

# Interim Report for the Second Quarter 2012

Stockholm, 19 July 2012

Geoffrey McDonough, CEO: "We continued to see steady progress across our businesses in the quarter with good underlying growth in revenues driven by investment in commercial infrastructure and geographical expansion. Our US affiliate is now fully operational and we have established a new subsidiary in Dubai, Sobi Middle East FZ. The quarter also contained several key milestones in the advancement of our pipeline, with the initiation of the pediatric trials in hemophilia and with the filing to expand the label for Kineret<sup>®</sup> in the United States. In July, we signed a research collaboration and option agreement with Affibody within the IL-1 field, which may allow us to build further value in this area in the future."

### Second quarter

- Total revenues were SEK 480.7 M (490.0). Revenues for 2011 include discontinued products and co-promotion for ReFacto AF<sup>®</sup>/BeneFIX<sup>®</sup> amounting to SEK 43.3 M. Adjusted for these items total revenues increased by 8%, of which 3% refers to currency.
- Product revenues<sup>1)</sup> amounted to SEK 316.1 M (302.1), an increase of 5% adjusted as above. Revenues include a milestone of SEK 13.1 M from a new distribution agreement for Orfadin<sup>®</sup>.
- Revenues from ReFacto manufacturing and royalty rose by 5%.
- Gross margin was 51% (56), impacted by costs for the transfer of Kineret<sup>®</sup> production and the divestment of the co-promotion rights.
- Operating profit was SEK -69.8 M (127.3). The figure for 2011 includes the allowance for Multiferon® of SEK 149.2 M and co-promotion of SEK 26.2 M.
- A 5-year unsecured bond loan in the amount of SEK 600 M was issued on June 26.
- The previously published outlook for 2012 remains unchanged.

	Q2			Jan-J	lun		Full year
Amounts in SEK million	2012	2011	Change	2012	2011	Change	2011
Total revenues	480.7	490.0	-2%	987.4	1,027.4	-4%	1,910.8
Gross profit	246.9	276.4	-11%	506.3	560.4	-10%	974.6
Gross margin	51%	56%	-9%	51%	55%	-6%	51%
Operating profit before amortizations and non-recurring							
items	-5.6	180.4	<-100%	336.6	240.1	40%	127.3
Operating profit	-69.8	127.3	<-100%	172.8	63.5	>100%	-318.6
Profit/loss for the period	-67.7	113.4	<-100%	87.1	44.5	96%	17.9
Earnings/loss per share, SEK <sup>2</sup>	-0.26	0.50	<-100%	0.33	0.20	63%	0.07

<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 second quarter of 2012 were SEK 480.7 M (490.0). Revenues for 2012 include a milestone of SEK 13.1 M related to a new distribution agreement with Astellas Pharma Inc for Orfadin in Japan. Total revenues in the second quarter of 2011 included discontinued products and co-promotion for ReFacto AF®/BeneFIX®. The co-promotion rights were divested as of February 2012.

### **Revenues by Business Line**

	Q2		Change	Change	Jan - J	lun	Change	Change	
Amounts in SEK million	2012	2011	%	% at CER	2012	2011	%	% at CER	
Core Products									
Kineret	104.5	102.9	2%	-2%	239.2	210.1	14%	10%	422.0
Orfadin	89.1	85.2	5%	3%	182.7	161.2	13%	12%	315.7
Other core products	22.8	18.7	22%	22%	44.6	35.9	24%	24%	74.6
Total	216.4	206.8	5%	2%	466.5	407.2	15%	12%	812.3
Partner Products									
Current portfolio	99.7	95.3	5%	3%	203.3	176.1	15%	14%	373.6
Discontinued products	0.0	17.1	-100%	-100%	0.0	39.6	-100%	-100%	45.0
Co-promotion revenues	0.0	26.2	-100%	-100%	12.0	54.5	-78%	-78%	105.0
Total	99.7	138.5	-28%	-29%	215.3	270.2	-20%	-21%	523.6
ReFacto									
Manufacturing revenues	107.5	108.5	-1%	-1%	224.4	274.9	-18%	-18%	451.7
Royalty revenues	44.0	36.3	21%	11%	68.1	75.2	-9%	-15%	123.3
Total	151.5	144.8	5%	2%	292.5	350.1	-16%	-18%	575.0
Other revenues	13.1	-0.3	>100%	>100%	13.1	-0.2	>100%	>100%	-
Total revenues	480.7	490.0	-2%	-4%	987.4	1,027.4	-4%	-5%	1,910.8
Total revenues excl co-promotion and									
discontinued products	480.7	446.8	8%	5%	975.4	933.3	5%	3%	1,760.8

