



# 09

Annual Report 2009



# Contents

Comments by the CEO	4
Markets	6
BioInvent's business model and strategy	12

Project BI-505	15
Project BI-204	16
Project TB-402	18
Project TB-403	20

Preclinical research	22
Human antibody technology	24

Director's report	28
Income statements	33
Balance sheets	34
Cash-flow statements	36
Changes in shareholders' equity	37
Accounting principles and information in notes	38
Audit report	51
Corporate governance report	52
The BioInvent share	56
Five-year review	58

The Board and auditors	60
Senior management	61
Glossary	62
Annual General Meeting	63

Preclinical  
research

TB-402

BI-204

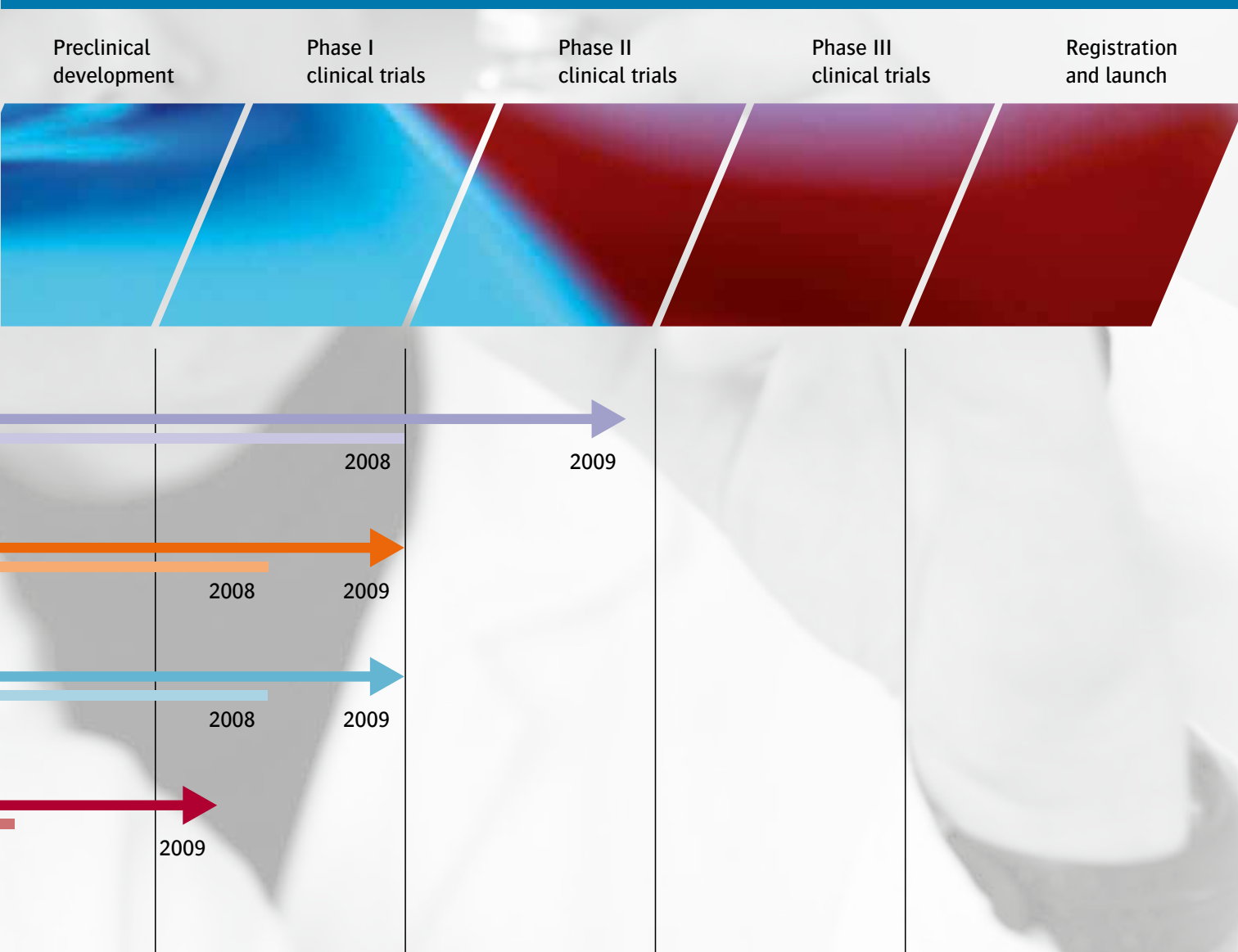
TB-403

BI-505

2008

## BioInvent's projects have made important progress in 2009

- In the phase II study of the TB-402 product candidate for the prevention of thrombosis, the treatments were administered to all patients in October 2009.
- The phase I study of TB-403 on patients with advanced cancer was successfully concluded in November 2009. The product candidate was well tolerated. A successful technology transfer under the alliance with Roche relating to TB-403 resulted in the 1st milestone payment in the 1st quarter of 2009 in the amount of EUR 5 million (SEK 54 million) to the Company and its partner ThromboGenics.
- The phase I study of BI-204 to prevent myocardial infarction in patients with coronary artery disease was concluded in the second quarter of 2009. The study showed that the product candidate was well tolerated. The project is being developed in cooperation with Genentech, a wholly-owned company within the Roche Group.
- At the end of the year the 1st patient was treated in a phase I study of the BI-505 for the treatment of multiple myeloma.
- In the third and fourth quarters of 2009 BioInvent signed agreements with Mitsubishi Tanabe and Daiichi Sankyo respectively for research and development of antibody-based drugs.
- In February 2010 BioInvent implemented a directed new issue of shares for a value of SEK 150 million.
- In March 2010 BioInvent entered into a product collaboration with Human Genome Sciences (HGS) for the development and commercialisation of therapeutic antibodies.



## Comments by the CEO

2009 was a successful year for BioInvent in which our drug candidates made great progress and advanced in the value chain. Our project development was largely in line with or even slightly ahead of the original schedule. Progress in the clinical studies we conducted during the year further strengthens our conviction that we are on the right path in our efforts to build an innovative and research-oriented biotech company focusing on antibody-based drugs.

The clinical phase II study of the anticoagulant TB-402 advanced in 2009 much faster than we had originally expected. The recruitment of all of the study's 315 patients was completed six months ahead of schedule and we expect to be able to present the results in the second quarter of 2010. At that time we will consult with our partner ThromboGenics to determine how to engage a partner with the strength and the infrastructure required to realise the major commercial potential of the drug candidate.

In May 2009 we concluded a phase I study in cooperation with our partner Genentech for our BI-204 drug candidate for the treatment of atherosclerosis. We expect to be able to launch the phase II study, in which BioInvent will play an active role, in 2010.

The TB-403 cancer project, in which our partner Roche has primary responsibility for the clinical programme, is also expected to enter phase II. A clinical phase I study on patients with advanced cancer was concluded successfully in November 2009.

Our fourth drug candidate, BI-505 for the treatment of multiple myeloma, also took a step forward when the clinical phase I study was initiated just after year-end in the US. This addresses a form of cancer where there is a great need for new, effective treatment alternatives. The study is expected to take around a year and a half and we intend to conduct it ourselves.

The clinical and medical progress of BioInvent's project portfolio in 2009 has also resulted in a number of positive financial consequences. We are expecting revenues from our partners Genentech and Roche when our BI-204 and TB-403 drug candidates advance further in clinical development. We have retained the commercial rights in all markets outside North America for BI-204 for the treatment of atherosclerosis. This will provide us with opportunities to sign agreements on favourable terms with partners in these territories after the project has entered phase II. The alternative is to wait until data from the phase II study is available in the hope of getting better leverage from the rights.

One of BioInvent's most significant challenges is finding a balance between operating costs, risks and future commercial opportunities. Analysing this balance is vital when we are considering at what stage in an individual project it is most beneficial to engage a partner. In some cases it may be wise to sign partnership agreements at an early stage when it is clear that the future clinical programme will require considerable investment. This is the reason for our agreements with Genentech and Roche. In other cases it may be better to run the projects internally until they have advanced much further.

Our general objective is to run our own projects until they have advanced further in the value chain and thereby secure a greater future commercial return on our investment. Naturally, we also want to be perceived as a credible and strong partner by the companies we want to work with, and this requires having the necessary financial strength and flexibility.

This is one of the reasons we implemented a directed share issue amounting to SEK 150 million. The issue did not involve any significant discount to the share price. It broadened the Company's long-term institutional ownership and provided us with financial flexibility which is particularly important. From a position of strength we can choose our own path – either to drive projects forward ourselves or to engage partners when we consider this appropriate.

Although our project portfolio has developed well, we are aiming to expand it further to include new drug candidates. We therefore intend to strengthen our preclinical research through cooperation with external groups or by launching new, internal development programmes. The share issue we implemented increases our options in this regard as well.

We demonstrated one way of ensuring we can launch new projects when we recently announced our collaboration with the US company Human Genome Sciences. This collaboration is an example of how two companies with complementary technology can combine their technological and financial resources to develop innovative drugs jointly. This partnership gives BioInvent access to commercially attractive target proteins at the same time as the risks involved in drug development are shared with a partner. Experience from our multi-year partnership with the Belgian company ThromboGenics tells us how productive such partnerships can be.

In 2009 we were able to add Mitsubishi Pharma and Daiichi Sankyo to the group of pharmaceutical companies that have chosen to develop their own antibody candidates with the help



“2009 was a successful year for BioInvent in which our drug candidates made great progress and advanced in the value chain.”

Svein Mathisen, CEO

of BioInvent’s antibody technology. This provides BioInvent with new sources of revenue, and in the longer term, milestone payments and royalties for the products that successfully advance in clinical development and reach the commercial phase. This business initiative represents considerable potential for the Company without involving any significant risk for us.

We were also delighted that BioInvent was honoured with the award “Licensing Deal of the Year” at the Scrip Awards annual meeting in November 2009.

In light of the above, there is every indication that 2010 will be a successful year for BioInvent in which exciting new things will happen. We have a project portfolio that is developing rapidly and we expect another two of our drug candidates to

enter clinical phase II studies. Revenues from our partners combined with the proceeds from the new share issue we have implemented provide us with the financial security that will allow us to be flexible in our choices and with the necessary conditions to continue to generate value and to be a credible partner in our relationships with both our current and future partners as well as external research teams.

In conclusion, I want to express my gratitude to our employees for their contributions during yet another successful year.

Svein Mathisen  
Chief Executive Officer, March 2010



## **Antibodies – a rapidly growing segment in the pharmaceuticals industry**

The antibody-based drug segment is one of the fastest growing segments in the pharmaceutical industry with an average annual growth over the past ten years of around 30 percent. Since the beginning of 2000 sales have increased more than tenfold from USD 2 billion to close to USD 30 billion in 2008. This strong growth is likely to continue over the next few years, and by 2014, the market is expected to be worth more than USD 60 billion<sup>1</sup>. There are several reasons why antibody-based drugs have become successful and represent significant value for the companies that have developed them. Antibodies are nature's own defence molecules. As such they are highly selective and, in their natural form, are very well tolerated by the body. Consequently the mechanisms of action can be expected to be more predictable and the risk of undesired side effects lower than for conventional medicines. Also, antibody-based drugs have other application areas than traditional medicines; they are useful when targeted at extracellular molecules or cell-surface proteins – two significant groups of target proteins that may be difficult for traditional, small molecular drugs to impact. This is the task of naturally occurring antibodies of the organism: to recognise foreign substances and cells so that they can be rendered harmless.

The time needed to develop antibody-based drugs is shorter than for traditional pharmaceuticals and development costs are therefore lower<sup>2</sup>. In addition, the risk of setbacks in clinical development appears to be lower for antibodies than for traditional drugs<sup>3</sup>.

### **Longer life cycles**

An additional benefit with antibody-based drugs is that they may be expected to have longer life cycles than small molecular drugs and may be subject to less competition from companies that produce copies of the drugs after patent expiration. This is because antibodies are biological products that are produced from living cells which makes them difficult to copy. The successors, so-called "biosimilars," do not become exact copies and must go through quite extensive comparative clinical trials before they can be approved for sale. This complexity may be expected to result in fewer competing biosimilar drugs than is generally the case for traditional drugs when products will lose patent protection. Moreover, price erosion is expected to become much less pronounced for antibody-based drugs that may be subjected to competition from biosimilars. This was confirmed when

the first biosimilars, such as the growth hormone somatropin or the blood growth factor G-CSF, both of which are recombinant proteins, were approved in the EU. The difference in price between the originals and the copies of these products is significantly smaller, 20-40 percent, than is usually the case when small molecular drugs are exposed to generic competition which can lead to a fall in price of up to 80 percent.

### **Considerable market activity**

There is a great demand in the market for innovative drugs that can affect the disease process specifically and effectively with a favourable side-effect profile. This has had a positive effect on the pricing of antibody-based drug projects in development, which is confirmed by a number of recent transactions in the market. Abbott, for example, paid USD 170 million upfront when the company licensed a product in initial clinical phases from Pangenetics in November 2009<sup>4</sup>. In another recently reported licensing deal, Alder Pharmaceuticals received USD 85 million in advance payment from Bristol-Myers Squibb Company ("BMS")




1 Datamonitor 2009

2 Scrip 2002

3 CMR International 2004 R&D Factbook

4 Pangenetics press release, 12 November 2009



The market for antibody-based drugs continues to grow rapidly. Considerable market activity and a number of significant transactions have been recently reported.

for an antibody against inflammatory diseases. The total amount of future milestone payments, excluding royalties, exceeded USD 1 billion in this deal<sup>5</sup>. In this context it should also be noted that BioInvent and ThromboGenics received EUR 50 million in upfront payment when they licensed TB-403 to Roche in June 2007.

Antibody companies continue to be attractive acquisition targets. Recently BMS purchased the US company Medarex, which has technology to produce human antibodies, for USD 2.4 billion. The Japanese company Daiichi Sankyo bought German U3 Pharma for USD 234 million. Eisai paid USD 325 million for Morphotek in 2007, and AstraZeneca bought Cambridge Antibody Technology for just over GBP 700 million in 2006.

#### **End markets for BioInvent's product candidates**

BioInvent currently has four product candidates in clinical development in the areas of thrombosis, atherosclerosis and cancer, diseases where there is a significant medical need. Below are brief descriptions of how BioInvent's product candidates can be positioned in these markets.

#### **Thrombosis**

TB-402 is being developed to prevent thrombosis. In clinical trials, the product candidate has demonstrated a favourable pharmacokinetic and safety profile, which reinforces the expectation that it will be a suitable treatment option for patients undergoing orthopaedic surgery, such as hip and knee operations. These patients are at high risk of developing deep vein thrombosis (DVT) if they do not receive prophylactic treatment. Another important category of patients that may be treated with TB-402 are patients with atrial fibrillation. These patients are at risk for serious complications such as stroke.

The mortality rate among patients affected by DVT is high if left untreated, and the cost for society as a result of the health-care needs of these patients and their subsequent long-term follow-up care is high. In the US alone the estimated number of individuals treated every year for DVT or pulmonary embolism (PE) is more than 600,000<sup>6</sup>. DVT and PE together may also cause more than 100,000 deaths in the US every year<sup>7</sup>.

The market for antithrombotics in 2007 was calculated to be worth around USD 26 billion and this is growing annually by

<sup>5</sup> Alder Pharmaceuticals, BMS press release 10 November 2009

<sup>6</sup> Barclays Capital Equity Research, 2008

<sup>7</sup> The Surgeon General's Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism, 2008

around 12 percent<sup>8</sup>. This includes drugs that affect the action of platelets and that are mainly used to prevent arterial thrombosis, e.g. the best-seller clopidogrel. Drugs that affects the coagulation factors of the blood, on the other hand, is used mainly in venous thrombosis. The annual global sales of these anticoagulants amounted to USD 6.7 billion in 2008 in the largest markets<sup>9</sup>. Anticoagulants currently available (mainly heparin substances) are inconvenient to administer and are associated with a risk of haemorrhaging. Better anticoagulants are therefore needed. In particular, drugs that are easier to administer (without the need for daily doses and frequent dose adjustment) would meet a significant medical need. The side-effect profile and in particular the risk of bleeding, is an important factor for new anticoagulant drugs.

The number of hip and knee surgeries in the large pharmaceutical markets was estimated at around 2.4 million in 2009 and is expected to grow to around 3.1 million by 2015<sup>10</sup>. The market is dominated by low molecular heparin that is injected daily during the treatment period. Today heparin is injected daily for up to 15 – 30 days following a knee or hip operation. A prolonged treatment period can reduce the number of cases of deep vein thrombosis.

BioInvent expects TB-402 to have a product profile that is highly suitable for this patient population because the antibody has a half-life that is believed to enable a single injection to be administered in connection with surgery. Based on available clinical results, the product is believed to have a favourable safety profile with a low risk of overdose and undesirable bleeding. Clinical results also show that the product's effect can be reversed, which is important in case another surgery is needed. The product's expected side-effect profile, e.g. low risk of undesirable bleeding, is also attractive. Another important benefit is that TB-402's function and metabolism are not affected by a patient's impaired liver or kidney function. The risk that TB-402 will have unwanted interactions with other drugs is thought to be small. These product properties can be expected to be particularly important for older patients who undergo hip or knee surgery and who may be being treated with a number of other drugs and who often have organs with impaired function.

The market for antithrombotics for patients with atrial fibrillation is large and is currently dominated by warfarin (varan). Factor Xa inhibitors such as rivaroxaban and apixaban are in development. These drugs can be administered orally and are expected to take a portion of the market<sup>11</sup>. TB-402, on the other hand, is expected to be able to be administered by injection with

long, i.e. monthly, intervals. The product is also expected to have a favourable side-effect profile, which means it is likely that patients will not need to be monitored. These product properties are expected to be particularly valuable to patients with atrial fibrillation who are hospitalised, elderly, or suffering from dementia.

### Cardiovascular diseases

Drugs for the treatment of cardiovascular diseases which include atherosclerosis, abnormal blood lipids, high blood pressure and diabetes, currently constitute the largest group of drugs and account for total sales of USD 90 billion in the seven largest markets alone<sup>12</sup>. This includes statins, which account for the largest portion in terms of value of the drugs used for the treatment of atherosclerosis.

BI-204 is being developed initially for a new market segment where there is a significant medical need – to prevent myocardial infarction or stroke in patients with prior manifestation of coronary artery disease. The number of patients who have suffered myocardial infarction and therefore belong to the risk population that may be appropriate for treatment with BI-204 is just over 15 million in the largest markets<sup>13</sup>. Patients with acute coronary artery disease have a significantly elevated risk of complications and 30 percent suffer an additional infarction within three years. Current treatments such as statins, fibrates, niacin and cholesterol absorption inhibitors, have a limited effect on the fundamental course of the disease – the extensive atherosclerosis that is common in the blood vessels of these patients.

Drugs being developed for the treatment of atherosclerotic disease include phospholipase A2 inhibitors (e.g. darapladib) HDL modifying drugs, CETP inhibitors (e.g. dalcetrapib, anacetrapib), and CCR2 inhibitors (MLN1202).

In addition to the large market for secondary prevention, BI-204 may be used for groups of patients with a significant risk of developing cardiovascular disease, such as individuals with insulin resistance and type II diabetes. This group of patients is very large and growing due to the age structure and lifestyle factors and patients are also often difficult to treat. The patients

8 Business Insights 2008  
9 Datamonitor 2009  
10 Datamonitor 2008  
11 Business Insights 2008

12 Datamonitor 2009  
13 Datamonitor 2008





BioInvent's product candidates in the areas of thrombosis, atherosclerosis and cancer, are all being developed to treat diseases where there is a great medical need. The antibodies are all based on innovative treatment principles and therefore have the potential for commercial success when they reach the market.

often develop metabolic syndrome<sup>14</sup>. The level of oxidised LDL is raised in patients with insulin resistance and individuals with raised oxLDL levels run a greater risk of developing metabolic syndrome. BI-204's expected competitive advantage is based on its mechanism of action and effect on the fundamental course of the disease; it has been shown to reduce both the plaque volume in general and inflammation in the vessel walls and thereby stabilise unstable plaque.

### Cancer

BioInvent has two product candidates in clinical development that are being developed to treat oncological diseases: TB-403 and BI-505.

TB-403 is a so-called angiogenesis inhibitor and has the potential to be used to fight several types of tumours. Its mechanism of action is general and kills tumours indirectly by blocking the blood supply to the tumour. This mechanism also means that TB-403 may be developed to treat other diseases outside of the field of oncology, e.g. certain eye diseases and inflammatory diseases.

The formation of new blood vessels is a process called angiogenesis. These newly formed vessels supply growing tissue with nutrients and transport waste away from the tissue. The formation of new vessels is essential for a tumour to grow, spread locally and metastasise. Tumours of a certain size are therefore dependent on the formation of new blood vessels to survive. Angiogenesis inhibition as a principle for cancer treatment has several advantages, e.g. the mechanism of action is different from other cancer therapies and it can therefore be useful in combination therapies. Interest in angiogenesis inhibitors in cancer treatment has increased significantly in recent years. These types of drugs have been shown to be effective in the treatment of a number of different types of cancer, e.g. kidney, colorectal, breast, ovarian and lung cancer as well as glioma. Drugs to treat each of these diseases have a sales potential of up to a few billion US dollars. One antibody, bevacizumab, has been approved for several of these indications and

has quickly become a commercial success with sales approaching USD 4.5 billion in 2008.

Today the above-mentioned types of cancer are usually treated with different combinations of chemotherapy, radiation and surgery. Some forms of cancer are also sensitive to hormone therapy. Angiogenesis inhibitors work better in combination with current therapies. This is supported by clinical trials that have been conducted with other angiogenesis inhibitors in development and on the market. The effect of treatment has been proved to be additive or even synergistic in both treatment-naïve patients and in patients who have undergone several rounds of treatment. Angiogenesis inhibitors as a class of drug therefore have a broad area of application, because many forms of tumours are suitable for treatment with them and because a large percentage of patients are expected to benefit from the treatment.

