts:

- the **n-CoDeR®** antibody library, one of the largest in the world with more than 30 billion unique antibodies
- and
- **F.I.R.S.T.™**, a unique tool to identify antibodies that can affect the target structures on tumour cells and in the immune system that inhibit or promote tumour development.

This unique technology platform is used both to help leading pharmaceutical companies identify antibodies for their own development projects and for BioInvent's own development of new drugs in carefully selected niche indications. Both n-CoDeR® and F.I.R.S.T.™ can also be used in the development of drugs in areas other than oncology.

## Status – an attractive pipeline and cash flows from existing customers

BioInvent has leading expertise in immuno-oncology and is therefore well-positioned to contribute to the ongoing revolution in cancer treatment. Six global pharmaceutical companies are already paying for access to the Company's antibody library and method for identifying the right candidates for new drug projects. In addition, BioInvent has three proprietary antibodies in or close to clinical development to fight various cancers. The Company recently secured financing for a comprehensive phase I/II trial with its BI-1206 drug candidate. The trial will be launched in 2015. BioInvent also intends to continue development of the BI-505 drug candidate into phase II in partnership with leading researchers at University of Pennsylvania. The primary indication for BI-505 is multiple myeloma, but the Company is also assessing the possibility of starting parallel clinical development for certain rare diseases, so-called orphan indications. A phase I/II study with TB-403 for medulloblastoma – a life-threatening cancer that exclusively affects children and adolescents – is expected to start in the latter part of 2015.

## The future – building value with balanced risk

BioInvent's proprietary drug projects have the potential to increase substantially in value as and when new data is generated and new licence agreements are signed. Alongside BioInvent's clinical projects, the Company has a broad preclinical pipeline containing antibodies aimed at target structures which the research community considers extremely attractive – principally regulatory T cells and macrophages associated with tumour growth – with potential application areas in a number of indications.

A risk-balanced business model is assured through sound cost control and secured financing for the next development stage for BI-1206 from one of the world's leading oncology research organizations, combined with cash flows from existing customers.

## Project portfolio



<sup>1)</sup> Include Bayer Pharma, Daiichi Sankyo, Mitsubishi Tanabe Pharma, Servier and Xoma

### n-CoDeR<sup>®</sup>

BioInvent's patent-protected n-CoDeR<sup>®</sup> library contains more than 30 billion antibodies, making it one of the largest in the world. With the help of automated processes it is possible to search the library to identify precisely those antibodies that bind to a specific target protein or a target cell of interest for a certain disease.

### F.I.R.S.T.<sup>TM</sup>

BioInvent has developed a unique tool to identify antibodies that bind specifically to target proteins on cancer cells, yet do not harm healthy tissue. F.I.R.S.T.<sup>TM</sup> makes it possible to simultaneously identify target proteins of interest for a certain disease and the antibodies that bind to them. BioInvent has developed partnerships with local cancer clinics for access to various types of tumour tissue. With the help of F.I.R.S.T.<sup>TM</sup>, BioInvent can in an effective way utilize the full potential in the n-CoDeR<sup>®</sup> antibody library.

### BI-505 – multiple myeloma

BI-505 was primarily developed to treat multiple myeloma, a haematological disease that occurs in the patient's bone marrow. BI-505 is a fully human antibody targeting ICAM-1, a protein on the surface of cancer cells. The substance's good safety profile was documented in a phase I study in patients who were resistant to existing drugs and where there were also signs of a positive effect against the disease. Preclinical data shows improved activity against the tumour if the substance is administered in combination with the registered drugs Velcade<sup>®</sup> or Revlimid<sup>®</sup>. A limited pilot study in patients with asymptomatic multiple myeloma has been terminated for strategic reasons as a result of an analysis of BI-505's data package and a targeted product positioning. Instead a collaboration has been initiated with Penn Medicine to investigate whether BI-505 in combination with low dose Revlimid<sup>®</sup> can deepen the response achieved with today's treatment. BioInvent has identified an opportunity to develop BI-505 for the treatment of other orphan indications, and is evaluating parallel clinical development of these.

### BI-1206 – non-Hodgkin lymphoma

BI-1206 is an antibody that blocks the protein CD32b which is over-expressed in patients with lymphoma. The protein is involved in the development of resistance to the current state-of-the-art treatment – rituximab (Rituxan<sup>®</sup>/MabThera<sup>®</sup>). Researchers believe that by combining this treatment with BI-1206, a better effect against the tumour can be achieved. Planning is currently under way for a phase I/II study in patients with non-Hodgkin lymphoma and chronic lymphatic leukaemia. The study will be executed and funded by a consortium headed by one of the world's largest scientific non-profit organisations – Cancer Research UK. Alongside this clinical study, preclinical studies will continue, principally focused on proving the combination effects of BI-1206 and CD38 antibodies in the multiple myeloma indication and to identify interesting subpopulations within NHL based on CD32b expression.

### TB-403 – medulloblastoma

BioInvent and partner ThromboGenics are planning to start a new clinical study with the antibody TB-403 in the latter part of 2015. The study will be carried out in patients with medulloblastoma – a life-threatening cancer that exclusively affects children and adolescents. In addition to this, preclinical studies will evaluate the effect of the antibody in models for neuroblastoma. TB-403 has already been evaluated in clinical studies for other indications and has demonstrated a good safety profile. The project's new direction is based on new knowledge about the antibody's mechanism of action. The TB-403 drug project is being run in cooperation with a subsidiary to the Belgian biopharma company ThromboGenics. BioInvent is paying half of the development costs and has the right to 40 percent of all future revenue from the project.



# CEO's statement

## Immuno-oncology – the cancer treatment of the future

Immuno-oncology drugs based on antibodies are about to revolutionise the treatment of cancer and there is an intensive search under way for promising drug projects. With over 30 billion antibodies in our library and a unique tool in the form of F.I.R.S.T.™ to select the most effective of these, BioInvent is well positioned to contribute to the development of new, effective drugs in the field of oncology. We already have a number of promising projects, three of which are in or close to the clinical phase. We are also assisting several international pharmaceutical companies in their drug development work. The cash flow from this type of partnership helps to balance our basic costs. The key to the Company's value creation is, however, the progress we can make in our own clinical projects. BioInvent has an opportunity in 2015 to take a big step forward to become a company that has several ongoing clinical studies for various antibodies, as new data is generated for the clinical drug candidates BI-505, TB-403 and BI-1206, as well as the preclinical projects targeting regulatory T cells and tumour macrophages. This means more opportunities for entering into partnerships and licence agreements that offer significant financial potential.

## Financing secured for the first clinical study with BI-1206

We are focusing on immuno-oncology, with a particular emphasis on finding new forms of treatment for various haematological cancers. In 2014 we worked intensively to find the best way forward for our BI-1206 drug candidate. Our efforts resulted in January 2015 in a unique agreement with one of the world's leading oncology research organisations – Cancer Research UK (CRUK). Through a partnership with CRUK and two related organisations – Cancer Research Technology and Leukaemia & Lymphoma Research – financing was secured for a first phase I/II study in patients with non-Hodgkin lymphoma and chronic lymphatic leukaemia. The support from CRUK is equivalent to more than SEK 60 million for BioInvent and the agreement also gives us access to a network of leading clinical and scientific experts in the UK. The agreement provides BioInvent with access to data from the study in return for limited milestone payments and royalties on future sales of an approved drug, but without the financial risk for BioInvent associated with conducting a comprehensive clinical trial of this kind. This is an excellent example of a small company like BioInvent being able to build value in projects to prepare for future outlicensing, without compromising our financial situation.

## Progress for BI-505 – a new way of treating multiple myeloma

In 2014 we also made significant progress with our BI-505 project for the treatment of multiple myeloma. Among other things, BioInvent was granted an important patent giving us broad protection in the US and also facilitating future outlicensing negotiations. Success in developing robust drug patents is a challenge today because a large number of target structures have been identified. This patent is based on the discovery of new functions in known target structures and demonstrates our ability to identify competitive and patentable antibodies using our F.I.R.S.T.™ screening platform. In 2014 we made clear progress in identifying several alternative and complementary phase II studies as well as attractive financial solutions to implement these. As a result of this we plan to conduct a Phase IIa study in MM patients that have undergone autologous stem cell transplantation (ASCT) to investigate the ability of BI-505 to increase the depth and quality of response after ASCT in combination with standard of care. The intention is to recruit approximately 30 patients, and study start is planned for early 2016. The study will be conducted as an investigator sponsored study in close collaboration with leading clinicians at the Abramson Cancer Center of the, University of Pennsylvania.

## New clinical study planned with TB-403

In March 2015 it was announced that BioInvent and partner ThromboGenics are together planning to start a new clinical study during the latter part of the year with the TB-403 antibody. The study will be carried out in patients with medulloblastoma – a life-threatening cancer that exclusively affects children and adolescents. In addition to this, preclinical studies will evaluate the effect of the antibody in models for neuroblastoma. TB-403 has already been evaluated in clinical studies for other indications and has demonstrated a good safety profile. Based on new knowledge about its mechanism of action, we have now decided to take the development of this antibody in a new and interesting direction.

## Capital-intensive operations

Even though we are taking advantage of the opportunities to limit our investment expenditure and secure regular revenue streams, the capital requirement for our type of company is considerable, and in order to build significant value we must be prepared to take risks. This requires committed, knowledgeable and long-term owners. In 2014 in connection with a capital procurement process, we had the pleasure of welcoming two additional, highly reputable investors with many years of experience in life sciences – Rhenman Healthcare Equity L/S och East Bay AB (Peter Thelin family office). We are hoping to receive support through the ongoing new share issue from our current and new investors to create the financial resilience necessary to develop our projects to the point when they can attract external partners and generate significant revenues. The capital markets around the world have for some time been showing a great deal of interest in investing in immuno-oncology, which will, of course, facilitate this process.

### The right place at the right time

Through our hard work and with support from long-term shareholders, BioInvent has created a unique platform for the development of antibody-based drugs to treat various types of cancer. This has resulted in an attractive proprietary pipeline and revenues from successful projects being run independently by our partners based on our expertise. Although there are no guarantees for success with a research-intensive company, we are convinced that BioInvent is now in exactly the right place at the right time. We will do our utmost to take advantage of this unique situation to create the greatest possible value for our shareholders in the years ahead.

Lund, March 2015

Michael Oredsson  
President and CEO

"Through our hard work and with support from long-term shareholders, BioInvent has created a unique platform for the development of antibody-based drugs to treat various types of cancer. This has resulted in an attractive proprietary pipeline and revenues from successful projects being run independently by our partners based on our expertise."

**Michael Oredsson**





# Objectives and business strategy

BioInvent's goal is to contribute to the development of immuno-oncology drugs to improve the ability to treat different types of cancer. With one of the world's largest antibody libraries, n-CoDeR®, and the unique development tool, F.I.R.S.T.™, BioInvent can identify optimal cellular targets and antibodies for the treatment of various types of tumours. This makes it possible to develop proprietary drug projects, but also to supply leading international pharmaceutical companies with effective tools for their drug development. Revenue from these customers helps to finance the development of the Company's proprietary projects and provides a risk-balanced business model. BioInvent currently has three proprietary projects in or close to clinical development and partnership agreements with six global pharmaceutical and biotech companies.

## Broad-based expertise in immuno-oncology

Over the past decade the Company has accumulated a significant body of experience of relevant disease models within cancer biology and tumour immunology. BioInvent's oncology research is mainly focused on types of haematological cancer and so-called immunomodulatory therapies, i.e. using antibodies with the ability to activate the patient's own immune defences to fight cancer. BioInvent is also focusing on developing drugs to treat severely ill patients within niche indications, i.e. orphan drug indications. The Company will benefit from the value created through clinical development programmes with shorter lead times and significantly lower development costs compared to programmes aimed at larger patient groups.

## Unique ability to select the right antibodies in one of the world's largest antibody libraries

The Company's technology platforms consist of the n-CoDeR® antibody library and the unique F.I.R.S.T.™ development tool. From n-CoDeR®, a library developed by BioInvent containing fully human antibodies, drug candidates that bind specifically and firmly to their target structures can be identified. With the help of the unique, function-based F.I.R.S.T.™ platform where patient material is the foundation throughout the development process, the most clinically relevant target structures in a cancer cell and specific antibodies against these can be identified simultaneously.



## Production of BioInvent's proprietary antibodies

In addition to conducting preclinical and clinical development of antibody-based drugs, BioInvent also has a facility where antibodies are produced. Over a period of several decades, the Company has accumulated considerable experience in developing cell lines that produce antibodies and in manufacturing antibodies according to the cGMP industry standard for clinical studies and commercial products.

## Objective

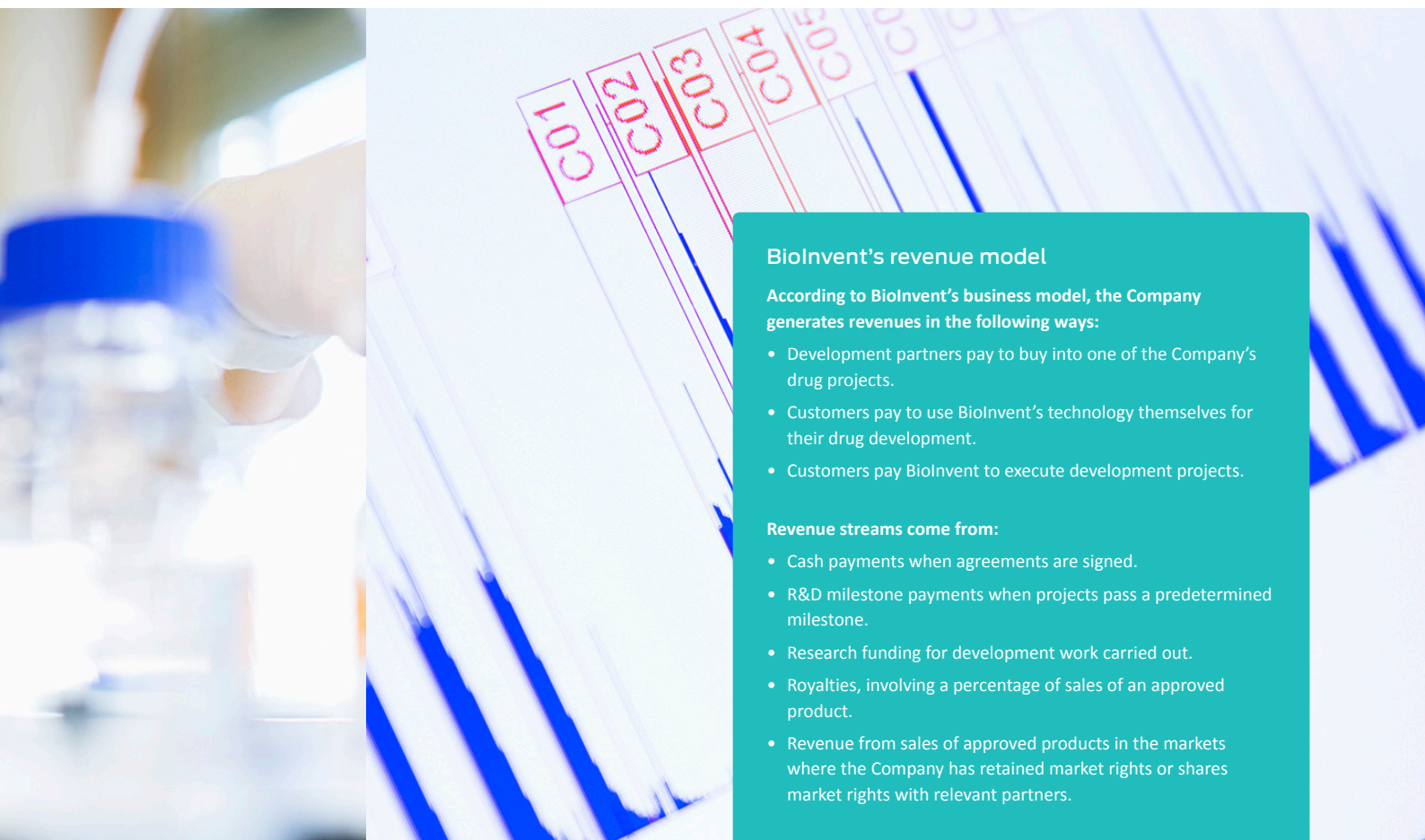
BioInvent's objective is to create value for the shareholders, patients and the medical community by contributing to the development of immuno-oncology drugs that improve the potential to treat various types of cancer.

## Business strategy

The foundation for value creation is the BioInvent's patented technology platforms F.I.R.S.T.™ and n-CoDeR®, combined with the Company's considerable expertise in preclinical and clinical development, and in the production of immuno-oncology drugs. This enables the Company to launch and run its own projects, but significant revenues can also be generated from customers who want access to BioInvent's platforms and know-how to identify drug candidates for their own projects.

New projects can be generated based both on the





### BioInvent's revenue model

According to BioInvent's business model, the Company generates revenues in the following ways:

- Development partners pay to buy into one of the Company's drug projects.
- Customers pay to use BioInvent's technology themselves for their drug development.
- Customers pay BioInvent to execute development projects.

#### Revenue streams come from:

- Cash payments when agreements are signed.
- R&D milestone payments when projects pass a predetermined milestone.
- Research funding for development work carried out.
- Royalties, involving a percentage of sales of an approved product.
- Revenue from sales of approved products in the markets where the Company has retained market rights or shares market rights with relevant partners.

Company's internal research and on partnerships with external research teams. BI-505 for the treatment of multiple myeloma and BI-1206 for the treatment of non-Hodgkin lymphoma are both the result of BioInvent's internal research.

In order to advance product candidates through late clinical development to full commercialisation, BioInvent intends to work in partnership with large pharmaceutical companies. As a rule, the longer a company waits before selling the rights, the more the commercial value of a project increases. For certain projects partnership agreements may be entered into early on in the development process, while other projects may be developed by the Company for a longer period.

### Risk management

BioInvent focuses on developing antibodies for the treatment of haematological cancers. In this area, the Company can use the extensive knowledge it has built up of the biological aspects of producing new antibody-based drug candidates. As early as in the early development phase, by recreating the disease biology in a laboratory setting, it is possible to get an indication of the effects of different substances. This increases the possibility of producing competitive drug candidates and reduces the risk of failure in clinical phases.

In general, the medical supervisory authorities and physicians have a higher tolerance level with respect to side-effects in

oncology if a drug is highly effective. This means there is a lower risk of a regulatory setback than when developing treatments that are not potentially life-saving. Furthermore, the medical supervisory authorities are currently working intensely on promoting and simplifying the process of drug development for serious, life-threatening diseases where there are still insufficient treatments. Accordingly, the development path within many of the indications that BioInvent's drug projects are aimed at can be shortened significantly compared to the process for traditional development programme.

BioInvent seeks development partners with complementary expertise for research projects in relatively early development phases to reduce the financial risk. One example is a partnership with Professor Martin Glennie and Professor Mark Cragg at the University of Southampton. They have a world-leading research team focusing on antibodies and oncology. This type of collaboration also enables BioInvent to retain all or most of the value in its projects. The outlicensing objective is to retain significant value in the project through active, competitive project marketing initiatives aimed at a broad group of potential licensees.

By giving external partners access, for a fee, to the n-CoDeR® and F.I.R.S.T.™ technology platforms, cash flows are created that help to offset the Company's basic operating expenses.

