

Biovitrum Full Year Report 2009 (translation only)

Strong revenue growth and profit turn around.

This full year report refers to the Biovitrum group before acquisition of Swedish Orphan. A financial pro forma statement for Swedish Orphan Biovitrum 2009 is shown on page 8 in this report.

January - December

- Total revenues before licensing and milestone revenues increased by 22 percent and amounted to SEK 1,234.4 M (1,008.1) mainly driven by Kineret[®] and Kepivance[®]. Profit for the period amounted to SEK 32.5 M (-335.5). This corresponds to a reported earnings per share¹⁾ of SEK 0.32 (-3.66).
- Core EPS²⁾ was SEK 0.84 (0.18).
- Cash flow from operations was SEK 58.8 M (-506.6). Cash and cash equivalents and short-term investments as of December 31 amounted to SEK 306.6 M (460.1).
- Positive progressions were seen in late stage clinical programmes and successful out-licensing and divestments of non core R&D projects and operations were made.

October - December

- Total revenues amounted to SEK 347.7 M (314.3).
- Fourth quarter combined sales of Kineret[®] and Kepivance[®] were the highest since Biovitrum acquired the products in December 2008. ReFacto[®] co-promotion revenues were up 25 percent compared to Q4 2008.
- Operating result was SEK 51.4 M (-290.2). Profit for the period amounted to SEK 31.5 M (-246.6). This corresponds to a reported earnings per share¹⁾ of SEK 0.31 (-2.64).
- Core EPS²⁾ was SEK 0.44 (-0.20).
- Cash flow from operations was SEK 149.3 M (-382.6).
- The first patient was dosed in a phase I/IIa study with the long-acting rFVIII Fc, a programme partnered with Biogen Idec.
- Results were positive in one of two clinical phase II studies with Kiobrina[™] (rhBSSL). A statistically significant improvement of growth velocity in preterm infants was observed. The safety profile was comparable to placebo.
- An agreement to expand Biovitrum's Kineret[®] license to include certain additional orphan indications was signed with Amgen. Cambridge Biotechnology Ltd (CBT) was divested to Proximagen Neuroscience plc. Astra Zeneca acquired all of Biovitrum's rights to its preclinical leptin modulator program aimed at treating obesity. Upfront payments amounted to EUR 6 M. Biovitrum will receive future milestone payments contingent on development progress and sales, as well as single digit percentage royalties on future sales.

Events after the period

- Biovitrum announced on November 5, 2009 the acquisition of Swedish Orphan. The transaction was closed on January 14, 2010 and was financed by a rights issue, an issue in kind and bank financing.
- Biovitrum and Biogen Idec reconstructed the collaboration agreement for the companies' long-acting, recombinant Factor VIII Fc and Factor IX Fc fusion proteins for treatment of hemophilia A and B respectively.
- Biovitrum and Biogen Idec enrolled the first patients in the registrational, open-label, multicenter trial designed to evaluate the efficacy, pharmacokinetics and safety of the long-acting rFIX Fc protein in hemophilia B patients (the B- LONG study).

¹⁾ Adjusted for new share issue completed in January 2010, after which total number of shares are 151,704,533.

²⁾ Core EPS is calculated from P/L for the period excluding amortizations and restructuring and other one-time expenses and based on average number of shares.

<i>Amounts in SEK million</i>	Oct 1 - Dec 31		Full year	Full year
	2009	2008	2009	2008
Total revenues before license revenues	285.1	314.3	1,234.4	1,008.1
Total revenues	347.7	314.3	1,297.0	1,140.6
Gross profit	255.0	231.2	921.3	875.9
Operating profit/loss before restructuring and other one-time expenses	51.4	-64.0	16.2	-40.1
Operating profit/loss before depreciations and amortizations (EBITDA)	77.0	-73.8	125.9	-118.8
Operating profit/loss before amortizations (EBITA)	64.9	-288.6	68.0	-380.3
Operating profit/loss (EBIT)	51.4	-290.2	16.2	-386.3
Profit/loss for the period	31.5	-246.6	32.5	-335.5
Earnings/loss per share after tax (SEK) ¹⁾	0.31	-2.64	0.32	-3.66
Core EPS ^{1) 2)} (SEK)	0.44	-0.20	0.84	0.18
Restructuring and other one-time expenses	–	-226.2	–	-346.2
Research and development expenses	109.4	185.8	569.4	670.6
Liquid funds and short-term investments	306.6	460.1	306.6	460.1

¹⁾ Adjusted for new share issue completed in January 2010, after which total number of shares are 151,704,533

²⁾ Calculated from P/L for the period excluding amortizations and restructuring and other one-time expenses and based on average number of shares before dilution.

