



BioInvent Interim Report

1 January – 30 September 2008

- ❑ A phase II study with the product candidate TB-402, for the prevention of blood clots, is under preparation to be conducted in several European countries. The first application to start the study, in patients who have received an artificial knee joint, has been submitted.
- ❑ Product candidate BI-505, for treatment of cancer, obtained orphan drug designation in the US for the indication multiple myeloma.
- ❑ BioInvent and ThromboGenics entered in June into a strategic license agreement with Roche for development and commercialisation of TB-403. BioInvent and ThromboGenics received in July an upfront payment of EUR 50 million. In addition, BioInvent and ThromboGenics could potentially receive up to EUR 450 million in milestone payments, as well as double digit royalties on potential product sales.
- ❑ The first Phase I study with TB-403, for treatment of cancer, was successfully completed in June and showed that TB-403 was safe and well tolerated. The study was conducted in healthy volunteers.
- ❑ The follow-up study, the second Phase I trial with TB-403, is a multi-dose study in patients with advanced cancer was started in June.
- ❑ The Phase I programme with product candidate BI-204 for treatment of atherosclerosis proceeds as planned. All subjects in the study are expected to be enrolled during the fourth quarter 2008.
- ❑ Entered into an agreement in March with Bayer HealthCare for research and development of antibody-based drugs.
- ❑ Net revenues for January - September 2008: SEK 229.0 million (140.0).
- ❑ Current investments together with cash and bank as of 30 September 2008: SEK 252.7 million (230.3).
- ❑ Cash flow from current operations and investment activities for January - September 2008: SEK 35.9 million (22.2).
- ❑ Profit after tax for January - September 2008 amounted to SEK 61.6 million (21.9) and the profit after tax per share was SEK 1.11 (0.44).

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

With the turbulence in today's financial markets it is gratifying to report that our projects are making good progress and meeting the objectives set in the individual project plans. Our clinical development portfolio is maturing with several projects advancing to phase II studies. First in line is TB-402, our thrombosis project for which a study including patients undergoing knee surgery is expected to begin toward the end of the year. The study is planned to be carried out in several European countries.

We expect to complete recruitment of individuals to the phase I study with BI-204 for the treatment of atherosclerosis during the fourth quarter. Together with our collaborator Genentech, we are currently working hard to prepare the upcoming phase II programme. We can also be pleased with the progress of the cancer drug TB-403, where a phase Ib study for patients with severe forms of cancer is making progress. The technology transfer to our new partner Roche has gone well and we expect the clinical programme to expand with studies for several cancer indications.

Our most recent product candidate, BI-505, was recently recognized by the US Food and Drug Administration which granted it orphan drug designation. This status provides stronger protection in the form of market exclusivity for 10 years after marketing approval is obtained. The product candidate will initially be developed for the treatment of patients with multiple myeloma, a severe form of hematologic cancer, for which there is a great need for new medications that can replace or complement existing drugs. Orphan drug designation for this indication also means an opportunity for regulatory assistance, which may facilitate development of the medication.

In summary, we are well on the way to meeting the expectations I announced last spring in the 2007 annual report, with the goal of having all four development projects reach clinical phase early next year, at the same time that we are ready to take several of them into the next phase of the clinical development process.

Financially, over the past two years we have been able to report revenues from major partnerships that more than well balance our own cost and investment undertakings. Both last year and so far this year we have been able to report a positive cash flow from operations. With our existing cash, revenue opportunities from existing agreements and the potential for new agreements relating to our projects and technology, we are meeting the current challenges of the financial markets from a position of strength.

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 an overdose resulting in undesirable bleedings. Extensive testing in several animal models has shown that TB-402 strongly reduces the risk of thrombosis without increasing the risk of bleeding. The project is carried out within the alliance with ThromboGenics NV.

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 Factor VIII 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 potential to be developed as a safe and well controlled treatment for several diseases where prevention of blood clots are of great importance. To further evaluate safety of the drug and ability to prevent deep vein thrombosis, a phase II study is under preparation in patients who have received an artificial knee joint. The study is planned to be conducted in several European countries. The first application to start the study has been submitted.

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. BI-204 is developed in collaboration with Genentech, Inc.