TB-403 has a promising product profile with partially unique mechanisms of action; in addition to its direct angiogenesis inhibiting function, preclinical data shows that TB-403 inhibits the inflow of macrophages associated with tumours<sup>15</sup>. Macrophages are a type of cell believed to counter the effect of and contribute to the development of resistance to bevacizumab and other similar angiogenesis inhibitors. TB-403 may therefore be used as a single drug or in combination with bevacizumab to treat different patient groups including those who have developed resistance to or do not tolerate bevacizumab. Supporting preclinical data indicates that the effect of the two substances is additive and that TB-403 may have an effect on tumours that do not respond to treatment with bevacizumab. Based on pre-clinical data and the mechanisms of action for TB-403, there are other reasons to expect that it will have fewer side effects such as gastrointestinal perforations, hypertension, and bleeding complications. It is therefore believed that TB-403 will be able to be used for indications such as colorectal, breast, lung and kidney cancer and thereby prolong disease-free survival and overall survival of these patients. It is also hoped that it will be possible in the future to expand beyond these indications.

<sup>14</sup> JAMA 2008, Kopprasch Diabetes 2002

<sup>15</sup> Fischer et al Cell 2007

BI-505 is the other product candidate BioInvent is developing for the treatment of oncological diseases. Unlike TB-403, it fights tumours directly by binding specifically to cancer cells and killing them through programmed cell death (apoptosis) and other direct effector mechanisms.

The first form of cancer for which BI-505 is being developed is multiple myeloma, a disease where there is a great medical need. BI-505 has been granted orphan drug designation in the US and the EU for this indication. This may give BI-505 market exclusivity as an antibody against ICAM-1 in these markets for up to ten years after market approval has been obtained.

The bone marrow disease multiple myeloma is mainly treated today with chemotherapy and bone marrow transplantation. Notable among newer treatments is the proteasome inhibitor bortezomib and immunomodulating drugs such as lenalidomide and thalidomide. Sales of lenalidomide and bortezomib in 2008 amounted to just over USD 2 billion<sup>16</sup> and sales of these drugs is expected to continue to rise sharply in the near future<sup>17</sup> because the medical need is still great. Drugs such as lenalidomide and bortezomib have improved survival somewhat in the hard to treat population of relapse patients, but the mortality rate remains high. The average survival for myeloma patients is 3 – 5 years and the disease is often painful since the tumour affects bone tissue and the patients therefore often suffer from severe bone pain and bone destruction as well as neurological symptoms. In addition these patients are infection prone and may suffer from severe kidney damage.

At present there is a handful of new drug candidates in late clinical development phases that target myeloma. Some of these may obtain approval for clinical use over the next few years. Bevacizumab (anti-VEGF) and tocilizumab (anti-IL6) are two interesting examples of biologics that are currently being tested in clinical phase II studies in myeloma patients.

BioInvent believes that BI-505 may have potential as a monotherapy for relapsed refractory patients with myeloma. These patients have been clinically proven to have elevated levels of ICAM-1 in their tumours, a more serious disease and

lower chance of survival<sup>18</sup> and ICAM-1 is believed to be involved in the occurrence and development of multiple myeloma<sup>19</sup>. The mechanism behind BI-505 makes it also conceivable that it may have the potential to be used in combination therapies with other antimyeloma drugs. This would mean that BI-505 could be used as a treatment alternative at an earlier stage and could therefore prolong survival in these patients. There is also a commercial opportunity in developing BI-505 as a treatment for other forms of tumours, such as lymphoma, stomach/intestinal, lung and breast cancer etc.

### Competition

Traditionally, antibody-based drugs have mainly been developed by biotech companies. The company that sells the most antibody-based drugs is the US company Genentech, now part of Roche. Other biotech companies that have successfully launched antibody-based drugs include Biogen IDEC, Amgen and Alexion. As antibody-based drugs demonstrate commercial success, interest from big pharma for these products increases. In addition to Roche, companies like Novartis, Johnson & Johnson (through its subsidiary Centocor), BMS (Medarex), Pfizer (Wyeth), AstraZeneca (MedImmune), Eli Lilly (ImClone), UCB and Abbott currently have products on the market and in late clinical development.

More companies that are focusing on developing antibody-based drugs and antibody technologies have in recent years been acquired by larger companies. Companies that have not been bought, but belong independent, and that are developing antibody-based drugs include MorphoSys, XOMA, Regeneron, Ablynx and Seattle Genetics. Like BioInvent these companies enter into strategic development partnerships with large pharmaceutical companies where they utilise their expertise and technology within antibody development.

There are also other more product-oriented companies such as Genmab, Facet, Human Genome Sciences, Immunomedics and Micromet, which are successfully developing antibody-based drugs in late clinical phases.

<sup>16</sup> MedTRACK database 2010  
<sup>17</sup> MedTRACK database 2010

<sup>18</sup> Migkou et al. ASH poster 2009, Schmidmaier Int J Biol Markets 2006  
<sup>19</sup> Hideshima Nat Rev Cancer 2007



# BioInvent's business model and strategy

BioInvent develops innovative antibody-based drugs for the treatment of diseases where there is a large unmet medical need. The goal is to generate value by building a sustainable portfolio of clinical development projects and, over time, commercialise several innovative drugs.

## **BioInvent's business model**

BioInvent focuses on developing antibody-based drugs and documenting their biological activity and efficacy in clinical trials.

To be able to move the product candidates forward through late clinical development to full commercialisation, the Company works with large pharmaceutical companies such as Genentech and Roche.

In the case of certain projects, partnership agreements may be signed early on in the development phase, while other projects may be developed by the Company for a longer period. The timing of entering into partnerships is determined by costs, risk, the need for expertise and the value added from continuing to develop the project in-house. The strategic purpose of the agreements is to ensure that the projects have the necessary

expertise and resources and that BioInvent avoids tying up too much resources in any individual project. To maximise the Company's potential to benefit from the overall value creation and provide the greatest possible flexibility, the Company will, in certain cases, also retain the market rights in individual geographical markets where the Company considers it feasible to establish a competitive marketing and sales organisation. This strategy reduces business risk and can be adapted to market-specific and company-specific conditions. It also makes it possible to take maximum advantage of the growth in value of successful projects. The Company's potential for realising this strategy is supported by its ability to attract strong partners.

BioInvent has also entered into a number of development alliances where the development partner gains access to parts of BioInvent's antibody platform and antibody-based drug development expertise. These partnerships relate both to development and production of antibodies. This normally means that BioInvent, with the help of the n-CoDeR antibody library, identifies antibodies that bind to the target proteins that a partner has selected. The selected antibodies are then developed, either by the partner alone or within the framework of a continuing alliance with BioInvent. BioInvent receives licence fees, milestone payments and sales royalties from such projects.

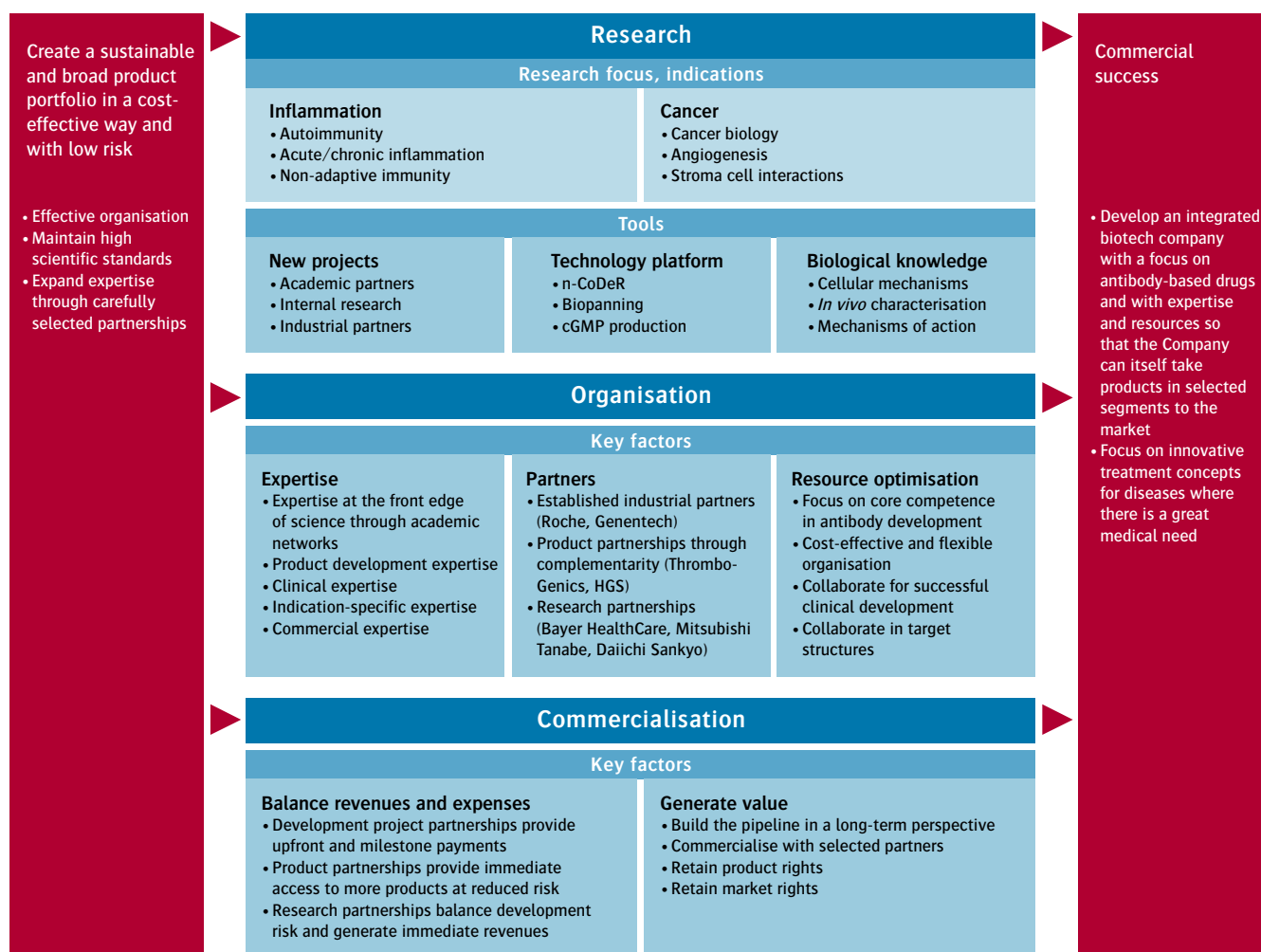
## Biolinvent's strategy

Below is a diagram showing the strategy of Biolinvent, how the Company's resources are allocated and how the strategy relates to the Company's operational and long-term goals.

### Operational goals

### Strategy

### Vision

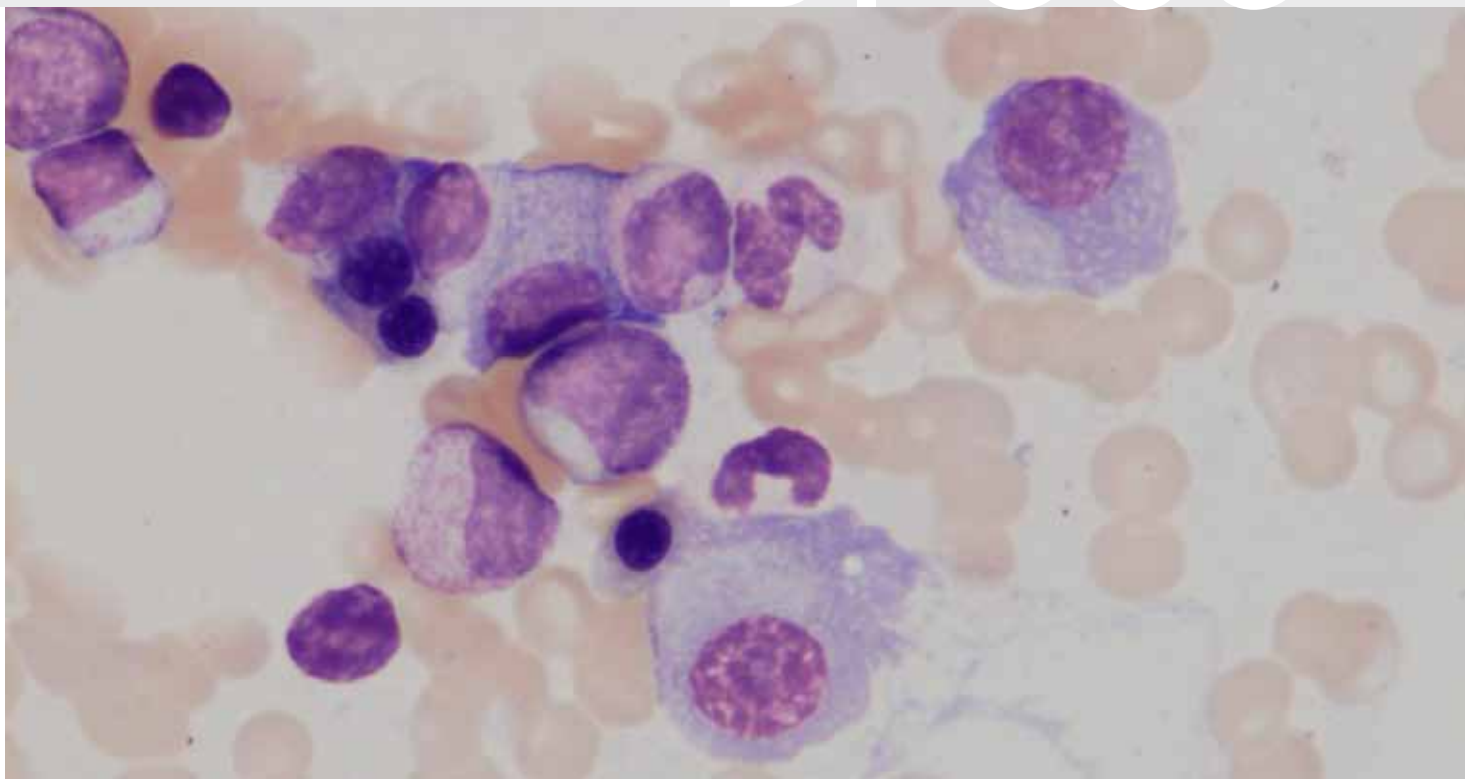






Projects ▶

# BI-505



Bone marrow smear from a myeloma patient

BI-505 is a fully human antibody that was developed using BioInvent's biopanning technology. The antibody binds to the adhesion molecule ICAM-1 (CD54), a naturally occurring protein on the surface of certain cells. Expression of ICAM-1 is elevated in a number of types of cancer, while expression in most healthy tissue is low. In a first step, BI-505 is being developed for the treatment of multiple myeloma that expresses ICAM-1. BioInvent is developing BI-505 in-house.

#### **Product characteristics**

BI-505 binds to ICAM-1, which is expressed by cancer cells in a number of types of cancer. The antibody induces programmed cell death (apoptosis) and mediates immune effector functions that also contribute to fighting tumour cells.

#### **Clinical need**

In preclinical models, BioInvent has shown that BI-505 is especially effective against multiple myelomas that express ICAM-1. Multiple myeloma is currently mainly treated with chemotherapy

and bone marrow transplantation. Notable among new treatments are the proteasome inhibitor bortezomib, and immunomodulating drugs such as lenalidomide and thalidomide. These drugs have improved survival somewhat in the hard to treat population of relapse patients, but mortality remains high. The average survival is 3-5 years for myeloma patients and the course of the disease is often painful since the tumour attacks bone tissue and patients suffer from severe bone pain and bone destruction as well as neurological symptoms. In addition, these patients are infection prone and may suffer from severe kidney damage.

#### **Project status**

BI-505 has a high-affinity, specific antibody against ICAM-1. It has been shown to kill tumours very effectively in several preclinical models. The US Food & Drug Administration (FDA) approved BI-505 last year for clinical phase I studies in the US and these were launched in the beginning of January 2010. BI-505 has been granted orphan drug designation for the multiple myeloma indication by both the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

#### **Patent protection**

BioInvent has applied for patents for antibodies against ICAM-1 and their ability to induce apoptosis in various types of tumours such as multiple myeloma, lymphoma and carcinoma.

# BI-204

BI-204 targets oxidised forms of apoB100, a lipoprotein that is part of the LDL particle. Research in recent years has shown strong links between oxidised LDL and harmful inflammation of the vessel walls. This type of inflammation leads to the formation of atherosclerotic plaque that may fragment and cause blood clots. The mechanism of action supports the idea that BI-204 can be developed as a treatment for atherosclerosis to reduce the occurrence of myocardial infarction in high-risk patients. These are primarily patients with coronary artery disease (CAD), especially individuals who have already suffered a myocardial infarction.

BioInvent has entered into a strategic partnership with Genentech where the companies are jointly developing and commercialising BI-204. Under the agreement the companies have joint responsibility for clinical development. Genentech has licensed the North American commercialisation rights, while BioInvent has retained the rights for the rest of the world.

## Product characteristics

BI-204 has an attractive product profile since it has the potential to stabilise plaque at risk of fragmentation, and may also reduce its size. BI-204 therefore has the potential to attack the underlying cause of coronary artery disease – the extensive atherosclerosis that is common in these patients. An important component in this disease is believed to be harmful inflammation in the patients' blood vessels. BI-204 has been shown to modulate this process in the vessel walls by the antibody binding to the oxidised LDL. Links have been shown between these

oxidised forms of LDL and the inflammatory processes that lead to plaque formation in the vessel walls. Preclinical trials support the idea that the mechanism behind BI-204 is modulation of the inflammatory processes with a reduction of pro-inflammatory cells in treated plaque as a result, which in turn reduces the formation of new plaque and reduces existing plaque.

## Clinical need

The goal is for BI-204 to be able to prevent myocardial infarction in patients with coronary artery disease. These patients have a substantially higher risk for complications; 30 percent have another myocardial infarction within three years. Currently no effective drugs are available that have a significant effect on the underlying cause of the disease – the extensive atherosclerosis that is common in the vessels of these patients.

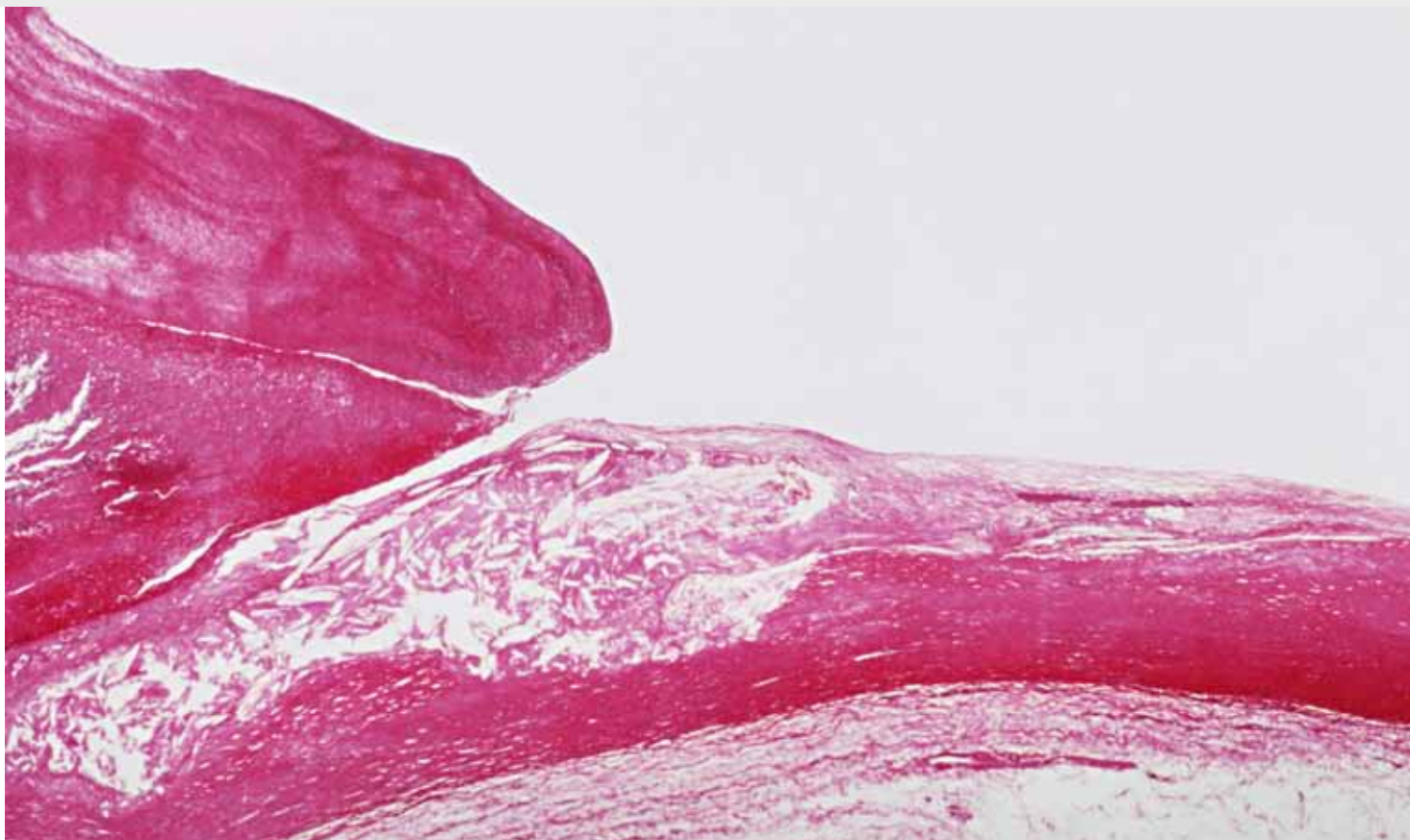
There is a significant medical need for new treatments for atherosclerosis that can stabilise plaque at risk of fragmenting, and hopefully also reduce its size. Since a drug of this kind would have great commercial potential, considerable research initiatives are under way in this field. Clinical observations show that metabolic syndrome, like the syndrome components insulin resistance and hyperglycaemia, are more common in individuals with high concentrations of oxidised LDL. Thus BI-204 may be a potential treatment for patients with type 2 diabetes and metabolic syndrome.

## Alliance with Genentech

In January 2007 the Company entered into a strategic partnership with Genentech Inc. to develop and commercialise BI-204. Genentech made a cash payment to BioInvent of USD 15 million and BioInvent may receive additional milestone payments of up to USD 175 million as well as royalties on sales in North America.

