

# Biovitrum Interim Report January 1 – September 30, 2007

# Kiobrina<sup>™</sup> and Factor IXFc approaching clinical phase

### July - September

- Net revenues amounted to SEK 199.8 M (248.2). The quarter showed a negative result of SEK -22.5 M (5.6), which is equivalent to earnings per share of SEK -0.49 (0.13). This is in line with previously communicated outlook and is mainly due to lower ReFacto® deliveries in the third quarter as a consequence of high delivery levels in the first half year as well as lower revenues from contract development.
- Cash flow from operations improved in the third quarter and increased by SEK 25 M and amounted to SEK -46.4 M.
- Biovitrum obtained the first approval for initiation of a clinical phase II trial of Kiobrina<sup>TM</sup> in Italy and France.
- An application to start the first clinical phase I/II study of FIXfc in hemophilia B patients was submitted to the US Food and Drug Administration, FDA.
- Marketing activities started for the hemophilia B product BeneFIX® in the Nordic region.
- Biovitrum signed an agreement with the Danish pharmaceutical company Lundbeck. Under the agreement, Lundbeck has licensed certain non-exclusive patent rights related to the 5-HT area and in fields outside Biovitrum's primary therapeutic area interests.

## January - September

- Net revenues were the same as in the corresponding period last year, and amounted to SEK 956.9 M (956.3). Net profit for the period amounted to SEK 81.4 M (99.0), which is equivalent to earnings per share of SEK 1.78 (2.12). This outcome, which has been previously communicated, is mainly due to increased research expenses and reduced revenues from contract development, which is though compensated by higher delivery levels of ReFacto<sup>®</sup>.
- Revenues from the hemophilia A product, ReFacto<sup>®</sup>, increased during the period by 18 percent to SEK 695.8 M (591.0).
- Revenues from other products increased by 30 percent.
- The cash flow from operations improved and amounted to SEK -14.7 M (-44.6). Cash and cash equivalents and short-term investments as of September 30 amounted to SEK 805.3 M (929.4).

Biovitrum will arrange Capital Market Days on 7 and 8 November in Stockholm and London respectively. More information can be found at <a href="https://www.biovitrum.com">www.biovitrum.com</a>.

|                                       | Jul 1 - Sep | 30     | Jan 1 - Sep | 30     | Full year |
|---------------------------------------|-------------|--------|-------------|--------|-----------|
| Amounts in SEK million                | 2007        | 2006   | 2007        | 2006   | 2006      |
| Total revenues                        | 199.8       | 248.2  | 956.9       | 956.3  | 1,201.1   |
| Operating profit/loss                 | -28.8       | -7.4   | 65.3        | 82.4   | 54.6      |
| Profit/loss after financial items     | -22.5       | 6.1    | 81.4        | 99.0   | 94.2      |
| Profit/loss for the period            | -22.5       | 5.6    | 81.4        | 99.0   | 92.7      |
| Earnings/loss per share               | -0.49       | 0.13   | 1.78        | 2.12   | 2.00      |
| Research & Development expenses       | -163.2      | -166.3 | -509.7      | -469.5 | -650.4    |
| Liquid funds & short term investments | 805.3       | 929.4  | 805.3       | 929.4  | 903.8     |

### **CEO** comments

"The financial results of the third quarter reflect the effect of extensive ReFacto® deliveries in the first six months and a conscious decision to allocate more resources to internal projects with lower contract development revenues as a result. It is gratifying to note the continued strong ReFacto® revenues in the first nine months of the year as well as the sustained strong growth in revenues from other products. Research expenses were slightly higher than the same period last year, which demonstrates that we are advancing our positions. One example of this is that we have taken important steps towards the first clinical trials for two of our key projects, Kiobrina and FIXFc", says Martin Nicklasson, CEO of Biovitrum.



# Overview third quarter

### Specification of Revenues

| Jul 1-Sep 30 Jan 1-Sep 30            |       |       |       |       | Full<br>year |
|--------------------------------------|-------|-------|-------|-------|--------------|
| Amounts i SEK million                | 2007  | 2006  | 2007  | 2006  | 2006         |
| Licensing and<br>Milestone revenues  | 63,8  | 44,2  | 152,1 | 132,5 | 176,6        |
| ReFacto® revenues                    | 103,3 | 135,7 | 695,8 | 591,0 | 768,0        |
| Revenues from Other<br>Product Sales | 22,2  | 16,2  | 57,7  | 44,4  | 57,9         |
| Other <sup>1)</sup>                  | 10,5  | 52,1  | 51,4  | 188,4 | 198,7        |
| Rörelsens intäkter                   | 199,8 | 248,2 | 956,9 | 956,3 | 1 201,1      |

 $<sup>^{1)}</sup>$  Other revenues includes e.g. research revenues, revenues from contract development and royalty from other products than ReFacto  $\!\!^{\otimes}$ 

Total revenues for the third quarter amounted to SEK 199.8 M (248.2). The decrease is in line with plan and is mainly referred to lower revenues from ReFacto® as well as from contract development and research collaborations.

# ReFacto® Specification of ReFacto® revenues

| Jul 1-Sep 30 Jan 1-Sep 30 |       |       |        |       | Full<br>year |
|---------------------------|-------|-------|--------|-------|--------------|
| Amounts in SEK million    | 2007  | 2006  | 2007   | 2006  | 2006         |
| Manufacturing revenues    | 44,7  | 77,1  | 516,0  | 416,0 | 536,0        |
| Co-promotion revenues     | 17,3  | 16,0  | 53,4   | 52,9  | 71,4         |
| Royalty revenues          | 41.3  | 42,7  | 126.54 | 122,1 | 160,6        |
| Total revenues            | 103.3 | 135,7 | 695.8  | 591,0 | 768,0        |

Revenues from ReFacto $^{\$}$  amounted to SEK 103.3 M in the third quarter of 2007 compared to SEK 135.7 M in the same period in 2006.

