

# Interim financial report for the period 1<sup>st</sup> January to 30<sup>th</sup> September, 2010

(Translation only)

# Weak European performance in the third quarter, offset by continued US sales growth

Third quarter revenues and EBITA, excluding restructuring costs, amounted to SEK 444 M and SEK 63 M, respectively

- Revenues, excluding Tracleer, increased by 5% in Constant Exchange Rate (CER) and was unchanged in SEK
  - Sales in North America increased by 16% in CER and by 17% in SEK
  - Sales in Europe decreased by 1% in CER, corresponding to -11% in SEK
  - Sales of Kineret® increased by 2% in CER and decreased by 2% in SEK
  - Sales of Orfadin® increased by 21% in CER and by 14% in SEK
  - Total ReFacto® revenues increased by 4% in CER
- EBITA, excluding restructuring costs was SEK 63.1 M (proforma 34.0) and core EPS was SEK 0.19 (0.20)
- Net income and EPS amounted to SEK -27.5 M (7.9) and SEK -0.13 (0.08)
- A Letter of Intent to form a Commercial Alliance with the Chinese company Dongbao was announced
- rFIXFc phase I/II results, showing a three-fold increase in half-life, were presented
- Based on positive phase I/II data, a decision to proceed rFVIIIFc into Phase III studies was taken. rFVIIIFc also received orphan drug designation in Europe
- Kineret® received orphan drug designation in the US for cryopyrin-associated periodic syndromes (CAPS)
- Xagrid, Fosrenol, and Equasym distribution agreements will sequentially be discontinued during 2011
- Full year guidance adjusted (see outlook 2010, page 9)

## Significant events after the reporting period

- Sym001 (rozrolimupab) for ITP received orphan drug designation in the US
- The Exinalda project has been discontinued

## **CEO Comments**

Martin Nicklasson, CEO, said: We are seeing strong continued US sales growth, directly linked to the build-up of our Marketing & Sales resources and activities. Unfortunately, since many European countries are facing budget troubles, we have seen a weaker sales performance in the European market. This was particularly manifested at the end of the third quarter. We have also seen lately, a risk adverse buying pattern on a wholesaler and distribution level, with no or delayed purchase of products, awaiting the implementation of announced price cuts in some countries. During the year an increased level of parallel trade has also occurred. Finally, launches of new growth products in Europe have been delayed or hampered, and sales from these products will not have a significant impact until 2011. Due to this, we have to adjust our full year guidance.



## Financial Summary

		Jul 1 - Sep	30	J	an 1 - Sep 30		Full year
		Pr	o forma		Pro f	orma	Pro forma
Amounts in SEK million	2010	2009	Change	2010	2009	Change	2009
Total revenues, Constant Exchange Rate	466.6	465.4	0%	1,526.8	1,519.5	0%	
Total revenues, reported	444.0	465.4	-5%	1,441.7	1,519.5	-5%	2,065.6
Gross profit	285.2	300.9	-5%	907.8	1,021.7	-11%	1,401.3
Operating profit/loss before amortizations, restructuring and other one-time expenses (EBITA)	63.1	34.0	85%	179.4	176.1	2%	283.8
Profit/loss for the period							
before restructuring and other one-time expenses	-21.2			-33.6			
Profit/loss for the period	-27.5			-91.5			
Earnings/loss per share after tax <sup>1)</sup> (SEK) Core EPS <sup>1)</sup> (SEK)	-0.13 0.19			-0.47 0.57			
Restructuring and other one-time expenses Research and development expenses Liquid funds and short-term investments	6.3 114.1 219.1			57.9 355.2 219.1			

 $<sup>^{\</sup>rm 1)}\,$  Based on Net Income adjusted for amortization and other one time expenses.

## Interim Report January 1st – September 30th, 2010



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## Revenue development by key product and region<sup>1)</sup>

## Revenue development by key product

		Jul 1	- Sep 30			Jan 1	Sep 30	
		CER		CER		CER		CER
Amounts in SEK million	2010	2010	2009	change	2010	2010	2009	Change
ReFacto®	124.9	129.9	124.9	4%	429.7	440.9	495.4	-11%
of which Manufacturing revenues	77.3	77.3	63.2	22%	268.2	268.2	294.9	-9%
of which Co-promotion	23.8	24.9	19.5	28%	71.0	74.5	66.6	12%
of which Royalty	23.8	27.7	42.2	-34%	90.5	98.2	133.9	-27%
Kineret®	103.4	107.7	105.9	2%	321.0	345.2	320.3	8%
Orfadin®	84.4	89.4	73.8	21%	246.8	268.6	225.8	19%
Kepivance®	19.5	19.8	27.2	-27%	76.5	82.6	83.7	-1%
Ammonaps®	19.1	21.0	17.6	19%	55.5	61.0	53.9	13%
Yondelis®	9.4	10.0	12.7	-21%	27.2	29.0	31.4	-8%
Willfact <sup>®</sup>	4.2	4.5	_		8.7	9.1	_	
Other product revenues	79.1	84.3	80.7	4%	246.6	260.7	239.6	9%
Other revenues	_	_	3.4		23.8	23.8	12.9	
Total revenues continued products	444.0	466.6	446.2	5%	1,435.8	1,520.9	1,463.0	4%
Tracleer	-	_	19.2	-100%	5.9	5.9	56.5	-90%
Total revenues	444.0	466.6	465.4	0%	1,441.7	1,526.8	1,519.5	0%

