

## Interim Report January 1<sup>st</sup> – September 30<sup>th</sup>, 2009 (translation only)

### Continued top line growth and positive R&D progress – rFIXFc advances into registrational trial

#### July - September

- Total revenues before licensing revenues for the period increased by 10 percent to SEK 274.2 M (250.0).
  - Q3 sales of Kineret<sup>®</sup> and Kepivance<sup>®</sup> in local currency were the highest since Biovitrum acquired the products
- Operating result was SEK -34.1 M (10.4). Profit for the period amounted to SEK 7.9 M (9.8), which is equivalent to earnings per share of SEK 0.16 (0.21).
- Cash flow from operations was SEK -7.4 (-25.5). Cash and cash equivalents and short-term investments as of September 30 amounted to SEK 309.4 M (534.1).
- The last patient in the rFIXFc hemophilia B clinical phase I/II study was recruited.
- Aloxi<sup>®</sup> was recommended by the Multinational Association for Supportive Care in Cancer and the European Society of Medical Oncology as the preferred 5-HT<sub>3</sub> antagonist for emesis prevention in patients undergoing highly emetogenic chemotherapy.

#### January - September

- Total revenues before licensing revenues increased by 37 percent to SEK 949.3 M (693.8) driven mainly by Kineret<sup>®</sup> and Kepivance<sup>®</sup>. Profit for the period amounted to SEK 1.0 M (-88.8), which is equivalent to earnings per share of SEK 0.02 (-1.94).
- Cash flow from operations was SEK -90.5 M (-124.0).

#### Events after the period

- Biovitrum and Biogen/Idec announced decision to advance long-acting hemophilia B therapy (rFIXFc) into a registrational trial based upon the successful outcome of a phase I/II clinical trial.
- An open label exploratory phase II study on Exinalda<sup>™</sup> (rhBSSL) in patients with cystic fibrosis and pancreatic insufficiency was completed. The primary end point was not met (CFA). Biovitrum is currently evaluating next steps.
- A Letter of Intent was signed with Proximagen Neuroscience plc ("Proximagen"), according to which Proximagen will acquire Biovitrum's UK based research unit Cambridge Biotechnology Ltd (CBT).]

<i>Amounts in SEK million</i>	Jul 1 - Sep 30		Jan 1 - Sep 30	
	2009	2008	2009	2008
<b>Total revenues before license revenues</b>	<b>274.2</b>	<b>250.0</b>	<b>949.3</b>	<b>693.8</b>
Total revenues	274.2	294.2	949.3	826.3
Operating profit/loss before depreciations and amortizations (EBITDA)	-6.3	27.8 <sup>1)</sup>	48.9	-45.0 <sup>1)</sup>
Operating profit/loss (EBIT)	-34.1	10.4 <sup>1)</sup>	-35.2	-96.1 <sup>1)</sup>
<b>Profit/loss for the period</b>	<b>7.9</b>	<b>9.8 <sup>1)</sup></b>	<b>1.0</b>	<b>-88.8 <sup>1)</sup></b>
Earnings/loss per share before dilution	0.16	0.21 <sup>1)</sup>	0.02	-1.95 <sup>1)</sup>
Research and development expenses	154.0	146.1	460.0	484.8
Liquid funds and short-term investments	309.4	534.1	309.4	534.1

<sup>1)</sup> Amount including restructuring expenses of SEK 120.0 M

## CEO comments:

“The third quarter showed both a gratifying sales development for our marketed products and a continued good progress of our prioritized R&D projects. In particular, the sales of Kineret and Kepivance in local currency were the highest since Biovitrum acquired the products. The financial performance for the quarter as well as for the nine month period is yet another step forward becoming a profitable company. I am particularly pleased that we after the period have decided to move the hemophila B project (rFIXFc) into the final registrational development phase, based on successful outcome of a phase I/II clinical trial. Furthermore the sale of our UK research company is also highly satisfying and in line with the transformation of our business. In order to drive future growth, we continue to strengthen our commercial infrastructure needed for our key products”, says CEO Martin Nicklasson.

## Overview July– September 2009

### Sales & Marketing

New marketing strategies are being developed to prepare for market expansion of Kineret® and Kepivance®. These products were not actively promoted for a couple of years before they were acquired by Biovitrum at the end of 2008. Since then, we have gradually build up the sales organization for both products, focusing on the US and Europe. Already, we begin to see effects of our work, and the third quarter was our strongest quarter so far in local currencies.

Biovitrum is continuously striving towards to be perceived as a preferred health care provider and patient partner; a critical success factor within the hemophilia area. In line with this effort, Biovitrum launched [www.minhemofili.se](http://www.minhemofili.se) a website for people suffering from hemophilia and their relatives, as well as other people who get in contact with hemophilia related issues. The first Biovitrum Nordic Hemophilia Expert Group Meeting was held in Stockholm. Biovitrum invited Nordic hemophilia experts to discuss current research and development activities in hemophilia care. Also, Biovitrum was represented at the European Hemophilia Consortium Conference (EHC) in Vilnius, where 288 hemophilia patients, health care providers and people from the pharmaceutical industry participated.