# BioInvent's technology platforms

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

## **n-CoDeR<sup>®</sup> antibody library**

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

## **F.I.R.S.T.<sup>™</sup> – a platform for effective drug development**

BioInvent has developed a patented screening tool called F.I.R.S.T.<sup>™</sup>, which is an important technical tool for drug development for external partners as well as the Company's own drug development. The platform 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 for diseased tissue in terms of binding and expression. Through functional, high-capacity screening, antibodies are then selected based on their ability to, for example, induce cell death of primary cancer cells or affect the immune system's capacity to eliminate tumour cells.

Essentially, F.I.R.S.T.<sup>™</sup> facilitates the development of new antibody therapies as new drug candidates can be produced without detailed knowledge of the antibodies' target proteins.



## Five-stage antibody development:

1

### Comparative screening

The first stage involves isolating antibodies that recognise diseased cancer cells but avoid healthy cells. At this stage, a large number (hundreds to tens of thousands) of antibodies that bind very specifically to different target structures on cancer cells are identified.

2

### Functional screening

Here the functional properties of the antibodies are studied, often their ability to kill cancer cells. i.e. their ability to inhibit the cancer cells' biological activity, as well as the ability to activate the patient's immune defence cells.

3

### Identifying target structures

The third stage involves determining which target structures (antigens) the antibodies bind to. These may be both known and new target structures. This work is also important to the ability to protect the biological material through patents.

4

### Testing in animal models

Selected antibodies and target structures are evaluated in clinically relevant animal models to predict the anticipated effect and side-effect profile in humans.

5

### Clinical studies

Clinical studies are then carried out on patients with relevant cancers. The safety profile and effects of the antibodies is documented in preparation for an application for market approval.

# Project overview

BioInvent currently has three cancer projects in or close to the clinical development phase: BI-505, BI-1206 and TB-403. BioInvent also has a number of projects in the preclinical phase and several partnerships with external pharmaceutical companies relating to the n-CoDeR® antibody library.



## BI-505 for the treatment of multiple myeloma

### Background

Every year an estimated 40,000 patients become ill with the haematological disease multiple myeloma. Multiple myeloma is an incurable cancer for which there are no good drugs to prevent the relapses that affect all patients after treatment with cytotoxic drugs or after a stem cell transplant. Expression of an adhesion protein, ICAM-1 (also called CD54), is elevated in myeloma cells, which makes it a suitable target for a drug candidate. The BI-505 drug candidate is a human antibody that specifically binds to the ICAM-1. BI-505 affects tumours in two ways – by inducing cell death of myeloma cells and by engaging the patient's immune cells, known as macrophages, to attack myeloma cells. Macrophages are abundant in the bone marrow of myeloma patients, where they are thought to contribute to disease progression and development of resistance to currently available drugs. BI-505 has the ability to get macrophages to attack myeloma cells and has, in several relevant animal models, proved to be more effective at killing tumours than existing drugs. The good safety profile and the effectiveness of the substance against cancer cells that do not bind to tumours, even where these are expressed in low quantities, makes BI-505 especially suitable in preventing multiple myeloma relapses.

### Project status

The initial results from the phase I study of BI-505 on patients in advanced stages of multiple myeloma showed that the substance has a good safety profile. In the dosage groups to which extended therapy was offered, 24 percent of these severely ill patients demonstrated stable disease for at least two months, which indicates a positive effect of BI-505, and is in parity with Phase I data from other monoclonal antibodies in clinical development for multiple myeloma. Results from the phase I study were presented in an international conference on multiple myeloma in Kyoto, Japan, and were published in the scientific journal, *Clinical Cancer Research*, in February 2015. New pre-clinical data was also presented on the same occasion showing significantly enhanced anti-tumour activity compared with monotherapy when combining the registered drugs Velcade® or Revlimid® with BI-505.

The scientific journal, *Cancer Cell*, presented data showing preclinical proof-of-concept for both BI-505 and for BioInvent's function-based F.I.R.S.T.™ platform. The article presents data showing the potent action of BI-505 in several preclinical multiple myeloma models.

In April 2013 a phase II study in patients with asymptomatic smoldering myeloma was initiated. The study has now been



prematurely terminated due to a strategic review of the commercial potential of BI-505 in light of the preclinical and clinical data package. BI-505 will be repositioned to target residual disease in combination with "sledgehammer" treatments and after stem-cell transplantation in patients with myeloma.

Asymptomatic multiple myeloma is currently not treated with drugs because the side effects are not acceptable in symptom free patients. This indication therefore has very limited commercial potential and the development path is expected to be relatively complicated.

Instead, a clinical study in collaboration with Penn Medicine will be initiated to investigate the potential of BI-505 to deepen the response after autologous stem cell transplantation in combination with low dose Revlimid®. BioInvent has also identified an opportunity to develop BI-505 in other orphan indications, and is evaluating parallel clinical development of these at a

significantly lower cost and in a shorter timeframe compared with the multiple myeloma indication.

BI-505 has received Orphan Drug Designation for the multiple myeloma indication by both the U.S. Federal Drug Administration (FDA) and European Medicines Agency (EMA).

### Patent protection

BioInvent has applied for patents relating to antibodies against ICAM-1 and their ability to induce cell death in different types of tumours such as multiple myeloma, lymphoma and carcinoma. Patents have so far been granted in 13 countries, including the US, Australia, Japan and China. BioInvent has also applied for patents relating to ICAM-1 antibodies for the treatment of other multiple myeloma-related diseases, of patients with resistance to, for example, chemotherapy, and treatment in combination with other cancer drugs.

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## BI-1206 to treat non Hodgkin lymphoma and chronic lymphatic leukaemia

### Background

Non-Hodgkin lymphoma (NHL) is an umbrella term for a group of cancers that develop in the body's lymphatic system. Since lymphatic tissue is present throughout the body, lymphoma can start anywhere. High-grade lymphoma is treated with radiation and/or cytostatic drugs and in many cases with rituximab (Rituxan®, Mabthera®, Roche). Low-grade lymphoma has a better prognosis and treatment is often only initiated once a patient has disease symptoms.

Chronic lymphatic leukaemia (CLL) is an incurable lymphoma that normally affects older men. The disease progression is often slow and patients are normally treated with cytostatic drugs, often in combination with monoclonal antibodies.

In Europe and North America, around 157,000 people every year are diagnosed with NHL and around 35,000 with chronic lymphatic leukaemia (CLL).

BioInvent's drug candidate BI-1206 is a fully human antibody aimed at CD32b, an immunosuppressive protein that is over-expressed in patients with lymphoma, especially in patients who respond poorly to currently available drugs like anti CD20 treatment, rituximab.

It is well known that CD32b is involved in the development of resistance to current state-of-the-art treatments for NHL and CLL – rituximab. In models for different cancers, CD32b has also been shown to be involved in the development of resistance to treatment with other antibodies. BI-1206 therefore has a very interesting mechanism with the potential for use in both NHL and CLL, as well as other cancer indications. As BI-1206 blocks the immunosuppressant effect of CD32b, the immune system can be stimulated, which can strengthen the therapeutic effect of both rituximab as well as other antibody-based drugs. Combination therapy with BI-1206 and rituximab in clinically

relevant animal models with tumour cells from patients with NHL has demonstrated significantly improved antitumour effects compared to monotherapy with rituximab. Combination therapy therefore has the potential to significantly improve the treatment of patients with this disease. A series of studies have shown that as many as half of the cancer patients who responded to an initial rituximab treatment proved to be resistant to the drug at relapse, which indicates a significant medical need for improved therapies for these patients.

BI-1206 has also shown a strong ability to kill lymphoma cells in preclinical models using tumour cells taken directly from patients. The results indicate that BI-1206 may have the potential to be used as a monotherapy.

### Project status

In January 2015 BioInvent entered into an agreement with Cancer Research UK (CRUK), Cancer Research Technology (CRT) and Leukaemia & Lymphoma Research (LLR) on implementation of a phase I/II study with BI-1206 in patients with chronic lymphatic leukaemia (CLL) and non-Hodgkin lymphoma (NHL). The first study in patients will be financed and executed by CRUK, CRT and LLR. BioInvent has the opportunity to utilise an exclusive licence for the study data in return for low milestone payments and royalties paid to Cancer Research Technology.

The plan is for this open phase I study to include 50–60 patients who will be treated either only with BI-1206 or BI-1206 in combination with rituximab. Patients with CLL will be recruited first, but smaller groups of patients with other types of NHL, such as mantle cell lymphoma, follicular lymphoma and diffuse large B cell lymphoma, may also be included in the study. The study is expected to start in the second half of 2015.

Alongside this clinical study, preclinical studies will continue,

principally focused on proving the combination effects of BI-1206 and CD38 antibodies within multiple myeloma. CD38 antibodies constitute a new, very promising class of drug where market approval is pending in the multiple myeloma indication. Despite proven good effects in clinical studies, the data indicates that patients develop resistance to these new drugs as well, which shows that there is a medical need to complement this class of drugs to optimise the treatment of patients. In addition investigations regarding CD32b expression in subpopulations within

NHL will be done, with the potential to identify the optimal populating for treatment with BI-1206.

#### Patent protection

Patent applications have been filed relating to antibodies against CD-32b in combination with other antibodies, such as rituximab for the treatment of cancer patients who are resistant or respond poorly to cancer therapies available today. Applications have been filed in nine large markets, including the US, Europe, Japan and China.



## TB-403 for the treatment of medulloblastoma

### Background

Medulloblastoma and neuroblastoma are two life-threatening, debilitating cancer diseases that exclusively affect children and adolescents. Both diseases are rare and are diagnosed in just over ten individuals per million and year. Preclinical data from models for medulloblastoma with the monoclonal antibody TB-403 indicates the potential for better clinical results for these patients than with available therapies. The antibody will therefore be evaluated in a clinical study for this indication.

The TB-403 drug project is being run in cooperation with a subsidiary to the Belgian biopharma company ThromboGenics. BioInvent is paying half of the development costs and has the right to 40 percent of all future revenue from the project.

### Project status

There are plans to start a new clinical study with TB-403 in children with medulloblastoma in the latter part of 2015. In addition to this, preclinical studies will evaluate the effect of the antibody in models for neuroblastoma. The antibody TB-403 has demonstrated an excellent safety profile in previous clinical trials in patients with liver cancer and glioblastoma. The decision to launch a new clinical trial and further preclinical evaluations

is based on more detailed knowledge about the antibody's mechanism of action, which is described in an article published by Jain et al in the respected journal Cell. Before the start of the planned clinical trial, BioInvent will, in consultation with the medical products agencies in Sweden, the UK and the US, conduct certain additional preclinical trials.

The relatively high development risk of the project is being weighed against the favourable safety profile that TB-403 has demonstrated in earlier trials, the project's low development costs, and the possibility of using a faster development process than is normally the case.

### Patent status

Patents covering treatment with antibodies against PIGF for the purpose of reducing or preventing cancer have been granted in the US and additional applications are under review there, including one relating to inflammation. Patent applications for TB-403 and similar antibodies have also been submitted in Europe, Japan, Canada, the US and Australia and several other countries. A number of patents have been granted, including in the US, Europe and Japan.



## Preclinical projects

BioInvent's preclinical research is aimed at expanding the Company's portfolio of drug candidates. Since 2012 the Company has focused its own research resources entirely on the cancer indication. Over the past decade the Company has accumulated a significant body of experience of relevant disease models within cancer biology and tumour immunology. The basis of the preclinical research is the test models used to identify the most effective and potent antibody candidates. These models make it possible to simultaneously conduct an extensive study of the safety and tolerability of the antibody, based on the biology of the disease and the mechanism of action of the antibody.

BioInvent's research is aimed at developing antibodies with

the ability to kill tumour cells through apoptosis (programmed cell death) or by activating the body's own immune system. With the help of the F.I.R.S.T.™ platform, the Company is actively seeking new drug candidates for the treatment of different haematological cancers. BioInvent is also working with leading Swedish and international academic teams to gain access to new therapeutic concepts for the treatment of both serious haematological and solid cancers, which can serve as a basis for the development of new projects. One example is a partnership with Professor Martin Glennie and Professor Mark Cragg and their team at the University of Southampton with whom BioInvent is running several parallel collaborative immuno-oncology projects.

## External collaborations

The Company has had licensing agreements for some time and, in some cases, research collaborations with a number of external partners including Bayer Pharma and Daiichi Sankyo, Mitsubishi Tanabe Pharma, Servier and Xoma. The structure and terms of these agreements and partnerships vary, but they all have in

common that BioInvent receives licence fees, research financing, milestone payments and royalties on the sale of commercial products. Of these external drug programmes, four projects are currently in phase I, four are in the preclinical phase and more than ten are in the early research phase.

Partners	Project description	Comments
Bayer Pharma	Identification and development of up to 14 antibody-based products using the n-CoDeR® library.	The agreement was renegotiated and extended in 2013. In 2014 BioInvent received two milestone payments linked to start of phase I studies.
Daiichi Sankyo	Licensing and research agreement for the development of therapeutic antibodies aimed at several target proteins, using the n-CoDeR® library.	The agreement gives BioInvent certain rights to market products in Scandinavia and the Baltic region.
Mitsubishi Tanabe Pharma	Identification and development of antibody-based products using the n-CoDeR® library.	The agreement allows for development of up to five antibody-based therapeutic products.
Servier	Collaboration on development of an antibody against a target structure relevant to tumour cell metabolism. Servier provides the target structure and BioInvent selects antibodies from the n-CoDeR® library.	Servier also has access to BioInvent's preclinical expertise in optimising antibody candidates for further clinical development. The collaboration was intensified in 2013 and in 2015 BioInvent received a milestone payment for progress in the project.

# Market overview

## Anticipated sales in 2018 (USD billion)

Avastin®	7.8
Revlimid®	7.8
Rituxan®/Mabthera®	6.4
Herceptin®	4.6
Kadcyla®	1.9
Vervoy®	1.6

## Market for antibodies

BioInvent develops antibody-based drugs in the field of cancer, focusing on haematological cancers. The antibody-based drug segment is one of the fastest growing segments in the global pharmaceutical market. Annual sales growth is estimated to be around 16 percent for the years 2010–2016, which is significantly higher than the estimated growth for traditional drugs based on small molecules. However, some slowing is expected in the years ahead as patents expire, despite additional launches of improved antibodies. During the period 2004–2010 the market capitalization for antibody-based drugs in the oncology field increased from USD 10 billion to USD 40 billion, and by 2016 the total is expected to exceed USD 65 billion.<sup>1)</sup> Around 30 percent of all research in new original drugs consists of research in the antibody area. Of the 360 antibodies that are currently in clinical development, 75 percent are aimed at cancer and immunology. Antibodies have a beneficial risk profile and several studies have shown that a significantly larger percentage of projects in the antibody area reach the market today compared to traditional pharmaceuticals.

The three top-selling antibody-based drugs in the world are Rituxan/Mabthera® (rituximab, Roche), Herceptin® (trastuzumab, Roche) and Avastin® (bevacizumab, Roche). The combined sales of these substances amounted to around USD 21 billion<sup>1)</sup> in 2014.

## Market trends

In the next five years the patents for Rituxan/Mabthera® and Herceptin® will expire at the same time as new, improved therapies are expected to reach the market. The market prognosis from analysis company Datamonitor for 2018 is presented in the table below.

## Success factors

There are several success factors that explain the strong market growth for antibody-based drugs. Antibodies are nature's own defence molecules. They are highly selective and, in their natural form, are very well tolerated. They exert a precise effect and integrate naturally with the rest of the immune system which can also modulate the antibody's therapeutic effect. Another success factor is that antibody-based drugs maintain higher prices, mainly due to the fact that, compared to traditional drugs, they are exposed to much less competition from generics. This type of biopharmaceutical is much more complex than small molecules, which makes them difficult to copy. The time needed to develop antibody-based drugs has also proved to be shorter than for traditional pharmaceuticals, and development costs are therefore lower.<sup>2)</sup>

## Competition

BioInvent's competitors are mainly global pharmaceutical companies that are developing their own antibody-based drugs. Roche/Genentech are known for their strong market position with products such as Avastin®, Rituxan/Mabthera® and Herceptin® in their portfolio. In the market where there are companies that supply global pharmaceutical companies with antibody projects, BioInvent competes with a number of biotech companies that are developing cancer products in general and products to treat haematological cancer in particular. They include companies such as Morphosys, Regeneron, Ablynx, Immunogen, Genmab and Seattle Genetics. With respect to companies with competing technologies for developing antibody-based drugs, many players have been acquired by larger companies, although a few independent platform companies still exist, including Dyax, Morphosys, Regeneron and Adimab.

<sup>1)</sup> Datamonitor

<sup>2)</sup> Tufts Center for the Study of Drug Development – Impact Report November/December 2011.



### Haematological cancers

BioInvent develops antibody-based drugs to treat haematological cancers, as well as therapies which, by affecting normal blood cells, can become new treatments for several other types of cancer. There are many types of cells with various functions in the blood and all of them can be turned into cancer cells. Some examples of cells that give rise to various types of haematological cancer are lymphocytes (B-lymphocytes and T-lymphocytes) and myeloid cells (neutrophils and macrophages).

### Lymphoma

Lymphoma is an umbrella term used for a number of tumour diseases originating from lymphocytes. The prognosis and treatment depends on the type of lymphoma. Most types of lymphoma mainly affect older people. Lymphoma can be divided roughly into Hodgkin's lymphoma, high-grade and low-grade B-cell lymphomas, and T-cell lymphoma. In total there are more than sixty types of lymphoma.

### Leukaemia

Leukaemia is a collective term for cancer-like haematological diseases in the blood-building bone marrow resulting in an uncontrolled in-

crease in the number of white blood cells. Leukaemia is usually divided into two sub-types: myeloid and lymphatic leukaemia. Acute leukaemia occurs from immature cells and develops rapidly, often within a few weeks. Chronic leukaemia has a slow disease progression and can progress for many years without the need for treatment. Both types of leukaemia can consist of tumour cells/cancer cells with a lymphatic or myelogenic origin. Acute lymphatic leukaemia is the most common in children and chronic lymphatic leukaemia as well as acute myeloid leukaemia are most common on adults. Symptoms of leukaemia are that people bruise easily and sores take a long time to heal, as well as anaemia due to disruptions in the production of red blood cells in the bone marrow. A lack of white blood cells also makes people more prone to infection.

### Myeloma

Myeloma is a difficult type of cancer which originates from B-cells and where there is a great need for improved therapies. About one in five patients with haematological cancer have myeloma, which is why large sums of money are invested in research and development in the pharmaceutical industry in this area.

### Shorter lead times and lower development costs for orphan drugs

When a new therapy has the potential to add significant value for patients, the US Food and Drug Administration (FDA) may, in certain cases, expedite and simplify the drug registration process through its Expedited Programs. The Expedited Programs are an option that was introduced in 2012 to give priority to relevant drug candidates. Under the program, pharmaceutical companies have a dialogue at an early stage with the FDA and receive support from the agency in planning their study programmes. They can also register a drug based on less data than is normally required, and in certain cases are given the option of a concurrent registration process. The time to registration – if a drug is efficacious and safe – can be significantly reduced compared to the traditional clinical review process for registration. This means that products can be launched onto the market faster and at a significantly lower cost than would be the case in the normal drug registration process. Patients who are seriously ill can benefit from new, innovative treatments at an earlier stage than would otherwise be possible.

