

# Biovitrum Interim Report January 1 – September 30, 2006

# January – September

- Net revenues for the period increased by 69 percent to SEK 956.3 M (567.3)
- Net profit for the period amounted to SEK 99.0 M (-54.0) and earnings per share amounted to SEK 2.1 (-1.0)
- Cash and cash equivalents and short-term investments amounted to SEK 929.4 M (1,021.4) on September 30

July - September

- Net revenues for the third quarter increased by 19 percent to SEK 248.2 M (209.4)
- Net profit for the quarter amounted to SEK 5.6 M (-4.0) and earnings per share amounted to SEK 0.1 (-0.1)
- Biovitrum was listed on the Stockholm Stock Exchange on September 15
- Phase I study initiated within the 5-HT<sub>6</sub> project for the treatment of obesity
- Phase IIa study initiated within the 5-HT<sub>2A</sub> project for the treatment of glaucoma

# CEO comments

"During our first period as a public company we continued to enjoy the strong trend of increasing revenues and positive development in our project portfolio," says Mats Pettersson, CEO of Biovitrum.

"Our position as an integrated biopharma company with stable finances and a broad project portfolio provides us with a solid platform for the future.

I would also like to take this opportunity to express my gratitude for all of the interest and appreciation we have met in connection with our IPO and to welcome all of our new shareholders."



Biovitrum's CEO Mats Pettersson is welcomed to the Stockholm Stock Exchange by Magnus Böcker, CEO OMX

	July 1 – Se	eptember 30	January 1 – Sep	otember 30	Full year
Amounts in SEK million	2006	2005	2006	2005	2005
Total revenues	248.2	209.4	956.3	567.3	936.6
Operating profit/loss	-7.4	-7.0	82.3	87.7	129.9
Profit/loss after financial items	6.1	-3.4	99.0	-53.0	177.8
Profit/loss for the period	5.6	-4.0	99.0	-54.0	176.2
Earnings/loss per share (SEK)	0.1	-0.1	2.1	-1.0	3.4
Research & Development expenses	-166.2	-135.0	-469.4	-399.7	-576.0
Cash and cash equivalents & short term investments	929.4	1,021.4	929.4	1,021.4	1,621.3



# Overview January – September 2006

During the January-September 2006 period Biovitrum continued its positive development as an integrated biopharma company with increasing revenues, a strong financial position and a growing project portfolio. The total revenues for the period were SEK 956.3 M, which is 69 percent higher than the same period last year (567.3). Several projects have advanced and the project portfolio now includes five projects in the clinical development phase with an option to acquire a sixth, for both niche indications and common diseases. During the period Biovitrum also went public and the company's shares are listed on the Stockholm Stock Exchange since September 15.

#### **ReFacto**®

Biovitrum manufactures, on a global basis, the drug substance for the hemophilia product ReFacto<sup>®</sup> for Wyeth. Biovitrum also collects royalty global sales and co-promotion revenues for sales of the same product in the Nordic region. Revenues from ReFacto<sup>®</sup> increased from SEK 233.8 M for the first nine months of 2005 to SEK 591.0 M for the same period in 2006.

#### ReFacto® revenues and gross profit

	July 1 -	- Sep 30	Jan 1-	Full year	
Amounts in SEK million	2006	2005	2006	2005	2005
Manufacturing revenues	77.1	45.5	416.0	77.3	191.7
Contract development revenues	-	-	-	2.6	2.6
Product Sales revenues	16.0	14.1	52.9	39.7	55.3
Royalty revenues	42.8	41.1	122.1	114.2	156.0
Total revenues	135.9	100.7	591.0	233.8	405.6
Gross profit	110.7	81.7	455.0	201.7	319.4

The considerable improvement is mainly explained by a sharp increase in revenues from the manufacture of ReFacto® from SEK 77.3 to 416.0 M. This is explained by the fact that, during the January-September 2006 period, Biovitrum produced and delivered quantities in line with market demand (except during the first quarter when deliveries to Wyeth were greater than market requirements), while Wyeth sold from a large inventory in the January-September 2005 period. Full-scale commercial production of ReFacto® did not start until March 2005, and the first deliveries took place at the end of the third quarter. The increase in global sales of ReFacto® in the January-September 2006 period increased royalties for Biovitrum. Co-promotion revenues from the sale of ReFacto® in the Nordic region under Biovitrum's own management have increased which is attributable to an increasing market share on the Nordic market.