## Product revenue development by region (excluding ReFacto manufacturing and royalty revenues)

		Jul 1 - Se	ep 30			Jan 1 - 9	Sep 30	
		CER		CER		CER		CER
Amounts in SEK million	2010	2010	2009	Change	2010	2010	2009	Change
Nordic	112.5	118.1	127.0	-7%	347.5	363.9	381.6	-5%
Europe	125.6	138.7	139.9	-1%	410.8	453.8	431.6	5%
North America	97.5	97.2	83.5	16%	271.2	288.2	235.8	22%
RoW	7.4	7.3	5.8	26%	29.8	30.4	28.4	7%
Total product revenues	343.0	361.3	356.2	1%	1,059.3	1,136.3	1,077.4	5%

#### ReFacto®

Total ReFacto revenues increased by 4% in CER, compared to the same period last year. Manufacturing revenues increased by 22% and co-promotion revenues increased by 28% in CER, whereas royalties decreased by 34%. For the period January 1 to September 30, total ReFacto revenues were 11% lower in CER compared to the same period last year, mainly because of lower drug substance ordering during the period and a lower royalty rate from ReFacto AF®/Xyntha® compared to ReFacto.

## Kineret®

Sales in Europe were affected by mandatory price decreases, or mandatory discounts, implemented in several countries. As a consequence of anticipated lower price, a destocking pattern at the distributor- and wholesaler level was seen, which negatively impacted sales during the period. Third quarter revenues in Europe decreased by 6% (CER) compared to last year.

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<sup>&</sup>lt;sup>1</sup> Values for 2009 are pro forma



Despite these factors, global sales of Kineret increased by 2% (CER) and decreased by 2% in SEK, since North American sales were strong, showing an increase of 13%, compared to the same quarter 2009. Re-launch activities are ongoing to further drive sales.

#### Orfadin®

Global sales of Orfadin increased by 21% (CER) or 14% in SEK, which is in line with the sales development year to date.

In North America, sales continued to develop strongly. During the third quarter sales increased by 72% (CER) or by 71% in SEK compared to the same period last year. There is a continued focus on educational and promotional activities together with increased screening of newborns to identify, diagnose and treat the newborns as early as possible, in order to save lives and further improve the prognosis for these children. In Europe sales increased by 8.5 % (CER) or 0% in SEK, compared to the third quarter 2009. The relatively low growth during Q3, compared to the period January to June 2010 (14%), is explained by the buying pattern, primarily in Spain and Turkey. Mandatory price decreases or discounts have only had a minimal impact on the price of Orfadin in Europe. Parallel distribution impacted revenues somewhat during the period.

## Kepivance®

Global sales of Kepivance decreased 27% (CER) or 29% in SEK during the quarter.

In Europe, sales decreased by 63% (CER) or 67% in SEK during the quarter, compared to last year, mainly related to mandatory discounts or price decreases, implemented by some governments, and a restriction of the approved indication, agreed with the European health authority (EMA).

The continued high underlying demand in North America has increased gross sales by 16% in CER year to date. However, sales in North America in the quarter decreased by 9% (CER) and 9% in SEK, due to temporary high levels of stock returns, related to expired product.

## Yondelis®

Sales of Yondelis decreased by 21 % (CER) or 26% in SEK, compared to the same period last year. This is mainly explained by discontinued hospital budget funding in the Czech Republic. Also, the pricing decision in Slovenia is delayed. Funding is expected to be granted before the year end. The launch of the second indication in ovarian cancer has been started.

#### Ammonaps®

Sales increased by 19% (CER) or 8% in SEK during the quarter, compared to the same period last year.,

#### Willfact®

Sales of Willfact amounted to SEK 4.5 M (0). Sales are currently booked in Germany, where it is approved, as well as from a few additional patients elsewhere on a named patient basis. The sales are expected to further increase when marketing authorization is gained also in the Nordic and Baltic countries plus part of central and eastern Europe.

## Other products

Sales for the products declined during the quarter, compared to the same period last year by 16% (CER) or 21% in SEK, mainly attributed to Tracleer, which is no longer part of the product portfolio. Adjusted for Tracleer, other product sales increased by 4% (CER) and decreased by 2% in SEK.



## Proforma Financial statement

	Ju	Il 1 - Sep 30 Pro forma		J	an 1 - Sep 30 Pro forma		Full year Pro forma
Amounts in SEK million	2010	2009	Change	2010	2009	Change	2009
Total revenues	444.0	465.4	-5%	1,441.7	1,519.5	-5%	2,065.6
Cost of goods and services sold	-158.8	-164.5	-3%	-533.9	-497.8	7%	-664.3
Gross profit	285.2	300.9	-5%	907.8	1,021.7	-11%	1,401.3
Sales and administration expenses	-124.7	-93.6	33%	-396.0	-360.2	10%	-493.6
Research and development expenses	-114.1	-161.1	-29%	-355.2	-481.6	-26%	-603.0
Other operating revenues/expenses	16.7	-12.2		22.8	-3.8		-24.9
EBITA excl. Restructuring exp.	63.1	34.0	-	179.4	176.1	-	279.9
Restructuring expenses	-6.3	_		-57.9	_		_
Amortization	-51.8	-52.2		-155.4	-157.3		-207.6
Operating profit/loss	5.0	-18.2	-	-33.9	18.8	-	72.3
Financial income/expenses	-30.8	<u> </u>		-55.6			
Profit/loss after financial items	-25.8			-89.5			
Income tax expense	-1.7	_		-2.0			
Profit/loss for the period	-27.5	-		-91.5			

Total revenues reported in the third quarter amounted to SEK 444.0 M, which was slightly below the pro forma revenues in 2009. Excluding currency effects, total revenues were unchanged. The sales in the US showed strong growth, whereas sale in Europe were hampered by a variety of factors, such as price pressure, parallel trade, no or delayed orders from wholesalers and distributors, , and the discontinuation of distribution rights for Tracleer. Total revenues in CER showed a growth of 3% adjusted for Tracleer sales. The agreement was terminated late 2009.