In the third quarter of 2007 manufacturing revenues decreased to SEK 44.7 M (77.1) as a result of the considerable deliveries during the first six months. The fourth quarter is expected to be in line with last year or somewhat higher. Total revenues for the full year are estimated at SEK 870–910 M. This is higher than 2006 and mainly attributable to first quarter deliveries of validation batches for the next generation of ReFacto®.

Global sales of ReFacto® increased by 10 percent to USD 85.7 M in the third quarter. Co-promotion revenues from ReFacto® sales in the Nordic region increased by 8 percent during the quarter.

### Other Product Sales

Revenues from product sales in the third quarter, including co-promotion, increased by just over 37 percent to SEK 22.2 M (16.2).

| Product    | Indication                |
|------------|---------------------------|
| BeneFIX®   | Hemophilia B              |
| Novastan®  | Anticoagulation           |
| Mimpara®   | Hyperparathyroidism       |
| Kineret®   | Rheumatoid arthritis      |
| Kepivance® | Side effects chemotherapy |
| Aloxi®     | Side effects chemotherapy |

In the third quarter Biovitrum started marketing the product  $BeneFIX^{\otimes}$  for the treatment of hemophilia B.

# Contract Manufacturing and Process Development

Biovitrum has unique manufacturing expertise and conducts advanced process development of recombinant protein drugs. This capacity is utilized both for the Company's internal projects and is offered as a service to external customers. Biovitrum has started to gradually reduce the proportion of external projects and accordingly, during the quarter, a greater proportion of the Company's capacity was used for the internal projects Exinalda<sup>TM</sup>, Anti-RhD, FIXFc and Kiobrina<sup>TM</sup>.

As a consequence of this and the fact that Biovitrum's agreements with Pfizer and Amgen expired in 2006 as planned, the external contract development revenues in the third quarter amounted to SEK 10.1 M (34.7).



# Research & Development

|          |                    |                               |             | Pre-<br>clinical<br>develop |         |          |           |
|----------|--------------------|-------------------------------|-------------|-----------------------------|---------|----------|-----------|
|          | Indication area    | Project                       | Partner     | ment                        | Phase I | Phase II | Phase III |
|          | Hemophilia A       | ReFacto® next                 | Wyeth       |                             |         |          |           |
|          | Fat malabsorption  | Exinalda™                     |             |                             |         |          |           |
|          | Glaucoma           | 5-HT <sub>2A</sub>            |             |                             |         |          |           |
|          | Neuropathic pain   | A <sub>2A</sub>               |             |                             |         |          |           |
| Clinical | Pre-term nutrition | Kiobrina™                     |             |                             |         |          |           |
|          | Diabetes           | 11β-HSD₁                      | Amgen       |                             |         |          |           |
|          | Obesity            | 5-HT <sub>6</sub>             |             |                             |         |          |           |
|          | AntiD prophylaxis  | Anti-Rh(D)                    | Symphogen   |                             |         |          |           |
|          | Platelet disorder  | Anti-Rh(D)                    | Symphogen   |                             |         |          |           |
|          | Hemophilia B       | FIXFc                         | Biogen/Idec |                             |         |          |           |
|          | Diabetes           | DPP-IV                        |             |                             |         |          |           |
|          | Obesity            | Leptin mimetic                |             |                             |         |          |           |
|          | Glaucoma           | 11 <b>β</b> -HSD <sub>1</sub> |             |                             |         |          |           |
|          | Diabetes           | Mnk                           |             |                             |         |          |           |
|          | Obesity            | SCD                           |             |                             |         |          |           |

The project portfolio continued to progress during the July to September 2007 period. Clinical trial applications were submitted to the relevant authorities and ethical committees for two projects. An application for two phase II trials was submitted in several European countries for Kiobrina<sup>TM</sup>, which is being developed to optimize fat absorption in preterm infants. The project has also received its first approvals in Italy and France and preparations are being made to initiate the studies.

The application to initiate the first clinical phase I/II study with FIXfc for hemophilia B patients has been submitted to the FDA. Biovitrum is working on this project in cooperation with the Company's partner Syntonix/Biogen Idec.

Most of the other projects are progressing according to plan. The dosing in the phase I study for the Anti-Rh (D) and  $5\text{-HT}_6$  projects have been concluded.

### Clinical Projects

Exinalda<sup>™</sup> for the treatment of fat malabsorption due to pancreatic insufficiency

Using biotechnological processes, Biovitrum is developing BSSL under the Exinalda™ brand. Exinalda™ is intended to improve the quality of life for patients suffering from fat malabsorption due to pancreatic insufficiency, for example in cystic fibrosis. A clinical study is currently under way to support the development of the preparation of Exinalda™.

### $5\text{-HT}_{2A}$ for the treatment of glaucoma

Biovitrum is developing compounds for the treatment of glaucoma with 5-HT $_{\rm 2A}$  antagonists, an entirely new principal for glaucoma drugs. The project is in clinical phase II, and the results will be available at the beginning of 2008.

### A<sub>2A</sub> for the treatment of neuropathic pain

The project objective is to develop a new substance with a unique mechanism of action for the treatment of neuropathic pain, a form of chronic pain arising from nerve damage. Unlike existing treatments that work via the brain, Biovitrum's substance is expected to act on the pain directly in the damaged nerve. Recruitment for the phase II study is progressing according to plan and the study may include up to 300 patients. The results are expected in the first half of 2008.