CEO comments:

“2009 was a very successful and active year for Biovitrum. Our revenues before licensing revenues grew strongly and I am pleased that the operating profit was in line with our guidance, demonstrating a turn around into a profitable business. The positive progression of our clinical projects is also exciting as well as the fact that we were successful in out-licensing and divestment of the remaining non core R&D projects and operations. Finally, the acquisition of Swedish Orphan was a significant achievement. The new company, Swedish Orphan Biovitrum, will have a diverse product portfolio and an interesting late stage project pipe-line within rare diseases. I am personally committed to deliver future profitable growth reaching our 2015 business target of more than SEK 5 B in revenues and an EBITA margin of at least 30% based on the existing product/project range but also by adding new business opportunities to the company”, says CEO Martin Nicklasson.

Overview 2009

Sales & Marketing

Sales & Marketing has seen an addition of several key staff strengthening the skills and capabilities around Kineret and Kepivance. New marketing strategies are being developed to prepare for market expansion of these products. They were not actively promoted for a couple of years before the acquisition by Biovitrum at the end of 2008. Already, effects of this work can be seen. The fourth quarter sales were our strongest so far in local currencies. In addition to the geographical expansion, the Sales & Marketing unit has further developed the medical communication capabilities as well as improved the brand management.

In the second quarter 2009, Biovitrum launched ReFacto AF[®] in the Nordic region. ReFacto AF[®] is a further development of ReFacto[®] (recombinant factor VIII for hemophilia A). ReFacto AF[®] is produced with the latest production technology without using any components of human or animal origin. The switch to ReFacto AF[®] has been successful, and new patients have also been put on this new therapy.

Biovitrum is continuously striving towards being a preferred provider of valuable medicines and a patient partner within the hemophilia area. In line with this effort, Biovitrum launched 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.

Product sales

Amounts in SEK million	Oct 1 - Dec 31		Full year	Full year
	2009	2008	2009	2008
Kineret ^{® 1)}	120.9	25.8	440.7	25.8
Kepivance ^{® 1)}	26.3	5.7	109.9	5.7
Aloxi [®]	2.3	1.0	9.4	5.3
Stemgen [®]	0.4	0.6	3.4	0.6
Novastan [®]	0.9	0.4	1.3	0.8
Total revenues	150.9	33.5	564.8	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.

Total product sales revenues for the year amounted to SEK 564.8 M (38.2). The fourth quarter combined sales for Kineret[®] and Kepivance[®] were the highest since Biovitrum acquired the products.

Due to increased sales of Kineret[®] and the expected future sales development, Biovitrum will purchase additional Kineret[®] supply of from Amgen. A pre-payment of USD 4.4 M was made during the fourth quarter 2009.

Sales of Aloxi[®] in the Nordic region doubled during fourth quarter 2009 compared to the same quarter 2008.

The table below shows how sales have developed based on fixed exchange rates, using the average Swedish Kronor exchange rate in Q1 as reference.

Sales at Fixed Exchange Rate (average exchange rate during Q1 2009)

Amounts in SEK million	2009			
	Q1	Q2	Q3	Q4
Kineret	104.0	113.5	114.9	133.5
Kepivance	29.6	28.1	30.4	29.9
Total revenues	133.6	141.6	145.3	163.4
Revenue growth (%) in local currency per quarter		6.0%	2.6%	12.5%

Co-promotion revenues

Amounts in SEK million	Oct 1 - Dec 31		Full year	Full year
	2009	2008	2009	2008
ReFacto®	23.1	18.5	89.7	80.2
BeneFIX®	3.6	2.2	11.2	10.4
Mimpara®	7.1	5.6	26.2	22.7
Kineret®	-0.2	15.0	0.2	61.2
Kepivance®	0.0	–	0.0	0.2
Total revenues	33.6	41.3	127.3	174.7

Co-promotion revenues for ReFacto® increased by 12 percent in 2009 and amounted to SEK 89.7 M (80.2). In the fourth quarter corresponding figures were SEK 23.1 M (18.5), an increase with 25 percent compared to the same period in 2008.

BeneFIX® showed a continued increase in usage and an increase in co-promotion revenues compared to previous year.

Co-promotion revenues for Mimpara® increased during 2009 by 15 percent and amounted to SEK 26.2 M (22.7).

For product information see www.biovitrum.com

Royalty

Royalty revenues in 2009 amounted to SEK 165.6 M (176.2). The royalty is based entirely on revenues from Wyeth's sales of ReFacto® and ReFacto AF®/ Xyntha®. The decrease is explained by the switch from ReFacto® to ReFacto AF®/ Xyntha®, at a lower royalty rate.

Manufacturing and Contract Development

Biovitrum is the sole global manufacturer of the active substance for ReFacto AF® (sold in the US under the name Xyntha®). The newly developed manufacturing process entails significant advantages compared to the earlier process used for ReFacto. In addition to the exclusion of all foreign proteins, the new process also gives a higher yield, which enables an increased production volume in response to future raised market demands. To further improve process capabilities, an extensive renewal of the production facilities is in progress.

