



Strong cash flow from core business. By product acquisition, Biovitrum now is an international biopharmaceutical company.

# October - December

- Biovitrum acquired on the December 15<sup>th</sup> the drugs Kepivance<sup>®</sup> and Stemgen<sup>®</sup> from Amgen as well as an exclusive license for Kineret<sup>®</sup>. The acquisition implies an expansion of Biovitrum's commercial operations to include other areas in Europe, North America and Australia/New Zealand. Sales in the second half of December amounted to SEK 32.1 M for these products.
- Net revenues increased by 5 percent to SEK 314.3 M compared to the same period last year (299.5). Profit for the quarter before non-recurring expenses was SEK 15.4 M (-2.4).
- Profit, including non-recurring cost amounted to SEK -246.6 M (-2.4). Non-recurring cost includes restructuring of Research & Development and write-downs of assets, SEK 226.2 M and cost for building-up of commercial infrastructure SEK 66.4 M. Earnings per share before non-recurring costs was 0.33 SEK (-0.05) and including non-recurring costs -5.26 SEK (-0.05).
- Cash flow from operations, excluding the acquisition of the three new products, improved by SEK 220.5 M to SEK 209.8 M (-10.7). Including the acquisition, the cash flow amounted to SEK -382.7 M (-10.7).
- The agreement regarding manufacturing of the hemophilia drug ReFacto<sup>®</sup> for Wyeth was extended until December 31<sup>st</sup>, 2015.
- Factor IXFc for the treatment of hemophilia B received orphan drug status in the US.
- Positive results were reported from a clinical study showing that the Sym001 drug candidate eliminates RhD positive red blood cells from the circulation.

## January - December

- Net revenues amounted to SEK 1,140.6 M (1,256.4) and the profit for the year before non-recurring costs was SEK 60.4 M (79.0), which represents earnings per share of SEK 1.31 (1.73). Results including non-recurring costs were -335.5 SEK M, representing earnings per share of SEK -7.28 (1.73).
- Cash flow from operations was -506.7 M (-25.4). Before acquisition and restructuring costs cash flow was SEK 164.8 M. Cash and cash equivalents and short-term investments as of December 31<sup>st</sup> amounted to SEK 460.1 M (760.4).
- In line with the new business strategy to focus on protein drugs within specialist indications, the number of employees working in research and development will be reduced. The final parts of the restructuring process will be implemented during 2009 after which the number of employees within R&D will be reduced from 353 at the end of 2007 to 170.
- At the end of the year, Biovitrum had six specialist pharmaceutical projects in clinical studies and one in preclinical development.

## After the end of period

• The process of selling the UK research unit Cambridge Biotechnology (CBT) has been initiated.



## Financial Overview 2008

	Oct 1 -	Dog 24	E.II V	/aa#	
	Oct 1-	Dec 31	Full Year		
Amounts in SEK million	2008	2007	2008	2007	
Total revenues Profit/loss before restructuring and other one-time expenses	314.3	299.5	1,140.6	1,256.4	
Operating profit/loss	2.3	-10.2	40.1	55.1	
Profit/loss after financial items	15.4	-2.4	60.3	79.0	
Profit/loss for the period	15.4	-2.4	60.4	79.0	
Profit/loss including restructuring and other of	one-time expen	ses			
Operating profit/loss	-290.2	-10.2	-386.3	55.1	
Profit/loss after financial items	-277.2	-2.4	-366.1	79.0	
Profit/loss for the period	-246.6	-2.4	-335.5	79.0	
Earnings/loss per share before dilution Earnings/loss per share after dilution (SEK)	-5.26 -5.26	-0.05 -0.05	-7.28 -7.28	1.73 1.69	
Research and development expenses	185.8	184.7	670.6	694.3	
Liquid funds and short-term investments	460.1	760.4	460.1	760.4	

## CEO's comments:

"In 2008 Biovitrum went through a comprehensive process to transform the company's commercial operations according to the business strategy launched at the end of 2007. We acquired three unique marketed products with growth potential. The acquisition also means that Biovitrum has established a commercial presence in Europe, North America and Australia/New Zealand. We also implemented a radical restructuring of our research organization. The R&D organization is now focusing on protein drugs, and the restructuring will lead to lower research costs. The extension of the manufacturing agreement with Wyeth for ReFacto was also a very important event. Thanks to these radical and successful initiatives we are well on the way towards long-term profitability. We now also have the infrastructure to handle additional product acquisitions, licensing and a broad-based launch of our own products, and thereby generate further growth" says Biovitrum's CEO Martin Nicklasson.