The gross margin decreased from 65% to 64%, during the third quarter, and from 67% to 63% for the first nine month of the year. Gross margin in Q3 was mainly impacted by lower royalty revenues, related to the shift to Refacto AF as well as a general price pressure in Europe and negative currency effects.

Operating expenses, excluding amortization and restructuring expenses, decreased by 16% during the third quarter, mainly due to lower R&D expenses and positive currency revaluation effects. The Sales & Marketing organization has continued to invest behind the key products, which is reflected in an increase of the sales and administration expenses.

The operating income, before amortization and restructuring costs (EBITA), amounted to SEK 63.1 M (34.0). Amortization of intangibles amounted to SEK 51.8 M in the third quarter and restructuring expenses amounted to SEK 6.3 M. This resulted in an reported operating profit of SEK 5.0 M (-18.2).

Expenses for restructuring amounted to SEK 57.9 M during the first nine months, and SEK 6.3 M in the third quarter. The restructuring expenses were mainly severance payments and other restructuring costs related to the integration of the two companies. Further work is ongoing to identify additional synergies. The full year cost for the restructuring of the new company is estimated to about SEK 70 M.

## Net financials and tax

The financial net for the third quarter was SEK -30.8 M (42.0). The financial net was impacted by a write down of a loan to iNovacia and interest expenses related to the net debt.

Sobi has a loss-carry forward which has not been booked as an asset, meaning that the tax rate deviates from the general Swedish tax rate. The current tax expense for the quarter was SEK 13.0 M (0), and deferred tax was SEK 11.3 M (0), resulting in a negative net of SEK 1.7 M.

Loss during the period amounted to SEK -27.5 M.



## Capital expenditure and free cash flow

Investments in tangible fixed assets, during the third quarter, amounted to SEK 3.7 M (19.8).

Investment in intangible fixed assets for the period amounted to SEK 1.1 M (4.7).

Depreciations and amortizations in the third quarter amounted to SEK 63.9 M (27.8), of which SEK 51.8 M (12.3) was related to product rights, acquired technology and license agreements.

Cash flow from operations, during the third quarter, amounted to SEK 8.0 M (-7.4). Payments related to restructuring amounted to SEK 2.0 M.

The planned build-up of inventories related to Kineret during the first nine months of the year was ended and during the fourth quarter inventories are expected to be reduced, starting to impact working capital positively.

## Financial position

Cash and cash equivalents as of September 30, 2010, amounted to SEK 219.1 M (309.4), including SEK 152.0 M (66.1) in bank balances and SEK 67.1 M (123.3) in investments in securities, with a term of less than three months from the date of acquisition. Other short term investments with a term of more than three months amounted to SEK 0 M (120.0).

Bank loan financing amounted, as per September 30, 2010, to SEK 1,350.0 M.

## Equity

The consolidated shareholders' equity as of September 30, 2010, amounted to SEK 4,436.0 M, compared to SEK 1,352.8 M on December 31, 2009. During the first nine month of 2010, shares have been issued at an amount of SEK 3,227.7 M in connection to the acquisition of Swedish Orphan International.

## Personnel

As of September 30, 2010, Swedish Orphan Biovitrum had 500 employees (542 proforma), of which 59 percent (60) were women.



## Outlook 2010 and long term objectives

The outlook for 2010 has been revised. The explanation for this is the weaker sales performance for many of our key products in Europe, in particular seen at the end of the third quarter. Many European countries are facing budget troubles, which have hampered our sales performance. We have also seen an increased level of parallel trade during the year. Furthermore, a dramatic change in wholesaler and distributor buying pattern has been noticed, with no or delayed purchase of products in the third quarter, awaiting implementation of announced price cuts in some countries. Finally, regulatory approvals or sales of new growth products have been delayed or hampered, respectively, in Europe.

Consequently, we expect revenues, excluding milestone revenues, to reach SEK 1,900 - 1,950 M, which corresponds to a growth of 1-4% in CER. Our previous guidance was 8-10% growth in CER<sup>2)</sup>.

Operating income, before amortizations and restructuring (EBITA), is expected to be in the range of SEK 240 - 260 M, corresponding to a growth of 10-18% in SEK, and 20-28% in CER. Our previous guidance was 30-35% growth in CER  $^{1}$ .

The long term objectives are unchanged. Our business target is to grow revenues to SEK 5 B and reach an EBITA margin of above 30 % by 2015.

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<sup>&</sup>lt;sup>2)</sup> Revenues and operating income(EBITA) 2009, adjusted by SEK 63 M, related to the out-licensing of Leptin to AstraZeneca



## Research and development update

## rFVIIIFc for the treatment of hemophilia A

On July 9, Swedish Orphan Biovitrum and BiogenIdec announced the plan to advance the long-lasting, fully recombinant factor VIII Fc fusion protein (rFVIIIFc) into phase III in hemophilia A patients. The decision to advance the project into registrational programs is based on promising data from a Phase I/II open-label, crossover, multi-center, dose-escalation study that evaluated the safety and pharmacokinetics of intravenous rFVIIIFc in previously-treated patients with severe hemophilia A. In the study, rFVIIIFc was well tolerated and demonstrated a prolonged half-life compared to Advate®, supporting advancement of the program.

On September 23, rFVIIIFc was granted orphan drug designation (ODD) by the European Commission in EU.