Aloxi was recommended by the Multinational Association for Supportive Care in Cancer (MASCC) and the European Society of Medical Oncology (ESMO) as the preferred 5-HT<sub>3</sub> antagonist in the combined regimen recommended for emesis prevention in patients undergoing highly emetogenic chemotherapy (HEC). Aloxi is a 5-HT<sub>3</sub> receptor antagonist for the prevention of chemotherapy induced nausea and vomiting (CINV).

#### Product sales

Amounts in SEK million	Jul 1 - Sep 30		Jan 1 - Sep 30		Full year
	2009	2008	2009	2008	2008
Kineret	105.6	–	319.8	–	25.8
Kepivance	27.2	–	83.6	–	5.7
Aloxi	3.3	1.6	7.1	4.3	5.3
Stemgen	1.2	–	3.0	–	0.6
Novastan	0.1	0.1	0.4	0.4	0.8
Other	-0.4	–	–	–	–
<b>Total revenues <sup>1)</sup></b>	<b>137.0</b>	<b>1.7</b>	<b>413.9</b>	<b>4.7</b>	<b>38.2</b>

<sup>1)</sup> 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.

Third quarter sales figures in local currency for both Kineret and Kepivance are the highest since Biovitrum acquired the products. The table below shows how sales have developed based on fixed exchange rates using the average Swedish Krona exchange rate in Q1 as reference.

#### Sales at Fixed Exchange Rate (average Q1 2009)

Amounts in SEK million	2009		
	Q1	Q2	Q3
<b>Revenues</b>			
Kineret	104.0	113.5	114.9
Kepivance	29.6	28.1	30.4
<b>Total revenues</b>	<b>133.6</b>	<b>141.6</b>	<b>145.3</b>
<b>Increase% by quarter</b>		<b>6.0%</b>	<b>2.6%</b>

Due to increased sales of Kineret<sup>®</sup> as well as expected future sales development, Biovitrum would need to purchase a supply of additional Kineret drug substance from Amgen in order to meet its current projected demand for the product in 2011 before a new contract manufacturer could start supplying Kineret drug substance. Biovitrum is at present negotiating agreements with Amgen to manufacture Kineret drug substance and provide fill services for such drug substance. In the third quarter of 2009, Biovitrum made a prepayment of approx. 30 MSEK for Amgen's purchase of raw material to be used in the manufacture of Kineret drug substance, which raw material will be returned to Biovitrum in the event that the parties do not enter into a definitive agreement for the manufacture of Kineret drug substance.

Sales of Aloxi<sup>®</sup> in the Nordic region doubled during the third quarter 2009 compared to the same period 2008.

For product information see [www.biovitrum.com](http://www.biovitrum.com).

### Co-promotion revenues

<i>Amounts in SEK million</i>	Jul 1 - Sep 30		Jan 1 - Sep 30		Full year
	2009	2008	2009	2008	2008
ReFacto/ReFacto AF	19.5	19.7	66.6	61.7	80.2
BeneFIX	2.5	2.5	7.6	8.2	10.4
Mimpara	6.4	6.0	19.1	17.1	22.7
Kineret	–	15.3	–	46.2	61.2
Kepivance	–	0.1	–	0.2	0.2
Other	–	–	0.4	–	–
<b>Total revenues</b>	<b>28.4</b>	<b>43.6</b>	<b>93.7</b>	<b>133.4</b>	<b>174.7</b>

In comparison with the same period 2008, co-promotion revenues for ReFacto<sup>®</sup> showed a marginal decrease in the third quarter and amounted to SEK 19.5 M (19.7). Sales growth in the third quarter has been affected by the fact that some of our patients have been included in an ongoing clinical study. These patients will be treated with free of charge drug for the next 6 – 12 months.

Co-promotion revenues for Mimpara<sup>®</sup> increased by 7 percent and amounted to SEK 6.4 M (6.0). For BeneFIX<sup>®</sup>, the co-promotion revenues was at the same level as previous year.

For product information see [www.biovitrum.com](http://www.biovitrum.com).

### Royalty

Royalty revenues amounted to SEK 42.4 M (48.2) in the third quarter. The royalty is based entirely on revenues from Wyeth's sales of ReFacto and ReFacto AF<sup>®</sup>/ Xyntha<sup>®</sup>. The decrease is explained by the introduction and switch from ReFacto to ReFacto AF/ Xyntha<sup>®</sup> at a lower royalty rate.