## **Core Products**

### Kineret

Sales of Kineret in the second quarter were SEK 104.5 M (102.9), an increase of 2%. Sales for the first half increased by 14% as compared with the first half in 2011.

The technical issues related to the transfer of Kineret production from Amgen in the US to a contract manufacturer in Europe have been resolved, and final process validation runs have been completed. Costs for the production transfer amounted to SEK 33 M (12) in the quarter and SEK 64 M (31) for the first half, and will not recur.

### Orfadin

Sales in the quarter were SEK 89.1 M (85.2), an increase of 5%, on the basis of higher volumes in particularly the US and the Middle East. Sales for the first half increased by 13% as compared with the first half in 2011.

### **Partner Products**

Revenues for Partner Products were SEK 99.7 M (138.5). After adjustment for SEK 17.1 M in discontinued products and SEK 26.2 M in co-promotion in 2011, total revenues increased by 5%. Adjusted revenues for the first half increased by 15% as compared with the first half in 2011.

Sales of Kepivance<sup>®</sup> were unchanged and amounted to SEK 17.6 M (17.7).

Sales of Yondelis<sup>®</sup> were SEK 12.9 M (12.2), an increase of 6% based on positive trends in several markets in Central- and Eastern Europe.

Sales of Aloxi<sup>®</sup> were SEK 6.7 M (4.6), an increase of 46% as a result of good growth in the Nordic region.



### **ReFacto Manufacturing and Royalties**

Total ReFacto manufacturing and royalty revenues were SEK 151.5 M (144.8). The increase of 5% refers to royalty, while revenues from manufacturing were largely unchanged from the previous year.

	Q2			Change	Jan - Ju	in		Change	Full year
Amounts in SEK million	2012	2011	Change	% at CER	2012	2011	Change	% at CER	2011
Nordic	74.4	120.4	-38%	-38%	161.3	228.9	-30%	-30%	427.9
Europe	156.8	134.7	16%	17%	320.1	262.7	22%	22%	540.9
North America	76.3	77.7	-2%	-11%	186.9	163.7	14%	7%	328.2
RoW	8.6	12.5	-31%	-37%	13.5	22.1	-39%	-41%	38.9
Total revenues	316.1	345.3	-8%	-10%	681.8	677.4	1%	-1%	1,335.9

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

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

## **Gross profit**

Gross profit in the second quarter of 2012 was SEK 246.9 M (276.4), corresponding to a margin of 51.4% (56.4).

The decline in the gross margin from the previous year was due to costs of SEK 33 M (12) for the transfer of Kineret production, and the divestment of the co-promotion rights (SEK 26.2 M in 2011). Gross margin was positively impacted by the SEK 13.1 M milestone for Orfadin.

## **Operating profit**

Operating profit before amortization of intangible assets and non-recurring items (EBITA) was SEK -5.6 M (180.4). The figure for 2012 includes costs for the transfer of Kineret production and the milestone for Orfadin. The figure for the previous year includes SEK 149.2 M referring to the agreement regarding Multiferon, as well as contribution from co-promotion of ReFacto  $AF^{\circ}/BeneFIX^{\circ}$ .

Operating expenses<sup>2)</sup> amounted to SEK 260.3 M (251.5). The increase was driven by investment in commercial infrastructure and geographic expansion. This was partially offset by reduced R&D expenses resulting from previously implemented restructuring and lower project costs than in the previous year.

Amortization of intangible assets amounted to SEK 64.2 M (53.1). Other operating revenues and expenses amounted to SEK 7.8 M (155.4).

Operating profit (EBIT) was SEK -69.8 M (127.3).