In January 2008 BioInvent and its collaborator Genentech initiated a Phase I study in Denmark. The Phase I study is 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 are planned to be included in the trial. In addition to monitoring the tolerability and safety of BI-204, the study will evaluate pharmacokinetic and pharmacodynamic parameters in order to help set the dosage of BI-204 administered to patients in future Phase II trials.

All subjects in the Phase I study are expected to be enrolled during the fourth quarter 2008.

Cancer (TB-403)

The product candidate TB-403, 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 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 was started in June. Up to 30 patients will be enrolled in this multi-dose study.

Agreement with Roche

In June 2008 BioInvent and the 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. 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. Until transfer of manufacturing to Roche, BioInvent will supply clinical material, funded by Roche. In addition, Roche will also provide funding to BioInvent and ThromboGenics for research on non-cancer indications. BioInvent and ThromboGenics in conjunction with Roche will form a Joint Steering Committee to oversee research and development activities.

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.

BiolInvent'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 was granted orphan drug designation in the United States for the indication of multiple myeloma. This status gives BI-505 market exclusivity for treatment of multiple myeloma with an antibody against ICAM-1 in the US market for 10 years after marketing approval is obtained.

BI-505 is in the preclinical development phase, the stage preceding clinical trials.

Research projects

BiolInvent 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.

To strengthen the company's research activities in angiogenesis, BiolInvent has in April acquired intellectual property from the research company AngioGenetics AB, located at Karolinska Institutet (KI). In connection with the takeover BiolInvent set up a branch at KI to strengthen and expand collaboration with research groups at KI.

A deal with Bayer HealthCare was signed in March related to the discovery and development of antibody products. The agreement allows for up to 14 antibody products to be developed. As well as undisclosed license fees and research funding, BiolInvent will receive milestone payments and royalties on sales of any products commercialized.

Revenues and result

Net revenues for the January – September period amounted to SEK 229.0 million (140.0). BiolInvent's share of the initial installment from Roche for TB-403, SEK 187.6 million (40% of SEK 469 million) is included in its entirety in reported net revenues. The first installment from Genentech of SEK 105.5 million for BI-204 was received in January 2007 and is included in its entirety in net revenues for the first quarter of previous year. Net revenues for the July – September period amounted to SEK 17.2 million (9.8).

The Company's total costs for the January – September period amounted to SEK 173.7 million (124.4). Operating costs are divided between external costs of SEK 108.8 million (61.4), personnel costs of SEK 56.5 million (53.7) and depreciation of SEK 8.4 million (9.3). External costs relate mainly to toxicology studies, clinical studies, commissioned research and milestone payments. About one third of the increase in external costs is attributable to milestone payments in the BI-204 project and the acquisition of intangible rights recognized as expenses during the first half of the year.

Research and development costs for January – September amounted to SEK 150.6 million (103.0). Depreciation according to plan reduced the operating result for the period by SEK 8.4 million (9.3), of which depreciation of intangible fixed assets amounts to SEK 4.5 million (4.9).

The profit after tax for January – September amounted to SEK 61.6 million (21.9). The loss after tax for July - September amounted to SEK -32.1 million (-18.6). The net financial items, January – September, amounted to SEK 6.2 million (4.5). Earnings per share after tax, January – September, amounted to SEK 1.11 (0.44).

Financial position and cash flow

As of 30 September 2008, the Group's current investments together with cash and bank amounted to SEK 252.7 million (230.3). The cash flow from current operations and investment activities for January – September amounted to SEK 35.9 million (22.2). Compared with the corresponding period last year, operating profit was higher, which had a positive impact on cash flow, offset in part by the negative effect of the normal fluctuations in working capital and larger investments.

The shareholders' equity amounted to SEK 276.1 million (252.2) 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 77.8 (85.8) per cent. Shareholders' equity per share amounted to SEK 4.96 SEK (4.53). The Group had no interest-bearing liabilities.

Investments

Investments in tangible fixed assets amounted to SEK 5.9 million (1.5). Investments in intangible fixed assets amounted to SEK 6.0 million (-).

Organisation

As of 30 September 2008, BioInvent had 100 (96) employees. 85 (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 468,750 employee options took place in June 2008.

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. The accounting principles applied are consistent with those used when preparing the most recent Annual Report. The cost of the employee options was calculated in accordance with IFRS 2.