## Manufacturing and Contract Development

ReFacto manufacturing revenues declined according to plan in the third quarter to SEK 63.2 M (147.6) despite higher delivered volumes compared to the same period 2008. As previously stated, this is due to a lower unit price for the ReFacto AF/Xyntha. For the first nine months, a 23 percent revenue decline was noted compared to the same period 2008. Volumes will continue to vary from one quarter to the other as a result of Wyeth's production planning.

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

<i>Amounts in SEK million</i>	Jul 1 - Sep 30		Jan 1 - Sep 30		Full year
	2009	2008	2009	2008	2008
ReFacto	63.2	147.6	294.9	382.9	569.3
of which validation batches	–	–	–	–	47.0
Contract development	3.2	8.7	12.9	38.1	49.7
<b>Total</b>	<b>66.4</b>	<b>156.3</b>	<b>307.8</b>	<b>421.0</b>	<b>619.0</b>

## Product development

Clinical Development, Regulatory Affairs and Pharmacovigilance competences and capabilities have been reinforced throughout the year to fully optimize the commercial potential as well as to manage the day-to-day work on Kepivance® and Kineret®. The short- and long-term strategy of our marketed products is managed in cross-functional Brand Teams, also including our growing marketing competence.

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.

The R&D organization has established a new Anakinra research program to design and test new improved IL-1 antagonist proteins, for the treatment of rare inflammatory and autoimmune diseases.

## Development projects

### **Factor IX Fc (rFIXFc) for the treatment of hemophilia B**

After the period, Biovitrum and Biogen Idec decided to proceed the rFIXFc development program into a final registrational trial. The decision is based upon positive data from a phase I/II clinical study in severe hemophilia B patients that confirmed that rFIXFc is tolerable in the patients studied. Furthermore, the criteria for prolonged plasma half-life were met.

The registrational trial in Hemophilia B patients will include studies assessing the potential for prolonging bleeding prophylaxis, efficacy at bleeding incidences, as well as prophylaxis in the surgical setting. The study will commence as soon as local regulatory study approvals have been obtained.

### **Kepivance® for the treatment of oral mucositis associated with blood cancer treatment in children**

A clinical study in children with acute leukemia who are undergoing stem cell transplants is currently ongoing. The purpose of the study is primarily to study safety and pharmacokinetics. The study, conducted in the US, will also document the therapeutic effect on inflammation in the mouth and throat. Approximately 27 children aged 1 to 16 years are expected to be included. Results of this study will be available during 2010.

### **Kiobrina™ for the treatment of fat malabsorption in premature infants**

Two phase II clinical trials are currently ongoing in Italy and France. In one of them rhBSSL is administered in pasteurized breast milk and in the other it is administered in infant formula. Results are expected during the end of 2009.

### **Exinalda™ for the treatment of fat malabsorption due to pancreatic insufficiency**

An open label exploratory phase II study on Exinalda (rhBSSL) in patients with cystic fibrosis and pancreatic insufficiency has been completed. The aim was to study the effect of Exinalda on fat absorption as well as safety in this patient population. The results showed that Exinalda is safe and tolerable at a dose level of 170 mg three times a day. In terms of efficacy (coefficient of fat absorption) the primary end-point was not met. Biovitrum is currently evaluating next steps in the development of Exinalda.

### **Sym001 for the treatment of immune thrombocytopenic purpura (ITP) and Rhesus immunization prophylaxis**

A phase I study has been successfully completed. A clinical study that shows that Sym001 can eliminate Rhesus (RhD) positive red blood cells from the circulation of RhD negative healthy volunteers has also been concluded. In addition, a clinical phase II study with the aim to study the safety and efficacy of Sym001 in ITP patients is ongoing at 23 clinics in Europe. Good progress has been achieved since the previous quarter. Three out of four planned dose cohorts have now been treated, and the independent safety committee has recommended a continuation to the next dose group. This study is expected to be completed in the first half of 2010.

### **Factor VIII Fc (FVIII Fc) for the treatment of hemophilia A**

Final preparatory work is ongoing to initiate the First-in-Human study in hemophilia A patients.

## Business development

After the period Biovitrum signed a Letter of Intent with the British biopharmaceutical company Proximagen, according to which Proximagen will acquire Biovitrum's wholly-owned subsidiary Cambridge Biotechnology Ltd (CBT). Biovitrum will in return receive future revenues generated from the CBT pipeline. The clinical projects consist of 5-HT2C agonists and 5-HT6 antagonists. The preclinical projects include VAP-1 and Trk A programs. Deal completion is expected by mid November.

To further enhance sales of Kineret<sup>®</sup> and Kepivance<sup>®</sup>, Biovitrum is currently evaluating a number of possible partners for distribution of the products in territories outside USA and Europe primarily in Southeast Asia and Latin America.