Under the agreement Genentech and BioInvent will be jointly responsible for clinical development. Genentech will be responsible for, and will have sole control of, all commercialisation of the drug in North America, while BioInvent will be responsible and will have sole control of, commercialisation in the rest of the world. During the development period Genentech and BioInvent will share the development costs according to an undisclosed split.





Atherosclerotic aorta

### **Project status**

The phase I programme was concluded in the second quarter of 2009. The study was a double-blind randomised dose-escalating trial where both individual and repeated doses of BI-204 were administered intravenously or subcutaneously. A total of 80 healthy men and women with elevated levels of LDL cholesterol were included in the trial. The drug was well tolerated and the pharmacokinetic result showed that the half-life was within the expected range for human antibodies. BioInvent and its partner Genentech are currently in the final stages of designing the upcoming phase II programme.

### **Patent protection**

The oxidised forms of the apolipoprotein apoB-100 that cause harmful inflammation within the vascular wall, the use of these in drug development, products aimed at these target proteins, the mechanisms of action, as well as the formulation of BI-204 are patent pending in about 40 countries, including major markets such as the United States, Europe, Canada, Japan, Australia, China and India. Patents have been granted in the US and Europe among other places.

# TB-402

TB-402 is a human monoclonal antibody targeting coagulation Factor VIII. The product is intended to be an anticoagulant to prevent deep vein thrombosis in orthopaedic surgery and to prevent stroke in patients with atrial fibrillation. TB 402 is being developed in collaboration with ThromboGenics.

## Product characteristics

TB-402 effectively inhibits thrombosis by binding to Factor VIII which is essential for the coagulation of the blood. It is important that the inhibition of factor VIII will be controlled and not give rise to unwanted bleeding. This effective but controlled anti-coagulant effect is possible because TB-402 has shown a beneficial partial inhibition of Factor VIII. Thus, the drug's effect levels out at a certain dosage and is not subsequently affected by a further dose increase. This, combined with other research results and completed clinical studies, indicates that the risk of overdose and side effects will be lower with TB-402 than with other anticoagulants on the market today. The need for patient monitoring is likely to be reduced as well.

The prolonged half-life of TB-402 reduces the need for maintenance treatment compared to other anticoagulants and is therefore believed to be easier to administer than current treatments available today.

## Clinical need

Several patient groups, such as patients undergoing major orthopaedic surgery, are in great need of safe and improved anticoagulant therapy. These patients are at risk of deep vein thrombosis.

Current treatment, such as various heparin drugs, requires daily injections and may cause serious haemorrhaging. The side-effect profile of new anticoagulants is therefore very important, especially with respect to the risk of bleeding. The mortality rate of patients affected by deep vein thrombosis is high and the costs for society relating to the acute healthcare needs of these patients and their subsequent long-term follow-up care is great.

Another group requiring effective antithrombotic treatment consists of patients with atrial fibrillation who may suffer from complications such as stroke.

In contrast with currently available treatment, TB-402 is expected to be administered as a single dose in connection with the surgical procedure, or with an interval of up to two – four weeks for chronic conditions. The benefits of this approach are patient convenience and compliance. The treatment is also expected to be associated with a low risk of bleeding and other side effects such as liver toxicity. The need for patient monitoring is not expected to be great.

## Alliance with ThromboGenics

BioInvent and ThromboGenics Ltd entered into an alliance in September 2004 for the joint development of antibody-based drugs to treat vascular diseases. Under the alliance the expertise of both companies is combined for the discovery, development and production of antibodies. BioInvent is contributing knowledge and experience in antibody development, production and immunology, and ThromboGenics is contributing expertise in research and clinical development in the area of vascular medicine. The partnership covers both TB-402 and TB-403.

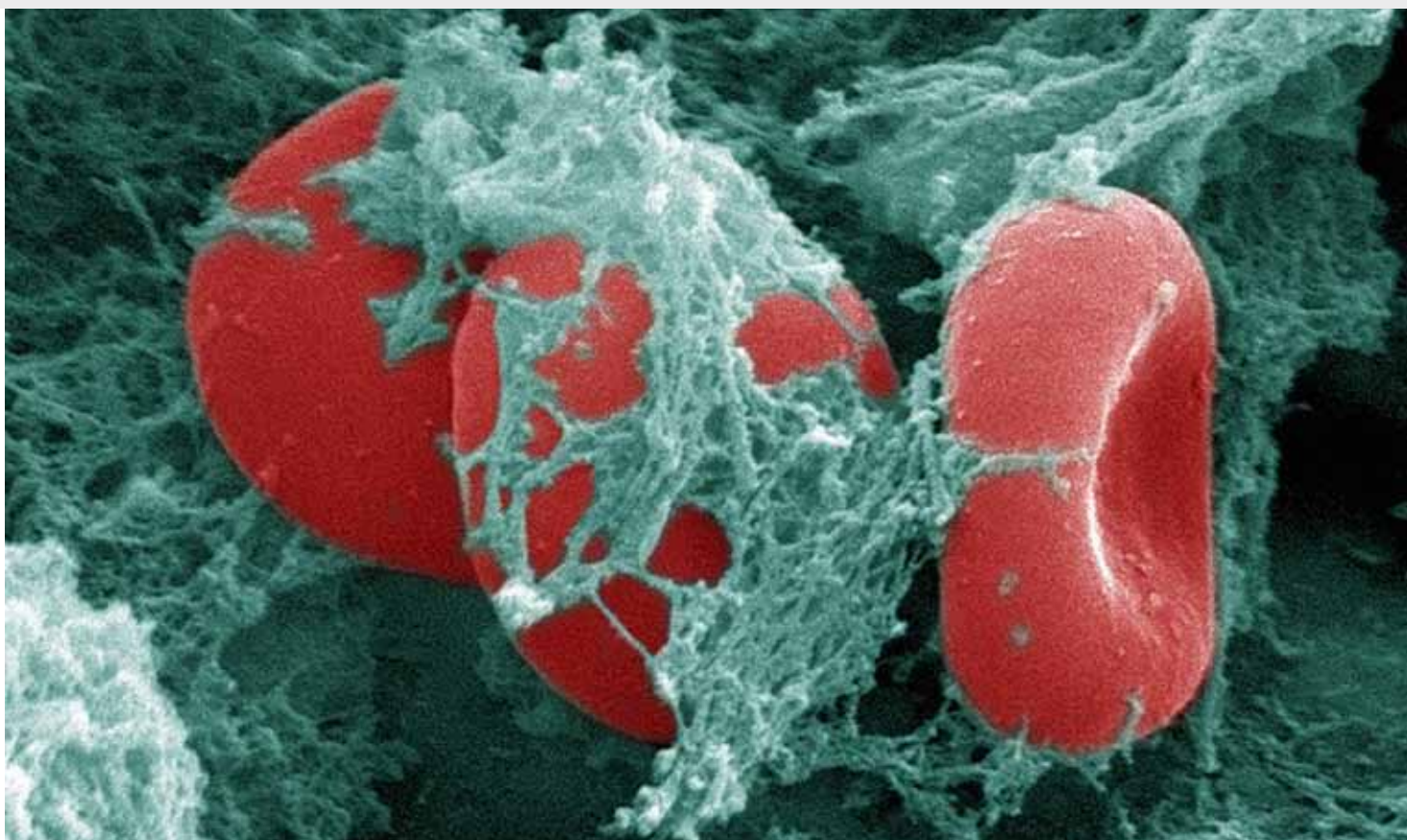
The TB-402 development programme is being conducted jointly by the parties and the costs are shared equally between them. Since ThromboGenics had already developed a product candidate when the parties entered into the alliance, the revenues generated within the project are shared 60/40 to ThromboGenics' advantage according to the agreement.

## Project status

A clinical phase II study began in February 2009 for patients who have undergone knee replacement surgery, to further evaluate the safety of the medication and its ability to prevent deep vein thrombosis. The study includes 315 patients at 30 clinics, mainly in Europe. All patients in the study have been treated, ahead of the original schedule, and the results of the study are expected to be reported in the second quarter of 2010.

The phase II study is an active (enoxaparin)-controlled, dose-escalating, prospective, randomised, open-label multicentre trial to evaluate TB-402 for the prevention of deep vein thrombosis after knee surgery. The study is assessing three different





Red blood cells in a fibrin net

doses of TB-402 that are administered in a single intravenous bolus injection after the patients have undergone knee replacement surgery. The primary efficacy parameters for the three escalating doses of TB-402 are safety and efficacy.

Previously reported phase I study results confirmed that the antibody provided beneficial partial inhibition of Factor VIII with a plateau effect at higher doses shown in earlier preclinical studies. A stable and long-acting anticoagulant effect was also demonstrated.

BioInvent and ThromboGenics have also successfully conducted two interaction studies on TB-402. One of the studies showed that the effect of TB-402 is reversed by administering the target protein (Factor VIII) that is blocked by TB-402. The second study showed that TB-402 was safe and well-tolerated in patients who had received standard therapy (enoxaparin and warfarin) for deep vein thrombosis.

### **Patent protection**

Antibodies that only partially inhibit Factor VIII, pharmaceutical preparations containing such antibodies and their use in drug development are all patent pending in markets such as Europe, Japan, Canada, the United States and Australia. A patent has been granted in Europe and Japan among other places.

# TB-403

TB-403 is a humanised monoclonal antibody targeting PIGF, a protein that affects the development of new blood vessels (angiogenesis). The project is being developed primarily to treat types of cancer that are dependent on the growth of new blood vessels.

TB-403 was originally developed within the framework of BioInvent's strategic partnership with ThromboGenics. In June 2008 the Company entered into a strategic product alliance with Roche. This gives Roche exclusive, worldwide rights to develop and commercialise TB-403 at the same time as BioInvent and ThromboGenics retain the right to market the product in the Nordic, Baltic and Benelux countries. Roche is currently financing the development of TB-403.

## Product characteristics

TB-403 is a new form of angiogenesis inhibitor that is specific to the PIGF target protein. PIGF is often upregulated in cancer and chronic inflammatory conditions. This makes it a suitable target protein in the treatment of these diseases. PIGF stimulates the formation of new blood vessels like the vascular endothelial growth factor ("VEGF"), but unlike VEGF, PIGF is not believed to affect the patients' physiological, normal angiogenesis. TB-403 can therefore be expected to have a favourable side-effect profile.

When patients are treated with other angiogenesis inhibitors, an upregulation of PIGF is sometimes observed. It is likely therefore that PIGF plays a role in the body's adaptive reaction, which in turn may cause resistance to these drugs. BioInvent therefore believes that TB-403 should be able to reinforce the effect of these angiogenesis inhibitors and further be an effective supplement to chemotherapy. The antibody also has the potential to be used in patients who has developed resistance to VEGF inhibitors.

There is also preclinical data to suggest that the risk of developing resistance is lower in treatment with PIGF inhibitors than treatment with VEGF inhibitors.

## Clinical need

Cancer constitutes a heterogeneous group of diseases, which complicates the development of drugs directed at tumour cells with the intention of killing them. A new and attractive strategy is to attack the tumours indirectly by blocking the growth of new blood vessels. These blood vessels supply growing tissue with nutrients and transport waste away from the tissue. Tumours over a certain size are dependent on the formation of new blood vessels in order to grow and survive. A substance that inhibits the growth of new blood vessels could therefore reduce tumour growth and increase the patient's chances of survival.

Current treatment for these types of cancer usually includes various combinations of chemotherapy or radiation, as well as surgery. Certain types of cancer are also sensitive to hormone therapy. Angiogenesis inhibitors work better in combination with currently available treatments. This is supported by clinical trials that have been conducted with other angiogenesis inhibitors under development and on the market. The effect of the treatment has been shown to be additive or even synergistic, both among patients who recently began treatment and in patients who received several rounds of treatment. Therefore as a class, angiogenesis inhibitors have a broad spectrum of application, in part because a large percentage of patients are expected to benefit from the treatment.

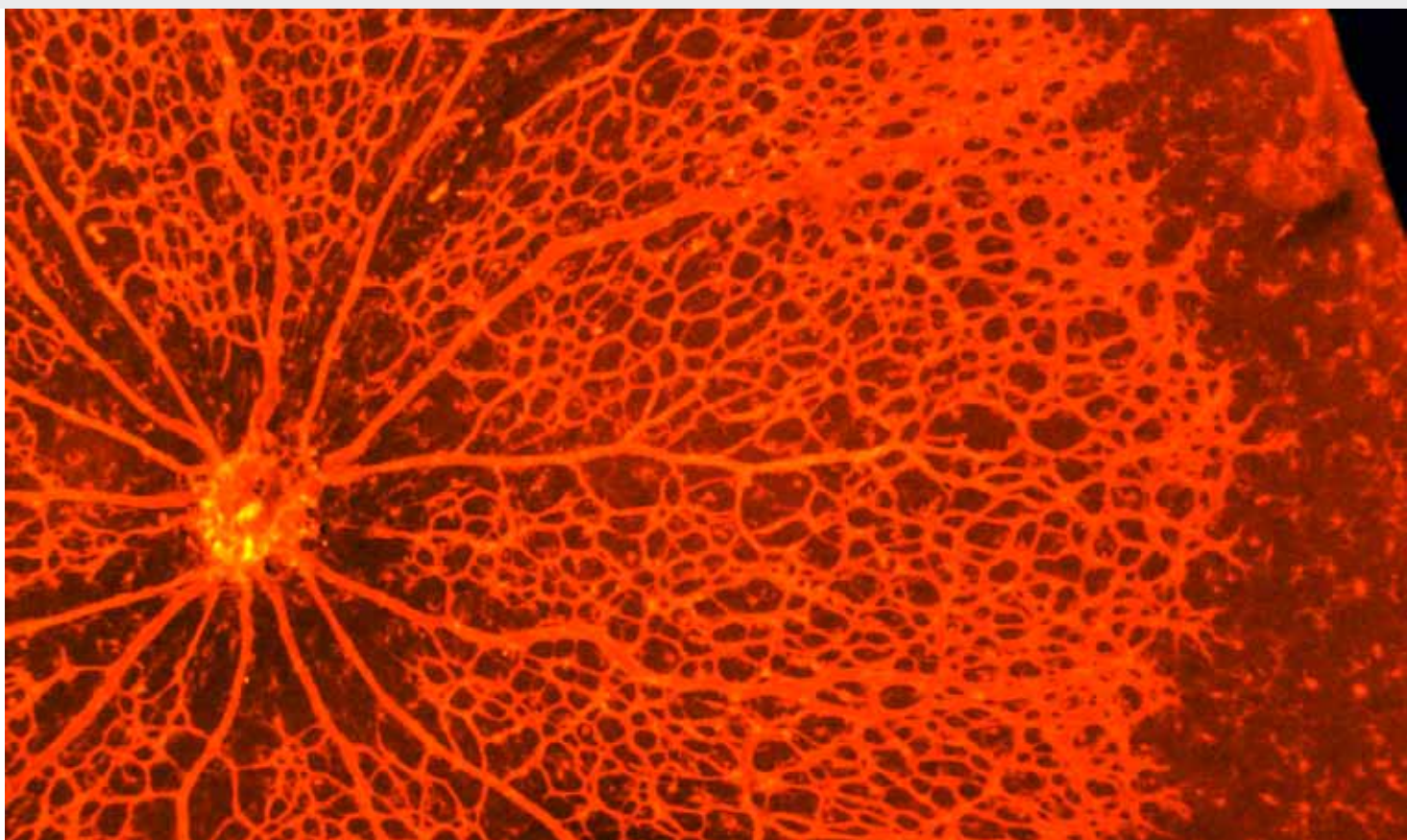
## Alliance with Roche

In June 2008 BioInvent and its partner ThromboGenics entered into a strategic licence agreement with Roche for development and commercialisation of TB-403. Roche paid BioInvent and ThromboGenics a cash payment of EUR 50 million in July 2008.

In January 2009 the transfer and implementation of technology and process development to Roche for ongoing clinical development of TB-403 were successfully concluded and an additional payment from Roche of EUR 5 million was received by BioInvent and ThromboGenics.

If successful development and commercial milestones are reached, BioInvent and ThromboGenics stand to receive an additional EUR 445 million in milestone payments and a double-digit percentage of sales of TB-403 in royalties and any back-up programmes based on inhibition of PIGF.

Roche received a global licence with soles rights to develop and commercialise TB-403. ThromboGenics, which discovered TB-403, will receive 60 percent and BioInvent 40 percent of the revenues from Roche.



Angiogenesis in the retina of the eye

BioInvent and ThromboGenics have retained the right to market the drug in the Nordic, Baltic and Benelux countries. Roche is responsible for all development costs.

### **Project status**

BioInvent and ThromboGenics have successfully completed two clinical phase I studies. The first phase I study on 16 healthy males was concluded successfully in June 2008 and showed that TB-403 was safe, well-tolerated and had the desired pharmacokinetic properties.

The results of a follow-up study on patients with advanced cancer who were treated with repeated doses of TB-403 were reported in November 2009. The study showed that TB-403 is well tolerated and no dose-limiting toxicity was observed. Six of 23 patients demonstrated stable disease for at least eight weeks and two of these for twelve months.

Phase II studies are expected to be initiated by BioInvent's partner Roche in 2010.

### **Patent protection**

Patents that cover treatment with antibodies against PIGF for the purpose of reducing or preventing pathologic angiogenesis, vascular leakage, pulmonary hypertension, cancer and inflammation, have been granted in Europe. Similar patent applications are pending in markets such as the US and Canada. An objection has been filed against the European patent. The objection was rejected in the court of first instance. In addition, patent applications for TB-403 and similar antibodies have been filed in Europe, Japan, Canada, the US, Australia and several other countries.



# Preclinical research

BioInvent's preclinical research is currently focused on oncology and inflammation. By using the Company's key competence and through select alliances with internationally recognised academic teams and industrial partners, such as ThromboGenics and Human Genome Sciences, the Company has built up expertise in fields such as cancer biology, angiogenesis, tumour immunology, acute and chronic inflammatory diseases and immunology.

Over the past decade BioInvent has accumulated a substantial amount of experience using the most relevant disease models in these fields. These models are used to identify the most effective and potent antibody candidates, while extensively investigating the expected safety and tolerability of the antibody, based on the biology of the disease and the mechanism of action of the antibody.

The Company's preclinical research is aimed at building a portfolio of drug candidates. This research is supplemented by select research collaboration with large pharmaceutical companies, giving these companies access to BioInvent's technology for the production of product candidates. These alliance programmes involve little risk for BioInvent and provide an opportunity to earn revenues in the future in the form of milestone and royalty payments.

## **BioInvent's research**

BioInvent's strategy for research and development is to produce antibody-based drugs and document their biological effect in clinical research.

In order for the product candidates to advance through late clinical development towards full commercialisation, BioInvent works with large pharmaceutical companies. In certain projects a partnership agreement is signed early on in development, while other projects may be developed for a longer period by



the Company. The strategic purpose of the agreements is to ensure that the projects have the expertise and resources they need and that BioInvent avoids tying up excessive amounts of resources in individual projects.

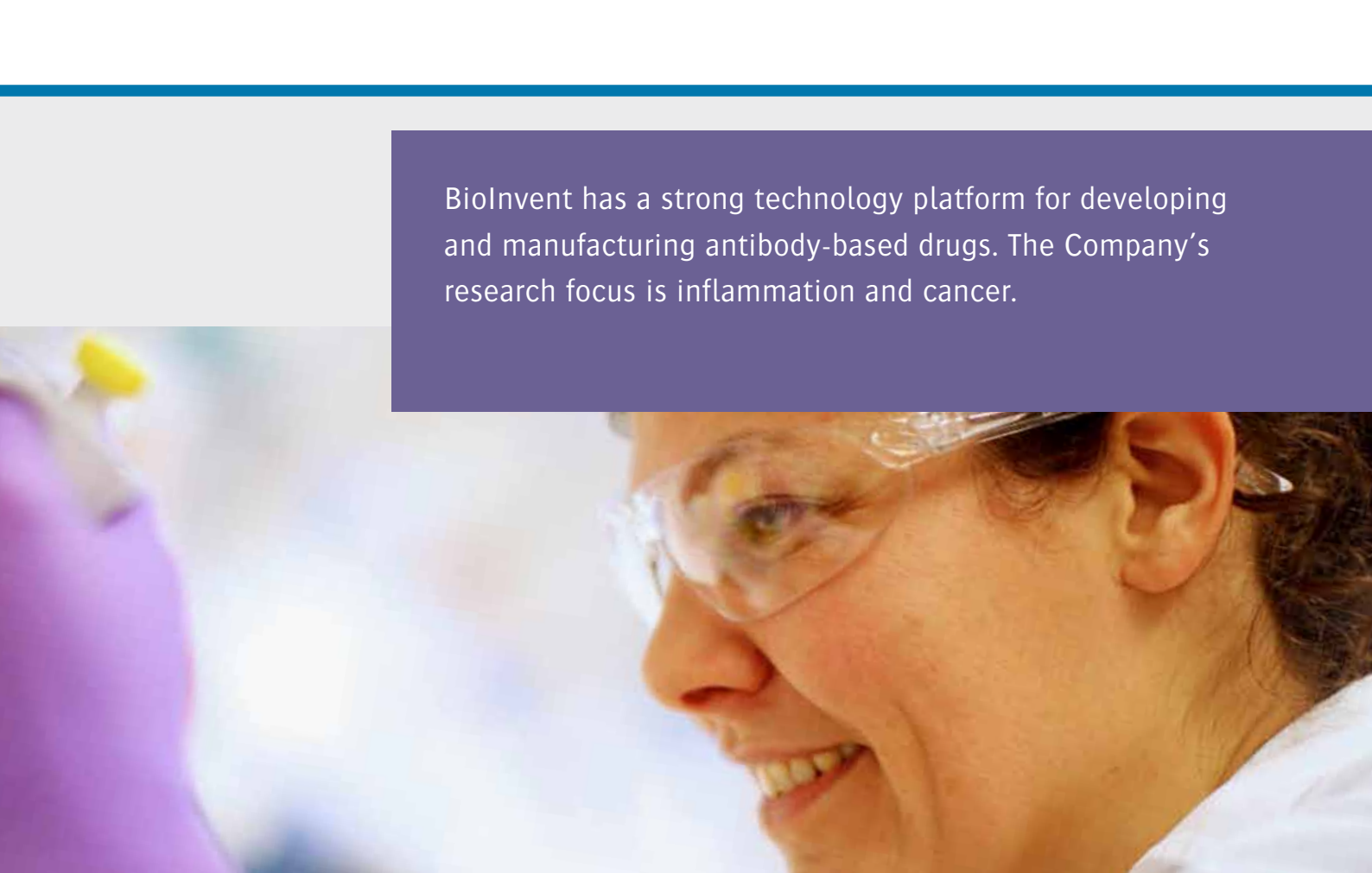
BioInvent is aiming to broaden and expand its portfolio of drugs to give the Company several opportunities to successfully develop new products and thereby increase the likelihood of commercial success.