Kiobrina  $\ensuremath{^{\mathsf{TM}}}$  for optimizing fat absorption in preterm infants

BSSL produced using biotechnological processes under the Kiobrina<sup>TM</sup> brand, is developed to increase fat absorption in preterm infants. There is no product of this type on the market today. Applications to conduct two parallel clinical trials, one where BSSL will be administered in pasteurized breast milk and one where it will be administered in baby formula have been submitted to the regulatory authorities and ethical committees in a number of European countries. The project has received its first approvals, in Italy and France and preparations are being made to initiate the studies.

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This program is outlicensed to Amgen which owns the exclusive global rights to develop and commercialize these compounds. The project is in phase I and is being carried out by Amgen and overseen by a joint steering committee.

### 5-HT<sub>6</sub> for the treatment of obesity

Biovitrum is developing a  $5-HT_6$  antagonist for the treatment of obesity. The project is in phase I and the study is testing the safety and tolerability in healthy volunteers. The active study phase has been concluded and the results are expected before the end of the year.

Anti-Rh D for the treatment of thrombocytopenia and anti-D prophylaxis

In cooperation with the Danish company, Symphogen A/S, Biovitrum has, through biotechnological processes, developed an anti-Rhesus D (anti-RhD) with a new polyclonal technology. Anti-RhD is being developed for two different indications: for the treatment of a disease that affects the blood platelets (thrombocytopenia) and for the prevention of Rhimmunization in pregnancy (anti-D prophylaxis). The dosing in phase I is now concluded and the results from this first clinical study are expected to be ready by the end of the year.

### **Preclinical Projects**

FIXFc for the treatment of hemophilia B

Biovitrum and Syntonix/Biogen Idec are co-developing a recombinant protein drug for the treatment of hemophilia B, a hereditary disorder that leads to impairment in the production of factor IX and thereby also the blood's ability to coagulate. The objective of the FIXFc project is to develop a product with an extended half-life, which could mean that the patients would need only one injection per week for prophylactic treatment compared to 2–3 times per week as is the case today. The application for the first phase I/II study has been submitted to the FDA.

In addition to the above, Biovitrum has another five research programs: DPP IV to treat type 2 diabetes, Mnk inhibitor to treat type 2 diabetes, leptin mimetic and SCD inhibitors to treat obesity and inhibition of  $11B\text{-}HSD_1$  for glaucoma. These projects are based on mechanisms that have not been used before in therapies for the respective indications. More information about the projects is available at <a href="https://www.biovitrum.se">www.biovitrum.se</a>.

### Other

Throughout the years, Biovitrum has been accumulating extensive biological and chemical knowledge on



seratonergic mechanisms (5-HT) and their significance, among other things, for regulating food intake. Research & development work has resulted in numerous substances which can specifically interact with different 5-HT receptors. Under an agreement with the Danish pharmaceutical company Lundbeck, Biovitrum is now granting Lundbeck certain non-exclusive patent rights related to the 5-HT area and in fields outside Biovitrum's primary therapeutic area interests.

At the Annual General Meeting 2007 it was resolved upon an employee stock option plan. The employee stock options can be allotted within two categories. Category 1 includes the managing director with an allocation of no more than 300 000 employee stock options. Category 2 includes other members of the management with an allocation of no more than 150 000 employee stock options per member. An allotment of 300 000 employee stock options has been made to category 1.

Each employee stock option may be exercised up until and including 1 April 2012 to acquire one share with an exercise price of SEK 110.



# Financial Statements

### Revenues

Net revenues for the third quarter of 2007 amounted to SEK 199.8 M (248.2).

ReFacto® revenues in the third quarter amounted to SEK 103.3 M compared to SEK 135.7 M in the same period in 2006. Manufacturing revenues decreased to SEK 44.7 M (77.1) as a result of significant delivery levels in the first half of the year. In the fourth quarter, manufacturing revenues expected to be in line with or slightly higher than the previous year. Sales of ReFacto® in the Nordic region increased slightly during the period and copromotion revenues amounted to SEK 17.3 M (16.0).

The reported global sales of ReFacto® increased by 10 percent to USD 85.7 M. Biovitrum is, however, reporting a reduction in royalty revenues in the third quarter as a result of the weakening of the US dollar against SEK. However, the net profit was improved by just over SEK 6 M due to currency hedging of future royalty payments which are reported as other operating revenues/expenses.

Income from sales of other products increased by 37 percent, SEK 22.2 M (16.2).

In the third quarter, licensing and milestone revenues amounted to SEK 63.8 M (44.2).

Other revenues amounted to SEK 10.5 M (52.1). No research revenues were generated during the period. Research revenues in the third quarter of 2006, SEK 17.2 M, were mainly derived from a research agreement with Amgen which expired in 2006. Contract development revenues decreased to SEK 10.1 M (34.7) due to the fact that the framework agreements with Pfizer and Amgen expired in 2006 and a growing portion of the

