biovitrum.

# Interim Report 1st April – 30th June, 2009
*(translation only)*

## Continued strong revenue growth and good progress of R&D projects

### April - June

- Total revenues before license revenues increased by 31 percent to SEK 319.9 M (243.8).
- Operating result (EBIT) was SEK -13.1 M (-98.0). Earnings for the period amounted to SEK 16.8 M (-96.6), which is equivalent to an earnings per share of SEK 0.33 (-2.12).
- Cash flow from operations was SEK 45.1 (-75.6). Cash and cash equivalents and short-term investments as of June 30th amounted to SEK 341.2 M (635.6).
- Transfer costs related to Kineret® and Kepivance® have increased the product rights with SEK 39.1 M and will be amortized over 15 years.
- On June 1st, the launch of ReFacto AF® in Europe was started.
- One of the two clinical phase II studies with Kiobrina™, successfully completed patient recruitment and the proof of concept study with Exinalda™ also completed the enrolment of patients.
- A clinical phase II study is proceeding well at 23 clinics in Europe to study the safety and the therapeutic efficacy of Sym001 in ITP patients. Two dose cohorts have been treated, and the independent safety committee has recommended to continue to the next dose group.
- Out-licensing and divestment of primary care projects continue. On June 22nd , Biovitrum signed a Transferring Agreement with iNovacia AB to continue development of two metabolic disease projects.
- A new performance based, long term share program was initiated and 231,585 new series C shares will be issued.
- Peter Sellei and Hans Glemstedt from Investor AB were elected new members of the Board, Håkan Åström was re-elected Chairman of the Board and the rest of the 2008 Board members were re-elected except from Anders Hultin and Toni Weitzberg from Nordic Capital who had declined re-election

### January – June

- Total revenues before license revenues increased by 52 percent to SEK 675.1 M (443.8). Earnings for the period amounted to SEK -6.9 M (-98.7), which is equivalent to an earnings per share of SEK -0.14 (-2.16).
- Cash flow from operations was SEK -83.1 M (-98.5).

### Events after the period

- Biovitrum has entered into an exclusive distribution and marketing agreement with Megapharm Ltd. allowing Kineret and Kepivance to be commercialized in Israel.
- Biovitrum has selected The Bank of New York Mellon (NYSE: BK), as the depositary bank for its Level I American Depositary Receipt (ADR) program.

| *Amounts in SEK million* | Apr 1 - Jun 30 2009 | Apr 1 - Jun 30 2008 | Jan 1 - Jun 30 2009 | Jan 1 - Jun 30 2008 |
|---|---|---|---|---|
| **Total revenues before license revenues** | **319.9** | **243.8** | **675.1** | **443.8** |
| Total revenues | 319.9 | 287.9 | 675.1 | 532.1 |
| Operating profit/loss before depreciations and amortizations (EBITDA) | 4.6 | -74.2 [1)] | 32.6 | -67.0 [1)] |
| Operating profit/loss (EBIT) | -13.1 | -98.0 [1)] | -1.1 | -106.5 [1)] |
| **Profit/loss for the period** | **16.8** | **-96.6** [1)] | **-6.9** | **-98.7** [1)] |
| Earnings/loss per share before dilution | 0.33 | -2.12 [1)] | -0.14 | -2.16 [1)] |
| Research and development expenses | 162.2 | 167.7 | 306.0 | 338.6 |
| Liquid funds and short-term investments | 341.2 | 635.6 | 341.2 | 635.6 |

[1)] Amount including restructuring expenses of SEK 120.0 M

## CEO comments:

"In 2009 we have successfully continued our transformation of Biovitrum into an international pharmaceutical company, which is reflected both by a gratifying sales development for our marketed products, and a good progress of our R&D projects. At the same time, we further divested non-core projects, of which the agreement with iNovacia regarding two projects is a good example. We continue strengthening the infrastructure needed for our key products and going forward, we intend to grow both organically and through acquisitions", says CEO Martin Nicklasson.

# Overview April – June 2009

## Sales & Marketing

Sales & Marketing has seen an addition of several key staff strengthening the skills and capabilities around Kineret® and Kepivance®. Furthermore, intense work is carried out to develop future marketing strategies and prepare for market expansion of Kineret and Kepivance. The Kineret Commercial Team had an exhibition booth at the annual meeting of the European League Against Rheumatism (EULAR) in Copenhagen. At a Key Opinion Leader workshop, hosted by Scientific Communications at EULAR, the role of IL-1 in rheumatoid arthritis as well as the benefits of Kineret treatment in IL-1 level elevated patients, were discussed.

On June 1st, 2009, ReFacto AF® was launched in Europe, initially in the Nordic region. ReFacto AF (Xyntha® in the US and Canada) is produced in a further developed production process and is therefore purer in terms of foreign proteins, a step that further enhances safety for hemophilia patients. Some 15 educational meetings were held in Finland, in order to facilitate the shift from ReFacto® to ReFacto AF. At the Nordic hemophilia meeting in Oslo, Biovitrum presented its hemophilia products, as well as the thrombin inhibitor Novastan®.

Changed guidelines in Denmark related to the use of anti emetics when treating certain cancer diseases now also include Aloxi®, which during April and May resulted in an increased demand in Denmark.

