

BioInvent Interim Report

1 January–31 March 2005

- ❑ **Toxicology studies involving the BI-201 drug candidate for the treatment of HIV infection have been successfully concluded. An application for permission to start clinical studies has been submitted to the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK.**
- ❑ **Pre-clinical data further supports the claim that BI-201 minimises the risk of resistance development. The results were published in February in connection with the 12th Conference on Retroviruses and Opportunistic Infections in Boston.**
- ❑ **Net revenues for January-March 2005: SEK 9.6 million (16.2).**
- ❑ **Cash flow from current operations and investment activities for January – March 2005: SEK -19.0 million (-28.2). Liquid funds at the end of the period: SEK 156.0 million (240.5).**
- ❑ **Loss after tax for January – March 2005 amounted to SEK -26.0 million (-20.1) and the loss after tax per share was SEK -0.88 (-0.68).**

Comments by the CEO

Our projects continue to make progress toward the clinical phases. As we reported earlier, our product candidate, BI-201, for the treatment of HIV infection fulfils the safety requirements and can be administered to humans. Concluding reports and analysis from the toxicology programme confirm these results. The results and other data have been compiled and submitted to the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK with an application for permission to start clinical trials. Our plan to start these trials during the first half of the year therefore still stands.

The resistance data that we presented in Boston in February supports our claim that BI-201 will not permit the development of resistance. The development of resistance to today's drugs is a growing problem. Patients develop resistance to the treatments and additionally there are recent reports of multi-resistant viruses being transferred from person to person. Hence it is a great need for new drugs with more favourable resistance profiles than today's therapy options.

Based on the data we have obtained so far, we expect to enter the clinical phase with a product candidate with the potential to be a new class of drug for the treatment of HIV infection. By taking the project from the concept stage to clinical phases in less than three years, we have shown that, through our technology and organisation, we are able to effectively deliver clinical projects.

Operations

BioInvent develops antibody-based drugs against diseases where there is a significant unmet medical need. The antibody field is a strongly growing segment in the pharmaceutical market.

BioInvent focuses on discovery and development of proprietary antibody-based drugs and to document their effect in pre-clinical and early clinical trials. Clinical development, marketing and distribution are conducted in cooperation with pharmaceutical companies. Today BioInvent conducts innovative proprietary drug projects in the areas of HIV-infection, thrombosis, cancer, atherosclerosis, and diseases of the joints.

The scope and strength of BioInvent's technology platform is also utilized by partners in the development of new drugs. BioInvent's partners include ALK-Abelló, Antisoma, Celltech, GlaxoSmithKline, Igeneon, ImmunoGen, Orbus and XOMA.

HIV-infection/AIDS

Background:

HIV infection is one of the most serious epidemics of our time. HIV has a high degree of variability and adaptability. When a new treatment is introduced, the virus usually changes quickly and develops resistance to the treatment, making it ineffective.

The Tat protein is vital for HIV's ability to replicate itself and spread to new cells. Antibody-based drugs against the Tat protein are expected to be able to neutralise its activity so that the level of HIV particles in the patient's blood is reduced to such an extent that the development of the disease will be arrested. The antibody that BioInvent develops is targeted to a part of the Tat protein that is unchanged (conserved) between different virus strains. The target protein circulates freely in the blood and is not directly connected to a virus particle. Thus, the virus's capacity to change and adapt to avoid the effect of the antibodies is eliminated. Based on the characteristics of the unique target protein, the Company expects that the antibodies against these conserved parts of the Tat protein will avoid the development of resistance and will therefore have a lasting effect. The project is based on patent rights licensed in July 2002 from Thymon, USA.

Project status:

Toxicology studies on the selected drug candidate (BI-201) have been successfully completed. The results of these studies show that BI-201 meets the safety criteria and that BI-201 can be administered to humans. An application to begin clinical studies in the UK has been submitted to the MHRA.

BI-201 has in several pre-clinical tests carried out at the Karolinska Institute and Smittskyddsinstitutet, proved to effectively prevent the spread of the virus between human cells *in vitro* and to inhibit viruses with different Tat sequences in a similar way.

