

## **BioInvent Interim Report**

1 January - 31 March 2010

A directed new share issue that raised SEK 150 million for the company before transaction costs was implemented in February.
In March BioInvent entered into a product partnership with Human Genome Sciences to develop and commercialise therapeutic antibodies.
A phase I study of the BI-505 product candidate for the treatment of multiple myeloma was launched at the beginning of the year.
Net revenues for January - March 2010: SEK 15.1 million (36,8 including BioInvent's share, SEK 21.7 million, of the first milestone payment for TB-403).
Current investments together with cash and bank as of 31 March 2010: SEK 179.1 million (192.3).
Cash flow from current operations and investment activities for January – March 2010: SEK -49.3 million (-20.1).
Loss after tax for January - March 2010 amounted to SEK -37.9 million (-34.7) and the profit after tax per share was SEK -0.65 (-0.62).

BioInvent 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.

## Comments by the CEO

The new share issue carried out in February has put us in a stronger position to be able to further develop our project portfolio and exploit the commercial opportunities that our portfolio and our technology platform represent.

Our agreement with Human Genome Sciences demonstrates our goal of broadening our product portfolio to include new drug candidates. This partnership will initially focus on inflammatory diseases and is an example of how collaboration can pave the way for broadening our participation in a number of innovative new drug concepts. As we establish strong alliances with other companies, we are also continuing to forge ties with academic teams with projects and technology that can result in new drug projects. Within the framework for these types of partnerships we have recently started projects based on interesting mechanisms within cancer and diabetes.

Now that BI-505 has entered into the clinical development phase, we have four clinical projects. Both the product concept itself and our in-house developed screening technology that led to the discovery of the product candidate have attracted a lot of interest recently.

We ended last year by stepping up efforts to develop our own drug portfolio. This year we intend to take additional steps with a view to strengthening the portfolio and the company's profile as a strong organisation in the development of antibody-based drugs. These ambitions combined with the fact that we expect to reach milestones in the form of reporting clinical results and starting new phase II studies makes me optimistic about 2010.

## **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 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 current 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 halflife 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, PIGF. TB-403 binds PIGF 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 PIGF 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. PIGF is not required for survival of normal resting vasculature and blocking PIGF is expected to be relatively safe, because mice lacking PIGF are healthy and reproduce normally. Preclinical research has also shown that inhibition of PIGF 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.

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 immuno-effector 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 undesirable vessel growth and thus the blood supply to tumours, as well as at programmed cell death inducing antibodies that kill tumour cells. BioInvent has together with a leading academic group launched a project focusing on new drug concepts based on the role of cancer-associated fibroblasts in tumour development.

The company's inflammation research is being enhanced by a partnership entered into in March with the US company Human Genome Sciences. Under this partnership the companies will work together to develop and commercialise antibody-based drugs based on target proteins from Human Genome Sciences' research and BioInvent's antibody technology.

BioInvent has initiated a new project in cooperation with a leading academic group for the treatment of type I diabetes.

The company is also conducting research and development on antibody-based drugs on behalf of other external partners. Such partners includes Bayer HealthCare, Daiichi Sankyo and Mitsubishi Tanabe. 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.

#### Revenues and result

Net revenues for the January – March period amounted to SEK 15.1 million (36.8). Revenues for the January – March 2010 period mainly come from partnerships where antibody-based drugs are developed using the n-CoDeR antibody library. BioInvent's share, SEK 21.7 million, of the first milestone payment for TB-403 is included in reported net revenues for 2009.

The Company's total costs for the January – March period amounted to SEK 52.7 million (72.5). Operating costs are divided between external costs of SEK 28.0 million (48.0), personnel costs of SEK 22.2 million (21.6) and depreciation of SEK 2.5 million (2.9).

Research and development costs for January – March amounted to SEK 44.4 million (63.8). Depreciation according to plan reduced the operating result for the period by SEK 2.5 million (2.9), of which depreciation of intangible fixed assets amounts to SEK 1.3 million (1.5).

The loss after tax for January – March amounted to SEK -37.9 million (-34.7).. The net financial items, January – March, amounted to SEK -0.5 million (1.6). Earnings per share after tax, January – March, amounted to SEK -0.65 (-0.62).

## Financial position and cash flow

As of 31 March 2010, the Group's current investments together with cash and bank amounted to SEK 179.1 million (192.3). The cash flow from current operations and investment activities for January – March amounted to SEK -49.3 million (-20.1). Cash flow was reduced by normal fluctuations in working capital.

In February BioInvent implemented a directed new share issue totalling 5,434,800 shares that raised SEK 150 million for the company before transactions costs. The subscription price was set at SEK 27.60 per share.

