

BioInvent Interim Report

1 January - 31 March 2009

A phase II study with the product candidate TB-402, for the prevention of blood clots, in patients who have received an artificial knee joint, was started in February.
Technology transfer under the terms of the alliance with Roche has triggered a success fee of EUR 5 million to BioInvent and ThromboGenics.
Product candidate BI-505, for treatment of cancer, has been granted orphan drug designation in Europe for the indication multiple myeloma. Equivalent status was previously granted in the US.
Net revenues for January - March 2009: SEK 36.8 million (16.2).
Current investments together with cash and bank as of 31 March 2009: SEK 192.3 million (157.7).
Cash flow from current operations and investment activities for January – March 2009: SEK -20.1 million (-59.2).
Profit after tax for January - March 2009 amounted to SEK -34.7 million (-39,9) and the profit after tax per share was SEK -0.62 (-0.72).

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

This year has started out well with two important events reported. The progress in our collaboration with Roche on product candidate TB-403 was confirmed by the first success-based milestone payment in January. In February the phase II program was initiated with TB-402 for the prevention of blood clots. The study, which includes 300 patients who have had knee replacement surgery, will compare the effect of TB-402 with current standard treatment. TB-402 is administered once in conjunction with the surgical procedure, in contrast with current therapy, which requires daily dosing for several weeks with extensive patient monitoring. TB-402 is expected to have a favourable safety profile.

Results from the phase I programme with BI-204, for the treatment of atherosclerosis, is expected to be reported during the current quarter. We expect that after the report we will be able to take the decision together with our partner Genentech to initiate phase II trials.

Compilation of the application to begin clinical trials for BI-505 in the United States is in ongoing. During the first quarter of 2009 parts of our research findings were presented at two scientific conferences. With the great interest that the project has attracted and after receiving orphan drug designation for the first indication, multiple myeloma, in Europe and the United States, we look forward with great enthusiasm to the upcoming clinical trial.

Overall, the clinical platform that we created provides excellent prospects for building added value in the project portfolio and we look forward to a year with many important milestones.

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 350,000 individuals are affected by DVT or pulmonary embolism (PE) each year. It is estimated that by 2015, 1.4 million patients will undergo knee replacement and 600,000 patients will undergo hip replacement in the U.S. if current trends persist. 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 able to be developed into a safe and well-controlled treatment for several medical conditions in which thrombosis prevention is of great importance.

In February 2009 a phase II trial was initiated to prevent deep vein thromboses (DVT) in patients who undergo knee replacement surgery. 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 will assess three different doses of TB-402 given as a single intravenous bolus injection post knee replacement surgery. The trial will enrol 300 patients across 36 centers mainly in Central Europe. The primary endpoint is 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 secondary prevention of cardiac events, such as heart attack or stroke, in high-risk patients. 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, Inc.

All subjects in the Phase I programme have been enrolled and the monitoring is completed. The study is expected to be reported during the second quarter 2009. The Phase I 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. In addition to monitoring the tolerability

and safety of BI-204, the study evaluated pharmacokinetic and pharmacodynamic parameters in order to help set the dosage of BI-204 administered to patients in future Phase II trials.

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 that may enable escape from therapy. This angiogenic rescue phenomenon has been demonstrated with some angiogenesis inhibitors.

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. The follow-up study, a second Phase I trial, is a study of tolerability, pharmacokinetics and pharmacodynamics in patients with advanced cancer, and was started in June 2008. Up to 30 patients will be enrolled in this multi-dose study.

Agreement with Roche

In June 2008 BioInvent and partner ThromboGenics entered into a strategic license agreement with Roche for development and commercialisation of TB-403. Roche paid BioInvent and ThromboGenics an upfront payment of EUR 50 million in July 2008. In addition, BioInvent and ThromboGenics could potentially receive up to EUR 450 million over the term of the collaboration based on the successful completion of a series of development and commercial milestones, as well as double digit royalties on potential product sales, including any backup antibodies based on inhibition of PIGF. ThromboGenics, which discovered TB-403, will receive 60% and BioInvent 40% of the revenue from the deal.

Roche has a worldwide, exclusive license to develop and commercialise TB-403. BioInvent and ThromboGenics will retain co-promotion rights for the product in the Nordic, Baltic and Benelux regions. Roche will assume responsibility for all future development costs.

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

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 in these markets for 10 years after marketing approval is obtained.

BioInvent intends to initiate clinical development of BI-505 in the United States. As part of preparations to submit an application to start clinical trials in the United States, in early February 2009 the company met with the US Food and Drug Administration.