### Market for multiple myeloma

BioInvent's BI-505 drug candidate has been developed to treat multiple myeloma, a haematological cancer that occurs in the patient's bone marrow.

Multiple myeloma accounts for about 1 percent of all cancer cases and 13 percent of the number of cases of haematological cancer, which makes it the second most common haematological cancer after non-Hodgkin lymphoma. In the western world, an average of 5.6 new cases of multiple myeloma per 100,000 people are registered every year, which is equivalent to around 60,000 new cases a year<sup>1)</sup>. The disease usually occurs among older people; the average patient is age 70 at diagnosis.

The pharmaceutical market in the multiple myeloma indication is expected to amount to around USD 8.2 billion in 2022. The two largest drugs are Revlimid® (Celgene) and Velcade® (Takeda/Johnson & Johnson). Sales of Revlimid® amounted to around USD 4.9 billion in 2014 and Velcade® to around USD 1.7 billion<sup>2)</sup>, as a result, among other things, of the fact that the treatment is being administered increasingly often at an early stage in the disease. Another reason for the market growth is that older medicines are being replaced by new and more effective ones with a higher price point. The substances that have the highest potential to compete with BI-505 are antibodies that are still in clinical development, primarily elotuzumab (Bristol-Myers Squibb) and daratumumab (Genmab/Johnson&Johnson).

### The haematological cancer market

BioInvent's BI-1206 drug candidate is being developed to treat haematological cancer, primarily non Hodgkin Lymphoma. BioInvent believes there is significant market potential for treatment with BI-1206 in combination with other antibodies. In 2014, sales of Rituxan/Mabthera® alone amounted to USD 5.6 million<sup>2)</sup>, most of which were in the area of haematological cancer. In various studies up to half of all cancer patients who responded to an initial course of Rituxan/Mabthera® proved to be resistant to the drug on recurrence of the disease.

In 2013 the market for pharmaceutical treatment of non Hodgkin lymphoma (the US, Japan, the UK, Germany, France, Italy, Spain and Canada) was estimated at USD 5.6 billion and is expected to rise to USD 9.2 billion by 2019<sup>3)</sup>. These markets have an estimated annual growth rate of 8 percent.

The main competitors in the market for haematological cancers, are Rituxan®, Arzerra® (GSK – Glaxo Smith Kline), Treanda® (Cephalon/ TEVA) and Revlimid® (Celgene).

<sup>1)</sup> National Cancer Institute, statistics review 1975 – 2007.

<sup>2)</sup> Company 2014 results

<sup>3)</sup> GBI Research

## BIOINVENT'S ORGANISATIONAL STRUCTURE:

# Increased focus on clinical development and licensing deals

BioInvent's operations centre around developing new antibodies against life-threatening diseases based on the Company's unique scientific expertise and technology platforms. But to create good profitability more activity is needed. The value of the projects increase if they are managed professionally in the clinical development phase. The Company's revenue is entirely dependent on the ability to attract new collaboration and licensing partners. BioInvent has therefore in recent years reinforced its resources in clinical development and marketing.

## Selling drug projects

Not even drug projects that are highly innovative have the ability to sell themselves. Like other businesses, the success of research companies also depends on professional marketing, albeit in a more sophisticated form than in many other sectors. What is needed is arduous footwork, structured networking in the industrial pharmaceutical industry and constant contact with key representatives for potential licensees. The time from the first contact with an interested customer, to the signing of a partnership agreement is not measured in weeks but in years. Marketing of drug projects requires good continuity, a first-class personal network of contacts and an ability to discuss both scientific and commercial aspects. BioInvent has in recent years reinforced its resources in these important areas, both by recruiting people to the Company and in partnerships with leading international consultants.

Jeff Davies is responsible for marketing BioInvent's projects and technology platforms in the US. Jeff, who is based on Boston, has been involved in thirty or so licensing transactions for a total value of more than USD 1 billion.

### How well to you think BioInvent's drug projects meet the needs of the larger companies?

"Monoclonal antibodies are playing a bigger and bigger role in the treatment of cancer, and demand for drug projects aimed at new target structures is great from the global pharmaceutical companies. This applies above all to the antibodies that can be used against diseases where today's drug therapies are insufficient. I have noticed a great interest in the very types of drugs that BioInvent is working on. You don't always find yourself in that enviable position when you're working on drug project outlicensing. Also, BioInvent's projects are characterized by high quality, robust data and a well thought-through IP strategy, which further facilitates discussions with potential partners. Since most companies want to see clinical effect data, the results from the studies planned for BioInvent's projects will be extremely valuable in outlicensing efforts over the next few years."

### Which projects are attracting the most interest among potential partners?

"Interest is great in general, but I would highlight our projects aimed at T-reg and TAM – here we are seeing a lot of interest from just about every large oncology company, including in the preclinical phase."

### What is the most important aspect of your work to promote interest among big pharma in BioInvent's technology platforms and projects?

"A large measure of patience and tenacity – bringing about a partnership agreement is a long and complicated process, and you have to be able to handle both commercial and scientific discussions. It's about steadily building trust, informing the other party more and more about the project and hopefully being able to present new, promising data during the course of the discussion. Publishing new research results in highly reputable scientific journals and at conferences can do wonders to increase interest and get more potential partners into the process."

### BioInvent's organisational structure

BioInvent's organisational structure is divided into four divisions: Preclinical Research and Development, Technical Operations, Clinical Development, and Business Development. These divisions work in an integrated way to create the best possible conditions for the various research projects to succeed.

The research division is divided into Antibody Discovery which is responsible for development the technology platforms F.I.R.S.T.<sup>™</sup> and n-CoDeR<sup>®</sup>, and the Oncology Team which develops antibodies for BioInvent's own project portfolio.

Technical Operations works on the production of antibodies for clinical studies, quality assurance, protein chemistry and analytical chemistry.

The Clinical Development and Business Development divisions are described above.

As of 31 December 2014 BioInvent had 37 employees, 31 of whom work in research and development. 93 percent of Company's employees have university degrees and 35 percent have PhDs.



“BioInvent has solid scientific expertise in immuno-oncology. The Company is now building on this expertise by entering into partnerships with some of the world’s leading clinics in haematological cancer.”

**Anna Wickenberg**



## A mature pipeline is worth more

Over the past few years BioInvent has spent a significant amount of time and resources on enabling selected projects to enter clinical development. Soon after the beginning of the year the Company made a key recruitment in the form of Anna Wickenberg, who was appointed as Vice President Clinical Development. Anna is a doctor in medical sciences specialising in immunology and has a Master’s degree in molecular biology. She has 15 years of experience of directing clinical development projects from various positions at Teva Pharmaceuticals, Neurosearch and AstraZeneca.

### Has a small company like BioInvent really got the expertise and resources to run substantial and complicated clinical trials?

“BioInvent has solid scientific expertise in immuno-oncology. The Company is now building on this expertise by entering into partnerships with some of the world’s leading clinics in haematological cancer. These types of partnerships make it possible to conduct the initial phase I and phase II studies with our projects. Then we look for partnerships with global pharmaceutical companies to take the projects through the final development phases. Our partnership with CRUK for BI-1206 is the first example of a project where we get access to powerful resources to implement clinical studies, without the need to build up a big organization for this ourselves. But BioInvent is also evaluating projects in so-called ultra-orphan indications – here, clinical development requires fewer resources, which enables us to develop them much further on our own.”

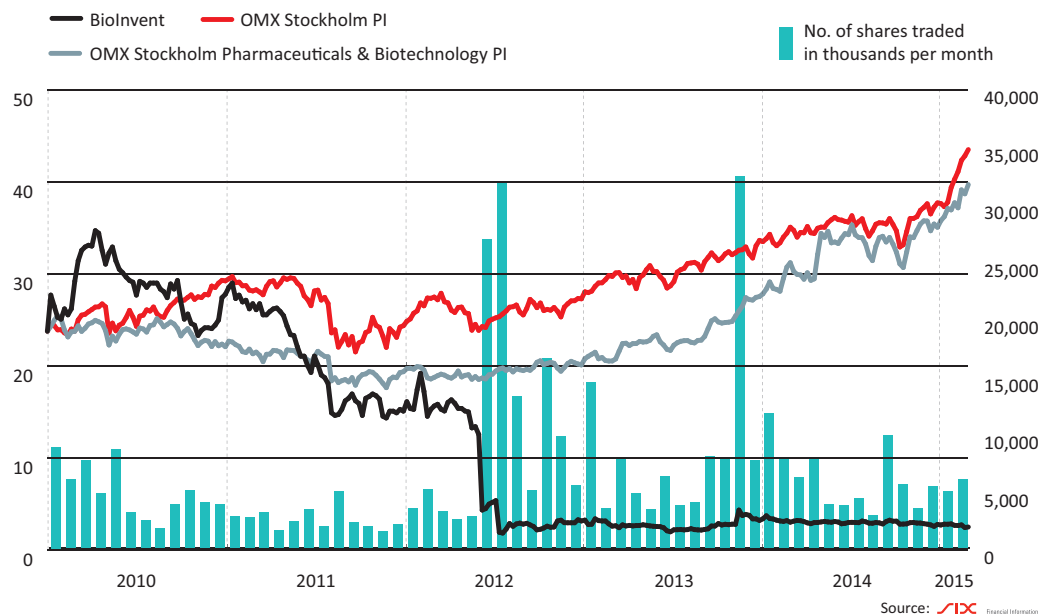
### Which clinical trials are next for BioInvent?

“Next up is a phase I/II study with BI-1206 in patients with non-Hodgkin lymphoma which will be conducted by Cancer Research UK (CRUK). We are also planning to work with University of Pennsylvania to conduct a phase IIa study with BI-505 in combination with Revlimid in patients with multiple myeloma who have undergone stem cell transplantation. In cooperation with researchers and physicians in the US, we are also looking at some other indications that might be interesting for clinical studies with BI-505. We are also working on starting a phase I/II study with TB-403 in cooperation with our partner ThromboGenics.”

### Can you describe the partnership with CRUK on the BI-1206 project?

“The partnership with CRUK is extremely important to us for a number of reasons. It gives us full financing of a relatively large phase I/II study with one of our most interesting drug candidates, without requiring us to relinquish control of the rights to the project. Plus we get access to CRUK’s knowledge and experience in cancer drug research and development. Last but not least, we get a partner with the capacity to conduct a multi-centre clinical study. A positive outcome in the planned study would put us in a strong position to sign a lucrative commercial partnership agreement with a larger pharmaceutical company,” says Anna Wickenberg.

# The BioInvent share



BioInvent has been listed on NASDAQ Stockholm since 2001.

## Price trend and trading volume

In 2014, the share price decreased 21 %, from SEK 3.39 to SEK 2.67. During 2014 the OMX Stockholm\_PI increased 12 % and OMX Stockholm Pharmaceuticals & Biotechnology\_PI increased 29 %. The highest price paid in 2014 was SEK 3.81 and the lowest price was SEK 2.44. BioInvent's market capitalization totalled SEK 301 million at the end of 2014.

During the year 70.5 million (97.1) BioInvent shares were traded for a value of SEK 218 million (315). This corresponds to a rate of turnover of 69 % (139).

Average trading volume per trading day was 282,984 (388,466) shares for a value of SEK 0.9 million (1.3). Average number of trades per trading day were 87 (110).

## Largest shareholders, 31 December 2014

	No. of shares	Percentage of capital and votes
Van Herk Investments B.V.	18,277,620	16.2
B&E Participation AB	8,310,021	7.4
Avanza Pension Försäkring	6,610,883	5.9
Staffan Rasjö	4,537,227	4.0
Rhenman Healthcare Equity L/S	4,347,831	3.9
Nordnet Pensionsförsäkring	4,319,715	3.8
Peter Hoglin	4,232,832	3.8
East Bay AB	2,312,728	2.1
Pershing LLC	2,117,776	1.9
Mikael Lönn	1,840,000	1.6
Other shareholders	55,883,417	49.5
<b>Total</b>	<b>112,790,050</b>	<b>100.0</b>

## Ownership structure

In 2014, the number of shareholders decreased 4 %, from 6,651 to 6,357. Foreign owners held 26 % (33) of the share capital and votes. The ten largest shareholders owned 50 % (52) of the shares.

## Analysts covering BioInvent

Klas Palin – Redeye, Stockholm

## Share capital

The extraordinary general meeting in March 2014 approved the Board of Directors' resolutions in February 2014 to carry out a new share issue with pre-emptive rights for shareholders of SEK 48.9 million and a directed new share issue of SEK 15.0 million. The new share issues were completed in April 2014 and amounts to a total of SEK 63.9 million before issue costs. The subscription price for the new share issues was set to SEK 2.30 per share. The rights issue was oversubscribed. The shares in the directed new share issue have been subscribed by two investors of institutional character; Henrik Rhenman through Rhenman Healthcare Equity L/S and Peter Thelin through East Bay AB. After the share issue the share capital consists of 112,790,050 shares.

If fully exercised, Employee Incentive Programme 2011/2015 and Employee Incentive Programme 2013/2017 will represent a dilution equivalent to around 1.1 percent of the shares in the Company. The Company's Employee Incentive Programmes are described on page 46.

There is only one class of share. Each share entitles the holder to one vote at shareholders' meetings and all shares carry equal rights to the Company's assets and profit.



## Dividend and dividend policy

The Board of Directors do not recommend payment of any dividend for the 2014 financial year. The Company will continue to focus on research and development of new products. Available financial resources will be used to finance these projects. The Board of Directors therefore do not recommend that any dividend be paid for the next few years.

## Distribution of financial reports

Annual reports will be sent to shareholders upon request and may be ordered at the address BioInvent international AB, 223 70 Lund, or by fax +46 (0)46-211 08 06, or telephone +46 (0)46-286 85 50, or by e-mail [info@bioinvent.com](mailto:info@bioinvent.com). The annual report is published in Swedish and English.

## Upcoming financial information

Interim reports: 22 April, 22 July, 22 October 2015

## Share statistics, 31 December 2014

Size of holdings	No. of shareholders	No. of shareholders, %	No. of shares in %
1–500	2,211	34.8%	0.4%
501–1,000	817	12.9%	0.6%
1,001–2,000	928	14.6%	1.2%
2,001–5,000	990	15.6%	2.9%
5,001–10,000	549	8.6%	3.7%
10,001–20,000	396	6.2%	5.2%
20,001–50,000	287	4.5%	8.2%
50,001–100,000	84	1.3%	5.4%
100,001–500,000	71	1.1%	11.5%
500,001–1,000,000	8	0.1%	4.9%
1,000,001–5,000,000	13	0.2%	26.4%
5,000,001–10,000,000	2	0.0%	13.2%
10,000,001–50,000,000	1	0.0%	16.2%
<b>Total</b>	<b>6,357</b>	<b>100.0%</b>	<b>100.0%</b>

## Changes in the share capital

Year	Transaction	Increase in share capital, SEK	Increase in no. of shares	Share capital, SEK	Share capital, no. of shares	Ratio value
1996	BioInvent International AB was founded <sup>1)</sup>			100,000	10,000	10.00
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 <sup>2)</sup>	181,000	181,000	1,145,260	1,145,260	1.00
1999	New share issue <sup>3)</sup>	108,527	108,527	1,253,787	1,253,787	1.00
2000	New share issue <sup>4)</sup>	250,000	250,000	1,503,787	1,503,787	1.00
2000	Warrants exercised	11,013	11,013	1,514,800	1,514,800	1.00
2001	Bonus issue	9,846,200		11,361,000	1,514,800	7.50
2001	Share split 1:15		21,207,200	11,361,000	22,722,000	0.50
2001	Warrants exercised	461,152.5	922,305	11,822,152.5	23,644,305	0.50
2001	New share issue <sup>5)</sup>	2,250,000	4,500,000	14,072,152.5	28,144,305	0.50
2002	New share issue <sup>6)</sup>	665,625.5	1,331,251	14,737,778	29,475,556	0.50
2005	New share issue <sup>7)</sup>	8,842,666.5	17,685,333	23,580,444.5	47,160,889	0.50
2007	New share issue <sup>8)</sup>	4,250,000	8,500,000	27,830,444.5	55,660,889	0.50
2010	New share issue <sup>9)</sup>	2,717,400	5,434,800	30,547,844.5	61,095,689	0.50
2011	New share issue <sup>10)</sup>	3,054,784	6,109,568	33,602,628.5	67,205,257	0.50
2012	New share issue <sup>11)</sup>	3,360,263	6,720,525	36,962,891	73,925,782	0.50
2013	Reduction of the share capital	-31,048,828		5,914,063	73,925,782	0.08
2013	New share issue <sup>12)</sup>	887,109	11,088,867	6,801,172	85,014,649	0.08
2014	New share issue <sup>13)</sup>	2,222,032	27,775,401	9,023,204	112,790,050	0.08

<sup>1)</sup> BioInvent International AB was established by its managers, Stiftelsen Industrifonden, Pronova a.s. and Aragon Fondkommission.

<sup>2)</sup> In November 1998 the Company issued 181,000 new shares aimed at institutional investors. The issue price was SEK 125 and SEK 22.6 million was raised after deductions of issue costs.

<sup>3)</sup> In November 1999 the Company issued 108,527 new shares aimed at institutional investors. The issue price was SEK 175 and SEK 18.7 million was raised after deductions of issue costs.

<sup>4)</sup> 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.

<sup>5)</sup> 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.

<sup>6)</sup> In March 2002, the Company carried out a directed issue of 1,331,251 new shares for Oxford GlycoSciences. The issue price was SEK 39 and this raised SEK 52.0 million. There were no issue costs.

<sup>7)</sup> In November 2005 the Company carried out a new share issue. The issue price was SEK 9 and SEK 146.2 million was raised after deductions of issue costs.

<sup>8)</sup> In July 2007 the Company carried out a directed issue. The issue price was SEK 14.75 and SEK 120.0 million was raised after deductions of issue costs.

<sup>9)</sup> 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.

<sup>10)</sup> 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.

<sup>11)</sup> 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.

<sup>12)</sup> 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.

<sup>13)</sup> 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.