No development of resistance to BI-201 was identified in resistance tests. The *in vitro* tests carried out show that BI-201 did not allow resistance to develop after having inhibited the virus for 20 weeks. Another recently launched drug against HIV was tested under the same conditions. Resistance to this drug developed after six weeks, which is in line with previous experiences. The results of the tests were presented in February this year at the 12th Conference of Retroviruses and Opportunistic Infections in Boston.

Clinical trials are expected to start during the first half of the year.

Thrombosis

Background:

Thrombosis is a serious complication in connection with certain types of heart arrhythmia, e.g. atrial fibrillation, and in surgical procedures as hip surgery. In the US and the five largest pharmaceutical markets in Western Europe alone, more than 6 million people suffer from atrial fibrillation, while the number of surgeries where knees and hips are replaced by artificial joints is around 1.4 million a year.

Factor VIII plays a crucial role in the coagulation of the blood. Inhibiting Factor VIII is therefore an approach of great interest in the prevention of thrombosis. The challenge is to inhibit coagulation without increasing the risk of spontaneous bleeding.

BioInvent's partner, ThromboGenics, has developed a human antibody against Factor VIII. The anti-Factor VIII lead candidate has shown a beneficial partial inhibition of the blood coagulation Factor VIII, even when applied in excess dosage. These characteristics indicate a well-controlled inhibition of Factor VIII activity with low risk of spontaneous bleeding, reduced risk of overdose and reduced need

for patient monitoring. Results from animal models makes it likely that a drug can be developed that can be given one time for treatment of acute indications, or once-a-month for chronic indications such as atrial fibrillation (all available anticoagulants require daily drug administration). This suggests that a product with a favourable safety profile, with ease of administration, can be developed.

The project is progressing within the framework of the alliance with ThromboGenics and is based on research on inhibiting the Factor VIII coagulation factor. The project is headed by Professor Marc Jacquemin of Flanders Interuniversity Institute of Biotechnology (VIB) and the university in Leuven, Belgium in cooperation with ThromboGenics.

Project status:

The parties have selected a drug candidate for toxicology studies. Extensive testing in several animal models has shown that the drug strongly reduces the risk of thrombosis without increasing the risk of spontaneous bleeding. Currently the cell line that will be used for production of material for the toxicology programme is being developed. This production is planned to start this summer.

Cancer

General background:

Cancer is a heterogeneous disease, which makes it more difficult to develop drugs aimed directly at tumour cells for the purpose of killing them. A new and interesting strategy is to attack the tumour's blood supply by blocking the growth of new blood vessels to the tumour – so-called angiogenesis. BioInvent is conducting two projects using this strategy, one of which is a joint project with ThromboGenics.

Angiomotin:

Background:

BioInvent's initial angiogenesis project is based on the discovery of a new and central receptor called angiomotin. This is only expressed on normal cells in new blood vessels that are developing and is believed to be crucial to the growth of new blood vessels. Targeting antibodies to the relevant target protein prevents tumours growth through blocking the formation of new blood vessels.

The project is based on patent rights acquired in April 2003 from a research group at the Karolinska Institute.

Project status:

A large number of antibodies with specificity for the relevant target protein have been selected from BioInvent's n-CoDeR[®] antibody library. Several of the antibodies have shown ability to prevent migration of endothelial cells, which is an important step in the formation of new vessels. The Company is currently conducting testing in animal models at the Karolinska Institute to study the effect of the antibodies on vessel formation and tumour growth.

As an additional project opportunity the Company is also preparing studies in animal models to evaluate the antibodies' effects on harmful vessel growth in the eye. Such vessel growth frequently results in considerable medical complications, for example among diabetes patients, and there is a great need for new, effective drugs for the treatment of this condition.