## Overview 2008

#### **Specification of Revenues**

	Oct 1	Oct 1 - Dec 31		Full year	
Amounts in SEK million	2008	2007	2008	2007	
ReFacto <sup>®</sup> revenues	246.6	219.6	825.7	915.4	
Revenues from other product sales	56.3	23.4	132.7	81.1	
Other 1)	11.3	12.4	49.7	63.8	
Total revenues before licensing and milestone revenues	314.3	255.4	1,008.1	1,060.2	
Licensing and milestone revenues	0.0	44.2	132.5	196.2	
Total revenues	314.3	299.5	1,140.6	1,256.4	

Other revenues includes e.g. research revenues, revenues from contract development and royalty from other products than ReFacto<sup>®</sup>

In 2008 the work continued of building up an international pharmaceutical company focusing on development, marketing and production of protein drugs for the treatment of specialist indications. Biovitrum acquired from Amgen the global rights to the protein drugs Kepivance<sup>®</sup> (palifermin) and Stemgen<sup>®</sup> (ancestim), and obtained an exclusive global license for Kineret<sup>®</sup> (anakinra), see note 6. The three products generated sales revenues of almost USD 70 M in 2007. The agreement also involves Biovitrum acquiring stocks of the three products equivalent to a value at acquisition of SEK 540.6 M (around USD 75 M).

The purchase price paid was SEK 857.7 M (equivalent to USD 118 M), of which SEK 701.3 M was paid in cash and in new Biovitrum shares issued to Amgen (in total 3,768,516 ordinary shares worth SEK 156.4 M). In connection with this transaction a loan totaling SEK 600.0 M was secured, SEK 399.8 M of which has been utilized. When Kineret® and Kepivance® reach certain cumulative net sales levels, Biovitrum will pay milestone payments, see note 6.

With the acquisition of the three products, Biovitrum has built up an international distribution and sales infrastructure and thereby also a platform for both newly acquired drugs and products from the company's own development portfolio. Building infrastructure of this kind has involved increased one-time costs for Biovitrum, and the 2008 profits were charged with a total of SEK 80.2 M.

Total revenues for the year amounted to SEK 1,140.6 M (1,256.4), which is 9 percent less than 2007.

The reduction is mainly attributable to the fact that licensing revenue payments ended in the third quarter and to lower revenues from the production of ReFacto® compared to 2007. The lower revenues are explained by large non-recurring revenues in 2007 and somewhat lower production volumes as a result of a production stoppage for the conversion to a new version of ReFacto®, ReFacto AF. The new process will lead to future higher production volumes due to better yields. Other revenues increased by 15 percent in 2008.

## ReFacto® Revenues

	Oct 1 -	Oct 1 - Dec 31		Full year
Amounts in SEK million	2008	2007	2008	2007
Manufacturing revenues	186.4	161.2	569.3	677.2
Co-promotion revenues	18.5	19.3	80.2	72.7
Royalty revenues	41.7	39.1	176.2	165.5
Total ReFacto revenues	246.6	219.6	825.7	915.4

Revenues from ReFacto<sup>®</sup> fell to SEK 825.7 M in 2008 compared to SEK 915.4 M in 2007.

## TRANSLATION ONLY

## Biovitrum Full year Report 2008



The total manufacturing revenues for the full year were SEK 569.3 M (677.2). In the fourth quarter manufacturing revenues increased by 16 percent compared to the same period the previous year.

Royalty revenues from ReFacto<sup>®</sup> increased by 6 percent to SEK 176.2 M in 2008. Co-promotion revenues from the sale of ReFacto<sup>®</sup> in the Nordic region increased by 10 percent during the year to SEK 80.2 M (72.7).

The pharmaceutical substance for ReFacto AF is produced by Biovitrum in an advanced production process entirely without the addition of human or animal components. In 2008, production was entirely converted for ReFacto AF and deliveries of ReFacto AF began in the fourth quarter. ReFacto AF is approved for sale in the US and Canada under the Xyntha® brand and is expected to be approved in Europe in 2009.

The delivery agreement with Wyeth for ReFacto<sup>®</sup> has been extended until December 31<sup>st</sup>, 2015. Biovitrum is still the sole manufacturer of the substance for ReFacto<sup>®</sup> and Xyntha<sup>®</sup>/ReFacto AF for Wyeth, and continues to receive royalty payments from Wyeth's global sales. Biovitrum's co-promotion rights in the Nordic region remain unchanged.

#### **Other Product Sales**

BeneFIX <sup>®</sup>	Hemophilia B
Novastan <sup>®</sup>	Anticoagulation
Mimpara <sup>®</sup>	Hyperparathyroidism
Kineret <sup>®</sup>	Rheumatoid arthritis
Kepivance <sup>®</sup>	Mycocitis as an effect of chemotherapy
Aloxi <sup>®</sup>	Nausea as an effect of chemotherapy
Stemgen <sup>®</sup>	Blood stem cell transplantation

Revenues from other products in 2008, including co-promotion revenues, increased by 64 percent to SEK 132.7 M (81.1). In the fourth quarter revenues rose by 141 percent to SEK 56.3 M. The increase in the fourth quarter is mainly attributable to the acquisition of Kineret<sup>®</sup>, Kepivance<sup>®</sup> and Stemgen<sup>®</sup> from December 15<sup>th</sup> , 2008.

