

BIOINVENT INTERIM REPORT 1 JANUARY–30 SEPTEMBER 2004

- ❑ **Strategic alliance with ThromboGenics strengthens the emphasis in the portfolio on the clinical development phase. The initial drug candidate aims to inhibit thrombosis.**
- ❑ **Toxicology studies initiated within the HIV project**
- ❑ **Research results in the atherosclerosis project published in the well-reputed journal Circulation**
- ❑ **Net revenues for January-September 2004: SEK 40.3 million (50.7).**
- ❑ **Cash flow from current operations and investment activities for January – September 2004: SEK -69.0 million (-39.4). Liquid funds at the end of the period: SEK 199.7 million (304.6).**
- ❑ **Loss after net financial items for January – September 2004 amounted to SEK -68.6 million (-65.2) and the loss after net financial items per share was SEK -2.33 (-2.21).**

Comments by the CEO

During the period we have reported several steps forward in our project portfolio. Our drug candidate for the treatment of HIV infection is advancing rapidly through pre-clinical development towards tests on humans. In order to meet this challenge, we have reinforced our development organisation with the addition of individuals with profound knowledge and many years of experience in the clinical development of antibody-based drugs. Also, we can confirm that the technology platform we have built is able to deliver product candidates. In just over two years, we have taken the HIV project from an idea to a drug candidate that is now being tested in toxicology studies. Provided that we achieve expected progress, the next phase is to test the drug candidate on humans.

As a result of the alliance we entered into in September with ThromboGenics, the emphasis in our project portfolio has shifted further towards the clinical development phases. The initial collaborative programme will focus on development of an antibody-based drug candidate to reduce the risk of thrombosis in connection with a number of medical conditions. In experiments carried out on animal models, the drug candidate has been shown to effectively inhibit thrombosis. Before the clinical development programme can begin, toxicology studies must be carried out in the pre-clinical phase. This collaboration provides more evidence of the interest that is being shown in our technology platform and competence. By offering this platform within the framework of the collaboration, we have been able to secure a significant stake in a promising product candidate in a market segment that is very attractive from a commercial point of view.

We have also made significant progress in our other programmes. Recently some of the results obtained from our atherosclerosis project were published in the well-reputed journal Circulation published by the American Heart Association.

As we shift our positions forward towards the clinical development phase, part of the capacity in the production facility will be used in our drug projects. Accordingly, revenue from development assignments will vary to some extent from quarter to quarter.

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 is conducted in cooperation with established pharmaceutical companies. Today BioInvent conducts innovative proprietary drug projects in the areas of AIDS, vascular diseases, 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 prevent 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 are currently under way on the selected drug candidate. At the same time, the process of manufacturing material for the clinical development programme is almost complete. As a result of good productivity from the cell line developed by the Company, the returns from production have been very good. This is a strong indication that the product will have a favourable margin once it reaches the market.

Other preparatory activities for the clinical programme involved, among other things, the development of tests to make it possible to monitor the therapeutic antibody's pharmaco-kinetics and pharmaco-dynamics, recruitment of clinical centres and planning for future meetings with the authorities.

The chosen candidate drug have, in several pre-clinical tests carried out at the Karolinska Institute and at 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. Expanded pre-clinical studies continue to test, among other things, for the absence of development of resistance.

Thrombosis

Background:

Thrombosis is a complication of atrial fibrillation and artificial joint replacement, e.g. hip joints. 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 aimed at 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. This indicates well-controlled inhibition of Factor VIII activity with low risk of spontaneous bleeding. This expects to lead to 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 an 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. The next stage is to develop the cell line that will be used for large-scale production of the drug candidate and manufacture of the material needed for the toxicology programme.

Cancer

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's angiogenesis project is based on the discovery of a new and central receptor called angiomin. 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 from developing their own new blood vessels and thereby blocks their nutrient supply.

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 in 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 results received have prompted the Company to start 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.

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 very significantly reduce plaque formation in pre-clinical animal models. The experiments conducted at the MAS University Hospital in Malmö show that plaque formation in the vessel walls has been reduced by half, even though the treatment has only been under way for a short period. These results were published recently in the well-reputed journal *Circulation*.

Pre-clinical tests continue on several animal models for the purpose of further documenting the effect of the product candidates and the mechanism of action and the inhibitory effects that were observed earlier have now been repeated in another animal model.

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 treated by artificial replacement.

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 discovered that a specific protein (belonging to a class of receptors called integrins) is found in large quantities 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 down 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*.

Several animal models are currently being evaluated with a view to using them in further development programmes. The antibodies that have been shown to have an effect *in vitro* will be tested in such animal models in order to establish an effect on collagen synthesis and cartilage formation.

Organisation

As of 30 September, BioInvent had 102 employees, compared to 104 at the same time the previous year. 85 (85) of these work in research and development.