## Net financial items and tax

Net financial items in the second quarter amounted to SEK -5.5 M (-20.5). The improvement is mainly due to a reduction of the net debt. Net debt as of 30 June 2012 amounted to SEK 250.0 M (584.7).

The tax expense for the second quarter was SEK 7.6 M (6.7).

### Profit for the period

Profit for the period was SEK -67.7 M (113.4), corresponding to earnings per share of SEK -0.26 (0.50).

### **Cash flow and investments**

Cash flow from operations before changes in working capital in the second quarter of 2012 was SEK -4.3 M (21.2). Non-cash items amounted to SEK 63.4 M (-92.2) and were mainly due to amortization of product rights and licenses.

Working capital impacted cash flow by SEK -25.1 M (-31.4). A continued reduction in inventory of Kineret was offset by increased inventories in ReFacto manufacturing. Working capital was also negatively impacted by a reduction of current liabilities, mainly trade payables.

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



Cash flow from investing activities amounted to SEK -42.1 M (-8.3), mainly related to the agreement with the sellers of Arexis regarding Kiobrina<sup>®</sup>. Cash flow after investing activities amounted to SEK -71.5 M (-18.5).

Cash flow from financing activities amounted to SEK 107.5 M and related to the issue of the SEK 600 M unsecured bond and the following amortization of the bank loan of SEK 492.5 M.

## **Financial position**

Cash and cash equivalents and short-term investments as of 30 June 2012 amounted to SEK 350.0 M (115.0). The company's financing through bank loans as of 30 June 2012 amounted to SEK 0 M (699.7).

### **Bond loan**

On June 26 Sobi issued a 5-year SEK 600 million senior unsecured bond with maturity in 2017. When issued, the bond had a floating interest of 3 months Stibor + 500 bps which has been swapped to a fixed rate of 6.9%.

The bond has replaced Sobi's existing term facility and will improve the Company's financial flexibility as well as extend the maturity profile of Sobi's debt. The loan will be listed on NASDAQ OMX Stockholm.

### Equity

Consolidated shareholders' equity as of 30 June 2012 amounted to SEK 5,040.4 M compared to SEK 4,963.4 M as of 31 December 2011.

## Outlook for 2012

The outlook was first published on 23 February 2012 and has not been changed:

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 trials for hemophilia programs initiated

The first patient has been dosed in the pediatric study of Sobi's and Biogen Idec's long-lasting recombinant rFIXFc fusion protein for treatment of hemophilia B. The pediatric study of rFVIIIFc for treatment of hemophilia A is actively recruiting patients.



The clinical trials, KIDS B-LONG and KIDS A-LONG, are open-label, multicenter studies designed to evaluate the safety, pharmacokinetics and efficacy of rFVIIIFc and rFIXFc in previously-treated children with severe hemophilia A or B under the age of 12 years. For more information on the studies, visit www.biogenidechemophilia.com or www.clinicaltrials.gov (NCT01440946).

The global registration studies of rFVIIIFc and rFIXFc in previously-treated patients aged 12 years and older with severe hemophilia A or B are ongoing. Data from both studies are expected in the second half of 2012.

## Filing for NOMID indication for Kineret in US

Sobi has filed an application for Kineret<sup>®</sup> (anakinra) for the indication of neonatal-onset multisystem inflammatory disease (NOMID) with the Food and Drug Administration (FDA) in the US. The filing is made under an Orphan Drug Designation for the indication cryopyrin associated periodic syndromes (CAPS), which was granted in 2010. If the application is granted priority review, Sobi expects a review period of 6-8 months.

### Kiobrina

The Kiobrina phase III program is proceeding according to plan and actively recruiting patients.

### **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 <sup>®</sup> , 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

#### Personnel

As of 30 June 2012, the number of full-time employees was 476 (495).

## **Other Information**

### **Changes in Executive Management**

Birgitte Volck has been appointed Senior Vice President, Chief Medical Officer with responsibility for Clinical Development, Regulatory Affairs, Drug Safety and Medical Affairs. Birgitte has held various senior positions within Amgen since 2007, most lately as Executive Development Director, Bone and Neuroscience & Inflammation at Amgen Limited in Uxbridge, UK. She is MD and PhD from the University of Copenhagen and has had various clinical and scientific assignments, mainly within rheumatology, at the Copenhagen University. Birgitte will assume her position as of 1 August 2012.