### Product sales

| *Amounts in SEK million* | Apr 1 - Jun 30 | | Jan 1 - Jun 30 | | Full year |
|---|---|---|---|---|---|
| | **2009** | **2008** | **2009** | **2008** | **2008** |
| Kineret | 110.2 | – | 214.2 | – | 25.8 |
| Kepivance | 26.8 | – | 56.4 | – | 5.7 |
| Stemgen | 0.8 | – | 1.8 | – | 0.6 |
| Aloxi | 0.6 | 1.5 | 3.8 | 2.7 | 5.3 |
| Novastan | 0.1 | -0.4 | 0.3 | 0.3 | 0.8 |
| Other | 0.4 | – | 0.4 | – | – |
| **Total revenues** [1)] | **138.9** | **1.1** | **276.9** | **3.0** | **38.2** |

[1)] In 2008, until the time of the acquisition, Biovitrum reported sales of Kepivance and Kineret as co-promotion revenues. Kineret and Kepivance are sold globally, Stemgen® is sold in Canada and Australia while Aloxi and Novastan are sold in the Nordic countries.

Kineret showed a solid performance and grew 6 percent in SEK and 10 percent in local currency in the second quarter compared to the first quarter in 2009.

Kepivance sales showed a slight decrease during the second quarter mainly due to the performance in Europe, in particular in Germany, where changes in reimbursement levels have taken place. An action program is being developed to secure desired reimbursement levels in the near future. However, in the US an increase of Kepivance volumes was noticed.

For product information see *www.biovitrum.com*.

### Co-promotion revenues

| Amounts in SEK million | Apr 1 - Jun 30 | | Jan 1 - Jun 30 | | Full year |
|---|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 | 2008 |
| ReFacto | 28.9 | 21.0 | 47.1 | 42.0 | 80.2 |
| BeneFIX | 2.9 | 2.3 | 5.1 | 5.7 | 10.4 |
| Mimpara | 6.2 | 5.5 | 12.7 | 11.1 | 22.7 |
| Kineret | – | 16.1 | – | 30.9 | 61.2 |
| Kepivance | – | 0.1 | – | 0.1 | 0.2 |
| Other | 0.3 | – | 0.4 | – | – |
| **Total revenues** | **38.3** | **45.0** | **65.3** | **89.8** | **174.7** |

In comparison with 2008, co-promotion revenues for ReFacto increased in the second quarter by 37 percent and amounted to SEK 28.9 M (21.1). Sales to end customers have increased even more, by 51 percent during the second quarter and by 30 percent during the first six months compared to our reported revenues. ReFacto's market share in the Nordic countries has increased during the second quarter.

Co-promotion revenues for Mimpara® and Benefix® also showed a strong increase in the period and amounted to SEK 6.2 M (5.5) and SEK 2.9 (2.3) respectively.

For product information see *www.biovitrum.com*.

### Royalty

The royalty revenues consist entirely of revenues from Wyeth's sales of ReFacto and ReFacto AF. The royalty amounted to SEK 43.2 M (44.3) in the second quarter. The slight decrease is explained by the introduction of ReFacto AF and Xyntha at a lower royalty rate.

## Manufacturing and Contract Development

Biovitrum solely manufactures the active substances for ReFacto AF® (Xyntha®). The newly developed manufacturing process entails great advantages compared to the former one used for ReFacto®. In addition to the exclusion of all foreign proteins the new process gives a higher yield which enables an increased production volume in response to future raised market demands. Also the purification procedure that is part of the manufacturing process has been scaled up and updated.

ReFacto manufacturing revenues declined according to plan in the second quarter to SEK 95.1 M (139.0) despite the fact that the volume delivered was higher compared with the same period 2008. This is the result of a lower unit price for the new drug substance. For the first six months, a 2 percent decline of the revenues can be noticed compared to 2008. As stated before, volumes will continue to vary from one quarter to the other as a result of Wyeth's production planning.

Other contract development revenues continue to decline as a result of the strategic decision to use the company's biopharmaceutical expertise entirely for in-house projects/products.

| Amounts in SEK million | Apr 1 - Jun 30 | | Jan 1 - Jun 30 | | Full year |
|---|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 | 2008 |
| ReFacto | 95.1 | 139.0 | 231.7 | 235.3 | 569.3 |
| *of which validation batches* | – | – | – | – | 47.0 |
| Contract development | 4.4 | 14.5 | 9.7 | 29.4 | 49.7 |
| **Total** | **99.5** | **153.5** | **241.4** | **264.7** | **619.0** |

## Product development

The clinical and regulatory organizations have been strengthened in order to manage the new products. In addition, Kepivance® and Kineret® are now supported by so called Brand Teams which include representatives from various parts of the organization. Their assignment is to manage the short and long term strategy for optimizing the commercial potential of these products.

As part of the regulatory post-marketing commitments for Kepivance, follow-up clinical studies are being conducted. Assessment of additional line extension or label extension opportunities is ongoing.

Biovitrum has also initiated a survey of rare diseases where insufficient control of the IL-1 system is the cause of the disease. In addition, during the second quarter, a new pre-clinical program was started, to develop IL-1 inhibitors for treating rare diseases with large unmet medical needs.

### Development projects

***Kepivance*** *for the treatment of oral mucositis associated with cancer treatment in children*
A clinical study with Kepivance is currently ongoing in which children with acute leukemia who are undergoing stem cell transplants are being treated. The purpose of the study, which is expected to include approximately 27 children aged 1 to 16 years, is primarily to study safety and pharmacokinetics. The study, which is being conducted in the US, will also document the therapeutic effect on inflammation in the mouth and throat. Results of this study will be available during 2010.

***Kiobrina™*** *for the treatment of fat malabsorption in premature infants*
In parallel, two phase II clinical trials – one in which rhBSSL is administered in pasteurized breast milk and one in which it is administered in baby formula – are currently ongoing in Italy and France. Patient recruitment for the first study has now been completed. Results and decision to start the phase III trials are expected during the end of 2009.