Based on received feedback, we expect to be able to start the clinical program at the turn of the half-year 2009.

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 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. One such partner is Bayer HealthCare, the agreement allows for up to 14 antibody products to be developed. 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 36.8 million (16.2). 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.

The Company's total costs for the January – March period amounted to SEK 72.5 million (58.0). Operating costs are divided between external costs of SEK 48.0 million (37.0), personnel costs of SEK 21.6 million (18.4) and depreciation of SEK 2.9 million (2.6). Costs for preclinical and clinical trials, SEK 25 million, comprise the largest share of external costs. External costs have been reduced with research funding of SEK 5 million from development partners to cover their share of BioInvent's internal development costs.

Research and development costs for January – March amounted to SEK 63.8 million (51.1). Depreciation according to plan reduced the operating result for the period by SEK 2.9 million (2.6), of which depreciation of intangible fixed assets amounts to SEK 1.5 million (1.4).

The profit after tax for January – March amounted to SEK -34.7 million (-39.9). The net financial items, January – March, amounted to SEK 1.6 million (1.8). Earnings per share after tax, January – March, amounted to SEK -0.62 (-0.72).

Financial position and cash flow

As of 31 March 2009, the Group's current investments together with cash and bank amounted to SEK 192.3 million (157.7). The cash flow from current operations and investment activities for January – March amounted to SEK -20.1 million (-59.2). Capital tied up in short-term receivables (mainly accounts receivable) received during the quarter has had a positive effect on cash flow.

The shareholders' equity amounted to SEK 196.8 million (174.1) 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 75.6 (79.2) per cent. Shareholders' equity per share amounted to SEK 3.54 SEK (3.13). The Group had no interest-bearing liabilities.

Investments

No significant investments were made in tangible fixed assets or intangible assets during the period.

Organisation

As of 31 March 2009, BioInvent had 108 (95) employees. 92 (81) 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 498,750 employee options took place during 2008. Extra allotment of 69,750 employee options took place during February 2009.

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

For the group's part this interim report is prepared according to IAS 34, Interim Financial Reporting, and the Annual Accounts Act and for the parent company's part according to the Annual Accounts Act and the Swedish Financial Reporting Board's Recommendation RFR 2.2, Accounting for legal entities. The accounting principles applied are consistent with those used when preparing the most recent Annual Report with the following exceptions due to new or revised standards, interpretations and improvements adopted by the EU and which came into force on 1 January 2009: IFRS 8 Operating segments, revised IAS 1 Presentation of financial statements, IAS 23 Borrowing costs, IAS 32 Financial instruments, amendment to IAS 27 changing the rules for recognition of dividend revenue from subsidiaries, associates, and jointly controlled entities, and IFRIC 13 Customer Loyalty Programmes. The only change that affects the Group and the parent company is revised IAS 1 Presentation of financial statements. This standard divides changes in shareholders' equity resulting from transactions with owners and other changes. Reporting of changes in equity will only include details relating to owner-related transactions. Non-owner changes in equity are presented on a separate line in changes in equity. In addition, the standard concept "Statement of comprehensive income" is being introduced, which shows all recognised income and expense items either in a single statement, or in two consecutive statements. The Group has chosen to present the Statement of comprehensive income in a single statement.

Upcoming financial reports

BioInvent will present the following financial reports:

Interim reports 15 July, 15 October 2009 Financial statement for 2009 17 February 2010

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
	2009	2008	2008
	Jan March	Jan March	JanDec.
Net revenues	36,849	16,184	252,138
Operating costs			
Research and development costs	-63,771	-51,096	-215,434
Sales and administrative costs	-8.726	-6,940	-30,882
Other operating revenues and costs	-692	171	749
	-73,189	-57,865	-245,567
Operating profit/loss	-36,340	-41,681	6,571
Profit/loss from financial investments	1,615	1,779	9,680
Profit/loss after financial items	-34,725	-39,902	16,251
Tax	-	-	-
Profit/loss	-34,725	-39,902	16,251
Other comprehensive income			
Changes in reserve, actual value	-56	-82	313
Comprehensive income	-34,781	-39,984	16,564
Profit/loss pertaining to the parent company's shareholders	-34,781	-39,984	16,564
Earnings per share, SEK			
Before dilution	-0.62	-0.72	0.29
After dilution	-0.62	*	0.29

^{*} At the end of the period there were no outstanding warrants or employee options.