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Lars Sandström, Chief Financial Officer, will leave Sobi as of 31 August 2012. The recruitment of his successor is ongoing. Annika Muskantor has joined Sobi as interim CFO. Annika holds a Bachelor of Arts from Northwestern University, USA and a Master of Business Administration from J.L. Kellogg Graduate School of Management, USA.

Göran Arvidson, Head of Corporate Strategy, has left his position at Sobi as of 1 July 2012.

## Distribution agreement for Orfadin in Japan

Sobi has signed a 10 year distribution agreement with Astellas Pharma Inc for Orfadin in Japan. Regulatory approval by Japanese authorities is expected in early 2014. The agreement includes a payment to Sobi of EUR 2 M, of which EUR 1.5 M was paid at signing in June and the remaining part to be paid after regulatory approval.

## Significant events after the reporting period

## Collaboration with Affibody within the IL-1 field

In July Sobi announced a research collaboration and option agreement with the Swedish biotech company Affibody AB for the discovery and development of novel treatments for inflammatory diseases where Interleukin-1 (IL-1) is implicated.

The research will be based on Affibody's proprietary technology platforms Affibody<sup>®</sup> molecules and Albumod<sup>™</sup> and includes up to five different targets within the IL-1 field. All targets are key proteins involved in the regulation of human immune and inflammatory processes. One project is a lead candidate for the inhibition of IL-1 beta at the preclinical phase, and the others are in discovery.

The agreement covers an initial two-year period during which Sobi has an option to enter into a licensing agreement with worldwide exclusive rights to any or all of the development projects. The agreement includes a payment by Sobi in the amount of SEK 12 M, of which SEK 2.5 M at signing and the remaining part to be paid over a 21-months period. In addition, the licensing agreement includes potential future milestones and royalty after the two year period.

The research will be carried out by both companies and will be led by a joint steering committee. Affibody will have responsibility through the discovery phase, and Sobi for clinical development. Each company will bear their own costs. The agreement follows an earlier collaboration between the companies regarding a biological candidate which has recently been moved into IND-enabling studies.

### Amended agreement regarding Aloxi®

An amended agreement to the existing distribution agreement with Helsinn Healthcare was signed in July. The amended agreement gives Sobi the exclusive rights to distribute an oral capsule formulation of Aloxi in addition to the intravenous injection formulation. The agreement includes a payment from Sobi in the amount of EUR 150,000. Aloxi is used in adults to prevent nausea and vomiting in connection with chemotherapies.

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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" and in other information provided for a description of the operational risks.

Stockholm, 19 July 2012

Bo Jesper Hansen

Adine Grate Axén Chairman of the Board Matthew Gantz

Hans GCP Schikan

Lennart Johansson

Helena Saxon

Hans Wigzell

Catarina Larsson Employee representative Bo Gunnar Rosenbrand Employee representative

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

	Q2		Jan - J	un	Full year	
Amounts in SEK million	2012	2011	2012	2011	2011	
Total revenues	480.7	490.0	987.4	1,027.4	1,910.8	
Total cost of goods and services sold	-233.8	-213.5	-481.1	-467.0	-936.3	
Gross profit	246.9	276.4	506.3	560.4	974.6	
Sales and administration expenses <sup>1)</sup>	-216.0	-180.0	-409.3	-350.1	-804.4	
Research and development expenses <sup>2)</sup>	-108.5	-124.6	-205.9	-227.1	-555.7	
Non-recurring items 3)	0.0	0.0	-34.0	-70.1	-80.4	
Other operating revenues/expenses	7.8	155.4	315.7	150.4	147.4	
Operating profit/loss	-69.8	127.3	172.8	63.5	-318.6	
Financial income/expenses	-5.5	-20.5	-18.8	-38.6	-52.2	
Profit/loss after financial items	-75.3	106.7	154.0	24.9	-370.8	
Income tax expense	7.6	6.7	-66.9	19.6	388.8	
Profit/loss for the period	-67.7	113.4	87.1	44.5	17.9	
Other comprehensive income						
Translation difference	-0.2	0.1	-0.3	-0.1	-0.2	
Cash flow hedge	12.1	0.0	12.1	0.0	0.0	
Comprehensive income for the period	-55.8	113.5	98.9	44.4	17.7	
Earnings/loss per share after tax (SEK)	-0.26	0.50	0.33	0.20	0.07	
Earnings/loss per share after dilution (SEK)	-0.26	0.43	0.33	0.17	0.07	
1)						
<sup>1)</sup> Amortization and write-down of intangible assets included in Sales & Adm expenses	-64.2	-53.1	-129.8	-106.5	-237.9	
<sup>2)</sup> Amortization and write-down of intangible assets included in Research and Development expenses	_	-	_	_	-127.6	
<sup>3)</sup> Amortization and write-down of intangible assets included in non-recurring items	_	_	_	_	-2.6	