At the end of 2008 Biovitrum established itself in the markets in Europe, the US, Canada, Australia and New Zealand by acquiring Kepivance<sup>®</sup>, Stemgen<sup>®</sup> and Kineret<sup>®</sup>. In the Nordic region Biovitrum is also marketing ReFacto<sup>®</sup> and another three specialist products, Mimpara<sup>®</sup>, Aloxi<sup>®</sup> and BeneFIX<sup>®</sup>.

Kineret® is a recombinant protein drug used by patients with rheumatoid arthritis to prevent the damaging effects of an inflammatory signal transducer, so-called interleukin. The effect on patients is a reduction in pain and swelling.

Kepivance<sup>®</sup> is a recombinant protein drug used to treat mucositis in patients with leukemia and being treated with chemotherapy and radiation in conjunction with bone marrow transplants. This drug reduces pain in the mouth and throat and makes it easier for patients to eat and drink.

Stemgen® is a growth factor which is used in connection with blood progenitor cell transplants in the treatment of leukemia.



# Research and Development

Biovitrum's strategy, in addition to in-licensing and acquisitions, is to develop specialist pharmaceuticals in-house up to registration and then to market them globally. In 2008 the focus on specialist pharmaceuticals has accelerated and the entire business is now targeted on this research, at the same time as all research in small molecular drugs has ceased. Within the new organization, most employees are working with development products at the same time as a greater portion of the research and development budget consists of variable costs (e.g. costs relating to clinical studies). As the specialist pharmaceutical projects have advanced into the clinical phase, costs have increased. Due to the restructuring, approximately SEK 200 M on a rolling twelve-month basis has been freed up for continued development of our projects within protein-based specialist pharmaceuticals.

With respect to the existing primary care projects (for more information see <a href="www.biovitrum.com">www.biovitrum.com</a>), Biovitrum intends to enter into agreements with other pharmaceutical companies.

# Biovitrum's portfolio of specialist care products

Kepivance® for the treatment of oral mucositis in children following cancer treatment

A clinical study with Kepivance is under way in which children with acute leukemia who have undergone a transplant of stem cells are being treated. The aim of the study, which is expected to include around 27 children ages 1 to 16, is primarily to study safety and pharmacokinetics. The study is also registering the therapeutic effect on inflammation in the mouth and throat.

Kiobrina™ for the treatment of fat malabsorption in preterm infants

Two parallel clinical phase II trials – one where rhBSSL is administered in pasteurized breast milk and one where it is administered in infant formula – are currently under way in Italy and France.

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

A clinical phase II study with ExinaldaTM has started. The aim of the study is to document the clinical effect of ExinaldaTM in patients with pancreatic insufficiency as a result of cystic fibrosis. The study involves 18 patients and is being conducted in Poland and the Netherlands.

Anti-Rh(D) for the treatment of idiopathic thrombocytopenia purpura (ITP) and prophylaxis of Rh immunization

A phase I study has been concluded with good results. A clinical study which shows that Sym001 can eliminate RhD positive red blood cells from the circulation of RhD negative healthy volunteers has also been conducted. In addition, a clinical phase II study is ongoing to test the safety and therapeutic effect of Sym001 in ITP patients at 23 clinics in Europe.

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

A clinical phase I/IIa study of FIXFc with hemophilia B patients is ongoing. The study is being conducted at clinics in the US and is testing the safety, tolerability and pharmacokinetics of FIXFc in these patients.

Factor VIIIFc (FVIIIFc) for the treatment of hemophilia A

The product is in the preclinical phase.

	Indication	Project	Partner	Ph I	Ph II	Ph III	Reg
	Hemophilia A *	ReFacto AF	Wyeth				
	Hemophilia B	FIXFc	Syntonix/ Biogen Idec				
	Fat malabsorption in premature infants	Kiobrina™					
Clincal	Fat malabsorption	Exinalda™					
	RH-immunization	Anti-Rh(D)	Symphogen		**		
	Platelet disorder (ITP)	Anti-Rh(D)	Symphogen				
	Oral mucositis, pediatrics (3-16 yrs)	Kepivance <sup>®</sup>					
Preclinic	Hemophilia A	FVIIIFc	Syntonix/ Biogen Idec				

 <sup>\*</sup> Approved in USA and Canada. Registered trademark Xyntha<sup>®</sup>

<sup>\*\*</sup> A dose adjusting red blood cell challenge healthy volunteer study preceding phase III



## Financial Statements

## Revenues

Revenues for the fourth quarter of 2008 amounted to SEK 314.3 M (299.5).

Revenues from ReFacto<sup>®</sup> in the fourth quarter amounted to SEK 246.6 M (219.6).