So far the Company has mainly launched projects in alliances with external research teams, either in academic environments or in industry. These research teams not only contribute target proteins, but also significant biological and medical expertise. The Company continues to place great emphasis on cooperation with external research teams as an important source of new medical concepts.

As the Company matures and its expertise in individual areas increases, medical concepts from internal research programmes will also be launched. BI-505 for the treatment of multiple myeloma is the result of one such programme. The functional screening system developed by BioInvent which identified this candidate is a platform for further research programmes.

## **Biopanning: Combined discovery of target protein and antibody**

BioInvent has developed a method known as biopanning which makes it possible to directly detect new drug candidates without prior knowledge of the target proteins of the antibodies. The method is based on isolating antibodies from the n-CoDeR antibody library that selectively bind to one cell population (or other complex collection of target proteins) in preference to another.



BioInvent has a strong technology platform for developing and manufacturing antibody-based drugs. The Company's research focus is inflammation and cancer.

This is achieved by screening antibodies, step-by-step, that bind to one cell population over the other population through so-called differential screening. Identified antibodies are then selected based on their functional properties.

The advantage with this method is that it is possible to detect antibodies that bind to target proteins which was previously not known to be linked to a specific effect, such as initiating the death of a tumour cell. Another advantage with this method is that antibodies are identified as they bind to target proteins found in their natural environment (e.g. the cell surface), which increases the probability that the antibodies will mediate the desired effect when administered as a medication in vivo. The method also makes it possible to find antibodies that bind to target proteins which are in a relative state of surplus or deficit, irrespective of whether this is due to differences in protein expression, or if disease-associated epitopes that arise in other ways are exposed on the target cell.

BioInvent has used this method to identify antibodies that bind specifically to cancer cells and which, when they bind to their target protein, initiate cell death through various mechanisms. Consequently, antibodies with a direct therapeutic effect are identified in a single step. This method was used to identify BI-505, the Company's product candidate for the treatment of haematological cancer such as multiple myeloma. BioInvent currently uses biopanning actively in its own research and together with partners.

### Product partnerships

One way of gaining access to promising target structures and projects is to enter into partnerships with companies that have

assets and competence that complement those of BioInvent. BioInvent's aim is for these strategically important product partnerships to be characterised by balanced and equal ownership and resource allocation between the partners. BioInvent currently has two such product partnerships – one with ThromboGenics in vascular diseases (including TB-402 and TB-403), and a recently initiated collaboration with Human Genome Sciences within inflammatory diseases.

### Research partnerships

BioInvent has entered into a series of partnerships to develop and manufacture antibodies. In these partnerships, BioInvent received one-off payments and research support, as well as future rights to milestone payments and royalties on sales of products from the partnerships. A number of the current partnerships are described below:

- **Bayer HealthCare:** Identifying and developing antibody-based products with the help of the n-CoDeR library. The agreement covers the development of up to 14 antibody-based products.
- **Daiichi Sankyo:** Licence and research agreement for the development of therapeutic antibodies targeting several target proteins with the help of the n-CoDeR library. The agreement gives BioInvent certain rights to market products in Scandinavia and the Baltic region.
- **Mitsubishi Tanabe:** Identifying and developing antibody-based products with the help of the n-CoDeR library. The agreement covers development of up to five antibody-based therapeutic products.

BioInvent has also been manufacturing materials for several years for clinical studies for a number of customers.



# Human antibody technology

BioInvent develops therapeutic, fully human, monoclonal antibodies using the Company's own n-CoDeR platform. Monoclonal means that all antibody molecules in a given drug are exact copies of each other. This simplifies characterisation of the product and the manufacturing process and makes the biological effect of the drug more precise and predictable. One important reason why antibodies are so effective as pharmaceuticals is that they comprise a natural part of the organism's defence against diseases. Therefore they have naturally evolved to be specifically targeted and cause an appropriate biological reaction as they bind to their target protein. This activates the immune system's effector functions, a collective term for a host of different reactions of the body's defense system with the purpose of neutralising the threat by initiating the antibody binding reaction. Since this is a very precise reaction, it is important for the antibody drug that is introduced to be as similar to the body's own antibodies as possible.

The first generation of monoclonal antibody-based drugs came from animals, primarily mice. These mouse antibodies, with components that were foreign to the human immune system, triggered an immune response to the introduced antibodies. Later, in the mid-1990s, genetic engineering made it possible for these mouse antibodies to become more similar to those found in humans. Several such "chimeric" antibody-based drugs (e.g. rituximab) are currently approved and widely used. The "humanised antibodies" (e.g. bevacizumab) represent a further improvement; although still derived from mice, they appear more human-like to the immune system. The final link in this chain of development is to introduce fully human antibodies.

There are currently two fundamental technologies for manufacturing human antibodies. One involves genetic manipulation of mice, in which the mouse genes for antibody production are

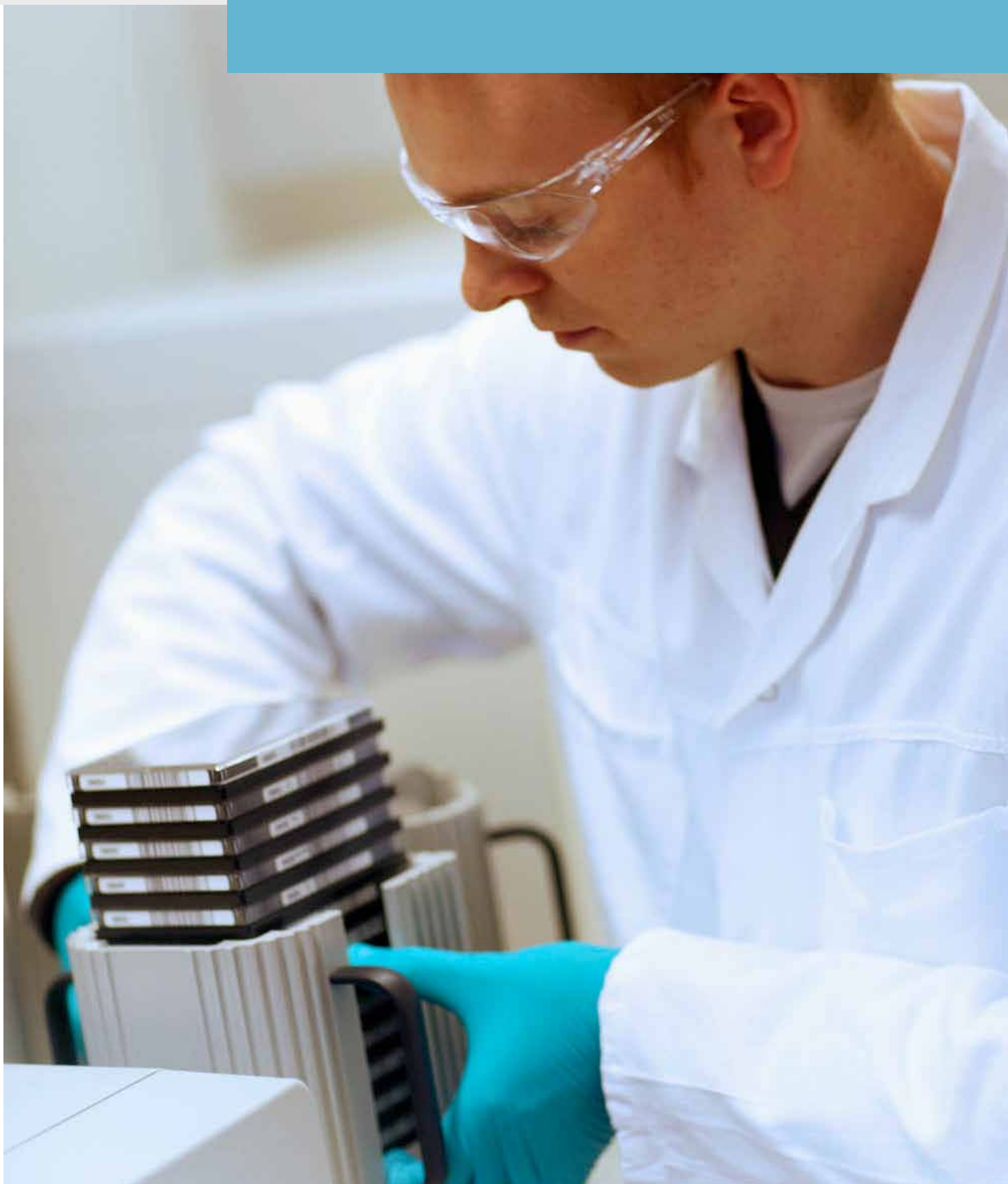
replaced by the corresponding human genes, resulting in a genetically altered mouse capable of producing human antibodies directly. The second technology involves creation of "antibody libraries" in test tubes containing human antibodies, which can then be used to produce fully human antibodies.

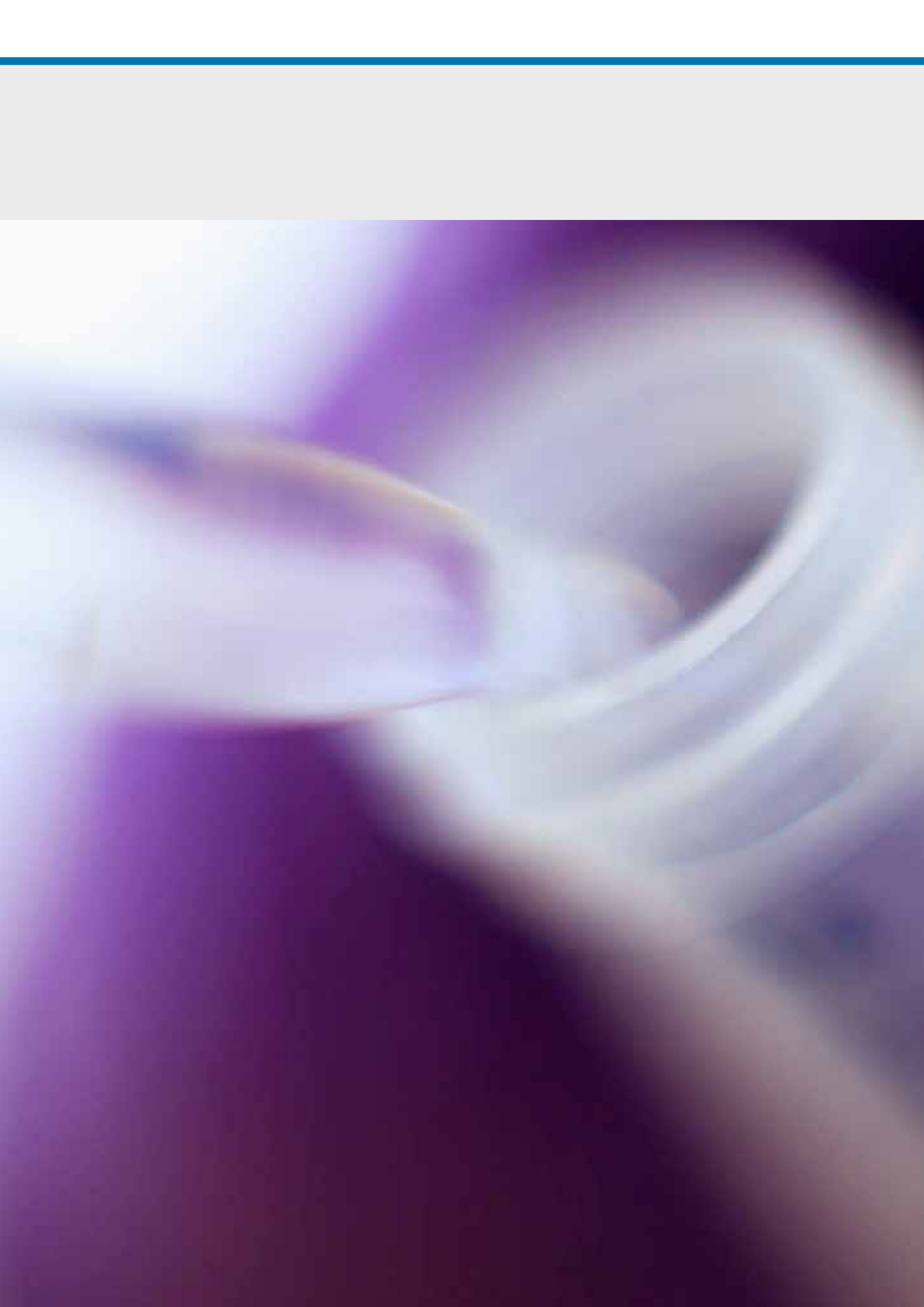
There are different ways of designing an antibody library. Important parameters that determine library quality include size, variability and stability and functionality of the produced molecules. These factors determine the likelihood of finding an antibody with the desired binding properties against all types of target proteins.

## **n-CoDeR antibody library**

BioInvent has developed a powerful technology platform for discovery, development and production of human antibodies. The n-CoDeR antibody library is the source of the Company's drug candidates. The antibody-library is the cornerstone of BioInvent's technology platform. The library contains a collection of more than 20 billion human antibody genes that are stored within bacteria in test tubes. The bacteria act as production units for the antibodies making it possible to search through the library to identify precisely those antibodies that bind to a specific target protein. The n-CoDeR library is searched using an established technology called phage display. To identify the optimal antibody, BioInvent has developed automated processes in which robots carry out the analysis on an industrial scale. The n-CoDeR library consists of naturally occurring 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 library is protected by patents and patent applications in the largest markets.

Fully human antibodies can quickly be retrieved from the n-CoDeR antibody library to develop the Company's drug candidates.





Financial information ►

# 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, 2009. 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, listed on the NASDAQ OMX Stockholm (BINV), is a research-based pharmaceutical company that focuses on developing antibody drugs. The Company is currently running innovative drug projects mainly within the areas of thrombosis, cancer and atherosclerosis.

## Development projects

BioInvent is currently running four projects in the development phase. In the development phase the safety profile of the product candidate is tested in animal models, before testing safety and efficacy in clinical trials.

### Thrombosis (TB-402)

TB-402 is a human antibody binding to Factor VIII. The antibody has shown a beneficial partial inhibition of Factor VIII, even when applied in excess dosage. This reduces the risk of undesirable bleedings. The objective is to initially develop a drug that prevents Deep Vein Thrombosis (DVT) following orthopaedic surgery. DVT is caused when a blood clot forms in a deep vein, most commonly in the deep veins of the lower leg. DVT is a major public health issue and it is estimated that in the US alone, more than 600,000 individuals are affected by DVT or pulmonary embolism (PE) each year. The number of patients undergoing total hip or knee replacement is estimated at around 2.4 million in 2009 and is expected to grow to approximately 3.1 million in 2015 in the seven major pharmaceutical markets. Patients undergoing hip replacement or knee surgery are particularly at risk of developing DVT and all patients are therefore treated with anticoagulants prophylactically in order to reduce the risks of blood clots. The project is carried out within the alliance with ThromboGenics.

Results from the Phase I trial show that TB-402 is both safe and well-tolerated. No serious adverse events related to TB-402 were reported. The pharmacokinetic analysis undertaken as part of the Phase I trial confirm a prolonged half-life of approximately three weeks, which will allow for single dose treatment in orthopaedic surgery patients and/or a once-a-month administration for long-term stroke prevention in atrial fibrillation (AF), as opposed to daily treatment with current anticoagulants. The pharmacodynamic analysis confirms that TB-402 achieves only partial inhibition of Factor VIII activity without the undesired effect of total inactivation. A stable long-acting anticoagulant effect based on partial Factor VIII inhibition could also be shown.

Additional studies have shown that the effect of TB-402 can be reversed by giving the target protein (Factor VIII) that blocks TB-402 and also that TB-402 is safe and well tolerated in patients that are given standard treatment (enoxaparin and warfarin) for deep vein thrombosis. The results show that TB-402 has prospects to be developed into a safe and well-controlled treatment for several medical conditions in which thrombosis prevention is of great importance.

A phase II study was launched in February 2009 for the prevention of DVT in patients receiving artificial knee joints. All of the patients, 315 in all, had been treated by the end of October 2009. The results are expected to be reported in the second quarter.

The Phase II trial is an active (enoxaparin)-controlled, dose-escalating, multicenter, prospective, randomised, open label trial evaluating TB-402 for the prophylaxis of DVT after knee surgery. The study assesses three different doses of TB-402 given as a single intravenous bolus injection post knee replacement surgery. The objective of the study is to assess the safety and efficacy of the three escalating doses of TB-402.

### Atherosclerosis (BI-204)

The product candidate BI-204 targets oxidized forms of the LDL cholesterol (oxLDL). Links have been shown between oxidized forms of certain lipoproteins and the inflammatory processes that lead to plaque formation in the vessel walls. BI-204 has in preclinical studies reduced inflammatory processes and reduced plaque formation significantly. The results also show a considerable reduction in the size of existing plaques in animals treated with BI-204. Results supports that the mechanism behind BI-204 is a modulation of the inflammatory process resulting in a reduction of pro-inflammatory cells in treated plaques, which in turn leads to a reduction in new plaque formation and the regression of existing plaques. It is being developed as a drug for the prevention of secondary events in patients with cardiovascular disease. In a population-based, prospective, observational study of the risk of development of coronary artery disease (JAMA. 2008; 299 (19) 2287-2293) higher concentration of oxidized LDL was associated with increased incidence of metabolic syndrome overall, as well as its components of insulin resistance and hyperglycemia. These observations support the picture that oxidized LDL can be an important target structure for developing new medications to treat patients with type 2 diabetes and metabolic syndrome. BI-204 is developed in collaboration with Genentech, a wholly-owned member of the Roche Group.

The phase I programme was completed in the second quarter 2009. The study was a double-blind, within-group randomised dose-escalation trial testing both single and multiple doses of BI-204 administered either intravenously or subcutaneously. In total, 80 healthy male or female subjects with elevated levels of LDL cholesterol were included in the trial. BI-204 was well tolerated and pharmacokinetic results showed the half-life was in the expected range for fully human antibodies.

### Cancer (TB-403)

The product candidate TB-403, is a monoclonal antibody directed against placental growth factor, PlGF. TB-403 binds PlGF with high affinity and specificity and has been shown to inhibit tumour growth in animal models. TB-403 blocks tumour angiogenesis, the development of new blood vessels, which is required for tumour nutrient and oxygen supply supporting tumour growth. Angiogenesis is also required for disease progression and metastasis, the dissemination of the tumour to distal sites of the body.

The PlGF growth factor is secreted by tumours and is specifically over expressed in cancer and chronic inflammatory conditions. It affects the formation of new vessels in tissue that is under stress. PlGF is not required for survival of normal resting vasculature and blocking PlGF is expected to be relatively safe, because mice lacking PlGF are healthy and reproduce normally. Preclinical research has also shown that inhibition of PlGF does not induce resistance mechanisms because it does not induce "angiogenic rescue" mechanisms, whereby tumour expression of proangiogenic growth factors is upregulated, which may enable escape from therapy. This angiogenic rescue phenomenon has been demonstrated with some angiogenesis inhibitors.



Up to June 2008 the project was carried out within the alliance with ThromboGenics. In June 2008 BioInvent and partner ThromboGenics entered into a strategic license agreement with Roche for development and commercialisation of TB-403. Roche received a worldwide, exclusive license to develop and commercialise TB-403. BioInvent and ThromboGenics retained co-promotion rights for the product in the Nordic, Baltic and Benelux regions.

In January 2009 transfer and implementation of technology and process development to Roche for the ongoing clinical development of TB-403 was successfully finalized. This triggered a success fee of EUR 5 million to BioInvent and ThromboGenics.

The first Phase I study in 16 healthy male subjects was successfully completed in June 2008 and showed that TB-403 is safe and well tolerated, with pharmacokinetic properties enabling it to be developed as a novel anti-cancer agent. A follow-up study in patients with advanced cancer was presented in November 2009 at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in Boston, U.S.. This dose escalation study examined tolerability, pharmacokinetics and pharmacodynamics of TB-403 in 23 patients. TB-403 was shown to be well tolerated and no dose limiting toxicity was observed with doses up to 10 mg/kg weekly and 30 mg/kg every three weeks. In this patient population with advanced solid tumours, stable disease was observed in six of 23 patients whereof two patients had stable disease in 12 months.

#### **Cancer (BI-505)**

The drug candidate BI-505 is a human antibody that targets the adhesion protein ICAM-1 (also called CD54). In tumour cells the expression of ICAM-1 is elevated and it is therefore a candidate for being a suitable target protein for a therapeutic antibody. In addition to inducing apoptosis the antibody also provides important immunoeffector functions that help to kill tumour cells. BI-505 has in different animal models proved to be very effective at killing tumours and more effective than existing drugs.

BioInvent's intention is, in an initial stage, to treat patients with multiple myeloma. Other forms of hematologic cancer may also become relevant as indications. The possibility of treating ICAM-1 expressing solid tumours will also be examined further in additional preclinical trials. The number of newly diagnosed patients with multiple myeloma is more than 40,000 per year and the number of newly diagnosed patients with blood cancer is more than 200,000 per year.

BI-505 has been granted orphan drug designation in the United States and Europe for the indication of multiple myeloma. This status gives BI-505 possibility for market exclusivity for treatment of multiple myeloma with an antibody against ICAM-1 for up to 10 years after marketing approval is obtained.

A phase I study for the treatment of multiple myeloma was launched in the US at the beginning of the year. The study will investigate safety, pharmacokinetics and pharmacodynamics and will aim to define the optimal dose of the antibody for upcoming clinical phase II development. The study will involve 30 – 40 patients. The patients will be treated with intravenous doses of BI-505 every other week for a 28-day period with the possibility of extending the treatment until the condition deteriorates again.