## **Balance Sheet**

	Jun	Mar	Dec	Sep	Jun
Amounts in SEK million	2012	2012	2011	2011	2011
ASSETS					
Fixed assets					
Intangible fixed assets <sup>1)</sup>	4,802.9	4,862.6	4,885.1	5,070.9	5,125.0
Tangible fixed assets	140.3	147.0	155.9	219.3	230.9
Financial fixed assets	7.6	7.7	11.4	22.7	20.0
Total fixed assets	4,950.8	5,017.3	5,052.4	5,312.9	5,375.8
Current assets					
Inventories	810.5	829.8	893.8	953.2	1,008.6
Accounts receivable	350.6	413.0	309.6	406.8	355.1
Current receivables, non-interest bearing	248.9	201.4	224.6	198.4	236.0
Cash and cash equivalents	350.0	314.1	219.0	73.1	115.0
Total current assets	1,760.0	1,758.3	1,647.1	1,631.4	1,714.6
Total assets	6,710.8	6,775.6	6,699.5	6,944.3	7,090.5
EQUITY AND LIABILITIES					
Shareholders equity	5,040.4	5,094.5	4,963.4	4,948.3	4,984.1
Long-term liabilities					
Long-term debt	600.0	492.5	700.7	686.1	713.3
Long-term liabilities, non-interest bearing	461.5	472.2	358.7	730.9	740.7
Total long-term liabilities	1,061.5	964.7	1,059.4	1,417.0	1,454.0
Current liabilities					
Short term debt	13.7	13.7	13.9	14.0	14.8
Current liabilities, non-interest bearing	595.2	702.7	662.8	565.0	637.6
Total short-term liabilities	608.9	716.4	676.7	579.0	652.4
Total equity and liabilities	6,710.8	6,775.6	6,699.5	6,944.3	7,090.5

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

## Changes in Equity

	Jan - Ju	n	Full year	
Amounts in SEK million	2012	2011	2011	
Opening balance	4,963.4	4,342.4	4,342.4	
Change in accounting principle <sup>1)</sup>	-24.6	-	-	
Opening balance	4,938.8	4,342.4	4,342.4	
Sharebased compensation to employees	2.7	3.3	9.3	
Issue of shares	-	594.0	594.0	
Comprehensive income for the period	98.9	44.4	17.7	
Equity, end of period	5,040.4	4,984.1	4,963.4	