Manufacturing revenues amounted to SEK 186.4 M (161.2). The increase is due to higher ReFacto® delivery levels.

Sales of ReFacto<sup>®</sup> in the Nordic region declined somewhat during the period due to a change in wholesaler stocks of ReFacto, and co-promotion revenues amounted to SEK 18.5 M (19.3). Biovitrum's royalty revenues in the fourth quarter increased by 7 percent, resulting in revenues of SEK 41.7 M (39.1).

Revenues from sales of other products increased in the fourth quarter to SEK 56.3 M (23.4). The increase is mainly attributable to the acquisition of Kineret<sup>®</sup>, Kepivance<sup>®</sup> and Stemgen<sup>®</sup>. Sales of these three products in the second half of December amounted to SEK 32.1 M (0).

No license and milestone revenues have been reported for the fourth quarter. The previous year these revenues amounted to SEK 44.2 M. Other revenues amounted to SEK 11.3 M (12.4) and consist of revenues from biotechnological pharmaceutical manufacturing.

The total revenues for 2008 are lower than the previous year by SEK 115.8 M. The decrease is due to lower deliveries of ReFacto<sup>®</sup>. In addition to normal sales in the first half of 2007, a payment for validation batches of the new ReFacto protein in the amount of SEK 93 M was received. Furthermore, accrual over five years of license revenues from Amgen ceased.

#### Consolidated income statement

	Oct 1	1 - Dec 31	Full year	Full year
Amounts in SEK million	2008	2007	2008	2007
Total revenues	314.3	299.5	1,140.6	1,256.4
Cost of goods and services sold	-83.2	-88.2	-264.7	-348.8
Gross profit	231.2	211.3	875.9	907.7
Sales and marketing expenses	-18.1	-14.6	-51.8	-43.7
Administration expenses	-111.8	-29.3	-216.2	-121.1
(costs related to product acquisition)	(-66,4)	(-)	(-80,2)	(-)
Research and development expenses	-185.8	-184.7	-670.6	-694.3
Restructuring expenses	-226.2	_	-346.2	-
Other operating revenues	19.5	6.2	34.3	20.0
Other operating expenses	1.1	0.8	-11.7	-13.3
Operating profit/loss	-290.2	-10.2	-386.3	55.1
Financial income	13.9	8.3	21.4	25.3
Financial expenses	-0.9	-0.6	-1.2	-1.4
Profit/loss after financial items	-277.2	-2.4	-366.1	79.0
Income tax expense	30.6	0.0	30.6	0.0
Profit/loss for the period	-246.6	-2.4	-335.5	79.0
Earnings/loss per share after tax (SEK)	-5.26	-0.05	-7.28	1.73
Earnings/loss per share				
after dilution (SEK)	-5.26	-0.05	-7.28	1.69

## Profit/loss

The cost of goods and services fell slightly in the fourth quarter to SEK 83.2 M (88.2) mainly as a result of lower manufacturing costs after conversion to a new process in producing ReFacto<sup>®</sup>.

The gross profit was SEK 231.2 M (211.3).

Research and development expenses in the fourth quarter amounted to SEK 185.8 M (184.7). In connection with the restructuring of R&D, the fixed costs were down by around 17 percent compared to the fourth quarter in 2007. The equivalent figure for the full year is also 17 percent.

The operating profit before restructuring costs and other non-

recurring costs for the fourth quarter was SEK 2.3 M (-10.2). The profits for the fourth quarter have been charged with SEK 226.2 M in restructuring costs, see note 3. In addition to this, profits have been charged with SEK 66.4 M relating to the cost of developing commercial structures, see table above.

The loss for 2008 was SEK -335.5 M (79.0). Excluding restructuring and other non-recurring costs, the profit for the period was SEK 60.4 M. The loss for the fourth period amounted to SEK -246.6M (-2.4).

Net financial income for the quarter was SEK 13.0 M (7.7). Net financial income full year was SEK 20.2 M (23.9).



## Financial Position

Cash and cash equivalents and short-term investments as of December 31<sup>st</sup>, 2008 amounted to SEK 460.1 M (760.4). Of this amount, SEK 193.6 M (94.6) were bank balances, and SEK 60.6 M (271.2) 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 December 31<sup>st</sup>, 2008 the company had other short-term investments with a term of more than three months amounting to SEK 205.9 M (394.6).

A loan of SEK 600.0 M was secured for the acquisition of the three products. SEK 399.8 M of the loan has been utilized.

SEK 369.1 M of cash and cash equivalents and short-term investments has been utilized for product acquisition in 2008.

In 2008 4,476,082 new shares were issued. In connection with the product acquisition from Amgen, shares corresponding to a value of SEK 156.4 M (3,768,516 shares) were utilized.

The consolidated shareholders' equity as of December  $31^{st}$ , 2008 amounted to SEK 1,285.0 M compared to SEK 1,452.8 M on December  $31^{st}$ , 2007.

