

**PRESS RELEASE**  
**12 February 2004**



## **BIOINVENT FINANCIAL STATEMENT**

### **1 JANUARY–31 DECEMBER 2003**

- ❑ **Promising pre-clinical data for BioInvent's HIV project:** The Company's antibodies against HIV are effectively preventing the spread of the virus between human cells.
- ❑ **Progress within BioInvent's atherosclerosis treatment project:** Antibodies tested in pre-clinical animal models indicate a clear reduction in plaque in the blood vessels.
- ❑ **Project portfolio strengthened:** Drug projects initiated for the treatment of widespread diseases such as cancer and osteoarthritis according to new therapeutic principles.
- ❑ **Cross-licensing agreement regarding antibody technologies signed with XOMA, a US pharmaceutical company.**
- ❑ **Patent portfolio strengthened:** European patent granted for the n-CoDeR antibody library.
- ❑ **Net revenues for January – December 2003:** SEK 66.7 million (87.1)
- ❑ **Cash flow from current operations and investment activities for January – December 2003:** SEK –75.5 million (–47.1). **Liquid funds at the end of the year:** SEK 268.5 million (343.6).
- ❑ **Loss after net financial items for January – December 2003** amounted to SEK –89.7 million (–46,2) and the loss after net financial items per share was SEK –3.04 (1.60).

## Operations and strategy

BioInvent develops antibody-based drug candidates against diseases where there is a significant unmet medical need. The antibody field is a strongly growing segment in the pharmaceuticals market and is expected to account for a large portion of drug sales in the future.

BioInvent conducts proprietary drug projects for diseases such as AIDS, atherosclerosis, cancer and osteoarthritis. The scope and strength of BioInvent's technology platform is also used by partners in the development of new drugs. BioInvent's partners include Antisoma, Celltech, GlaxoSmithKline, Igeneon, ImmunoGen and XOMA.

BioInvent focuses on producing proprietary antibody-based drugs and documenting their effect in pre-clinical and early clinical trials. The starting point for the projects is a target protein to which the relevant antibody binds specifically. BioInvent is not normally involved in the actual discovery of such target proteins. Instead, the Company seeks to form alliances with external research groups who have discovered target proteins associated with widespread diseases.

The Company seeks partnerships with established pharmaceutical companies who will have primary responsibility for clinical development, marketing and distribution. Agreements will be signed in the final phase of pre-clinical development or in the early clinical phase. The timing is determined by costs, risk, skill requirements, and the value generated if BioInvent carries out a further phase in the process.

BioInvent's strategic role in the value chain means that the Company has sole responsibility for research and development for a period of two to five years. Thereafter, an established pharmaceutical company takes over the primary responsibility. The duration of the period is mainly determined by the degree to which the target protein has been validated in relation to the development of the disease in question and by BioInvent's assessment of the commercial potential.

## Proprietary drug projects

### HIV infection

**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 antibodies that BioInvent develops are targeted to parts of the Tat protein that are 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 blocked. 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 LLC, USA.

**Project status:** Pre-clinical tests show that the product candidates the Company has produced are able to prevent the spread of the virus between human cells *in vitro*. These results have been confirmed in extended tests carried out at Smittskyddsinstitutet and the Karolinska Institute. Currently the absence of resistance is also being tested in extended pre-clinical trials.

Alongside the pre-clinical work, process development is underway for cell lines used for large-scale production of drug candidates. This work has progressed to an advanced stage.

Provided that the pre-clinical studies continue to be successful, the Company expects to select the final product candidate this year for further pre-clinical safety tests and clinical trials.

## **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. At this time, the antibodies are being tested in animal models that express the human target protein. The purpose of these studies is to confirm earlier results in a model that can more reliably predict the effects that may be expected in humans.

Provided that the pre-clinical studies continue to be successful, the Company expects to select the final product candidate this year for further pre-clinical safety tests and clinical trials.

## **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. This starves the tumour and prevents it from growing.

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. Aiming the antibodies at 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 number of antibodies with specificity for the relevant target protein have been identified in BioInvent's n-CoDeR antibody library. These antibodies will now be tested in existing *in vitro* and *in vivo* models at the Karolinska Institute to assess their ability to prevent the growth of new blood vessels in growing tumours and thereby arrest the tumour's growth.

## **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 provide 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. This kind of antibody is expected to be able to stimulate the synthesis of new cartilage tissue and thereby slow the progression of osteoarthritis.

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

**Project status:** Antibodies with specificity for the relevant target proteins have been identified. Additional specific antibodies are expected to be identified in ongoing selection processes. These and the antibodies already produced will be tested in a series of *in vitro* and *in vivo* models to assess their effect on cartilage formation.