#### **Research projects**

BioInvent is running a number of projects in the research phase i.e. the stage prior to selection of a Candidate Drug. The company's research portfolio currently includes projects mainly within the areas of cancer and inflammation. The research in the cancer field is aimed at additional product candidates that will impede undesir-

able vessel growth and thus the blood supply to tumours, as well as at apoptotic antibodies that kill tumour cells. BI-505 is one result of the apoptosis programme.

The company is also conducting research and development on antibody-based drugs on behalf of external partners. Such partners includes Bayer HealthCare, Daiichi Sankyo and Mitsubishi Tanabe Pharma. All in all BioInvent has entered into agreements of this kind with the possible development of up to 30 antibody-based products. As well as undisclosed license fees and research funding, BioInvent will receive milestone payments and royalties on sales of any products commercialized.

#### **Personnel and organisation**

All research and development is conducted in project format with a matrix containing the following main areas:

The preclinical department is mainly responsible for discovering new product candidates.

The groups working in protein technology and pharmacy are responsible for developing the cell lines that will produce the products and for other process development, as well as for all production, characterisation and quality control of the products in compliance with directives from authorities.

The Clinical department is responsible for preclinical safety tests and clinical development of the Company's product candidates, as well as for ensuring that the Company's drug development is carried out in compliance with pharmaceutical legislation. The activities within this unit's area of responsibility are largely outsourced to external contract research organisations.

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.

As of 31 December 2009 BioInvent had 105 (103) employees, 89 (89) of whom work in research and development. About 90 per cent of the Company's employees have university degrees, including 42 per cent with PhDs.

Total absence due to sickness increased somewhat compared with 2008. Long-term absence decreased and short-term absence increased. Sickness absence and other key figures can be seen in note 1.

#### **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 has a permit in accordance with the Swedish Environmental Code for manufacturing pharmaceutical substances. Self-monitoring is carried out to monitor the Company's operations on an ongoing basis to counteract and prevent negative environmental impact. As part of this self-monitoring process, the Company has

introduced a description of environmental consequences and a plan for the self-monitoring process.

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 processes of developing, manufacturing and distributing pharmaceutical substances are becoming more and more complex and require energy. Like most other companies, BioInvent's emissions are largely the result of energy consumption at plants as well as in transportation. BioInvent focuses on handling environmental impact in all parts of the Company's operations and introduces improvement initiatives on an ongoing basis.

The Group's operations require permits according to the Swedish Environmental Code, and reports are required to be submitted to Lund municipality. 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.

In 2010 BioInvent is continuing its active efforts to manage the Company's environmental impact in line with the goals for its operations.

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

The Company's organization and facilities have been approved by the Swedish Medical Products Agency for the production of biological investigational medicinal products and it is also GMP-approved according to applicable EU regulations. The Swedish Medical Products Agency and BioInvent's partners conduct regular inspections to secure whether the facility is maintaining an approved quality level.

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 revenues amounted to SEK 80.7 million (252.1). Reported net revenues include BioInvent's share, SEK 21.7 million, of the first milestone payment for TB-403. The milestone payment is for the successful technology transfer within the collaboration with Roche. BioInvent's share of the initial installment from Roche for TB-403, SEK 187.6 million is included in its entirety in reported net revenues for 2008.

The Company's total costs amounted to SEK 264.7 million (246.3). Operating costs are divided between external costs of SEK 167.4 million (155.6), personnel costs of SEK 86.2 million (79.2) and depreciation of SEK 11.1 million (11.5). Costs for toxicology studies and clinical studies, SEK 84 million, comprise the largest share of external costs.

Research and development costs amounted to SEK 229.2 million (215.4). Depreciation according to plan reduced the operating result for the period by SEK 11.1 million (11.5), of which depreciation of intangible fixed assets amounts to SEK 5.4 million (6.1). BioInvent's portion of the subsidy from the EU's Sixth Framework

Programme amounted to SEK 3.7 million (0.5) and has been reported in the income statement under "Other operating revenues and costs."

The loss after tax amounted to SEK -176.7 million (16.2). The net financial items amounted to SEK 2.8 million (9.7). Earnings per share after tax amounted to SEK -3.17 (0.29).

#### **Financial position and cash flow**

As of 31 December 2009, the Group's current investments together with cash and bank amounted to SEK 84.0 million (212.5). The cash flow from current operations and investment activities amounted to SEK -128.4 million (-4.4). Last year a higher operating profit had a positive effect on cash flow.

The shareholders' equity amounted to SEK 55.6 million (231.3) at the end of the period. The Company's share capital was SEK 27.8 million. The equity/assets ratio at the end of the period was 44.1 (78.3) per cent. Shareholders' equity per share amounted to SEK 1.00 (4.15). The Group had no interest-bearing liabilities.

The five-year review is described on page 58.

#### **Investments**

Investments in tangible fixed assets amounted to SEK 1.3 million (7.6). No investments were made in intangible assets during the period (6.0).

#### **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 revenues amounted to SEK 80.7 million (252.1). The loss after tax amounted to SEK -175.5 million (16.9). The cash flow from current operations and investment activities amounted to SEK -128.2 million (-4.7). The Parent Company coincides in every material way with the Group.

#### **The share**

The BioInvent share has been listed on NASDAQ OMX Stockholm since 2001. As of 31 December 2009, share capital amounted to SEK 27.8 million, made up of 55,660,889 shares. Assuming that all options (1,920,090) issued due to the 2008/2012 employee stock option plan are exercised, the number of shares will be 57,580,979.

After the end of the financial year BioInvent implemented a directed share issue with a total of 5,434,800 shares for the purpose of raising proceeds of SEK 150 million for the Company before transaction costs. The subscription price was set at SEK 27.60 per share.

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. 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.

#### **Future prospects**

BioInvent's future revenue flows are primarily expected to come from co-operation agreements linked to own drug projects in the form of license fees, milestone payments and royalties on the final

sale of its products, as well as from its own sales. Future revenue trends will largely depend on the success of outlicensing of the company's product candidates and the results of future product development and launches.

Sustainable profitability is expected when one of our projects reaches the market. In the meantime, profit may be reported for individual years before this time, when essential breakthroughs are made in any of our projects.

### **Risks and risk management**

#### **Risks associated with pharmaceutical development**

Developing a new biotech drug up to and including its launch costs about USD 1.2 billion (source: Tufts Center for the Study of Drug Development, May 2006). At the same time, statistically only one in ten drug candidates in clinical Phase I reaches the market, while the probability of successfully launching an antibody-based drug is somewhat higher. The likelihood of reaching the market increases as the project is moved forward in the development chain. However, the costs also increase, rising sharply in the late clinical phases. To sum up, the risk associated with developing a new drug is very high.

As the company matures and the project portfolio develops, the company's knowledge and experience in important areas continues to grow, which benefits all important decisions in the projects and collectively reduces the risk of investing in the wrong project.

Building a large project portfolio will, in the long term, make the company less dependent on the success of individual projects. At this point, however, the portfolio is relatively limited and consists of projects in early phases – which means that a setback in an individual project may have a significantly negative impact on the company.

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

BioInvent endeavours to advance its projects through the value chain, which will mean increased expenses for clinical trials. Before any product under development can be sold, the Company or its partners must demonstrate the safety and efficacy of each potential product for human use, for each stated indication.

There is no guarantee that clinical trials carried out by the Company or its partners can demonstrate sufficient safety and efficacy to obtain necessary government authority approvals or that the trials will lead to competitive products. If during development the Company or its partners cannot demonstrate with sufficient reliability that the intended products are safe and effective, authorisation for these products could be denied, which would mean that they cannot be launched on the market.

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 products cause illness, physical injury, death or damage to, loss of or destruction of 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 no guarantee that coverage will be adequate in the event of a legal claim.

#### **Cooperation agreements**

Forming alliances with partners for several of the Company's clinical projects provides BioInvent with expertise and experience, while

reducing the Company's own investment needs in the individual projects. This strategy also reduces BioInvent's risk level because the company is able to invest in several projects.

Even if the company tries to develop and strengthen such partnerships there is no guarantee that the collaboration will 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.

#### **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 a similar product or that entirely new product concepts will prove superior.

By allying itself with external research groups in the forefront of medical development, the company hopes to gain access to target proteins that can be developed for long-term competitive medical treatment options. In order to further strengthen the company's own position, great emphasis is placed on strong patent protection.

The selection of future partners will also be a crucial factor in the competitiveness of the company's own products. BioInvent will therefore look for partnerships with companies that have an established and strong infrastructure, strategic commitment to future product development, and can provide the necessary resources.

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

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. There is no guarantee that the company's products and processes which may in fact be covered by granted patents will not be attacked or contested by competitors or that granted patents will not infringe upon competitors' rights. BioInvent monitors and evaluates the activities, patents and patent applications of competitors on an ongoing basis for the purpose of identifying activities that are covered by the company's intellectual property and patents that could cover parts of the company's sphere of activity.

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

#### **Changes in healthcare systems**

In several countries proposals have been submitted to change the healthcare system in ways that could affect BioInvent's ability to profitably engage in its business.

BioInvent's success depends in part on the extent to which the Company's products qualify for various types of subsidies. 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 commercialised 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 highly 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, it cannot guarantee that this will be able to occur on satisfactory terms in relation to the competition from other pharmaceutical and biotech companies, universities and other institutions.

#### **Obtaining additional financial resources**

The focus on producing drug candidates is expected to involve significant costs and generate annual revenue from products on the market in the longer term. Accordingly, the business is expected to continue to report a negative cash flow. The capital requirement is financed through (i) sales of rights to individual projects, (ii) partnerships that guarantee product financing, (iii) shareholders' equity. Failure to secure such financing could negatively affect the company's business, financial position and operating income.

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

Remuneration of Directors, the CEO and other senior executives and auditors is described in notes 2 and 3.

The 2009 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 2010 Annual General Meeting.

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 2.5 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).

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 executives 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.

At the time of the 2010 Annual General Meeting BioInvent does not have any remuneration undertakings due for payment.

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

At the end of 2009/beginning of 2010, BioInvent launched a clinical phase I study with BI-505.

BioInvent has implemented a directed share issue setting aside the shareholders' preferential rights encompassing a total of 5,434,800 shares for the purpose of raising proceeds of SEK 150 million for the Company before transactions costs.

In March 2010 BioInvent entered into a product partnership with Human Genome Sciences for the development and commercialisation of therapeutic antibodies. No other significant events have occurred since the end of the financial year.

#### **Proposed appropriation of losses**

At the disposal of the Annual General Meeting is the loss for the year of SEK -175,453,767. The Board of Directors and the CEO propose that the statutory reserve be reduced SEK 175,453,767 to cover the accumulated loss. Consequently, no dividend is proposed.

# Consolidated statement of comprehensive income for the Group

## *Consolidated income statement for the Parent Company*

SEK thousands	Note	Group		Parent company	
		2009	2008	2009	2008
Net revenues		80,659	252,138	80,659	252,138
<i>Operating costs</i>					
Research and development costs		-229,187	-215,434	-228,207	-214,933
Sales and administrative costs		-35,466	-30,882	-35,239	-30,767
Other operating revenues		5,896	1,523	5,896	1,523
Other operating costs		-1,404	-774	-1,404	-774
		-260,161	-245,567	-258,954	-244,951
<b>Operating profit/loss</b>	1-6	<b>-179,502</b>	<b>6,571</b>	<b>-178,295</b>	<b>7,187</b>
<i>Profit/loss from financial investments</i>					
Interest income and similar items	7	3,004	9,733	3,004	9,733
Interest costs and similar items	8	-163	-53	-163	-53
<b>Profit/loss after financial items</b>		<b>-176,661</b>	<b>16,251</b>	<b>-175,454</b>	<b>16,867</b>
Tax on profit for the year	9	-	-	-	-
<b>Profit/loss for the year</b>	6	<b>-176,661</b>	<b>16,251</b>	<b>-175,454</b>	<b>16,867</b>
<i>Other comprehensive income</i>					
Changes in actual value current investments		-211	313		
<b>Comprehensive income</b>		<b>-176,872</b>	<b>16,564</b>		
Profit/loss pertaining to the parent company's shareholders		-176,872	16,564		
Earnings per share, SEK	10				
Before dilution		-3.17	0.29		
After dilution		-3.17	0.29		



# Consolidated statement of financial position for the Group

## *Consolidated balance sheet for the Parent Company*

SEK thousands	Note	Group		Parent company	
		2009	2008	2009	2008
<b>ASSETS</b>					
<b>Fixed assets</b>					
<b>Intangible fixed assets</b>					
Acquired intangible fixed assets	11	7,022	12,384	7,022	12,384
<b>Tangible fixed assets</b>	12				
Equipment		11,682	15,423	11,682	15,423
Investments in rented premises		287	1,004	287	1,004
		11,969	16,427	11,969	16,427
<b>Financial fixed assets</b>					
Shares in subsidiaries	13	-	-	100	100
<b>Current assets</b>					
<b>Inventories etc</b>					
Work on contract	14	484	142	484	142
Raw materials and consumables		1,553	2,162	1,553	2,162
		2,037	2,304	2,037	2,304
<b>Current receivables</b>					
Accounts receivables		3,441	37,616	3,441	37,897
Other receivables		11,379	8,878	11,379	8,597
Prepaid expenses and accrued income	15	6,378	5,358	6,378	5,358
		21,198	51,852	21,198	51,852
<b>Current investments and cash and bank*</b>					
Current investments		9,984	161,180	9,986	161,019
Current investments that constitute liquid funds		45,974	34,886	45,987	34,851
Cash and bank		28,062	16,394	28,062	16,394
		84,020	212,460	84,035	212,264
<b>Total assets</b>		<b>126,246</b>	<b>295,427</b>	<b>126,361</b>	<b>295,331</b>

\*See also specification at the bottom of page 36.

SEK thousands	Note	Group 2009	Group 2008	Parent company 2009	Parent company 2008
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>					
<b>Shareholders' equity</b>				<b>Restricted Equity</b>	
Share capital		27,830	27,830	27,830	27,830
Other allocated capital		805,160	805,160		
Statutory reserve				203,285	186,418
Reserves		-14	197	231,115	214,248
				<b>Non-restricted Equity</b>	
Accumulated loss		-777,343	-601,889		
Profit/loss for the year				-175,454	16,867
<b>Total shareholders' equity</b>		<b>55,633</b>	<b>231,298</b>	<b>55,661</b>	<b>231,115</b>
Shareholder's equity pertaining to the parent company's shareholders		55,633	231,298		
<b>Current liabilities</b>					
Work on contract	14	1,908	972	1,908	972
Accounts payables		16,510	12,784	16,510	12,815
Liabilities to subsidiaries		-	-	101	101
Other liabilities		32,559	33,182	32,560	33,152
Accrued expenses and deferred income	16	19,636	17,191	19,621	17,176
		70,613	64,129	70,700	64,216
<b>Total shareholders' equity and liabilities</b>		<b>126,246</b>	<b>295,427</b>	<b>126,361</b>	<b>295,331</b>
<b>Total shareholders' equity and liabilities</b>					
<b>Pledged assets</b>		-	-	-	-
<b>Contingent liabilities</b>		-	-	-	-

# Consolidated statement of cash flows for the Group

## Consolidated statement of cash flows for the Parent Company

SEK thousands	Group		Parent company	
	2009	2008	2009	2008
<b>Current operations</b>				
Operating profit/loss	-179,502	6,571	-178,295	7,187
Adjustments for other non-cash items				
Depreciation	11,117	11,543	11,117	11,543
Other adjustments for non-cash items	1,207	616	-	-
Interest received	4,886	9,414	4,886	9,414
Interest paid	-163	-53	-163	-53
<b>Cash flow from current operations before changes in working capital</b>	<b>-162,455</b>	<b>28,091</b>	<b>-162,455</b>	<b>28,091</b>
Changes in working capital				
Changes in inventories, etc.	267	1,521	267	1,521
Changes in current receivables	28,561	-27,610	28,772	-27,932
Changes in current liabilities	6,484	7,246	6,484	7,255
	<b>35,312</b>	<b>-18,843</b>	<b>35,523</b>	<b>-19,156</b>
<b>Cash flow from current operations</b>	<b>-127,143</b>	<b>9,248</b>	<b>-126,932</b>	<b>8,935</b>
<b>Investment activities</b>				
Acquisition of intangible fixed assets	-	-6,001	-	-6,001
Acquisition of tangible fixed assets	-1,297	-7,638	-1,297	-7,638
<b>Cash flow from investment activities</b>	<b>-1,297</b>	<b>-13,639</b>	<b>-1,297</b>	<b>-13,639</b>
<b>Cash flow from current operations and investment activities</b>	<b>-128,440</b>	<b>-4,391</b>	<b>-128,229</b>	<b>-4,704</b>
<b>Cash flow from financing activities</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Changes in current investments**</b>	<b>151,196</b>	<b>-6,815</b>	<b>151,033</b>	<b>-6,560</b>
<b>Change in liquid funds</b>	<b>22,756</b>	<b>-11,206</b>	<b>22,804</b>	<b>-11,264</b>
Opening liquid funds	51,280	62,486	51,245	62,509
<b>Liquid funds at year-end</b>	<b>74,036</b>	<b>51,280</b>	<b>74,049</b>	<b>51,245</b>
<b>Liquid funds, specification:</b>				
Current investments that constitute liquid funds*	45,974	34,886	45,987	34,851
Cash and bank	28,062	16,394	28,062	16,394
	<b>74,036</b>	<b>51,280</b>	<b>74,049</b>	<b>51,245</b>
Current investments**	9,984	161,180	9,986	161,019
	<b>84,020</b>	<b>212,460</b>	<b>84,035</b>	<b>212,264</b>

\*duration less than 3 months

\*\*duration more than 3 months

# Statement of changes in equity for the Group

## *Statement of changes in equity for the Parent Company*

### GROUP

SEK thousands	Share-capital	Other allocated capital	Reserves	Accumulated loss	Total
<b>Shareholders' equity 31 December 2007</b>	<b>27,830</b>	<b>805,160</b>	<b>-116</b>	<b>-618,756</b>	<b>214,118</b>
Effect of employee incentive program				616	616
Profit/loss for the year				16,251	16,251
Changes in actual value current investments			313		313
<b>Shareholders' equity 31 December 2008</b>	<b>27,830</b>	<b>805,160</b>	<b>197</b>	<b>-601,889</b>	<b>231,298</b>
Effect of employee incentive program				1,207	1,207
Profit/loss for the year				-176,661	-176,661
Changes in actual value current investments			-211		-211
<b>Shareholders' equity 31 December 2009</b>	<b>27,830</b>	<b>805,160</b>	<b>-14</b>	<b>-777,343</b>	<b>55,633</b>

Shareholders' equity is attributable in its entirety to shareholders of the parent company. Share capital as of 31 December 2009, consists of 55,660,889 shares and the share's ratio value is 0.5.

### PARENT COMPANY

SEK thousands	Share-capital	Statutory reserve	Non-restricted equity	Total
<b>Shareholders' equity 31 December 2007</b>	<b>27,830</b>	<b>202,515</b>	<b>-16,097</b>	<b>214,248</b>
Appropriation of profit/loss		-16,097	16,097	0
Profit/loss for the year			16,867	16,867
<b>Shareholders' equity 31 December 2008</b>	<b>27,830</b>	<b>186,418</b>	<b>16,867</b>	<b>231,115</b>
Appropriation of profit/loss		16,867	-16,867	0
Profit/loss for the year			-175,454	-175,454
<b>Shareholders' equity 31 December 2009</b>	<b>27,830</b>	<b>203,285</b>	<b>-175,454</b>	<b>55,661</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 1.2, Supplementary Accounting Regulations for Groups. The Parent Company's annual accounts have been prepared in compliance with Annual Accounts Act and with application of the Swedish Financial Reporting Board's recommendation RFR 2.2, Reporting for Legal Entities.

## 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 and assessment for impairment of intangible assets.

## Accounting principles

The following new and revised IASB standards and IFRIC statements came into effect on 1 January 2009.

- IFRS 2, Share-Based Payment. Amendment for vesting conditions (Approved by the EU 16 December 2008)
  - IFRS 7, Financial Instruments: Amendment for disclosures. (Approved by the EU 27 November 2009)
  - IFRS 8, Operating Segments (Approved by the EU 21 November 2007)
  - Revised IAS 1, Presentation of Financial Statements (Approved by the EU 17 December 2008)
  - Revised IAS 23, Borrowing Costs (Approved by the EU 10 December 2008)
  - IAS 27, Consolidated and Separate Financial Statements. Amendment for accounting for dividends received (Approved by the EU 23 January 2009)
  - IAS 32, Financial Instruments: Classification and IAS 1, Presentation of Financial Statements. Amendment regarding classification of certain puttable financial instruments as equity/liabilities (Approved by the EU 21 January 2009)
  - IFRIC 9, Reassessment of Embedded Derivatives and IAS 39, Financial Instruments: Recognition and Measurement. (Approved by the EU 27 November 2009)
  - IFRIC 13, Customer Loyalty Programmes (Approved by the EU 16 December 2008)
  - IFRIC 16, Hedges of a net Investment in a Foreign Operation (Approved by the EU 4 June 2009)
  - IFRIC 18, Transfers of Assets from Customers (Approved by the EU 27 November 2009)
- Application of these standards and interpretations has not had any effect on the Group's financial performance or position. However, due to the revised IAS 1, changes have been made to the presentation of the financial statements.

IFRS 9, IFRIC 19 and amendments to IFRS 2, IAS 24, IAS 32, IFRIC 14 and improvements to IFRS have not yet been adopted by the EU and are therefore only applied at this point unless they conflict with the previous IFRS rules. BioInvent has decided not to apply any of the revisions/amendments to IFRS below prospectively.

The future application of the standards and interpretations below is not, unless specifically indicated, expected to have any effect on the Group's financial results or position.