## Financial Statements

### Revenues

Amounts in SEK million	Jul 1 - Sep 30		Jan 1 - Sep 30		Full year
	2009	2008	2009	2008	2008
Product sales	137.0	1.7	413.9	4.7	38.2
Co-promotion revenues	28.4	43.6	93.7	133.4	174.7
Manufacturing and contract development	66.4	156.3	307.8	421.0	619.0
Royalty revenues	42.4	48.2	133.9	134.5	176.2
Licensing and milestone revenues <sup>1)</sup>	–	44.2	–	132.5	132.5
Other	–	0.2	–	0.2	–
<b>Total revenues</b>	<b>274.2</b>	<b>294.2</b>	<b>949.3</b>	<b>826.3</b>	<b>1,140.6</b>

<sup>1)</sup> During the first nine months of 2008, deferred license milestone revenues of in total SEK 132.5 M were reported as part of the total revenues. These were related to agreements made with Amgen in 2003 and 2005 that had no impact on the cash flow in 2008. This deferral ceased during the third quarter 2008.

Total revenues for the third quarter decreased by 7 percent to SEK 274.2 M (294.2). Total revenues before license and milestone revenues increased by 10 percent to SEK 274.2 M (250.0). The most significant contributor to the revenue growth is the additional sales volume generated by Kineret and Kepivance.

Total product sales for the period January – September 2009 amounted to SEK 413.9 M (4.7), of which the third quarter accounted for SEK 137.0 M (1.7)

Co-promotion revenues during the third quarter amounted to SEK 28.4 M (43.6), of which SEK 19.5 M (19.7) are related to ReFacto<sup>®</sup>. Other co-promotion revenues relate to the products BeneFIX<sup>®</sup> and Mimpara<sup>®</sup>, and amounted to SEK 8.9 M (8.5). The corresponding number for the third quarter of 2008 includes co-promotion revenues from Kineret and Kepivance of SEK 15.4 M.

Manufacturing revenues, all of which relate to ReFacto, decreased to SEK 63.2 M (147.6). This is due to normal fluctuations of Wyeth's production planning and a lower unit price for the new rFVIII-protein currently manufactured. 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 third quarter amounted to SEK 3.2 M (8.7).

### Revenues by regions

Amounts in SEK million	Jul 1 - Sep 30		Jan 1 - Sep 30	
	2009	2008	2009	2008
<b>Revenues</b>				
Europe	195.9	233.9	719.8	651.5
North America	66.0	45.1	193.3	135.0
Other	12.3	15.2	36.2	39.8
<b>Total revenues</b>	<b>274.2</b>	<b>294.2</b>	<b>949.3</b>	<b>826.3</b>

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

## Results

Due to the increased sales of Kineret and Kepivance, the cost of goods and services sold increased during the third quarter 2009 compared to the corresponding period 2008. Gross profit margin decreased to 66.8 percent (73.7). This is explained by the margins generated by the new products and the fact that there are no longer any deferred licensing revenues reported in 2009. The ReFacto manufacturing generated improved margins due to higher yields and success rate that partly offset the impact on the gross margin due to the new product mix. Biovitrum is currently

building inventory for a planned maintenance shutdown during first half of 2010, which means that the current production is substantial higher than the market demand.

Research and development expenses increased by 5 percent in the third quarter compared to the same period 2008, and amounted to SEK 154.0 M (146.1). Due to the rapid advancement of the rFVIII-Fc project, front loaded expenses relating to large scale manufacturing at our partner Biogen/Idec of phase III material were significant during the third quarter. Clinical trial costs related to Kepivance<sup>®</sup> and an overall positive advancement of the late stage clinical projects, further explain the difference between 2008 and 2009 third quarter expenses. However, the fixed in-house costs decreased significantly due to the previous transformation and downsizing of the organization. The cost for the CBT unit amounted to SEK 8 M in the period.

Sales and Administration expenses in third quarter continued to decrease compared with previous quarter and amounted to SEK 55.9 M (SEK 89.0 M in Q1, SEK 87.5 M in Q2). During the third quarter SEK 11.5 M has been reclassified from Sales and Administration expenses to Cost of Goods Sold. Likewise Sales and Administration expenses decreased with SEK 20.1 M vs. previous quarter.

Year to date, Sales and Administration expenses increased by SEK 94 M. The increase is explained by:

Amounts in SEK million	
Amortization of product rights	35.8
Distribution costs	23.7
Onetime expenses related to acquisition of Kineret and Kepivance	12.6
Build up of Marketing & Sales	26.0
Other	-3.8
	<b>94.3</b>

Operating result for the quarter amounted to SEK -34.1 M (10.4) and the profit reported for the period amounted to SEK 7.9 (9.8), which corresponds to an earnings per share of SEK 0.16 (0.21).

## Financial items

The financial net for the third quarter amounted to SEK 42.0 M (-0.5), and the corresponding amount for the first nine months was SEK 36.2 M (7.2). The variation of the US dollar exchange rate led to a recalculation of future milestones payments and loans in US dollar that were booked in connection with the product acquisition from Amgen in December 2008. The change of the exchange rate in 2009, has an impact on the result that amounted to SEK 46.9 M. The calculated interest concerning the milestones amounted to SEK -11.4 M.