***Exinalda™*** *for the treatment of fat malabsorption due to pancreatic insufficiency*
A clinical proof of concept study with Exinalda has completed the patient recruitment. The purpose of the study is to document the clinical efficacy of Exinalda in patients with pancreatic insufficiency due to cystic fibrosis. The study has been performed in Poland and the Netherlands. Results will be reported during the second half of 2009.

***Sym001*** *for the treatment of idiopathic thrombocytopenia purpura (ITP) and prophylaxis of Rh immunization*
A phase I study has been successfully completed. A clinical study that shows that Sym001 can eliminate RhD positive red blood cells from the circulation of RhD negative healthy volunteers has also been concluded. In addition, a clinical phase II study is progressing well at 23 clinics in Europe with the aim to study the safety and efficacy of Sym001 in ITP patients. Two dose cohorts have been treated, and the independent safety committee has recommended to continue to the next dose group. This study is expected to be completed in the first half of 2010.

***Factor IX Fc*** *(FIXFc) for the treatment of hemophilia B*
A clinical phase I/IIa study with FIXFc in hemophilia B patients is ongoing. The study is being conducted at clinics in the US and is studying the safety, tolerability and pharmacokinetics of FIXFc in these patients. Results are expected towards the end of 2009 and will form the basis for a decision to proceed to phase III studies.

***Factor VIIIFc*** *(FVIIIFc) for the treatment of hemophilia A*
This project is currently in the preclinical phase. The first clinical phase I/II study is planned to start at the end of 2009.

### Business development

As part of Biovitrum's strategy, a process is ongoing to find partners for the small molecule primary care projects. In early 2009, the divestment of Cambridge Biotechnology Ltd. was initiated. The process is expected to be finalized during the third quarter.

On June 22nd, Biovitrum announced that two pre-clinical metabolic disease projects, GPR 119 and SCD-1 will be transferred to iNovacia AB. The agreement includes a split of all future revenues from the projects, where Biovitrum receives 30 percent. Biovitrum will also receive royalties from future product sales resulting from the projects. Within the agreement, iNovacia will be able to add additional partners to further develop the projects. In the first quarter of 2009, Biovitrum also announced the divestment of a project to Karolinska Development.

A program has been launched aiming at increasing the geographical presence of Kineret and Kepivance. Several contacts have been made with potential distribution partners. The first deal was made in early July with Megapharm in Israel.

# Financial Statements

## Revenues

| *Amounts in SEK million* | Apr 1 - Jun 30 2009 | Apr 1 - Jun 30 2008 | Jan 1 - Jun 30 2009 | Jan 1 - Jun 30 2008 | Full year 2008 |
|---|---|---|---|---|---|
| Product sales | 138.9 | 1.1 | 276.9 | 3.0 | 38.2 |
| Co-promotion revenues | 38.3 | 45.0 | 65.3 | 89.8 | 174.7 |
| Manufacturing and contract development | 99.5 | 153.5 | 241.4 | 264.7 | 619.0 |
| Royalty revenues | 43.2 | 44.3 | 91.5 | 86.3 | 176.2 |
| Licensing and milestone revenues | – | 44.1 | – | 88.3 | 132.5 |
| Other | – | -0.1 | – | – | – |
| **Total revenues** | **319.9** | **287.9** | **675.1** | **532.1** | **1,140.6** |

During the first two quarters of 2008, deferred license milestone revenues of in total SEK 88.3 M were reported as part of the total revenues. This was related to agreements made with Amgen in 2003 and 2005 which had no impact on the cash flow in 2008. This deferral ceased during the third quarter 2008. Total revenues for the second quarter increased by 11 percent to SEK 319.9 M (287.9). Total revenues before license and milestone revenues increased by 31 percent to SEK 319.9 M (243.8). The most significant contributor to the revenue growth is the additional sales volume generated by Kineret®, Kepivance® and Stemgen® .

Total product sales amounted to SEK 138.9 M (1.1).

Co-promotion revenues during the period amounted to SEK 38.3 M (45.0), of which SEK 28.9 M (21.1) relates to ReFacto®. Other co-promotion revenues relate to the products BeneFIX® and Mimpara®, and amounted to SEK 9.1 M (7.8). The corresponding number for the second quarter of 2008 includes co-promotion revenues from Kineret and Kepivance of SEK 16.2 M.

Manufacturing revenues, all of which relate to ReFacto, decreased to SEK 95.1 M (139.0) despite a higher volume being produced. This is due to a lower unit price for the new protein being manufactured currently. The aim of utilizing the company's expertise in the development of protein drugs for in-house projects/products explains the decline in contract development revenues. Contract development revenues in the second quarter amounted to SEK 4.4 M (14.5).

### Revenues by regions

| *Amounts in SEK million* | Apr 1 - Jun 30 2009 | Apr 1 - Jun 30 2008 | Jan 1 - Jun 30 2009 | Jan 1 - Jun 30 2008 |
|---|---|---|---|---|
| **Revenues** | | | | |
| Europe | 246.7 | 229.2 | 523.9 | 417.6 |
| North America | 64.3 | 44.8 | 127.3 | 89.9 |
| Other | 8.9 | 13.9 | 23.9 | 24.6 |
| **Total revenues** | **319.9** | **287.9** | **675.1** | **532.1** |

Royalty revenues from Wyeth's global sales are distributed according to the information available from Wyeth.