- IFRS 2, Share-Based Payment. Amendment. Group cash-settled share-based payment transactions (Expected to be approved by the EU first quarter 2010)
- IFRS 3R Business Combinations and IAS 27R Consolidated and Separate Financial Statements (Approved by the EU 3 June 2009)
- IFRS 9, Financial Instruments: Recognition and Measurement (Not yet approved by the EU and no schedule for approval exists at this time). Pending completion of all parts of the standard, the Group has not assessed the effects of the new standard.
- IAS 24, Related Party Disclosures. Amendment (Expected to be approved by the EU second quarter 2010)
- IAS 32, Financial Instruments: Classification. Amendment. Classification of rights issues (Approved by the EU 23 December 2009)
- IAS 39 Financial Instruments: Recognition and Measurement – Amendment. Items qualifying for hedge accounting (Approved by the EU 15 September 2009)
- IFRIC 12, Service Concession Arrangements (Approved by the EU 25 March 2009)
- IFRIC 14, The Limit on a Defined Benefit Asset, Minimum Funding Requirements and their Interaction. Amendment (Expected to be approved by the EU second quarter 2010)
- IFRIC 15, Agreements for the Construction of Real Estate (Approved by the EU 22 July 2009)

- IFRIC 17, Distributions of Non-Cash Assets to Owners (Approved by the EU 26 November 2009)
- IFRIC 19, Extinguishing Financial Liabilities with Equity Instruments (Expected to be approved by the EU second quarter 2010)

## Basis for preparation of the accounts

The consolidated accounts are based on historical acquisition values, with the exception of financial assets intended for trading and financial derivatives, which are carried at fair value.

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 antibody-based drugs. The Company's risks and opportunities are mainly affected by the progress of the projects. The Company engages in integrated activities, in which the projects are considered to carry similar risks and opportunities, and there is therefore only one business segment, which is apparent in the consolidated income statement, balance sheet, cashflow 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	2009	2008
<b>Net revenues</b>		
Sweden	-	-
Europe	61.6	242.1
Other countries	19.1	10.1
	80.7*	252.2**
<b>Fixed assets</b>		
Sweden	19.0	28.8
<b>Investment activities</b>		
Sweden	1.3	13.6

\* The revenues come mainly from six customers and include BioInvent's portion, SEK 21.7 million, of the first milestone payment from Roche for TB-403.

\*\* The revenues come mainly from five customers and include BioInvent's portion of the initial partial payment from Roche for TB-403, SEK 187.6 million.

## 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 when all terms and conditions of the agreement are met. Payment for development work in conjunction with collaboration agreements is recognised as the work is completed.

*Revenues from technology licenses* refers to access fees for a technology, maintenance 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. Maintenance fees are treated on an accrual basis over the period of the license.



Biolnvent also carries out *external development projects* such as developing antibody candidates, process development and production of products for customers' clinical trials. In such agreements Biolnvent receives ongoing compensation for work carried out and in connection with agreements for developing antibody candidates from the n-CoDeR<sup>®</sup> antibody library also milestone payments as well as future royalties on product sales. Ongoing compensation for work carried out is recognised as revenue as the project is completed in accordance with the principle for the percentage of completion method. 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. In the balance sheet, receivables from customers and liabilities to customers are reported as "Work on contract" on both the asset and liabilities side of the balance sheet.

Government grants are recognized as revenue at actual value when it is reasonable to assume that the subsidy will be received and that all associated conditions will be met. When the subsidy is linked to a cost, it is reported as income during the periods required to offset the cost reported in a systematic way and for which the subsidy is intended to compensate. Government grants are reported in the income item Other operating revenue.

#### Research and development costs

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

#### Remuneration to employees

##### Short-term remuneration

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

##### Compensation after end of employment

Biolnvent mainly has defined benefit pension obligations. Biolnvent's pension commitment is secured by an Alecta insurance policy. According to a statement issued by the Swedish Financial Reporting Board, UFR 3, this is a benefit-based plan that covers several employers. For the 2009 financial year, the Company did not have access to the information necessary to report this plan as a benefit-based plan. The ITP pension plan secured by an Alecta insurance is therefore reported as a premium based plan. At the end of 2009 Alecta's surplus in the form of the collective funding ratio was 141 per cent (112). 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 assumptions. Note 2 provide information about the premiums for Alecta pension insurance. The Company reports pension payments as a cost during the period that the employee carries out the work to which the benefit relates.

##### 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 on 14 April 2008 resolved to adopt the employee stock option programme 2008/2012. The Annual General Meeting on 21 April 2009 decided on a supplement to the programme. This programme is described in greater detail in note 2.

#### Disclosure of related party transactions

In May 2009 Biolnvent transferred a patent to Immunovia AB relating to a method for analysing complex proteins and peptide tests based on affinity capturing of defined sub-populations of analytes followed by analysis with e.g. mass spectroscopy, for which the patent was covered by one the Company's discontinued research projects. Carl Borrebaeck, through his shareholding and assignment as one of the company's board members, has considerable influence over Immunovia AB. Biolnvent's Board of Directors has determined that the patent lacks commercial value and, in return for its transfer, Biolnvent has obtained the right to a portion of any future licensing revenues or an option under certain conditions to re-enter the project following proof-of-concept.

#### 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 2009.

Deferred tax assets relating to unutilised loss carry-forwards and deductible temporary differences are only reported if it is likely that they will be utilised against future taxable earnings. The Group's accumulated unutilised loss carry-forwards amounted to SEK 812 million as of 31 December 2009. It is unclear when these loss carry-forwards will be utilised 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. Changes in the estimated useful life are recognised by changing the amortisation period. 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 straight-line method over the expected useful life of the assets.

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 checked on each balance sheet date to determine whether there is any indication that an impairment loss is necessary.

##### 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).

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 receivable, 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.

#### 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 receivable 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.

#### 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 receivable, accounts payable, accrued expenses and derivative instruments. Liquid funds consist of cash and bank balances, as well as shortterm investments with maturity shorter than 3 months. Current investments consist of investments with maturity longer than 3 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 receivable 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 payable 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 recognised 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 and financial liabilities 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.

##### *Held-to-maturity investments*

This category includes non-derivative financial assets with fixed or determinable payments and with specified terms, which a company intends and has the ability to hold until maturity. These investments are valued at amortised cost.

##### *Loan receivables and accounts receivable*

Loan receivables and accounts receivable 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 receivable are reported at the amount expected to be received and are individually assessed. Impairment losses on accounts receivable are recognised in operating expenses. Other receivables with an expected maturity of more than one year are classed as noncurrent. Those with shorter maturities are classed 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 are 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 payable. Liabilities are valued at amortised cost. Accounts payable 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

In order to apply hedge accounting the following criteria must be met: the position being hedged is identified and exposed to exchange-rate or interest-rate movements, the purpose of the instrument is to serve as a hedge and that the hedging effectively protects the underlying position against changes in the market rates. Financial instruments used for the purpose of hedging future currency flows are accounted for as hedges if the currency flows are considered probable to occur. BioInvent has chosen not to apply hedge accounting because the criteria cannot always be deemed to be met. Changes in fair value of such derivative instruments are therefore recognised in the income statement.

#### Financial Risks

##### Currency risks

BioInvent's currency exposure has increased as the development projects move forward in the value chain. Costs of services such as toxicological studies and clinical trials have increased. These services are often carried out abroad and are paid for in foreign currencies. At the same time the percentage of revenues in foreign currencies has increased.

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 2009 67 per cent (86) of revenues were invoiced in foreign currencies, mainly EUR. Around 48 per cent (39) of costs in 2009 were invoiced in foreign currencies, mainly in USD, EUR and GBP. Realised forward contracts for flows in 2009 had an effect on the operating income in the amount of SEK -2.3 (-0.8) million. A sensitivity analysis shows that the Company's operating profit/loss in 2009 before hedging transactions would have been affected in the amount of SEK -0.6 million if the Swedish krona had weakened by 1 per cent 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 2009 was 1.6 per cent (4.8). A change in the interest rate of 1 per cent in 2009 would have affected the net interest income by SEK 1.5 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 the excess liquidity in 2009 was 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 is therefore low.

**NOTE 1** Key ratios human resources

	2009	2008
<b>Absence due to illness</b>		
Total absence due to illness <sup>1)</sup>	2.3%	2.2%
Of which long-term absence >60 days	0.8%	1.1%
Absence due to illness, women <sup>2)</sup>	2.4%	1.4%
Absence due to illness, men <sup>2)</sup>	2.1%	3.6%
29 years or younger <sup>2)</sup>	2.1%	1.6%
30-49 years <sup>2)</sup>	1.8%	1.3%
Older than 50 years <sup>2)</sup>	3.6%	4.7%
<b>Average number of employees, of which women</b>	<b>105 (63%)</b>	<b>99 (63%)</b>
<b>Age distribution</b>		
-30 years	8%	14%
31-40 years	45%	42%
41-49 years	20%	21%
50- years	27%	23%
<b>Staff turnover<sup>3)</sup></b>	<b>2.6%</b>	<b>11.8%</b>

1) Absence is indicated as a percentage of total normal working hours.

2) Absence is indicated as a percentage of the groups total normal working hours.

3) Staff turnover is shown as the number of individuals leaving the Company as a percentage of the average number of employees.

**NOTE 2** Salaries, other remuneration and social security

	2009		2008	
SEK thousands	Salaries and other remuneration	Social security costs (of which pension costs)	Salaries and other remuneration	Social security costs (of which pension costs)
Parent company	55,800	27,422 (8,417)	50,989	25,022 (7,288)
Subsidiaries	-	-	-	-
<b>Group total</b>	<b>55,800</b>	<b>27,422 (8,417)</b>	<b>50,989</b>	<b>25,022 (7,288)</b>

Salaries and other remuneration distributed between the board of directors, the CEO and other employees.

	2009		2008	
SEK thousands	Board and CEO	Other employees	Board and CEO	Other employees
Parent company	4,100	51,700	4,144	46,845
Subsidiaries	-	-	-	-
<b>Group total</b>	<b>4,100</b>	<b>51,700</b>	<b>4,144</b>	<b>46,845</b>

**NOTE 2** Salaries, other remuneration and social security, continue

Pensions costs distributed between the board of directors, the CEO and other employees.

	2009		2008	
SEK thousands	Board and CEO	Other employees	Board and CEO	Other employees
Parent company	927	7,490	786	6,502
Subsidiaries	-	-	-	-
<b>Group total</b>	<b>927</b>	<b>7,490</b>	<b>786</b>	<b>6,502</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 2009 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 per cent of fixed annual cash salaries may be paid out on an annual basis to senior executives. The performance-related components in the current program, for the period 1 January – 31 December 2010, are based primarily on high expectations for technical and commercial milestones in proprietary drug projects. The Board of Directors resolved in January 2010 to pay variable remuneration to the CEO, SEK 216 thousands, and other senior executives, SEK 577 thousands, for the period 1 January – 31 December 2009. 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 43.

**Remuneration and other benefits in 2009**

	Fixed salary	Board and committee fees	Variable remuneration	Other benefits	Pension costs	Total
<b>Board and CEO</b>						
Karl Olof Borg, Chairman		360				360
Carl Borrebaeck, member	616			59	131	806
Lars Henriksson, member		170				170
Lars Ingelmark, member		190				190
Elisabeth Lindner, member		170				170
Björn Nilsson, member		190				190
Kenth Petersson, member		190				190
Svein Mathisen, CEO and member	1,921		216	19	796	2,952
	<b>2,537</b>	<b>1,270</b>	<b>216</b>	<b>78</b>	<b>927</b>	<b>5,028</b>
<b>Other senior executives (5 individuals)</b>	<b>5,947</b>	-	<b>577</b>	<b>284</b>	<b>1,733</b>	<b>8,541</b>
<b>Total</b>	<b>8,484</b>	<b>1,270</b>	<b>793</b>	<b>362</b>	<b>2,660</b>	<b>13,569</b>

**Benefits for the Board and CEO**

The Board's fees were set by the 2009 Annual General Meeting at a total of SEK 1,110 thousands. The Chairman of the Board received a fee of SEK 360 thousands and each of the other Board members who are not employed by the company received a fee of SEK 150 thousands. In addition, the meeting resolved to set the Board's fee at SEK 160 thousands for committee work (not to the Chairman of the Board), including SEK 40 thousands to each of the members of the Audit Committee (3 people) and SEK 20 thousands to each of the members of the Remuneration Committee (2 people).

Carl Borrebaeck, a member of BioInvent's Board, is the Company's Senior Scientific Advisor. In 2009 he received SEK 616 thousands in cash gross salary and SEK 59 thousands in other benefits (primarily car benefits). He received no Board fees in 2009. Carl Borrebaeck is entitled to pension benefits under the ITP plan. Retirement age is 65. The total cost of Carl Borrebaeck's pension benefits amounted to SEK 131 thousands in 2009. Carl Borrebaeck and the Company have a mutual

period of notice of six months. He is not entitled to any redundancy pay over and above his salary during the period of notice.

The President and CEO, Svein Mathisen, received a fixed gross cash salary in 2009 of SEK 1,921 thousands and SEK 216 thousands in variable remuneration, as well as SEK 19 thousands in other benefits (primarily car benefits). The CEO has a defined contribution retirement benefit that may not exceed 35% of the wage calculation base. Retirement age is 65. The total cost of the CEO's pension benefits amounted in 2009 to SEK 796 thousands, of which SEK 83 thousands relate to retro-active adjustments. 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 18 monthly salaries. Redundancy pay is not deducted from other income. If the CEO resigns, no redundancy pay is payable.

The CEO has received a basic allotment of 7,500 employee options in 2008 and an extra allotment of 7,500 employee options in February 2009 and also an extra allotment of 6,000 employee options in January 2010.

## NOTE 2 Salaries, other remuneration and social security, continue

### 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 or defined contribution occupational pension that does not exceed 35 per cent of the wage calculation base. 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 2009 of SEK 5,947 thousands and SEK 577 thousands in variable salary, as well as SEK 284 thousands

in other benefits (primarily car benefit). The total pension costs relating to other senior executives in 2009 amounted to SEK 1,733 thousands.

Other senior executives received a basic allotment of 105,000 employee options in 2008 and 2009 and also an extra allotment of 30,000 employee options in February 2009 and an extra allotment of 30,000 employee options in January 2010.

### Academic partnerships

An important aspect of BioInvent's strategy is to develop and maintain a research base with ties to a number of academic institutions. One such relationship, with the department of Immunotechnology at Lund University, is particularly strong. BioInvent provides research funding to the institution and in return BioInvent obtains the results and patent rights that arise from the partnership.

Carl Borrebaeck is a professor and responsible for these activities at the Department of Immunotechnology. Carl Borrebaeck has not participated in preparations or decisions relating to agreements that BioInvent has entered into with Lund University.

### Percentage of women/men

	2009		2008	
	Number*	Of which women	Number*	Of which women
Board and CEO	9	22%	9	22%
Other senior executives	5	20%	4	25%

\*Number on 31 December

### Employee stock option plan 2008/2012

The Annual General Meeting on 14 April 2008 resolved to adopt an incentive programme, Employee Stock Option Plan 2008/2012, comprising a maximum of 1,450,000 employee options, and to issue 1,920,090 warrants for the subsidiary BioInvent Finans AB, free of charge, to secure the Company's commitment under the incentive programme and to cover the Company's associated social security contributions. BioInvent Finans AB subscribed to all warrants. Each option entitles the holder to subscribe to a new share at a subscription price of SEK 26.84. Employees received the basic allotment of 513,750 employee options in 2008 and 2009. Employees received an extra allotment of 69,750 employee options in February 2009 and an extra allotment of 429,750 employee options in January 2010. The annual general meeting on 21 April 2009 resolved to adopt an amendment to the existing employee options program 2008/2012. The amendment program comprise a maximum of 240,250 employee options. Each employee option entitles the holder to subscribe to a new share at a subscription price of SEK 26.84. A basic allocation of 33,750 employee options took place during 2009 and 2010. Extra allotment of 8,127 employee options took place in January 2010.

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. Basic allotment complies with the following guidelines: (i) 7,500 options to the CEO, members of senior management, the heads of a section and persons with other key positions (about 15 people), except for members of senior management without a substantial shareholding in the Company, who will receive 30,000 options, and (ii) 3,750 options to other employees (about 90 people). Further, extra allotment may be obtained based on performance according to the following guidelines: (i) maximum 15,000 employee options each year 2009-2011 to the CEO and other members of management, (ii) maximum 7,500 employee options each year 2009-2011 to Heads of sections and other key employees and (iii) maximum 3,750 employee options for 2010 to other employees. The maximum basic allotment may be adjusted proportionate to the length of employment with the Company for each individual. Extra allotment will be adjusted proportionate to the length of employment with the company.

Basic allotment may take place until the 2010 Annual General Meeting. Employee stock options received through basic allotment within the framework of Employee Stock Option Programme 2008/2012 entitle the holder to exercise 50 per cent of the options from the three-year anniversary of the allotment and 50 per cent from the four-year anniversary of the allotment. Employee options received within the

framework of the amendment programme can be exercised from 1 November 2012. The extra allotment is carried out in connection with the year-end report for 2008, 2009, and 2010 respectively. Employee stock options received through extra allotment within the framework of Employee Stock Option Programme 2008/2012 may be exercised from the 2012 Annual General Meeting and options received through extra allotment within the framework of the amendment programme may be exercised from 1 November 2012. 1 December, 2012, is the last day on which employee options may be exercised.

Assuming that all issued options relating to the Employee stock option plan 2008/2012, including the amendment programme, are exercised for subscription of new shares, the Company's share capital will increase by SEK 960,045 from SEK 27,830,444.50 to SEK 28,790,489.50, equivalent to about 3.3 per cent 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 in 2008 and 2009. The data below has been used for the calculation. The data is presented in intervals taking into account the fact that allotment took place on several occasions in 2008 and 2009.

Employee stock option plan	2009	2008
Allotted options	107,250	498,750
Fair value per option (SEK)	3.99-5.41	1.67-8.14
Share price for underlying shares (SEK)	20.50-23.60	14.80-24.60
Subscription price (SEK)	26.84	26.84
Estimated life of the option	3.42-3.67 years	3.92-4.42 years
Risk-free interest rate during the life of the option	1.80%-1.99%	1.83%-4.70%
Assumed volatility	35%	35%
Expected dividends	-	-

In 2009 wage costs for the employee stock option programme had a negative impact on operating profit of SEK 1,544 thousands. 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 3** Information about auditors' fees

SEK thousands	2009	Group 2008	2009	Parent company 2008
<b>Ernst &amp; Young</b>				
Audit assignments	268	182	268	182
Other assignments	82	93	82	93
<b>Total</b>	<b>350</b>	<b>275</b>	<b>350</b>	<b>275</b>

**NOTE 4** Depreciation according to plan of intangible and tangible fixed assets

SEK thousands	2009	Group 2008	2009	Parent company 2008
Research and development costs	10,651	11,214	10,651	11,214
Sales and administrative costs	466	329	466	329
<b>Total</b>	<b>11,117</b>	<b>11,543</b>	<b>11,117</b>	<b>11,543</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 5,362 thousands (6,149) and is included in the income statement item "Research and development costs."

**NOTE 5** Operational leasing

Leasing charges are for laboratory, production and office premises. Leasing costs in 2009 and 2008 amounted to SEK 10,555 thousands (9,984) for the group and the parent company. The table below shows the minimum lease payments for non-cancellable operational leasing agreements.

SEK thousands	Group	Parent company
Payments due:		
Year 2010	10,956	10,956
Year 2011-2014	11,815	11,815
Year 2015 or later	-	-
<b>Total</b>	<b>22,771</b>	<b>22,771</b>

**NOTE 6** Exchange rate differences that affected profit/loss for the period

SEK thousands	2009	Group 2008	2009	Parent company 2008
Exchange rate differences that affected the operating profit/loss	-709	278	-709	278
Financial exchange rate differences	340	253	340	253
<b>Total</b>	<b>-369</b>	<b>531</b>	<b>-369</b>	<b>531</b>

**NOTE 7** Interest income and similar items

SEK thousands	2009	Group 2008	2009	Parent company 2008
Interest income	2,501	9,427	2,501	9,427
Exchange rate differences	503	306	503	306
<b>Total</b>	<b>3,004</b>	<b>9,733</b>	<b>3,004</b>	<b>9,733</b>

**NOTE 8** Interest costs and similar items

SEK thousands	2009	Group 2008	Parent company 2009	2008
Interest costs	0	0	0	0
Exchange rate differences	-163	-53	-163	-53
<b>Total</b>	<b>-163</b>	<b>-53</b>	<b>-163</b>	<b>-53</b>

**NOTE 9** Tax on profit for the year

Tax on profit for the year	2009	Group 2008	Parent company 2009	2008
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 the profit for the year</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

Reconciliation of effective tax	2009	Group 2008	Parent company 2009	2008
Reported profit/loss before tax	-176,661	16,251	-175,454	16,867
Tax according to the applicable tax rate, 26,3% (28%)	46,462	-4,550	46,144	-4,723
Tax effect of costs that are not deductible	-200	-243	-200	-243
Tax effect of loss carry forward for which the deferred tax claim has not been /shall be considered	-46,262	4,793	-45,944	4,966
<b>Reported tax on profit/loss for the year</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

**NOTE 10** Earnings per share

Earnings per share before dilution	2009	2008
Profit/loss for the period	-176,661	16,251
Average number of outstanding shares (thousands)	55,661	55,661
<b>Earnings per share before dilution, SEK</b>	<b>-3.17</b>	<b>0.29</b>
Earnings per share after dilution	2009	2008
Profit/loss for the period	-176,661	16,251
Average number of outstanding shares (thousands)	55,661	55,661
<b>Earnings per share after dilution, SEK</b>	<b>-3.17</b>	<b>0.29</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. The subscription price of the 2008/2012 employee stock option programme is SEK 26.84 per share. No dilution is present since the subscription price exceeds the share price.