## rFIXFc for the treatment of hemophilia B

On July 11, positive data from the Phase I/II study of the long-lasting, fully-recombinant factor IX Fc fusion protein (rFIXFc), in 14 previously-treated patients with severe hemophilia B was presented at the World Federation of Hemophilia Congress in Buenos Aires, Argentina. The study design was as an open-label, multicenter, dose-escalation study to evaluate the safety and pharmacokinetics (PK) of different single doses of rFIXFc given as an intravenous injection.

rFIXFc demonstrated an approximately three-fold increase in half-life (52.5±9.2 hours), compared to data reported in the literature for existing factor IX therapies. rFIXFc was generally well tolerated, and there were no signs of injection site reactions. During the three-month observation period, no anti-rFIXFc drug antibodies, and thus no inhibitor development, were detected. There were no reports of drug-related serious adverse events.

## Kineret® in CAPS

Kineret is currently approved for treatment of Rheumatoid Arthritis (RA). The potential for label expansion by documentation of available data on Kineret for certain orphan indications is under investigation, as part of a life-cycle management initiative. On August 19, FDA granted Kineret Orphan Drug designation for the indication Cryopyrin-associated periodic syndromes (CAPS).

## Sym001 in ITP

On September 13, FDA granted orphan drug designation (ODD) to Sym001 (rozrolimupab) for the treatment of primary Immune Thrombocytopenia.

The recruitment of patients in the ongoing phase II study with Sym001 in ITP has been slower than originally anticipated and the study has been prolonged, therefore completion of the study is targeted for H2 2011.

## Exinalda in fat malabsorption

The development of the supportive treatment in cystic fibrosis patients and pancreas insufficiency has been discontinued as the project is no longer viewed as being commercially viable due to the high cost of goods.



## **Development pipeline**

Indication	Product/Project	Preclinical	Phase I	Phase II	Phase III	Reg phase
Hemophilia B	rFIXFc					
Hemophilia A	rFVIIIFc					
Fat malabsorption in premature infants	Kiobrina®					
Second line treatment of Hepatitis C	Multiferon®					
Rh-Immunization	Sym001					
Autoimmune platelet disorder (ITP)	Sym001					

## **Development news flow**

Activity	Expected timing
rFVIIIFc (hemophilia A): start dosing phase III	H2 2010
Kiobrina (fat malarbsorption): start dosing phase III	H1 2011
Sym001 (ITP): report phase II study	H2 2011
rFIXFc (hemophilia B): report phase III	2012



## **Business Development update**

On July 6, a Letter of Inten,t to form a strategic Commercial Alliance with Chinese pharmaceutical company Dongbao was announced. In the alliance, Sobi would be the marketing and sales partner of choice for Dongbao's pipeline of Biopharmaceuticals and other drugs in Europe and Dongbao would be the marketing and sales partner of choice for some of Sobi's marketed and pipeline products in China. The intended Commercial Alliance would be a partnership where both parties will benefit in two ways.

- Each party secures a marketing and sales partner for its own products in an important new territory, China for Sobi and Europe for Dongbao.
- Each party gains access to a new portfolio of exciting products for its home markets.

On September 16, it was announced that marketing, distribution and medical support of Xagrid, Fosrenol, and Equasym in the Nordic countries will be discontinued when the various distribution contracts with Shire expire during 2011. The reason for the termination of the partnership is that Shire intends to establish its own marketing and sales organization in the Nordic region. The total yearly sales of the products in the Nordic countries are some 90 MSEK.



## **Tables And Figures**

## Statement of comprehensive income

	Jul 1 -	Sep 30	Jan 1 - 9	Sep 30	Full year		
Amounts in SEK million	2010	2009	2010	2009	2009		
Total revenues	444.0	274.2	1,441.7	949.3	1,297.0		
Cost of goods and services sold	-158.8	-91.0	-533.9	-283.0	-375.7		
Gross profit	285.2	183.2	907.8	666.3	921.3		
Sales and administration expenses 1)	-176.5	-55.9	-551.4	-232.4	-302.9		
Research and development expenses	-114.1	-154.0	-355.2	-460.0	-569.4		
Restructuring expenses	-6.3	_	-57.9	_	_		
Other operating revenues/expenses	16.7	-7.4	22.8	-9.1	-32.7		
Operating profit/loss	5.0	-34.1	-33.9	-35.2	16.2		
Financial income/expenses	-30.8	42.0	-55.6	36.2	16.3		
	-30.8	42.0	-55.6	36.2	16.3		
Profit/loss after financial items	-25.8	7.9	-89.5	1.0	32.5		
Income tax expense	-1.7	_	-2.0	_	_		
Profit/loss for the period	-27.5	7.9	-91.5	1.0	32.5		
Other comprehensive income <sup>2)</sup>							
Translation difference	-0.5	-3.3	-1.2	-	-4.1		
Comprehensive income for the period	-28.0	4.6	-92.7	1.0	28.4		
Earnings/loss per share after tax <sup>3)</sup> (SEK)	-0.13	0.08	-0.47	0.01	0.32		
Earnings/loss per share after dilution <sup>3)</sup> (SEK)	-0.13	0.08	-0.47	0.01	0.32		
1) Amortization of product rights, acquired technology							
and license agreements included in Selling & Adm expenses	-51.8	-12.3	-155.4	-35.8	-47.9		

<sup>&</sup>lt;sup>2)</sup> In correspondence with Revised IAS 1 all changes in equity that do not arise from transactions with owners should be reported in statement of comprehensive income. Translation difference does entirely concern equity in foreign subsidiary.