During the third quarter of 2006, total revenues from ReFacto<sup>®</sup> increased to SEK 135.9 M compared to SEK 100.7 M for the same period in 2005. This, however, is 23 percent lower than the second quarter of 2006. The decrease is related to lower production revenues due to a planned production stoppage. This does not reflect a long-term trend. The outlook for the full year 2006 will not change, but remains positive (see Outlook on page 8). The revenues will, however, continue to fluctuate from quarter to quarter depending on Wyeth's procurement planning.

#### **Product** sales

Biovitrum markets drugs with a dedicated sales force in the Nordic region and has currently marketing rights for ReFacto<sup>®</sup> and five other approved specialist drugs as well as the European rights for one of these. An overview of the products is provided in the table on page 3. All of the products have been launched with the exception of Aloxi<sup>®</sup>, which was developed by the Swiss company Helsinn and is a long-acting drug for the treatment of nausea and vomiting that often occur in connection with cancer chemotherapy. The launch of Aloxi<sup>®</sup> is planned in Norway for the last quarter of 2006 and with the rest of the Nordic region following in 2007. Revenues for the January-September period from drug sales including co-promotion revenues from Nordic sales of ReFacto<sup>®</sup> increased by 30 percent to SEK 97.3 M, compared to the same period in 2005.

In the third quarter of 2006 revenues from drug sales rose to SEK 32.2 M, an increase of 17 percent compared to the same period in 2005.

#### **Contract Manufacturing and Process Development**

Biovitrum has considerable expertise in manufacturing and advanced process development of recombinant protein drugs. This capacity is utilized for the company's internal projects and offered as a service to external customers. During the period a growing portion of the capacity was utilized for the internal projects Exinalda™, Anti-RhD, FIX:Fc and Kiobrina™. Internal projects will continue to utilize a large portion of the company's capacity.

The process development contracts with Pfizer and Amgen expired during the third quarter. It is likely that Biovitrum will continue to deliver services to these companies in the future, albeit to a lesser extent than in the past. Biovitrum is working actively with marketing initiatives aimed at existing and new, potential customers, mainly small and medium-sized biotech companies. This has resulted in a number of new assignments, such as a three-year agreement signed in October with the Swedish company Resistentia. Contract development revenues during the January-September period amounted to SEK 144.3 M, decreasing 7 percent compared to the same period in 2005.

The external process development revenues in the third quarter amounted to SEK 34.7 M, which was 26 percent lower than the same period in 2005. This effect was anticipated and is a result of the increasing share of the capacity that is utilized for internal projects.

#### **Research & Development**

Biovitrum has a broad and balanced project portfolio and develops projects to treat common diseases (such as obesity, diabetes and pain) as well as niche indications, such as hemophilia. The company's strategy is to develop niche projects internally all the way to the market, whereas for projects in broader indication areas the intention is to form partnerships with larger pharmaceutical companies before phase III. Biovitrum currently has five projects in clinical development and an option to acquire another clinical project that is being run by a partner. The portfo-



lio also includes ten projects in pre-clinical development or late Lead Optimization, and around 15 discovery projects. The most advanced projects are set forth in the table below.

Exinalda<sup>™</sup> for the treatment of lipid malabsorption in cystic fibrosis patients is in phase II. The project is currently focused on improving the drug formulation and production processes. At the same time, two smaller supplementary phase IIa studies are expected to be initiated in the first half of 2007. This means that the following phase IIb-study will be postponed compared to the timelines communicated earlier.

Biovitrum's  $11\beta$ -HSD<sub>1</sub> inhibitors for the treatment of diabetes are out-licensed to Amgen who owns the exclusive global rights to develop and commercialize these compounds. The project is in phase I and the development is carried out by Amgen overseen by a joint development committee.

The  $A_{2A}$  receptor agonist project for the treatment of neuropathic pain is also in phase I. The project is being prepared for a phase II a study that is estimated to be initiated in the first half of 2007.

In addition to the above-mentioned projects a number of new clinical studies have been initiated. During the third quarter, a phase I study was initiated within the 5-HT<sub>6</sub> antagonist project for the treatment of obesity. The drug candidate, called BVT.74316, acts through a mechanism to control food intake by stimulating the sense of satiety in the brain. BVT.74316 has been shown to decrease food intake and reduce bodyweight in animals in both short and long-term studies. The ongoing clinical study, with the objective to test safety and tolerability in both single-dose and

#### Biovitrum's marketed products and project pipeline

repeated-dose administration, includes a total of 75 to 100 healthy volunteers. The results from the study are expected during the first half of 2007.