## **Taxes**

The company has an accumulated loss carryforward that has not been booked as an asset. Consequently, the company's tax rate deviates from the general Swedish tax rate. The Company has brought back a deferred tax liability of SEK 30.6 M.

## Personnel

As of December 31<sup>st</sup>, 2008 Biovitrum had 497 employees (542), of which 57 percent (58) are women. During the period 281,144 warrants in the 2006/2008 warrant program were exercised. This generated a new issue of 281,144 shares. For more information, see Note 4.

#### Condensed consolidated balance sheet

Condensed Consolidated Dalance Sheet		
	Dec 31	Dec 31
Amounts in SEK million	2008	2007
ASSETS		
Fixed assets		
Intangible fixed assets 1)	1,026.0	501.3
Tangible fixed assets	215.5	289.7
Financial fixed assets	46.2	29.2
Total fixed assets	1,287.7	820.3
Current assets		
Inventories	587.7	84.6
Current receivables, non-interestbearing	240.0	282.8
Short-term investments	205.9	394.6
Cash and cash equivalents	254.2	365.8
Total current assets	1,287.8	1,127.8
Total assets	2,575.5	1,948.1
EQUITY AND LIABILITIES		
Shareholders' equity	1,285.0	1,452.8
Long-term liabilities		
Long-term liabilities	397.1	-
Long-term liabilities, non-interestbearing	426.1	86.4
Total long-term liabilities	823.2	86.4
Current liabilities		
Current liabilities, non-interestbearing	467.3	408.9
Total short-term liabilities	467.3	408.9
Total equity and liabilities	2,575.5	1,948.1

<sup>1)</sup> Including goodwill SEK 25,3 M (39.4 as per December 31, 2007)

#### Change of consolidated shareholders' equity

	2008	2007
	Jan 1 -	Jan 1 -
Amounts in SEK million	Dec 31	Dec 31
Opening balance	1,452.8	1,381.8
Issue of share	183.5	-
Sharebased compensation to employees	7.9	-
Exchange rate difference	-23.8	-8.0
Net profit/loss for the year	-335.4	79.0
Equity, end of period	1,285.0	1.452.8



## Cash flow

Cash flow from operations in the fourth quarter amounted to SEK -382,7 M (-10.7). Before payments relating to restructuring, cash flow from operations for the fourth quarter of 2008 amounted to SEK 209.8 M.

The total purchase price was SEK 857.7 M, of which SEK 701.3 M was paid in cash and in new Biovitrum shares in total 3,768,516 ordinary shares worth SEK 156.4 M. In connection with this transaction a loan totaling SEK 600.0 M was secured, SEK 399.8 M of which has been utilized.

Cash and cash equivalents and short-term investments as of December 31<sup>st</sup>, 2008 amounted to SEK 460.1 M (760.4).

#### Investments

Acquisitions of intangible assets in the fourth quarter amounted to SEK 235.5 M. In the cash flow analysis, non-cash issue (SEK 156.4 M) has been net accounted to the investment in intangible assets (for more information see note 6) . For full year the corresponding figure is SEK 336.1 M, of which SEK 313.1 M relates to product rights for Kineret® and Kepivance®.

The Group's investments in tangible fixed assets during the quarter amounted to SEK 13.3 M (20.9). Depreciation amounted to SEK 23.8 M (15.8).

## Outlook 2009

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

The changed focus to specialist products will result in lower total R&D costs, despite the fact that external project costs will increase

#### Condensed consolidated cash flow

	Oct 1 - Dec 31		Full year	Full year
Amounts in SEK million	2008	2007	2008	2007
Net result	-246.6	-2.4	-335.4	79.0
Adjustment for items not affecting cash flow:				
Depreciations and Write down	217.4	15.8	268.5	70.5
Capital gain/loss from divestment fixed assets	0.6	0.1	0.4	-2.4
Revaluation of fixed financial assets	-2.9	_	-2.9	-
Pensions	-3.2	-3.1	-5.1	-3.0
Deferral of fees from Amgen	0.0	-44.2	-132.5	-176.6
Restructuring expenses, excl. Depreciations and write-downs	-2.6	_	117.4	_
Payments related to restructuring reserves	-17.0	1.1	-63.2	-10.8
Deferred tax liability	-30.6	_	-30.6	_
Other items 1)	1.4	_	7.9	_
Cash flow from operations before change in working				
capital	-53.1	-32.8	-145.0	-43.3
Change in working capital	-329.6	22.1	-361.7	17.9
Cash flow from operations	-382.7	-10.7	-506.7	-25.4
Investment in intangible fixed assets	-79.5	-13.0	-180.7	-44.0
Investment in tangible fixed assets	-13.3	-20.9	-24.5	-95.8
Divestment of tangible fixed assets	0.0	_	8.1	6.1
Investment/Divestment of financial assets	0.0	-0.2	-11.8	16.0
Short-term investments	73.8	8.4	188.7	132.6
Cash flow from investing activities	-18.9	-25.7	-20.2	14.8
Loans - Raising/Amortization	399.8	_	399.8	_
Issue of shares	1.8	_	16.6	_
Cash flow from financing activities	401.6	-	416.4	_
Net change in cash	0.1	-36.4	-110.5	-10.6
Liquid funds at the beginning of the period	254.4	402.4	365.8	376.6
Equita rando at the beginning of the period	254.4	402.4	303.6	370.0
Translation difference in cash flow and liquid funds	-0.1	-0.2	-1.0	-0.3
Liquid funds at the end of the period	254.3	365.8	254.3	365.8
Short-term investments	205.8	394.6	205.8	394.6
Liquid funds and short-term				
investments at the end of the period	460.1	760.4	460.1	760.4