## Results

The cost of goods and services sold increased during the second quarter 2009 compared to the corresponding period 2008. This increase is mainly due to the sharp increase of revenues from sales of Kineret and Kepivance. Gross profit margin decreased by 7.5 percentage points to 75.2 percent (82.7), which is explained by the margins generated by the new products and the fact that there is no longer deferred licensing revenues reported in 2009. However, the ReFacto manufacturing have generated improved margins thanks to higher yields and success rate which partly offset the impact on the gross margin due to the new product mix. Biovitrum is currently building inventory for a planned maintenance shut-down during first half of 2010 which means that the current production is substantial higher than the market demand.

Research and development expenses in the second quarter amounted to SEK 162.2 M (167,7). The fixed in house costs have decreased significantly due to the previous transformation and downsizing of the organization. However, due to the acquisition of Kepivance and Kineret and the advancement of several clinical projects into later development phases, the external costs have increased by 40 percent compared with the same period 2008. R&D project expenses relating to manufacturing at our partner Biogen/Idec of phase III material for the FVIIIFc project , were significant during the second quarter. The cost for the CBT unit amounted to SEK 13 M in the period. The unit is expected to be sold during the third quarter.

Sales and administration expenses increased during the second quarter of 2009, mainly as a result of increased cost for the new sales organization as well as distribution and administration of the new products. Furthermore SEK 11.4 M related to amortization of product rights are included. Transfer costs related to Kineret and Kepivance have increased the product rights with SEK 39.1 M.

Operating result for the quarter amounted to SEK -13.1 M (-98.0) and the earnings reported for the period amounted to SEK 16.8 M (-96.6) which corresponds to an earnings per share of SEK 0.33 (-2.12). Restructuring expenses of SEK 120 M are included in the figures for 2008.

## Financial items

The financial net for the second quarter amounted to SEK 29.9 M (1.3). The change of the US dollar exchange rate has led to a recalculation of future milestone payments and loans in US dollars which were booked in connection with the product acquisition from Amgen in December 2008. Corresponding amounts for the first quarter was SEK -35.7 M (6.4) and the financial net for the first six month amounted to SEK -5.8 M (7.7). Provisions have increased in the first two quarters by SEK 3 M, which have had a negative impact on the financial net.

## Financial Position

Cash and cash equivalents and short-term investments as of June 30th, 2009 amounted to SEK 341.2 M (635.6), which is a decline since year end 2008 by SEK 118.9 M. Of this amount, SEK 105.4 M were bank balances (63.6) and SEK 122.2 M (209.6) 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. Besides cash and cash equivalents, on June 30th, 2009, the company had other short-term investments with a term of more than three months amounting to SEK 113.6 M (362.4).

The consolidated shareholders' equity as of June 30th, 2009 amounted to SEK 1,317.3 M, compared to SEK 1,285.0 M on December 31st, 2008.

## 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).

## Cash flow

Cash flow from operations amounted to SEK 45.1 M (-75.6). During the second quarter accounts receivables decreased by SEK 45 M to SEK 174 M. Still Biovitrum is binding a large capital in accounts receivables. Payments related to restructuring reserves amounted to SEK 31.1 M during the period. Remaining payments concerning restructuting reserves amounts to SEK 35 M, which will have a negative effect on the cash flow for quarter three and four with SEK 14 M each.

## Investments

The Group's investments in tangible fixed assets during the second quarter amounted to SEK 17.3 M (6.5). Depreciation amounted to SEK 27.6 M (17.7), of which SEK 11.4 M is related to product rights.

Acquisitions of intangible fixed assets for the period amounted to SEK 46.5 M (18.0).

## Personnel

As of June 30th, 2009 Biovitrum had 427 employees (492), of which 59 percent (56) are women. On April 29th, the AGM approved Biovitrum's new performance based, long term share program ("Share Program 2009"), consisting of a direct issue of totally 231,585 new series C shares. The program includes up to 50 managers and key employees. The previous program ("Share Program 2008") have experienced a positive development of the value of the underlying shares. The assessment period will run up to and including November 25, 2011. Considering the result of the first year the assignment will be 100 percent.

During the first six months, 581,534 warrants in the 2006/2008 warrant program were forfeited and 581,534 were exercised. In the 2006/2011 warrant program 5,000 warrants were forfeited. For further information see note 2.

## Outlook 2009

Outlook for the full year 2009 remains unchanged.

Total revenues for the full year 2009, excluding licensing revenues, are expected to increase by approximately 20 percent. This is a result of the acquisition of Kineret, Kepivance and Stemgen, which offsets the previously communicated continued decline in ReFacto revenues, which is due to the switch to Xyntha/ReFacto AF in 2009.

The changed focus to specialist products will result in lower total R&D costs, despite the fact that external project costs will increase as we enter into subsequent clinical phases and with the addition of costs for the acquired products. The R&D costs are expected to fall by around 15 percent.

The gross margin will fall by around 10 percentage points due to a changed mix of revenues compared to 2008.