A clinical phase IIa study of the drug candidate BVT.28949 within the 5-HT<sub>2A</sub> project for the treatment of glaucoma was initiated in October 2006. BVT.28949 has already successfully completed a phase I study and the hypothesis is that BVT.28949 reduces intraocular pressure by stimulating the outflow of aqueous humor through a mechanism different from that of presently available products, which means that BVT.28949 could function as a monotherapy or as a combination alternative with existing products. The phase II study now under way is a placebo-controlled study (results are compared with patients treated with a substance with no pharmacological effect) and includes 150 patients with elevated intra-ocular pressure (characteristic for glaucoma). The study is being conducted at a number of clinics in both Sweden and Ukraine and is expected to be concluded in spring 2007 with results ready in mid-2007.

In September Biovitrum entered into a development agreement with the Swedish biotechnology company Synphora. The agreement concerns Synphora's candidate drug JB991 for the treatment of the skin disease psoriasis and other conditions, which is currently in clinical phase I. JB991 is a prostaglandin derivative, i.e. a substance based on prostaglandin. This is a local hormone that occurs naturally in the body and is important, among other things, for controlling inflammation. Under the terms of the agreement Biovitrum will co-finance Synphora's ongoing study and, if the

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				Lead optin tion	Pre-clinical developme	Phase I	Phase II	Phase III	Approved	Market
	Product/project	Indication area	Partner	υÞ	6.0	₽.	₽.	۵.	<	2
	ReFacto <sup>® 1) 2)</sup>	Hemophilia	Wyeth							
	Novastan <sup>® 1)</sup>	Anticoagulation	Mitsubishi							
Approved/ Marketed	Mimpara <sup>® 1)</sup>	Parathyroid hormone disorders	Amgen							
Products	Kineret <sup>® 1)</sup>	Rheumatology	Amgen							
	Kepivance <sup>® 1)</sup>	Cancer, supportive care	Amgen							
	Aloxi <sup>® 1)</sup>	Cancer, supportive care	Helsinn							
	Exinalda™	Cystic fibrosis								
		,								
	5-HT <sub>2A</sub>	Glaucoma								
Clinical	11β-HSD1	Diabetes	Amgen							
Projects	A <sub>2A</sub>	Neuropathic pain								
	5-HT₀	Obesity								
	JB991 <sup>3)</sup>	Psoriasis	Synphora							
	IZ: I · TM									
	Kiobrina™	Preterm nutrition								
	Anti-Rh(D)	Rh Immunization	Symphogen							
Pre-clinical	Anti-Rh(D)	Thrombocytopenia	Symphogen				Hemat	ology		
Projects	FIX:Fc	Hemophilia	Syntonix				Metab	olic dis	. (prote	in)
	Leptin	Obesity					Metab	olic dis	. (small	mol.)
	DPP-IV	Diabetes	Santhera				Inflam	mation		
	5-HT <sub>2C</sub>	Obesity	GSK				Other			

1) Products for which Biovitrum has been granted co-promotion- and/or distribution rights by other companies.

2) Biovitrum has co-promotion rights to the next generation of ReFacto® which is expected to be commercialized in mid-2008.

3) The project is developed by, and is the property of, Biovitrum's partner Synphora. Biovitrum has an option to acquire the project, under certain provisions, after phase IIa.



study is successful, also the following Phase II study with a maximum of SEK 5 M in total. Synphora remains fully responsible for conducting development of JB991 up to and including clinical phase IIa. In return for the investment, Biovitrum will after Phase IIa, under certain provisions, be entitled to acquire the project according to predetermined terms.

The preclinical portfolio is also evolving. The Anti-RhD collaboration project with Symphogen is estimated to enter phase I during the first half of 2007. This is a delay compared to the timelines communicated earlier due to a request by the FDA for additional documentation regarding a generic manufacturing step which is unrelated to the polyclonal aspect of the antibody production process.

The collaboration project between Biovitrum and Syntonix, regarding long-acting recombinant factor IX against hemophilia B (FIX:Fc), reached an important milestone when a candidate drug was selected during the third quarter.

# **Other information**

In May 150 000 new warrants were issued to be used as part of an employee option program for certain key employees, out of which 55 000 have been allotted so far. Each of these warrants gives the right to purchase two shares for SEK 110 with an exercise period ending May 31, 2011.

On September 15 Biovitrum reached a milestone in its history when the company was listed on the Stockholm Stock Exchange. In connection with the listing the existing shareholders executed an initial public offering. The offering comprised a public offering of shares in Sweden and an international institutional offering, including a private placement in the United States of an aggregate of 7.7 million existing shares (including an over-allotment option of 1 million shares) in the range SEK 90-105 per share. The offering was oversubscribed more than ten times and the price was set at SEK 100. After the listing Biovitrum has more than 4,000 shareholders.