# Five-year review

INCOME STATEMENT, SEK MILLION	2014	2013	2012	2011	2010
Net sales	46.9	81.7	42.9	124.6	82.9
Research and development costs	-73.4	-71.2	-207.3	-163.9	-178.9
Sales and administrative costs	-31.9	-30.2	-39.2	-32.6	-32.2
Other operating revenues and costs	3.4	0.5	12.5	0.2	0.4
	-101.9	-100.9	-234.0	-196.3	-210.7
<b>Operating profit/loss</b>	<b>-54.9</b>	<b>-19.2</b>	<b>-191.1</b>	<b>-71.7</b>	<b>-127.8</b>
Net financial items	0.9	1.1	3.2	4.6	-0.6
<b>Profit/loss before tax</b>	<b>-54.0</b>	<b>-18.0</b>	<b>-187.8</b>	<b>-67.1</b>	<b>-128.4</b>
Tax	–	–	–	–	–
<b>Profit/loss for the year</b>	<b>-54.0</b>	<b>-18.0</b>	<b>-187.8</b>	<b>-67.1</b>	<b>-128.4</b>
BALANCE SHEET, SEK MILLION	2014	2013	2012	2011	2010
Intangible fixed assets	0.0	0.0	0.0	1.9	3.1
Tangible fixed assets	2.3	3.9	6.8	11.0	11.2
Financial fixed assets	4.5	–	–	–	–
Inventories	0.1	0.2	0.2	0.3	0.7
Current receivables	21.6	12.6	9.5	18.7	17.0
Liquid funds	45.6	64.7	100.1	174.0	106.1
<b>Total assets</b>	<b>74.1</b>	<b>81.4</b>	<b>116.5</b>	<b>205.8</b>	<b>138.0</b>
Shareholders' equity	52.4	49.0	47.6	138.0	74.2
Non-interest-bearing liabilities	21.7	32.4	68.9	67.8	63.8
Interest-bearing liabilities	–	–	–	–	–
<b>Total shareholders' equity and liabilities</b>	<b>74.1</b>	<b>81.4</b>	<b>116.5</b>	<b>205.8</b>	<b>138.0</b>
CASH FLOW, SEK MILLION	2014	2013	2012	2011	2010
Operating profit/loss	-54.9	-19.2	-191.1	-71.7	-127.8
Adjustments for depreciation, interest and other items	2.7	3.9	11.1	12.3	12.6
Changes in working capital	-23.8	-39.4	9.7	3.9	-2.4
<b>Cash flow from current operations</b>	<b>-76.0</b>	<b>-54.7</b>	<b>-170.4</b>	<b>-55.5</b>	<b>-117.7</b>
Cash flow from investment activities	-0.4	0.0	-0.1	-4.9	-4.6
<b>Cash flow from current operations and investment activities</b>	<b>-76.4</b>	<b>-54.7</b>	<b>-170.4</b>	<b>-60.4</b>	<b>-122.3</b>
Cash flow from financing activities	57.3	19.4	96.5	128.3	144.4
<b>Increase/decrease in liquid funds</b>	<b>-19.1</b>	<b>-35.3</b>	<b>-73.9</b>	<b>67.9</b>	<b>22.1</b>



KEY FINANCIAL RATIOS	2014	2013	2012	2011	2010
Net revenue growth, %	-42.6	90.3	-65.5	50.4	2.7
Net working capital, SEK million	0.0	-19.7	-59.2	-48.9	-46.1
Net working capital/net sales, %	0.0	-24.1	-137.9	-39.2	-55.7
Operating capital, SEK million	6.8	-15.7	-52.4	-36.0	-31.9
Operating capital/net sales, %	14.5	-19.3	-122.1	-28.9	-38.5
Capital employed, SEK million	52.4	49.0	47.6	138.0	74.2
Capital employed/net sales, %	111.7	60.0	110.9	110.7	89.5
Shareholders' equity, SEK million	52.4	49.0	47.6	138.0	74.2
Return on shareholders' equity, %	-106.4	-37.3	-202.4	-63.2	-197.8
Return on capital employed, %	-106.4	-37.3	-202.4	-63.2	-197.8
Capital turnover, times	0.9	1.7	0.5	1.2	1.3
Equity/assets ratio, %	70.7	60.2	40.9	67.0	53.7
Intangible fixed assets investments, SEK million	-	-	-	-	-
Tangible fixed assets investments, SEK million	0.4	0.0	0.1	4.9	4.6
Average number of employees	38	47	76	89	96
Net sales per employee, SEK million	1.2	1.7	0.6	1.4	0.9

DATA PER SHARE	2014	2013	2012	2011	2010
Earnings per share, SEK					
Before dilution	-0.53	-0.23	-2.61	-1.04	-2.12
After full dilution	-0.53 <sup>1)</sup>	-0.23 <sup>1)</sup>	-2.61 <sup>1)</sup>	-1.04 <sup>1)</sup>	-2.12 <sup>1)</sup>
Shareholders' equity per share, SEK					
Before dilution	0.46	0.58	0.64	2.05	1.21
After full dilution	0.46 <sup>2)</sup>	0.58 <sup>2)</sup>	0.64 <sup>2)</sup>	2.05 <sup>2)</sup>	1.19
Cash flow per share, SEK	-0.75	-0.70	-2.37	-0.93	-2.02
Average no. of shares					
Before dilution (thousands)	101,989	78,084	72,022	64,660	60,522
After full dilution (thousands)	101,989 <sup>2)</sup>	78,084 <sup>2)</sup>	72,022 <sup>2)</sup>	64,660 <sup>2)</sup>	61,542
Number of shares at end of period					
Before dilution (thousands)	112,790	85,015	73,926	67,205	61,096
After full dilution (thousands)	112,790 <sup>2)</sup>	85,015 <sup>2)</sup>	73,926 <sup>2)</sup>	67,205 <sup>2)</sup>	62,151
Share price, 31 December, SEK	2.67	3.39	3.30	16.10	29.70

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

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

The 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

### Net working capital

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

### Operating capital

The balance sheet total less non-interest-bearing liabilities, other non-interest-bearing provisions and current investments and liquid funds.

### Capital employed

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

### Return on shareholders' equity

Profit/loss after financial items as a percentage of the average shareholders' equity.

### Return on capital employed

Profit/loss after financial items plus financial costs as a percentage of average capital employed.

### Capital turnover

Net revenue divided by the average capital employed.

### Equity/assets ratio

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

### Average number of employees

Weighted average number of employees during the year.

### Earnings per share

Profit/loss after financial items divided by the average number of shares.

### Shareholders' equity per share

Shareholders' equity divided by the number of shares at the end of the period.

### Cash flow per share

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

# The Board and Auditors



## Björn O. Nilsson

### Chairman of the Board

Doctor of Science. Born in 1956. Lives in Sollentuna, Sweden. Professor, CEO and member of the Royal Swedish Academy of Engineering Sciences. Associate professor at the Royal Institute of Technology (KTH) in Stockholm. Member of the Board since 1999. Chairman of the Board since 2011. Member of the Audit Committee.

### Other board appointments:

Vice Chairman of the Board of Ångpanneföreningen's Foundation for Research and Development. Member of the Boards of ÅF AB and SwedNanoTech AB.

**Shareholding:** 23,571



## Vessela Alexieva

### Employee representative

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

### Other board appointments:

**Shareholding:** 20,850 (own and affiliated holdings)

**Employee options:** 3,750



## Lars Backsell

B.Sc. in Economics at SSE and has completed AMP at Insead. Born in 1952. Lives in Stockholm, Sweden. Previous roles include CEO of Recip AB and senior positions within Pharmacia AB and Coloplast A/S. Member of the Royal Swedish Academy of Engineering Sciences. Member of the Board since 2010. Member of the Audit Committee.

### Other board appointments:

Chairman of the Boards of Recipharm AB and Backsell Elderred Holding AB. Member of the Boards of B&E Participation AB, Rohirrim AB and Skärmare Drifts AB.

**Shareholding:** 8,310,021 (through companies)



## Dharminder Chahal

M.Sc. in Aerospace Engineering and M.Sc. in Business Economics. Born in 1976. Lives in Netherlands. Founder of Skyline Dx. CEO and co-founder of CardioGenx. Consultant to the Van Herk Groep. Member of the BioInvent Board since 2013. Member of the Audit Committee.

### Other board appointments:

Member of the Board of VitalneXt B.V., Agencia Inc. and Isobionics.

**Shareholding:** 97,856



## Lars Ingelmark

Bachelor of Medicine. Born in 1949. Lives in Halmstad, Sweden. Consul of Luxembourg. Member of the Board since 2006. Chairman of the Audit Committee.

### Other board appointments:

Chairman of the Boards of Svensk Vätmarksfond and Skedala Säteri AB. Member of the Boards of Gytörp AB and Svenska Jägarförbundet.

**Shareholding:** 1,100



## Jonas Jendi

M.Sc. in Economics, Stockholm School of Economics. Born in 1970. Lives in Stockholm, Sweden. Previous roles include CEO of Cogmed Systems AB. Member of the Board since 2013.

### Other board appointments:

Chairman of the Board of Hoa's Tool Shop AB. Member of the Board of AB Leichte & Jendi and Imsys AB, CEO and member of the Board of Franz Besserwisser AB.

**Shareholding:** 5,000



## Elisabeth Lindner

M.Sc., MBA. Born in 1956. Lives in Stockholm, Sweden. CEO of OxThera AB. Member of the Royal Swedish Academy of Engineering Sciences. Member of the Board since 2005.

### Other board appointments:

Chairman of the Board and CEO of Biosource Europe AB. Member of the Board of Cobra Biologics AB.

**Shareholding:** 10,056



## Ulrika T. Mattson

### Employee representative

University degree in Biomedical Laboratory Science. Born in 1968. Lives in Malmö, Sweden. Biomedical Scientist. Member of the Board since 2007.

### Other board appointments:

**Shareholding:** 400 (own and affiliated holdings)

**Employee options:** 3,750

## Auditors

### KPMG AB

Auditor in charge: Alf Svensson, Authorised Public Accountant. Born in 1949. Lives in Bjärred, Sweden. Auditor for BioInvent International AB since 2012.



# Senior management



## Michael Oredsson

### President and CEO

Degree in International Business Administration from Lund University. Born 1960. Lives in Beddingestrand, Sweden. Employed since 2013. He was CEO of Probi AB 2007-2013. Former CEO of Biosignal in Australia, 2002-2007, and Nutripharma in Norway, 1999-2001. Before that he was responsible for building up Pharmacia's OTC product division in Australia. He also held senior marketing positions at Nestlé and Mars Inc in Sweden, Germany and France. Chairman of the Board of LIDDS AB. Member of the Board of SP Technical Research Institute of Sweden.

**Shareholding:** 43,000

**Employee options:** 8,219



## Björn Frendéus

### Chief Scientific Officer

Doctor of Immunology. Born in 1973. Lives in Landskrona, Sweden. Employed since 2001. Graduated from the Swedish Foundation for Strategic Research funded Biomedicine programmes within the Infection & Vaccinology programme in 2001. Honorary Professor at University of Southampton.

**Shareholding:** 804 (own and affiliated holdings)

**Employee options:** 6,000



## Per-Anders Johansson

### Senior Vice President, Technical Operations

M.Sc., Chemistry. Born in 1955. Lives in Kivik, Sweden. Employed since 1984. Over 25 years' experience of process development and manufacturing of antibodies for clinical use. Quality assurance and GMP regulatory expertise.

**Shareholding:** 250,300

**Employee options:** 6,000



## Anna Wickenberg

### Vice President, Clinical Development

Doctor in Medical Sciences, Immunology, and M.Sc. in Molecular Biology. Born in 1974. Lives in Lund, Sweden. Employed since 2015. Responsible for the clinical development of BioInvent's drug development projects. She has 15 years of experience of leading clinical development projects from various positions at Teva Pharmaceuticals, NeuroSearch, and AstraZeneca. Most recently, Anna was responsible for the clinical development of new chemical entities in an orphan indication within CNS at Teva.

**Shareholding:** -

**Employee options:** -

# Directors' report

The Board of Directors and the CEO of BioInvent International AB (publ), co. reg. no. 556537-7263, hereby present the annual accounts and consolidated accounts for the financial year 1 January–31 December, 2014. The Company is registered in Sweden and is located in the Lund municipality. The visiting address is Sölvegatan 41, Lund and the postal address is 223 70 Lund. The descriptions below of the status of BioInvent's projects are current at the time this annual report was presented.

## Operations

BioInvent International AB, listed on the NASDAQ Stockholm (BINV), is a research-based pharmaceutical company focused on discovery and development of innovative antibody-based drugs against cancer.

The company has unique expertise in antibody drug development from initial concept to late clinical phase. The screening tool F.I.R.S.T.<sup>™</sup> and the antibody library n-CoDeR<sup>®</sup> are two patented tools that enable identification of relevant human antibodies and disease targets during the discovery phase. BioInvent has also considerable experience in and a facility for process development and production of antibodies for clinical studies. The scope and strength of this platform is also used to develop antibody-based drugs in collaboration with partners who finance the development of new drugs, and provide BioInvent with the right to milestone payments and royalties on sales. These partners include Bayer Pharma, Daiichi Sankyo, Mitsubishi Tanabe Pharma, Servier, and Xoma.

## Project overview

### Multiple myeloma (BI-505)

#### Background

Every year an estimated 40,000 patients become ill with the haematological disease multiple myeloma. Multiple myeloma is an incurable cancer for which there are no good drugs to prevent the relapses that affect all patients after treatment with cytotoxic drugs or after a stem cell transplant. Expression of an adhesion protein, ICAM-1 (also called CD54), is elevated in myeloma cells, which makes it a suitable target for a drug candidate. The BI-505 drug candidate is a human antibody that specifically binds to the ICAM-1. BI-505 affects tumours in two ways – by inducing cell death of myeloma cells and by engaging the patient's immune cells, known as macrophages, to attack myeloma cells. Macrophages are abundant in the bone marrow of myeloma patients, where they are thought to contribute to disease progression and development of resistance to currently available drugs. BI-505 has the ability to get macrophages to attack myeloma cells and has, in several relevant animal models, proved to be more effective at killing tumours than existing drugs. The good safety profile and the effectiveness of the substance against cancer cells that do not bind to tumours, even where these are expressed in low quantities, makes BI-505 especially suitable in preventing multiple myeloma relapses.

#### Project status

The initial results from the phase I study of BI-505 on patients in advanced stages of multiple myeloma showed that the substance has a good safety profile. In the dosage groups to which extended therapy was offered, 24 percent of these severely ill patients

demonstrated stable disease for at least two months, which indicates a positive effect of BI-505, and is in parity with Phase I data from other monoclonal antibodies in clinical development for multiple myeloma. Results from the phase I study were presented in an international conference on multiple myeloma in Kyoto, Japan, and were published in the scientific journal, *Clinical Cancer Research*, in February 2015. New preclinical data was also presented on the same occasion showing significantly enhanced anti-tumour activity compared with monotherapy when combining the registered drugs Velcade<sup>®</sup> or Revlimid<sup>®</sup> with BI-505.

The scientific journal, *Cancer Cell*, presented data showing preclinical proof-of-concept for both BI-505 and for BioInvent's function-based F.I.R.S.T.<sup>™</sup> platform. The article presents data showing the potent action of BI-505 in several preclinical multiple myeloma models.

In April 2013 a phase II study in patients with asymptomatic smoldering myeloma was initiated. The study has now been prematurely terminated due to a strategic review of the commercial potential of BI-505 in light of the preclinical and clinical data package. BI-505 will be repositioned to target residual disease in combination with "sledgehammer" treatments and after stem-cell transplantation in patients with myeloma. Asymptomatic multiple myeloma is currently not treated with drugs because the side effects are not acceptable in symptom free patients. This indication therefore has very limited commercial potential and the development path is expected to be relatively complicated.

Instead, a clinical study in collaboration with Penn Medicine will be initiated to investigate the potential of BI-505 to deepen the response after autologous stem cell transplantation in combination with low dose Revlimid<sup>®</sup>. BioInvent has also identified an opportunity to develop BI-505 in other orphan indications, and is evaluating parallel clinical development of these at a significantly lower cost and in a shorter timeframe compared with the multiple myeloma indication.

BI-505 has received Orphan Drug Designation for the multiple myeloma indication by both the U.S. Federal Drug Administration (FDA) and European Medicines Agency (EMA).

### Non-Hodgkin lymphoma and chronic lymphatic leukemia (BI-1206)

#### Background

Non-Hodgkin lymphoma (NHL) is an umbrella term for a group of cancers that develop in the body's lymphatic system. Since lymphatic tissue is present throughout the body, lymphoma can start anywhere. High-grade lymphoma is treated with radiation and/or cytostatic drugs and in many cases with rituximab (Rituxan<sup>®</sup>, Mabthera<sup>®</sup>, Roche). Low-grade lymphoma has a better prognosis and treatment is often only initiated once a patient has disease symptoms.

Chronic lymphatic leukaemia (CLL) is an incurable lymphoma that normally affects older men. The disease progression is often slow and patients are normally treated with cytostatic drugs, often in combination with monoclonal antibodies.

In Europe and North America, around 157,000 people every year are diagnosed with NHL and around 35,000 with chronic lymphatic leukaemia (CLL).

BioInvent's drug candidate BI-1206 is a fully human antibody aimed at CD32b, an immunosuppressive protein that is over-



expressed in patients with lymphoma, especially in patients who respond poorly to currently available drugs like anti CD20 treatment, rituximab.

It is well known that CD32b is involved in the development of resistance to current state-of-the-art treatments for NHL and CLL – rituximab. In models for different cancers, CD32b has also been shown to be involved in the development of resistance to treatment with other antibodies. BI-1206 therefore has a very interesting mechanism with the potential for use in both NHL and CLL, as well as other cancer indications. As BI-1206 blocks the immunosuppressive effect of CD32b, the immune system can be stimulated, which can strengthen the therapeutic effect of both rituximab as well as other antibody-based drugs.

Combination therapy with BI-1206 and rituximab in clinically relevant animal models with tumour cells from patients with NHL has demonstrated significantly improved antitumour effects compared to monotherapy with rituximab. Combination therapy therefore has the potential to significantly improve the treatment of patients with this disease. A series of studies have shown that as many as half of the cancer patients who responded to an initial rituximab treatment proved to be resistant to the drug at relapse, which indicates a significant medical need for improved therapies for these patients.

BI-1206 has also shown a strong ability to kill lymphoma cells in preclinical models using tumour cells taken directly from patients. The results indicate that BI-1206 may have the potential to be used as a monotherapy.

### Project status

In January 2015 BioInvent entered into an agreement with Cancer Research UK (CRUK), Cancer Research Technology (CRT) and Leukaemia & Lymphoma Research (LLR) on implementation of a phase I/II study with BI-1206 in patients with chronic lymphatic leukaemia (CLL) and non-Hodgkin lymphoma (NHL). The first study in patients will be financed and executed by CRUK, CRT and LLR. BioInvent has the opportunity to utilise an exclusive licence for the study data in return for low milestone payments and royalties paid to Cancer Research Technology.

The plan is for this open phase I study to include 50–60 patients who will be treated either only with BI-1206 or BI-1206 in combination with rituximab. Patients with CLL will be recruited first, but smaller groups of patients with other types of NHL, such as mantle cell lymphoma, follicular lymphoma and diffuse large B cell lymphoma, may also be included in the study. The study is expected to start in the second half of 2015.

Alongside this clinical study, preclinical studies will continue, principally focused on proving the combination effects of BI-1206 and CD38 antibodies within multiple myeloma. CD38 antibodies constitute a new, very promising class of drug where market approval is pending in the multiple myeloma indication. Despite proven good effects in clinical studies, the data indicates that patients develop resistance to these new drugs as well, which shows that there is a medical need to complement this class of drugs to optimise the treatment of patients. In addition investigations regarding CD32b expression in subpopulations within NHL will be done, with the potential to identify the optimal population for treatment with BI-1206.

### Medulloblastoma (TB-403)

#### Background

Medulloblastoma and neuroblastoma are two life-threatening, debilitating cancer diseases that exclusively affect children and adolescents. Both diseases are rare and are diagnosed in just over ten individuals per million and year. Preclinical data from models for medulloblastoma with the monoclonal antibody TB-403 indicates the potential for better clinical results for these patients than with available therapies. The antibody will therefore be evaluated in a clinical study for this indication.

The TB-403 drug project is being run in cooperation with a subsidiary to the Belgian biopharma company ThromboGenics. BioInvent is paying half of the development costs and has the right to 40 percent of all future revenue from the project.

