

# Interim Report, January – March 2012

Stockholm, 26 April 2012

Geoffrey McDonough, CEO: "The first quarter marks a solid beginning for 2012 with consistent growth across our product business lines. We finalized two significant transactions with Pfizer and made an important revision of the agreement regarding the acquisition of Arexis and have no remaining obligations towards the sellers for any development program including Kiobrina®. We are focusing on creating a strong base for growing our commercial portfolio and to improve operational efficiency. The first phase in the establishment of the new subsidiary in the US was finalized during the quarter. In addition we are very pleased to have received approval for our Pediatric Investigation Plans for both Kineret® in new indications and for Orfadin® in a liquid formulation. At approval the new Orfadin formulation would also extend the orphan designation in Europe through 2017."

- Total revenues declined by 6% to SEK 506.7 M (537.4), and by 3% adjusted for currency and discontinued products.
- Product revenues<sup>1)</sup> rose by 10% to SEK 365.6 M (332.1), and by 16% adjusted for currency effects and discontinued products, mainly driven by Core Products.
- Gross margin declined to 51% (53%), mainly due to costs for the transfer of Kineret production and the divestment of the co-promotion rights for ReFacto AF®/BeneFIX® as of 15 February 2012.
- Proceeds of SEK 307.5 M from the divestment of the co-promotion rights included in operating profit.
- Operating profit also includes non-recurring items of SEK -34 M related to the amended purchase agreement with the sellers of Arexis on 30 March 2012.
- The previously published outlook for 2012 remains unchanged.

	Q1			Full year
Amounts in SEK million	2012	2011	Change	2011
Total revenues	506.7	537.4	-6%	1,910.8
Gross profit	259.4	283.9	-9%	974.6
Gross margin	51%	53%	-3%	51%
Operating profit before amortizations and non-recurring items	342.2	59.7	>100%	127.3
Operating profit	242.6	-63.7	>100%	-318.6
Profit/loss	154.8	-68.9	>100%	17.9
Earnings/loss per share, SEK <sup>2)</sup>	0.58	-0.29	>100%	0.07

<sup>&</sup>lt;sup>1)</sup> Product revenues include Core Products and Partner Products.

 $<sup>^{2)}</sup>$  Comparative figures have been adjusted to reflect the rights issue in June 2011.



#### Revenues

Total revenues for the first quarter of 2012 declined by 6% to SEK 506.7 M (537.4). Adjusted for positive currency effects of SEK 5.7 M and discontinued products amounting to SEK 22.5 M, revenues declined by 3%. Discontinued products include the Shire products Xagrid®, Fosrenol® and Equasym® that were sold in the Nordic region.

Product revenues, i.e. revenues for Core Products and Partner Products, rose by 10% to SEK 365.6 M (332.1), and by 16% adjusted for currency effects and discontinued products. Product revenues were positively impacted by approximately SEK 23 M related to stock building of Kineret and Kepivance by wholesalers in the US to ensure deliveries to local customers until the new subsidiary Sobi Inc has received licenses to sell in all states. Product revenues were negatively impacted by the divestment of the co-promotion rights for ReFacto AF/BeneFIX as of February 2012. Revenues from co-promotion amounted to SEK 12.0 M in the quarter as compared with SEK 28.3 M in the first quarter of 2011.

ReFacto manufacturing and royalty revenues were lower than in the previous year, mainly due to the delivery of validation batches in the first quarter of 2011. The decline in revenues from royalty is a result of a different timing between quarters compared with the previous year.

### **Revenues by Business Line**

As previously communicated, revenues will be reported in three business lines: Core Products, Partner Products and ReFacto, starting in the first quarter of 2012.

	Q:	1	Change	Change	Full year
Amounts in SEK million	2012	2011	%	% at CER	2011
Core products					
Kineret	134.7	107.2	26%	23%	422.0
Orfadin	93.6	76.0	23%	23%	315.7
Other core products	21.8	17.2	27%	26%	74.6
Total	250.2	200.4	25%	23%	812.3
Partner products					
Current portfolio	103.4	80.8	28%	27%	373.6
Discontinued products	0.0	22.5	-100%	-100%	45.0
Co-promotion revenues	12.0	28.3	-58%	-58%	105.0
Total	115.4	131.6	-12%	-13%	523.6
ReFacto					
Manufacturing revenues	116.9	166.4	-30%	-30%	451.7
Royalty revenues	24.2	38.9	-38%	-39%	123.3
Total	141.1	205.3	-31%	-31%	575.0
Other revenues	-	0.1	-100%	-100%	-
Total revenues	506.7	537.4	-6%	-7%	1,910.8
Totalt revenues excl co-promotion and discontinued products	494.7	486.6	2%	1%	1,760.8

### **Core Products**

### Kineret

Sales of Kineret in the first quarter increased by 26% to SEK 134.7 M (107.2). Sales were positively impacted by approximately SEK 20 M related to stock building by wholesalers in the US. Adjusted for this effect, sales of Kineret increased by 7%.