In connection with the stock exchange listing, Biovitrum implemented a warrant repurchase offering aimed at current and former employees who held warrants in the original warrant program offered to the employees when the company was formed. Each warrant in this program (expiring on 30 November 2006) gives the right to purchase two shares for an exercise price of SEK 59. Briefly, the warrant holders were given the opportunity to sell their warrants to Biovitrum in connection with the stock exchange listing for the real value at the time of the listing (the offering price less the call price multiplied by two). Biovitrum repurchased a total of 1,840,100 warrants through this offering and 28,000 warrants were exercised to purchase shares, resulting in a net outflow of SEK 147.6 M.

Before the listing, 1,651,250 warrants in the same program were also repurchased and certain members of Biovitrum's senior management did instead subscribe to a total of 2,326,136 warrants in a new program. This new program, divided into four tranches with different expiry dates, will run until May 31, 2009, and each warrant gives the right to purchase one share for an exercise price of SEK 59 instead of two shares per warrant as was the case in the previous program. The purpose of this program is to keep an effective incentive scheme in place for Biovitrum's senior management.

After the listing and up to September 30, an additional 456,550 warrants from the original program were exercised to purchase 913,100 new shares.

During the third quarter, Biovitrum entered an agreement with Akademiska Hus to lease new premises within Karolinska Science Park. This will give Biovitrum access to newly constructed, costeffective premises that will house the entire Research & Development unit starting from the summer of 2009.

According to the Swedish Corporate Governance Code a nomination committee shall propose and nominate directors and auditors to be elected by the shareholders' meeting of a company, with the objective of supplying the shareholders' meeting with an appropriate foundation for such decisions. The shareholders' meeting shall elect the members of the nomination committee or decide on how such members shall be elected. At an extraordinary shareholders' meeting of the company on May 3, 2006 it was resolved that the nomination committee shall consist of four members, three of whom shall be representatives of the three largest shareholders in the company the week prior to the date when the company presents its third quarter report, and the fourth to be the chairman of the board of directors. The nomination committee shall be announced simultaneously with the third quarter report.

With reference to this decision, the nomination committee has been established and consists of: Henrik Lif, representing Nordic Capital; Nick Simon, representing MPM; Alix Marduel, representing Alta Partners and Håkan Åström, chairman of the board of directors. Henrik Lif is the chairman of the nomination committee. According to the Swedish Corporate Governance Code the members of the nomination committee shall be announced at the latest six months prior to the annual meeting of shareholders of a company. Biovitrum will hold its annual meeting of shareholders on May 3, 2006, and is thus deviating from this rule. The reason for the deviation is motivated by the fact that the company was just recently listed on the Stockholm Stock Exchange. Consequently, it has been deemed appropriate to allow a period of time to elapse prior to reading off the shareholder structure, and to announce the election simultaneously with the third quarter report. Biovitrum will henceforth comply with the rule of announcing the nomination committee six months prior to the annual meeting of shareholders.

# Significant events following the period

The start of the phase IIa study within the 5-HT<sub>2A</sub> described under Research & Development, took place in October. The process development agreement with Resistentia, described under Contract Manufacturing and Process Development, was entered into in October.

# Financial statements

# **Revenues**

Net revenues for the January-September 2006 period amounted to SEK 956.3 M, compared to SEK 567.3 M for the same period in 2005, while the corresponding figure for the third quarter was SEK 248.2 M (209.4).

The significant improvement is mainly explained by a sharp increase in ReFacto® manufacturing revenues to SEK 416.0 M over the nine-month period compared to SEK 77.3 M in the same period in 2005, which is described on page 2. At the same time as full-scale commercial manufacturing restarted, the global demand for ReFacto® increased and as a result, royalty revenues rose to SEK 122.3 M (114.2). The corresponding figure for the third quarter was SEK 42.8 M (41.1). The market share of ReFacto® in the Nordic region also increased during the period and this led to increased copromotion revenues from product sales. The revenues from product sales totaled SEK 97.3 M (74.9) and in the third quarter these revenues rose to SEK 32.2 M (27.6) Contract development revenues amounted to SEK 144.3 M (155.5) and for the third guarter to SEK 34.7 M (46.8). As outlined on page 2, the decrease is related to the fact that agreements with Amgen and Pfizer are expiring and that a growing percentage of the capacity is being utilized for internal projects. See also the Outlook section on page 8. Licensing and milestone revenues, which mainly consist of revenue recognition of deferred license fees from Amgen, increased during the January-September period to SEK 132.5 M (106.6) and to SEK 44.2 M (35.6) in the third quarter as a result of the additional licensing fee that was paid when the agreement with Amgen was expanded in 2005. Research revenues for the January-September period amounted to SEK 43.8 M (38.8) and to SEK 17.2 (12.9) in the third guarter. These originate mainly from a research agreement with Amgen that expires in October 2006 and will not be renewed. These revenues will therefore decline