Revenues and result

Net revenues for the January – September period amounted to SEK 40.3 million (50.7). Net revenues for the July – September period amounted to SEK 11.3 million (16.9). Revenues come mainly from payments for development and production assignments carried out for partners. During the second and third quarter the production facility's capacity was utilized to produce material for the toxicology programme and the clinical programme with the Company's drug candidate for the treatment of HIV infection. As a result of this capacity being used for the Company's proprietary drug projects, the income from partner projects will vary somewhat from quarter to quarter.

The Company's total costs for January – September were reduced by SEK 11.8 million and amounted to SEK 113.3 million (125.1). Operating costs are divided between external costs of SEK 46.1 million (47.9), personnel costs of SEK 51.5 million (63.8) and depreciation of SEK 15.7 million (13.4). Analysis of the Company's costs, January – September, shows that personnel-related costs and external costs have fallen in line with the anticipated annual cost savings of some SEK 20 million following the re-organisation and staff reduction measures carried out in September 2003. The Company's costs relating to proprietary drug projects may, however, gradually increase as and when individual projects are moved forward in the value chain.

Research and development costs for January – September amounted to SEK 90.9 million (96.6). Depreciation according to plan lowered the operating result for the period by SEK 15.7 million (13.4), of which depreciation of intangible fixed assets amounts to SEK 6.4 million (4.8).

The loss after financial items for January – September amounted to SEK -68.6 million (-65.2). The loss after financial items for July – September amounted to SEK -23.9 million (-20.8). Despite lower total costs the result decreased slightly due to lower net sales and lower interest income. The net financial

items amounted to SEK 4.4 million (9.0). The reduction is the result of lower market interest and reduced liquid funds.

Financial position and cash flow

As of 30 September 2004, the Group's liquid funds amounted to SEK 199.7 million (304.6). The cash flow from current operations and investment activity for January – September amounted to SEK -69.0 million (-39.4). The corresponding cash flow for the July - September period amounted to SEK -14.9 million (-14.7). The difference between this and the cash flow for the same period last year, January – September, is mainly due to fluctuations in operating capital and the acquisition of intangible fixed assets.

The shareholders' equity amounted to SEK 236.6 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 89.1 (89.5) per cent. The Group had no interest-bearing liabilities.

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.

Benefits for senior executives

During the period the senior executives within the Company acquired at market terms warrants equivalent to 50,000 shares.

Investments

Investments during January - September amounted to SEK 5.5 million (1.9) and related mainly to the acquisition of licenses for the future use of technology linked to an antibody format – the so-called single chain format.

The parent company

Net revenues for January – September amounted to SEK 40.3 million (50.7). The parent company reported a loss after net financial items for January – September of SEK -68.6 million (-65.2).

Nominating committee

The Annual General Meeting on 22 April 2004 decided to appoint a nominating committee consisting of the Chairman of the Board as the convenor and a representative from each of the Company's three largest shareholders as of 30 September 2004. The nominating committee's assignment will be to present proposals before the next Annual General Meeting regarding the election of Board members and setting of Board fees, and, where applicable, the election of auditors and setting of auditor's fees.

The following individuals have been appointed to the nominating committee: Jörgen Lönngren (Stiftelsen Industrifonden), Björn Franzon (Fjärde AP-fonden) and Per-Olof Mårtensson (Chairman of the Board). The Company is still waiting to hear from the second largest shareholder, Pronova a.s. (Norsk Hydro ASA). BioInvent will announce on the web site when this information becomes available.

Accounting principles

This interim report has been prepared in accordance with the recommendation on interim reports (RR 20) issued by the Swedish Financial Accounting Standards Council. The accounting principles are the same as those used in the preparation of the most recent annual report. The Company also complies with the new recommendation from the Swedish Financial Accounting Standards Council, RR 29 Remunerations to employees, which went into effect on 1 January 2004. This recommendation has not had any effect on the Company's accounting procedures with respect to pension accounting since all payments within the company are considered premium-related. However, the ITP pension plan, in accordance with a statement issued by the Swedish Financial Accounting Standards Council's urgent issues task force, will be treated for accounting purposes as benefit-related when Alecta is able to provide the necessary information.