### Consolidated Income Statement

|   | Jul 1 - Sep 30 | Ja     | n 1 - Sep 30 |        | Full year          |
|---|----------------|--------|--------------|--------|--------------------|
| Amounts in SEK million  | 2007           | 2006   | 2007         | 2006   | 2006               |
| Total revenues  | 199.8          | 248.2  | 956.9        | 956.3  | 1,201.1            |
| Cost of goods and services sold   | -34.1          | -51.5  | -260.6       | -241.9 | -293.8             |
| Gross profit  | 165.7          | 196.7  | 696.3        | 714.4  | 907.3              |
| Sales and Marketing expenses  | -8.6           | -7.4   | -29.1        | -24.5  | -41.6              |
| Administration expenses   | -27.2          | -33.9  | -91.8        | -100.1 | -121.9             |
| Research and Development expenses   | -163.2         | -166.3 | -509.7       | -469.5 | -650.4             |
| Other operating revenues  | 8.0            | 2.6    | 13.8         | 8.0    | 8.9                |
| Other operating expenses  | -3.7           | 0.8    | -14.1        | -46.1  | -47.7              |
| Operating profit/loss   | -28.8          | -7.4   | 65.3         | 82.4   | 54.6               |
| Interest income and similar items   | 6.7            | 13.8   | 16.9         | 17.9   | 41.1               |
| Interest expenses and similar items                                       | -0.4           | -0.3   | -0.8         | -1.2   | -1.5               |
| Profit/loss after financial items   | -22.5          | 6.1    | 81.4         | 99.0   | 94.2               |
| Tax on profit/loss for the period   | _              | -0.5   | _            | _      | -1.5               |
| Profit/loss for the period  | -22.5          | 5.6    | 81.4         | 99.0   | 92.7               |
| Earnings/loss per share after tax (SEK) Earnings/loss per share after tax | -0.49          | 0.13   | 1.78         | 2.12   | 2.00               |
| after full dilution (SEK) 1)  | -0.49          | 0.122) | 1.75         | 1.942) | 1.86 <sup>1)</sup> |

<sup>1)</sup> Average share market value for the period September 15 - December 29, 2006, has been used to calculate dilution.
2) Average share market value for the period September 15 - September 30, 2006, has been used to calculate dilution

Company's capacity is being used to develop internal projects.

### Profit/Loss

The cost of goods and services sold fell during the quarter to SEK 34.1 M (51.5), due to lower ReFacto® delivery levels and lower revenues from contract development. The gross profit was SEK 165.7 M (196.7).

The improved gross margin is the result of a better product mix, higher ReFacto® revenues, lower contract development revenues with low margins, as well as licensing revenues from Lundbeck.

Research & development expenses in the third quarter were in line with the same period in 2006, and amounted to SEK 163.2 M (166.3).

The operating profit for the third quarter decreased to SEK -28.8 M (-7.4).

The net financial income was SEK 6.3 M (13.5), and the net result for the quarter was SEK -22.5 M (5.6).



### Financial Position

Cash and cash equivalents and short term investments September 30, 2007 amounted to SEK 805.3 M (929.4). Of this, SEK 92 M was bank balances (111.9), and SEK 310.4 M (245.7) investments in securities with a term of less than three months from the date of acquisition. These short term investments are classified as cash and cash equivalents. Beside these cash and cash equivalents, the Company had, as of September 30, 2007 other short term investments with a term of more than three months, amounting to SEK 402.9 M (571.8).

# Changes in Shareholders' Equity

On September 30, 2007 share-holders' equity in the Group amounted to SEK 1,463.9 M compared to SEK 1,381.8 on December 31, 2006.

### Parent Company

In the third quarter the Parent Company reported revenues amounting to SEK 199.4 M (248.0). Cash and cash equivalents as of September 30, 2007 amounted to SEK 395.0 M (352.2). Shareholders' equity in Biovitrum AB (publ) amounted to SEK 1,460.6 M (1,376.3). For more detailed information, see enclosure 2

### **Taxes**

The Company has an accumulated loss carry-forward that has not been booked as an asset, which means that the Company's tax rate deviates from the general Swedish tax rate. Biovitrum's tax cost for the quarter was SEK 0 M (0).

### Personnel

As of September 30, 2007 Biovitrum had 546 employees of which 58 percent are women. No warrants were exercised during the period.

### Consolidated Balance Sheet

|  | Sep 30              | Sep 30              | Dec 31  |
|--|---------------------|---------------------|---------|
| Amounts in SEK million                     | 2007                | 2006                | 2006    |
| ASSETS                                     |                     |                     |         |
| Fixed assets                               |                     |                     |         |
| Intangible fixed assets                    | 499.6 <sup>1)</sup> | 446.3 <sup>1)</sup> | 472.9   |
| Tangible fixed assets                      | 283.3               | 247.2               | 262.5   |
| Financial fixed assets                     | 26.0                | 32.6                | 42.3    |
|  | 808.9               | 726.1               | 777.7   |
| Current assets                             |                     |                     |         |
| Inventories                                | 96.8                | 134.6               | 161.2   |
| Current receivables, non-interestbearing   | 291.6               | 313.7               | 235.0   |
| Short-term investments                     | 402.9               | 571.8               | 527.2   |
| Cash and cash equivalents                  | 402.4               | 357.6               | 376.6   |
|  | 1,193.8             | 1,377.7             | 1,300.0 |
| Total assets                               | 2,002.6             | 2,103.8             | 2,077.7 |
| EQUITY AND LIABILITIES                     |                     |                     |         |
| Shareholders' equity                       | 1,463.9             | 1,315.0             | 1,381.8 |
| Long term liabilities                      |                     |                     |         |
| Long term liabilities, non-interestbearing | 89.3                | 268.7               | 224.1   |
|  | 89.3                | 268.7               | 224.1   |
| Current liabilities                        |                     |                     |         |
| Current liabilities, non-interestbearing   | 449.4               | 520.1               | 471.8   |
|  | 449.4               | 520.1               | 471.8   |
| Total equity and liabilities               | 2,002.6             | 2,103.8             | 2,077.7 |