## Statement of comprehensive income

| *Amounts in SEK million* | Apr 1 - Jun 30 | | Jan 1 - Jun 30 | | Full year |
|---|---|---|---|---|---|
| | **2009** | **2008** | **2009** | **2008** | **2008** |
| Total revenues | 319.9 | 287.9 | 675.1 | 532.1 | 1,140.6 |
| Cost of goods and services sold | -79.3 | -49.7 | -192.0 | -104.1 | -264.7 |
| **Gross profit** | **240.6** | **238.1** | **483.1** | **428.1** | **875.9** |
| Sales and administration expenses | -87.5 | -48.7 | -176.5 | -85.3 | -268.0 |
| Research and development expenses | -162.2 | -167.7 | -306.0 | -338.6 | -670.6 |
| Restructuring expenses | – | -120.0 | – | -120.0 | -346.2 |
| Other operating revenues/axpenses | -4.0 | 0.3 | -1.7 | 9.3 | 22.6 |
| **Operating profit/loss** | **-13.1** | **-98.0** | **-1.1** | **-106.5** | **-386.3** |
| Financial income | 1.0 | 1.5 | 6.5 | 7.9 | 21.4 |
| Financial expenses | 28.9 | -0.2 | -12.3 | -0.2 | -1.2 |
| **Profit/loss after financial items** | **16.8** | **-96.7** | **-6.9** | **-98.8** | **-366.1** |
| Income tax expense | – | 0.1 | – | 0.1 | 30.6 |
| **Profit/loss for the period** | **16.8** | **-96.6** | **-6.9** | **-98.7** | **-335.5** |
| **Other comprehensive income** [1)] | | | | | |
| Translation difference | 1.4 | 1.7 | 3.3 | -13.7 | -23.8 |
| **Comprehensive income for the period** | **18.2** | **-94.9** | **-3.6** | **-112.4** | **-359.3** |
| Earnings/loss per share after tax (SEK) | 0.33 | -2.12 | -0.14 | -2.16 | -7.29 |
| Earnings/loss per share after dilution (SEK) | 0.33 | -2.12 | -0.14 | -2.16 | -7.29 |

[1)] In correspondence with Revised IAS 1 all changes in equity that do not arise from transactions with owners should be reported in statement of comprehensive income. Translation difference does entirely concern equity in foreign subsidiary.

## Condensed consolidated balance sheet

| *Amounts in SEK million* | Jun 30 2009 | Jun 30 2008 | Dec 31 2008 |
|---|---|---|---|
| **ASSETS** | | | |
| ***Fixed assets*** | | | |
| Intangible fixed assets [1)] | 1,042.0 | 481.7 | 1,026.0 |
| Tangible fixed assets | 210.9 | 257.5 | 215.5 |
| Financial fixed assets | 46.7 | 31.1 | 46.2 |
| **Total fixed assets** | **1,299.6** | **770.3** | **1,287.7** |
| ***Current assets*** | | | |
| Inventories | 587.6 | 103.9 | 587.7 |
| Current receivables, non-interestbearing | 372.0 | 256.7 | 243.3 |
| Short-term investments | 113.6 | 362.4 | 205.9 |
| Cash and cash equivalents | 227.6 | 273.2 | 254.2 |
| **Total current assets** | **1,300.8** | **996.2** | **1,291.1** |
| **Total assets** | **2,600.4** | **1,766.5** | **2,578.8** |
| **EQUITY AND LIABILITIES** | | | |
| ***Shareholders' equity*** | **1,317.3** | **1,346.8** | **1,285.0** |
| ***Long-term liabilities*** | | | |
| Long-term liabilities | 396.3 | – | 397.1 |
| Long-term liabilities, non-interestbearing | 430.0 | 88.2 | 426.1 |
| **Total long-term liabilities** | **826.3** | **88.2** | **823.2** |
| ***Current liabilities*** | | | |
| Current liabilities, non-interestbearing | 456.8 | 331.6 | 470.6 |
| **Total short-term liabilities** | **456.8** | **331.6** | **470.6** |
| **Total equity and liabilities** | **2,600.4** | **1,766.5** | **2,578.8** |

[1)] Including goodwill SEK 25.3 M (25.3 as per December 31, 2008)

## Statement of changes in equity

| *Amounts in SEK million* | 2009 Jan 1 - Jun 30 | 2008 Jan 1 - Jun 30 | 2008 Jan 1 - Dec 31 |
|---|---|---|---|
| **Opening balance** | **1,285.0** | **1,452.8** | **1,452.8** |
| Sharebased compensation to employees | 1.6 | 6.4 | 7.9 |
| Issue of share | 34.3 | – | 183.5 |
| Net profit/loss for the year | -3.6 | -112.4 | -359.2 |
| **Equity, end of period** | **1,317.3** | **1,346.8** | **1,285.0** |