 $<sup>^{\</sup>rm 3)}$  Comparison numbers adjusted for new share issue completed in 2010.



## **Balance Sheet**

	Sep 30	Jun 30	Mar 31	Dec 31	Sep 30
Amounts in SEK million	2010	2010	2010	2009	2009
ASSETS					
Fixed assets					
Intangible fixed assets 1)	5,382.6	5,422.5	5,434.0	1,159.1	1,034.0
Tangible fixed assets	262.2	270.5	270.4	252.0	215.4
Financial fixed assets	35.2	55.2	55.7	114.5	46.7
Total fixed assets	5,680.0	5,748.2	5,760.1	1,525.6	1,296.1
Current assets					
Inventories	1,071.0	994.7	670.7	578.4	581.5
Current receivables, non-interestbearing	484.8	483.8	548.3	394.9	303.1
Short-term investments	_	_	_	48.4	120.0
Cash and cash equivalents	219.0	220.0	349.1	258.2	189.4
Total current assets	1,774.8	1,698.5	1,568.1	1,279.9	1,194.0
Total assets	7,454.8	7,446.7	7,328.2	2,805.5	2,490.1
EQUITY AND LIABILITIES					
Shareholders' equity	4,436.0	4,454.2	4,427.6	1,352.8	1,322.9
Long-term liabilities					
Long-term debts	1,369.9	1,380.0	1,172.2	656.0	387.8
Long-term liabilities, non-interestbearing	766.5	777.8	788.9	48.2	400.0
Total long-term liabilities	2,136.4	2,157.8	1,961.1	704.2	787.8
Current liabilities					
Short term debts	164.3	164.3	164.3	50.0	-
Current liabilities, non-interestbearing	718.1	670.4	775.2	698.5	379.4
Total short-term liabilities	882.4	834.7	939.5	748.5	379.4
Total equity and liabilities	7,454.8	7,446.7	7,328.2	2,805.5	2,490.1

 $<sup>^{\</sup>rm 1)}$  Including goodwill SEK 1, 655.7 M (25.3 as per December 31, 2009)

## **Changes in Equity**

Amounts in SEK million	2010 Jan 1-Sep 30	2009 Jan 1-Sep 30	2009 Jan 1 - Dec 31
Opening balance	1,352.8	1,285.0	1,285.0
Change in accounting principles <sup>1)</sup>	-58.8	_	_
Opening balance	1,294.0	1,285.0	1,285.0
Sharebased compensation to employees	7.0	2.5	5.1
Issue of share	3,227.7	34.4	34.4
Redemption of shares	_	_	-0.2
Comprehensive income for the period	-92.7	1.0	28.4
Equity, end of period	4,436.0	1,322.9	1,352.8

<sup>&</sup>lt;sup>1)</sup> As a consequence of adopting a new accounting principle, IFRS 3, as from January 1,2010, prepaid expenses related to acquisition in progress as per December 31, 2009, has been charged to equity as an adjustment of opening balance.



## **Cash flow Statement**

	Jul 1 - Se	p 30	Jan 1 - S	ep 30	Full year
Amounts in SEK million	2010	2009	2010	2009	2009
Net result	-27.5	7.9	-91.5	1.0	32.5
Adjustment for items not affecting cash flow:					
Depreciations and write down 1/	63.9	27.8	200.4	84.1	109.7
Capital gain/loss from divestment of fixed assets	0.1	_	6.2	-0.2	19.4
Revaluation of fixed financial assets	18.4	_	18.4	_	4.7
Revaluation of long-term liabilities	-6.0	-38.6	1.1	-35.5	-19.1
Revaluation of operating receivables and payables	_	3.3	_	_	_
Pensions	0.0	_	0.5	2.5	-5.6
Restructuring expenses	2.3	_	46.4	_	_
Payments related to restructuring reserves	-2.0	-16.0	-47.7	-85.5	-97.9
Reversal of deferred tax	-8.2	_	-32.4	_	-
Other items	-0.7	1.0	7.4	2.5	5.1
Cash flow from operations before change in working capital	40.3	-14.6	108.8	-31.1	48.8
Change in working capital	-32.4	7.2	-355.7	-59.4	10.0
Cash flow from operations	8.0	-7.4	-246.9	-90.5	58.8
Divestment of business	_	_	_	_	22.7
Acquisition of business, net of cash acquired	-0.4	_	-1,812.2	-	-60.8
Investment in intangible fixed assets	-1.1	-4.7	-33.4	-46.6	-62.6
Investment in tangible fixed assets	-3.7	-19.8	-39.8	-45.0	-96.0
Divestment of tangible fixed assets	_	_	_	_	2.1
Investment/Divestment of financial assets	0.1	_	1.4	-3.0	-1.9
Short-term investments	0.0	-6.4	48.4	85.9	157.5
Cash flow from investing activities	-5.0	-30.9	-1,835.6	-8.7	-39.0
Loans - Raising/Amortization	-3.2	_	630.9	-	-50.0
Issue of shares	-0.1	0.1	1,414.1	34.4	34.4
Redemption of shares	_	_	_	_	-0.2
Cash flow from financing activities	-3.3	0.1	2,045.0	34.4	-15.8
Not shange in each	-0.3	-38.2	-37.5	-64.8	4.0
Net change in cash Liquid funds at the beginning of the period	- <b>0.3</b> 219.9	- <b>38.2</b> 227.6	- <b>37.3</b> 258.2	- <b>64.8</b> 254.2	<b>4.0</b> 254.2
Translation difference in cash flow and liquid funds	-0.5	227.0	-1.6	254.2	0.0
Liquid funds at the end of the period	219.1	189.4	219.1	189.4	258.2
Short-term investments	219.1	120.0	213.1	120.0	48.4
Short term investments		120.0		120.0	10.1
Liquid funds and short-term investments at the end of the period	219.1	309.4	219.1	309.4	306.6
1) Depreciations and write down:					
·	11.3	15.5	42.7	48.3	57.9
Depreciation tangible fixed assets	11.5	13.3		40.5	37.5
Depreciation tangible fixed assets  Amortization intangible assets	52.6	12.3	157.7	35.8	51.8