Annual General Meeting and upcoming financial reports

The Annual General Meeting will be held on Tuesday 21 April 2009 at 4 p.m., at Ideon, Lund. Details about the composition of the Nominating Committee will be posted on the web site.

BioInvent will present the following financial reports:

Financial statement for 2008	12 February 2009
Interim reports	16 April, 15 July, 15 October 2009

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The report is also available at www.bioinvent.com

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

	3 MONTHS 2008 July-Sep.	3 MONTHS 2007 July-Sep.	9 MONTHS 2008 Jan.-Sep.	9 MONTHS 2007 Jan.-Sep.	12 MONTHS 2007 Jan.-Dec.
Net revenues	17,171	9,759	229,003	140,022	143,437
<i>Operating costs</i>					
Research and development costs	-44,679	-24,120	-150,637	-103,004	-140,861
Sales and administrative costs	-7,438	-6,381	-23,023	-21,352	-28,715
Other operating revenues and costs	-34	118	59	1,757	2,690
	-52,151	-30,383	-173,601	-122,599	-166,886
Operating profit/loss	-34,980	-20,624	55,402	17,423	-23,449
Profit/loss from financial investments	2,842	2,070	6,241	4,460	7,356
Profit/loss after financial items	-32,138	-18,554	61,643	21,883	-16,093
Tax	-	-	-	-	-
Profit/loss	-32,138	-18,554	61,643	21,883	-16,093
Profit/loss pertaining to the parent company's shareholders	-32,138	-18,554	61,643	21,883	-16,093
Earnings per share, average no. of shares, SEK					
Before dilution	-0.58	-0.34	1.11	0.44	-0.31
After full dilution	**	*	**	*	*
Average no. of shares					
Before dilution (thousands)	55,661	54,716	55,661	49,679	51,175
After full dilution (thousands)	56,130	*	55,850	*	*

* At the end of the period there were no outstanding warrants.

**No dilution is present since the subscription price exceeds the average share price.

Consolidated balance sheet in brief for the Group (SEK thousands)

	2008 30 Sep.	2007 30 Sep.	2007 31 Dec.
Assets			
Fixed assets			
Intangible fixed assets	13,989	13,964	12,532
Tangible fixed assets	16,217	13,310	14,182
Current assets			
Inventories etc.	3,596	6,839	3,825
Current receivables	68,254	29,449	23,611
Current investments	239,239	221,441	191,212
Cash and bank	13,482	8,849	25,639
Total assets	354,777	293,852	271,001
Shareholders' equity and liabilities			
Shareholders' equity	276,078	252,229	214,118
Current liabilities	78,699	41,623	56,883
Total shareholders' equity and liabilities	354,777	293,852	271,001

Change in shareholders' equity for the Group (SEK thousands)

	2008 July-Sep.	2007 July-Sep.	2008 Jan.-Sep.	2007 Jan.-Sep.	2007 Jan.-Dec.
Opening balance	307,976	150,760	214,118	110,152	110,152
Changes in reserve, actual value	-32		-13	72	-63
Effect of employee incentive program	272		330		
Profit/loss for the period	-32,138	-18,554	61,643	21,883	-16,093
Warrant premiums				99	99
Directed new share issue		120,023		120,023	120,023
Closing balance	276,078	252,229	276,078	252,229	214,118
Shareholders' equity pertaining to the parent company's shareholders	276,078	252,229	276,078	252,229	214,118

The share capital as of 30 September 2008 consists of 55,660,889 shares and the share's ratio value is 0.5. The directed new share issue carried out in July 2007, raised SEK 120,023 thousands after issue expenses, which amounted to SEK 5,352 thousands.