## Statement of cash flow

| *Amounts in SEK million* | Apr 1 - Jun 30 2009 | Apr 1 - Jun 30 2008 | Jan 1 - Jun 30 2009 | Jan 1 - Jun 30 2008 | Full year 2008 |
|---|---|---|---|---|---|
| Net result | 16.8 | -96.6 | -6.9 | -98.7 | -335.5 |
| *Adjustment for items not affecting cash flow:* | | | | | |
| Depreciations and Write down | 27.8 | 17.7 | 56.3 | 33.7 | 267.5 |
| Capital gain/loss from divestment fixed assets | 0.1 | – | -0.2 | – | 0.4 |
| Revaluation of fixed financial assets | – | – | – | – | -2.9 |
| Revaluation of milestones present value | -26.0 | – | 3.9 | – | – |
| Revaluation of long-term liabilities | -7.5 | – | -0.8 | – | – |
| Revaluation of accounts receivable/payable | – | – | -3.3 | – | – |
| Pensions | 2.5 | -1.9 | 2.5 | -1.9 | -5.1 |
| Deferral of fees from Amgen | – | -44.1 | – | -88.3 | -132.5 |
| Restructuring expenses | – | 120.0 | – | 120.0 | 149.1 |
| Payments related to restructuring reserves | -31.1 | -17.5 | -69.5 | -17.5 | -63.2 |
| Reversal of deferred tax | – | – | – | – | -30.6 |
| Translation difference | – | – | – | – | – |
| Other items [1)] | 1.1 | 2.0 | 1.5 | 6.4 | 7.9 |
| **Cash flow from operations before change in working capital** | **-16.3** | **-20.4** | **-16.5** | **-46.3** | **-144.9** |
| Change in working capital | 61.4 | -55.1 | -66.6 | -52.1 | -361.7 |
| **Cash flow from operations** | **45.1** | **-75.6** | **-83.1** | **-98.5** | **-506.6** |
| Divestment of operation | – | – | | – | – |
| Investment in operation | – | – | | – | – |
| Investment in intangible fixed assets | -46.5 | -18.0 | -41.9 | -18.0 | -180.7 |
| Investment in tangible fixed assets | -17.3 | -6.5 | -25.2 | -8.1 | -24.5 |
| Divestment of tangible fixed assets | – | – | – | – | 8.1 |
| Investment/Divestment of financial assets | – | – | -3.0 | – | -11.8 |
| Short-term investments | 5.6 | -3.7 | 92.3 | 32.1 | 188.7 |
| **Cash flow from investing activities** | **-58.2** | **-28.1** | **22.2** | **6.0** | **-20.2** |
| Loans - Raising/Amortization | – | – | – | – | 399.8 |
| Change in short term investment | – | – | | – | – |
| Issue of shares | 34.3 | – | 34.3 | – | 16.6 |
| Redemption of shares | – | – | | – | – |
| Issue of warrants | – | – | | – | – |
| Re-purchase of warrants | – | – | – | – | – |
| **Cash flow from financing activities** | **34.3** | **–** | **34.3** | **–** | **416.4** |
| **Net change in cash** | **21.2** | **-103.7** | **-26.6** | **-92.4** | **-110.4** |
| Liquid funds at the beginning of the period | 206.4 | 376.9 | 254.2 | 365.8 | 365.8 |
| One-time effect implementing IAS39 | – | – | – | – | – |
| Translation difference in cash flow and liquid funds | – | – | – | -0.2 | -1.2 |
| **Liquid funds at the end of the period** | **227.6** | **273.2** | **227.6** | **273.2** | **254.2** |
| Short-term investments | 113.6 | 362.4 | 113.6 | 362.4 | 205.8 |
| **Liquid funds and short-term investments at the end of the period** | **341.2** | **635.6** | **341.2** | **635.6** | **460.0** |

[1)] Expenses related to sharebased compensation to employees.

## Key ratios and other information

| | Apr 1 - Jun 30 | | Jan 1 - Jun 30 | | Full year |
|---|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 | 2008 |
| **Return on** | | | | | |
| Shareholders' equity | 1.3% | -6.9% | -0.5% | -7.0% | -24.5% |
| Total capital | 0.9% | -5.3% | 0.2% | -5.3% | -16.1% |
| **Margins** | | | | | |
| Gross margin | 75.2% | 82.7% | 71.6% | 80.4% | 76.8% |
| EBITDA-margin | 4.6% | -11.9% | 8.2% | -5.0% | -10.4% |
| EBIT-margin | -4.1% | -34.1% | -0.2% | -20.0% | -33.9% |
| Profit margin | 5.3% | -33.5% | -1.0% | -18.5% | -29.4% |
| **Per share data (SEK)** | | | | | |
| Shareholders' equity per share | 26.0 | 29.5 | 26.0 | 29.5 | 25.6 |
| Shareholders' equity per share after dilution | 25.8 | 29.0 | 25.8 | 29.0 | 25.4 |
| Cash flow per share | 0.4 | -2.3 | -0.5 | -2.0 | -2.4 |
| Cash flow per share after dilution | 0.4 | -2.3 | -0.5 | -2.0 | -2.4 |
| **Other information** | | | | | |
| Equity ratio | 50.7% | 76.2% | 50.7% | 76.2% | 49.8% |
| Number of shares | 50,680,316 | 45,622,700 | 50,680,316 | 45,622,700 | 50,098,782 |
| Average number of shares | 50,239,373 | 45,622,700 | 50,169,466 | 45,622,700 | 46,048,631 |
| Outstanding warrants | 335,000 | 2,671,136 | 335,000 | 2,671,136 | 1,503,068 |
| Number of shares after dilution | 51,050,316 | 46,325,109 | 51,050,316 | 46,399,462 | 50,567,342 |
| Average number of shares after dilution | 50,660,950 | 46,325,109 | 51,247,833 | 46,412,910 | 46,593,267 |

[1)] There are two different warrant programs outstanding, exercisable for a maximum of 370,000 new shares in total.