#### **Consolidated income statement**

	July 1	I– Sep 30	Jan '	1– Sep 30	Full year
Amounts in SEK million	2006	2005	2006	2005	2005
Total revenues	248.2	209.4	956.3	567.3	936.6
Cost of goods and services sold	-51.5	-62.2	-241.9	-166.6	-270.7
Gross profit	196.7	147.2	714.4	400.7	665.9
Sales and Marketing expenses	-7.4	-7.8	-24.5	-20.9	-38.6
Administration expenses	-33.9	-14.0	-100.1	-69.3	-151.2
Research and Development expenses	-166.2	-135.0	-469.4	-399.7	-576.0
Other operating revenues	2.6	6.1	8.0	26.5	272.6
Other operating expenses	0.8	-3.5	-46.1	-25.0	-42.8
Operating profit/loss	-7.4	-7.0	82.3	-87.7	129.9
Financial income	13.6	3.8	17.1	34.9	49.4
Financial expenses	-0.1	-0.2	-0.4	-0.2	-1.5
Profit/loss after financial items	6.1	-3.4	99.0	-53.0	177.8
Tax on profit/loss for the period	-0.5	-0.6	-	-1.0	-1.6
Profit/loss for the period	5.6	-4.0	99.0	-54.0	176.2
Earnings/loss per share after tax (SEK) Earnings/loss per share after tax	0.1	-0.1	2.1	-1.0	3.4
after full dilution (SEK) <sup>1)</sup>	0.1	-0.1	1.9	-1.0	3.1

 $^{\rm p}$  The average market price of the share for the period September 15 – September 30, 2006 has been used to calculate the dilution.

#### **Revenue specification**

	July 1	– Sep 30	Jan 1	– Sep 30	Full year
Amounts in SEK million	2006	2005	2006	2005	2005
Licensing and milestone revenues	44.2	35.6	132.5	106.6	205.6
Research revenues	17.2	12.9	43.8	38.8	54.5
ReFacto manufacturing revenues	77.1	45.5	416.0	77.3	191.7
Contract development revenues	34.7	46.8	144.3	155.5	224.7
Product sales revenues	32.2	27.6	97.3	74.9	103.8
Royalty revenues	42.8	41.1	122.3	114.2	156.0
Other	-	-	0.1	-	0.3
Total revenues	248.2	209.4	956.3	567.3	936.6

#### **Expenses**

During the January-September 2006 period, administrative costs increased to SEK 100.1 M (69.3) and to SEK 33.9 M (14.0) in the third quarter. The increase is mainly due to non-recurring costs related to the stock exchange listing of SEK 25 M. Research & Development costs increased in the January-September period to SEK 469.4 M (399.7) and in the third quarter to SEK 166.2 M (135.0). The increase is related to Biovitrum's growing clinical portfolio with greater CRO costs for clinical studies and production costs for clinical materials for the protein projects.

# **Profit/loss**

The operating profit for the January-September period amounted to SEK 82.3 M (-87.7) and the third quarter loss to SEK -7.4 M (-7,0). The result for the ninemonth period was expensed with SEK 42 M relating to the spin-off of the contract research company iNovacia in April. Excluding the costs associated with the stock exchange listing and iNovacia, the operating profit increased by SEK 237 M. The net financial income for the January-September 2006 period was SEK 16.7 M (34.7). The reduction is related to rising interest rates. The profit for the January-September period amounted to SEK 99.0 M (-54.0) and SEK 5.6 M (-4.0) for the quarter.

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# **Financial position**

Cash and cash equivalents and short-term investments on September 30, 2006 amounted to SEK 929.4 M (September 30, 2005: 1,021.4). Of this amount, SEK 111.9 M was cash balances (26.4), and SEK 245.7 M (437.8) investments in securities with a duration 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 also had other short-term investments with a duration of more than three months on September 30, 2006, amounting to SEK 571.8 M (557.2).

# Changes in shareholders' equity

Shareholders' equity in the Group on September 30 was SEK 1,315.0 M, compared to SEK 1,477.2 on September 30, 2005.