**NOTE 11** Intangible fixed assets

<b>Acquired intangible fixed assets</b>	<b>Group</b>		<b>Parent company</b>	
SEK thousands	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Opening acquisition value	47,885	51,567	47,885	51,567
Acquisitions	-	6,001	-	6,001
Disposals	-	-9,683	-	-9,683
<b>Closing accumulated acquisition value</b>	<b>47,885</b>	<b>47,885</b>	<b>47,885</b>	<b>47,885</b>
Opening depreciation	-35,501	-39,035	-35,501	-39,035
Disposals	-	9,683	-	9,683
Depreciation for the year	-5,362	-6,149	-5,362	-6,149
<b>Closing accumulated depreciation</b>	<b>-40,863</b>	<b>-35,501</b>	<b>-40,863</b>	<b>-35,501</b>
<b>Closing residual value according to plan</b>	<b>7,022</b>	<b>12,384</b>	<b>7,022</b>	<b>12,384</b>

**NOTE 12** Tangible fixed assets

<b>Equipment</b>	<b>Group</b>		<b>Parent company</b>	
SEK thousands	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Opening acquisition value	77,355	71,247	77,355	71,247
Acquisitions	1,297	7,638	1,297	7,638
Disposals	-2,644	-1,530	-2,644	-1,530
<b>Closing accumulated acquisition value</b>	<b>76,008</b>	<b>77,355</b>	<b>76,008</b>	<b>77,355</b>
Opening depreciation	-61,932	-58,966	-61,932	-58,966
Disposals	2,644	1,530	2,644	1,530
Depreciation for the year	-5,038	-4,496	-5,038	-4,496
<b>Closing accumulated depreciation</b>	<b>-64,326</b>	<b>-61,932</b>	<b>-64,326</b>	<b>-61,932</b>
<b>Closing residual value according to plan</b>	<b>11,682</b>	<b>15,423</b>	<b>11,682</b>	<b>15,423</b>
<b>Investments in rented premises</b>	<b>Group</b>		<b>Parent company</b>	
SEK thousands	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Opening acquisition value	10,967	10,967	10,967	10,967
Acquisitions	-	-	-	-
<b>Closing accumulated acquisition value</b>	<b>10,967</b>	<b>10,967</b>	<b>10,967</b>	<b>10,967</b>
Opening depreciation	-9,963	-9,066	-9,963	-9,066
Depreciation for the year	-717	-897	-717	-897
<b>Closing accumulated depreciation</b>	<b>-10,680</b>	<b>-9,963</b>	<b>-10,680</b>	<b>-9,963</b>
<b>Closing residual value according to plan</b>	<b>287</b>	<b>1,004</b>	<b>287</b>	<b>1,004</b>

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

**NOTE 13** Shares in subsidiaries

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

BiolInvent Finans AB administers the warrants issued by BiolInvent International AB.

**NOTE 14** Work on contract

SEK thousands	2009	Group 2008	2009	Parent company 2008
Value of work completed	3,018	11,392	3,018	11,392
Invoiced amounts	-2,534	-11,250	-2,534	-11,250
<b>Receivables from customers</b>	<b>484</b>	<b>142</b>	<b>484</b>	<b>142</b>
Value of work completed	3,668	2,974	3,668	2,974
Invoiced amounts	-5,576	-3,946	-5,576	-3,946
<b>Liabilities to customers</b>	<b>-1,908</b>	<b>-972</b>	<b>-1,908</b>	<b>-972</b>

Receivables from customers and liabilities to customers are reported in the balance sheet as work on contract in the balance sheet's assets and liabilities sections respectively.

**NOTE 15** Prepaid expenses and accrued income

SEK thousands	2009	Group 2008	2009	Parent company 2008
Prepaid rent	2,684	2,571	2,684	2,571
Other items	3,694	2,787	3,694	2,787
<b>Total</b>	<b>6,378</b>	<b>5,358</b>	<b>6,378</b>	<b>5,358</b>

**NOTE 16** Accrued expenses and deferred income

SEK thousands	2009	Group 2008	2009	Parent company 2008
Payroll liabilities	10,526	9,879	10,526	9,879
Social security fees	4,939	4,630	4,939	4,630
Other items	4,171	2,682	4,156	2,667
<b>Total</b>	<b>19,636</b>	<b>17,191</b>	<b>19,621</b>	<b>17,176</b>

## NOTE 17 Financial instruments

### FAIR VALUES

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

SEK thousands	Book value		Actual value	
	2009	2008	2009	2008
<b>Financial assets</b>				
<i>Loan receivables and accounts receivables</i>				
Accounts receivables	3,441	37,616	3,441	37,616
<i>Available-for-sale financial assets</i>				
Current investments	9,984	161,180	9,984	161,180
Current investments that constitute liquid funds	45,974	34,886	45,974	34,886
Cash and bank	28,062	16,394	28,062	16,394
	84,020	212,460	84,020	212,460
<i>Financial assets carried at fair value through profit or loss for the year</i>				
Derivatives	7	281	7	281
<b>Total</b>	<b>87,468</b>	<b>250,357</b>	<b>87,468</b>	<b>250,357</b>
<b>Financial liabilities</b>				
<i>Other financial liabilities</i>				
Accounts payables	-16,510	-12,784	-16,510	-12,784
Accrued expenses	-19,636	-17,191	-19,636	-17,191
<i>Financial liabilities recognised at fair value through profit or loss for the year</i>				
Derivatives	-14	-31	-14	-31
<b>Total</b>	<b>-36,160</b>	<b>-30,006</b>	<b>-36,160</b>	<b>-30,006</b>

### MATURITIES

Maturities for financial instruments are presented below

Remaining term, 31 Dec. 2010, SEK thousands	On demand	< 3 months	3-12 months	Total
<b>Financial assets</b>				
<i>Loan receivables and accounts receivables</i>				
Accounts receivables (where of past due but not recognised as impairment losses)		3,441 (-)		3,441 (-)
<i>Available-for-sale financial assets</i>				
Current investments			9,984	9,984
Current investments that constitute liquid funds		45,974		45,974
Cash and bank	28,062			28,062
<i>Financial assets carried at fair value through profit or loss for the year</i>				
Derivatives		7		7
<b>Total</b>	<b>28,062</b>	<b>49,422</b>	<b>9,984</b>	<b>87,468</b>



**NOTE 17** Financial instruments

Remaining term, 31 Dec. 2009, SEK thousands	On demand	< 3 months	3-12 months	Total
<b>Financial liabilities</b>				
<i>Other financial liabilities</i>				
Accounts payables		-16,510		-16,510
Accrued expenses		-19,636		-19,636
<i>Financial liabilities recognised at fair value through profit or loss for the year</i>				
Derivatives		-14		-14
<b>Total</b>	-	<b>-36,160</b>	-	<b>-36,160</b>
<b>Remaining term, 31 Dec. 2008</b>				
<b>Financial assets</b>	<b>16,394</b>	<b>72,783</b>	<b>161,180</b>	<b>250,357</b>
<b>Financial liabilities</b>	-	<b>-30,006</b>	-	<b>-30,006</b>

**NET GAINS/LOSSES**

Below are the net gains/losses for financial instruments recognised through profit or loss for the year

SEK thousands	2009	2008
<b>Financial assets</b>		
<i>Loan receivables and accounts receivables</i>	516	-109
<i>Available-for-sale financial assets</i>	340	253
<i>Financial assets carried at fair value through profit or loss for the year</i>	-	-
<b>Financial liabilities</b>		
<i>Other financial liabilities</i>	-1,225	387
<i>Financial liabilities recognised at fair value through profit or loss for the year</i>	-	-
<b>Total</b>	<b>-369</b>	<b>531</b>

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 management 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, 16 March 2010

Karl Olof Borg  
Chairman of the Board

Carl Borrebaeck

Lars Henriksson

Lars Ingelmark

Elisabeth Lindner

Ulrika T Mattson

Björn Nilsson

Kenth Petersson

Svein Mathisen  
President and CEO

Our audit report was submitted on 16 March 2010  
ERNST & YOUNG AB

Johan Thuresson  
Authorised Public Accountant

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

We have audited the annual accounts, the consolidated accounts, the accounting records and the administration of the board of directors and the CEO of BioInvent International AB for the year 2009. The annual accounts and the consolidated accounts of the company are included in the printed version of this document on pages 28–50. The board of directors and the CEO are responsible for these accounts and the administration of the company as well as for the application of the Annual Accounts Act when preparing the annual accounts and the application of International Financial Reporting Standards IFRSs as adopted by the EU and the Annual Accounts Act when preparing the consolidated accounts. Our responsibility is to express an opinion on the annual accounts, the consolidated accounts and the administration based on our audit.

We conducted our audit in accordance with generally accepted auditing standards in Sweden. Those standards require that we plan and perform the audit to obtain reasonable assurance that the annual accounts and the consolidated accounts are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the accounts. An audit also includes assessing the accounting principles used and their application by the board of directors and the CEO and significant estimates made by the board of directors and the CEO when preparing the annual accounts and consolidated accounts as well as evaluating the overall presentation of information in the annual accounts and the consolidated accounts. As a basis for our opinion concerning discharge from liability, we examined significant decisions, actions taken and circumstances of the company in order to be able to determine the liability, if any, to the company of any board member or the CEO. We also examined whether any board member 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 our audit provides a reasonable basis for our opinion set out below.

The annual accounts have been prepared in accordance with the Annual Accounts Act and give a true and fair view of the company's financial position and results of operations in accordance with generally accepted accounting principles in Sweden. The consolidated accounts have been prepared in accordance with the International Financial Reporting Standards IFRSs as adopted by the EU and the Annual Accounts Act and give a true and fair view of the group's financial position and results of operations. The statutory administration report is consistent with the other parts of the annual accounts and the consolidated accounts.

We recommend to the Annual General Meeting that the income statement and balance sheet of the parent company and the consolidated statement of comprehensive income and the consolidated statement of financial position for the Group be adopted, that the loss of the parent company be dealt with in accordance with the proposal in the directors' report and that the members of the Board and the CEO be discharged from liability for the financial year.

Lund, 16 March 2010  
Ernst & Young AB

Johan Thuresson  
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 OMX Stockholm, and good practices on the stock market.

This corporate governance report was prepared in compliance with the rules of chapter 10 of the Code with the purpose of describing how BioInvent has applied the Code. The report does not constitute a part of the formal annual report documentation and has not been reviewed by the Company's auditor.

## 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 AGM considers the Company's progress and resolves on a number of key issues such as dividends, Directors fees, amendments to the Articles of Association, appointing auditors, discharge of the Board of Directors from liability, and the election of a new Board of Directors until the next Annual General Meeting. The auditor is appointed every four years, as is the remuneration for the auditor.

The 2009 Annual General Meeting was held on 21 April 2009 and the minutes are available on the BioInvent website.

The Annual General Meeting will be held on Tuesday 20 April 2010 at 4 p.m., at Ideon, Lund.

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 2009 Annual General Meeting comprised Björn Ogenstam (Stiftelsen Industrifonden), Ulrica Slåne (Tredje AP-fonden), Karin Lind-Mörnsten (Östersjöstiftelsen) and the Chairman of the Board Karl Olof Borg. The Nominating Committee formulated proposals for the chairman of the general meeting, and the composition of the Board of Directors, as well as explanations for these choices, along with directors' fees, election of the auditor and the auditor's fee. The Nominating Committee had three meetings and a number of telephone calls. The Nominating Committee did not receive any remuneration.

The composition of the Nominating Committee for the 2010 Annual General Meeting was presented on the BioInvent website on 16 October 2009. The Nominating Committee for the 2010 Annual General Meeting consists of Lennart Hansson (Stiftelsen Industrifonden), Ulrica Slåne (Tredje AP-fonden), Karin Lind-Mörnsten (Östersjöstiftelsen) and the Chairman of the Board Karl Olof Borg. Proposals to the Nominating Committee should be addressed to Marie Serwe, by mail: BioInvent International AB (publ.), SE-223 70 Lund or tel: +46 (0)46-46 286 85 50. The Nominating Committee has prepared proposals for the 2010 Annual General Meeting for the chairman of the general meeting and composition of the Board of Directors, along with explanations for these choices, as well as directors' fees. The Nominating Committee had three meetings 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 Board currently consists of eight AGM-elected directors and one employee representative. The 2009 AGM discharged the Board members and the President and CEO from liability and re-elected the Board members: Karl Olof Borg, Carl Borrebaeck, Lars Henriksson, Lars Ingelmark, Elisabeth Lindner, Svein Mathisen, Björn Nilsson and Kenth Petersson. The AGM elected Karl Olof Borg to be Chairman of the Board.

The Board of Directors is presented on page 60 of the 2009 annual report. CEO Svein Mathisen is on the Board of Directors. Carl Borrebaeck, member of BioInvent's Board of Directors, is employed as a senior scientific advisor for the Company. He does not work with BioInvent's operations in his capacity as scientific advisor. Other elected directors are independent, both in relation to the major shareholders and in relation to the Company and senior management. Since no Company shareholders control 10 percent or more of the shares and are not therefore catego-

rized as major shareholders, there can be no relationship of dependence between the AGM-elected directors and major shareholders.

The 2009 AGM set the Board's fees at SEK 1,110,000, of which SEK 360,000 should be the fee for the Chairman of the Board and SEK 150,000 should be the fee for each other member of the board not employed by the Company. In addition hereto, it was decided that SEK 160,000 shall be the fee for committee work (not including the chairman of the board), of which SEK 40,000 shall be the fee for each of the members in the Audit Committee (3 persons) and SEK 20,000 shall be the fee for each of the members in the Remuneration Committee (2 persons).

The Board has two preparatory committees, the Remuneration Committee and the Audit 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 2009 the Board of Directors held eight regular meetings and three extra meetings. Attendance was high, as can be seen in the table below. 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 this evaluation is provided to the Nominating Committee.

<b>Board member</b>	<b>Attendance</b>
Karl Olof Borg (chairman)	11 (11)
Carl Borrebaeck	9 (11)
Lars Henriksson	10 (11)
Lars Ingelmark	9 (11)
Elisabeth Lindner	8 (11)
Svein Mathisen	11 (11)
Ulrika T Mattson	10 (11)
Björn Nilsson	10 (11)
Kenth Petersson	10 (11)

## Remuneration Committee

The Board has appointed a remuneration committee consisting of Chairman of the Board, Karl Olof Borg, as well as two other Directors, Lars Henriksson and Elisabeth Lindner. All directors are independent of the Company and its senior management. The Board's Remuneration Committee, whose work is regulated in the instructions that comprise part of the rules of procedure for the Board of Directors, considers and decides on issues pertaining to remuneration and benefits to all senior executives except the CEO, whose compensation is decided by the Board of Directors. The committee also prepares other remuneration issues of greater importance, such as incentive programs. The remuneration committee reports to the Board of Directors. The committee met three times in 2009.

<b>Member of the Remuneration Committee</b>	<b>Attendance</b>
Karl Olof Borg (chairman)	3 (3)
Lars Henriksson	3 (3)
Elisabeth Lindner	2 (3)

## Audit Committee

The Board of Directors has appointed an Audit Committee consisting of Björn Nilsson (chairman), Karl Olof Borg, Lars Ingelmark and Kenth Petersson. All directors are independent of the Company, its senior management, and major shareholders. 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 earnings report 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 seven meetings in 2009.

<b>Member of the Audit Committee</b>	<b>Attendance</b>
Björn Nilsson (chairman)	7 (7)
Karl Olof Borg	7 (7)
Lars Ingelmark	7 (7)
Kenth Petersson	7 (7)



## **Auditors**

According to the Articles of Association, BioInvent is to appoint at least one and no more than three auditors for a term as prescribed by law. 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 2008 Annual General Meeting elected Ernst & Young AB to serve as the Company's auditors for the period until the end of the Annual General Meeting held during the fourth financial year after the auditors were elected, which is 2012. Johan Thuresson, authorised public accountant, is principal auditor.

## **Group Management**

According to its guidelines and instructions, the Board of Directors has delegated day-to-day management to CEO Svein Mathisen. 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. Senior management is presented on page 61 of the 2009 annual report.

## **Remuneration to senior executives**

The 2009 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 stable 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 32.

## **The Board of Directors' description of Internal Control over Financial Reporting for the 2009 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 Swedish Code of Corporate Governance (in the wording that existed prior to 1 February 2010), sections 10.5 and 10.6, and is accordingly limited to internal control for financial reporting. This description is not part of the formal financial statements.

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, organisational structure and decision-making procedures, as well as the allocation of powers and responsibilities. The most essential components of the control environment at BioInvent are documented in its policies and other governing documents. BioInvent's rules of procedure describe the allocation of responsibilities between the Board of Directors and the Chief Executive Officer, 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 authorisation 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**

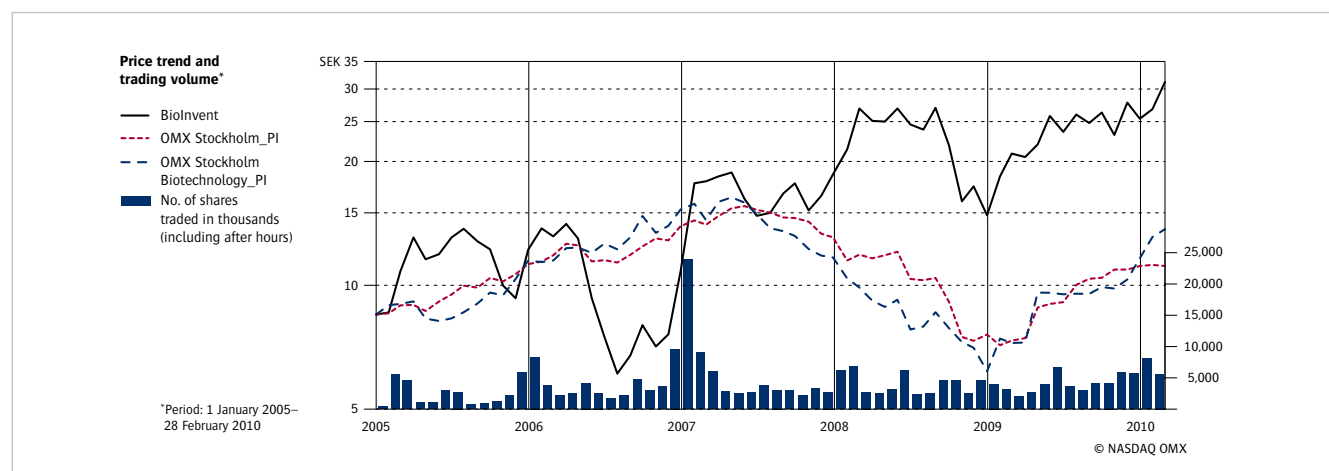
BioInvent follows up and assesses its compliance with internal policies and other policy documents on a regular and annual basis. Suitability and functionality are also evaluated on a regular and annual basis. Inadequacies are reported and remedied in accordance with specific established procedures.

## **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 re-considered annually by the Board of Directors.



# The BioInvent share



BioInvent has been listed on NASDAQ OMX Stockholm since 2001.

## Price trend and trading volume

In 2009, the share price increased 72%, from SEK 14.80 to SEK 25.40. During 2009 the OMX Stockholm\_PI increased 47 % and OMX Stockholm Biotechnology\_PI increased 88 %. The highest price paid in 2009 was SEK 29.80 and the lowest price was SEK 15.20. BioInvent's market capitalization totalled SEK 1,414 million at the end of 2009.

During the year 48.9 (48.6) million BioInvent shares were traded for a value of SEK 1,186 (1,076) million. This corresponds to a rate of turnover of 90% (86). Average trading volume per trading day was 194,923 (192,830) shares for a value of SEK 4.7 (4.3) million. Average number of trades per trading day were 177 (104).

## Largest shareholders, 31 December 2009

Shareholders	No. of shares	Percentage of capital and votes
JP Morgan Bank	5,508,548	9.9
Stiftelsen Industrifonden	4,461,342	8.0
Avanza Pension Försäkring	2,141,079	3.8
SEB Life Ltd	2,018,100	3.6
Tredje AP-fonden	1,880,500	3.4
Hans Ståhlgren	1,334,000	2.4
Sjätte AP-fonden	1,268,718	2.3
Carl Borrebaeck*	1,242,908	2.2
Mikael Lönn	1,200,000	2.2
Other shareholders	34,605,694	62.2
<b>Total**</b>	<b>55,660,889</b>	<b>100.0</b>

\* Board member

\*\* As of 9 February 2010, after a directed share issue, B&E Participation AB owns 3,913,000 shares in the Company, equivalent to 6.4% of the capital and votes. As of 8 February 2010 the total number of shares is 61,095,689.

## Ownership structure

In 2009, the number of shareholders increased 58%, from 4,202 to 6,650. Foreign owners held 36% (38) of the share capital and votes. The ten largest shareholders owned 40% (40) of the shares. About 72% (66) of the shareholders owned 1,000 or fewer shares each.

## Analysts covering BioInvent

Björn Fahlén – Redeye  
 Alexander Lindström – ABG Sundal Collier  
 Luc A. Otten – Helvea SA, Geneva  
 Camilla Oxhamre – D. Carnegie  
 Gustaf Vahlne – Enskilda Securities  
 Sten Westerberg, Yilmaz Mahshid  
 – E. Öhman J:or Fondkommission

## Share capital

As of 31 December 2009 the Company's share capital amounted to SEK 27.8 million distributed between 55,660,889 shares. Assuming that all options 1,920,090 issued due to the 2008/2012 employee stock option programme are exercised, the number of shares will be 57,580,979.

After the end of the financial year, BioInvent implemented a directed share issue setting aside the shareholders' preferential rights with a total of 5,434,800 shares for the purpose of raising proceeds of SEK 150 million for the Company before transactions costs. Following the new share issue the total number of shares in the Company is 61,095,689.

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.

## Employee incentive program

The annual general meeting on 14 April 2008 resolved to adopt an incentive program comprising a maximum of 1,450,000 employee options (Sw. personaloptioner) and to issue 1,920,090 warrants for the subsidiary BioInvent Finans AB, free of charge, to secure the company's commitment under the incentive program and to cover the company's associated social security contributions. BioInvent Finans AB has subscribed all the warrants.

Each employee option entitles the holder to subscribe to a new share at a subscription price of SEK 26.84. A basic allocation of 513,750 employee options took place during 2008 and 2009. Extra allotment of 69,750 employee options took place in February 2009 and in January 2010 with 429,750 employee options.

The annual general meeting on 21 April 2009 resolved to adopt an amendment to the existing employee options program 2008/2012, resolved by the AGM 2008. The amendment program comprise a maximum of 240,250 employee options, directed to the employees of the Company, entitling the holder to subscribe for new shares. Each employee option entitles the holder to subscribe to a new share at a subscription price of SEK 26.84. A basic allocation of 33,750 employee options took place during 2009 and 2010. Extra allotment of 8,127 employee options took place in January 2010.

### Dividend and dividend policy

The Board of Directors and the CEO do not recommend payment of any dividend for the 2009 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 and the CEO 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. The annual report is published in Swedish and English.