## Financial Position

Cash and cash equivalents and short-term investments as of September 30, 2009, amounted to SEK 309.4 M (534.1). Of this amount, SEK 66.1 M (90.7) were bank balances and SEK 123.3 M (163.7) 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. Besides cash and cash equivalents, on September 30, 2009, the company had other short-term investments with a term of more than three months amounting to SEK 120.0 M (279.7).

The consolidated shareholders' equity as of September 30, 2009, amounted to SEK 1,322.9 M, compared to SEK 1,285.0 M on December 31, 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 -7.4 M (-25.5). A prepayment of approx. 30 MSEK was made in the third quarter concerning raw material supply of Kineret. During the third quarter, accounts receivables decreased by SEK 61 M to SEK 113 M. Payments related to restructuring reserves amounted to SEK 16 M during the period. Remaining payments concerning restructuring reserves amounted to SEK 18 M, which will have a negative effect on the cash flow for the fourth quarter with SEK 10 M.

## Investments

The Group's investments in tangible fixed assets during the third quarter amounted to SEK 19.8 M (3.1). Depreciation amounted to SEK 27.8 M (17.4), of which SEK 12.3 M (0) is related to product rights.

Acquisitions of intangible fixed assets for the period amounted to SEK 4.7 M (83.2).

## Personnel

As of September 30<sup>th</sup>, 2009 Biovitrum had 409 employees (476), of which 60 percent (57) are women. Excluding CBT, which is to be divested, Biovitrum had 384 employees at the end of the third quarter.

On April 29<sup>th</sup>, 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") has experienced a positive development of the value of the underlying shares. The assessment period will run up to and including November 25<sup>th</sup>, 2011. Considering the result of the first year the assignment will be 100 percent.

During the first nine 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 regarding revenues and R&D costs.

Total revenues for the full year 2009, excluding licensing revenues, are expected to increase by approximately 20 percent, mainly driven by revenues from Kineret<sup>®</sup> and Kepivance<sup>®</sup>. These revenues offset the previously communicated decline in ReFacto<sup>®</sup> revenues, which is due to the switch to Xyntha<sup>®</sup>/ReFacto AF<sup>®</sup> in 2009.

The changed R&D focus is expected to lower total R&D costs by around 15 percent, despite the fact that external project costs will increase as a consequence of the expected advancement of several projects into late stage clinical phases combined with clinical costs for the acquired products.

Gross margin is now expected to decrease by 7 – 8 percentage points vs. previously communicated 10 percentage points due to improved efficiency in the ReFacto manufacturing compared with 2008.



**Statement of comprehensive income**

<i>Amounts in SEK million</i>	Jul 1 - Sep 30		Jan 1 - Sep 30		Full year
	2009	2008	2009	2008	2008
Total revenues	274.2	294.2	949.3	826.3	1,140.6
Cost of goods and services sold	-91.0	-77.5	-283.0	-181.5	-264.7
<b>Gross profit</b>	<b>183.2</b>	<b>216.7</b>	<b>666.3</b>	<b>644.7</b>	<b>875.9</b>
Sales and administration expenses <sup>1)</sup>	-55.9	-52.8	-232.4	-138.1	-268.0
Research and development expenses	-154.0	-146.1	-460.0	-484.8	-670.6
Restructuring expenses	–	–	–	-120.0	-346.2
Other operating revenues/expenses	-7.4	-7.3	-9.1	2.0	22.6
<b>Operating profit/loss</b>	<b>-34.1</b>	<b>10.4</b>	<b>-35.2</b>	<b>-96.1</b>	<b>-386.3</b>
Financial income	40.8	-0.4	47.3	7.5	21.4
Financial expenses	1.2	-0.1	-11.1	-0.3	-1.2
<b>Profit/loss after financial items</b>	<b>7.9</b>	<b>9.8</b>	<b>1.0</b>	<b>-88.9</b>	<b>-366.1</b>
Income tax expense	–	–	–	0.1	30.6
<b>Profit/loss for the period</b>	<b>7.9</b>	<b>9.8</b>	<b>1.0</b>	<b>-88.8</b>	<b>-335.5</b>
<b>Other comprehensive income <sup>2)</sup></b>					
Translation difference	-3.3	4.8	0.0	-8.9	-23.8
<b>Comprehensive income for the period</b>	<b>4.6</b>	<b>14.6</b>	<b>1.0</b>	<b>-97.7</b>	<b>-359.3</b>
Earnings/loss per share after tax (SEK)	0.16	0.21	0.02	-1.94	-7.29
Earnings/loss per share after dilution (SEK)	0.15	0.21	0.02	-1.94	-7.29
<sup>1)</sup> Amortization of product rights included in adm expenses	-12.3	–	-35.8	–	–