The transfer of Kineret production from Amgen Inc. in the US to a contract manufacturer in Europe is ongoing. Final process validation runs are still expected to be completed in the second quarter of 2012.



#### Orfadin

Sales in the first quarter rose by 23% to SEK 93.6 M (76.0) on the basis of higher volumes in Central- and Eastern Europe and in the Middle East/North African region.

Sales in Russia increased following the establishment of reimbursement for the first HT-1 patients. During 2012 new legislation will come into effect in Russia granting all HT-1 patients reimbursement for treatment with Orfadin.

#### **Partner Products**

Revenues for Partner Products declined in the quarter by 12% to SEK 115.4 M (131.6), but increased by 6% after adjustment for the discontinued Shire products. Revenues were also negatively affected by lower co-promotion for ReFacto AF/BeneFIX in the Nordic region following the divestment of these rights to Pfizer as of 15 February 2012. Co-promotion revenues amounted to SEK 12.0 M in the first quarter of 2012 as compared to SEK 28.3 M in the first quarter of 2011.

Sales of Kepivance® in the first quarter increased by 19% to SEK 22.8 M (19.2). The increase relates mainly to the US where the impact of stock building by wholesalers was approximately SEK 3.2 M. Higher sales were also achieved in several markets in Central- and Eastern Europe.

Sales of Yondelis® in the first quarter rose by 34% to SEK 10.9 M (8.1) on the basis of positive trends in several markets in Central- and Eastern Europe.

### **ReFacto Manufacturing and Royalties**

Total ReFacto manufacturing and royalty revenues decreased by 31% to SEK 141.1 M (205.3). The decline was mainly due to the delivery of validation batches in the amount of SEK 35 M in the first quarter of 2011. The decrease in revenue from royalties is a result of a different timing between quarters compared with the previous year.

## Revenues by Region (excluding ReFacto revenues<sup>1</sup>)

	Q1			Change	Full year
Amounts in SEK million	2012	2011	Change	% at CER	2011
Nordic	86.4	108.5	-20%	-21%	427.9
Europe	163.3	128.0	28%	27%	540.9
North America	110.6	86.0	29%	24%	328.2
RoW	5.3	9.6	-45%	-46%	38.8
Total revenues	365.6	332.1	10%	9%	1,335.8

<sup>&</sup>lt;sup>1)</sup> Excluding ReFacto manufacturing and royalty revenues, including discontinued products.

### **Gross profit**

Gross profit amounted to SEK 259.4 M (283.9), corresponding to a margin of 51.2% (52.8).

Gross margin was positively impacted by an improved margin on ReFacto manufacturing. This was more than offset however, by cost for the transfer of Kineret production of SEK 31 M (19) and lower co-promotion revenues of SEK 16.3 M. Excluding both costs for the production transfer and revenues from co-promotion, the gross margin was 56.3%.

## **Operating profit**

Operating profit before amortization of intangible assets and non-recurring items was SEK 342.2 M (59.7).

Operating expenses<sup>2</sup> increased by 3% to SEK 225.1 M (219.2). The increase was driven by costs in sales and administration, while R&D expenses declined overall despite higher investment in the Kiobrina phase III program.

Amortization of intangible assets amounted to SEK 65.6 M (53.4). Other operating revenues and expenses amounted to SEK 307.9 M (-5) and related mainly to the divestment of co-promotion rights for ReFacto AF/BeneFIX.

<sup>&</sup>lt;sup>2)</sup> Excluding amortization of intangible assets, non-recurring items, and other operating revenues and expenses.



Operating profit before non-recurring items was SEK 276.6 M (6.3).

Non-recurring items amounted to SEK -34.0 M(-70.1) and related to the amended agreement with the sellers of Arexis on 30 March 2012, see page 5.

Operating profit before amortizations (EBITA) was SEK 308.2 M (-10.3) and EBIT was SEK 242.6 M (-63.7).