<sup>1)</sup> Including goodwill 41.1 M

# Change of Consolidated Shareholders' Equity

|                                | 2007    | 2006    | 2006    |
|--------------------------------|---------|---------|---------|
|                                | Jan 1 - | Jan 1 - | Jan 1 - |
| Amounts in SEK million         | Sep 30  | Sep 30  | Dec 31  |
| Opening balance                | 1,381.8 | 1,707.7 | 1,707.7 |
| Warrants issue (+)             | -       | 105.6   | 105.6   |
| Repurchase warrants (-)        | -       | -282.3  | -282.3  |
| Non registered issue of shares | -       | 5.9     | _       |
| Issue of share                 | _       | 57.2    | 136.9   |
| Redemption of shares 1)        | _       | -378.9  | -378.9  |
| Exchange rate difference       | 0.7     | 0.8     | 0.1     |
| Net profit/loss for the year   | 81.4    | 99.0    | 92.7    |
| Equity, end of period          | 1,463.9 | 1,315.0 | 1,381.8 |

<sup>1)</sup> Refering to redemption and payment of Pfizer's shares



### Cash Flow

Cash flow from operations for the third quarter of 2007 amounted to SEK -46.4 M (-71.4).

Intangible asset acquisitions amounted to SEK 0 M (0).

Cash and cash equivalents and short term investments as of September 30, 2007 amounted to SEK 805.3 M (929.4).

### Investments

The Group's investments in fixed assets in the third quarter amounted to SEK 25.4 M (18.2). Depreciation in the third quarter amounted to SEK 15.2 M (19.2).

### Outlook 2007

ReFacto® revenues for the full year are expected to be in the range of SEK 870–910 M. The increase in 2007 is mainly attributable to first quarter deliveries of validation batches for the next generation of ReFacto®.

The increase in ReFacto® revenues, combined with other product sales, compensates for the decline in revenues from contract development and research collaborations. In the full year forecast, the total revenues are expected to be in line with previous year or slightly better, i.e. in the range of SEK 1,200–1,250 M.

Research & development expenses in the fourth quarter are expected to be at the same level as in the fourth quarter of 2006.

### Capital Markets Days

Following the Q3 results and the continued development of our growing portfolio of both R&D projects and marketed products, Biovitrum will arrange Capital Markets days on November 7 and 8 in Stockholm and London respectively. We will then present our strategy going forward and give a closer look at our R&D pipeline. Further information will be found at <a href="https://www.biovitrum.com">www.biovitrum.com</a>.

### Condensed Consolidated Cash Flow

|  | Jul 1 - Se | p 30   | Jan 1 - Sep 30       |         | Full year |  |
|--|------------|--------|----------------------|---------|-----------|--|
| Amounts in SEK million   | 2007       | 2006   | 2007                 | 2006    | 2006      |  |
| Net result   | -22.5      | 5.5    | 81.4                 | 99.0    | 92.7      |  |
| Adjustment for items not affecting cash flow:                    | 22.5       | 5.5    | 01.4                 | 77.0    | ,2.,      |  |
| Depreciations and Write down                                     | 15.2       | 19.2   | 54.7                 | 56.1    | 74.5      |  |
| Capital gain/loss from divestment fixed                          | 10.2       |        |                      |         |           |  |
| assets   | -          | 1.5    | -2.5                 | 45.4    | 45.4      |  |
| Revaluation of fixed financial assets                            | -          | -      | -                    | -       | -7.8      |  |
| Pensions   | 0.1        | -      | 0.1                  | -       | -4.9      |  |
| Deferral of fees from Amgen                                      | -44.2      | -44.2  | -132.5               | -132.5  | -176.6    |  |
| Other items  | -          | -      | -                    | -3.5    | -3.5      |  |
| Cash flow from operations before                                 |            |        |                      |         |           |  |
| change in working capital  | -51.3      | -18.0  | 1.3                  | 64.6    | 19.9      |  |
| Change in working capital excl changes in restructuring reserves | 8.3        | 6.0    | -4.1                 | -35.8   | -24.7     |  |
| Change in restructuring reserves                                 | -3.4       | -59.4  | -11.9                | -73.4   | -83.1     |  |
| Cash flow from operations  | -46.4      | -71.4  | -14.7                | -44.6   | -88.0     |  |
| Investment in operation  | -          | -41.2  | -                    | -41.2   | -41.1     |  |
| Investment in intangible fixed assets                            | 0.0        | 0.0    | -31.0                | -53.6   | -84.3     |  |
| Investment in tangible fixed assets                              | -25.4      | -18.2  | -75.0                | -40.3   | -70.2     |  |
| Divestment of tangible fixed assets                              | -          | -      | 6.1                  | -       | -         |  |
| Investment/Divestment of financial assets                        | 0.4        | -5.0   | 16.1                 | -20.8   | -15.8     |  |
| Short term investments   | 62.3       | -34.1  | 124.3                | -9.2    | 35.5      |  |
| Cash flow from investing activities                              | 37.2       | -98.4  | 40.5                 | -165.0  | -175.9    |  |
| Issue of shares  | _          | 63.1   | _                    | 63.1    | 136.9     |  |
| Redemption of shares   | -          | 0.1    | _                    | -378.9  | -378.9    |  |
| Issue of warrants  | _          | 105.6  | _                    | 105.6   | 105.6     |  |
| Re-purchase of warrants  | -          | -281.6 | -                    | -281.6  | -282.3    |  |
| Cash flow from financing activities                              | -          | -112.8 | -                    | -491.8  | -418.7    |  |
| Net change in cash   | -9.1       | -282.7 | 25.8                 | -701.4  | -682.6    |  |
| Liquid funds at the beginning of the period                      | 411.5      | 638.6  | <b>25.6</b><br>376.6 | 1,058.6 | 1,058.6   |  |
| Translation difference in cash flow and liquid funds             | 0.1        | 1.7    | 0.0                  | 0.4     | 0.6       |  |
| Liquid funds at the end of the period                            | 402.4      | 357.6  | 402.4                | 357.6   | 376.6     |  |
| Short-term investments   | 402.9      | 571.8  | 402.9                | 571.8   | 527.2     |  |
| Liquid funds and short-term                                      |            |        |                      |         |           |  |
|  |            |        |                      |         |           |  |