Amounts in SEK million	Oct 1 - Dec 31		Full year	Full year
	2009	2008	2009	2008
ReFacto	67.6	186.4	362.5	569.3
of which validation batches	–	47.0	–	47.0
Contract development	1.2	11.6	14.1	49.7
Total	68.7	198.0	376.5	619.0

In accordance with expectations, ReFacto® manufacturing revenues declined in the fourth quarter to SEK 67.6 M (186.4) due to a lower unit price for ReFacto AF®/Xyntha®. In 2009 a 36 percent manufacturing revenue decline was noted compared to 2008. Volumes will continue to vary from one quarter to the next as a result of Pfizer's production planning.

The revenues from other contract development 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.

Product development

Clinical Development, Regulatory Affairs and Pharmacovigilance competences and capabilities have been reinforced throughout 2009, to fully manage the day-to-day work around the newly acquired products as well as late-stage development programs.

Development projects

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

A registrational open-label, multicenter trial has recently been initiated. The trial is designed to evaluate the safety, pharmacokinetics and efficacy of Biovitrum's and Biogen Idec's long-acting, recombinant Factor IX Fc fusion protein (rFIXFc) in hemophilia B patients. The trial, called the B-LONG study, will determine the efficacy of rFIXFc in the prevention and treatment of bleeding in approximately 75 previously-treated patients with severe hemophilia B.

Kiobrina™ for the treatment of fat malabsorption in premature infants

The first phase II clinical trial in preterm infants, where rhBSSL is administered to infant formula, is now completed with positive results. The results show statistically significant improvement in the growth velocity. The safety profile was comparable to that of placebo, and no drug-related serious adverse events were reported. The second study, where rhBSSL is added to pasteurized breast milk, is currently ongoing.

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

A clinical study, demonstrating that Sym001 is capable of eliminating Rhesus D (RhD) positive red blood cells from the circulation of RhD negative healthy volunteers, has been finalized. A clinical phase II study, with the aim to study safety and efficacy of Sym001 in ITP patients, is ongoing in Europe. Three out of four planned dose cohorts have been treated, and the independent safety committee has recommended a continuation to the last dose group.

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

A phase I/IIa study of the long-acting fully-recombinant Factor VIII Fc fusion (rFVIII Fc) protein is ongoing. This open-label study will assess the safety, tolerability and pharmacokinetics of rFVIII Fc in severe, previously-treated, hemophilia A patients. The rFVIII Fc program is partnered with Biogen Idec.

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

A clinical study in children, with acute leukemia undergoing stem cell transplants, is currently ongoing. The primary purpose is to study safety and pharmacokinetics.

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. 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.

Business development

The development of compounds for treatment of leukemia, within the Flt3 program, will continue in a company jointly owned by Biovitrum and Karolinska Development AB, in accordance with an agreement signed in March 2009. The development of the program will be financed by Karolinska Development. In accordance with the agreement Biovitrum will receive royalties on future sales of products, originating from the Flt3 program.

In March 2009, Biovitrum signed a collaboration agreement with Affibody AB, which gave Biovitrum access to the proprietary technology platforms of Affibody® molecules, as well as the unique albumin-binding technology for development of pharmaceuticals. The agreement includes a product license.

In June 2009, Biovitrum announced that two pre-clinical metabolic disease projects (GPR 119 and SCD-1) were transferred to iNovacia AB. Biovitrum will receive royalties from future product sales resulting from the projects.

In order to increase the geographical presence of Kineret® and Kepivance®, several contacts have been made with potential distribution partners. A first deal was made in July 2009 with Megapharm in Israel.

In November 2009, Biovitrum divested its wholly-owned subsidiary Cambridge Biotechnology Ltd to Proximagen Neuroscience plc., including the sale of a number of small molecule drug development programs. The drug development programs consist of the pre-clinical stage programs VAP-1 and Trk A, as well as two clinical stage programs, the 5-HT2c agonist and the 5-HT6 antagonist programs. In return Biovitrum will receive a share of future revenues generated from the pipeline.

Also in November 2009, Biovitrum signed an agreement with Amgen to the Kineret license to include certain orphan indications.

In December 2009, AstraZeneca acquired all Biovitrum's rights to its preclinical leptin modulator program, aimed at treating obesity. Biovitrum received an upfront payment of EUR 6 M. If a product is approved, the agreement allows Biovitrum to receive up to Euro 186M in total upfront and milestone payments, as well as a single digit royalties on sales.

On February 18, 2010, Biovitrum and Biogen Idec announced a reconstruction of the collaboration agreement for the companies' long-acting, recombinant Factor VIII Fc and Factor IX Fc fusion proteins for treatment of hemophilia A and B respectively. Under the amended agreement, Biogen Idec will assume full development responsibilities and costs, as well as manufacturing rights for the rFVIII Fc and rFIX Fc programs. Biogen Idec also gains marketing responsibility for the rest-of-world territories that had previously been shared between the two companies, in addition to its existing commercial rights in North America. Biovitrum will retain commercial rights in Europe, Russia, Turkey and the Middle East. The cross-royalty rates has been reduced for both companies. The royalty rates will be further adjusted until Biogen Idec's increased costs are reimbursed.