### Upcoming financial information

Interim reports: 15 April, 14 July, 14 October 2010  
Financial statement 2010: 10 February 2011

### Share statistics, 31 December 2009

Size of holdings	No. of shareholders	No. of shareholders, %	No. of shares in %
1–500	3,396	51.1	0.7
501–1,000	1,392	20.9	1.5
1,001–2,000	780	11.7	1.7
2,001–5,000	575	8.6	2.9
5,001–10,000	226	3.4	2.9
10,001–20,000	113	1.7	2.8
20,001–50,000	67	1.0	3.9
50,001–100,000	36	0.5	4.9
100,001–500,000	43	0.6	13.0
500,001–1,000,000	9	0.1	15.6
1,000,001–5,000,000	12	0.2	40.8
5,000,001–10,000,000	1	0.0	9.3
<b>Total</b>	<b>6,650</b>	<b>100.0</b>	<b>100.0</b>

### Changes in the share capital

Year	Transaction capital, SEK	Increase in share no. of shares	Increase in 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	107,140	10,714	10.00
1997	Bonus issue	857,120	964,260	96,426	10.00
1998	Share split 1:10		964,260	964,260	1.00
1998	New share issue <sup>2)</sup>	181,000	1,145,260	1,145,260	1.00
1999	New share issue <sup>3)</sup>	108,527	1,253,787	1,253,787	1.00
2000	New share issue <sup>4)</sup>	250,000	1,503,787	1,503,787	1.00
2000	Warrants exercised	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		11,361,000	22,722,000	0.50
2001	Warrants exercised	461,152.5	11,822,152.5	23,644,305	0.50
2001	New share issue <sup>5)</sup>	2,250,000	14,072,152.5	28,144,305	0.50
2002	New share issue <sup>6)</sup>	665,625.5	14,737,778	29,475,556	0.50
2005	New share issue <sup>7)</sup>	8,842,666.5	23,580,444.5	47,160,889	0.50
2007	New share issue <sup>8)</sup>	4,250,000	27,830,444.5	55,660,889	0.50
2010	New share issue <sup>9)</sup>	2,717,400	30,547,844.5	61,095,689	0.50

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

2) In November 1998 the Company issued 181,000 new shares aimed at institutional investors. The issue price was SEK 125 and SEK 22.6 million was raised for BioInvent International AB after issue cost deductions.

3) In November 1999 the Company issued 108,527 new shares aimed at institutional investors. The issue price was SEK 175 and SEK 18.7 million was raised for BioInvent International AB after issue cost deductions.

4) In March 2000, the Company issued 250,000 shares aimed at institutional investors. The issue price was SEK 720 and SEK 169.0 million was raised for BioInvent International AB after issue cost deductions.

5) New share issue in connection with the listing. The issue price was SEK 62 and SEK 261.6 million was raised for BioInvent International AB after issue cost deductions.

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

7) In November 2005 the Company carried out a new share issue. The issue price was SEK 9 and SEK 146.2 million was raised for BioInvent International AB after deductions of issue costs.

8) In July 2007 the Company carried out a directed issue. The issue price was SEK 14.75 and SEK 120.0 million was raised for BioInvent International AB after deductions of issue costs.

9) In February 2010 the Company carried out a directed issue. The issue price was SEK 27.60 and SEK 144.4 million was raised for BioInvent International AB after deductions of issue costs.

## Five-year review

<b>INCOME STATEMENT, SEK MILLION</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>
Net revenues	80.7	252.1	143.4	50.8	28.2
Research and development costs	-229.2	-215.4	-140.9	-135.4	-142.4
Sales and administrative costs	-35.5	-30.9	-28.7	-29.8	-28.1
Other operating revenues and costs	4.5	0.7	2.7	2.6	0.0
	-260.2	-245.6	-166.9	-162.6	-170.5
<b>Operating profit/loss</b>	<b>-179.5</b>	<b>6.6</b>	<b>-23.4</b>	<b>-111.7</b>	<b>-142.3</b>
Profit/loss from financial investments	2.8	9.7	7.4	2.9	2.5
<b>Profit/loss after financial items</b>	<b>-176.7</b>	<b>16.3</b>	<b>-16.1</b>	<b>-108.8</b>	<b>-139.9</b>
Tax on profit for the year	–	–	–	–	–
<b>Profit/loss for the year</b>	<b>-176.7</b>	<b>16.3</b>	<b>-16.1</b>	<b>-108.8</b>	<b>-139.9</b>
<b>BALANCE SHEET, SEK MILLION</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>
Intangible fixed assets	7.0	12.4	12.5	18.9	26.5
Tangible fixed assets	12.0	16.4	14.2	16.2	15.1
Inventories etc.	2.0	2.3	3.8	7.8	3.0
Current receivables	21.2	51.9	23.6	17.4	26.5
Current investments and liquid funds	84.0	212.5	216.9	88.0	195.3
<b>Total assets</b>	<b>126.2</b>	<b>295.4</b>	<b>271.0</b>	<b>148.3</b>	<b>266.3</b>
Shareholders' equity	55.6	231.3	214.1	110.2	219.0
Non-interest-bearing liabilities	70.6	64.1	56.9	38.2	47.3
Interest-bearing liabilities	–	–	–	–	–
<b>Total shareholders' equity and liabilities</b>	<b>126.2</b>	<b>295.4</b>	<b>271.0</b>	<b>148.3</b>	<b>266.3</b>
<b>CASH FLOW, SEK MILLION</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>
Operating profit/loss	-179.5	6.6	-23.4	-111.7	-142.3
Adjustments for depreciation, interest and other items	17.0	21.5	18.3	18.3	23.2
Changes in working capital	35.3	-18.8	17.8	-4.9	16.6
<b>Cash flow from current operations</b>	<b>-127.1</b>	<b>9.2</b>	<b>12.6</b>	<b>-98.3</b>	<b>-102.5</b>
Cash flow from investment activities	-1.3	-13.6	-3.9	-9.0	-23.4
<b>Cash flow from current operations and investment activities</b>	<b>-128.4</b>	<b>-4.4</b>	<b>8.7</b>	<b>-107.3</b>	<b>-125.9</b>
Cash flow from financing activities	-	-	120.1	-	146.2
<b>Increase/decrease in current investments and liquid funds</b>	<b>-128.4</b>	<b>-4.4</b>	<b>128.8</b>	<b>-107.3</b>	<b>20.3</b>

KEY FINANCIAL RATIOS	2009	2008	2007	2006	2005
Net revenue growth, %	-68.0	75.8	182.2	80.3	-52.0
Net working capital, SEK million	-47.4	-10.0	-29.4	-13.0	-17.9
Net working capital/net revenue, %	-58.7	-4.0	-20.5	-25.5	-63.5
Operating capital, SEK million	-28.4	18.8	-2.7	22.1	23.7
Operating capital/net revenue, %	-35.2	7.5	-1.9	43.6	84.0
Capital employed, SEK million	55.6	231.3	214.1	110.2	219.0
Capital employed/net revenue, %	69.0	91.7	149.3	216.7	776.7
Shareholders' equity, SEK million	55.6	231.3	214.1	110.2	219.0
Return on shareholders' equity, %	-123.1	7.3	-9.9	-66.1	-64.8
Return on shareholders' equity, %	-123.1	7.3	-9.9	-66.1	-64.8
Capital turnover, times	0.6	1.1	0.9	0.3	0.1
Equity/assets ratio, %	44.1	78.3	79.0	74.3	82.2
Intangible fixed assets investments, SEK million	-	6.0	-	-	19.5
Tangible fixed assets investments, SEK million	1.3	7.6	3.9	9.0	3.9
Average number of employees	105	99	96	96	95
Net revenue per employee, SEK million	0.8	2.5	1.5	0.5	0.3
DATA PER SHARE	2009	2008	2007	2006	2005
Earnings per share, SEK					
Before dilution	-3.17	0.29	-0.31	-2.31	-4.41
After full dilution	-3.17 <sup>3)</sup>	0.29 <sup>3)</sup>	<sup>2)</sup>	<sup>1)</sup>	<sup>1)</sup>
Shareholders' equity per share, SEK					
Before dilution	1.00	4.15	3.85	2.34	4.64
After full dilution	1.00 <sup>3)</sup>	4.15 <sup>3)</sup>	<sup>2)</sup>	2.34	4.64
Cash flow per share, SEK	-2.31	-0.08	0.17	-2.28	-3.97
Average no. of shares					
Before dilution (thousands)	55,661	55,661	51,175	47,161	31,686
After full dilution (thousands)	55,661	55,661	<sup>2)</sup>	47,161	31,691
Number of shares at end of period					
Before dilution (thousands)	55,661	55,661	55,661	47,161	47,161
After full dilution (thousands)	55,661	55,661	<sup>2)</sup>	47,161	47,165
Share price, 31 December, SEK	25.40	14.80	18.60	10.80	12.20

1) The outstanding warrants lead to no dilution of earnings per share as a redemption to shares would lead to an improvement of earnings per share.

2) At the end of the period there were no outstanding warrants or employee options.

3) No dilution is present since the subscription price exceeds the 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-interest-bearing 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



### Karl Olof Borg

#### Chairman of the Board

Doctor of Pharmacy. Born 1941. Lives in Trosa, Sweden. Previously Vice President of Research at Astra AB, Pharmacia AB and Active Biotech AB. Member of the Board since 2001. Chairman of the Board since 2007. Chairman of the Remuneration Committee and member of the Audit Committee.

Other board appointments: Member of the Boards of Eurocine Vaccine AB, Galencia AB, Alligator Bioscience AB and Biocrine AB.

Shareholding: 8,000



### Lars Ingelmark

Bachelor of Medicine. Born 1949. Lives in Halmstad, Sweden. Head of Business Area Life Science of Sjötte AP-fonden. Member of the Board since 2006. Member of the Audit Committee.

Other board appointments: Chairman of the Boards of Gyltorp AB, SLS Invest AB and Svensk Vätmarksfond. Member of the Boards of Niconovum AB, Innoventus AB, Innoventus Projekt AB, KA Intressenter AB, Svenska Jägarförbundet, Healthcare Göteborg AB and Skedala Säteri AB. Member of the Board and CEO of IQQU Styrelseutveckling AB.

Shareholding: -



### Carl Borrebaeck

Doctor of Science. Born 1948. Lives in Lund, Sweden. Deputy Vice-Chancellor at Lund University, Professor at the Department of Immunotechnology and Centre Director for the translational cancer centre - CREATE Health, Lund. Member of the Royal Swedish Academy of Engineering Sciences. Senior Scientific Advisor to the Company. Member of the Board since 1997.

Other board appointments: Chairman of the Boards of Lund Universitet Innovationsystem AB and Immunovia AB. Member of the Boards of Alligator Bioscience AB and Nordic Vaccine A/S.

Shareholding: 1,242,908



### Elisabeth Lindner

Master of Science, MBA. Born 1956. Lives in Hägersten, Sweden. CEO and President of Diamyd Medical AB. Member of the Royal Swedish Academy of Engineering Sciences. Member of the Board since 2005. Member of the Remuneration Committee.

Other board appointments: Chairman of the Board and CEO of Biosource Europe AB. Member of the Boards of Diamyd Therapeutics AB, Diamyd Diagnostics AB and Diamyd Inc.

Shareholding: 6,400



### Lars Henriksson

Master of Science. Born 1961. Lives in Stockholm, Sweden. Investment Manager/Controller of Business Area Life Science of Stiftelsen Industrifonden. Member of the Board since 2005. Member of the Remuneration Committee.

Other board appointments: Member of the Boards of Diashunt Intressenter AB and SHS Intressenter AB.

Shareholding: -



### Svein Mathisen

#### President and CEO

Master of Science, Engineering Physics. Born 1956. Lives in Malmö, Sweden. President and CEO since 1997. Previously held senior positions within the Norsk Hydro Group. Member of the Board since 2001.

Other board appointments: Chairman of the Board of Biotech Pharmacon ASA and member of the Board of SwedenBIO.

Shareholding: 1,050 000

Employee options: 21,000



### Ulrika T Mattsson

#### Employee representative

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

Other board appointments: -

Shareholding: 400 (own and affiliated holdings)

Employee options: 7,500



### Björn Nilsson

Doctor of Science. Born 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 Audit Committee.

Other board appointments: Vice Chairman of the Board of ÅForsk.

Shareholding: 10,000



### Kenth Petersson

Bachelor of Arts. Born 1956. Lives in Stockholm, Sweden. Member of the Board since 1997. Member of the Audit Committee.

Other board appointments: Chairman of the Boards of AlphaBeta AB, Biocrine AB, Diabetes Tools AB, Spiber Technologies AB and Science Pacific AB. Member of the Board of Alligator Bioscience AB.

Shareholding: 80,000

#### Auditors

Ernst & Young AB

Auditor in charge: Johan Thureson, Authorised Public Accountant. Born 1964. Lives in Höllviken, Sweden. Auditor for BioInvent International AB since 2008.

## Senior management



### Svein Mathisen

#### President and CEO

Master of Science, Engineering Physics. Born 1956. Lives in Malmö, Sweden. President and CEO since 1997. Previously held senior positions within the Norsk Hydro Group. Member of the Board since 2001.

Chairman of the Board of Biotech Pharmacon ASA and member of the Board of SwedenBIO.

Shareholding: 1,050,000  
Employee options: 21,000



### Björn Frendéus

#### Vice President, Preclinical Research

Björn is a Doctor of Immunology. Born 1973. Lives in Landskrona, Sweden. Employed since 2001. Graduated as the nation's first student from the Swedish Foundation for Strategic Research funded Biomedicine programs within the Infection & Vaccinology programme in 2001.

Shareholding: 740 (own and affiliated holdings)  
Employee options: 41,250



### Cristina Glad

#### Executive Vice President

Doctor of Science, Biochemistry, MBA. Born 1952. Lives in Malmö, Sweden. Employed in 1987 by the former subsidiary Bioinvent Production AB. Member of the Royal Swedish Academy of Engineering Sciences. Member of the Boards of Ideonfonden AB and Lunds University, Faculty of Medicine.

Shareholding: 1,043,301  
Employee options: 21,000



### Steven Glazer

#### Senior Vice President, Development

Doctor of Medicine. Born 1948. Lives in Copenhagen, Denmark. Employed since 2004. 2001-2004 Medical Director and Director of Development at Maxygen A/S, Denmark. Previously employed at NovoNordisk A/S etc.

Shareholding: -  
Employee options: 43,500



### Per-Anders Johansson

#### Vice President, Quality Assurance and Regulatory Affairs

Master of Science, Chemistry. Born 1955. Lives in Lund, Sweden. Employed in 1984 by the former subsidiary Bioinvent Production AB.

Shareholding: 250,000  
Employee options: 21,000



### Martin Wiles

#### Senior Vice President, Business Development

Ph. D. Chemistry, MBA. Born 1963. Lives in London, Great Britain. Employed since 2003. 1999-2003 Head of Business Development at KS Biomedix Holdings Plc, listed on the London Stock Exchange.

Shareholding: -  
Employee options: 43,500

# Glossary

**Administer drugs** To give drugs to patients, e.g. by injection.

**Angiogenesis** Formation of new blood vessels.

**Antigen** A substance that is foreign to the body and that can stimulate the immune system.

**Anticoagulants** Drugs that reduce the blood's ability to coagulate that are used, for example, to prevent blood clots from forming.

**Antibody** Reaction product in the body induced by antigens. Antibodies are proteins from the group collectively called immunoglobulins and can now be produced in laboratories.

**Atherosclerosis** Condition where deposits of fats and minerals form on the walls of large blood vessels.

**Biological drugs** Drugs, e.g. antibodies, with varying biological origins, including vaccines, blood products, cells, gene therapy, tissue and recombinant proteins. Recombinant proteins are produced from living cells.

**Blockbuster** A drug with sales of at least USD 1 billion a year.

**Cell line** Cultured cells with the same genetic origin.

**Clinical trials** Studies carried out on humans to test the effect and safety of future drugs.

**DNA** Deoxyribonucleic acid. The chemical material in a cell that contains the genetic code; genetic make-up.

**Drug candidate/product candidate** A substance with the potential to be developed into a drug.

**Embolism** When part of a blood clot breaks loose and is transported by the blood flow through the heart and elsewhere in the body, e.g. to the lungs.

**Endothelial cells** Cells that line the inside of blood vessels.

**Enzyme** A substance that triggers and stimulates chemical reactions in living organisms.

**Fermentor** A reactor where microorganisms are cultivated.

**Genetic make-up** All of the genetic material in a cell or an individual.

**Genome** See above.

**GMP** Good Manufacturing Practice. A set of instructions for manufacturing pharmaceuticals and ensuring their quality and safety.

**Heparin** Drug that impedes the coagulation of the blood.

**Homologous** Here, proteins with similar functions.

**Human antibodies** Antibodies that are perceived by the immune system as human.

**Immunology** Study of the origins and consequences of immune responses (i.e. antibody and cell responses).

**Inflammation** Reactive condition of tissue -following damage to the tissue or infection.

**Inhibitory** Inhibits a physiological process.

**In vitro** Within a test tube or another artificial environment -(opposite of in vivo).

**In vivo** "Within the living body." In biomedicine, something that is done to a living organism. In everyday speech, synonymous with experiments on animals.

**LDL** Transport molecule for blood lipids Commonly known as "the bad cholesterol."

**Lipids** Collective term for naturally occurring organic compositions that are not soluble in water, e.g. steroids, prostaglandins, fats and wax.

**Lipoprotein** Chemical compounds of proteins that transport lipids in the blood. They can be divided, for example into HDL and LDL.

**Lymphoma** Disease involving a tumor in the lymphoid tissue.

**Macula** degeneration/oedema Breakdown or accumulation of fluid in macula, i.e. "yellow spots" in the retina.

**Mediate** To bridge or transfer.

**Metabolism** All of the biochemical reactions that take place in living organisms.

**Milestone payment** Payment when targets are reached in a drug development project; often linked to the successful implementation of phases in clinical development.

**OxLDL** Oxidized LDL. A substance that can contribute to blood clots or infarction; a target protein for the development of a treatment for atherosclerosis.

**Pathological** Diseased, abnormal, changed by disease.

**Phage** Virus that can infect bacteria.

**Phage display** Technology for expressing molecules, e.g. -antibodies, on the surface of phages.

**Pharmaceutical** Referring to drugs or their preparation.

**Pharmacokinetic** How a drug is absorbed, distributed, broken down and excreted from the body.

**Pharmacy** The science of preparing and making drugs.

**PIGF** Growth factor that is secreted by tumor cells; target protein for one of BioInvent's anti-angiogenesis projects.

**Plaque** Deposits of substances/materials, for example on vessel walls.

**Pre-clinical development** Testing and documentation of a drug candidate's properties in a model system.

**Protein** The most important components in all organisms. There are many thousands of different proteins.

**Pulmonary hypertension** Elevated blood pressure in the pulmonary circulation.

**Receptor** Here, molecules on the surface of or inside cells that have the task of receiving and transferring signals.

**Resistance** The ability of e.g. tumor cells to avoid treatment that was originally effective. Resistance is developed when genes change and vary and the inhibitor therapy favours the variations that survive and multiply.

**Retinopathy** Medical term for a disease of the retina.

**Royalty** Payment linked to the sale of a drug; often a percentage of sales.

**Screening** Searching and final selection of the antibody fragments that bind the best to a given antigen.

**Selection** Selection of a number of possible antibody fragments that bind to a given antibody.

**Specificity** The ability of antibodies to recognise the 'right' -antigen and ignore all others.

**Statins** A group of antibodies that reduce the level of cholesterol in the blood.

**Stroke** Blood clot in the brain.

**Safety study** Study of side effects in animal models to ensure that a product is safe enough to begin clinical trials.

**Target protein** The proteins in the body upon which a drug can have an effect. An antigen can be a target protein upon which antibodies can have a therapeutic effect.

**Therapeutic antibody** Antibody that is used for the treatment of a disease; antibody-based drug.

**Therapy** Treatment; here in general with drugs.

**Thrombosis** Formation of a blood clot.

**Toxicology** Scientific study of poisons and their effects.

**Toxin, toxic** Toxic substance, with toxic effect.

**Vaccine** A medicine that is used in immunisation (vaccination) to produce protection against a disease that is often caused by an infection.

**Validation** Assessment of an antibody or target structure to -discover if they have the desired effect or characteristics.

**Vascular** That belongs to or has a connection with an organism's vascular system.

**Vascular leakage** Pathological condition characterised by leakage of cells and fluid from vessels.

**VEGF inhibitor** Substance that inhibits angiogenesis, where this is caused by the growth factor VEGF.

### **Annual General Meeting**

The Annual General Meeting will be held on Tuesday 20 April 2010 at 4 p.m., at Ideon, Lund. Notice to attend will be announced in the Swedish press in Post- och Inrikes Tidningar, Sydsvenska Dagbladet and Dagens Industri, and will be posted on the Company's website.

Shareholders wishing to attend the AGM must be registered in the shareholders' register kept by Euroclear Sweden AB ("Euroclear") no later than Wednesday 14 April 2010 and must inform BioInvent of their intention to attend no later than 4 p.m. on 14 April 2010 by sending a letter to: BioInvent International AB, SE-223 70 Lund, attn: Marie Serwe, or by fax to +46 (0)46-211 08 06, or by phone +46 (0)46-286 85 50, or by e-mail to [marie.serwe@bioinvent.com](mailto:marie.serwe@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 14 April 2010 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.

### **Financial calender**

BioInvent will present the following financial reports:

Interim reports: 15 April, 14 July, 14 October 2010

Financial statement 2010: 10 February 2011

### **Investor Relations**

Svein Mathisen, President and CEO,

+46 (0)46-286 85 50, mobile: +46 (0)708-97 82 13

BioInvent's financial reports are also available at [www.bioinvent.com](http://www.bioinvent.com)

### **Legal disclaimer**

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 by their very nature, in the same way as research and development work in the biotech segment, are associated with risk and uncertainty. With this in mind, the actual outcome may deviate significantly from the scenarios described in this annual report.

BioInvent International AB (publ.)  
Corp. ID 556537-7263  
Address: Sölvegatan 41  
Mailing address: SE-223 70 Lund  
Tel: +46 (0)46-286 85 50  
[info@bioinvent.com](mailto:info@bioinvent.com)  
[www.bioinvent.com](http://www.bioinvent.com)