Anti-PIGF

Background:

In December 2004 another project was initiated within the framework of BioInvent's collaboration with ThromboGenics involving a humanised antibody aimed at the placental growth factor (PIGF), which is secreted by tumours. PIGF expression is increased in connection with cancer or chronic inflammatory conditions etc. and affects the formation of new vessels in tissue that is under stress. Unlike VEGF, which is targeted by the drug Avastin, PIGF does not seem to affect normal, physiological angiogenesis. This characteristic is important because it means that the inhibition of PIGF is not expected to cause any significant side effects, but will still have the desired effect on various diseases. This hypothesis is strongly supported by animal tests published in Nature Medicine by Professor Peter Carmeliet at the University of Leuven, Belgium.

Project status:

A product candidate has been selected and has undergone extensive pre-clinical studies that have demonstrated good specificity for the relevant target protein and inhibition of PIGF-associated angiogenesis in several *in vitro* and *in vivo* studies. Development of the cell line that will be used for production of the drug candidate has begun. The next stage is to manufacture material for the toxicology programme.

Atherosclerosis

Background:

Atherosclerosis can lead to blood clot formation and infarction. In the industrialised world infarction is the main cause of death. Atherosclerosis develops as a result of plaque formation in the blood vessels. There is a risk that these plaques will be pulled apart by the blood flow, which may lead to infarction.

New research has shown strong links between oxidized forms of certain lipoproteins and the inflammatory processes that lead to plaque formation in the vessel walls. Antibodies aimed at these oxidized lipoproteins are expected to be able to stabilise plaque formation and possibly also reduce it.

The patent rights for the project are the result of research at the MAS University Hospital in Malmö and Cedars-Sinai in Los Angeles. The rights were licensed in December 2002.

Project status:

The product candidates identified by the Company have been shown to reduce plaque formation significantly in a number of animal models in experiments conducted at MAS University Hospital in Malmö. Further animal experiments are planned in order to select the final product candidate. These experiments are expected to be concluded in the third quarter 2005.

Osteoarthritis

Background:

Osteoarthritis is a disease of the joints caused by an imbalance in the formation of cartilage. The disease leads to stiffness, poor function and pain in joints in the fingers, knees and hips etc. The only treatment alternatives today for osteoarthritis are pain medication and surgery in which the affected joints are replaced by artificial ones.

Osteoarthritis is very widespread, and in the US alone, an estimated 40 million people suffer from the disease. The activity level of seven million of these people is limited by the disease, which causes costs for society of over USD 60 billion.

New research has shown that a specific protein, belonging to a class of receptors called integrins, is found on the cells that are responsible for synthesis of new cartilage tissue. Data from this research provides strong indications that this target protein can be linked to regulation and control of the cartilage tissue in the joints. BioInvent intends to develop a therapeutic antibody that will bind to the protein in question. The antibody is expected to be able to stimulate the synthesis of new cartilage tissue and thereby slowing the progression of osteoarthritis.

The rights to develop antibody-based drugs against the specific integrin were licensed in October 2003 from Cartela AB.

Project status:

A large number of antibodies with specificity for the target proteins in question have been identified. Several of the antibodies that have been developed have been shown to be able to modulate collagen synthesis in tests carried out *in vitro*, which means that the target protein is capable of mediating the relevant signals induced by antibodies. The concept is thereby validated *in vitro*.

Antibodies that have shown an effect *in vitro* are currently being evaluated in animal models in order to establish an effect on collagen synthesis and cartilage formation.

Organisation

As of 31 March, BioInvent had 95 employees, compared to 102 at the same time the previous year. 78 (83) of these work in research and development.

Revenues and result

Net revenues for the January – March period amounted to SEK 9.6 million (16.2). Revenues come from payments for development contracts carried out for partners. The reduction in revenues compared to the previous year is mainly related to a lower capacity utilization. The capacity utilized during the period was negatively affected by the fact that an expected assignment did not materialize.

The Company's total costs for the January – March period amounted to SEK 36.5 million (38.1). Operating costs are divided between external costs of SEK 14.6 million (15.5), personnel costs of SEK 16.9 million (17.6) and depreciation of SEK 5.0 million (5.0).

Research and development costs for January – March amounted to SEK 30.4 million (29.8). Depreciation according to plan lowered the operating result for the period by SEK 5.0 million (5.0), of which depreciation of intangible fixed assets amounts to SEK 2.2 million (2.0).