Consolidated cash-flow statement in brief for the Group (SEK thousands)

	2008 July-Sep.	2007 July-Sep.	2008 Jan.-Sep.	2007 Jan.-Sep.	2007 Jan.-Dec.
Current operations					
Operating profit/loss	-34,980	-20,624	55,402	17,423	-23,449
Depreciation	3,091	2,920	8,429	9,316	12,312
Interest received and paid	<u>1,584</u>	<u>1,260</u>	<u>4,772</u>	<u>3,342</u>	<u>6,012</u>
Cash flow from current operations before changes in working capital	-30,305	-16,444	68,603	30,081	-5,125
Changes in working capital	<u>169,505</u>	<u>-16,518</u>	<u>-20,813</u>	<u>-6,451</u>	<u>17,752</u>
Cash flow from current operations	139,200	-32,962	47,790	23,630	12,627
Investment activities					
Acquisition of intangible fixed assets	-6,001	-	-6,001	-	-
Acquisition of tangible fixed assets	<u>-2,176</u>	<u>-270</u>	<u>-5,919</u>	<u>-1,473</u>	<u>-3,909</u>
Cash flow from financing activities	-8,177	-270	-11,920	-1,473	-3,909
Changes in current investments**	131,023	-33,232	35,870	22,157	8,718
Financing activities					
Directed new share issue	-	120,023	-	120,023	120,023
Warrant premiums	<u>-</u>	<u>-</u>	<u>-</u>	<u>99</u>	<u>99</u>
Cash flow from financing activities	-	120,023	-	120,122	120,122
Changes in current investments**	-131,405	-90,121	-84,874	-149,753	-134,408
Change in liquid funds	-382	-3,330	-49,004	-7,474	-5,568
Opening liquid funds	<u>13,864</u>	<u>63,910</u>	<u>62,486</u>	<u>68,054</u>	<u>68,054</u>
Liquid funds at end of period	13,482	60,580	13,482	60,580	62,486
Liquid funds, specification:					
Current investments that constitute liquid funds*	-	51,731	-	51,731	36,847
Cash and bank	<u>13,482</u>	<u>8,849</u>	<u>13,482</u>	<u>8,849</u>	<u>25,639</u>
	13,482	60,580	13,482	60,580	62,486
Current investments**	<u>239,239</u>	<u>169,710</u>	<u>239,239</u>	<u>169,710</u>	<u>154,365</u>
	252,721	230,290	252,721	230,290	216,851

*Duration less than 3 months

**Duration more than 3 months

Key financial ratios for the Group

	2008 30 Sep.	2007 30 Sep.	2007 31 Dec.
Shareholders' equity per share at end of period, SEK			
Before dilution	4.96	4.53	3.85
After full dilution	**	*	*
Number of shares at end of period			
Before dilution (thousands)	55,661	55,661	55,661
After full dilution (thousands)	56,130	*	*
Equity/assets ratio, %	77.8	85.8	79.0
Number of employees at end of period	100	96	94

* At the end of the period there were no outstanding warrants.

**No dilution is present since the subscription price exceeds the share price.

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

	9 MONTHS 2008 Jan.-Sep.	9 MONTHS 2007 Jan.-Sep.	12 MONTHS 2007 Jan.-Dec.
Net revenues	229,003	140,022	143,437
<i>Operating costs</i>			
Research and development costs	-150,370	-103,004	-140,861
Sales and administrative costs	-22,960	-21,352	-28,715
Other operating revenues and costs	<u>59</u>	<u>1,695</u>	<u>2,686</u>
	-173,271	-122,661	-166,890
Operating profit/loss	55,732	17,361	-23,453
Profit/loss from financial investments	6,241	4,519	7,356
Profit/loss after financial items	61,973	21,880	-16,097
Tax	-	-	-
Profit/loss	61,973	21,880	-16,097

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

	2008 30 Sep.	2007 30 Sep.	2007 31 Dec.
Assets			
Fixed assets			
Intangible fixed assets	13,989	13,964	12,532
Tangible fixed assets	16,217	13,310	14,182
Financial fixed assets	100	100	100
Current assets			
Inventories etc.	3,596	6,839	3,825
Current receivables	68,227	29,389	23,602
Current investments	239,369	221,500	191,329
Cash and bank	13,482	8,849	25,639
Total assets	354,980	293,951	271,209
Shareholders' equity and liabilities			
Shareholders' equity	276,221	252,225	214,248
Current liabilities	78,759	41,726	56,961
Total shareholders' equity and liabilities	354,980	293,951	271,209

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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 outcome 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 October, 2008.

Lund, 16 September 2008

Svein Mathisen, President and CEO

Review report

We have reviewed this interim report for the period 1 January 2008 – 30 September 2008. 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 September 2008
ERNST & YOUNG AB

Johan Thuresson
Authorised Public Accountant