## **Key Ratios and other information**

	Jul 1	Jul 1 - Sep 30		1 - Sep 30	Full year	
	2010	2009	2010	2009	2009	
Return on						
Shareholders' equity	-0.6%	0.6%	-3.2%	0.1%	2.5%	
Total capital	-0.4%	0.3%	-1.8%	0.0%	2.2%	
Margins						
Gross margin	64.2%	66.8%	63.0%	70.2%	71.0%	
EBITDA-margin	15.5%	-2.3%	11.5%	5.2%	9.7%	
EBITA-margin	12.8%	-8.0%	8.4%	0.1%	5.2%	
EBIT-margin	1.1%	-12.4%	-2.4%	-3.7%	1.2%	
Profit margin	-6.2%	2.9%	-6.3%	0.1%	2.5%	
Per share data (SEK)						
Shareholders' equity per share	20.9	26.0	20.9	26.0	26.6	
Shareholders' equity per share after dilution	20.8	25.8	20.8	25.8	26.4	
Cash flow per share	0.0	-0.7	-0.2	-1.3	0.1	
Cash flow per share after dilution	0.0	-0.7	-0.2	-1.3	0.1	
Other information						
Equity ratio	59.5%	53.1%	59.5%	53.1%	48.2%	
Number of ordinary shares	212,181,279	50,911,901	212,181,279	50,911,901	50,911,901	
Average number of ordinary shares	212,052,346	50,967,280	194,212,175	50,438,326	50,485,362	
Outstanding warrants 1)	335,000	2,089,602	335,000	2,089,602	335,000	
Number of shares after dilution	212.880.579	51.281.901	212.880.579	51.281.901	51.281.901	
	, ,	, ,	, ,			
Cash flow per share Cash flow per share after dilution  Other information Equity ratio  Number of ordinary shares Average number of ordinary shares  Outstanding warrants 1)	0.0 0.0 59.5% 212,181,279 212,052,346	-0.7 -0.7 53.1% 50,911,901 50,967,280	-0.2 -0.2 59.5% 212,181,279 194,212,175	-1.3 -1.3 53.1% 50,911,901 50,438,326	0.1 0.1 48.2% 50,911,901 50,485,362	

 $<sup>^{1)}</sup>$  There are two different warrant programs outstanding, exercisable for a maximum of 699,300 new shares in total



## Financial Statements – Parent Company

## **Profit and Loss Statement – Parent Company**

	Jul 1 - 9	Sep 30	Jan 1 -	Sep 30	Full year
Amounts in SEK million	2010	2009	2010	2009	2009
Total revenues	260.3	274.2	895.4	949.3	1,297.0
Cost of goods and services sold	-92.1	-91.0	-325.4	-283.0	-375.7
Gross profit	168.2	183.2	570.0	666.3	921.2
Sales and administration expenses 1)	-75.5	-55.8	-244.6	-229.8	-309.0
Research and development expenses	-109.7	-154.4	-336.5	-461.2	-570.7
Restructuring expenses	-6.2	_	-52.0	_	_
Other operating revenues/expenses	21.0	-4.0	35.1	-9.0	-5.1
Operating profit/loss	-2.2	-31.0	-28.0	-33.7	36.4
Result from participation in Group companies	_	_	_	_	17.6
Financial income	0.8	40.8	2.2	47.3	28.7
Financial expenses	-37.1	1.2	-66.8	-11.1	-12.3
Profit/loss after financial items	-38.5	11.0	-92.6	2.5	70.4
Income tax expense	-	-	_	_	-
Profit/loss for the period	-38.5	11.0	-92.6	2.5	70.4
1) Amortization of product rights, acquired technology and license					
agreements included in Adm expenss	-12.5	-12.5	-37.5	-37.5	-50.0

## **Balance Sheet – parent Company**

	Sep 30	Jun 30	Mar 31	Dec 31	Sep 30
Amounts in SEK million	2010	2010	2010	2009	2009
ASSETS					
Fixed assets					
Intangible fixed assets	923.7	935.7	947.1	959.7	834.5
Tangible fixed assets	247.7	255.4	256.6	252.0	213.3
Financial fixed assets	4,498.4	4,506.5	4,496.7	670.3	610.7
Total fixed assets	5,669.8	5,697.6	5,700.4	1,882.0	1,658.5
Current assets					
Inventories	924.4	852.1	541.9	578.4	581.5
Current receivables, non-interestbearing	281.6	374.9	356.6	396.5	302.3
Short-term investments	-	_	-	48.4	120.0
Cash and cash equivalents	188.5	177.9	268.9	258.0	188.3
Total current assets	1,394.5	1,404.9	1,167.4	1,281.2	1,192.1
Total assets	7,064.3	7,102.5	6,867.8	3,163.2	2,850.6
EQUITY AND LIABILITIES					
Shareholders' equity	4,468.2	4,490.6	4,453.0	1,326.1	1,255.6
Long-term liabilities					
Long term liabilities	1,355.3	1,351.5	1,143.2	656.0	387.8
Long term liabilities, non-interestbearing	-	_	-	-	351.8
Total long-term liabilities	1,355.3	1,351.5	1,143.2	656.0	739.6
Current liabilities					
Current liabilities	164.3	164.3	164.3	50.0	-
Current liabilities, non-interestbearing	1,076.5	1,096.1	1,107.3	1,131.1	855.4
Total short-term liabilities	1,240.8	1,260.4	1,271.6	1,181.1	855.4
Total equity and liabilities	7,064.3	7,102.5	6,867.8	3,163.2	2,850.6