### Net financial items and tax

Net financial items in the first quarter amounted to SEK -13.3 M (-18.1). The financial expense is mainly related to the company's net debt which was reduced substantially following the rights issue in the second quarter of 2011 and the divestment of the co-promotion rights in the first quarter of 2012. Net debt as of 31 March 2012 amounted to SEK 178.3 M (1,174.0).

The tax expense for the first quarter was SEK -74.5 M (12.9).

# Profit for the period

Profit for the period was SEK 154.8 M (-68.9), corresponding to earnings per share of SEK 0.58 (-0.29).

### Cash flow and investments

Cash flow from operations before changes in working capital in the first quarter was SEK 336.6 M (53.4), positively impacted by the proceeds of SEK 307.5 M from the divestment of the co-promotion rights. Non-cash items amounted to SEK 181.8 M (122.3) and referred mainly to amortization of intangible assets and deferred taxes.

An increase in working capital had a negative impact on cash flow of SEK -32.5 M (-75.3), as lower inventory of Kineret was more than offset by increased receivables related to manufacturing. Cash flow from net investments in the first quarter amounted to SEK -1.4 M (-3.6).

This resulted in a cash flow after investing activities of SEK 302.7 M (-25.5).

### **Financial position**

Cash and cash equivalents and short-term investments as of 31 March 2012 amounted to SEK 314.1 M (37.7). The company's financing through bank loans as of 31 March 2012 amounted to SEK 492.5 M (1,208.1).

### Equity

Consolidated shareholders' equity as of 31 March 2012 amounted to SEK 5,094.5 M compared to SEK 4,963.4 M as of December 31, 2011.

### **Outlook for 2012**

The outlook has not been changed since it was first published on 23 February 2012.

Market conditions are expected to continue to be challenging, particularly in Europe due to the uncertain macroeconomic environment, and in the US related to the evolution of the new healthcare regime. The outlook is based on the assumption that the current SEK/USD and SEK/EUR exchange rates prevail during the year, and that market conditions do not significantly deteriorate.

Total revenues for the full year 2012 are expected to be approximately SEK 100 M lower than in 2011 reflecting the divestment of the ReFacto co-promotion rights.

Revenues for Core Products and Partner Products are expected to show mid to high single digit growth, while revenues for ReFacto manufacturing and royalty are expected to show low single digit growth. Revenues in 2011 from validation batches (SEK 42 M) and discontinued products (SEK 45 M) will not recur in 2012.

The gross margin for the full year 2012 is expected to be in line with the 2011 margin, which was 54% after adjustment for both the balance sheet write-downs and the divestment of co-promotion rights. Costs in 2012 related to the transfer of Kineret production are estimated at SEK 60 M and are expected to impact the gross



margin primarily in the first half of the year. As a result of the renegotiated ReFacto manufacturing agreement with Pfizer, reduced quarterly variations in the ReFacto manufacturing gross margin are expected.

Operating expenses, excluding amortizations, are estimated at or below SEK 950 M.

The earlier reported milestone payment to Amgen of USD 55 M is now estimated to become due in Q4 2012 or in Q1 2013, with the ultimate timing dependent on the cumulative sales of Kineret.

# **Research and Development**

## Pediatric investigation plans for Orfadin and Kineret

Sobi has received formal agreements from the EMA Pediatric Committee on its Pediatric Investigation Plans (PIP) for Orfadin and Kineret.

The agreed PIP for Orfadin outlines the development of a liquid formulation to enable more convenient and sustainable dosing for pediatric patients. The plan outlines a small clinical trial to establish bioequivalence between the new formulation and the present capsule formulation and a second study to evaluate the taste and palatability of the new formulation.

The agreed PIP for Kineret covers the indications Cryopyrin Associated Periodic Syndrome (CAPS) as well as Systemic Juvenile Rheumatoid Arthritis (SJIA). Sobi intends to file for the CAPS indication in Europe in the second half of this year.

### **Development pipeline**

Indication	Product/Project	Partner	Phase I	Phase II	Phase III	Reg phase
Hemophilia A	rFVIIIFc	BiogenIdec				
Hemophilia B	rFIXFc	BiogenIdec				
Prevent growth restriction in premature infants	Kiobrina®					
Diuresis and seizures in neonates	Reformulated Bumetanide	Only For Children Pharmaceuticals (O4CP)				

### Life cycle management

Indication	Product/Project
CAPS	Kineret®
Hereditary tyrosinemia type 1	Orfadin®, liquid formulation

### **Key dates**

Activity	Expected timing
rFVIIIFc (hemophilia A): report phase III data	H2 2012
rFIXFc (hemophilia B): report phase III data	H2 2012
Kiobrina® (prevent growth restriction): phase III data	2013

# **Other Information**

# **Amended Agreement with Sellers of Arexis**

On 30 March 2012, Sobi amended its share purchase agreement regarding the acquisition in 2005 of the pharmaceutical company Arexis AB, which included a number of development programs one of which was Kiobrina.