Financial Statements

Revenues

<i>Amounts in SEK million</i>	Oct 1 - Dec 31		Full year	Full year
	2009	2008	2009	2008
Product sales	150.9	33.5	564.8	38.2
Total co-promotion revenues, of which:	33.6	41.3	127.3	174.7
Co-promotion revenues from current co-promotion agreements	33.8	26.3	127.1	113.3
Co-promotion revenues from Kineret® and Kepivance®	-0.2	15.0	0.2	61.4
Manufacturing and contract development	68.7	198.0	376.5	619.0
Royalty revenues	31.7	41.7	165.6	176.2
Licensing and milestone revenues ¹⁾	62.6	–	62.6	132.5
Other	0.1	-0.2	0.1	–
Total revenues	347.7	314.3	1,297.0	1,140.6

¹⁾ 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 and had no impact on the cash flow in 2008. This deferral ceased during the third quarter 2008.

Total revenues in 2009 increased to SEK 1,297.0 M (1,140.6). However, total revenues excluding licensing and milestone revenues, decreased by 9 percent in the fourth quarter to SEK 285.1 M (314.3). This is due to decreasing manufacturing and royalty revenues, in line with guidance. Including licensing and milestone revenues, the total revenues in the fourth quarter increased to SEK 347.7 M (314.3).

Total product sales in 2009 amounted to SEK 564.8 M (38.2). The corresponding number for fourth quarter reached SEK 150.9 M (33.5)

Co-promotion revenues (ReFacto®, BeneFIX®, Mimpara® and other) increased both in the fourth quarter and for the full year 2009. Kineret® and Kepivance® revenues are now referred to as product sales.

Manufacturing revenues, all of which relate to ReFacto®, decreased to SEK 67.6 M (186.4)³⁾. This is due to normal fluctuations of Pfizer'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 decrease in contract development revenues, SEK 1.2 M (11.6).

Revenues by regions

<i>Amounts in SEK million</i>	Oct 31 - Dec 31		Full Year	Full Year
	2009	2008	2009	2008
Europe	263.1	260.5	982.9	912.0
North America	66.7	21.6	260.0	156.6
Other	17.9	32.2	54.1	72.0
Total revenues	347.7	314.3	1,297.0	1,140.6

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

Results

Due to the increased sales of Kineret® and Kepivance®, the cost of goods and services sold increased during the fourth quarter 2009, compared to the corresponding period 2008. This had a negative impact on the gross profit margin, which was partly offset by licensing and milestone revenues received during the fourth quarter. Gross profit margin, excluding licensing and milestone revenues, was 67.5 percent (73.6). Furthermore, the ReFacto® manufacturing generated improved margins, due to higher yields and success rate, which also 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 production in 2009 was substantial higher than the market demand.

Research and development expenses decreased by 41 percent in the fourth quarter compared to the same period 2008, and amounted to SEK 109.4 M (185.8). Expenses related to the FVIII and FIX projects have been re-negotiated with Biogen Idec. The cost for the CBT unit amounted to SEK 2.9 M in the period.

³⁾ Manufacturing revenues for fourth quarter 2008 included revenues for validation batches amounting to SEK 47.0 M.

Sales and Administration expenses in fourth quarter amounted to SEK 70.5 M (129.9). The corresponding numbers for previous quarters in 2009 were SEK 89.0 M in Q1, SEK 87.5 M in Q2 and SEK 55.9 M in Q3. During the third quarter 2009 SEK 11.5 M was reclassified from Sales and Administration expenses to Cost of Goods Sold.

Operating result for the fourth quarter amounted to SEK 51.4 M (-290.2), and the profit reported for the period amounted to SEK 31.5 M (-246.6). This corresponds to reported earnings per share of SEK 0.31 (-2.64), adjusted for new share issue completed in January 2010.

Divestment of the preclinical leptin modulator program and the subsidiary Cambridge Biotechnology Ltd. had a SEK 35 M net positive effect on the result.

Financial items

The financial net for the fourth quarter amounted to SEK -19.9 M (13.0). The corresponding amount for the full year 2009 was SEK 16.3 M (20.2). The variation of the US dollar exchange rate has 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 in exchange rate during 2009 had a positive impact on the result amounting to SEK 33.1 M. The calculated interest for the future milestone payments amounted to SEK -14.0 M, for the full year 2009.