The shareholders' equity amounted to SEK 162.6 million (196.8) at the end of the period. The Company's share capital was SEK 30.5 million. The equity/assets ratio at the end of the period was 73.5 (75.6) per cent. Shareholders' equity per share amounted to SEK 2.66 (3.54). The Group had no interest-bearing liabilities.

#### Investments

Investments in tangible fixed assets amounted to SEK 0.9 million (0.0). No investments were made in intangible assets during the period (-).

## **Organisation**

As of 31 March 2010, BioInvent had 104 (108) employees. 88 (92) of these work in research and development.

### **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.

### Risk factors

The Company's operations are associated with risks related to factors such as drug development, competition, collaboration with partners, technology development, patents, capital requirements, currency and interest rates. The aforementioned risks summarize the factors of significance for BioInvent and thus an investment in the BioInvent share.

## **Accounting principles**

This interim report was prepared in accordance with IAS 34, Interim Financial Reporting, the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2.3, Accounting for Legal Entities. The accounting principles applied are consistent with those used in the preparation of the most recent Annual Report. The updates and changes adopted by the EU and applied from 1 January 2010 and that will affect the financial reporting are the following: IFRS 3R Business Combinations and IAS 27R Consolidated and Separate Financial Statements. Their effect on the financial reporting is described in the 2009 Annual Report. The following new standards and amendments have not at this time had any effect on BioInvent's financial reporting: IFRIC 12 Service Concession Arrangements, IFRIC 15 Agreements for the Construction of Real Estate, IFRIC 16 Hedges of a Net Investment in a Foreign Operation, IFRIC 17 Distribution of Non-Cash Assets to Owners and IFRIC 18 Transfers of Assets from Customers. These statements will be applied to the extent BioInvent International executes the transactions in question.

## **Upcoming financial reports**

BioInvent will present the following financial reports:

Interim reports 14 July, 14 October 2010

Financial statement for 2010 10 February 2011

### Contact

Any questions regarding this report will be answered by:

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The report is also available at www.bioinvent.com

Consolidated statement of comprehensive income in brief for the Group (SEK thousands)

3 MONTHS	3 MONTHS	12 MONTHS
2010	2009	2009
JanMarch	JanMarch	JanDec.
15,101	36,849	80,659
44.440	00.774	000 407
,	,	-229,187
- ,	-, -	-35,466
		<u>4,492</u> -260,161
-52,516	-73,109	-200,101
-37.415	-36.340	-179,502
,	,	,
-519	1,615	2,841
27.024	24 725	476 664
-37,934	-34,725	-176,661
-	-	-
-37,934	-34,725	-176,661
-28	-56	-211
-37,962	-34,781	-176,872
-37 062	-3/1 701	-176,872
-31,302	-34,701	-170,072
-0.65	-0.62	-3.17
-0.65	-0.62	-3.17
	2010 JanMarch  15,101  -44,448 -8,217 149 -52,516  -37,415 -519 -37,934  -28 -37,962 -37,962 -0.65	2010 JanMarch         2009 JanMarch           15,101         36,849           -44,448 -63,771 -8,726 -8,217 -8,726 -73,189         -692 -73,189           -52,516 -73,189         -37,415 -36,340           -519 1,615         -37,934 -34,725          37,934 -34,725         -34,725           -28 -56         -37,962 -34,781           -37,962 -34,781         -0.65 -0.62

# Consolidated statement of financial position in brief for the Group (SEK thousands)

•	2010	2009	2009
	31 March	31 March	31 Dec.
Assets			
Fixed assets			
Intangible fixed assets	5,749	10,843	7,022
Tangible fixed assets	11,569	15,041	11,969
Current assets			
Inventories etc.	1,157	2,454	2,037
Current receivables	23,782	39,698	21,198
Current investments	149,804	168,411	55,958
Cash and bank	29,310	23,928	28,062
Total assets	221,371	260,375	126,246
Shareholders' equity and liabilities			
Shareholders' equity	162,615	196,791	55,633
Current liabilities	58,756	63,584	70,613
Total shareholders' equity and liabilities	221,371	260,375	126,246

## Statement of changes in equity for the Group (SEK thousands)

	2010	2009	2009
	JanMarch	JanMarch	JanDec.
Opening balance	55,633	231,298	231,298
Effect of employee incentive program Directed new share issue	566 144.378	274	1,207
Comprehensive income	-37,962	-34,781	-176,872
Closing balance	162,615	196,791	55,633
Shareholders' equity pertaining to the			
parent company's shareholders	162,615	196,791	55,633

The share capital as of 31 March 2010 consists of 61,095,689 shares and the share's ratio value is 0.5. The directed new share issue carried out in February 2010 raised SEK 144,378 thousands after issue expenses, which amounted to SEK 5,622 thousands.