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

## Condensed consolidated cash flow, core business

	Full year		Full year	
Amounts in SEK million	2008	Core bus	Prod. aqu.	Reconstr.
Net result	-335.4	74.1	-63.3	-346.2
Adjustment for items not affecting cash flow:	190.4	-92.6	_	283.0
Cash flow from operations before change in working				
capital	-145.0	-18.5	-63.3	-63.2
Change in working capital	-361.7	183.3	-545.0	_
Cash flow from operations	-506.7	164.8	-608.3	-63.2
Cash flow from investing activities	-208.9	-48.3	-160.6	_
Cash flow from financing activities	416.4	16.6	399.8	_
Translation difference in cash flow and liquid funds	-1.0	-1.0	_	_
Net change in cash and short term investments	-300.2	132.1	-369.1	-63.2

as and when we enter subsequent clinical phases and with the addition of costs for the acquired products. The R&D costs are expected to fall by around 15 percent.

The gross margin will fall by around 10 percentage points in relation to the total revenues for 2008 due to a changed sales mix compared to total revenues 2008 (incl. license revenues).



.

# Key ratios and other information

	Oct 1 - Dec 31		Full year	Full year
	2008	2007	2008	2007
Petron on				
Return on	40.50/	0.00/	04.50/	<b>5.00</b> /
Shareholders' equity	-18.5%	-0.2%	-24.5%	5.6%
Total capital	-12.9%	-0.1%	-16.2%	3.9%
Margins				
Gross margin	73.5%	70.6%	76.8%	72.2%
Operating margin	-92.3%	-3.4%	-33.9%	4.4%
Profit margin	-78.4%	-0.8%	-29.4%	6.3%
EBITDA-margin	-23.2%	1.9%	-10.3%	10.0%
Per share data (SEK)				
Shareholders' equity per share	25.6	31.8	25.6	31.8
Shareholders' equity per share after dilution	24.9	31.2	25.4	30.9
Cash flow per share	0.0	-0.8	-2.4	-0.2
Cash flow per share after dilution	0.0	-0.8	-2.4	-0.2
Other information				
Equity ratio	49.9%	74.6%	49.9%	74.6%
Number of shares	50,098,782	45,622,700	50,098,782	45,622,700
Average number of shares	46,871,825	45,622,700	46,048,631	45,622,700
Outstanding warrants	1,503,068	2,686,136	1,503,068	2,686,136
Number of shares after dilution	51,641,850	46,596,403	50,567,342	46,963,172
Average number of shares after dilution	48,732,583	46,596,403	46,593,267	46,840,459

<sup>1)</sup> There are three different warrant programs outstanding, exercisable for a maximum of 1,543,068 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.

## Operating margin

Operating profit as a percentage of net sales.

## Profit margin

Profit for the period as a percentage of net sales.

## **EBITDA** margin

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

## Shareholders' equity per share

Shareholders' equity divided by the number of shares.

# Shareholders' equity per share after 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.



# Parent Company Biovitrum AB (publ)

# Revenues and profit/loss

The Parent Company reported revenues for the quarter of SEK 314.3 M (299.5) and a loss of SEK -304.2 M (-42.5).

# Financial position

Cash and cash equivalents and short-term investments on December  $31^{st}$ , 2008 amounted to SEK 458.1 M (754.5). Shareholders' equity in Biovitrum AB (publ) amounted to SEK 1,216.2 M, compared to SEK 1,418.1 M on December  $31^{st}$ , 2007.