#### Project status

There are plans to start a new clinical study with TB-403 in children with medulloblastoma in the latter part of 2015. In addition to this, preclinical studies will evaluate the effect of the antibody in models for neuroblastoma. The antibody TB-403 has demonstrated an excellent safety profile in previous clinical trials in patients with liver cancer and glioblastoma. The decision to launch a new clinical trial and further preclinical evaluations is based on more detailed knowledge about the antibody's mechanism of action, which is described in an article published by Jain et al in the respected journal *Cell*. Before the start of the planned clinical trial, BioInvent will, in consultation with the medical products agencies in Sweden, the UK and the US, conduct certain additional preclinical trials.

The relatively high development risk of the project is being weighed against the favourable safety profile that TB-403 has demonstrated in earlier trials, the project's low development costs, and the possibility of using a faster development process than is normally the case.

#### Preclinical projects

BioInvent's preclinical research is aimed at expanding the Company's portfolio of drug candidates. Since 2012 the Company has focused its own research resources entirely on the cancer indication. Over the past decade the Company has accumulated a significant body of experience of relevant disease models within cancer biology and tumour immunology. The basis of the preclinical research is the test models used to identify the most effective and potent antibody candidates. These models make it possible to simultaneously conduct an extensive study of the safety and tolerability of the antibody, based on the biology of the disease and the mechanism of action of the antibody.

BioInvent's research is aimed at developing antibodies with the ability to kill tumour cells through apoptosis (programmed cell death) or by activating the body's own immune system. With the help of the F.I.R.S.T.™ platform, the Company is actively seeking new drug candidates for the treatment of different haematological cancers. BioInvent is also working with leading Swedish and international academic teams to gain access to new therapeutic concepts for the treatment of both serious haematological and solid cancers, which can serve as a basis for the development of new projects. One example is a partnership with Professor Martin Glennie and Professor Mark Cragg and their team at the University of Southampton with whom BioInvent is running several parallel collaborative immuno-oncology projects.

### External collaborations

The Company has had licensing agreements for some time and, in some cases, research collaborations with a number of external partners including Bayer Pharma and Daiichi Sankyo, Mitsubishi Tanabe Pharma, Servier and Xoma. The structure and terms of these agreements and partnerships vary, but they all have in common that BioInvent receives licence fees, research financing, milestone payments and royalties on the sale of commercial products. Of these external drug programmes, four projects are currently in phase I, four are in the preclinical phase and more than ten are in the early research phase.

### Personnel and organisation

BioInvent's operations consist of R&D and Technical Operations where work is done in an integrated way to create the best possible conditions for the various research projects. This enables the Company to benefit from the accumulated cancer and biology know-how, ensuring that prioritised research projects have the resources they need for their development.

The research department has the following two teams: the Antibody Discovery team which focuses on developing BioInvent's technology platforms, F.I.R.S.T.<sup>™</sup> and n-CoDeR<sup>®</sup>, and the Oncology Team which develops antibodies for BioInvent's own research portfolio. 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 treasury and IT.

As of 31 December 2014 BioInvent had 37 (43) employees, 31 (36) of whom work in research and development. 93 percent of the Company's employees have university degrees, including 35 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. Selfmonitoring is carried out to monitor the Company's operations on an ongoing basis to counteract and prevent negative environmental impact. As part of this self-monitoring process, the Company has introduced a description of environmental consequences and a plan for the self-monitoring process. In accordance with the plan, periodic inspections are carried out to check compliance with authorisations and current legislations.

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

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

### Quality and regulatory approval

The Company has a permit under the EU rules on producing investigational pharmaceutical products for clinical trials according to Good Manufacturing Practice (GMP). This permit was 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.

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.

### Revenues and result

Net sales amounted to SEK 47 million (82). Revenues for the period are derived from partners developing therapeutic antibodies from the n-CoDeR<sup>®</sup> antibody library and from sales of the Company's rights to the drug development candidate ADC-1013 to Alligator Bioscience AB. BioInvent received in 2013 a significant license fee when BioInvent and Bayer extended and broadened the collaboration for the development of therapeutic antibodies.

The Company's total costs amounted to SEK 105 million (101). Operating costs are divided between external costs of SEK 69 million (46), personnel costs of SEK 34 million (52) and depreciation of SEK 2.0 million (2.9). Personnel costs as per 31 December 2013 included a provision of SEK 2.1 million for dismissal payments to the former acting CEO Cristina Glad and provisions for restructuring costs (personnel costs) of SEK 4.4 million in connection with cutbacks in the work force. Research and development costs amounted to SEK 73 million (71).

During the period financial support from the EU's framework programme was reported for early research projects. The subsidy

amounted to SEK 3.4million (0.9) and has been reported in the income statement under "Other operating revenues and costs".

Earnings after tax amounted to SEK -54 million (-18). The net financial items amounted to SEK 0.9 million (1.1). Earnings per share before and after dilution amounted to SEK -0.53 (-0.23).

### Financial position and cash flow

As of 31 December 2014, the Group's liquid funds amounted to SEK 46 million (65). The cash flow from current operations and investment activities amounted to SEK -76 million (-55). In 2014 reported but not yet paid revenues and payment of restructuring costs from 2013 affected cash flow negatively in 2014. Payment of reserves from 2012 for remaining costs of the TB-402 project and for restructuring costs affected cash flow negatively in 2013.

The shareholders' equity amounted to SEK 52 million (49) at the end of the period. The Company's share capital at the end of the period was SEK 9.0 million. The equity/assets ratio at the end of the period was 71 (60) per cent. Shareholders' equity per share amounted to SEK 0.46 (0.58). The Group had no interest-bearing liabilities.

The five-year review is described on page 22.

### Investments

Investments in tangible fixed assets amounted to SEK 0.4 million (0.0). No investments were made in intangible assets during the period (-).

### Parent company

The BioInvent Group consists of the parent company, BioInvent International AB, and the subsidiary BioInvent Finans AB, which administers warrants issued by BioInvent International AB. Net sales amounted to SEK 47 million (82). Earnings after tax amounted to SEK -54 million (-18). The cash flow from current operations and investment activities amounted to SEK -76 million (-55). The Parent company coincides in every material way with the Group.

### The share

The BioInvent share has been listed on NASDAQ Stockholm since 2001.

The extraordinary general meeting in March 2014 approved the Board of Directors' resolutions in February 2014 to carry out a new share issue with pre-emptive rights for shareholders of SEK 48.9 million and a directed new share issue of SEK 15.0 million. The new share issues were completed in April 2014 and amounts to a total of SEK 63.9 million before issue costs. The subscription price for the new share issues was set to SEK 2.30 per share. The rights issue was oversubscribed. The shares in the directed new share issue have been subscribed by two investors of institutional character; Henrik Rhenman through Rhenman Healthcare Equity L/S and Peter Thelin through East Bay AB. After the share issue the share capital consists of 112,790,050 shares.

If fully exercised, Employee Incentive Programme 2011/2015 and Employee Incentive Programme 2013/2017 will represent a dilution equivalent to around 1.1 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 2014 authorised the Board of Directors to resolve on the issue of new shares on one or several occasions during the period up to the next annual general meeting. The number of shares to be issued by virtue of the authorization shall not exceed 15 per cent of the registered share capital (as per the date of the resolution on the issue of new shares). The Annual General Meeting has not authorised the Board of Directors to take decisions on acquisition of shares by the Company.

### Corporate governance report

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

### Future prospects

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

### Risks and risk management

#### Pharmaceutical development

Pharmaceutical development is generally associated with very high risk and this applies to BioInvent's projects as well. However, antibodies have a beneficial risk profile and a larger percentage of projects in the antibody area reach the market today compared to traditional pharmaceuticals. The probability that a drug candidate will reach the market increases as the project is advanced through the development chain. The same applies to the costs which increase sharply in the later clinical phases.

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

As BioInvent and the Company's project portfolio are developed, the Company's knowledge and experience in important areas will grow. A larger project portfolio could over time make the Company



less dependent on the success of an individual project. However, BioInvent's project portfolio is relatively limited and contains early phase projects, which means that a setback in an individual project could have a significantly negative impact on the Company. There is also a risk that development work will be delayed in relation to established schedules, which could also have a negative impact on BioInvent.

#### **Clinical trials and product responsibility**

BioInvent endeavours to advance its projects through the value chain, which will mean increased expenses for clinical trials and relevant market approval. To receive approval from the authorities for commercial sales of the Company's product candidates, the Company or its partners must demonstrate the safety and efficacy of each potential product for human use for each stated indication.

There is a risk that clinical trials performed by the company or its partners are unable to show that the intended products are sufficiently safe and effective to obtain the necessary authorisation from authorities, or that the company's projects will not result in competitive products, which may mean that the intended products cannot be launched on the market.

The possibility cannot be excluded that the use of the Company's products in clinical trials could lead to claims for damages being lodged against the Company in the event that such product should cause illness, physical injury, death or damage to property.

BioInvent's activities are exposed to potential liability risks, which are a normal aspect of research, development and manufacture of biopharmaceutical products. The Company has a commercial insurance policy that provides coverage in the geographic markets in which BioInvent currently is active. Although the Company considers its insurance coverage to be adequate, the scope and amount of the policy are limited and there is a risk that coverage will not be adequate in the event of a legal claim.

#### **Commercialisation and partners**

None of BioInvent's product candidates have yet been commercialised and may never be commercialised. There is a risk that the products launched on the market will not be well received or become commercial successes.

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

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

The market for all of the Company's future products is characterized by significant competition and fast technological development. BioInvent's competitors consist, among others, of major international pharmaceutical and biotech companies. Many of the

competitors have far greater resources than BioInvent. There is always a risk that the Company's product concept will be subject to competition from similar products or that entirely new product concepts will prove superior.

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

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

The patents relate both to the Company's core technology for antibody drug development and various aspects thereof, as well as different antibody products under development and their use as drugs. The patent rights status of pharmaceutical and biotech companies is in general uncertain and involves complex medical and legal assessments. There is a risk that the company's products and processes will not be able to be patented, that they will be deemed to infringe competitors' rights, that patents granted will not provide adequate protection or that patents granted will be attacked or disputed by competitors. BioInvent monitors and evaluates the activities, patents and patent applications of competitors on an ongoing basis for the purpose of identifying activities that are covered by the Company's intellectual property and patents that could cover parts of the Company's sphere of activity.

It may also be necessary to initiate legal proceedings to defend the Company's current or future patents, and to determine the extent and validity of patents that belong to a third party.

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

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

#### **Qualified personnel and key individuals**

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

### Additional financing requirements

The Company has narrowed the focus of operations and reduced costs. BioInvent's overall objectives are to build a portfolio of clinical development projects within cancer where risk is balanced and significant revenue streams are generated for the Company from licensing or sales, and to assist international pharmaceutical companies in their drug development and thereby generate revenue to help balance the Company's basic 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 revenues on an ongoing basis from products on the market. The capital requirement is financed through (i) revenues from collaboration agreements associated with outlicensing of proprietary projects, (ii) revenues from technology licenses, (iii) revenues 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. Revenues 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 44.

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

Remuneration of Directors, the CEO and other senior executives is described in note 1.

The 2014 Annual General Meeting adopted principles of remuneration to the CEO and benefits for other senior executives. There were no deviations from these guidelines. The Board proposes that the principles of remuneration to the CEO and other senior executives remain unchanged and apply from the 2015 Annual General Meeting with the addition that the company may grant stay-on bonuses which for a three year period may amount to a maximum of 100 per cent of the fixed salary for a year.

These guidelines will apply to those persons who during the period that the guidelines are in effect, belong to executive management and to other department heads who are directly subordinate to the CEO, referred to below as "senior executives".

BioInvent will offer compensation and terms of employment deemed necessary to recruit and retain qualified executives who are capable of achieving established goals. The overarching principle is to offer market-based salaries and other remuneration to senior executives at BioInvent. Senior executives will receive a fixed salary. In addition, variable compensation may also be paid to reward clearly target-related accomplishments in a simple and transparent way. Senior management's variable compensation will depend on the extent to which previously established targets are met within the frame of the Company's operation, mainly technical and commercial milestones within proprietary drug projects. Such targets will not be related to developments of the Company's share.

Senior management's variable compensation will not exceed 30 percent of the fixed salary. Such remuneration can be pensionable. The maximum result of variable compensation shall not entail

costs for the Company in excess of a total of SEK 1.3 million (excluding social security costs), calculated based on the number of persons currently included in executive management (such costs may change proportionately if the number of persons in management should change).

In addition to such fixed and variable compensation, the company may grant stay-on bonuses which for a three year period may amount to a maximum of 100 per cent of the fixed salary for a year.

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

Executive management's non-monetary benefits, such as company cars, computers, mobile phones, extra health insurance, or occupational health care, may be provided to the extent that such benefits are deemed market-based for senior executives in equivalent positions in the market where the Company is active. The collective value of these benefits must comprise a smaller portion of total compensation.

Senior executives have the right to retire with pension at the earliest from the date the individual reaches the age of 65. Senior executives will be covered by the prevailing ITP plan or a defined contribution occupational pension that does not exceed 35% of pensionable salary. Senior executive who reside outside Sweden or are foreign nationals and have their main pension in a country other than Sweden, may be offered other pension solutions that are reasonable in the relevant country. Such solutions must be defined contribution plans.

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

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

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

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

### Events after the end of the financial year

BioInvent announced in January that an agreement had been entered into with Cancer Research UK, Cancer Research Technology (CRT) and Leukaemia & Lymphoma Research (LLR) to take its investigational drug, BI-1206, into a collaborative phase I/II trial for patients with chronic lymphocytic leukaemia and non-Hodgkin lymphoma. The first in man study will be funded and conducted by Cancer Research UK, CRT and LLR. BioInvent has been granted the option to take up an exclusive license to the study data, subject to payment of milestones and royalties to Cancer Research Technology.

BioInvent announced in March that a Phase I/IIa program with TB-403 in medulloblastoma patients is expected to be initiated during the second half of 2015. Medulloblastoma is a rare, life-threatening cancer that exclusively affects children and adolescents. The project is conducted in collaboration with ThromboGenics NV.

BioInvent announced in March the intention to conduct a Phase IIa study in MM patients that have undergone autologous stem cell transplantation (ASCT) to investigate the ability of BI-505 to increase the depth and quality of response after ASCT in combination

with standard of care. The intention is to recruit approximately 30 patients, and study start is planned for early 2016. The study will be conducted as an investigator sponsored study in close collaboration with leading clinicians at the Abramson Cancer Center of the, University of Pennsylvania. As a consequence of strategic analysis of the potential of BI-505 in MM patients post ASCT, BioInvent will conclude its smouldering myeloma study.

The Board of Directors has resolved on a rights issue of approx. MSEK 75 subject to approval by the Annual General Meeting on 22 April 2014. The rights issue is secured by subscription undertakings and guarantee undertakings of up to approx. 100 percent of the issue.

### Proposed appropriation of profits

At the disposal of the Annual General Meeting: Share premium reserve of SEK 69,643,070, retained earnings of SEK 92,500 and loss for the year of SEK -53,985,143. The Board of Directors propose that profits at the disposal of 15,750,427 SEK is carried forward. Thus, it is proposed that no dividend be given for the financial year 2014.



# Consolidated statement of comprehensive income for the Group

SEK thousand	Note	2014	2013
Net sales		46,932	81,713
<i>Operating costs</i>	1–6		
Research and development costs		-73,372	-71,180
Sales and administrative costs		-31,900	-30,220
Other operating revenues	7	3,536	938
Other operating costs	7	-121	-427
		-101,857	-100,889
<b>Operating profit/loss</b>		<b>-54,925</b>	<b>-19,176</b>
Financial income	8	974	1,748
Financial expenses	9	- 34	- 611
<b>Net financial items</b>		<b>940</b>	<b>1,137</b>
<b>Profit/loss before tax</b>		<b>-53,985</b>	<b>-18,039</b>
Tax	10	-	-
<b>Profit/loss for the year</b>		<b>-53,985</b>	<b>-18,039</b>
<b>Other comprehensive income</b>			
<i>Items that have been or may be reclassified subsequently to profit or loss</i>			
Changes in actual value current investments		-	-10
<b>Comprehensive income for the year</b>		<b>-53,985</b>	<b>-18,049</b>
Other comprehensive income for the year attributable to parent company's shareholders		-53,985	-18,049
Earnings per share, SEK	11		
Before dilution		-0.53	-0.23
After dilution		-0.53	-0.23

# Consolidated statement of financial position for the Group

SEK thousand	Note	2014	2013
<b>ASSETS</b>			
Acquired intangible fixed assets	12	0	0
Equipment	13	2,136	3,644
Investments in rented premises	13	165	284
Long-term receivables		4,500	-
<b>Total fixed assets</b>		<b>6,801</b>	<b>3,928</b>
Inventories		61	205
Accounts receivables	18	4,434	6,603
Other receivables	18	12,205	2,047
Prepaid expenses and accrued income	15	4,980	3,909
Liquid funds	18	45,627	64,745
<b>Total current assets</b>		<b>67,307</b>	<b>77,509</b>
<b>Total assets</b>		<b>74,108</b>	<b>81,437</b>
<b>SHAREHOLDERS' EQUITY</b>			
	16		
Share capital		9,023	6,801
Other allocated capital		1,269,851	1,214,749
Reserves		1	1
Accumulated loss		-1,226,447	-1,172,544
<b>Total shareholders' equity</b>		<b>52,428</b>	<b>49,007</b>
Shareholder's equity pertaining to the Parent company's shareholders		52,428	49,007
<b>LIABILITIES</b>			
Accounts payables	18	7,588	9,446
Other liabilities	18	3,339	2,293
Accrued expenses and deferred income	17, 18	10,753	20,691
<b>Total short term liabilities</b>		<b>21,680</b>	<b>32,430</b>
<b>Total shareholders' equity and liabilities</b>		<b>74,108</b>	<b>81,437</b>
Pledged assets		-	-
Contingent liabilities		-	-

# Consolidated statement of cash flows for the Group

SEK thousand	2014	2013
<b>Current operations</b>		
Operating profit/loss	-54,925	-19,176
Depreciation	2,041	2,896
Adjustments for other non-cash items	82	49
Interest received	622	929
Interest paid	-	-
<b>Cash flow from current operations before changes in working capital</b>	<b>-52,180</b>	<b>-15,302</b>
Changes in working capital		
Changes in inventories	144	44
Changes in operating receivables	-13,560	-3,102
Changes in operating liabilities	-10,432	-36,292
	<b>-23,848</b>	<b>-39,350</b>
<b>Cash flow from current operations</b>	<b>-76,028</b>	<b>-54,652</b>
<b>Investment activities</b>		
Acquisition of tangible fixed assets	-414	-47
<b>Cash flow from investment activities</b>	<b>-414</b>	<b>-47</b>
<b>Cash flow from current operations and investment activities</b>	<b>-76,442</b>	<b>-54,699</b>
<b>Financing activities</b>		
Rights issue and directed new share issue	57,324	
Rights issue		19,383
<b>Cash flow from financing activities</b>	<b>57,324</b>	<b>19,383</b>
<b>Change in liquid funds</b>	<b>-19,118</b>	<b>-35,316</b>
Opening liquid funds	64,745	100,061
<b>Liquid funds at year-end</b>	<b>45,627</b>	<b>64,745</b>
<b>Liquid funds, specification:</b>		
Current investments	37,029	50,073
Cash and bank	8,598	14,672
	<b>45,627</b>	<b>64,745</b>



# Statement of changes in equity for the Group

SEK thousand	Share-capital	Other allocated capital	Reserves	Accumulated loss	Total
<b>Shareholders' equity 31 December 2012</b>	<b>36,963</b>	<b>1,165,204</b>	<b>11</b>	<b>-1,154,554</b>	<b>47,624</b>
<b>Comprehensive income for the year</b>					
Profit/loss for the year				-18,039	-18,039
Comprehensive other income for the year			-10		-10
<b>Total comprehensive income for the year</b>			<b>-10</b>	<b>-18,039</b>	<b>-18,049</b>
<b>Total, excluding transactions with equity holders of the Company</b>	<b>36,963</b>	<b>1,165,204</b>	<b>1</b>	<b>-1,172,593</b>	<b>29,575</b>
<b>Transactions with equity holders of the Company</b>					
Effect of employee incentive programme				49	49
Reduction of share capital	-31,049	31,049			0
Rights issue	887	18,496			19,383
<b>Shareholders' equity 31 December 2013</b>	<b>6,801</b>	<b>1,214,749</b>	<b>1</b>	<b>-1,172,544</b>	<b>49,007</b>
<b>Comprehensive income for the year</b>					
Profit/loss for the year				-53,985	-53,985
Comprehensive other income for the year			-		-
<b>Total comprehensive income for the year</b>			<b>-</b>	<b>-53,985</b>	<b>-53,985</b>
<b>Total, excluding transactions with equity holders of the Company</b>	<b>6,801</b>	<b>1,214,749</b>	<b>1</b>	<b>-1,226,529</b>	<b>-4,978</b>
<b>Transactions with equity holders of the Company</b>					
Effect of employee incentive programme				82	82
Rights issue and directed new share issue	2,222	55,102			57,324
<b>Shareholders' equity 31 December 2014</b>	<b>9,023</b>	<b>1,269,851</b>	<b>1</b>	<b>-1,226,447</b>	<b>52,428</b>

The share capital as of 31 December 2014 consists of 112,790,050 shares and the share's ratio value is 0.08. The rights issue and the directed new share issue carried out in April 2014 raised SEK 57,324 thousands after issue expenses, which amounted to SEK 6,559 thousands. The rights issue carried out in August 2013 raised SEK 19,383 thousands after issue expenses, which amounted to SEK 3,903 thousands.