Financial Position

Cash/cash equivalents and short-term investments as of December 31, 2009, amounted to SEK 306.6 M (460.1). This include SEK 129.6 M (193.7) in bank balances and SEK 128.6 M (60.5) in 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 these cash and cash equivalents, the company had other short-term investments, with a term of more than three months, amounting to SEK 48.4 M (205.9) as of December, 2009.

The consolidated shareholders' equity as of December 31, 2009, amounted to SEK 1,352.8 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 expense for the quarter was SEK 0 M (30.5). In the fourth quarter 2008 the Company brought back a deferred tax liability of SEK 30.5 M.

Cash flow

Cash flow from operations during the fourth quarter amounted to SEK 149.3 M (- 382.6). During the fourth quarter, accounts receivables decreased by SEK 7.4 M to SEK 105.2 M. Payments related to restructuring reserves amounted to SEK 12.4 M during the period. Remaining payments concerning restructuring reserves amounted to SEK 7.1 M, of which SEK 5.8 M will have a negative impact on the cash flow during the first quarter 2010. The remaining SEK 1.3 M will impact cash flow during the second quarter 2010.

Investments

The Group's investments in tangible fixed assets during the fourth quarter amounted to SEK 51.0 M (13.3). Depreciations amounted to SEK 25.6 M (23.8), of which SEK 12.1 M (0) is related to product rights.

Investment in intangible fixed assets for the period amounted to SEK 143.0 M (79.5), including a non-cash effecting transaction of SEK 127.0 M.

Personnel

As of December 31st, 2009 Biovitrum had 383 employees (476), of which 60 percent (57) are women.

On April 29th 2009, 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 25th, 2011. Considering the result of the first year the assignment will be 100 percent.

During the first nine months 2009, 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.

Swedish Orphan Biovitrum Pro forma full year 2009

Biovitrum acquired Swedish Orphan in early 2010 creating a new specialty pharmaceutical company focused on rare diseases. The transaction is built on a strong industrial logic and a profitable future growth of the business. The signing was announced on November 5, 2009 and completed on January 14, 2010.

The mission of the new company Swedish Orphan Biovitrum (SOBI) is to develop and make available orphan drugs and niche specialty pharmaceuticals for patients with rare diseases and with high unmet medical needs. Swedish Orphan Biovitrum has a pan-European commercial organization and representation in North America, a strong business development track-record and compelling product development and manufacturing capabilities. The company's product portfolio consists of about 60 orphan or niche specialty products. Several late stage development programs within rare diseases provide exciting future business value. Pro forma sales for 2009 have been estimated to 2 billion SEK.

The following pro forma financial statement has been prepared as if Biovitrum had acquired 100% of outstanding shares in Swedish Orphan as per January 1, 2009. Pro forma financial statements describes a hypothetical situation, and do not describe Swedish Orphan Biovitrum's actual result for the period. See note 5 on page 16 for a preliminary purchase price allocation.

<i>Amounts in SEK million</i>	Biovitrum	Swedish Orphan Intl.	Pro forma adjust-ments	Swedish Orphan Biovitrum
Total revenues	1,297.0	768.6	–	2,065.6
Cost of goods and services sold	-375.7	-288.6	–	-664.3
Gross profit	921.3	480.0	–	1,401.3
Sales and administration expenses ¹⁾	-302.9	-253.9	-144.6	-701.4
Research and development expenses ¹⁾	-569.4	-35.5	1.9	-603.0
Other operating revenues/expenses ²⁾	-32.7	0.3	7.5	-24.9
Operating profit/loss	16.2	191.0	-135.2	72.1

<i>Amounts in SEK million</i>	Biovitrum	Swedish Orphan Intl.	Pro forma adjust-ments	Swedish Orphan Biovitrum
Total revenues	1,297.0	768.6	–	2,065.6
EBITDA	125.9	199.6	18.6	344.2
<i>EBITDA margin</i>	10%	26%		17%
Depreciations	-57.9	-2.5	–	-60.4
EBITA	68.0	197.1	18.6	283.8
<i>EBITA margin</i>	5%	26%		14%
Amortizations ³⁾	-51.8	-6.1	-153.8	-211.7
EBIT	16.2	191.0	-135.2	72.1

¹⁾ Retention bonus expenses of SEK 11.1 M in Swedish Orphan have been excluded from the pro forma financial statement. Also effecting Sales and administration expenses is amortizations related to acquisition of Swedish Orphan of SEK 153.8 M.

²⁾ Other operating expenses includes loss SEK 27 M from sale of subsidiary Cambridge Biotechnology Ltd in November 2009 and excludes SEK 7.5 M in expenses related to work with prospectus during 2009 in Swedish Orphan.

³⁾ Amortizations consists of amortizations related to acquisition of product rights SEK 47.9 M, amortizations related to the acquisition of Swedish Orphan SEK 153.8 M and other SEK 10.0 M.