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

•	2009	2008	2008
	31 March	31 March	31 Dec.
Assets			
Fixed assets			
Intangible fixed assets	10,843	11,100	12,384
Tangible fixed assets	15,041	14,567	16,427
Current assets			
Inventories etc.	2,454	3,881	2,304
Current receivables	39,698	32,608	51,852
Current investments	168,411	142,203	196,066
Cash and bank	23,928	15,481	16,394
Total assets	260,375	219,840	295,427
Shareholders' equity and liabilities			
Shareholders' equity	196,791	174,134	231,298
Current liabilities	63,584	45,706	64,129
Total shareholders' equity and liabilities	260,375	219,840	295,427

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

	2009 Jan March	2008 Jan March	2008 JanDec.
Opening balance	231,298	214,118	214,118
Effect of employee incentive program	274		616
Comprehensive income	-34,781	-39,984	16,564
Closing balance	196,791	174,134	231,298
Shareholders' equity pertaining to the			
parent company's shareholders	196,791	174,134	231,298

The share capital as of 31 March 2009 consists of 55,660,889 shares and the share's ratio value is 0.5.

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

	2009	2008	2008
	Jan March	Jan March	JanDec.
Current operations			
Operating profit/loss	-36,340	-41,681	6,571
Depreciation	2,945	2,629	11,543
Interest received and paid	2,862	2,564	9,361
Cash flow from current operations			
before changes in working capital	-30,533	-36,488	27,475
Changes in working capital	10,430	<u>-21,097</u>	-18,227
Cash flow from current operations	-20.103	- <u>57.585</u>	9.248
Cash now from current operations	-20,103	-57,565	9,240
Investment activities			
Acquisition of intangible fixed assets	_	-	-6,001
Acquisition of tangible fixed assets	-18	<u>-1,582</u>	-7,638
Cash flow from investment activities	<u>-18</u> - 18	-1,582	-13,639
		•	•
Cash flow from current operations and investment activities	-20,121	-59,167	-4,391
Financing activities	-	-	-
Changes in current investments**	42,709	12,162	-6,815
Change in liquid funds	22 500	47.005	44 200
Change in liquid funds	22,588	-47,005	-11,206
Opening liquid funds Liquid funds at end of period	51,280 73,868	<u>62,486</u> 15,481	62,486 51,280
Liquid runds at end of period	13,000	10,401	31,200
Liquid funds, specification:			
Current investments that constitute liquid			
funds*	49,940	_	34,886
Cash and bank	23,928	15,481	16,394
	73,868	15,481	51,280
Current investments**	118,471	142.203	161,180
	192,339	157,684	212,460

Key financial ratios for the Group

	2009	2008	2008
	31 March	31 March	31 Dec.
Shareholders' equity per share at end of period, SEK			
Before dilution	3.54	3.13	4.15
After dilution	3.54	*	4.15
Number of shares at end of period			
Before dilution (thousands)	55,661	55,661	55,661
After dilution (thousands)	55,661	*	55,661
Equity/assets ratio, %	75.6	79.2	78.3
Number of employees at end of period	108	95	103

^{*} At the end of the period there were no outstanding warrants or employee options.

^{*}Duration less than 3 months
**Duration more than 3 months

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

	3 MONTHS 2009 Jan March	3 MONTHS 2008 Jan March	12 MONTHS 2008 JanDec.
Net revenues	36,849	16,184	252,138
Operating costs			
Research and development costs	-63,553	-51,096	-214,933
Sales and administrative costs Other operating revenues and costs	-8,670 -692	-6,940 171	-30,767 749
Other operating revenues and costs	- -092 -72,915	-57,865	-244,951
Operating profit/loss	-36,066	-41,681	7,187
Profit/loss from financial investments	1,615	1,779	9,680
Profit/loss after financial items	-34,451	-39,902	16,867
Tax	-	-	-
Profit/loss	-34,451	-39,902	16,867

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

	2009	2008	2008
	31 mars	31 mars	31 dec
Assets			
Fixed assets			
Intangible fixed assets	10,843	11,100	12,384
Tangible fixed assets	15,041	14,567	16,427
Financial fixed assets	100	100	100
Current assets			
Inventories etc.	2,454	3,881	2,304
Current receivables	39,698	32,608	51,852
Current investments	168,271	142,402	195,870
Cash and bank	23,928	15,481	16,394
Total assets	260,335	220,139	295,331
Shareholders' equity and liabilities			
Shareholders' equity	196,664	174,346	231,115
Current liabilities	63,671	45,793	64,216
Total shareholders' equity and liabilities	260,335	220,139	295,331

Lund, 16 April 2009

Svein Mathisen, President and CEO

Review report

We have reviewed this interim report for the period 1 January 2009 – 31 March 2009. 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, 16 April 2009 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 16 April, 2009.