## Change in Shareholders' equity – Parent Company

	2010	2009	2009
Amounts in SEK million	Jan 1 - Sep 30	Jan 1 - Sep 30	Jan 1 - Dec 31
Opening balance	1,326.1	1,216.2	1,216.2
Sharebased compensation to employees	7.0	2.5	5.1
Issue of share	3,227.7	34.4	34.4
Redemption of shares	_	_	-0.2
Profit/loss for the period	-92.6	2.5	70.4
Equity, end of period	4,468.2	1,255.6	1,326.1



#### **Notes**

## Note 1 Accounting and valuation principles and other information

## Important accounting principles

Swedish Orphan Biovitrum AB (publ) prepares its consolidated financial statements in accordance with the Annual Accounts Act, the Swedish Financial Reporting Board's recommendation RFR 1.3. Supplementary Accounting Rules for Groups, and the International Financial Reporting Standards (IFRS) and IFRIC interpretations as adopted by the EU. The consolidated financial statements have been prepared according to the historical cost convention except in the case of financial assets and financial assets and liabilities (including derivative instruments) measured at fair value through profit and loss.

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

The Group applies the same accounting standards as those applied in the 2009 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 January 1, 2010. The fact that Biovitrum has acquired Swedish Orphan has not affected the company's reporting as regards IFRS 8 – Segment Reporting.

For Swedish Orphan Biovitrum AB (publ), the following amendments are relevant:

## Adopting revised accounting standard - IFRS 3 "Business Combinations"

Effective as of January 1, 2010, the Group is applying the revised accounting standard IFRS 3 Business Combinations. The revised standard still requires the acquisition method to be applied for business combinations, but with some significant changes. For example, all payments for the purchase of a business at fair value are recorded on the acquisition date, while subsequent conditional payments are classified as liabilities which are then re-measured in profit or loss. Non-controlling interests (replacing the previous term "minority interest") in the acquired business can either be valued at fair value or at the proportionate portion of the business's net assets held by the party with the non-controlling interest. All acquisition related transaction costs are to be expensed. The revision applies prospectively for acquisitions after the date it goes into force. The amendment to the standard will not involve any change with respect to previous acquisitions, but will only affect reporting of future acquisitions.

The amendment has affected the acquisition of Swedish Orphan which was in progress year-end 2009. Accrued acquisition related transaction costs as per December 31, 2009, amounting to SEK 58.8 M, has been charged to equity as an adjustment of opening balance as per January 1, 2010.

#### **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. Swedish Orphan 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 2009 Annual Report (see the Directors' Report).



Note 2 Shares and Warrants

Developmen	t in share capital and number	No of shares	Share capital, SEK
December 20	009	50,911,901	27,935,503
Jan 2010	New share issue	159,129,238	87,313,411
May 2010	Issue of shares in connection with convertible bonds	2,373,300	1,301,495
Aug 2010	New share issue	282,425	155,693
September 2	010	212,696,864	116,706,102

A preferential new share issue and an issue in kind were completed in January in connection with the acquisition of Swedish Orphan. In May a new share issue in connection with convertible bonds concerning termination of CBT were completed. As a milestone payment a new share issue were completed in August.

Issued shares break down as 212,181,279 ordinary shares and 515,585 C shares. The ordinary shares carry one vote per share and the C shares carry 1/10 vote per shares. All C shares are treasury shares.

## 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 427,130<sup>3)</sup> 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 375,387<sup>4)</sup> 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 programs

30-sen Full year 2009 Full vear 2010 Option program 2006/2011 Outstanding January 1 35,000 40,000 60,000 Forfeited during the period -5,000 35,000 40,000 35,000 Outstanding at of end of accounting period Exercisable at of end of accounting period 35.000 35.000 24.998 Full year 30-sep Full year Employee option program 2007/2012 2008 2010 2009 Outstanding January 1 300,000 300,000 300,000 Outstanding at of end of accounting period 300,000 300,000 300,000 Exercisable at of end of accounting period 300.000 200.000 100.000

<sup>&</sup>lt;sup>3)</sup> Adjusted for new share issue completed in January 2010.

<sup>&</sup>lt;sup>4)</sup> Adjusted for new share issue completed in January 2010.



Note 3 Transactions with related parties

	Full Year	Full Year
Amounts in SEK thousands	2010	2009
Loan to executive management in Parent Company:		
At beginning of the year:	153	153
Loans paid during the year:	-	_
	153	153

There was no change as to 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 2009.

A company related to the chairman of the Board, Orfacare, provides consultation as regards making available, marketing and distribution of drugs for the Sobi group in e.g. Switzerland and Austria. The costs year to date amounted to SEK 2.5 M.

## Note 4 Contingencies

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 Swedish Orphan 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 Swedish Orphan 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. Swedish Orphan Biovitrum takes the view that the Tax Agency ought not to succeed in proving its case in relation to this new ground either.