<sup>2)</sup> 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**

	Sep 30	Sep 30	Dec 31
<i>Amounts in SEK million</i>	<b>2009</b>	<b>2008</b>	<b>2008</b>
<b>ASSETS</b>			
<b>Fixed assets</b>			
Intangible fixed assets <sup>1)</sup>	1,034.0	572.1	1,026.0
Tangible fixed assets	215.4	227.8	215.5
Financial fixed assets	46.7	43.1	46.2
<b>Total fixed assets</b>	<b>1,296.1</b>	<b>843.0</b>	<b>1,287.7</b>
<b>Current assets</b>			
Inventories	581.5	74.3	587.7
Current receivables, non-interestbearing	303.1	289.1	243.3
Short-term investments	120.0	279.7	205.9
Cash and cash equivalents	189.4	254.4	254.2
<b>Total current assets</b>	<b>1,194.0</b>	<b>897.4</b>	<b>1,291.1</b>
<b>Total assets</b>	<b>2,490.1</b>	<b>1,740.4</b>	<b>2,578.8</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>	<b>1,322.9</b>	<b>1,386.7</b>	<b>1,285.0</b>
<b>Long-term liabilities</b>			
Long-term liabilities	387.8	–	397.1
Long-term liabilities, non-interestbearing	400.0	81.5	426.1
<b>Total long-term liabilities</b>	<b>787.8</b>	<b>81.5</b>	<b>823.2</b>
<b>Current liabilities</b>			
Current liabilities, non-interestbearing	379.4	272.2	470.6
<b>Total short-term liabilities</b>	<b>379.4</b>	<b>272.2</b>	<b>470.6</b>
<b>Total equity and liabilities</b>	<b>2,490.1</b>	<b>1,740.4</b>	<b>2,578.8</b>

<sup>1)</sup> Including goodwill SEK 25.3 M (25.3 as per December 31, 2008)

**Statement of changes in equity**

	2009	2008	2008
<i>Amounts in SEK million</i>	<b>Jan 1 - Sep 30</b>	<b>Jan 1 - Sep 30</b>	<b>Jan 1 - Dec 31</b>
<b>Opening balance</b>	<b>1,285.0</b>	<b>1,452.8</b>	<b>1,452.8</b>
Sharebased compensation to employees	2.5	6.5	7.9
Issue of share	34.4	25.1	183.5
Net profit/loss for the year	1.0	-97.7	-359.2
<b>Equity, end of period</b>	<b>1,322.9</b>	<b>1,386.7</b>	<b>1,285.0</b>

**Statement of cash flow**

<i>Amounts in SEK million</i>	<b>Jul 1 - Sep 30</b>		<b>Jan 1 - Sep 30</b>		<b>Full year</b>
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>	<b>2008</b>
Net result	7.9	9.8	1.0	-88.8	-335.5
<i>Adjustment for items not affecting cash flow:</i>					
Depreciations and Write down	27.8	17.4	84.1	51.1	267.5
Capital gain/loss from divestment fixed assets	–	-0.2	-0.2	-0.2	0.4
Revaluation of fixed financial assets	–	–	–	–	-2.9
Revaluation of milestones present value and exchange rate	-30.1	–	-26.2	–	–
Revaluation of long-term liabilities	-8.5	–	-9.3	–	–
Revaluation of accounts receivable/payable	3.3	–	–	–	–
Pensions	–	–	2.5	-1.9	-5.1
Deferral of fees from Amgen	–	-44.1	–	-132.5	-132.5
Restructuring expenses	–	–	–	120.0	149.1
Payments related to restructuring reserves	-16.0	-28.7	-85.5	-46.2	-63.2
Reversal of deferred tax	–	–	–	–	-30.6
Other items <sup>1)</sup>	1.0	0.1	2.5	6.5	7.9
<b>Cash flow from operations before change in working capital</b>	<b>-14.6</b>	<b>-45.6</b>	<b>-31.1</b>	<b>-91.9</b>	<b>-144.9</b>
Change in working capital	7.2	20.1	-59.4	-32.1	-361.7
<b>Cash flow from operations</b>	<b>-7.4</b>	<b>-25.5</b>	<b>-90.5</b>	<b>-124.0</b>	<b>-506.6</b>
Investment in intangible fixed assets	-4.7	-83.2	-46.6	-101.3	-180.7
Investment in tangible fixed assets	-19.8	-3.1	-45.0	-11.2	-24.5
Divestment of tangible fixed assets	–	8.1	–	8.1	8.1
Investment/Divestment of financial assets	–	-11.8	-3.0	-11.8	-11.8
Short-term investments	-6.4	82.7	85.9	114.9	188.7
<b>Cash flow from investing activities</b>	<b>-30.9</b>	<b>-7.4</b>	<b>-8.7</b>	<b>-1.3</b>	<b>-20.2</b>
Loans - Raising/Amortization	–	–	–	–	399.8
Issue of shares	0.1	14.8	34.4	14.8	16.6
<b>Cash flow from financing activities</b>	<b>0.1</b>	<b>14.8</b>	<b>34.4</b>	<b>14.8</b>	<b>416.4</b>
<b>Net change in cash</b>	<b>-38.2</b>	<b>-18.1</b>	<b>-64.8</b>	<b>-110.6</b>	<b>-110.4</b>
Liquid funds at the beginning of the period	227.6	273.2	254.2	365.8	365.8
Translation difference in cash flow and liquid funds	–	-0.7	–	-0.9	-1.2
<b>Liquid funds at the end of the period</b>	<b>189.4</b>	<b>254.4</b>	<b>189.4</b>	<b>254.4</b>	<b>254.2</b>
Short-term investments	120.0	279.7	120.0	279.7	205.8
<b>Liquid funds and short-term investments at the end of the period</b>	<b>309.4</b>	<b>534.1</b>	<b>309.4</b>	<b>534.1</b>	<b>460.0</b>