# Consolidated income statement for the Parent Company

SEK thousand	Note	2014	2013
Net sales	1–6	46,932	81,713
<i>Operating costs</i>			
Research and development costs		-73,372	-71,180
Sales and administrative costs		-31,900	-30,220
Other operating revenues	7	3,536	938
Other operating costs	7	-121	-427
		-101,857	-100,889
<b>Operating profit/loss</b>		<b>-54,925</b>	<b>-19,176</b>
Interest income and similar items	8	974	1,748
Interest costs and similar items	9	- 34	-611
<b>Profit/loss after financial items</b>		<b>-53,985</b>	<b>-18,039</b>
Tax	10	-	-
<b>Profit/loss for the year</b>		<b>-53,985</b>	<b>-18,039</b>
<i>Other comprehensive income</i>			
Changes in actual value current investments		10	-10
<b>Comprehensive income for the year</b>		<b>-53,975</b>	<b>-18,049</b>

# Consolidated balance sheet for the Parent Company

SEK thousand	Note	2014	2013
<b>ASSETS</b>			
<b>Fixed assets</b>			
<b>Intangible fixed assets</b>			
Acquired intangible fixed assets	12	0	0
<b>Tangible fixed assets</b>			
Equipment	13	2,136	3,644
Investments in rented premises	13	165	284
		2,301	3,928
<b>Financial fixed assets</b>			
Shares in subsidiaries	14	100	100
Other long-term receivables		4,500	-
		4,600	100
<b>Total fixed assets</b>		<b>6,901</b>	<b>4,028</b>
<b>Current assets</b>			
<b>Inventories</b>			
		61	205
<b>Current receivables</b>			
Accounts receivables		4,434	6,603
Other receivables		12,205	2,047
Prepaid expenses and accrued income	15	4,980	3,909
		21,619	12,559
<b>Liquid funds</b>			
Current investments		37,029	50,073
Cash and bank		8,598	14,672
		45,627	64,745
<b>Total current assets</b>		<b>67,307</b>	<b>77,509</b>
<b>Total assets</b>		<b>74,208</b>	<b>81,537</b>
SEK thousand	Note	2014	2013
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>			
<b>Restricted equity</b>			
Share capital		9,023	6,801
Statutory reserve		27,693	27,693
		36,716	34,494
<b>Non-restricted equity</b>			
Share premium reserve		69,643	32,541
Retained earnings		92	39
Profit/loss for the year		-53,985	-18,039
		15,750	14,541
<b>Total shareholders' equity</b>		<b>52,466</b>	<b>49,035</b>
<b>Short term liabilities</b>			
Accounts payables		7,588	9,446
Liabilities to subsidiaries		101	101
Other liabilities		3,315	2,268
Accrued expenses and deferred income	17	10,738	20,687
		21,742	32,502
<b>Total short term liabilities</b>		<b>21,742</b>	<b>32,502</b>
<b>Total shareholders' equity and liabilities</b>		<b>74,208</b>	<b>81,537</b>
<b>Pledged assets</b>			
		-	-
<b>Contingent liabilities</b>			
		-	-



# Consolidated statement of cash flows for the Parent Company

SEK thousand	2014	2013
<b>Current operations</b>		
Operating profit/loss	-54,925	-19,176
Depreciation	2,041	2,896
Adjustments for other non-cash items	82	49
Interest received	622	929
Interest paid	-	-
<b>Cash flow from current operations before changes in working capital</b>	<b>-52,180</b>	<b>-15,302</b>
Changes in working capital		
Changes in inventories	144	44
Changes in operating receivables	-13,560	-3,102
Changes in operating liabilities	-10,432	-36,282
	<b>-23,848</b>	<b>-39,340</b>
<b>Cash flow from current operations</b>	<b>-76,028</b>	<b>-54,642</b>
<b>Investment activities</b>		
Acquisition of tangible fixed assets	-414	-47
<b>Cash flow from investment activities</b>	<b>-414</b>	<b>-47</b>
<b>Cash flow from current operations and investment activities</b>	<b>-76,442</b>	<b>-54,689</b>
<b>Financing activities</b>		
Rights issue and directed new share issue	57,324	
Rights issue		19,383
<b>Cash flow from financing activities</b>	<b>57,324</b>	<b>19,383</b>
<b>Change in liquid funds</b>	<b>-19,118</b>	<b>-35,306</b>
Opening liquid funds	64,745	100,051
<b>Liquid funds at year-end</b>	<b>45,627</b>	<b>64,745</b>
<b>Liquid funds, specification:</b>		
Current investments	37,029	50,073
Cash and bank	8,598	14,672
	<b>45,627</b>	<b>64,745</b>

# Statement of changes in equity for the Parent Company

SEK thousand	Restricted equity		Non-restricted equity		Total
	Share capital	Statutory reserve	Share premium reserve	Accumulated loss	
<b>Shareholders' equity 31 December 2012</b>	<b>36,963</b>	<b>27,831</b>	<b>169,721</b>	<b>-186,863</b>	<b>47,652</b>
Appropriation of profit/loss			-186,863	186,863	0
<b>Comprehensive income for the year</b>					
Profit/loss for the year				-18,039	-18,039
Comprehensive other income for the year				-10	-10
<b>Total, comprehensive income for the year</b>				<b>-18,049</b>	<b>-18,049</b>
<b>Total, excluding transactions with equity holders of the Company</b>	<b>36,963</b>	<b>27,831</b>	<b>-17,142</b>	<b>-18,049</b>	<b>29,603</b>
<b>Transactions with equity holders of the Company</b>					
Effect of employee incentive programme				49	49
Reduction of share capital	-31,049	-138	31,187		0
Rights issue	887		18,496		19,383
<b>Shareholders' equity 31 December 2013</b>	<b>6,801</b>	<b>27,693</b>	<b>32,541</b>	<b>-18,000</b>	<b>49,035</b>
Appropriation of profit/loss			-18,000	18,000	0
<b>Comprehensive income for the year</b>					
Profit/loss for the year				-53,985	-53,985
Comprehensive other income for the year				10	10
<b>Total, comprehensive income for the year</b>				<b>-53,975</b>	<b>-53,975</b>
<b>Total, excluding transactions with equity holders of the Company</b>	<b>6,801</b>	<b>27,693</b>	<b>14,541</b>	<b>-53,975</b>	<b>-4,940</b>
<b>Transactions with equity holders of the Company</b>					
Effect of employee incentive programme				82	82
Rights issue and directed new share issue	2,222		55,102		57,324
<b>Shareholders' equity 31 December 2014</b>	<b>9,023</b>	<b>27,693</b>	<b>69,643</b>	<b>-53,893</b>	<b>52,466</b>

# Accounting principles and information notes

## Statement of compliance with the applicable rules

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

## Parent Company's accounting principles

The Parent Company's annual accounts have been prepared in compliance with the Annual Accounts Act and applying the Swedish Financial Reporting Board's recommendation RFR 2, Reporting for Legal Entities. The Parent Company's accounting principles are consistent with the Group's accounting principles. The Parent Company's accounting principles for 2014 are unchanged from the previous year.

## Critical accounting issues and accounting estimates

Senior management and the Board of Directors make estimates and assumptions about the future. These estimates and assumptions affect reported assets and liabilities, as well as revenues and expenses and other disclosures. These assessments are based on historical experience and the various assumptions that are assessed to be reasonable under prevailing circumstances. Actual outcomes can differ from these assessments if other assumptions are made or other conditions arise.

Conditions of material importance for the report which were specifically reviewed during the year are revenues and expenses in collaboration agreements.

## Accounting principles

The accounting principles are unchanged from the previous year. Amendments to standards and interpretations that went into force in 2014 have not had any significant impact on the Group's reporting.

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

A number of new standards and amendments of interpretations and existing standards that will go into effect during the upcoming financial year have not been applied in the preparation of the consolidated financial statements. None of these is expected to have any significant impact on the Group's financial statements.

## 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, which administers the warrants issued by BioInvent International AB. The consolidated financial statements are prepared using the acquisition method. Accordingly, shareholders' equity in the subsidiaries is entirely eliminated upon acquisition. The Group's equity consists of the equity in the Parent Company and the equity in the subsidiaries accrued after the acquisition.

## Segment reporting

BioInvent's executive officers, Board and management team monitor and manage the Company's operations based on the financial results and position at the consolidated level without dividing the business into segments.

BioInvent develops antibodybased drugs. The Company's risks and opportunities are mainly affected by the progress of the projects. The Company engages in integrated activities, in which the projects are considered to carry similar risks and opportunities, and there is 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 revenues originate from different geographic areas; however, the Company's risks and opportunities in these geographic areas are similar. All sales take place through the Company's own sales organisation in Sweden.

## Net revenues, fixed assets and investment activities

	2014	2013
<b>Net revenues</b>		
Sweden	22.1	-
Europe	14.9	57.3
Other countries	9.9	24.4
	<b>46.9*</b>	<b>81.7**</b>
<b>Fixed assets</b>		
Sweden	6.8	3.9
<b>Investment activities</b>		
Sweden	0.4	0.0

\* Revenues come mainly from six partners.

\*\* Revenues come mainly from five partners.

## Revenue recognition

BioInvent's net revenues consist of:

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

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

*Revenue from collaboration agreements associated with outlicensing of proprietary projects* consist of initial license fees, milestone payments and remuneration for development work as well as future royalties on sales of the medication. Initial license fees (upfront payments) are received at the time of signing of the agreement. These payments are recognised as revenue in their entirety when the collaboration agreement is signed provided that BioInvent have met all obligations in accordance with the agreement. Milestone payments are received when the outlicensed drug project passes essential steps in the development process, such as the start of different clinical phases. Milestone payments are recognised as revenue when all terms and conditions of the agreement are met. Payment for development work in conjunction with collaboration agreements is recognised as revenue as the work is completed. Future royalty revenues are recognised based on the economic substance of the agreements.

*Revenues from technology licenses* refers to access fees for a technology, annual fees for the license, milestone payments and future royalties on the sale of products developed under the license. Access fees for technology are recognised as revenue when all obligations of the agreement are met.



BioInvent also carries out *external development projects* such as developing antibody candidates and process development. In such agreements BioInvent receives ongoing compensation for work carried out and in connection with agreements for developing antibody candidates from the n-CoDeR antibody library also milestone payments as well as future royalties on product sales. Revenues and expenses as well as profit and loss are reported in the accounting period during which the work is carried out. If a risk of loss is deemed to exist, individual provisions are performed on an ongoing basis.

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

Interest income is recognised in the period to which it relates based on the effective interest method. Effective interest is the interest that results in the present value of all future payments during the fixed interest term being equivalent to the carrying amount of the asset. Interest income is reported as financial income, see note 8.

#### 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 2014 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 1.2 million (2014: 1.3). 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 2014 Alecta's surplus in the form of the collective consolidation level was 143 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

The Annual General Meeting in 2011 resolved to adopt Employee Incentive Programme 2011/2015 and the Annual General Meeting in 2013 resolved to adopt Employee Incentive Programme 2013/2017. See also note 1.

#### Disclosure of related party transactions

For information about benefits to senior executives, see note 1. Otherwise there are no transactions with related parties, in accordance with IAS 24, to report.

#### Leasing

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

#### Taxes

Deferred tax shall be reported in the balance sheet, which means that deferred tax is calculated for all identified temporary differences between, on the one hand, the fiscal value of assets and liabilities, and on the other hand, their reported value. There are no substantial deferred taxes that relate to temporary differences as of 31 December 2014.

Deferred tax assets relating to unutilised 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 unutilised loss carryforwards amounted to SEK 1,258 million as of 31 December 2014. 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.

#### Intangible fixed assets

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

#### Tangible fixed assets

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

Depreciation/amortisation according to plan is as follows:

Equipment	5 years
Investments in rented premises	5–10 years

### Inventories

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

### Impairment

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

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

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

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

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

### Impairment testing for financial assets

On each reporting date, the Company evaluates whether there is objective evidence that a financial asset or pool of assets is impaired. Objective evidence comprises observable conditions that occurred and that have a negative impact on the possibility of recovering the cost of the asset.

The recoverable amount of assets in the category loan receivables and accounts receivables, which are recognised at amortised cost, is determined as the present value of future cash flows discounted at the effective rate at initial recognition of the asset. Assets with short maturities are not discounted. An impairment loss is recognised in the income statement.

Impairment losses on available-for-sale financial assets are recognised through profit or loss for the year in "Net financial items".

### 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.

Impairment losses of loan receivables and accounts receivables that are reported at amortised cost are reversed if a later increase in the recoverable amount can objectively be attributed to an event that occurred after the impairment loss was made.

### Provisions

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

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

### Restructuring

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

### Transactions in foreign currencies

The consolidated financial statements are presented in Swedish kronor, which is the Company's functional and reporting currency. Transactions in foreign currencies are translated when they are entered in the accounts into the reporting currency, according to the spot rate on the transaction day. Receivables and liabilities in foreign currencies have been translated at the closing day exchange rate. Exchange rate gains and losses on operating receivables and liabilities are charged to the operating profit/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, financial liability, or equity instrument in another company. For BioInvent this encompasses liquid funds, current investments, accounts receivables, other receivables, accounts payables, other liabilities, accrued expenses and derivative instruments. Liquid funds consist of cash and bank balances, as well as short term investments with maturity shorter than 3 months. Current investments consist of investments with maturity longer than 3 months, but no longer than 12 months.

### Recognition of financial instruments

A financial asset or a financial liability is reported in the balance sheet when the Company becomes a party to the instrument's contractual terms and conditions. Accounts receivables are recognised in the balance sheet when an invoice is sent. A liability is recognised when the counterparty has performed under the agreement and there is a contractual obligation to settle, even if no invoice has been received. Accounts payables are recognised when an invoice has been received. A financial asset is derecognised from the balance sheet when the rights in the agreement are fulfilled, due, or the Company loses control of them. The same applies to part of a financial asset. A financial liability is derecognised in the balance sheet when the obligations of the contract have been met or otherwise concluded. The same applies to part of a financial liability. Acquisitions and disposals of financial assets are recognized on the date of the transaction, which is the date on which the Group undertakes to acquire or divest the asset.

### Classification and measurement of financial instruments

The classification depends on the acquirer's intention with the acquisition of the financial instrument. Financial assets and liabilities are classified in the following categories.

#### *Financial assets carried at fair value through profit or loss for the year*

This category consist of two sub-categories: financial assets held for trading and other financial assets that the Company initially decided to classify in this category. A financial asset is classified as held for trading if it is acquired for the purpose of selling in the near term. Example of assets classified in this category is derivatives with positive values. Assets in this category are measured on an ongoing basis at fair value and changes in value are recognised through profit or loss for the year.

#### *Loan receivables and accounts receivables*

Loan receivables and accounts receivables are financial assets that are not derivatives with fixed payments or with determinable payments that are not quoted on an active market. Assets in this category are valued at amortised cost. The amortised cost is determined based on the effective interest calculated at the time of acquisition. Assets with short maturities are not discounted. Accounts receivables are reported at the amount expected to be received and are individually assessed. Impairment losses on accounts receivables are recognised in operating expenses. Other receivables with an expected maturity of more than one year are classified as non-current. Those with shorter maturities are classified as other receivables.

#### *Available-for-sale financial assets*

Available-for-sale financial assets are non-derivatives that are either designated in this category or not classified in any of the three aforementioned categories. An example of assets that are classified in this category is interest-bearing securities. Assets in this category are continuously valued at fair value and are included in other comprehensive income.

#### *Financial liabilities recognised at fair value through profit or loss for the year*

This category consists of financial liabilities held for trading, such as derivatives with negative values. Liabilities in this category are continuously valued at fair value with changes in value recognised through profit or loss for the year.

#### *Other financial liabilities*

This category includes loans and other financial liabilities, such as accounts payables. Liabilities are valued at amortised cost. Accounts payables have a short expected maturity and are valued without discounting at a nominal amount. Noncurrent liabilities have an expected maturity longer than one year, while current liabilities have a maturity shorter than one year.

### Hedge accounting

Currency forward contracts are used to hedge receivables or liabilities against exchange rate risk. Both the underlying receivable or liability and the currency forward contract are reported at the exchange rate on the balance sheet date and exchange rate differences are recognised through profit or loss for the year. There is therefore no need for any special hedge

accounting in the financial statements to reflect the financing hedging. Exchange rate differences on receivables and liabilities relating to operations are recognised in "Operating profit/loss," while exchange rate differences on financial receivables and liabilities are recognised in "Net financial items".

### Financial 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 2014 52 percent (99) of revenues were invoiced in foreign currencies, mainly EUR. Around 32 percent (32) of costs in 2014 were invoiced in foreign currencies, mainly in GBP and USD. Realised forward contracts for flows in 2014 had an effect on the operating income in the amount of SEK 0.5 (0.0) million. A sensitivity analysis shows that the Company's operating profit/loss in 2014 before hedging transactions would have been affected in the amount of SEK -0.2 million if the Swedish krona had weakened by 1 percent compared with GBP and in the amount of SEK -0.1 million if the Swedish krona had weakened by 1 percent compared with USD.

#### 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 2014 was 1.0 percent (1.1). A change in the interest rate of 1 percent in 2014 would have affected the net interest income by SEK 0.6 million.