According to the amended agreement, Sobi will not have any remaining development obligations towards the sellers. Sobi will pay the sellers a total of SEK 77 M, of which SEK 43 M relates to the future milestone obligations



for the Kiobrina program. Sobi has paid SEK 36 M in the beginning of the second quarter of 2012, and will pay SEK 20 M in 2013, and SEK 21 M in 2014.

The payment of SEK 43 M referring to the milestones for Kiobrina will be included in intangible assets in the balance sheet. An amount of SEK -34 M has been charged against operating income as a non-recurring item in the quarter.

### Personnel

As of 31 March 2012, the number of full-time employees was 515 (518).

Solna, 26 April 2012

Geoffrey McDonough President and CEO

# 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.

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



# **Financials & Notes**

**Statement of Comprehensive Income** 

	Q1		Full year
Amounts in SEK million	2012	2011	2011
Total revenues	506.7	537.4	1,910.8
Total cost of goods and services sold	-247.3	-253.5	-936.3
Gross profit	259.4	283.9	974.6
Sales and Administration expenses 1)	-193.4	-170.1	-804.4
Research and Development expenses 2)	-97.4	-102.4	-555.7
Non-recurring items 3)	-34.0	-70.1	-80.4
Other operating revenues/expenses	307.9	-5.0	147.4
Operating profit/loss	242.6	-63.7	-318.6
Financial income/expenses	-13.3	-18.1	-52.2
Profit/loss after financial items	229.3	-81.8	-370.8
Income tax expense	-74.5	12.9	388.8
Profit/loss for the period	154.8	-68.9	17.9
Other comprehensive income 4)			
Translation difference	-0.1	-0.2	-0.2
Comprehensive income for the period	154.7	-69.1	17.7
Earnings/loss per share after tax (SEK) <sup>5)</sup>	0.58	-0.29	0.07
Earnings/loss per share after dilution (SEK) <sup>5)</sup>	0.58	-0.29	0.07
Earnings/1033 per share areer anation (SER)	0.50	0.23	0.07
1) Amortization and write-down of intangible assets included			
in Sales & Adm expenses	-65.6	-53.4	-237.9
<sup>2)</sup> Amortization and write-down of intangible assets included			
in Research and Development expenses	0.0	-	-127.6
3) Amortization and write-down of intangible assets included			•
in non-recurring items	_	_	-2.6

<sup>&</sup>lt;sup>4)</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 subsidiaries.

<sup>&</sup>lt;sup>5)</sup>Comparison numbers have been adjusted for the rights issue completed in June 2011.



## **Balance Sheet**

	Mar	Dec	Sep	Jun	Mar
Amounts in SEK million	2012	2011	2011	2011	2011
ASSETS					
Fixed assets					
Intangible fixed assets 1)	4,862.6	4,885.1	5,070.9	5,125.0	5,172.1
Tangible fixed assets	147.0	155.9	219.3	230.9	240.4
Financial fixed assets	7.7	11.4	22.7	20.0	20.9
Total fixed assets	5,017.3	5,052.4	5,312.9	5,375.8	5,433.5
Current assets					
Inventories	829.8	893.8	953.2	1,008.6	1,001.2
Accounts receivable	413.1	309.6	406.8	355.1	361.4
Current receivables, non-interest bearing	201.4	224.6	198.4	236.0	197.8
Cash and cash equivalents	314.1	219.0	73.1	115.0	37.7
Total current assets	1,758.4	1,647.1	1,631.4	1,714.6	1,598.2
Total assets	6,775.6	6,699.5	6,944.3	7,090.5	7,031.6
EQUITY AND LIABILITIES					
Shareholders equity	5,094.5	4,963.4	4,948.3	4,984.1	4,274.4
Long-term liabilities					
Long-term debt	492.5	700.7	686.1	713.3	1,208.1
Long-term liabilities, non-interest bearing	472.2	358.7	730.9	740.7	748.4
Total long-term liabilities	964.7	1,059.4	1,417.0	1,454.0	1,956.5
Current liabilities					
Short term debt	13.7	13.9	14.0	14.8	203.5
Current liabilities, non-interest bearing	702.7	662.8	565.0	637.6	597.2
Total short-term liabilities	716.4	676.7	579.0	652.4	800.7
Total equity and liabilities	6,775.6	6,699.5	6,944.3	7,090.5	7,031.6