## Partners

BioInvent has always had a strong customer focus, and an important aspect of the Company's business model is to balance part of the risk of proprietary projects with business that generates steady revenue. The following partnerships generated revenue in 2003:

- **Antisoma** Since 1996 this company has been a regular consumer. BioInvent produces several of Antisoma's antibody-based drug candidates for clinical trials, for example Pemtumomab (Theragyn), which is currently in advanced clinical phase III studies.
- **Celltech** In 2002 a development partnership was initiated with Oxford GlycoSciences (OGS) for the development and commercialisation of antibody-based drugs. Celltech, a British biotech company, subsequently acquired OGS. This scientific partnership is focusing on the cancer field.
- **GlaxoSmithKline (GSK)** BioInvent has been developing antibodies to be used in GSK's research and development work in the vaccine field. BioInvent has been working with GSK since 2001. The agreement will expire in its current form at the end of April. The partnership is believed to have been a valuable one for both parties and may lead to new joint projects.
- **ImmunoGen and Igeneon** Under the agreements with both the US company ImmunoGen and Austrian Igeneon, BioInvent produces antibody-based drug candidates for clinical development programmes conducted by these customers.

In November BioInvent entered into a cross-licensing agreement with the US pharmaceutical company XOMA. Under the agreement, BioInvent has the right to use XOMA's expression technology for the purpose of developing antibody-based drugs. The agreement also provides BioInvent with a new customer for its n-CoDeR antibody library, in that XOMA has acquired a license to use the library in its research programme with certain rights to manufacture antibodies for use as drugs and diagnostic tools.

In February, after the end of the reporting period, the Company entered into a production agreement with a returning customer, the Danish company ALK-Abelló, for the commercial delivery of antibodies for a new allergy test that is being marketed by Bayer Diagnostics. This agreement is in line with BioInvent's strategy to secure long-term supplier agreements within the field of antibody production.

## Explorative research

In order to exploit the Company's technology platform commercially to the greatest extent possible, BioInvent is conducting explorative research primarily within the following areas:

**Protein arrays** In an earlier project, a system was developed for global analysis of the proteome, which may have great significance in the discovery of new target proteins for drug development. The aim is for the system to enable detection of differences in protein content between different specimens, e.g. from diseased and healthy tissue. The system is based on antibodies isolated from the n-CoDeR antibody library.

**Leukaemia** In an earlier project conducted in cooperation with a research group at Lund University, tumour-specific genes within certain B-cell tumours were studied as well as the proteins that these code for. The aim is to validate these proteins as target structures for antibody-based therapy.

## **Patents**

In November the European Patent Office granted a patent for the n-CoDeR antibody library. The patent covers methods to create both the n-CoDeR antibody library itself, as well as individual antibody components in the library. BioInvent has already been awarded a similar patent in Australia, and patent applications have been filed in the US and other countries.

Through exclusive licenses or under its own name, BioInvent now has over 150 individual patents or patent applications. These cover the Company's core technology for the development of antibody-based drug candidates, as well as various aspects of this, such as various antibody products under development and their use as drugs.

## **Organisation**

As of 31 December, BioInvent had 104 employees, compared to 130 at the same time the previous year. 84 (108) of these work in research and development. The reduction in staff is the result of reorganisation, the purpose of which was to focus further on developing proprietary antibody-based drugs. This resulted in a change in the personnel structure and a reduction in the number of staff within certain areas of expertise.

## **Sales and revenue**

Net revenue for January – December amounted to SEK 66.7 million (87.1). Revenue for the October – December period amounted to SEK 16.0 million (21.8). The revenue comes from payments for development and production assignments. The capacity utilisation for such assignments was lower than the previous year. The level of utilisation is affected partly by the actual demand and partly by the amount of capacity that needs to be used for BioInvent's proprietary drug projects.

The loss after net financial items for January – December amounted to SEK –89.7 million (–46.2). Apart from a fall in net revenue, the result was also affected by increased research and development costs relating, in particular, to proprietary drug development projects. The Group's research and development costs for January – December amounted to SEK 131.0 million (111.7) after re-classification (see "Accounting Principles" below). The loss after net financial items for October–December, amounted to SEK –24.4 million (–16.4).

Depreciation according to plan of SEK 18.9 million (13.5) was deducted from the operating result for the period. The increase in depreciation is mainly due to investments in intangible fixed assets. The net financial income was SEK 11.1 million (16.2).

## **Financial position and cash flow**

The cash flow from current operations and investment activity for January – December amounted to SEK –75.5 million (–47.1). Apart from a weaker result, the difference between this and the cash flow for the same period the previous year is the result of substantial non-recurring payments from customers in 2002. These effects were neutralised to a certain extent by the lower level of investment. As of 31 December 2003, the Group's liquid funds amounted to SEK 268.5 million (343.6). The cash flow from current operations and investment activity for the October – December period amounted to SEK –36.1 million (–32.4).