	Oct 1	Dec 31	Full year	Full year
Amounts in SEK million	2008	2007	2008	2007
Total revenues	314.3	299.5	1,140.6	1,255.8
Cost of goods and services sold	-83.2	-88.2	-264.7	-348.8
Gross profit	231.2	211.3	875.9	907.0
Sales and marketing expenses	-18.1	-14.6	-51.8	-43.7
Administration expenses	-113.0	-30.1	-221.2	-124.2
Research and development expenses	-186.2	-183.5	-669.5	-689.5
Restructuring expenses	-81.2	-	-201.2	-
Other operating revenues	19.5	5.0	34.8	18.8
Other operating expenses	-0.8	-1.5	-11.5	-13.1
Operating profit/loss	-148.5	-13.3	-244.5	55.3
Result from participation in Group companies	-168.5	-36.8	-168.5	-36.8
Financial income	13.7	8.2	21.1	24.8
Financial expenses	-0.9	-0.6	-1.2	-1.4
	-155.7	-29.2	-148.6	-13.5
Profit/loss after financial items	-304.2	-42.5	-393.1	41.8
Income tax expense	-	-	-	-
Profit/loss for the period	-304.2	-42.5	-393.1	41.8

	Dec 31	Dec 31
Amounts in SEK million	2008	2007
ASSETS	2000	2007
Fixed assets		
Intangible fixed assets	826.5	160.8
Tangible fixed assets	211.7	282.5
Financial fixed assets	607.7	728.8
Total fixed assets	1,645.9	1,172.2
Current assets		
nventories	587.6	84.6
Current receivables, non-interestbearing	249.2	283.2
Short-term investments	205.8	394.6
Cash and cash equivalents	252.3	359.9
Total current assets	1,294.9	1,122.3
Total assets	2,940.8	2,294.5
EQUITY AND LIABILITIES		
Shareholders' equity	1,216.2	1,418.1
Long-term liabilities		
Long term liabilities, interestbearing	397.1	_
Long term liabilities, non-interestbearing	377.9	_
Total long-term liabilities	775.0	-
Current liabilities		
Current liabilities, non-interestbearing	949.6	876.4
Total short-term liabilities	949.6	876.4
Total equity and liabilities	2,940.8	2,294.5

#### Change of parent company's shareholders' equity 2008 2007 Jan 1 -Jan 1 -Amounts in SEK million Dec 31 Dec 31 1.418.1 1.376.3 Opening balance 7.8 Sharebased compensation to employees Issue of share 183.4 -393.1 Profit/loss for the period 41.8 Equity, end of period 1,216.2 1,418.1



# Accounting and valuation principles and other information

## Note 1 Accounting and valuation principles

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

Biovitrum AB (publ) is applying the International Financial Reporting Standards (IFRS) in accordance with EU regulations.

As of January 1, 2008, Biovitrum is applying IFRIC 11, IFRIC 12 and IFRIC 14. This has not affected Biovitrum's accounts. Otherwise, Biovitrum's interim report has been prepared applying the accounting principles described in the company's 2007 Annual Report.

## Note 2 Operational risks

All business operations involve risk. Managed risk is necessary to maintain good prosperity. 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 in product concepts
- Operational risks, 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 2007 Annual Report (see the Directors' Report and Note 3).

## Note 3 Operating expenses

Restructuring expenses

A restructuring of Biovitrum's R&D activities was implemented during the year.

During spring 2008, a total of around 150 positions have been subject to a careful review within the parts of the organization that have worked with primary care projects. During this process around 100 individuals were either reassigned or made redundant. Future cost savings from these cuts are estimated to amount to SEK 115 M on a rolling twelve-month basis. In the 2008 year-end report a restructuring cost totaling SEK 120 M is being reported in respect of these cuts. The costs break down as SEK 71.2 M for staff cuts and SEK 48.8 M relating to depreciation of fixed and intangible assets.

The decision to discontinue research around small molecules has led to a cost saving program which means that another 75 employees will be made redundant as from February 2009. Costs related to staff cut have been entered by SEK 49.7 M. Furthermore depreciation of assets and reserves for the cost of vacant premises have been made with SEK 31.5 M.

The Company also has initiated a divestment of its British research operations Cambridge Biotechnology (CBT), which will affect 25 employees.

Write-down of SEK 145.0 M of intangible assets related to primary care projects has been made.

Restructuring expenses	Q2	Q4	Total
Write-down of intangible fixed assets	28.3	145.0	173.3
Write-down of tangible fixed assets	17.8	7.2	25.0
Personal costs	71.2	49.7	120.9
Premises costs	0	19.3	19.3
Other	2.7	5.0	7.7
Total restructuring expenses	120.0	226.2	346.2



## Note 4 Shares, convertibles and warrants

#### Shares

During the period 142,422 shares were issued as part of a supplementary payment to the company Arexis AB. For more information, see Note 5.

On two occasions shares were issued when warrants in the 2006/2008 warrant program were exercised. A total of 281,144 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 2008 (a share based incentive program), 284,000 shares have been issued. These shares are being held by the Biovitrum.