Consolidated statement of cash flows in brief for the Group (SEK thousands)

,	2010	2009	2009
	JanMarch	JanMarch	JanDec.
Current operations			
Operating profit/loss	-37,415	-36,340	-179,502
Depreciation	2,540	2,945	11,117
Adjustment for other non-cash items	566	274	1,207
Interest received and paid	30	2,862	4,723
Cash flow from current operations			
before changes in working capital	-34,279	-30,259	-162,455
Changes in working capital	<u>-14,137</u>	10,156	35,312
Cash flow from current operations	-48,416	-20,103	-127,143
Investment activities			
Acquisition of tangible fixed assets	<u>-868</u>	<u>-18</u> <b>-18</b>	<u>-1,297</u>
Cash flow from investment activities	-868	-18	<u>-1,297</u> <b>-1,297</b>
Cash flow from current operations and investment activities	-49,284	-20,121	-128,440
Financing activities			
Directed new share issue	<u>144,378</u>	=	_
Cash flow from financing activities	144,378	-	-
Changes in current investments**	-104,839	42,709	151,196
Change in liquid funds	-9,745	22,588	22,756
Opening liquid funds	74,036	51,280	51,280
Liquid funds at end of period	64,291	73,868	74,036
Liquid funds, specification:			
Current investments that constitute liquid funds*	34,981	49,940	45,974
Cash and bank	29,310	23,928	28,062
	64,291	73,868	74,036
Current investments**	114,823	118,471	9,984
	179,114	192,339	84,020
*Duration less than 3 months			

**Key financial ratios for the Group** 

	2010	2009	2009
	31 March	31 March	31 Dec.
Shareholders' equity per share at end of period, SEK Number of shares at end of period	2.66	3.54	1.00
	61,096	55,661	55,661
Equity/assets ratio, % Number of employees at end of period	73.5	75.6	44.1
	104	108	105

Consolidated income statement in brief for the Parent Company (SEK thousands)

	3 MONTHS 2010	3 MONTHS 2009	12 MONTHS 2009
	JanMarch	JanMarch	JanDec.
Net revenues	15,101	36,849	80,659
Operating costs			
Research and development costs	-43,973	-63,553	-228,207
Sales and administrative costs	-8,126	-8,670	-35,239
Other operating revenues and costs	<u>149</u>	<u>-692</u>	4,492
	-51,950	-72,915	-258,954
Operating profit/loss	-36,849	-36,066	-178,295
Profit/loss from financial investments	-519	1,615	2,841
Profit/loss after financial items	-37,368	-34,451	-175,454
Тах	-	-	-
Profit/loss	-37,368	-34,451	-175,454

<sup>\*</sup>Duration less than 3 months
\*\*Duration more than 3 months

# Consolidated balance sheet in brief for the Parent Company (SEK thousands)

	2010 31 March	2009 31 March	2009 31 Dec.
Assets			
Fixed assets			
Intangible fixed assets	5,749	10,843	7,022
Tangible fixed assets	11,569	15,041	11,969
Financial fixed assets	100	100	100
Current assets			
Inventories etc.	1,157	2,454	2,037
Current receivables	23,782	39,698	21,198
Current investments	149,847	168,271	55,973
Cash and bank	29,310	23,928	28,062
Total assets	221,514	260,335	126,361
Shareholders' equity and liabilities			
Shareholders' equity	162,671	196.664	55.661
Current liabilities	58,843	63,671	70,700
Total shareholders' equity and liabilities	221,514	260,335	126,361

Lund, 15 April 2010

Svein Mathisen, President and CEO

#### Review report

#### Introduction

We have reviewed the summarised interim financial information for BioInvent International AB (publ) for the period 1 January 2010 – 31 March 2010. The board of directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

#### Scope of review

We conducted our review in accordance with the Standard on Review Engagements SÖG 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with the Standards on Auditing in Sweden RS and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

#### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the group's part according to IAS 34 and the Annual Accounts Act and for the parent company's part according to the Annual Accounts Act.

Lund, 15 April 2010 ERNST & YOUNG AB

Johan Thuresson Authorised Public Accountant

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## Legal disclaimer

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

Information disclosed in this press release is provided herein pursuant to the Swedish Securities Markets Act and/or the Swedish Financial Instruments Trading Act. The information was submitted for publication at 8.30 a.m. CET, on 15 April, 2010.