The shareholders' equity amounted to SEK 305.0 million at the end of the year. The Company's share capital was SEK 14.7 million, and the equity/assets ratio at the end of the period was SEK 88.9 (88.3) per cent. The Group had no interest-bearing liabilities.

## **Warrant programme**

The Annual General Meeting on 10 April 2003 voted in favour of a warrant programme equivalent to a maximum of 300,000 shares aimed at senior executives and key individuals. So far, 161,000 warrants have been acquired by the employees at market terms. The remaining 139,000 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 potential dilution of 1.0 per cent.

At the end of the year, warrants equivalent to 516,850 shares had been issued, including warrants in previous programmes. The subscription period for warrants for 216,850 shares expires on 16 February 2004 and no shares are expected to be subscribed for before this date.

## **Investments**

The Group's investments in tangible fixed assets amounted to SEK 3.0 million (14.0) and relate mainly to equipment for research and development activity. The level of investment the previous year was affected by the purchase of automation equipment. Investments in intangible fixed assets amounted to SEK 6.2 million (22.5) and relate mainly to cash payment for purchased target proteins used for proprietary drug projects, as well as licenses for the future use of expression technology.

## **The parent company**

Net revenue for January – December amounted to SEK 66.7 million (87.1). The parent company reported a loss after net financial items for January – December of SEK –89.7 million (–46.2).

## **Benefits for senior executives**

In 2003 BioInvent's senior executives acquired warrants equivalent to 60,000 shares.

## **Nominating committee**

In accordance with a decision at the Annual General Meeting, a nominating committee has been appointed consisting of Jörgen Lönngren (Stiftelsen Industrifonden), Ramsay Brufer (Alecta), Björn Franzon (Fjärde AP-fonden) and Per-Olof Mårtensson (Chairman of the Board).

The nominating committee works with nominations and proposals for Board members, auditors and fees. Such nominations and proposals are announced as soon as they arise.

## **Accounting principles**

This financial statement 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 recommendations from the Swedish Financial Accounting Standards Council that went into effect on 1 January 2003. One of these new recommendations, RR 27 Financial Instruments: Information and Classification, has affected the way the annual report is presented. From 1 January 2003 a re-classification was made in the income statement, whereby the item "Cost of goods and services sold" was removed. This was done to achieve a better representation of the Group's operations. The change has not had any impact on the result.

## **Annual General Meeting, dividend proposal and upcoming financial reports**

The Annual General Meeting will be held on 22 April 2004 at 4 p.m. Notice to attend will be announced in the usual way. The annual report will be distributed to shareholders no later than two weeks before the Annual General Meeting. Shareholders wishing to attend the Annual General Meeting are to be registered in the shareholders' register kept by the Swedish Securities Register Centre (VPC) no later than 8 April 2004, and should inform BioInvent of their intention to attend no later than Monday, 16 April 2004.

The Board of Directors and President & CEO do not propose the payment of any dividend for the 2003 business year.

BioInvent will present the following financial reports in 2004:

Annual report	Beginning of April 2004
Interim reports	21 April, 15 July, 14 October 2004
Financial statement for 2004	17 February 2005

## Consolidated income statement in brief (SEK thousands)

	3 MONTHS 2003 Oct.-Dec.	3 MONTHS 2002 Oct.-Dec.	12 MONTHS 2003 Jan.-Dec.	12 MONTHS 2002 Jan.-Dec.
Net revenues	16,004	21,760	66,716	87,053
<i>Operating costs</i>				
Research and development costs	-34,487	-31,147	-131,049	-111,682
Sales and administrative costs	-8,155	-10,818	-36,673	-37,983
Other operating revenues and costs	<u>63</u>	<u>-464</u>	<u>260</u>	<u>196</u>
<b>Operating profit/loss</b>	<b>-26,575</b>	<b>-20,669</b>	<b>-100,746</b>	<b>-62,416</b>
Profit/loss from financial investments	2,127	4,308	11,086	16,250
<b>Profit/loss</b>	<b>-24,448</b>	<b>-16,361</b>	<b>-89,660</b>	<b>-46,166</b>
Earnings per share, average no. of shares, SEK*				
Before dilution	-0.83	-0.56	-3.04	-1.60
Average no. of shares				
Before dilution (thousands)	29,476	29,476	29,476	28,939
After full dilution (thousands)	29,502	29,476	29,502	28,940

\* 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)