<sup>1)</sup> Expenses related to sharebased compensation to employees.

**Key ratios and other information**

	Jul 1 - Sep 30		Jan 1 - Sep 30		Full year
	2009	2008	2009	2008	2008
<b>Return on</b>					
Shareholders' equity	0.6%	0.7%	0.1%	-6.3%	-24.5%
Total capital	0.3%	0.6%	0.0%	-4.8%	-16.1%
<b>Margins</b>					
Gross margin	66.8%	73.7%	70.2%	78.0%	76.8%
EBITDA-margin	-2.3%	9.5%	5.2%	0.1%	-10.4%
EBIT-margin	-12.4%	3.5%	-3.7%	-11.6%	-33.9%
Profit margin	2.9%	3.3%	0.1%	-10.8%	-29.4%
<b>Per share data (SEK)</b>					
Shareholders' equity per share	26.0	30.1	26.0	30.1	25.6
Shareholders' equity per share after dilution	25.8	29.8	25.8	29.7	25.4
Cash flow per share	-0.8	-0.4	-1.3	-2.4	-2.4
Cash flow per share after dilution	-0.8	-0.4	-1.3	-2.4	-2.4
<b>Other information</b>					
Equity ratio	53.1%	79.7%	53.1%	79.7%	49.8%
Number of shares	50,911,901	46,015,624	50,911,901	46,015,624	50,098,782
Average number of shares	50,680,316	45,852,253	50,341,620	45,708,613	46,048,631
Outstanding warrants	2,089,602	2,089,602	2,089,602	2,089,602	1,503,068
Number of shares after dilution	51,281,901	46,464,603	51,281,901	46,622,963	50,567,342
Average number of shares after dilution	51,050,316	46,314,298	50,726,307	46,387,902	46,593,267

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**

	Jul 1 - Sep 30		Jan 1 - Sep 30		Full year
<i>Amounts in SEK million</i>	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>	<b>2008</b>
Total revenues	274.2	294.2	949.3	826.3	1,140.6
Cost of goods and services sold	-91.0	-77.5	-283.0	-181.5	-264.7
<b>Gross profit</b>	<b>183.2</b>	<b>216.7</b>	<b>666.3</b>	<b>644.7</b>	<b>875.9</b>
Sales and administration expenses <sup>1)</sup>	-55.8	-53.8	-229.8	-142.0	-273.0
Research and development expenses	-154.4	-146.5	-461.2	-483.3	-669.5
Restructuring expenses	–	–	–	-120.0	-201.2
Other operating revenues/expenses	-4.0	-6.3	-9.0	4.6	23.3
<b>Operating profit/loss</b>	<b>-31.0</b>	<b>10.1</b>	<b>-33.7</b>	<b>-96.0</b>	<b>-244.5</b>
Result from participation in Group companies	–	–	–	–	-168.5
Financial income	40.8	-0.5	47.3	7.4	21.1
Financial expenses	1.2	-0.1	-11.1	-0.3	-1.2
<b>Profit/loss after financial items</b>	<b>11.0</b>	<b>9.5</b>	<b>2.5</b>	<b>-88.9</b>	<b>-393.1</b>
Income tax expense	–	–	–	–	–
<b>Profit/loss for the period</b>	<b>11.0</b>	<b>9.5</b>	<b>2.5</b>	<b>-88.9</b>	<b>-393.1</b>
<sup>1)</sup> Amortization of product rights included in adm expenses	-12.3	–	-35.8	–	–