<sup>1)</sup> Including goodwill SEK 1,605.3 M

# **Changes in Equity**

	Q1		Full year
Amounts in SEK million	2012	2011	2011
Opening balance	4,963.4	4,342.4	4,342.4
Change in acconting principle 1)	-24.6	_	_
Opening balance	4,938.8	4,342.4	4,342.4
Sharebased compensation to employees	1.0	1.2	9.3
Issue of shares	_	_	594.0
Comprehensive income for the period	154.7	-69.1	17.7
Equity, end of period	5,094.5	4,274.4	4,963.4

<sup>&</sup>lt;sup>1)</sup>As a consequence of adopting new accounting principles, IAS 19, as from January 1, 2012, actuarial losses per December 31, 2011 has been charged to equity as an adjustment of opening balances.



# **Cash Flow Statement**

	Q1		Full year	
Amounts in SEK million	2012	2011	2011	
Net result	154.8	-68.9	17.9	
Non-cash items <sup>1)</sup>	181.8	122.3	100.4	
Cash flow from operations before change in working capital	336.6	53.4	118.3	
Change in working capital	-32.5	-75.3	-15.4	
Cash flow from operations	304.1	-21.9	102.9	
Acquisition of business, net of cash acquired	_	_	-29.8	
Investment in intangible fixed assets	-0.1	-2.6	-7.6	
Investment in tangible fixed assets	_	-1.9	-7.7	
Divestment of tangible fixed assets	-1.3	_	1.3	
Investment/Divestment of financial assets	_	0.9	_	
Cash flow from investing activities	-1.4	-3.6	-43.7	
Loans - Raising/Amortization	-207.5	24.9	-472.4	
Issue of shares	-	-	594.0	
Cash flow from financing activities	-207.5	24.9	121.6	
Net change in cash	95.2	-0.6	180.8	
Liquid funds at the beginning of the period	219.1	38.5	38.5	
Translation difference in cash flow and liquid funds	-0.2	-0.2	-0.2	
Liquid funds at the end of the period	314.1	37.7	219.1	
Short-term investments	-	_	_	
Liquid funds and short-term investments at the end of the period	314.1	37.7	219.1	
1) Depreciations, amortization and deferred tax:				
Depreciation tangible fixed assets	8.5	13.8	81.8	
Amortization intangible assets	65.6	53.4	368.1	
	00.0	55.1	550.1	



# **Key Ratios and Other Information**

	Q1		Full year
Amounts in SEK million	2012	2011	2011
Return on			
Shareholders' equity	3.1%	-1.6%	0.4%
Total capital	2.3%	-1.0%	-4.5%
Profit numbers			
Gross profit	259.4	283.9	974.6
EBITDA	316.7	3.5	131.3
Operating profit before amortizations and non-			
recurring items	342.2	59.7	127.3
Operating profit before non-recurring items	276.6	6.3	-238.2
EBITA	308.2	-10.3	49.5
EBIT	242.6	-63.7	-318.6
Profit	154.8	-68.9	17.9
Per share data (SEK)			
Shareholders' equity per share	19.2	20.1	18.7
Shareholders' equity per share after dilution	19.2	20.1	18.7
Cash flow per share	0.4	-0.0	0.7
Cash flow per share after dilution	0.4	-0.0	0.7
Other information			
Equity ratio	75.2%	60.8%	74.1%
Net debt	178.3	1,174.0	481.0
Number of ordinary shares	265,226,598	212,181,279	265,226,598
Number of C-shares	2,068,534	2,068,534	2,068,534
Average number of ordinary shares	265,226,598	212,181,279	242,119,185
Outstanding warrants 1)	300,000	315,000	300,000
Number of shares after dilution	265,226,598	212,804,979	265,226,598
Average number of ordinary shares after dilution	265,226,598	212,804,979	242,119,185
• • • • • • • • • • • • • • • • • • • •	, -,	, ,	, -,

 $<sup>^{1)}</sup>$  The company has one warrant program outstanding, exercisable for a maximum of 639,000 new shares in total.

Return on shareholders' equity

Profit after tax as a percentage of average shareholders' equity.

Return on total capital

Profit after financial items plus financial expenses as a percentage of average total assets.

Gross profit

Net sales less cost of goods

**EBITDA** 

Operating profit/loss before depreciation and amortization.