# Key Rations and Other Information

| Jul 1 - Sep 30          |   | Jan 1 - Se   | Full year   |  |
|-------------------------|---|--|---|--|
| 2007                    | 2006  | 2007   | 2006  | 2006   |
|                         |   |  |   |  |
| -1 5%                   | 0.4%  | 5 7%   | 6.6%  | 6,0%   |
| •                       | •   | •  | •   | 3,9%   |
| -1,170                  | 0,570   | 4,070  | 4,170   | 3,770  |
|                         |   |  |   |  |
| 82,9%                   | 79,3%   | 72,8%  | 74,7%   | 75,5%  |
| -14,4%                  | -3,0%   | 6,8%   | 8,6%  | 4,5%   |
| -11,2%                  | 2,3%  | 8,5%   | 10,4%   | 7,7%   |
| -6,8%                   | 4,8%  | 12,5%  | 14,5%   | 10,8%  |
|                         |   |  |   |  |
| 32,1                    | 29,7  | 32,1   | 29,7  | 30,3   |
| 31,5                    | 28,5  | 31,4   | 28,5  | 29,6   |
| -0,2                    | -6,5  | 0,6  | -15,0   | -14,7  |
| -0,2                    | -6,5  | 0,6  | -15,0   | -14,7  |
|                         |   |  |   |  |
| 73,1%                   | 62,5%   | 73,1%  | 62,5%   | 66,5%  |
| 45 622 700              | 44 271 700  | 45 622 700   | 44 271 700  | 45 622 700   |
| 45 622 700              | 43 325 137  | 45 622 700   | 46 683 593  | 46 323 738   |
| 2 686 136 <sup>3)</sup> | 3 151 636   | 2 686 136 <sup>3)</sup>  | 3 151 636   | 2 371 136  |
| 46 490 221              | 46 078 780 <sup>2)</sup>  | 46 626 409   | 46 078 780 <sup>2)</sup>  | 46 745 433 <sup>1)</sup>   |
| 46 490 221              | 47 283 689 <sup>2)</sup>  | 46 626 728   | 51 031 724 <sup>2)</sup>  | 49 855 707 <sup>1)</sup>   |
|                         | 2007  -1,5% -1,1%  82,9% -14,4% -11,2% -6,8%  32,1 31,5 -0,2 -0,2  73,1%  45 622 700 45 622 700 2 686 136 <sup>3</sup> 46 490 221 | 2007 2006  -1,5% 0,4% -1,1% 0,3%  82,9% 79,3% -14,4% -3,0% -11,2% 2,3% -6,8% 4,8%  32,1 29,7 31,5 28,5 -0,2 -6,5 -0,2 -6,5 -0,2 -6,5 -0,2 -6,5  73,1% 62,5%  45 622 700 44 271 700 45 622 700 43 325 137 2 686 136 <sup>3)</sup> 3 151 636 46 490 221 46 078 780 <sup>2)</sup> | 2007         2006         2007           -1,5%         0,4%         5,7%           -1,1%         0,3%         4,0%           82,9%         79,3%         72,8%           -14,4%         -3,0%         6,8%           -11,2%         2,3%         8,5%           -6,8%         4,8%         12,5%           32,1         29,7         32,1           31,5         28,5         31,4           -0,2         -6,5         0,6           -0,2         -6,5         0,6           73,1%         62,5%         73,1%           45 622 700         44 271 700         45 622 700           45 622 700         43 325 137         45 622 700           2 686 136 <sup>3)</sup> 3 151 636         2 686 136 <sup>3)</sup> 46 490 221         46 078 780 <sup>2)</sup> 46 626 409 | 2007         2006         2007         2006           -1,5%         0,4%         5,7%         6,6%           -1,1%         0,3%         4,0%         4,1%           82,9%         79,3%         72,8%         74,7%           -14,4%         -3,0%         6,8%         8,6%           -11,2%         2,3%         8,5%         10,4%           -6,8%         4,8%         12,5%         14,5%           32,1         29,7         32,1         29,7           31,5         28,5         31,4         28,5           -0,2         -6,5         0,6         -15,0           -0,2         -6,5         0,6         -15,0           73,1%         62,5%         73,1%         62,5%           45 622 700         44 271 700         45 622 700         44 271 700           45 622 700         43 325 137         45 622 700         46 683 593           2 686 136³         3 151 636         2 686 136³         3 151 636           46 490 221         46 078 780²         46 626 409         46 078 780² |

<sup>1)</sup> The average market price of the share for the period September 15 – December 29, 2006 has been used to calculate the dilution. Average number of shares after dilution has been adjusted compared to what was reported in annual report 2006 due to an error in previous calculations.

### Return on shareholders' equity

Profit after tax as a percentage of average shareholders' equity.

### Return on total capital

Profit after financial items plus financial expenses as a percentage of average total assets.