	2003 31 Dec.	2002 31 Dec.
<i>Assets</i>		
<b>Fixed assets</b>		
Intangible fixed assets	19,357	19,726
Tangible fixed assets	34,548	43,816
<b>Current assets</b>		
Inventories etc.	9,898	13,697
Short-term receivables	10,906	25,584
Liquid funds	268,476	343,584
<b>Total assets</b>	<b>343,185</b>	<b>446,407</b>
<i>Shareholders' equity and liabilities</i>		
Shareholders' equity	304,957	394,250
Short-term liabilities	38,228	52,157
<b>Total shareholders' equity and liabilities</b>	<b>343,185</b>	<b>446,407</b>

## Consolidated cash-flow statement in brief (SEK thousands)

	2003 Oct.-Dec.	2002 Oct.-Dec.	2003 Jan.-Dec.	2002 Jan.-Dec.
<b>Current operations</b>				
Operating profit/loss	-26,575	-20,669	-100,746	-62,416
Depreciation	5,438	3,927	18,867	13,475
Interest received and paid	<u>2,127</u>	<u>4,308</u>	<u>11,086</u>	<u>16,250</u>
<b>Cash flow from current operations before changes in working capital</b>	<b>-19,010</b>	<b>-12,434</b>	<b>-70,793</b>	<b>-32,691</b>
Changes in working capital	<u>-9,788</u>	<u>-9,611</u>	<u>4,548</u>	<u>22,122</u>
<b>Cash flow from current operations</b>	<b>-28,798</b>	<b>-22,045</b>	<b>-66,245</b>	<b>-10,569</b>
<b>Investment activities</b>				
Acquisition of intangible fixed assets	-5,819	-4,000	-6,244	-22,501
Acquisition of tangible fixed assets	<u>-1,503</u>	<u>-6,377</u>	<u>-2,986</u>	<u>-14,008</u>
<b>Cash flow from investment activities</b>	<b>-7,322</b>	<b>-10,377</b>	<b>-9,230</b>	<b>-36,509</b>
<b>Cash flow after investment activities</b>	<b>-36,120</b>	<b>-32,422</b>	<b>-75,475</b>	<b>-47,078</b>
<b>Financing activities</b>				
Warrant premiums	-	-	367	-
Directed new share issue	<u>-</u>	<u>-</u>	<u>-</u>	<u>52,000</u>
<b>Cash flow from financing activities</b>	<b>-</b>	<b>-</b>	<b>367</b>	<b>52,000</b>
<b>Change in liquid funds</b>	<b>-36,120</b>	<b>-32,422</b>	<b>-75,108</b>	<b>4,922</b>
<b>Liquid funds at end of period</b>	<b>268,476</b>	<b>343,584</b>	<b>268,476</b>	<b>343,584</b>

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

	Share capital	Share premium reserve	Other restricted reserves	Accumulated loss	Total
<b>Shareholders' equity on 31 December 2001</b>	<b>14,072</b>	<b>445,170</b>	<b>100</b>	<b>-70,926</b>	<b>388,416</b>
Directed new share issue	666	51,334			52,000
Transfer between restricted and unrestricted reserves		49,181	-100	-49,081	0
Profit/loss for the period				-46,166	-46,166
<b>Shareholders' equity on 31 December 2002</b>	<b>14,738</b>	<b>545,685</b>	<b>0</b>	<b>-166,173</b>	<b>394,250</b>
Transfer between restricted and unrestricted reserves		-166,174	1	166,173	0
Warrant premiums		367			367
Profit/loss for the period				-89,660	-89,660
<b>Shareholders' equity 31 December 2003</b>	<b>14,738</b>	<b>379,878</b>	<b>1</b>	<b>-89,660</b>	<b>304,957</b>

The share capital as of 31 December 2003 consisted of 29,475,556 shares, each with a nominal value of SEK 0.50.

## Key financial ratios

	2003 31 Dec.	2002 31 Dec.
Shareholders' equity per share at end of period, SEK		
Before dilution	10.35	13.38
After full dilution	10.34	13.38
Number of shares at end of period		
Before dilution (thousands)	29,476	29,476
After full dilution (thousands)	29,502	29,476
Equity/assets ratio, %	88.9%	88.3%
Number of employees at end of period	104	130

*Lund, 12 February 2004*

*The Board of Directors*

*This report is based on the 2003 financial statement, which has been reviewed by the auditors.*

### Contact:

Any questions regarding this report will be answered by:

Svein Mathisen, President & CEO, tel.+46 (0)46 286 85 67, mobile +46 (0)708 97 82 13 or

Cristina Glad, Executive Vice President, +46 (0)46 286 85 51, mobile +46 (0)708 16 85 70.

The report is also available at [www.bioinvent.com](http://www.bioinvent.com)

### BioInvent International AB (publ.)

Co. reg. no. 556537-7263

Address: Sölvegatan 41, 223 70 Lund

Tel.: +46 (0)46 286 85 50

info@bioinvent.com

[www.bioinvent.com](http://www.bioinvent.com)

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