Upcoming financial reports

Biolnvent will present the following financial reports:

Financial statement for 2004

17 February 2005

Consolidated income statement in brief (SEK thousands)

	3 MONTHS 2004 July-Sep.	3 MONTHS 2003 July-Sep.	9 MONTHS 2004 Jan.-Sep.	9 MONTHS 2003 Jan.-Sep.	12 MONTHS 2003 Jan.-Dec.
Net revenues	11,287	16,861	40,301	50,712	66,716
<i>Operating costs</i>					
Research and development costs	-30,410	-30,307	-90,946	-96,562	-131,049
Sales and administrative costs	-6,008	-9,779	-22,352	-28,518	-36,673
Other operating revenues and costs	<u>7</u>	<u>9</u>	<u>-9</u>	<u>197</u>	<u>260</u>
Operating profit/loss	-25,124	-23,216	-73,006	-74,171	-100,746
Profit/loss from financial investments	1,221	2,434	4,405	8,959	11,086
Profit/loss after financial items	-23,903	-20,782	-68,601	-65,212	-89,660
Tax	-	-	-	-	-
Profit/loss	-23,903	-20,782	-68,601	-65,212	-89,660
Earnings per share, average no. of shares, SEK*					
Before dilution	-0.81	-0.71	-2.33	-2.21	-3.04
Average no. of shares					
Before dilution (thousands)	29,476	29,476	29,476	29,476	29,476
After full dilution (thousands)	29,478	29,508	29,485	29,505	29,502

*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)

	2004 30 Sep.	2003 30 Sep.	2003 31 Dec.
Assets			
Fixed assets			
Intangible fixed assets	18,294	15,379	19,357
Tangible fixed assets	25,463	36,642	34,548
Current assets			
Inventories etc.	5,581	2,961	9,898
Current receivables	16,505	8,332	10,906
Liquid funds	199,731	304,596	268,476
Total assets	265,574	367,910	343,185
Shareholders' equity and liabilities			
Shareholders' equity	236,593	329,405	304,957
Current liabilities	28,981	38,505	38,228
Total shareholders' equity and liabilities	265,574	367,910	343,185

Consolidated cash-flow statement in brief (SEK thousands)

	2004 July-Sep.	2003 July-Sep.	2004 Jan.-Sep.	2003 Jan.-Sep.	2003 Jan.-Dec.
Current operations					
Operating profit/loss	-25,124	-23,216	-73,006	-74,171	-100,746
Depreciation	5,310	4,504	15,653	13,429	18,867
Interest received and paid	<u>1,221</u>	<u>2,434</u>	<u>4,405</u>	<u>8,959</u>	<u>11,086</u>
Cash flow from current operations before changes in working capital	-18,593	-16,278	-52,948	-51,783	-70,793
Changes in working capital	<u>3,729</u>	<u>1,787</u>	<u>-10,529</u>	<u>14,336</u>	<u>4,548</u>
Cash flow from current operations	-14,864	-14,491	-63,477	-37,447	-66,245
Investment activities					
Acquisition of intangible fixed assets	-	-	-5,352	-425	-6,244
Acquisition of tangible fixed assets	<u>-20</u>	<u>-237</u>	<u>-153</u>	<u>-1,483</u>	<u>-2,986</u>
Cash flow from investment activities	-20	-237	-5,505	-1,908	-9,230
Cash flow after investment activities	-14,884	-14,728	-68,982	-39,355	-75,475
Financing activities					
Warrant premiums	-	-	<u>237</u>	<u>367</u>	<u>367</u>
Cash flow from financing activities	-	-	237	367	367
Change in liquid funds	-14,884	-14,728	-68,745	-38,988	-75,108
Liquid funds at end of period	199,731	304,596	199,731	304,596	268,476

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

	Share capital	Share premium reserve	Other restricted reserves	Accumulated loss	Total
Shareholders' equity 31 December 2002	14,738	545,685	0	-166,173	394,250
Transfer between restricted and unrestricted reserves		-166,174	1	166,173	0
Warrant premiums		367			367
Profit/loss for the period				-65,212	-65,212
Shareholders' equity 30 September 2003	14,738	379,878	1	-65,212	329,405
Profit/loss for the period				-24,448	-24,448
Shareholders' equity 31 December 2003	14,738	379,878	1	-89,660	304,957
Transfer between restricted and unrestricted reserves		-89,660		89,660	0
Warrant premiums		237			237
Profit/loss for the period				-68,601	-68,601
Shareholders' equity 30 September 2004	14,738	290,455	1	-68,601	236,593

The share capital as 30 September 2004 consists of 29,475,556 shares with a nominal value of SEK 0.50 per share.

Key financial ratios

	2004 30 Sep.	2003 30 Sep.	2003 31 Dec.
Shareholders' equity per share at end of period, SEK			
Before dilution	8.03	11.18	10.35
After full dilution	8.02	11.16	10.34
Number of shares at end of period			
Before dilution (thousands)	29,476	29,476	29,476
After full dilution (thousands)	29,485	29,505	29,502
Equity/assets ratio, %	89.1%	89.5%	88.9%
Number of employees at end of period	102	104	104

Lund, 14 October 2004

Svein Mathisen, President and CEO

We have briefly examined this interim report for the period 1 January 2004 – 30 September 2004 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, 14 October 2004

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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