The loss after tax for January – March amounted to SEK -26.0 million (-20.1). The net financial items amounted to SEK 0.9 million (1.8). The reduction is the result of reduced liquid funds and lower market interest. The loss per share after tax, January – March, amounted to SEK -0.88 (-0.68).

Financial position and cash flow

As of 31 March 2005, the Group's liquid funds amounted to SEK 156.0 million (240.5). The cash flow from current operations and investment activity for January – March amounted to SEK -19.0 million (-28.2). The improvement in the cash flow compared to the previous year, despite the increased loss, is mainly due to normal fluctuation in working capital and lower investment levels.

The shareholders' equity amounted to SEK 186.7 million at the end of the period. The Company's share capital was SEK 14.7 million, and the equity/assets ratio at the end of the period was 88.0 (87.9) per cent. Shareholders' equity per share amounted to SEK 6.33 SEK (9.67). The Group had no interest-bearing liabilities.

Investments

The Group's investments amounted to SEK 0.0 million (5.4). The difference compared to the previous year is due to the acquisition of licenses in 2004 for the future use of technology linked to an antibody format – the so-called single chain format.

The parent company

Net revenues for January – March amounted to SEK 9.6 million (16.2). The loss after tax amounted to SEK -26.0 million (-20.1). The cash flow from current operations and investment activity amounted to SEK -19.0 million (-28.2).

Warrant programme

At the end of the period, warrants equivalent to 300,000 shares had been issued. The warrant programme was issued in April 2003 and is aimed at senior executives and key individuals, not in possession of large holdings of shares. So far, 211,000 warrants have been acquired by the employees at market terms. The remaining 89,000 warrants are reserved for future recruitments. The subscription period for the warrants is 1 January – 30 April 2007 and the subscription price is SEK 23. The warrant programme could provide a maximum dilution of 1.0 per cent.

Accounting principles

This consolidated interim report has been prepared in accordance with IAS 34 Interim Reporting, which is in accordance with the stipulations in the Swedish Financial Accounting Standards Council's recommendation RR 31 Consolidated Interim Reports.

The accounting principles used for this interim report are those described in the consolidated report for 2004 where it is stated, among other things, that the International Financial Reporting Standards (IFRS) shall be applied starting on 1 January 2005 and the comparative information for 2004 shall be re-stated in accordance with the new principles, with the exception of figures for financial instruments. According to the rules for the transition to IFRS, the new principles shall be applied for financial instruments only in the sections where the accounts refer to 2005. The loss reported for 2004 and the shareholders' equity as of 31 December 2004 is not affected by the standards that have been published to date.

The most significant impact on the Group of the transition to IFRS is related to reporting of financial instruments. From 2005, the Company is applying IAS 32 and 39 on financial instruments and the comparative figures for 2004 have, in compliance with the transition rules, not been re-stated. The application of IAS 32 upon its introduction on 1 January 2005, is not expected to have any impact on the shareholders' equity. The effects on the shareholders' equity on 1 January 2005 of the application of IAS 39 were minimal, SEK 22k. A more detailed account is provided in BioInvent's 2004 annual report.

Upcoming financial reports

Biolnvent will present the following financial reports:

Interim reports	14 July, 13 October 2005
Financial statement for 2005	16 February 2006

Consolidated income statement in brief (SEK thousands)

	3 MONTHS 2005 Jan.-March	3 MONTHS 2004 Jan.-March	12 MONTHS 2004 Jan.-Dec.
Net revenues	9,640	16,242	58,747
<i>Operating costs</i>			
Research and development costs	-30,361	-29,786	-126,087
Sales and administrative costs	-6,123	-8,344	-30,655
Other operating revenues and costs	<u>-20</u>	<u>-5</u>	<u>-17</u>
	-36,504	-38,135	-156,759
Operating profit/loss	-26,864	-21,893	-98,012
Profit/loss from financial investments	898	1,764	5,496
Profit/loss after financial items	-25,966	-20,129	-92,516
Tax	-	-	-
Profit/loss	-25,966	-20,129	-92,516
Earnings per share, average no. of shares, SEK*			
Before dilution	-0.88	-0.68	-3.14
Average no. of shares			
Before dilution (thousands)	29,476	29,476	29,476
After full dilution (thousands)	29,483	29,498	29,481

*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.