In connection with the acquisition of the products Kepivance<sup>®</sup> and Stemgen<sup>®</sup> and the exclusive license for Kineret<sup>®</sup>, Biovitrum issued 3,768,516 shares to cover part of the purchase price

Development in share ca	pital and number		Share
of shares		Number of shares	capital, SEK
December 2007		45,622,700	25,033,032
June 2008	Issue of shares in connection with additional purchase price related to Arexis AB	142,422	78,147
September 2008	Issue of shares in connection with warrant programs	250,502	137,450
September 2008	Issue of shares in connection with share based incentive program	284,000	159,237
November 2008	Issue of shares in connection with warrant programs	30,642	16,786
December 2008	Issue of shares in connection with purchase price related to Amgen products	3,768,516	2,064,393
December 2008		50,098,782	27,489,044
Are beeing held by Biovitrum		284,000	

## Option and share based incentive programs

## Share based incentive program 2008

At the Annual General Meeting on April 24, a long-term, performance based incentive program was adopted ("Aktieprogram 2008"). Aktieprogram 2008 covers management and key individuals in Biovitrum and may involve a total maximum allocation of 212,365 shares in Biovitrum AB (publ). The number of options 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.

## Warrant program

During the period 281,144 warrants in the 2006/2008 warrant program were exercised and 881,924 were forfeited when the subscription period expired.

## TRANSLATION ONLY

# Biovitrum Full year Report 2008



Warrant program 2006/2008 for certain members of management			
	2008	2007	
Outstanding January 1	2,326,136	2,326,136	
Exercised during the period	-281,144	-	
Forfeited during the period	-881,924		
Outstanding at of end of accounting period	1,163,068	2,326,136	
Redeemable at of end of accounting period	1,163,068	1,163,068	
Option program 2006/2011			
	2008	2007	
Outstanding January 1	60,000	45,000	
Allocated during the period	-	15,000	
Repurchased during the period	-20,000	_	
Outstanding at of end of accounting period	40,000	60,000	
Redeemable at of end of accounting period	24,998	14,999	
Employee option program 2007/2012			
	2008	2007	
Outstanding January 1	300,000	-	
Allocated during the period		300,000	
Outstanding at of end of accounting period	300,000	300,000	
Redeemable at of end of accounting period	100,000	-	

## Note 5 Acquisition and disposal of operations

No new acquisitions or disposals took place during the period.

During the period 142,422 shares were issued as part of a supplementary payment to the company Arexis AB. A total of SEK 15 M in cash has been paid as an additional payment and the above mentioned 142,422 shares corresponding to a value of SEK 10 M have been issued and transferred.

## **Note 6 Product Acquisition**

Amounts in SEK million	
Cash payment	701.3
Issue of share	156.4
Milestones, parent value	377.9
Purchase price	1,235.6
Purchase price, break down	
Inventory	540.7
Inventory Canada, transferred in jan 2009	3.9
Product rights	691.0
- of whitch milestones	377.9
- of whitch issue of shares	156.4
- of whitch cash payment	156.7
or willion each paymont	100.7



## Note 7 Transactions with related parties

There was no change as to loans to related parties during 2008. The conditions for these loans to executive management in the parent company are described in the Annual Report 2007

Loans to related parties		
	2008	2007
Loan to executive management in Parent Company:		
At beginning of the year:	153	_
Loans paid during the year:	<u> </u>	153
	153	153

## **Annual General Meeting 2009**

The Annual General Meeting of Biovitrum AB (publ) will be held at 4 p.m. on April 28, 2009 in Stockholm.

The Annual Report, including full financial and accounting data, will be published on <a href="www.biovitrum.com">www.biovitrum.com</a> at least 14 days before the AGM. It will also be made available at Biovitrum's headquarters in Solna, Berzelius väg 8, on the Karolinska Institutet campus. A printed business review will be distributed to shareholders by mail on April 6, 2009.

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

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

Solna, February 10, 2009

Martin Nicklasson Chief Executive Officer

## TRANSLATION ONLY

## Biovitrum Full year Report 2008



Biovitrum AB (publ): Corp. Reg. No. 556038-9321

SE-112 76 Stockholm Visitors: Berzelius väg 8 Telephone +46 8 697 20 00

For further information, please contact: Erik Kinnman, VP Investor Relations

Martin Nicklasson, CEO Göran Arvidson, CFO phone +46 73 422 15 40 phone +46 8 697 23 27 phone +46 8 697 23 68

**Financial Calendar:**Interim Report Jan-March, 2009
Interim Report April-June, 2009

Interim Report July-Sept, 2009

April 28, 2009 July 23, 2009 October 22, 2009



Biovitrum is a Swedish pharmaceutical company. The company markets a range of specialist pharmaceuticals internationally. Using its expertise and experience Biovitrum takes scientific innovation all the way to the market and to specialist indication patients with significant medical need. Research expertise and capabilities are focused on development and production of biotechnology therapeutics within our prioritized areas of hemophilia, inflammation/autoimmune diseases and malabsorption. The company has revenues of approximately SEK 1.1 billion and around 400 employees. It is listed on the OMX Nordic Exchange in Stockholm.

For further information visit www.biovitrum.com.