In April 4,514,400 shares held by Pfizer were redeemed. The amount paid was SEK 378.9 M.

In August 1,651,250 warrants from Biovitrum's original program were repurchased. The amount paid was SEK 131.4 M. In connection with this buy-back, a new program consisting of 2,326,136 warrants was issued to senior executives who paid a total of SEK 105.6 M for this new program.

In connection with the stock exchange listing in September, Biovitrum repurhased 1,840,100 warrants for an additional SEK 150.9 M. Altogether, including the buy-back from certain senior executives and other smaller transactions with former employees, Biovitrum repurchased 3,503,050 warrants during the period for SEK 282.3 M.

In connection with and after the listing, 484,550 warrants were exercised to subscribe for new shares, and this raised a total of SEK 57.2 M.

# Condensed consolidated balance sheet

	Septem	ber 30 D	ecember 31
Amounts in SEK million	2006	2005	2005
ASSETS			
Fixed assets			
Intangible fixed assets	446.3 <sup>1)</sup>	356.6	362.7
Tangible fixed assets	247.2	479.0	300.6
Financial fixed assets	32.6	24.5	13.9
	726.1	860.1	677.2
Current assets			
Inventories	134.6	145.6	126.3
Current receivables, non-interest bearing	313.7	300.3	303.4
Short-term investments	571.8	557.2	562.7
Cash and cash equivalents	357.6	464.2	1,058.6
	1,377.7	1,467.3	2,051.0
Total assets	2,103.8	2,327.4	2,728.1
EQUITY AND LIABILITIES			
Shareholders' equity			
	1,315.0	1,477.2	1,707.7
Long term liabilities			
Long term liabilities, non-interest bearing	268.7	366.6	409.4
	268.7	366.6	409.4
Current liabilities			
Current liabilities, non-interest bearing	520.1	483.6	611.1
	520.1	483.6	611.1
Total equity and liabilities	2,103.8	2,327.4	2,728.1

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

## Change of consolidated shareholders' equity

		Jan 1– Sep 30	Full year
Amounts in SEK million	2006	2005	2005
Opening balance	1,707.7	1,528.0	1,528.0
Warrants issue (+)	105.6	1.3	1.4
Repurchase warrants (-)	-282.3	-	-
Non registered issue of shares	5.9		
Issue of share	57.2	-	-
Redemption of shares	-378.91)	_	-
Exchange rate difference	0.8	1.9	2.1
Net profit/loss for the year	99.0	-54.0	176.2
Equity, end of period	1,315.0	1,477.2	1,707.7

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



# Cash flow

Cash flow from operations during the January-September period amounted to SEK -44.6 M (-189.8) and the cash flow for the third quarter to SEK -71.4 M (-101.2). The decline in the third quarter compared to earlier periods during the year is mainly the result of an increase in working capital of SEK 42.0 M, which in turn is attributable to an inventory buildup and a decrease in current liabilities that are mainly related to seasonal effects.

# Investments

The group's investments in fixed assets in the January-September 2006 period amounted to SEK 114.8 M (157.7). During this period the company made a supplementary payment for the acquisition of Cambridge Biotechnology (CBT) to CBT's previous owner. Depreciation during the period amounted to SEK 56.1 M (65.1).

# Tax

The company has an accumulated loss carry-forward that has not been accounted for as an asset, which means that the company's tax rate deviates from the general Swedish tax rate. Biovitrum had no tax cost for the period (-1.0).

# Personnel

At the end of September Biovitrum had 548 employees, 58 percent of which were women.