EBITA

Operating profit/loss before amortization.

EBIT

Operating profit/loss.

Profit

Net profit for the period.

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  $% \left( 1\right) =\left( 1\right) \left( 1\right) \left$ 

dilution.

Cash flow per share

Changes in cash and cash equivalents divided by the weighted

average number of outstanding 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.

Net debt

Long and short term liabilities to credit institutes less cash and cash

equivalents.

Non-recurring items

Non-recurring items are defined as transactions of non-recurring

nature.



# **Quarterly Data**

Amounts in SEK million	Q1-11	Q2-11	Q3-11	Q4-11	Q1-12
Total Revenues	537.4	490.0	447.1	436.4	506.7
COGS	-253.5	-213.5	-213.1	-256.1	-247.3
Gross profit	283.9	276.4	233.9	180.3	259.4
Gross margin	53%	56%	52%	41%	51%
Sales and administration expenses	-116.7	-126.9	-130.4	-192.5	-127.8
Research and development expenses	-102.4	-124.6	-97.3	-103.7	-97.4
OPEX	-219.2	-251.5	-227.7	-296.2	-225.1
% of sales	-41%	-51%	-51%	-68%	-44%
Other operating revenues/expenses	-5.0	155.4	-3.2	0.2	307.9
EBITA before non-recurring items	59.7	180.4	3.0	-115.7	342.2
% of sales	11%	37%	1%	-27%	68%
Non-recurring items	-70.1	0.0	0.3	-8.0	-34.0
EBITA	-10.3	180.4	3.3	-123.7	308.2
% of sales	-2%	37%	1%	-28%	61%
Amortizations	-53.4	-53.1	-57.7	-203.9	-65.6
EBIT	-63.7	127.3	-54.4	-327.7	242.6
EBIT margin	-12%	26%	-12%	-75%	48%

# **Revenues by Business Line**

Amounts in SEK million	Q1-11	Q2-11	Q3-11	Q4-11	Q1-12
Amounts in SER million	<del>~</del>	~	Ψ	<b>4.</b>	<b>~-</b>
Core Products					
Kineret	107.2	102.9	102.5	109.3	134.7
Orfadin	76.0	85.2	80.2	74.2	93.6
Other core products	17.2	18.7	19.0	19.8	21.8
Total	200.4	206.8	201.7	203.3	250.1
Partner Products					
Current portfolio	80.8	95.3	96.7	100.8	103.4
Discontinued products	22.5	17.1	5.4	0.0	0.0
Co-promotion revenues	28.3	26.2	24.5	26.0	12.0
Total	131.6	138.5	126.6	126.8	115.4
ReFacto AF ®					
Manufacturing revenues	166.4	108.5	98.9	77.9	116.9
Royalty revenues	38.9	36.3	19.7	28.3	24.2
Total	205.3	144.8	118.6	106.2	141.1
Other revenues	0.1	-0.3	0.1	0.0	_
Total revenues	537.4	490.0	447.1	436.4	506.6



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

	Q1		Full year
Amounts in SEK million	2012	2011	2011
Total revenues	296.2	383.9	1,170.1
Total cost of goods and services sold	-152.0	-189.9	-647.2
Gross profit	144.2	194.0	522.9
Sales and Administration expenses 1)	-86.4	-74.7	-380.1
Research and Development expenses 2)	-91.0	-94.3	-534.7
Non recurring items	_	-20.9	-77.9
Other operating revenues/expenses	309.6	0.3	993.1
Operating profit/loss	276.4	4.4	523.3
Result from participation in Group companies	_	_	-0.5
Financial income	-2.0	-1.3	11.1
Financial expenses	-12.3	-16.6	-65.0
Profit/loss after financial items	262.1	-13.5	468.8
Income tax expenses	-69.4	-	77.4
Profit/loss for the period	192.7	-13.5	546.2
1) Amortization and write-down of intangible assets included			
in Sales & Adm expenses	-14.2	-12.2	-62.9
<sup>2)</sup> Amortization and write-down of intangible assets included			
in Research and Development expenses	_	_	-127.6