Statement of comprehensive income

<i>Amounts in SEK million</i>	Oct 1 - Dec 31		Full year	Full year
	2009	2008	2009	2008
Total revenues	347.7	314.3	1,297.0	1,140.6
Cost of goods and services sold	-92.7	-83.2	-375.7	-264.7
Gross profit	255.0	231.2	921.3	875.9
Sales and administration expenses ¹⁾	-70.5	-129.9	-302.9	-268.0
Research and development expenses	-109.4	-185.8	-569.4	-670.6
Restructuring expenses	–	-226.2	–	-346.2
Other operating revenues/expenses	-23.6	20.6	-32.7	22.6
Operating profit/loss	51.4	-290.2	16.2	-386.3
Financial income	-4.6	13.9	42.7	21.4
Financial expenses	-15.3	-0.9	-26.4	-1.2
Profit/loss after financial items	31.5	-277.2	32.5	-366.1
Income tax expense	–	30.5	–	30.6
Profit/loss for the period	31.5	-246.6	32.5	-335.5
Other comprehensive income ²⁾				
Translation difference	-4.1	-14.6	-4.1	-23.5
Comprehensive income for the period	27.4	-261.2	28.4	-359.0
Earnings/loss per share after tax ³⁾ (SEK)	0.31	-2.64	0.32	-3.66
Earnings/loss per share after dilution ³⁾ (SEK)	0.31	-2.64	0.32	-3.66

¹⁾ Amortization of product rights included in Adm expenses

-12.1 – -47.9 –

²⁾ 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.

³⁾ Adjusted for new share issue completed in January 2010.

Condensed consolidated balance sheet

	Dec 31	Dec 31
<i>Amounts in SEK million</i>	2009	2008
ASSETS		
Fixed assets		
Intangible fixed assets ¹⁾	1,159.1	1,026.0
Tangible fixed assets	252.0	215.5
Financial fixed assets	114.5	46.2
Total fixed assets	1,525.6	1,287.7
Current assets		
Inventories	578.4	587.7
Current receivables, non-interestbearing	394.9	243.3
Short-term investments	48.4	205.9
Cash and cash equivalents	258.2	254.2
Total current assets	1,279.9	1,291.1
Total assets	2,805.5	2,578.8
EQUITY AND LIABILITIES		
Shareholders' equity	1,352.8	1,285.0
Long-term liabilities		
Long-term liabilities ²⁾	656.0	775.0
Long-term liabilities, non-interestbearing	48.2	48.2
Total long-term liabilities	704.2	823.2
Current liabilities		
Current liabilities	50.0	–
Current liabilities, non-interestbearing	698.5	470.6
Total short-term liabilities	748.5	470.6
Total equity and liabilities	2,805.5	2,578.8

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

²⁾ Discounted future milestone payments has previously been reported as non-interestbearing liabilities, as from full year report 2009 they are reported as long-term liabilities.

Statement of changes in equity

	2009	2008
<i>Amounts in SEK million</i>	Jan 1 - Dec 31	Jan 1 - Dec 31
Opening balance	1,285.0	1,452.8
Sharebased compensation to employees	5.1	7.9
Issue of share	34.4	183.5
Redemption of shares	-0.2	-0.2
Net profit/loss for the year	28.4	-359.0
Equity, end of period	1,352.8	1,285.0

Statement of cash flow

<i>Amounts in SEK million</i>	Oct 1 - Dec 31		Full year	Full year
	2009	2008	2009	2008
Net result	31.5	-246.6	32.5	-335.5
<i>Adjustment for items not affecting cash flow:</i>				
Depreciations and write down	25.6	216.4	109.7	267.5
Capital gain/loss from divestment of fixed assets	19.6	0.6	19.4	0.4
Revaluation of fixed financial assets	4.7	-2.9	4.7	-2.9
Revaluation of milestones (present value and exchange rate)	13.9	–	-12.3	–
Revaluation of long-term liabilities	2.5	–	-6.8	–
Pensions	-8.1	-3.2	-5.6	-5.1
Deferral of fees from Amgen	–	0.0	–	-132.5
Restructuring expenses	–	29.1	–	149.1
Payments related to restructuring reserves	-12.4	-17.0	-97.9	-63.2
Reversal of deferred tax	–	-30.6	–	-30.6
Other items ¹⁾	2.6	1.4	5.1	7.9
Cash flow from operations before change in working capital	79.9	-52.9	48.8	-144.9
Change in working capital	69.4	-329.6	10.0	-361.7
Cash flow from operations	149.3	-382.6	58.8	-506.6
Divestment of operation	23.1	–	23.1	–
Investment in operation	-60.8	–	-60.8	–
Investment in intangible fixed assets	-16.0	-79.5	-62.6	-180.7
Investment in tangible fixed assets	-51.0	-13.3	-96.0	-24.5
Divestment of tangible fixed assets	2.1	0.0	2.1	8.1
Investment/Divestment of financial assets	1.1	0.0	-1.9	-11.8
Short-term investments	71.6	73.8	157.5	188.7
Cash flow from investing activities	-29.9	-18.9	-38.6	-20.2
Loans - Raising/Amortization	-50.0	399.8	-50.0	399.8
Issue of shares	–	1.8	34.4	16.6
Redemption of shares	-0.2	–	-0.2	–
Cash flow from financing activities	-50.2	401.6	-15.8	416.4
Net change in cash	69.2	0.2	4.4	-110.4
Liquid funds at the beginning of the period	189.4	254.4	254.2	365.8
Cash and cash equivalent in divested operation	-0.4	–	-0.4	–
Translation difference in cash flow and liquid funds	0.0	-0.3	0.0	-1.2
Liquid funds at the end of the period	258.2	254.2	258.2	254.2
Short-term investments	48.4	205.9	48.4	205.9
Liquid funds and short-term investments at the end of the period	306.6	460.1	306.6	460.1