# Condensed consolidated cash flow statement

	July	1– Sep 30	Jan	1– Sep 30	Full year
Amounts in SEK million	2006	2005	2006	2005	2005
Net result	5.6	-4.0	99.0	-54.0	176.2
Adjustment for items not affecting cash flow:					
Depreciations and Write down	19.3	21.4	56.1	65.1	117.1
Deferral of fees from Amgen	-44.2	-35.5	-132.5	-106.6	-81.7
Capital gain/loss from divestment of fixed assets	1.4	_	45.4	_	-245.0
Restructuring costs	-11.5	_	-73.4	_	59.6
Other items	_	_	-3.4	_	_
Cash flow from operations before Change					
in working capital	-29.4	-18.1	-8.8	-95.5	26.2
Change in working capital	-42.0	-83.1	-35.8	-94.3	-91.7
Cash flow from operations	-71.4	-101.2	-44.6	-189.8	-65.5
Investment in subsidiary	-41.1	-137.9	-41.1	-222.5	-223.3
Investment in intangible fixed assets	-	-46.4	-53.7	-50.9	-50.9
Investment in tangible fixed assets	-18.2	-52.3	-40.3	-106.8	-122.3
Divestment of tangible fixed assets	-	-	-	0.1	492.0
Investment/Divestment of financial assets	-39.2	200.5	-29.9	-20.5	-26.0
Cash flow from investing activities	-98.5	-36.1	-165.0	-400.6	69.5
Issue of shares	63.1	-	63.1	-	-
Redemption of shares	-	-	-378.9	-	_
Issue of warrants	105.6	0.2	105.6	1.4	0.8
Re-purchase of warrants	-281.6	-	-281.6	-0.1	-0.1
Cash flow from financing activities	-112.9	0.2	-491.8	1.3	0.7
Net change in cash	-282.8	-137.1	-701.4	-589.1	4.8
Cash and cash equivalents at the beginning of the period	638.6	602.7	1,058.6	1,048.4	1,048.4
One-time effect implementing IAS39	-	-	-	4.5	4.5
Exchange rate differences in cash flow and cash and cash equivalents	1.8	-1.4	0.4	0.4	0.8
Cash and cash equivalents at the end of the period	357.6	464.2	357.6	464.2	1,058.6
Short-term investments	571.8	557.2	571.8	557.2	562.7
Cash and cash equivalents and short-term investments at the end of the period	929.4	1,021.4	929.4	1,021.4	1,621.3



#### Key ratios and other information

		July 1– Sep 30		Jan 1– Sep 30	Full year
	2006	2005	2006	2005	2005
Return on					
Shareholders' equity	0.4 %	-0.3 %	6.6 %	-3.6 %	10.9 %
Total capital	0.3 %	-0.2 %	4.1 %	-2.3 %	6.9 %
Margins					
Gross margin	79.3 %	70.3 %	74.7 %	70.6 %	71.1 %
Operating margin	-3.0 %	-3.3 %	8.6 %	-15.5 %	13.9 %
Net margin	2.3 %	-1.9 %	10.4 %	-9.5 %	18.8 %
EBITDA margin	4.8 %	6.9 %	14.5 %	-4.0 %	26.4 %
Per share data (SEK)					
Shareholders' equity per share	29.7	28.2	29.7	28.2	32.6
Shareholders' equity per share after full dilution <sup>1)</sup>	28.5	26.0	28.5	26.0	30.0
Cash flow per share	-6.5	-2.6	-15.0	-11.3	0.1
Cash flow per share after full dilution <sup>1)</sup>	-6.5	-2.6	-15.0	-11.3	0.1
Other information					
Equity ratio	62.5 %	63.5 %	62.5 %	63.5 %	62.6 %
Number of shares	44,271,700	52,331,400	44,271,700	52,331,400	52,331,400
Average number of shares	43,325,137	52,331,400	46,683,593	52,331,400	52,331,400
Outstanding warrants	3,151,636 <sup>2)</sup>	4,673,100	3,151,636 <sup>2)</sup>	4,673,100	4,663,100
Number of shares after full dilution <sup>1)</sup>	46,078,780	56,890,162	46,078,780	56,890,162	56,880,407
Average number of shares after full dilution $^{\eta}$	47,283,869	56,885,284	51,031,724	56,847,287	56,842,410

<sup>1)</sup> The average market price of the share for the period September 15 – September 30, 2006 has been used to calculate the dilution. <sup>2)</sup> There are three different warrant programs outstanding, exercisable for a maximum of 3,977,136 new shares in total.

Return on shareholders' equity	Net margin
Profit after tax as a percentage of average share- holders' equity.	Profit for the period as
<b>Return on total capital</b> Profit after financial items plus financial expenses as a percentage of average total assets.	<b>EBITDA margin</b> Operating profit plus c as a percentage of net

**Gross margin** Gross profit as a percentage of net sales.

. . .

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

# Outlook

# 2006

Total revenues for the full year are expected to amount to between SEK 1,180 and 1,210 M. Of this amount, revenues generated by ReFacto® are expected to amount to between SEK 750 and 780 M. Contract development revenues, as reported earlier, are expected to fall by 30 percent to SEK 150-160 M. Research & Development costs are expected to amount to between SEK 630 and 650 M.

Profit for the period as a percentage of net sales.

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 full dilution

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

#### Cash flow per share

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

#### Cash flow per share after full dilution

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

# Equity ratio

Shareholders' equity as a proportion of total assets.