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



## **Cash Flow Statement**

	Q2		Jan - J	lun	Full year
- Amounts in SEK million	2012	2011	2012	2011	2011
Net result	-67.7	113.4	87.1	44.5	17.9
Non-cash items <sup>1)</sup>	63.4	-92.2	245.2	30.1	100.4
Cash flow from operations before change in working capital	-4.3	21.2	332.3	74.6	118.3
Change in working capital	-25.1	-31.4	-57.6	-106.7	-15.4
Cash flow from operations	-29.4	-10.2	274.7	-32.1	102.9
Acquisition of business, net of cash acquired	_	-4.4	_	-4.4	-29.8
Investment in intangible fixed assets	-40.9	-2.5	-41.0	-5.1	-7.6
Investment in tangible fixed assets	-1.2	-2.2	-2.5	-4.1	-7.7
Divestment of tangible fixed assets	-	-	-	-	1.3
Investment/Divestment of financial assets	-	0.8	-	1.7	_
Cash flow from investing activities	-42.1	-8.3	-43.5	-11.9	-43.7
Loans - Raising/Amortization	107.5	-497.9	-100.0	-473.0	-472.4
Issue of shares	-	594.0	-	594.0	594.0
Cash flow from financing activities	107.5	96.1	-100.0	121.0	121.6
Net change in cash	36.0	77.6	131.2	77.0	180.8
Liquid funds at the beginning of the period	314.1	37.7	219.1	38.5	38.5
Translation difference in cash flow and liquid funds	-0.1	-0.2	-0.3	-0.4	-0.2
Liquid funds at the end of the period	350.0	115.0	350.0	115.0	219.1
Short-term investments	-	-	-	-	_
Liquid funds and short-term investments at the end of the period	350.0	115.0	350.0	115.0	219.1
<sup>1)</sup> Depreciations, amortization and deferred tax:					
Depreciation tangible fixed assets	8.3	12.8	16.8	26.6	81.8
Amortization intangible assets	64.2	53.1	129.8	106.5	368.1
Deferred tax	-12.1	-7.8	59.6	-21.6	-394.7



## **Key Ratios and Other Information**

	Q	2	Jan -	Jan - Jun		
Amounts in SEK million	2012	2011	2012	2011	2011	
Return on						
Shareholders' equity	-1.3%	2.5%	1.7%	1.0%	0.4%	
Total capital	-1.0%	1.9%	2.6%	0.9%	-4.5%	
Profit numbers						
Gross profit	246.9	276.4	506.3	560.4	974.6	
EBITDA	2.7	193.2	319.4	196.6	131.3	
Operating profit before amortizations and non-						
recurring items	-5.6	180.4	336.6	240.1	127.3	
Operating profit before non-recurring items	-69.8	127.3	206.8	133.6	-238.2	
EBITA	-5.6	180.4	302.6	170.0	49.5	
EBIT	-69.8	127.3	172.8	63.5	-318.6	
Profit	-67.7	113.4	87.1	44.5	17.9	
Per share data (SEK)						
Shareholders' equity per share	19.0	18.8	19.0	18.8	18.7	
Shareholders' equity per share after dilution	19.0	18.8	19.0	18.8	18.7	
Cash flow per share	0.1	0.3	0.5	0.3	0.7	
Cash flow per share after dilution	0.1	0.3	0.5	0.3	0.7	
Other information						
Gross margin	51.4%	56.4%	51.3%	54.5%	51.0%	
Equity ratio	75.1%	70.3%	75.1%	70.3%	74.1%	
Net debt	250.0	584.7	250.0	584.7	481.0	
Number of ordinary shares	265,226,598	265,226,598	265,226,598	265,226,598	265,226,598	
Number of C-shares	2,753,124	2,068,534	2,753,124	2,068,534	2,068,534	
Average number of ordinary shares	265,226,598	228,902,086	265,226,598	220,633,555	242,119,185	
Outstanding warrants	0	300,000	0	300,000	300,000	
Number of shares after dilution	265,226,598	265,793,598	265,226,598	265,793,598	265,226,598	
Average number of ordinary shares after dilution	265,226,598	229,507,297	265,226,598	221,247,909	242,119,185	

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 and services sold.

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 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.

Gross margin Gross profit as a percentage of net sales.