During the third quarter, the sellers of the pharmaceutical company Arexis, which was acquired in August 2005, have made a claim against Swedish Orphan Biovitrum in the amount of approx. MSEK 325, alleging that Swedish Orphan Biovitrum has not performed its obligations under the share purchase agreement entered into at the time of the acquisition. An assessment of the claim is ongoing and no provisions have been made.



#### Note 5 Acquired operations

Total purchase price

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 acquisition was concluded on January 14, 2010.

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

Purchase price allocation	
Amounts in SEK million	
Purchase price	
- cash payment	1 923,4
- discounted value est. future additional purchase price	165,0
- fair value of shares issue	1 738,4
Total purchase price	3 826,8
Assets and liabilities in acquired operation	Fair value
Amounts in SEK million	Tall Value
Other intangible assets	2 680,0
Tangible assets	14,0
Financial fixed assets	3,0
Other current assets	449,0
Total assets in acquired operation	3 146,0
Long-term borrowings	31,0
Retirement benefit obligations	3,0
Deferred income tax liabilities	749,0
Current liabilities	182,0
Total liabilities in acquired operation	965,0
Acquired net assets	2 181,0
Goodwill	1 645,8

Goodwill pertains to the established legal structure and market presence in most countries and the synergy effects that are expected to arise by coordinating the operations of Biovitrum and Swedish Orphan.

3 826.8

The estimated value of the capital contributed in kind is equivalent to a subscription price of around SEK 29.80 per ordinary share, representing a volume-weighted average price for the Biovitrum share during the 20 trading days preceding the announcement of the acquisition on November 5, 2009 adjusted for dilution of the rights issue that Biovitrum implemented to partially finance the cash payment for the acquisition.

The future conditional purchase sum is based on expected future sales volume of Multiferon. The purchase sum is calculated on a yearly basis and amounts to the net volume which exceeds a "High Watermark amount" multiplied by three. The initial High Watermark amount amounts to SEK 200 M and the maximum conditional purchase sum amounts to SEK 425 M. The duration of the purchase sum is 60 months after certain approvals and commercial launches in a number of EU countries, however, never later than the 31<sup>st</sup> December, 2017.

The fair value of the acquired identifiable intangible assets of SEK 2,680 Million is a preliminary figure pending the receipt of a final measurement of these assets, and also the final valuation of the additional purchase price.

Liquid funds	
Amounts in SEK million	
Liquid funds	
Cash payment	-1,923.4
Liquid funds in acquired operation	122.2
Effect on liquid funds	-1.801.2

## Interim Report January 1st – September 30th, 2010



The acquisition agreement includes e.g. an undertaking by former CEO of Swedish Orphan, Bo Jesper Hansen, not to compete with Biovitrum or its subsidiaries during a period of three years from completion of the transaction. For this undertaking, Bo Jesper Hansen is, under the relevant three-year period, entitled to a monthly compensation amounting to approximately DKK 565,000, however reduced with e.g. any compensation payable to Bo Jesper Hansen during the same period by Biovitrum or any group company under any employment or consultancy arrangement.

## Forward-looking statement

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 Swedish Orphan Biovitrum's results.

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

Solna, October 26, 2010

Martin Nicklasson Chief Executive Officer

## **Review Report**

We have reviewed this report for the period January 1, 2010, to September 30, 2010, for Biovitrum AB (publ). The board of directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

We conducted our review in accordance with the Standard on Review Engagements SÖG 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Standards on Auditing in Sweden, RS, and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

Based on our review, nothing has come to our attention that causes us to believe that the interim report has not, in all material respects, been prepared in accordance with IAS 34 and the Annual Accounts Act, regarding the Group, and with the Annual Accounts Act, regarding the Parent Company.

Stockholm, October 26, 2010 PricewaterhouseCoopers AB

Mikael Winkvist Authorized Public Accountant



## Conference call details

The Interim Report for the third quarter 2010 will be presented by Swedish Orphan Biovitrum's CEO Martin Nicklasson and CFO Göran Arvidson at a media and analyst telephone conference. The presentation will be held in English and can also be followed, direct or retrospectively, by a web cast via internet.

Time: Tuesday, October 26, 2010 at 3.00 p.m. (CET)

**Venue:** Grand Hôtel, Stockholm Sweden (room "Mårten Vinge"

Coffee will be served

Please register for participation to Maria Mattsson on <a href="mailto:maria.mattsson@zvm.se">maria.mattsson@zvm.se</a> or by phone +46 70 438 88 53

To participate in the Telephone Conference

**please call:** UK: +44 (0)20 3043 2436

SE: +46 (0)8 505 598 53 US: +1 866 458 40 87

To follow the Telephone conference via web cast, direct or retrospectively by Internet you will find the link on our web site, please visit: www.sobi.com

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Financial calendar for 2011

Full year Report 2010 February 23, 2011
Interim Report Jan - March, 2011 April 28, 2011
Annual General Meeting April 28, 2011
Interim Report April - June, 2011 July 19, 2011
Interim Report July - Sept, 2011 October 20, 2011

## About Swedish Orphan Biovitrum

Swedish Orphan Biovitrum is a Swedish based niche specialty pharmaceutical company with an international market presence. The company is focused on providing and developing specialist pharmaceuticals for rare disease patients with high medical needs. The portfolio consists of about 60 marketed products and an stage clinical development focus emerging late pipe-line. Our areas are: hemophilia, inflammation/autoimmune diseases, fat malabsorption, cancer supportive care and inherited metabolic disorders. Swedish Orphan Biovitrum had pro-forma revenues 2009e of about SEK 2 B and approximately 500 employees. The head office is located in Sweden and the share (STO: SOBI) is listed on NASDAQ OMX Stockholm. For more information please visit www.sobi.com.