**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 sales.

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

**EBIT margin**
Operating profit as a percentage of net sales.

**Profit margin**
Profit for the period as a percentage of net sales.

**Shareholders' equity per share**
Shareholders' equity divided by the number of shares.

**Shareholders' equity per share after dilution**
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.

## Profit and Loss Parent company

| *Amounts in SEK million* | Apr 1 - Jun 30 2009 | Apr 1 - Jun 30 2008 | Jan 1 - Jun 30 2009 | Jan 1 - Jun 30 2008 | Full year 2008 |
|---|---|---|---|---|---|
| Total revenues | 319.9 | 287.9 | 675.1 | 532.1 | 1,140.6 |
| Cost of goods and services sold | -79.3 | -49.7 | -192.0 | -104.1 | -264.7 |
| **Gross profit** | **240.6** | **238.1** | **483.1** | **428.1** | **875.9** |
| Sales and administration expenses | -95.4 | -51.2 | -174.0 | -88.2 | -273.0 |
| Research and development expenses | -152.7 | -166.7 | -306.8 | -336.9 | -669.5 |
| Restructuring expenses | – | -120.0 | – | -120.0 | -201.2 |
| Other operating revenues/expenses | -6.7 | 0.9 | -5.0 | 10.9 | 23.3 |
| **Operating profit/loss** | **-14.2** | **-98.9** | **-2.7** | **-106.0** | **-244.5** |
| Result from participation in Group companies | – | – | – | – | -168.5 |
| Financial income | 1.0 | 1.5 | 6.5 | 7.8 | 21.1 |
| Financial expenses | 28.9 | -0.2 | -12.3 | -0.2 | -1.2 |
| **Profit/loss after financial items** | **15.7** | **-97.6** | **-8.5** | **-98.4** | **-393.1** |
| Income tax expense | – | – | | – | – |
| **Profit/loss for the period** | **15.7** | **-97.6** | **-8.5** | **-98.4** | **-393.1** |

## Balance Sheet Parent company

| *Amounts in SEK million* | Jun 30 2009 | Jun 30 2008 | Dec 31 2008 |
|---|---|---|---|
| **ASSETS** | | | |
| ***Fixed assets*** | | | |
| Intangible fixed assets | 842.6 | 132.8 | 826.5 |
| Tangible fixed assets | 207.8 | 252.2 | 211.7 |
| Financial fixed assets | 610.7 | 743.8 | 607.7 |
| **Total fixed assets** | **1,661.1** | **1,128.8** | **1,645.9** |
| ***Current assets*** | | | |
| Inventories | 587.7 | 103.9 | 587.6 |
| Current receivables, non-interestbearing | 378.2 | 261.8 | 249.2 |
| Short-term investments | 113.6 | 362.4 | 205.8 |
| Cash and cash equivalents | 226.3 | 269.7 | 252.3 |
| **Total current assets** | **1,305.8** | **997.8** | **1,294.9** |
| **Total assets** | **2,966.9** | **2,126.7** | **2,940.8** |
| **EQUITY AND LIABILITIES** | | | |
| ***Shareholders' equity*** | **1,243.6** | **1,326.2** | **1,216.2** |
| ***Long-term liabilities*** | | | |
| Long term liabilities, interestbearing | 396.3 | – | 397.1 |
| Long term liabilities, non-interestbearing | 381.8 | – | 377.9 |
| **Total long-term liabilities** | **778.1** | **–** | **775.0** |
| ***Current liabilities*** | | | |
| Current liabilities, non-interestbearing | 945.2 | 800.5 | 949.6 |
| **Total short-term liabilities** | **945.2** | **800.5** | **949.6** |
| **Total equity and liabilities** | **2,966.9** | **2,126.7** | **2,940.8** |

## Change in Shareholders' equity Parent Company

| *Amounts in SEK million* | 2009 Jun 30 | 2008 Jun 30 | 2008 Dec 31 |
|---|---|---|---|
| **Opening balance** | **1,216.2** | **1,418.1** | **1,418.1** |
| Sharebased compensation to employees | 1.6 | 6.4 | 7.8 |
| Issue of share | 34.3 | – | 183.4 |
| Profit/loss for the period | -8.5 | -98.4 | -393.1 |
| **Equity, end of period** | **1,243.6** | **1,326.2** | **1,216.2** |

# Notes

## Note 1 Accounting and valuation principles and other information

***Important accounting principles***

Biovitrum AB (publ) prepares its consolidated financial statements in accordance with the International Financial Reporting Standards (IFRS) as adopted by the EU, the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2.2, Accounting for Legal Entities.

This interim report has been prepared in accordance with IAS 34, Interim Financial Reporting.

The Group applies the same accounting principles as those applied in the 2008 Annual Report with the exception of new or amended standards, interpretations or improvements that have been adopted by the EU and are to be applied from 1 January 2009. For Biovitrum AB (publ), the following amendments are relevant:

***Revised IAS 1 – Presentation of Financial Statements***

The revised standard prohibits the presentation of revenue and cost items (i.e. "changes in equity which exclude transactions with owners") in the statement of changes in equity, but instead requires "changes in equity which exclude transactions with owners" to be reported separately from changes in equity which arise from transactions with owners. All changes in equity that do not arise from transactions with owners should therefore be reported in one statement (statement of comprehensive income) or in two statements (separate income statement and statement of comprehensive income). The Group is applying IAS 1 from January 1, 2009 and has decided to present the statement of comprehensive income in one statement.

***Replacement of accounting principle – Operating Segments (IFRS 8)***

Effective January 1, 2009 the Group has implemented IFRS 8 Operating Segments, which replaces IAS 14 Segment Reporting. The new standard requires segment information to be presented from the management's perspective, which means that it is presented in the manner used for internal reporting. The basis for identifying reportable segments is the internal reporting as reported to and followed up by the highest executive decision-maker. The Group has identified the highest executive decision-maker as the CEO. The introduction of IFRS 8 has not resulted in the Group identifying any new operating segments compared to before. As a result of the acquisition of products from Amgen in December 2008, Biovitrum has sales in several geographical areas. From the beginning of 2009, Biovitrum AB (publ) will therefore report revenues by geographical area. Information about this can be found above "Revenues by regions".