*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 Trend Data**

Amounts in SEK million	Q1-11	Q2-11	Q3-11	Q4-11	Q1-12	Q2-12
Total Revenues	537,4	490,0	447,1	436,4	506,7	480,7
COGS	-253,5	-213,5	-213,1	-256,1	-247,3	-233,8
Gross profit	283,9	276,4	233,9	180,3	259,4	246,9
Gross margin	53%	56%	52%	41%	51%	51%
Sales and administration expenses	-116,7	-126,9	-130,4	-192,5	-127,8	-151,8
Research and development expenses	-102,4	-124,6	-97,3	-103,7	-97,4	-108,5
OPEX	-219,2	-251 <i>,</i> 5	-227,7	-296,2	-225,1	-260,3
% of sales	-41%	-51%	-51%	-68%	-44%	-54%
Other operating revenues/expenses	-5,0	155,4	-3,2	0,2	307,9	7,8
EBITA before non-recurring items	59,7	180,4	3,0	-115,7	342,2	-5,6
% of sales	11%	37%	1%	-27%	68%	-1%
Non-recurring items	-70,1	0,0	0,3	-8,0	-34,0	0,0
EBITA	-10,3	180,4	3,3	-123,7	308,2	-5,6
% of sales	-2%	37%	1%	-28%	61%	-1%
Amortizations	-53,4	-53,1	-57,7	-203,9	-65,6	-64,2
EBIT	-63,7	127,3	-54,4	-327,7	242,6	-69,8
EBIT margin	-12%	26%	-12%	-75%	48%	-15%
EBITDA	3,5	193,2	12,6	-77,9	316,7	2,7

## **Revenues Trend by Business Line**

	01.11	02.11	02.11	04.11	01 12	03.43
Amounts in SEK million	Q1-11	Q2-11	Q3-11	Q4-11	Q1-12	Q2-12
Core Products						
Kineret	107.2	102.9	102.5	109.3	134.7	104.5
Orfadin	76.0	85.2	80.2	74.2	93.6	89.1
Other core products	17.2	18.7	19.0	19.8	21.8	22.8
Total	200.4	206.8	201.7	203.3	250.1	216.4
Partner Products						
Current portfolio	80.8	95.3	96.7	100.8	103.4	99.7
Discontinued products	22.5	17.1	5.4	0.0	0.0	0.0
Co-promotion revenues	28.3	26.2	24.5	26.0	12.0	0.0
Total	131.6	138.5	126.6	126.8	115.4	99.7
ReFacto						
Manufacturing revenues	166.4	108.5	98.9	77.9	116.9	107.5
Royalty revenues	38.9	36.3	19.7	28.3	24.2	44.0
Total	205.3	144.8	118.6	106.2	141.1	151.5
Other revenues	0.1	-0.3	0.1	0.0	0.0	13.1
Total revenues	537.4	490.0	447.1	436.4	506.6	480.7



## Profit and Loss Statement – Parent Company

	Q2		Jan - Jun		Full year
Amounts in SEK million	2012	2011	2012	2011	2011
Total revenues	372.8	274.8	669.0	658.7	1,170.1
Total cost of goods and services sold	-220.8	-130.3	-372.8	-320.2	-647.2
Gross profit	152.0	144.5	296.2	338.5	522.9
Sales and Administration expenses <sup>1)</sup>	-123.2	-72.8	-209.6	-147.5	-380.1
Research and Development expenses <sup>2)</sup>	-103.2	-120.6	-194.2	-214.9	-534.7
Non recurring items	-	-	-	-20.9	-77.9
Other operating revenues/expenses	11.3	4.7	320.9	5.0	993.1
Operating profit/loss	-63.1	-44.3	213.3	-39.9	523.3
Result from participation in Group companies	-0.2	-0.2	-0.2	-0.2	-0.5
Financial income	22.1	4.0	20.1	2.7	11.1
Financial expenses	-3.0	-25.8	-15.3	-42.4	-65.0
Profit/loss after financial items	-44.2	-66.3	217.9	-79.8	468.8
Income tax expenses	-7.1	_	-76.5	_	77.4
Profit/loss for the period	-51.3	-66.3	141.4	-79.8	546.2
Other comprehensive income					
Cash flow hedge	12.1	-	12.1	-	_
Comprehensive income for the period	-39.2	-66.3	153.5	-79.8	546.2
<sup>1)</sup> Amortization and write-down of intangible assets included					
in Sales & Adm expenses	-13.1	-12.1	-27.3	-24.3	-62.9
<sup>2)</sup> Amortization and write-down of intangible assets included in Research and Development expenses	_	_	_	_	-127.6