**Balance Sheet Parent company**

	Sep 30	Sep 30	Dec 31
<i>Amounts in SEK million</i>	2009	2008	2008
<b>ASSETS</b>			
<b>Fixed assets</b>			
Intangible fixed assets	834.5	214.4	826.5
Tangible fixed assets	213.3	223.1	211.7
Financial fixed assets	610.7	776.2	607.7
<b>Total fixed assets</b>	<b>1,658.5</b>	<b>1,213.6</b>	<b>1,645.9</b>
<b>Current assets</b>			
Inventories	581.5	74.3	587.6
Current receivables, non-interestbearing	302.3	293.6	252.4
Short-term investments	120.0	279.7	205.8
Cash and cash equivalents	188.3	252.2	252.3
<b>Total current assets</b>	<b>1,192.1</b>	<b>899.8</b>	<b>1,298.1</b>
<b>Total assets</b>	<b>2,850.6</b>	<b>2,113.5</b>	<b>2,944.0</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>	<b>1,255.6</b>	<b>1,360.9</b>	<b>1,216.2</b>
<b>Long-term liabilities</b>			
Long term liabilities, interestbearing	387.8	–	397.1
Long term liabilities, non-interestbearing	351.8	–	377.9
<b>Total long-term liabilities</b>	<b>739.6</b>	<b>–</b>	<b>775.0</b>
<b>Current liabilities</b>			
Current liabilities, non-interestbearing	855.4	752.6	952.8
<b>Total short-term liabilities</b>	<b>855.4</b>	<b>752.6</b>	<b>952.8</b>
<b>Total equity and liabilities</b>	<b>2,850.6</b>	<b>2,113.5</b>	<b>2,944.0</b>

**Change in Shareholders' equity Parent Company**

	2009	2008	2008
<i>Amounts in SEK million</i>	Jan 1 - Sep 30	Jan 1 - Sep 30	Jan 1 - Dec 31
<b>Opening balance</b>	<b>1,216.2</b>	<b>1,418.1</b>	<b>1,418.1</b>
Sharebased compensation to employees	2.5	6.5	7.8
Issue of share	34.4	25.1	183.4
Profit/loss for the period	2.5	-88.9	-393.1
<b>Equity, end of period</b>	<b>1,255.6</b>	<b>1,360.8</b>	<b>1,216.2</b>

## 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 amounts of shares were issued. To secure the ability to deliver shares and from a liquidity perspective to secure payments of future social fees associated with Aktieprogram 2009 (a share based incentive program), 231 585 shares have been issued. These shares are being held by Biovitrum.

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
Sept 2009	Issue of shares in connection with share based incentive program	231,585	127,372
<b>September 2009</b>		<b>50,911,901</b>	<b>27,935,502</b>

### 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 - Sep 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 - Sep 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	35,000	24,998

Employee option program 2007/2012	Jan 1 - Sep 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	200,000	100,000



**Not 3 Transactions with related parties**

Loans to related parties	2009	2008
<i>Loan to executive management in Parent Company:</i>		
At beginning of the year:	153	153
Loans paid during the year:	<u>—</u>	<u>—</u>
	<b>153</b>	<b>153</b>

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.

**Not 4 Taxes**

In 2004, the real estate designated as Paradiset 14 was transferred to a substantially foreign-owned limited liability partnership called Nya Paradiset KB, whereupon the participating interests in Nya Paradiset KB were sold to an external party at market price. The real estate was transferred to Nya Paradiset KB in accordance with the rules regarding so-called transfers below market value in return for consideration equivalent to the real estate's value for tax purposes. In a submission to the county administrative court dated 17 April 2008, the Swedish Tax Agency has formally requested that, pursuant the Swedish Tax Avoidance Act, the rules regarding transfers below market value shall not be applied. In the opinion of the Tax Agency, this entails that Biovitrum shall be charged a capital gain of SEK 234.5 million as a consequence of the transfer of the real estate to Nya Paradiset KB. In Biovitrum's view, it is patently obvious that the company has not acted in contravention of the purpose of the legislation in the manner alleged by the Tax Agency in the aforementioned submission. Thereafter, on 9 October 2009, the Tax Agency lodged a new submission and, in reliance on two judgments from the Supreme Administrative Court dated 29 May 2009, has now alleged a new ground as to why the rules governing transfers below market value shall not be applied by virtue of the Tax Avoidance Act. Biovitrum takes the view that the Tax Agency ought not to succeed in proving its case in relation to this new ground either.

It may be noted by way of conclusion that Biovitrum currently has losses carried forward of SEK 1,045 M.

*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.*

Solna, October 22, 2009

Martin Nicklasson  
Chief Executive Officer

## Review Report

We have reviewed this report for the period January 1, 2009, to September 30, 2009, 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. 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, October 22, 2008  
PricewaterhouseCoopers AB

Mikael Winkvist  
Authorized Public Accountant

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**Financial Calendar:**

Full Year Report 2009	February 18, 2010
Interim Report Jan-March 2010	April 27, 2010
Interim Report April-June 2010	July 20, 2010
Interim Report July-Sept, 2010	October 22, 2010



**About 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 further information visit [www.biovitrum.com](http://www.biovitrum.com).