¹⁾ Expenses related to sharebased compensation to employees.

Key ratios and other information

	Oct 1 - Dec 31		Full year	Full year
	2009	2008	2009	2008
Return on				
Shareholders' equity	2.4%	-18.5%	2.5%	-24.5%
Total capital	1.2%	-11.4%	2.2%	-16.1%
Margins				
Gross margin	73.3%	73.6%	71.0%	76.8%
EBITDA-margin	22.1%	-23.5%	9.7%	-10.4%
EBIT-margin	14.8%	-92.3%	1.2%	-33.9%
Profit margin	9.1%	-78.5%	2.5%	-29.4%
Per share data (SEK)				
Shareholders' equity per share	26.6	25.6	26.6	25.6
Shareholders' equity per share after dilution	26.4	24.9	26.4	25.4
Cash flow per share	1.4	0.0	0.1	-2.4
Cash flow per share after dilution	1.3	0.0	0.1	-2.4
Other information				
Equity ratio	48.2%	49.8%	48.2%	49.8%
Number of shares ¹⁾	50,911,901	50,098,782	50,911,901	50,098,782
Average number of shares	50,911,901	46,871,825	50,485,362	46,048,631
Outstanding warrants ²⁾	335,000	1,503,068	335,000	1,503,068
Number of shares after dilution	51,281,901	51,641,850	51,281,901	50,567,342
Average number of shares after dilution	51,281,901	48,732,583	50,976,493	46,593,267

¹⁾ A preferential new share issue was finalized January 14, 2010, after which number of shares are 151,704,533.

²⁾ There are two different warrant programs outstanding, exercisable for a maximum of 699,300 new shares in total, adjusted for the preferential new share issue completed in January 2010.

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

<i>Amounts in SEK million</i>	Oct 1 - Dec 31		Full year	Full year
	2009	2008	2009	2008
Total revenues	347.7	314.3	1,297.0	1,140.6
Cost of goods and services sold	-92.7	-83.2	-375.7	-264.7
Gross profit	254.9	231.2	921.2	875.9
Sales and administration expenses ¹⁾	-79.2	-131.0	-309.0	-273.0
Research and development expenses	-109.5	-186.2	-570.7	-669.5
Restructuring expenses	–	-81.2	–	-201.2
Other operating revenues/expenses	3.9	18.7	-5.1	23.3
Operating profit/loss	70.1	-148.5	36.4	-244.5
Result from participation in Group companies	17.6	-168.5	17.6	-168.5
Financial income	-4.5	13.7	42.8	21.1
Financial expenses	-15.3	-0.9	-26.4	-1.2
Profit/loss after financial items	67.9	-304.2	70.4	-393.1
Income tax expense	–	–	–	–
Profit/loss for the period	67.9	-304.2	70.4	-393.1

¹⁾ Amortization of product rights included in adm expenses -12.1 – -47.9 –

Balance Sheet Parent company

<i>Amounts in SEK million</i>	Dec 31	Dec 31
	2009	2008
ASSETS		
Fixed assets		
Intangible fixed assets	959.7	826.5
Tangible fixed assets	252.0	211.7
Financial fixed assets	670.3	607.7
Total fixed assets	1,882.0	1,645.9
Current assets		
Inventories	578.4	587.6
Current receivables, non-interestbearing	396.5	252.4
Short-term investments	48.4	205.8
Cash and cash equivalents	258.0	252.3
Total current assets	1,281.2	1,298.1
Total assets	3,163.2	2,944.0
EQUITY AND LIABILITIES		
Shareholders' equity	1,326.1	1,216.2
Long-term liabilities		
Long term liabilities	656.0	775.0
Total long-term liabilities	656.0	775.0
Current liabilities		
Current liabilities	50.0	952.8
Current liabilities, non-interestbearing	1,131.1	952.8
Total short-term liabilities	1,181.1	952.8
Total equity and liabilities	3,163.2	2,944.0

Change in Shareholders' equity Parent Company

<i>Amounts in SEK million</i>	2009	2008
	Jan 1 - Dec 31	Jan 1 - Dec 31
Opening balance	1,216.2	1,418.1
Sharebased compensation to employees	5.1	7.8
Issue of share	34.4	183.4
Redemption of shares	-0.2	–
Profit/loss for the period	70.4	-393.1
Equity, end of period	1,326.1	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 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		Number 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
Sep 2009	Issue of shares in connection with share based incentive program	231,585	127,372
December 2009		50,911,901	27,935,502

A preferential new share issue was completed in January, 2010, after which total number of shares are 151,704,533.