#### Liquidity and credit risk

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 1 Salaries, other remuneration and social security etc

SEK thousand	Salaries and other remuneration	2014 Social security costs (of which pension costs)	Salaries and other remuneration	2013 Social security costs (of which pension costs)
Parent company	24,814	8,924 (3,074)	34,507	17,564 (6,186)
Subsidiaries			-	-
<b>Group total</b>	<b>24,814</b>	<b>8,924 (3,074)</b>	<b>34,507</b>	<b>17,564 (6,186)</b>

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

SEK thousand	Board and CEO	2014 Other employees	Board and CEO	2013 Other employees
Parent company	3,463	21,351	4,726	29,781
Subsidiaries	-	-	-	-
<b>Group total</b>	<b>3,463</b>	<b>21,351</b>	<b>4,726</b>	<b>29,781</b>

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

SEK thousand	Board and CEO	2014 Other employees	Board and CEO	2013 Other employees
Parent company	495	2,579	2,352	3,834
Subsidiaries	-	-	-	-
<b>Group total</b>	<b>495</b>	<b>2,579</b>	<b>2,352</b>	<b>3,834</b>

### 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 2014 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 programme for variable remuneration for the CEO and other

senior executives consists of a variable remuneration model that was introduced in 2003. Variable performance related remuneration of 0–30 percent of fixed annual cash salaries may be paid out on an annual basis to senior executives. The performance related components in the current programme, for the period 1 January – 31 December 2015, are based primarily on high expectations for technical and commercial milestones in proprietary drug projects. The Board of Directors resolved in February 2015 to pay SEK 95 thousand to CEO Michael Oredsson and SEK 100 thousand to other senior executives for the period 1 January – 31 December 2014. Variable remuneration is pensionable income.

In addition, the CEO and other senior executives are covered by an employee stock option incentive programme, described on page 46.

#### Remuneration and other benefits in 2014

	Fixed salary/fees	Board and committee fees	Variable remuneration	Other benefits	Pensions-costs	Total
<b>Board and CEO</b>						
Björn O. Nilsson, Chairman		400				400
Lars Backsell, member		200				200
Dharminder Chahal member		200				200
Lars Ingelmark, member		210				210
Jonas Jendi member		160				160
Elisabeth Lindner, member		160				160
Michael Oredsson, CEO	1,928		95	110	495	2,628
	<b>1,928</b>	<b>1,330</b>	<b>95</b>	<b>110</b>	<b>495</b>	<b>3,958</b>
<b>Other senior executives</b>						
(2.4 individuals*)	4,808		100	157	840	5,905
<b>Total</b>	<b>6,736</b>	<b>1,330</b>	<b>195</b>	<b>267</b>	<b>1,335</b>	<b>9,863</b>

\* Average number during the period.



**Benefits for the Board and CEO**

The Board's fees were set by the 2014 Annual General Meeting at SEK 400 thousand for the Chairman of the Board and SEK 160 thousand for each of the other members of the Board not employed by the Company. In addition hereto, but not to the Chairman of the Board, it was decided that SEK 50 thousand shall be the fee for the Chairman of the Audit Committee and SEK 40 thousand shall be the fee for each of the other members in the Audit Committee and SEK 20 thousand shall be the fee for each of the members in the Remuneration Committee.

Michael Oredsson, CEO and President, has received a fixed gross cash salary of SEK 1,928 thousand and SEK 95 thousand in variable remuneration, as well as SEK 110 thousand in other benefits. The total cost for Michael Oredsson's pension benefits amounted in 2014 to SEK 495 thousand and he is covered by the prevailing ITP plan. 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 6 monthly salaries. Redundancy pay is not deducted from other income. If the CEO resigns, no redundancy pay is payable.

The CEO received an allotment of 6,000 employee options in February 2015.

**Average number of employees**

	2014		2013	
	Number of employees	Of which women	Number of employees	Of which women
Parent company	38	65%	47	68%
Subsidiaries	-	-	-	-
<b>Group total</b>	<b>38</b>	<b>65%</b>	<b>47</b>	<b>68%</b>

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

	2014		2013	
	Number*	Of which women	Number*	Of which women
Board and CEO	9	33%	9	33%
Other senior executives	2	0%	5	0%

\*Number on 31 December

**Employee Incentive Programme 2011/2015**

The 2011 Annual General Meeting voted in favour of complementing the already established Employee Incentive Programme 2008/2012 aimed at newly employed senior executives and key individuals not participating in Employee Incentive Programme 2008/2012. The number of employee options was within the framework of the number of options still not exercised in Employee Incentive Programme 2008/2012, including previous supplementary programmes.

Each employee option entitles the holder to acquire 1.069 new shares in BioInvent for a subscription price of SEK 28.42 up to 1 December 2015. Subscription price and number of shares that each employee option entitles to are converted pursuant to rights issues carried out. Under the programme 48,105 employee options have been allotted.

Basic allotment could take place until the Annual General Meeting 2012. The holders shall be able to exercise 50 percent of the basic allotment of the employee options as from the third anniversary of the allotment and the remaining 50 percent as from the fourth anniversary of the allotment. Extra allotment could take place in connection with the interim statement for the financial year 2011, 2012 and 2013, respectively, and may be exercised as from the date of the Annual General Meeting 2015. The last day for exercising the options shall be 1 December, 2015.

The employee options are free of charge and are not transferable. Exercise of the employee options requires that the option holder is still employed by the Group. All new employees could receive a maximum of 7,500 options, except for members of management without a substantial shareholding in the company, who could receive a maximum of 30,000 employee options. The maximum basic allotment could be adjusted proportionate to the length of employment with the Company for each individual. Extra allotment could be obtained, based on performance, for the financial years 2011, 2012 and 2013, respectively, amounting to maximum 15,000 employee options each year to members of management and maximum 7,500 employee options

**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 2014 of SEK 4,685 thousand (of which SEK 1,446 thousand after employment ends) and SEK 100 thousand in variable salary, as well as SEK 157 thousand in other benefits. The total pension costs relating to other senior executives in 2014 amounted to SEK 840 thousand (of which SEK 102 thousand after employment ends). Other senior executives received an allotment of 6,000 of employee options in February 2015.

each year to key-employees. Extra allotment, in the case of members of management, involved the same criteria as payment of salary bonuses. These criteria consisted of technical milestone criteria relating to the Company's project and research portfolio, and the outcome of strategic partnering and financing. 50 percent of the extra allotment for individuals holding key positions was based on technical milestone criteria relating to the Company's project and research portfolio which provided a bonus and resulted in extra allotment management, and 50 percent was based on personal performance. Extra allotment was adjusted proportionate to the length of employment with the Company.

**Employee Incentive Programme 2013/2017**

The 2013 Annual General Meeting voted in favour of establishing a new, long-term employee incentive programme involving the allotment of a maximum of 900,000 employee options free of charge to all Group employees.

Each employee option will entitle the holder to acquire 1.064 new share in BioInvent for a subscription price of SEK 3.31 during the period from the date of publication of the Company's year-end financial statement for the 2016 financial year up to and including 1 December 2017. Subscription price and number of shares that each employee option entitles to are converted pursuant to rights issue carried out. Allotment of 100,747 employee options took place in February 2014 and 74,516 employee options in February 2015.

The employees will receive options based on their performance in the 2013, 2014 or 2015 financial years and allotment will take place in connection with the publication of the year-end financial statement for the subsequent year. Allotment is as follows: CEO maximum 30,000 options per year, members of management maximum 15,000 options per year, heads of sections and other key personnel maximum 7,500 options per year, other employees maximum 3,000 options per year. As regards the CEO and members of the management, allotment shall be based on the same criteria as for bonus benefits,

## Note 1 Salaries, other remuneration and social security etc

which principally are based on fixed technical milestone-criteria in projects, criteria for development of the project portfolio and other pre-determined criteria attributable to the business. Allotment for heads of sections and other key personnel shall be based at 50 per cent on technical milestone-criteria in projects which entitle to bonus and at 50 per cent on personal performance. Allotment for other employees shall be based on the assessment of the Remuneration Committee as regards whether and to what extent the company has fulfilled the company's general goals for development.

To guarantee BioInvent's commitment and cover the costs associated with Employee Incentive programme 2013/2017, the 2013 Annual General Meeting

resolved to issue a maximum of 1,182,780 warrants to BioInvent Finans AB.

Assuming that all issued warrants relating to Employee Incentive Programme 2011/2015 and Employee Incentive Programme 2013/2017 are exercised for subscription of new shares, the Company's share capital will increase by SEK 98,170.80 to SEK 9,121,374.80 equivalent to about 1.1 percent of shares and votes in the Company after full exercise.

The fair value of the options was determined using the Black-Scholes model for each allotment made during 2011-2014. This measurement model is considered to provide a fair representation of the value for the options. The data below has been used for the calculation.

Employee Incentive Programme 2011/2015	2014	2013	2012	2011
Allotted options	-	3,938	6,667	37,500
Fair value per option (SEK)		0.00	2.58	4.14
Share price for underlying shares (SEK)		3.20	19.11	20.80
Subscription price (SEK)		30.24	30.36	30.36
Estimated life of the option		2.78 år	3.81 år	4.44 år
Risk-free interest rate during the life of the option		1.00%	1.18%	2.50%
Assumed volatility		40%	35%	35%
Expected dividends		-	-	-
Wage costs in 2014 for employee incentive programme (SEK thousand)		0	5	32
Wage costs in 2013 for employee incentive programme (SEK thousand)		0	5	44
Wage costs in 2012 for employee incentive programme (SEK thousand)			5	42
Wage costs in 2011 for employee incentive programme (SEK thousand)				26

Employee Incentive Programme 2013/2017	2014
Allotted options	100,747
Fair value per option (SEK)	1.00
Share price for underlying shares (SEK)	3.30
Subscription price (SEK)	3.48
Estimated life of the option	3.78 years
Risk-free interest rate during the life of the option	1.10%
Assumed volatility	40%
Expected dividends	-
Wage costs in 2014 for employee incentive programme (SEK thousand)	45

In 2014 wage costs for Employee Incentive Programme 2011/2015 and Employee Incentive Programme 2013/2017 had a negative impact on operating profit of SEK 82 thousand. In 2013 wage costs for Employee Incentive Programme 2011/2015 had a negative impact on operating profit of SEK 49 thousand. The programme expenses refer to both the estimated cost of the value of the employees' service during the period, valued at market value at the time of the allocation, and the portion of the estimated social security fees earned during the period. BioInvent will pay social security fees on the gain that may result from the exercise of the employee options, estimated as the difference between the subscription price of the employee stock option and the market value of the shares.

## Note 2 Information about auditors' fees

	Group		Parent company	
SEK thousand	2014	2013	2014	2013
<b>KPMG</b>				
Audit	295	295	295	295
Other auditing activities besides the audit	-	70	-	70
Tax consultations	-	-	-	-
Other services	52	242	52	242
<b>Total</b>	<b>347</b>	<b>607</b>	<b>347</b>	<b>607</b>

## Note 3 Depreciation and impairment losses according to plan of intangible and tangible fixed assets

	Group		Parent company	
SEK thousand	2014	2013	2014	2013
Research and development costs	1,671	2,343	1,671	2,343
Sales and administrative costs	370	553	370	553
<b>Total</b>	<b>2,041</b>	<b>2,896</b>	<b>2,041</b>	<b>2,896</b>

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 4 Operational leasing

Leasing charges are for laboratory, production and office premises and is primarily included in research and development costs. Leasing costs in 2014 and 2013 amounted to SEK 6,554 thousand (6,154) for the Group and the Parent company. The table below shows the minimum lease payments for non-cancellable operational leasing agreements.

SEK thousand	Group	Parent company
Payments due:		
Year 2015	7,312	7,312
Year 2016-2019	6,872	6,872
Year 2020 or later	-	-
<b>Total</b>	<b>14,184</b>	<b>14,184</b>

## Note 5 Income statement classified according to type of cost

SEK thousand	Group		Parent company	
	2014	2013	2014	2013
External costs	69,307	46,137	69,307	46,137
Personnel costs	33,924	52,367	33,924	52,367
Depreciation	2,041	2,896	2,041	2,896
<b>Total</b>	<b>105,272</b>	<b>101,400</b>	<b>105,272</b>	<b>101,400</b>

## Note 6 Exchange rate differences that affected profit/loss for the period

SEK thousand	Group		Parent company	
	2014	2013	2014	2013
Exchange rate differences that affected the operating profit/loss	-6	-385	-6	-385
Financial exchange rate differences	351	453	351	453
<b>Total</b>	<b>345</b>	<b>68</b>	<b>345</b>	<b>68</b>

## Note 7 Other operating revenues and costs

SEK thousand	Group		Parent company	
	2014	2013	2014	2013
<b>Other operating revenues</b>				
Financial support from the EU's framework programme	3,422	897	3,422	897
Exchange rate gains	114	41	114	41
	<b>3,536</b>	<b>938</b>	<b>3,536</b>	<b>938</b>
<b>Other operating costs</b>				
Exchange rate losses	-121	-427	-121	-427
	<b>-121</b>	<b>-427</b>	<b>-121</b>	<b>-427</b>
<b>Total</b>	<b>3,415</b>	<b>511</b>	<b>3,415</b>	<b>511</b>

In 2013 and 2014 financial support from the EU's framework programme was reported for early research projects.

## Note 8 Financial revenues

SEK thousand	Group		Parent company	
	2014	2013	2014	2013
Interest income	589	684	589	684
Exchange rate differences	385	1,064	385	1,064
<b>Total</b>	<b>974</b>	<b>1,748</b>	<b>974</b>	<b>1,748</b>

## Note 9 Financial costs

SEK thousand	Group		Parent company	
	2014	2013	2014	2013
Interest costs	-	-	-	-
Exchange rate differences	-34	-611	-34	-611
<b>Total</b>	<b>-34</b>	<b>-611</b>	<b>-34</b>	<b>-611</b>

## Note 10 Tax on profit for the year

Tax on profit for the year	Group		Parent company	
	2014	2013	2014	2013
Current tax on profit for the year	0	0	0	0
Deferred taxes relating to temporary differences	0	0	0	0
<b>Reported tax on profit for the year</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

Reconciliation of effective tax	Group		Parent company	
	2014	2013	2014	2013
Reported profit/loss before tax	-53,985	-18,039	-53,985	-18,039
Tax according to the applicable tax rate, 22.0%	11,877	3,969	11,877	3,969
Tax effect of costs that are not deductible	-123	-123	-123	-123
Tax effect of loss carry forward for which the deferred tax claim has not been/shall be considered	-11,754	-3,846	-11,754	-3,846
<b>Reported tax on profit/loss for the year</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

## Note 11 Earnings per share

Earnings per share before dilution	2014	2013
Profit/loss for the period	-53,985	-18,039
Average number of outstanding shares (thousand)	101,989	78,084
<b>Earnings per share before dilution, SEK</b>	<b>-0.53</b>	<b>-0.23</b>

Earnings per share after dilution	2014	2013
Profit/loss for the period	-53,985	-18,039
Average number of outstanding shares (thousand)	101,989	78,084
<b>Earnings per share after dilution, SEK</b>	<b>-0.53</b>	<b>-0.23</b>

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.

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. Employee Incentive Programme 2011/2015 entitles the holder to acquire 1.069 new shares in BioInvent for a subscription price of SEK 28.42 and Employee Incentive Programme 2013/2017 entitles the holder to acquire 1.064 new

shares in BioInvent for a subscription price of SEK 3.31. An average share price of SEK 3.03 per share was used to determine whether a dilution effect exists for 2014.

Options issued under Employee Incentive Programme 2011/2015 and Employee Incentive Programme 2013/2017 have no dilution effect and are therefore excluded from the earnings per share after dilution calculation. The Company reported a loss for the period and accordingly there is no dilution effect. If in the future the share price exceeds the subscription price and the Company reports a profit, these options may lead to dilution.



## Note 12 Intangible fixed assets

Acquired intangible fixed assets SEK thousand	Group		Parent company	
	2014	2013	2014	2013
Opening acquisition value	47,885	47,885	47,885	47,885
Acquisitions	-	-	-	-
Disposals	-	-	-	-
<b>Closing accumulated acquisition value</b>	<b>47,885</b>	<b>47,885</b>	<b>47,885</b>	<b>47,885</b>
Opening depreciation	-47,885	-47,885	-47,885	-47,885
Disposals	-	-	-	-
Depreciation for the year	-	-	-	-
<b>Closing accumulated depreciation</b>	<b>-47,885</b>	<b>-47,885</b>	<b>-47,885</b>	<b>-47,885</b>
<b>Closing residual value according to plan</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

Intangible assets are described on page 42.

## Note 13 Tangible fixed assets

Equipment SEK thousand	Group		Parent company	
	2014	2013	2014	2013
Opening acquisition value	59,828	66,949	59,828	66,949
Acquisitions	414	47	414	47
Disposals	-2,060	-7,168	-2,060	-7,168
<b>Closing accumulated acquisition value</b>	<b>58,182</b>	<b>59,828</b>	<b>58,182</b>	<b>59,828</b>
Opening depreciation	-56,184	-60,587	-56,184	-60,587
Disposals	2,060	7,168	2,060	7,168
Depreciation for the year	-1,922	-2,765	-1,922	-2,765
<b>Closing accumulated depreciation</b>	<b>-56,046</b>	<b>-56,184</b>	<b>-56,046</b>	<b>-56,184</b>
<b>Closing residual value according to plan</b>	<b>2,136</b>	<b>3,644</b>	<b>2,136</b>	<b>3,644</b>

Investments in rented premises SEK thousand	Group		Parent company	
	2014	2013	2014	2013
Opening acquisition value	11,771	11,771	11,771	11,771
Acquisitions	-	-	-	-
<b>Closing accumulated acquisition value</b>	<b>11,771</b>	<b>11,771</b>	<b>11,771</b>	<b>11,771</b>
Opening depreciation	-11,487	-11,357	-11,487	-11,357
Depreciation for the year	-119	-130	-119	-130
<b>Closing accumulated depreciation</b>	<b>-11,606</b>	<b>-11,487</b>	<b>-11,606</b>	<b>-11,487</b>
<b>Closing residual value according to plan</b>	<b>165</b>	<b>284</b>	<b>165</b>	<b>284</b>

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

## Note 14 Shares in subsidiaries

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

Biolnvent Finans AB administers warrants issued by Biolnvent International AB.

## Note 15 Prepaid expenses and accrued income

	Group		Parent company	
SEK thousand	2014	2013	2014	2013
Prepaid rent	1,624	1,596	1,624	1,596
Other items	3,356	2,313	3,356	2,313
<b>Total</b>	<b>4,980</b>	<b>3,909</b>	<b>4,980</b>	<b>3,909</b>

## Note 16 Shareholders' equity

### Share capital

	Ordinary shares	
Thousands of shares	2014	2013
Issued as of 1 January	85,015	73,926
Rights issue and directed new share issue	27,775	11,089
<b>Issued as of 31 December</b>	<b>112,790</b>	<b>85,015</b>

The share capital as of 31 December 2014 consists of 112,790,050 shares and the share's ratio value is 0.08. Shareholders holding ordinary shares are entitled to dividends. Each share carries one vote at the Annual General Meeting.

### Other allocated capital

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

### Fair value reserve

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

### Retained earnings including profit/loss for the year

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

### Dividend

The Board of Directors proposes that no dividend be paid out for the 2014 financial year.