# **Balance Sheet - Parent Company**

	Mar 31	Dec 31	Sep 30	Jun 30	Mar 31
Amounts in SEK million	2012	2011	2011	2011	2011
ASSETS					
Fixed assets					
Intangible fixed assets	651.8	665.9	799.1	810.8	821.7
Tangible fixed assets	135.1	143.5	207.0	218.3	227.2
Financial fixed assets	4,177.7	4,156.9	4,275.2	4,269.7	4,414.6
Total fixed assets	4,964.6	4,966.3	5,281.3	5,298.8	5,463.5
Current assets					
Inventories	657.3	716.8	799.5	860.8	844.7
Current receivables, non-interest bearing	1,460.0	1,101.7	471.0	403.2	419.4
Cash and cash equivalents	250.4	175.0	44.7	82.3	4.0
Total current assets	2,367.7	1,993.5	1,315.2	1,346.3	1,268.1
Total assets	7,332.3	6,959.8	6,596.5	6,645.1	6,731.6
EQUITY AND LIABILITIES					
Shareholders' equity	5,725.1	5,530.0	4,832.3	4,893.5	4,363.6
Long-term liabilities					
Long-term debt	492.4	700.0	685.7	699.7	1,194.0
Long-term liabilities, non-interestbearing	19.0	_	_	_	-
Total long-term liabilities	511.4	700.0	685.7	699.7	1,194.0
Current liabilities					
Short term debt	=	_	_	_	223.0
Current liabilities, non-interest bearing	1,095.8	729.8	1,078.5	1,051.9	951.0
Total short-term liabilities	1,095.8	729.8	1,078.5	1,051.9	1,174.0
Total equity and liabilities	7,332.3	6,959.8	6,596.5	6,645.1	6,731.6

# **Change in Shareholder's Equity – Parent Company**

	Q1	Q1		
Amounts in SEK million	2012	2011	2011	
Opening balance	5,530.0	4,375.9	4,375.9	
Sharebased compensation to employees	1.0	1.2	9.3	
Issue of shares	_	_	594.0	
Liquidation	1.4	_	4.5	
Comprehensive income for the period	192.7	-13.5	546.2	
Equity, end of period	5,725.1	4,363.6	5,530.0	



#### **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. 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.

Accounting principles applied are in accordance with those described in the Annual Report 2011. Staring 1 January 2012, the group is no longer applying the "corridor method" in the current IAS 19, instead all actuarial gains and losses are recognized in other comprehensive income as incurred. Previous years' unrecognized actuarial losses, SEK 24.6 M, are reported as a change in accounting principle, directly against the opening balance of equity. More detailed information about the Group's accounting- and valuation principles can be found in the Annual Report 2011 which is available at www.sobi.com.

#### 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 and decisions by authorities regarding product use and prices.
- 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 Swedish Orphan Biovitrum's 2011 Annual Report (see the Directors' Report).

# Note 2 Shares and Warrants

Development in share capital and number	No of shares	Share capital, SEK
December 2011	267,295,132	146,664,000
March 2012	267,295,132	146,664,000

A preferential new share issue was completed in June, 2011, after which the total number of shares is 267,295,132. Issued shares break down as 265,226,598 ordinary shares and 2,068,534 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

Plan 2008 program expired on 25 November 2011. No shares were awarded under this program.

# Share based incentive program 2009

A long-term, performance based incentive program was adopted ("Share program 2009") at the Annual General Meeting on 28 April 2009. Share program 2009 covers management and key individuals in Swedish Orphan Biovitrum, and may involve a total maximum allocation of 307,601 shares in Swedish Orphan 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 Swedish Orphan Biovitrum share over a three-year assessment period. The program was implemented in June 2009, and the assessment period will run from 10 June, 2009 up to and including 9 June 2012.



### Share based incentive program 2010

A long-term, performance-based share program ("Share Program 2010") was adopted at the Annual General Meeting on 27 April 2010. Share Program 2010 covers management and key individuals in Swedish Orphan Biovitrum, and may involve a total maximum allocation of 526,242 shares in Swedish Orphan Biovitrum AB (publ). The program is designed to allow the participant to invest in a number of shares and receive the equivalent number of shares free of charge if the individual stays with the company for three years. Employees also have the opportunity to receive additional shares based on Swedish Orphan Biovitrum's performance over a three-year benchmark period. The program was implemented in December 2010 and the benchmark period extends from 13 December 2010, through 12 December 2013.

### Share based incentive program 2011

A new long-term, performance-based share program ("Share Program 2011") was adopted at the Annual General Meeting on 28 April 2011. Share Program 2011 covers management and key individuals in Swedish Orphan Biovitrum, and may involve a total maximum allocation of 608,283 shares in Swedish Orphan Biovitrum AB (publ). The program is designed to allow the participant to invest in a number of shares and receive the equivalent number of shares free of charge if the individual stays with the company for three years. Employees also have the opportunity to receive additional shares based on Swedish Orphan Biovitrum's performance over a three-year benchmark period. The program was implemented in December 2011 and the benchmark period extends from 15 December 2011, through 15 December 2014.