#### Gross margin

Gross profit as a percentage of net

#### Operating margin

Operating profit as a percentage of net sales

### Profit margin

Profit for the period as a percentage of net sales.

### EBITDA margin

Operating profit plus depreciation and amortization as a percentage of net sales.

#### Shareholders' equity per share

Shareholders' equity divided by the number of shares.

# Shareholders' equity per share after

Shareholders' equity divided by the number of shares after dilution.

## Cash flow per share

Changes in cash and cash equivalents divided by the weighted average number of shares.

### Cash flow per share after dilution

Changes in cash and cash equivalents divided by the weighted average number of shares after dilution.

### **Equity ratio**

Shareholders' equity as a proportion of total assets.

<sup>2)</sup> The average market price of the share for the period September 15 – September 30, 2006 has been used to calculate the dilution.

<sup>3)</sup> There are three different warrant programs outstanding, exercisable for a maximum of 2,746,136 new shares in total.



# Accounting and valuation principles and other information

# Accounting and valuation principles and other information

This interim report has been prepared in accordance with IAS 34 Interim Financial Reporting, which is in accordance with the requirements in the recommendation of the Swedish Financial Accounting Standards Council, RR 31 Interim Reporting for Groups. As of January 1, 2005, Biovitrum AB (publ) is applying the International Financial Reporting Standards (IFRS) in accordance with EU regulations. The accounting principles applied are those described in Biovitrum's 2006 Annual Report.

## Related party transactions

Autumn 2006, Biovitrum entered into an agreement with the Swedish biotech company Synphora AB. Under the agreement Biovitrum received rights to, under certain conditions, acquire Synphora's drug candidate for treatment, among other things, of the inflammatory

skin disease psoriasis. Under the terms of the agreement Biovitrum co-financed Synphora's studies with a maximum of SEK 5 M in total, of which SEK 2 M were paid in October 2006 and SEK 3 M were paid in February 2007.

A clinical phase II study was finalized in 2007 and the substance proved no significant effect with any of the tested doses. Biovitrum does not intend to invest further in the project.

Toni Weitzberg is a member of the board of Biovitrum AB (publ) and the chairman of the board of Synphora AB.

This interim report includes forward-looking statements. Actual results may differ from those stated. Internal factors such as the successful management of research programs and intellectual property rights may affect future results. There are also external conditions, for example, the economic climate, political changes and competing research programs that may affect Biovitrum's results.

Solna, October 23, 2007

Martin Nicklasson Chief Executive Officer

Interim Report January 1 – September 30, 2007



### Review Report

We have reviewed this report for the period 1 January 2007 to 30 September 2007 for Biovitrum AB (publ). 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. We conducted our review in accordance with the Standard on Review Engagements SÖG 2410, Review of Interim Report Performed by the Independent Auditor of the Entity, issued by FAR. 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 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.

Based on our review, nothing has come to our attention that causes us to believe that the interim report has not, in all material respects, been prepared in accordance with IAS 34 and the Annual Accounts Act, regarding the Group, and with the Annual Accounts Act, regarding the Parent Company.

Stockholm, 23 October, 2007 PricewaterhouseCoopers AB

Peter Bladh Authorised Public Accountant Auditor in charge Mikael Winkvist Authorised Public Accountant

Interim Report January 1 – September 30, 2007



Biovitrum AB (publ)

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Financial calendar:

Full year Report 2007 Interim Report Jan-March, 2008 Interim Report April-June, 2008 Interim Report July-Sept, 2008 February 21, 2008 April 24, 2008 July 24, 2008 October 22, 2008



Biovitrum is one of the largest biopharma companies in Europe. With operations in Sweden and the UK, Biovitrum conducts research and develops pharmaceuticals for unmet medical needs, both for common diseases and conditions that affect smaller patient populations. Biovitrum focuses on drugs for the treatment of obesity, diabetes, inflammation and blood diseases, as well as a number of well-defined specialist indications. Biovitrum develops and produces protein-based drugs on a contractual basis and markets a range of specialist pharmaceuticals primarily in the Nordic countries.

For more information, see www.biovitrum.com.

Interim Report January 1 – September 30, 2007



Enclosure 1

### Risk Management

All business operations involve risk. Managed risk taking is a condition for maintaining a sustained favourable profitability. Risks may be due to events in the world and can effect a given industry or market. Risk can also be specific to a certain company. Biovitrum work to identify, measure and manage risk, and in some cases we can also influence the likelihood that a risk related event will occur. In cases in which events are beyond our control, we focus on the work to minimize the consequences.

Biovitrum are exposed to three main risk categories:

#### External related risks, e.g.

- there is no guarantee that products and processes that are included in patents already granted, will not be challenged or contested by competitors, or that granted patents will not infringe upon a competitor's patent.
- there is always a risk that the company's product concepts will be driven out of the market by similar products or that entirely new product concepts will prove superior.

### Operational risks, e.g.

- Developing of a new drug up to and including launch is a both capital-intensive and hazardous process.
- Collaboration with external partners depends largely on the work of the company's partners or license holders, since these parties retain the right to a large extent to determine the amount of work and resources that will be invested in the projects
- Production and sale of ReFacto®, which represent the majority of the company's revenues, in the case that Biovitrum's production facilities were to be destroyed, damaged or for some other reason required to be shut down, would seriously affect the company's ability to manufacture ReFacto® and the company would lose a significant portion of its revenues.
- Manufacturing and sale of drug products carries significant risk for product liability claims.
- Handling hazardous materials, when The company is required to comply with laws and regulations that regulate the
  use, manufacture, storage, handling and disposal of such materials and waste products. Although the company feels
  that its safety routines for the management and disposal of such materials meet the prescribed standards, it is not
  possible to entirely eliminate the risk of unintentional contamination or personal injury from such materials.