## **Balance Sheet – Parent Company**

	Jun 30	Mar 31	Dec 31	Sep 30	Jun 30
Amounts in SEK million	2012	2012	2011	2011	2011
ASSETS					
Fixed assets					
Intangible fixed assets	643.5	651.8	665.9	799.1	810.8
Tangible fixed assets	137.3	135.1	143.5	207.0	218.3
Financial fixed assets	4,173.8	4,177.7	4,156.9	4,275.2	4,269.7
Total fixed assets	4,954.6	4,964.6	4,966.3	5,281.3	5,298.8
Current assets					
Inventories	766.5	657.3	716.8	799.5	860.8
Current receivables, non-interest bearing	1,306.9	1,460.0	1,101.7	471.0	403.2
Cash and cash equivalents	305.5	250.4	175.0	44.7	82.3
Total current assets	2,378.9	2,367.7	1,993.5	1,315.2	1,346.3
Total assets	7,333.5	7,332.3	6,959.8	6,596.5	6,645.1
EQUITY AND LIABILITIES					
Shareholders' equity	5,732.6	5,725.1	5,530.0	4,832.3	4,893.5
Long-term liabilities					
Long-term debt	600.0	492.4	700.0	685.7	699.7
Long-term liabilities, non-interest bearing	19.0	19.0	-	-	_
Total long-term liabilities	619.0	511.4	700.0	685.7	699.7
Current liabilities					
Current liabilities, non-interest bearing	981.9	1,095.8	729.8	1,078.5	1,051.9
Total short-term liabilities	981.9	1,095.8	729.8	1,078.5	1,051.9
Total equity and liabilities	7,333.5	7,332.3	6,959.8	6,596.5	6,645.1

## Change in Shareholder's Equity – Parent Company

	Jan - Jun		Full year	
Amounts in SEK million	2012	2011	2011	
Opening balance	5,530.0	4,375.9	4,375.9	
Sharebased compensation to employees	2.7	3.3	9.3	
Issue of shares	-	594.0	594.0	
Merger gain	46.4	-	-	
Liquidation	-	-	4.5	
Comprehensive income for the period	153.5	-79.8	546.2	
Equity, end of period	5,732.6	4,893.5	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 in comprehensive income.

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. Starting 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

			Share capital,
Development	in share capital and number	No of shares	SEK
December 201	11	267,295,132	146,664,000
June 2012	Rights issue of class C shares	684,590	375,632
June 2012		267,979,722	147,039,632

A preferential new share issue of C shares was completed in June, 2012, after which the total number of shares is 267,979,722. The class C shares are intended to ensure fulfilment of commitments under the company's long-term incentive programs. Issued shares break down as 265,226,598 ordinary shares and 2,753,124 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 2009

Plan 2009 program expired on 9 June 2012. No shares were awarded under this program.



### 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 484 038 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 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. 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. A maximum number of 500,000 performance shares can be allotted as follows:

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

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.

#### Employee option program 2007/2012

This program expired on 1 April 2012. No options were awarded under this program.

#### Warrant programs

Employee option program 2007/2012	Q2 2012	Full year 2011
Outstanding January 1	-	300,000
Outstanding at of end of accounting period	-	300,000
Exercisable at of end of accounting period	-	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. 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 to the Administrative Court of Appeal. The case was issued with a stay of proceedings in the Administrative Court of Appeal while awaiting the Supreme Administrative Court's (SAC) verdict on another separate tax avoidance issue, known as the Cyprus case, with certain similarities to Swedish Orphan Biovitrum's tax case. On 30 May 2012 SAC delivered its verdict in the Cyprus case. Although the verdict has similarities to Swedish Orphan Biovitrum's tax case, several key aspects are also different. Swedish Orphan Biovitrum is currently analyzing the verdict to assess how the Company's tax case may be affected. As there is no longer any ground for a stay of proceedings in the Administrative Court of Appeal, the case will be taken up for continued consideration and Swedish Orphan Biovitrum will have the opportunity to supplement and strengthen its legal submission.

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 have been 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. 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 has paid SEK 36 M in connection with the signing of the agreement and will pay SEK 20 M in 2013 and SEK 21 M in 2014.

## **Telephone Conference**

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

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Time: Thursday, 19 July 2012 at 3 p.m. (CET)

### To participate in the telephone conference, please call:

SE: +46 (0)8 505 629 32 UK: +44 (0)207 108 62 05 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-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 19 July 2012 at 8.30 CET.