# Accounting principles

This interim report has been prepared in accordance with IAS 34 "Interim Financial Reporting", which is in accordance with the requirements in the recommendation of Redovisningsrådet RR31 "Interim reporting".

As from 1 January 2005 Biovitrum AB (publ) is practising International Financial Reporting Standards (IFRS), in accordance with EU regulations. The accounting principles applied are those described in Biovitrum's Annual Report 2005. The Parent Company applies RR 32 accounting principles for juridical persons.

In this interim report the following new standards, amendments to standards and interpretations effective 1 January 2006 have been included. These new standards, amendments and interpretations have been approved by the EU, expect amendments in IAS 21.

#### IAS 19 Amendments Employee benefits

This amendment comes into effect for financial years beginning on or after 1 January 2006. At present Biovitrum has not yet decided whether or not to apply the new possibilities of reporting actuarial gains and losses. However, the expanded disclosure requirements will have an effect on reporting in the annual report for 2006.

# IAS 21 Amendments Effects of changes in exchange rates

The amendments come into effect 1 January 2006. At present, these changes to the standard are not deemed to have any effect on Biovitrum's reporting.

# IFRIC 4 Determination of whether an agreement constitutes a leasing agreement

The interpretation statement comes into effect 1 January 2006. According to IFRIC 4, a decision regarding whether an agreement is, or contains, a leasing agreement is based in substance of the agreement. An assessment shall be made of whether a) the agreement's completion is dependent upon the use of particular asset or and b) the agreement transfers a right to use the asset or asset. The current assessment is that IFRIC 4 will not result in existing agreements being reclassified as leasing agreements.

## IFRIC 5 Rights to interests arising from decommissioning, restoration and environmental funds

This interpretation is not relevant for Biovitrum.

# IFRIC 6 Liabilities arising from participation in a specific market - waste electrical and electronic equipment

This interpretation is not relevant for Biovitrum.

## IFRIC 7 Translation in conjunction with transition to high-inflation reporting The interpretation statement came into

The interpretation statement came into effect 1 March 2006 and applies to financial years beginning on or after 1 March 2006. Biovitrum has currently no operations in countries in which transition to high-inflation accounting is a matter of interest.

## IFRIC 8 Scope of application of IFRS 2

The interpretation statement comes into effect 1 May 2006 and applies to financial years beginning after 1 May 2006. According to IFRIC 8, the rules in IFRS 2 apply to goods and services received in exchange for an equity instrument, even if such goods or services cannot be specifically identified, either in part or in their entirety. This statement is not relevant for Biovitrum as no such transactions exist.

## Note 1 – Related party transactions

On September 25 Biovitrum entered a development agreement with the biotechnology company Synphora. Under the terms of the agreement Biovitrum will co-finance Synphora's studies with a maximum of SEK 5 M in total, of which SEK 2 M were paid in October. Toni Weitzberg is a member of the board of Biovitrum AB and the chairman of the board of Synphora AB.



This interim report includes statements that are forward-looking. 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, economic environment, political changes and competing research programs that may affect Biovitrum's results.

Solna, November , 2006

Mats Pettersson Chief Executive Officer

# **Review report**

We have reviewed the interim report for Biovitrum AB (publ) for the period 1 January 2006 to 30 September 2006. The accurate preparation and presentation of the interim report in accordance with IAS 34 and the Annual Accounts Act is the responsibility of the Board of Directors. Our responsibility is to express a conclusion on the interim report on the basis of our review.

We have performed our review in accordance with the Standard for Review SÖG 2410 Review of interim financial information performed by the company's appointed auditor, issued by the FAR, the institute for the accounting profession in Sweden. A review consists of making inquiries, primarily to individuals responsible for financial and accounting matters, performing an analytical examination and undertaking other review procedures. A review has a different focus and a significantly more limited scope than an audit conducted in accordance with RS, the Swedish auditing standards, and generally accepted auditing practice in general. The procedures involved in a review do not allow us to obtain a level of assurance that would make us aware of all important circumstances that might have been identified if an audit had been performed. Consequently, a conclusion provided on the basis of a review does not have the same level of certainty as a conclusion based on an audit.

Based on our review, no circumstances have come to our attention which would cause us to believe that the interim report does not, in all material respects, is prepared in accordance with IAS 34 and the Annual Accounts Act.

Stockholm, November , 2006

PricewaterhouseCoopers AB

Peter Bladh Authorised Public Accountant



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# Financial calendar:

Year-end Report, 2006 Annual general meeting February 23, 2007 May 3, 2007



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

For more information see: **www.biovitrum.com.**