### Financial risks, e.g.

• The company's business is exposed to currency rate risk as a considerable portion of the revenues are paid in foreign currency, and is subject to different forms of tax exposure as a result of numerous restructuring measures and other transactions that the company has carried out or been involved in, including restructuring in connection with the transfer of operations and property. Biovitrum believes that all of these transactions have been executed, accounted for and declared correctly and in accordance with the applicable tax laws and practices.

For a more detailed description of Biovitrum's risk exposure we refer to the Annual Report 2006 which can be found at <a href="https://www.biovitrum.se">www.biovitrum.se</a>.

# Interim Report January 1 – September 30, 2007



## Enclosure 2

# Financial Statements for parent company Biovitrum AB (publ)

### Income statement - Parent company

| ·  | Jul 1 - Sep 30 |        | Jan 1 - Sep 30 |        | Full year |  |
|--|----------------|--------|----------------|--------|-----------|--|
| Amounts in SEK million                       | 2007           | 2006   | 2007           | 2006   | 2006      |  |
| Total revenues                               | 199.4          | 248.0  | 956.3          | 955.7  | 1,200.3   |  |
| Cost of goods and services sold              | -34.1          | -51.4  | -260.6         | -241.9 | -293.8    |  |
| Gross profit                                 | 165.3          | 196.5  | 695.7          | 713.8  | 906.5     |  |
| Sales and Marketing expenses                 | -8.6           | -7.4   | -29.1          | -24.5  | -41.6     |  |
| Administration expenses                      | -18.9          | -34.0  | -94.0          | -102.6 | -125.6    |  |
| Research and Development expenses            | -162.0         | -163.5 | -506.0         | -446.6 | -634.2    |  |
| Other operating revenues                     | 8.0            | -0.1   | 13.8           | 1.6    | 2.4       |  |
| Other operating expenses                     | -11.4          | 1.1    | -11.6          | -44.1  | -47.4     |  |
| Operating profit/loss                        | -27.5          | -7.2   | 68.6           | 97.7   | 60.1      |  |
| Result from participation in Group companies | _              | 0.0    | _              | -2.0   | -56.7     |  |
| Interest income and similar items            | 6.5            | 13.7   | 16.5           | 17.7   | 40.9      |  |
| Interest expenses and similar items          | -0.4           | -0.3   | -0.8           | -1.0   | -1.3      |  |
| Profit/loss after financial items            | -21.4          | 6.2    | 84.3           | 112.4  | 43.0      |  |
| Tax on profit/loss for the period            | _              | _      | _              | _      | -1.5      |  |
| Profit/loss for the period                   | -21.4          | 6.2    | 84.3           | 112.4  | 41.5      |  |

### Condensed balance sheet - Parent company

|  | Sep 30  | Sep 30  | Dec 31  |
|--|---------|---------|---------|
| Amounts in SEK million                     | 2007    | 2006    | 2006    |
| ASSETS                                     |         |         |         |
| Fixed assets                               |         |         |         |
| Intangible fixed assets                    | 149.1   | 95.5    | 122.2   |
| Tangible fixed assets                      | 275.7   | 238.8   | 255.0   |
| Financial fixed assets                     | 760.5   | 802.7   | 776.8   |
|  | 1,185.4 | 1,137.0 | 1,154.0 |
| Current assets                             |         |         |         |
| Inventories                                | 96.8    | 134.6   | 161.2   |
| Current receivables, non-interestbearing   | 243.5   | 277.5   | 231.7   |
| Short-term investments                     | 402.9   | 571.9   | 527.2   |
| Cash and cash equivalents                  | 395.0   | 352.2   | 370.6   |
|  | 1,138.2 | 1,336.2 | 1,290.6 |
| Total assets                               | 2,323.6 | 2,473.2 | 2,444.6 |
| EQUITY AND LIABILITIES                     |         |         |         |
| Shareholders' equity                       | 1,460.6 | 1,374.1 | 1,376.3 |
| Long term liabilities                      |         |         |         |
| Long term liabilities, non-interestbearing | -       | 176.6   | 132.5   |
|  | -       | 176.6   | 132.5   |
| Current liabilities                        |         |         |         |
| Current liabilities, non-interestbearing   | 863.0   | 922.4   | 935.9   |
|  | 863.0   | 922.4   | 935.9   |
| Total equity and liabilities               | 2,323.6 | 2,473.2 | 2,444.6 |

## Change of parent company's shareholders' equity

|                                | 2007    | 2006    | 2006    |
|--------------------------------|---------|---------|---------|
|                                | Jan 1 - | Jan 1 - | Jan 1 - |
| Amounts in SEK million         | Sep 30  | Sep 30  | Dec 31  |
| Opening balance                | 1,376.3 | 1,753.5 | 1,753.5 |
| Warrants issue (+)             | _       | 105.6   | 105.6   |
| Repurchase warrants (-)        | -       | -281.6  | -282.3  |
| Non registered issue of shares | -       | 5.9     | -       |
| Issue of share                 | -       | 57.2    | 136.9   |
| Redemption of shares 1)        | -       | -378.9  | -378.9  |
| Net profit/loss for the year   | 84.3    | 112.4   | 41.5    |
| Equity, end of period          | 1,460.6 | 1,374.1 | 1,376.3 |

<sup>1)</sup> Referring to redemption and payment of Pfizer's shares