***Operating risks***

All business operations involve risk. Managed risk-taking is necessary to maintain good profitability. Risk may be due to events in the external environment and may affect a certain industry or market. Risk may also be specific to a certain company. Biovitrum is exposed to three main risk categories:

- External risks such as patent infringements and competition within product concepts
- Operational risk, e.g. the fact that developing a new drug is both capital-intensive and risky, dependence on external partners in various collaborations, product liability claims, as well as laws and rules on the treatment of hazardous materials
- Financial risks, such as currency risk, interest risk, credit risk and liquidity risk

A more detailed description of the Group's risk exposure and risk management is included in Biovitrum's 2008 Annual Report (see the Directors' Report).

## Note 2 Shares and warrants

***Shares***

When the subscription period for the 2006/2008 warrant program expired in May, 581,534 warrants were exercised and the corresponding amount of shares were issued.

| Development in share capital and number | | No of shares | Share capital, SEK |
|---|---|---|---|
| December 2008 | | 50,098,782 | 27,489,044 |
| May-Jun 2009 | Issue of shares in connection with warrant programs | 581,534 | 319,086 |
| **June 2009** | | **50,680,316** | **27,808,130** |

***Option and share based incentive programs***

*Share based incentive program 2008*
At the Annual General Meeting on April 24, 2008, a long-term, performance based incentive program was adopted ("Share program 2008"). Share program 2008 covers management and key individuals in Biovitrum and may involve a total maximum allocation of 205,236 shares in Biovitrum AB (publ). The number of shares to be received by program participants will be based on the development of the Biovitrum share over a three-year assessment period. The program was implemented at the end of 2008 and the assessment period will run from November 26, 2008 up to and including November 25, 2011.

*Share based incentive program 2009*
A new long-term, performance based incentive program was adopted ("Share program 2009") at the Annual General Meeting on April 28, 2009. Share program 2009 covers management and key individuals in Biovitrum and may involve a total maximum allocation of 175,433 shares in Biovitrum AB (publ). Like in the Share program 2008, the number of shares to be received by program participants will be based on the development of the Biovitrum share over a three-year assessment period The program was implemented in June 2009 and the assessment period will run from June 10, 2009 up to and including June 9, 2012.

*Warrant program*
During the first six months, 581,534 warrants in the 2006/2008 warrant program were forfeited when the subscription period expired in February. Additionally, 581,534 warrants were exercised in May. In the 2006/2011 warrant program, 5,000 warrants were forfeited in May.

| **Warrant program 2006/2008 for certain members of management** | **Jan 1 - Jun 30 2009** | **Full year 2008** |
|---|---|---|
| Outstanding January 1 | 1,163,068 | 2,326,136 |
| Exercised during the period | -581,534 | -281,144 |
| Forfeited during the period | -581,534 | -881,924 |
| Outstanding at of end of accounting period | - | 1,163,068 |
| Exercisable at of end of accounting period | - | 1,163,068 |

| **Option program 2006/2011** | **Jan 1 - Jun 30 2009** | **Full year 2008** |
|---|---|---|
| Outstanding January 1 | 40,000 | 60,000 |
| Repurchased during the period | - | -20,000 |
| Forfeited during the period | -5,000 | - |
| Outstanding at of end of accounting period | 35,000 | 40,000 |
| Exercisable at of end of accounting period | 24,998 | 24,998 |

| **Employee option program 2007/2012** | **Jan 1 - Jun 30 2009** | **Full year 2008** |
|---|---|---|
| Outstanding January 1 | 300,000 | 300,000 |
| Outstanding at of end of accounting period | 300,000 | 300,000 |
| Exercisable at of end of accounting period | 100,000 | 100,000 |

## Not 3 Transactions with related parties

| **Loans to related parties** | **2009** | **2008** |
|---|---|---|
| *Loan to executive management in Parent Company:* | | |
| At beginning of the year: | 153 | 153 |
| Loans paid during the year: | – | – |
| | **153** | **153** |

There was no change as to loans to related parties during the period. The conditions for these loans to executive management in the parent company are described in the Annual Report 2008.

Biovitrum has entered into a collaboration agreement with Affibody AB. Håkan Åström is chairman of the board in Biovitrum as well as in Affibody.

*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 such as the economic climate, political changes and competing research programs that may affect Biovitrum's results.*

*This interim report has not been reviewed by the company's auditors.*

The Board of Directors and the CEO of Biovitrum provide their assurance that the half-year interim report provides a fair and true overview of the Parent Company's and the Group's operations, financial position and results, and describes material risks and uncertainties faced by the parent Company and the companies in the Group. See under the heading "Accounting and valuation principles" above and in other information provided for a description of the operational risks.

Solna, July 23rd, 2009

| | | |
|---|---|---|
| Håkan Åström<br>Chairman of the Board | Hans Glemstedt | Mats-Olof Ljungkvist |
| Wenche Rolfsen | Peter Sellei | Michael Steinmetz |
| Hans Wigzell | Catarina Larsson<br>Union Representative | Bo-Gunnar Rosenbrand<br>Union Representative |
| Martin Nicklasson<br>Chief Executive Officer | | |

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**Financial Calendar:**

Interim Report July-Sept, 2009 October 22, 2009

biovitrum.

Biovitrum is an international pharmaceutical company that markets specialist pharmaceuticals in several regions. Using its expertise and experience Biovitrum takes scientific innovation to patients with significant unmet medical need. Research expertise and capabilities are focused on development and production of biotechnology therapeutics within our prioritized areas of hemophilia, inflammation/autoimmune diseases, cancer supportive care and malabsorption. The company has revenues of approximately SEK 1.2 billion and around 400 employees. The company head office is located in Sweden and it is listed on the Stockholm OMX Nordic Exchange.

For more information please visit www.biovitrum.com.