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 433,952⁴⁾ 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 380,735⁵⁾ 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	Full year 2009	Full year 2008
Outstanding January 1	1,163,068	2,326,136
Allocated during the period	-	-
Exercised during the period	-581,534	-281,144
Repurchased during the period	-	-
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	Full year 2009	Full year 2008
Outstanding January 1	40,000	60,000
Allocated during the period	-	-
Exercised during the period	-	-
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	Full year 2009	Full year 2008
Outstanding January 1	300,000	300,000
Allocated during the period	-	-
Exercised during the period	-	-
Repurchased during the period	-	-
Forfeited during the period	-	-
Outstanding at of end of accounting period	300,000	300,000
Exercisable at of end of accounting period	200,000	100,000

⁴⁾ Adjusted for new share issue completed in January 2010.

⁵⁾ Adjusted for new share issue completed in January 2010.

Note 3 Transactions with related parties

<i>Amounts in SEK million</i>	Full Year 2009	Full Year 2008
<i>Loan to executive management in Parent Company:</i>		
At beginning of the year:	153	153
Loans paid during the year:	–	–
	153	153

There was no change as to regarding 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 AB.

Note 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.

Note 5 Acquired operations

Biovitrum acquired Swedish Orphan, creating a new specialty pharmaceutical company, focused on rare diseases. The transaction is built on a strong industrial logic and a profitable future growth of the business. The signing was announced on November 5, 2009 and completed on January 14, 2010.

Below follows a preliminary purchase price allocation for the acquisition of Swedish Orphan.

Purchase price allocation	
<i>Amounts in SEK million</i>	
Purchase price	
- cash payment	1,923.0
- discounted value est. future additional purchase price	165.0
- direct cost related to the acquisition	33.0
- fair value of shares issue	1,739.0
Total purchase price	3,860.0
Book value acquired net assets	-456.0
Total adjustment in purchase price allocation	3,404.0

Assets and liabilities in acquired operation		
<i>Amounts in SEK million</i>		
Goodwill	1,679.0	213.0
Other intangible assets	2,680.0	37.0
Tangible assets	14.0	14.0
Financial fixed assets	3.0	3.0
Deferred income tax receivables	–	–
Other current assets	449.0	449.0
Total assets in acquired operation	4,825.0	716.0
Long-term borrowings	31.0	31.0
Retirement benefit obligations	3.0	3.0
Deferred income tax liabilities	749.0	44.0
Current liabilities	182.0	182.0
Total liabilities in acquired operation	965.0	260.0
Acquired net assets	3,860.0	456.0

Liquid funds	
<i>Amounts in SEK million</i>	
Liquid funds	
- cash payment	-1,923.0
Paid acquisition costs	-33.0
Liquid funds in acquired operation	122.0
Effect on liquid funds	-1,834.0

Annual General Meeting 2010

The Annual General Meeting of Biovitrum AB (publ) will be held at 4 p.m. on April 27th, 2010 in Wallenbergsalen at the Royal Swedish Academy of Engineering Sciences (IVA), Grev Turegatan 16, Stockholm.

The Annual Report, including full financial and accounting data, will be published on www.biovitrum.com, at the latest 14 days before the AGM. It will also be available at Biovitrum's headquarters in Solna, Tomtebodavägen 23 A, on The Karolinska Institutet campus.

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 full year report has not been reviewed by the company's auditors.

Solna, February 18, 2010

Martin Nicklasson
Chief Executive Officer

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Financial Calendar:

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 Swedish Orphan Biovitrum

On January 14, 2010, Biovitrum AB (publ) completed the acquisition of Swedish Orphan International Holding AB and created Swedish Orphan Biovitrum - a leading company focused on treatment of rare diseases.

Swedish Orphan Biovitrum is a Swedish based specialty pharmaceutical company with an international market presence. The company is focused on providing and developing orphan and niche specialist pharmaceuticals to patients with high medical needs. The portfolio consists of about 60 marketed products and an emerging late stage clinical development pipe-line within rare diseases. Swedish Orphan Biovitrum has pro-forma revenues 2009e of about 2 BSEK and approximately 500 employees. The head office is located in Sweden and the share (STO: BVT) is listed on NASDAQ OMX Stockholm.

For more information please visit www.biovitrum.com