#### Share program for CEO 2011

The Extraordinary General Meeting held on 24 August 2011, adopted a performance based, long-term share program for the CEO Geoffrey McDonough (the "CEO Share Program 2011"). The program is based on an own investment in shares in the market, to be held during a three-year period, and the allotment of performance shares free of charge based on an increase in Swedish Orphan Biovitrum's share price during the performance period ending on 15 August 2014. A maximum number of 500,000 performance shares can be allotted as follows:

### Pro-rata allotment of 400,000 performance shares

For any allotment of performance shares to be possible, the share price at the end of the performance period shall amount to more than SEK 25.77. If the share price at the end of the performance period amounts to at least SEK 45.00, 400,000 performance shares will be allotted. If the share price is between SEK 25.77 and SEK 45.00 at the end of the performance period, the portion of the 400,000 performance shares to be allotted shall be calculated on a pro-rata basis.

### Threshold allotment 1 of 30,000 performance shares

In addition to the Pro-rata allotment, 30,000 performance shares will be allotted if the share price at the end of the performance period amounts to at least SEK 30.00

### Threshold allotment 2 of 70,000 performance shares

In addition to the Pro-rata allotment and the Threshold allotment 1, 70,000 performance shares will be allotted if the share price at the end of the performance period amounts to at least SEK 35.00.

### Warrant programs

Option program 2006/2011	Q1 2012	Full year 2011
Outstanding January 1	-	15,000
Forfeited during the period	-	-15,000
Outstanding at of end of accounting period	-	-

	Q1	Full year
Employee option program 2007/2012	2012	2011
Outstanding January 1	300,000	300,000
Outstanding at of end of accounting period	300,000	300,000
Exercisable at of end of accounting period	300,000	300,000

### Note 3 Contingencies

In 2004, the real estate designated as Paradiset 14 was transferred to a substantially foreign-owned limited liability partnership, called NyaParadiset KB, whereupon the participating interests in NyaParadiset KB were sold to an external party, at market price. The real estate was transferred to NyaParadiset 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 M, as a consequence of the transfer of the real estate to NyaParadiset 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. On 3 March 2011, the Administrative Court announced that they uphold the Tax Agency's request, explaining that Swedish Orphan Biovitrum under the tax law will be charged an amount of SEK 232.2 M as revenue in the 2005 tax year. The company has appealed.

On 29 March 2012, Swedish Orphan Biovitrum amended its share purchase agreement regarding the acquisition in 2005 of the pharmaceutical company Arexis AB. As stated in Swedish Orphan Biovitrum's annual and quarterly reports, the sellers of Arexis initiated arbitration as well as an expert determination procedure in 2011 regarding certain claims related to the share purchase agreement. Both proceedings will be withdrawn as a consequence of the amended share purchase agreement. According to the amended agreement, Swedish Orphan Biovitrum has no remaining development obligations towards the sellers. In addition, Swedish Orphan Biovitrum will make a payment to remove all future milestone obligations for the Kiobrina program. Under the amended agreement, Swedish Orphan Biovitrum will pay the sellers a total of SEK 77 M, of which SEK 43 M relates to the future milestone obligations for the Kiobrina program. Swedish Orphan Biovitrum paid SEK 36 M in connection with signing of the amended agreement and will pay SEK 20 M in 2013 and SEK 21 M in 2014.

-0-

# **Telephone Conference**

The interim report for the first quarter 2012 will be presented by CEO Geoffrey McDonough, COO Alan Raffensperger and CFO Lars Sandström at a media and analyst telephone conference.

Time: Thursday, 26 April 2012 at 2 p.m. (CET)

To participate in the telephone conference, please call:

SE: +46 (0)8 505 597 72 UK: +44 (0)207 750 99 50 US: + 1 866 676 58 70

A recorded version will be available afterwards at www.sobi.com under Investors & Media/Audio cast. Slides used in the presentation will also be available on the web site under Investors & Media/Presentations.

For more information, please contact: Lars Sandström, CFO, Telephone: +46 8 697 26 33

Financial calendar 2012

Interim Report, January-June 19 July

Interim Report, January-September 30 October

The above information has been made public in accordance with the Swedish Securities Market Act and/or the Financial Instruments Trading Act. The information was released for public distribution on 26 April 2012 at 8.30 CET.