Consolidated balance sheet in brief (SEK thousands)

	2005 31 March	2004 31 March	2004 31 Dec.
Assets			
Fixed assets			
Intangible fixed assets	13,839	22,749	16,066
Tangible fixed assets	19,715	31,517	22,440
Current assets			
Inventories etc.	4,814	8,470	5,754
Current receivables	17,656	20,856	19,151
Liquid funds	156,018	240,540	174,994
Total assets	212,042	324,132	238,405
Shareholders' equity and liabilities			
Shareholders' equity	186,699	285,065	212,678
Current liabilities	25,343	39,067	25,727
Total shareholders' equity and liabilities	212,042	324,132	238,405

Consolidated cash-flow statement in brief (SEK thousands)

	2005 Jan.-March	2004 Jan.-March	2004 Jan.-Dec.
Current operations			
Operating profit/loss	-26,864	-21,893	-98,012
Depreciation	4,970	5,035	20,964
Interest received and paid	<u>760</u>	<u>1,764</u>	<u>6,206</u>
Cash flow from current operations before changes in working capital	-21,134	-15,094	-70,842
Changes in working capital	<u>2,176</u>	<u>-7,683</u>	<u>-17,312</u>
Cash flow from current operations	-18,958	-22,777	-88,154
Investment activities			
Acquisition of intangible fixed assets	-	-5,352	-5,352
Acquisition of tangible fixed assets	<u>-18</u>	<u>-44</u>	<u>-213</u>
Cash flow from investment activities	-18	-5,396	-5,565
Cash flow after investment activities	-18,976	-28,173	-93,719
Financing activities			
Warrant premiums	-	<u>237</u>	<u>237</u>
Cash flow from financing activities	-	237	237
Change in liquid funds	-18,976	-27,936	-93,482
Liquid funds at end of period	156,018	240,540	174,994

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

	Share capital	Share premium reserve	Other restricted reserves	Accumulated loss	Total
Shareholders' equity 31 December 2003	14,738	379,878	1	-89,660	304,957
Warrant premiums		237			237
Profit/loss for the period				-20,129	-20,129
Shareholders' equity 31 March 2004	14,738	380,115	1	-109,789	285,065
Transfer between restricted and unrestricted reserves		-89,660		89,660	0
Profit/loss for the period				-72,387	-72,387
Shareholders' equity 31 December 2004	14,738	290,455	1	-92,516	212,678
Effect of the transition to IAS 39			22		22
Shareholders' equity 1 January 2005	14,738	290,455	23	-92,516	212,700
Reserve, actual value			-35		-35
Profit/loss for the period				-25,966	-25,966
Shareholders' equity 31 March 2005	14,738	290,455	-12	-118,482	186,699

The share capital as 31 March 2005 consists of 29,475,556 shares with a nominal value of SEK 0.50 per share.

Key financial ratios

	2005 31 March	2004 31 March	2004 31 Dec.
Shareholders' equity per share at end of period, SEK			
Before dilution	6.33	9.67	7.22
After full dilution	6.33	9.66	7.21
Number of shares at end of period			
Before dilution (thousands)	29,476	29,476	29,476
After full dilution (thousands)	29,483	29,498	29,481
Equity/assets ratio, %	88.0	87.9	89.2
Number of employees at end of period	95	102	98

Lund, 13 April 2005

Svein Mathisen, President and CEO

We have briefly examined this interim report for the period 1 January 2005 – 31 March 2005 in accordance with the recommendation issued by the Swedish Institute of Authorised Public Accountants (FAR). A brief examination is very limited compared to a full audit. We have found nothing to indicate that this interim report does not meet the requirements of the stock exchange and annual accounts laws.

Lund, 13 April 2005

ERNST & YOUNG AB, Åke Stenmo, Authorised Public Accountant

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The report is also available at www.bioinvent.com

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