### 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 17 Accrued expenses and deferred income

	Group		Parent company	
SEK thousand	2014	2013	2014	2013
Payroll liabilities	4,981	11,534	4,981	11,534
Social security fees	2,067	4,169	2,067	4,169
Other items	3,705	4,988	3,690	4,984
<b>Total</b>	<b>10,753</b>	<b>20,691</b>	<b>10,738</b>	<b>20,687</b>

## Note 18 Financial instruments

### FAIR VALUES

Below is a comparison of the reported values and the fair values of the Group's financial instruments.

SEK thousand	Book value		Actual value	
	2014	2013	2014	2013
<b>Financial assets</b>				
<i>Loan receivables and accounts receivables</i>				
Accounts receivables	4,434	6,603	4,434	6,603
Other receivables	12,203	2,047	12,203	2,047
	16,637	8,650	16,637	8,650
<i>Available-for-sale financial assets</i>				
Current investments	37,029	50,073	37,029	50,073
Cash and bank	8,598	14,672	8,598	14,672
	45,627	64,745	45,627	64,745
<i>Financial assets carried at fair value through profit or loss for the year</i>				
Derivatives*	2	0	2	0
<b>Total</b>	<b>62,266</b>	<b>73,395</b>	<b>62,266</b>	<b>73,395</b>
<b>Financial liabilities</b>				
<i>Other financial liabilities</i>				
Accounts payables	-7,588	-9,446	-7,588	-9,446
Other liabilities	-3,281	-2,291	-3,281	-2,291
Accrued expenses	-10,753	-20,691	-10,753	-20,691
	-21,622	-32,428	-21,622	-32,428
<i>Financial liabilities recognised at fair value through profit or loss for the year</i>				
Derivatives*	-58	-2	-58	-58
<b>Total</b>	<b>-21,680</b>	<b>-32,430</b>	<b>-21,680</b>	<b>-32,430</b>

\* Measurement of derivatives falls under level 2 of the fair value hierarchy in IFRS 7, which means that fair values are determined indirectly based on observable market data (exchange rates).

### MATURITIES

Maturities for financial instruments are presented below

#### Remaining term, 31 Dec. 2014

SEK thousand	On demand	< 3 months	3-12 months	Total
<b>Financial assets</b>				
<i>Loan receivables and accounts receivables</i>				
Accounts receivables		4,434		4,434
(where of past due but not recognised as impairment losses)		(-)		(-)
Other receivables		12,203		12,203
<i>Available-for-sale financial assets</i>				
Current investments		37,029		37,029
Cash and bank	8,598			8,598
<i>Financial assets carried at fair value through profit or loss for the year</i>				
Derivatives		2		2
<b>Total</b>	<b>8,598</b>	<b>53,668</b>	<b>-</b>	<b>62,266</b>
<b>Financial liabilities</b>				
<i>Other financial liabilities</i>				
Accounts payables		-7,588		-7,588
Other liabilities		-3,281		-3,281
Accrued expenses		-10,753		-10,753
<i>Financial liabilities recognised at fair value through profit or loss for the year</i>				
Derivatives		-58		-58
<b>Total</b>		<b>-21,680</b>		<b>-21,680</b>
<b>Remaining term, 31 Dec. 2013</b>				
<b>Financial assets</b>	<b>14,672</b>	<b>58,723</b>	<b>-</b>	<b>73,395</b>
<b>Financial liabilities</b>		<b>-32,430</b>	<b>-</b>	<b>-32,430</b>

## Note 19 Important events after the end of the reporting period

BioInvent announced in January that an agreement had been entered into with Cancer Research UK, Cancer Research Technology (CRT) and Leukaemia & Lymphoma Research (LLR) to take its investigational drug, BI-1206, into a collaborative phase I/II trial for patients with chronic lymphocytic leukaemia and non-Hodgkin lymphoma. The first in man study will be funded and conducted by Cancer Research UK, CRT and LLR. BioInvent has been granted the option to take up an exclusive license to the study data, subject to payment of milestones and royalties to Cancer Research Technology.

BioInvent announced in March that a Phase I/IIa program with TB-403 in medulloblastoma patients is expected to be initiated during the second half of 2015. Medulloblastoma is a rare, life-threatening cancer that exclusively affects children and adolescents. The project is conducted in collaboration with ThromboGenics NV.

BioInvent announced in March the intention to conduct a Phase IIa study in MM patients that have undergone autologous stem cell transplantation (ASCT) to investigate the ability of BI-505 to increase the depth and quality of response after ASCT in combination with standard of care. The intention is to recruit approximately 30 patients, and study start is planned for early 2016. The study will be conducted as an investigator sponsored study in close collaboration with leading clinicians at the Abramson Cancer Center of the, University of Pennsylvania. As a consequence of strategic analysis of the potential of BI-505 in MM patients post ASCT, BioInvent will conclude its smouldering myeloma study.

The Board of Directors has resolved on a rights issue of approx. MSEK 75 subject to approval by the Annual General Meeting on 22 April 2014. The rights issue is secured by subscription undertakings and guarantee undertakings of up to approx. 100 percent of the issue.

## Note 20 Information about the Parent Company

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



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.

Lund, 25 March 2015

Björn O. Nilsson  
Chairman of the Board

Vessela Alexieva  
Board member

Lars Backsell  
Board member

Dharminder Chahal  
Board member

Lars Ingelmark  
Board member

Jonas Jendi  
Board member

Elisabeth Lindner  
Board member

Ulrika T. Mattson  
Board member

Michael Oredsson  
President and CEO

Our audit report was submitted on 25 March 2015  
KPMG AB

Alf Svensson  
Authorised Public Accountant

# Auditor's report

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

## Report on the annual accounts and consolidated accounts

We have audited the annual accounts and consolidated accounts of BioInvent International AB (publ) for the year 2014. The annual accounts and consolidated accounts of the company are included in the printed version of this document on pages 26–54.

## Responsibilities of the Board of Directors and the CEO for the annual accounts and consolidated accounts

The Board of Directors and the CEO are responsible for the preparation and fair presentation of these annual accounts in accordance with the Annual Accounts Act and of the consolidated accounts in accordance with International Financial Reporting Standards, as adopted by the EU, and the Annual Accounts Act, and for such internal control as the Board of Directors and the CEO 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.

## Auditor's responsibility

Our responsibility is to express an opinion on these annual accounts and consolidated accounts based on our audit. We conducted our audit in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the annual accounts and consolidated accounts are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the company's preparation and fair presentation of the annual accounts and consolidated accounts 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. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Board of Directors and the CEO, as well as evaluating the overall presentation of the annual accounts and consolidated accounts.

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

## Opinions

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the parent company as of 31 December 2014 and of its financial performance and its cash flows for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2014 and of their financial performance and cash flows for the year then ended in accordance with International Financial Reporting

Standards, as adopted by the EU, and the Annual Accounts Act. A corporate governance statement has been prepared. The corporate governance report and the corporate governance statement are consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the annual meeting of shareholders adopt the income statement and balance sheet for the parent company and the statement of comprehensive income and statement of financial position for the group.

## Report on other legal and regulatory requirements

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the proposed appropriations of the company's profit or loss and the administration of the Board of Directors and the CEO of BioInvent International AB (publ) for the year 2014.

## Responsibilities of the Board of Directors and the CEO

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss, and the Board of Directors and the CEO are responsible for administration under the Companies Act.

## Auditor's responsibility

Our responsibility is to express an opinion with reasonable assurance on the proposed appropriations of the company's profit or loss and on the administration based on our audit. We conducted the audit in accordance with generally accepted auditing standards in Sweden.

As 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.

As basis for our opinion concerning discharge from liability, in addition to our audit of the annual accounts and consolidated accounts, we examined significant decisions, actions taken and circumstances of the company in order to determine whether any member of the Board of Directors or the CEO is liable to the company. We also examined whether any member of the Board of Directors or the CEO has, in any other way, acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

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

## Opinions

We recommend to the annual meeting of shareholders that the profit be appropriated in accordance with the proposal in the Directors' report and that the members of the Board of Directors and the CEO be discharged from liability for the financial year.

Lund, 25 March 2015  
KPMG AB

Alf Svensson  
Authorised Public Accountant

# Corporate governance report

BioInvent applies the Swedish Code of Corporate Governance ("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 was prepared in compliance with the stipulations in the Annual Accounts Act and the Code. The corporate governance report has been prepared as a separate document from the annual report and as such is not part of the formal annual report documentation. The corporate governance report has been reviewed by the Company's auditor in accordance with the stipulations in the Annual Accounts Act. The auditor's statement is attached to the report.

## Annual General Meeting

The Annual General Meeting (AGM), or where appropriate an extraordinary general meeting, is the decision-making body for BioInvent at which all shareholders can participate. The Articles of Association do not stipulate any restriction with respect to how many votes each shareholder may exercise at shareholders' meetings and contain no specific provisions on amendments to the Articles of Association. The AGM considers the Company's progress and resolves on a number of key issues such as adoption of the income statement and balance sheet, allocation of result, discharge of the Board of Directors from liability, and the election of a new Board of Directors until the next Annual General Meeting. An auditor for the Company is appointed for a term of two years and a decision is made on compensation for the auditor.

The Annual General Meeting 2014 authorised the Board of Directors to resolve on the issue of not more than the number of new shares equivalent to 15 percent of the registered share capital (as per the date of the resolution on the issue of new shares), on one or several occasions during the period up to the next annual general meeting.

The 2014 Annual General Meeting was held on 22 April and the minutes are available on the BioInvent website.

The Annual General Meeting 2015 will be held on Wednesday 22 April at 4 p.m. The date and venue of the Annual General Meeting 2015 were presented on BioInvent's website on 14 November 2014. Under the Code, the company must post this information on its website at latest in conjunction with the interim report for the third quarter, which was published on 23 October 2014. The delay means that BioInvent deviated from this provision of the Code.

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

## Nominating Committee

In accordance with the resolution of the Annual General Meeting, the Nominating Committee shall consist of the Chairman of the Board as the convenor, and a representative for each of the Company's three largest shareholders as of 31 August each calendar year. The Nominating Committee shall prepare all the elections and proposals of remuneration that come into question, from the Nominating Committee has been appointed until a new Nominating

Committee is appointed. The Nominating Committee is tasked with preparing proposals to present to the AGM regarding the election of Chairman of the General Meeting, Chairman of the Board and other Board members, board remuneration, 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 2014 Annual General Meeting comprised Erik Esveld (van Herk Investments B.V.), Mikael Lönn (representing own holdings), Tony Sandell (B&E Participation AB) and the Chairman of the Board Björn O. Nilsson. The Nominating Committee formulated proposals for the chairman of the general meeting, the composition of the Board of Directors, the election of an auditor and the fees for the Board and auditor. The Nominating Committee had one meeting and a number of telephone calls. The Nominating Committee did not receive any remuneration.

The composition of the Nominating Committee for the 2015 Annual General Meeting was presented on the BioInvent website on 15 December 2014. 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 Annual General Meeting and, where applicable, information on which shareholders the Committee members represent. Due to the fact that it has taken longer than anticipated to appoint the Nominating Committee, BioInvent has deviated from the abovenamed requirement. The Nominating Committee for the 2015 Annual General Meeting consists of Erik Esveld (van Herk Investments B.V.), Mikael Lönn (representing own holdings), Tony Sandell (B&E Participation AB) and the Chairman of the Board Björn O. Nilsson. Other than van Herk Investments B.V., which holds 16.2 percent of the shares and voting rights in the company, no shareholder holds a stake equal to or greater than 10 percent. Proposals to the Nominating Committee should be addressed to Stefan Ericsson, by mail: BioInvent International AB (publ), SE-223 70 Lund or tel: +46 (0)46-46 286 85 50. The task of the Nominating Committee ahead of the Annual General Meeting 2015 is to formulate proposals for the chairman of the general meeting, the composition of the Board of Directors and the fees for the Board. The Nominating Committee had one meeting and a number of telephone conversations. The Nominating Committee did not receive any remuneration.

## 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, according to the Articles of Association, is to consist of no fewer than five and no more than nine members. The Articles of Association do not contain specific stipulations on the appointment or dismissal of Board.

The 2014 AGM discharged the Board members and the President and CEO from liability and re-elected the Board members Björn O. Nilsson, Lars Backsell, Dharminder Chahal, Lars Ingelmark, Jonas Jendi and Elisabeth Lindner. Björn O. Nilsson was reelected Chairman of the Board. The Board of Directors consists of six elected directors as well as employee representatives Vessela Alexieva and Ulrika T. Mattson.

The Board of Directors is presented on page 24. Dharminder Chahal is considered dependent in relation to major shareholders in the Company by holding positions for van Herk Investments B.V.. Other directors are independent in relation to the major shareholders.

The 2014 AGM resolved that the Board's fees shall remain unchanged at SEK 400 thousand for the Chairman of the Board and SEK 160 thousand for each of the other members of the Board not employed by the Company. In addition hereto, but not to the Chairman of the Board, it was decided that SEK 50 thousand shall be the fee for the Chairman of the Audit Committee and SEK 40 thousand shall be the fee for each of the other members in the Audit Committee and SEK 20 thousand shall be the fee for each of the members in the Remuneration Committee.

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

In 2014 the Board of Directors held eight regular meetings and nine extra 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 senior management. Attorney Madeleine Rydberger, Mannheimer Swartling Advokatbyrå, served as the secretary of the Board during the year. Regular items on the agenda at the meetings included following up on the operation in relation to the Company's budget and strategic plan. In addition the Board has considered and resolved on issues pertaining to research and development, financing, intellectual property, strategic focus and planning, the budget, essential agreements, audits, financial reporting and compensation related issues. Once a year the Board conducts an evaluation of its work and the work of the CEO and this evaluation is provided to the Nominating Committee.

Board member	Attendance
Björn O. Nilsson (Chairman)	17 (17)
Vessela Alexieva	17 (17)
Lars Backsell	14 (17)
Dharminder Chahal	11 (17)
Lars Ingelmark	17 (17)
Jonas Jendi	17 (17)
Elisabeth Lindner	10 (17)
Ulrika T. Mattson	11 (17)

### Remuneration Committee

After the 2014 AGM the Board of Directors decided to not establish a remuneration committee, considering it more appropriate for the entire Board to perform the tasks of a remuneration committee. These issues are addressed directly by the Board. 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.

### Audit Committee

The Board of Directors has appointed an Audit Committee consisting of Lars Ingelmark (Chairman), Lars Backsell, Dharminder Chahal and Björn O. Nilsson. All directors are independent in relation to the Company, senior executives and major shareholders, except for Dharminder Chahal who is considered dependent in relation to major shareholders. 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 pertaining to selection of auditors and remuneration, follow up of the auditors' work and the Company's internal control systems, follow up of the current risk scenario, follow up of external audits and the Company's financial information, adoption of the interim reports for quarters 1 and 3, preparation of the interim report for quarters 2 and 4, as well as the Company's annual report, follow up of issues pertaining to financing, and preparations to adopt and revise financial policy and other issues that the Board of Directors entrusts to the Committee. The Audit Committee reports to the Board of Directors. The committee held four meetings in 2014.

Member of the Audit Committee	Attendance
Lars Ingelmark (Chairman)	4 (4)
Lars Backsell	4 (4)
Dharminder Chahal	3 (4)
Björn O. Nilsson	4 (4)

### 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 2014 Annual General Meeting elected KPMG AB to serve as the Company's auditors, for a two-year mandate. Alf Svensson, authorized public accountant, is principal auditor.

### Group Management

According to its guidelines and instructions, the Board of Directors has delegated day-to-day management 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 management. The CEO reports regularly to the Board of Directors on the Company's business operations, financial performance and other issues relevant to the company. At one Board meeting a year the Board evaluates the work of the CEO. No member of senior management is present at this meeting. The CEO and senior management are presented on page 25.

### Remuneration to senior executives

The 2014 Annual General Meeting 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. Senior executives may also receive remuneration in the form of options or other share-related incentive programmes, as decided by the Annual General Meeting of shareholders. The complete guidelines can be seen in the Board of Directors' Report on page 31.

### The Company's systems for internal control and risk management with respect to financial reporting for the 2014 financial year

According to the Swedish Companies Act and the Swedish Code of Corporate Governance the Board is responsible for internal control. This description was prepared according to the Annual Accounts Act, chapter 6 § 6, and describes the Company's systems for internal control in connection with financial reporting.

Internal control over financial reporting is a process designed by the Board of Directors to provide the Board, senior management and others involved in the organisation with 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 firms.

### Control Environment

The foundation of the internal control process consists of the overall control environment: 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 authorisation instructions.

### Control activities

Control activities are necessary for senior management of the essential risks associated with the internal control process. To ensure the efficacy of its 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 policy 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, 25 March 2015  
The Board of Directors

# Auditor's report on the corporate governance statement

To the annual meeting of the shareholders of BioInvent International AB (publ) Co. reg. no 556537-7263

### Engagement and responsibility

We have audited the corporate governance statement for the year 2014 on pages 56–58. It is the Board of Directors who is responsible for the corporate governance statement and that it has been prepared in accordance with the Annual Accounts Act. Our responsibility is to express an opinion on the corporate governance statement based on our audit.

### Focus and scope of the audit

We conducted our audit in accordance with RevU 16 The auditor's examination of the corporate governance statement. That standard requires that we have planned and performed the audit to obtain reasonable assurance that the corporate governance statement is free of material misstatements. An audit includes examining, on

a test basis, evidence supporting the information included in the corporate governance statement. We believe that our audit procedures provide a reasonable basis for our opinion set out below.

### Opinion

In our opinion, the corporate governance statement has been prepared and is consistent with the annual accounts and the consolidated accounts.

Lund, 25 March 2015  
KPMG AB

Alf Svensson  
Authorised Public Accountant

# Annual General Meeting

The Annual General Meeting will be held on Wednesday 22 April 2015 at 4 p.m., Elite Hotel Ideon, Scheelevägen 27, Lund. Notice to attend will be announced in the Swedish press in Post- och Inrikes Tidningar and on the Company's website.

Shareholders wishing to attend the AGM must be registered in the shareholders' register kept by the Swedish Securities Register Centre (Euroclear) no later than Thursday 16 April 2015 and must inform BioInvent of their intention to attend no later than 4 p.m. on Thursday 16 April 2015 by sending a letter to: Sölvegatan 41, SE-223 70 Lund, attn: Stefan Ericsson, or by phone +46 (0)46 286 85 50, or by e-mail to stefan.ericsson@bioinvent.com.

In order to participate in the AGM, shareholders with nominee-registered shares must request that their shares be temporarily owner-registered in the Euroclear shareholders' register. Such registration must be completed no later than Thursday 16 April 2015 and the nominee must be informed of this well in advance of this date.

Shareholders must include their name, personal/company registration number, shareholding, telephone number and the name of any assistants that will be attending. Proxy to act on behalf of a shareholder shall be sent together with the notice of attendance. Representative of a legal person shall hand in a copy of a registration certificate or similar papers of authorisation. The company will supply proxy forms upon request from a shareholder.

## Upcoming financial reports

BioInvent will present the following financial reports:  
Interim reports 22 April, 22 July, 22 October 2015

## Investor Relations

Michael Oredsson, CEO, +46 (0)46 286 85 67,  
mobile +46 (0)707 18 89 30.  
BioInvent's financial reports are also available at  
[www.bioinvent.com](http://www.bioinvent.com)

## Forward looking information

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



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