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### **CEO Statement**

Sobi continued to make progress across multiple facets of the business in the second quarter. Revenue for the overall portfolio grew by 8% compared to last year, with Kineret®, Orfadin®, and Partner Products showing strong performance at the mid-point in the year. The gross margin is evolving as expected and we are making solid progress financially with improved profitability and a stable cash position.

In addition, shortly after the quarter closed we were very pleased to be selected by Auxilium of Pennsylvania, US to be the exclusive partner for the on-going commercialization of XIAPEX®, a biological therapy for Dupuytren's contracture. In addition, work is on-going to file for approval of XIAPEX for the treatment of Peyronie's disease in the EU. This new partnership further strengthens the Partner Product portfolio through Europe, Middle East, Africa and Russia.

Our pipeline programs also reached several important milestones.

Kineret received approval from the Food and Drug Administration (FDA) for the manufacture of drug substance for Kineret at Boehringer Ingelheim's microbial site in Vienna, Austria. This will allow us to supply the US market going forward and completes the tech transfer of the manufacturing process.

New findings were presented in partnership with Biogen Idec at the XXIV International Society on Thrombosis and Haemostasis (ISTH) meeting in Amsterdam regarding the long-lasting recombinant factor candidates, VIII (rFVIIIFc) and IX (rFIXFc) under development for haemophilia A and B. These findings reinforced the potential safety, efficacy and clinical data profiles for both programs. The on-going paediatric trials KIDS A-LONG and KIDS B-LONG are on track and we expect to release top line data from these trials during 2014.

We completed enrolment for the LAIF (Lipase Added to Infant Feeding) study, our on-going phase 3 trial exploring the impact of Kiobrina® on neonatal growth for premature infants, and we continue to expect to disclose top line data from this trial in the first quarter of 2014.

I am also very pleased to announce that we will host investor events in the week of November 4 2013 in Stockholm and New York City to give some perspectives on our on-going and early stage pipeline programs.

The first half of 2013 has been an important period in continuing to build the foundation for our future.

Solna, July 18, 2013

Geoffrey McDonough CEO and President





# **Business Highlights Q2 2013**

- Received FDA approval to manufacture drug substance for Kineret
- Biogen Idec and Sobi presented new data from the phase 3 studies of their long-lasting haemophilia factor candidates
- XTEN technology platform update
- Update on KIDS A-LONG and B-LONG studies
- Completed enrolment for Kiobrina LAIF phase 3 study
- Appointed Mats-Olof Wallin as Chief Financial Officer

# Financial Highlights Q2 2013 (Q2 2012)

- Total revenues were SEK 520.2 M (480.7)
- Product revenues were SEK 371.7 M (316.1)
- Gross margin was 61 percent (51)
- Ended the quarter with a cash position of SEK 438.1 M
- Earnings per share: SEK -0.04 (-0.26)



## **Business Review**

# Received FDA approval to manufacture drug substance for Kineret

Sobi announced receipt of approval from the FDA for the manufacture of drug substance for Kineret at Boehringer Ingelheim's microbial site in Vienna, Austria. The approval allows for distribution of Kineret in the US, and comes as the result of a Supplemental Biologics License Application (sBLA) filed with the FDA in February 2013.

# Biogen Idec and Sobi presented new data from the phase 3 studies of their long-lasting haemophilia factor candidates

New findings for the long-lasting recombinant factors VIII and IX candidates (rFVIIIFc and rFIXFc) for haemophilia A and B were presented at the ISTH congress in Amsterdam, the Netherlands in June.

The newly released rFVIIIFc data support the potential clinical and safety profile, highlighting its potential to reduce the number of intravenous injections versus current therapies, its efficacy in controlling bleeding during and after surgery, and its efficacy in treating acute bleeding episodes.

The newly released rFIXFc data reinforced the potential safety, efficacy and pharmacokinetic profile. The data also highlighted the consistency of results with rFIXFc across patient types and favourable physician ratings of its efficacy in treating acute bleeding episodes and controlling bleeding during and after major surgery.

#### XTEN technology platform update

During ISTH Biogen Idec presented data from pre-clinical studies of new factor VIII molecules (utilizing XTEN technology) that achieved a circulating half-life of 30 hours in mice, representing a 4-fold half-life extension over factor VIII. The new molecules were developed under a research collaboration between Biogen Idec and Amunix, announced in April 2011.

If this research project progresses to further development and Biogen Idec exercises its rights under its agreement with Amunix, Sobi has rights under its development and commercialization agreement with Biogen Idec to obtain the exclusive right to commercialize such products in the same geographies as its current partnership with Biogen Idec on rFVIIIFc and rFIXFc. The terms that apply to XTEN products are broadly similar to the original partnership with Biogen Idec, and also include obligations to share Biogen Idec's related payment obligations to Amunix.

## **Update on KIDS A-LONG and B-LONG studies**

Biogen Idec and Sobi expect to release top line data from the companies' paediatric trials regarding rFVIIIFc and rFIXFc during 2014. For the KIDS A-LONG study, top line data is expected in H1 2014 and for the KIDS B-LONG study, top line data is expected in H2 2014.

EU Marketing Authorization Application (MAA) filings are planned following completion of the paediatric trials.

# Completed enrolment for Kiobrina LAIF phase 3 study

Enrolment was completed during the second quarter of 2014 for the on-going phase 3 LAIF trial in Europe for Kiobrina, recombinant bile salt stimulated lipase for premature infants. As previously communicated, Sobi expects to communicate top line data from the phase 3 trial in the first quarter of 2014.

# Appointed Mats-Olof Wallin as Chief Financial Officer

After a thorough search process, Mats-Olof Wallin was appointed CFO for Sobi. Wallin brings more than 30 years of experience in the pharmaceutical industry, gained from various executive positions within companies such as Pharmacia, Ortivus and, most recently, Biotage where he held the role of CFO between 2003 and 2011.



# **Financial Review**

Total revenues for the second quarter 2013 were SEK 520.2 M (480.7).

# **Key Therapeutic Areas**

Revenues for Key Therapeutic Areas for the second quarter were SEK 243.1 M (213.8), an increase of 14 percent.

#### Inflammation: Kineret

Revenue for Kineret for the second quarter was SEK 139.5 M (104.5). Sobi announced a price increase for Kineret in the US as of April 1.

#### **Genetics: Orfadin**

Revenue for Orfadin for the second quarter was SEK 83.3 M (89.1). The decrease was mainly attributable to phasing of orders following a very strong first quarter, and higher government rebates in the US.

# **Financial Summary**

	Q2	Q2		H1	H1		FY
Amounts in SEK M	2013	2012	Change	2013	2012	Change	2012
Total revenues	520.2	480.7	8%	1,048.7	987.4	6%	1,923.2
Gross profit	316.7	246.9	28%	619.6	506.3	22%	1,040.4
Gross margin	61%	51%		59%	51%		54%
Adjusted EBITA <sup>1)</sup>	37.8	-5.6	>100%	99.0	336.6	-71%	404.1
Operating profit/loss	-31.9	-69.8	54%	-35.3	172.8	<-100%	-54.6
Profit/loss for the period	-10.9	-67.7	84%	-23.1	87.1	<-100%	-100.9
Earnings/loss per share, SEK	-0.04	-0.26	84%	-0.09	0.33	<-100%	-0.38

 $<sup>^{1)}</sup>$  Operating profit before amortizations and non-recurring items.

#### **Revenues by Business Line**

	Q2	Q2	Change	Change %	H1	H1	Change	Change %	FY
Amounts in SEK M	2013	2012	%	at CER <sup>2)</sup>	2013	2012	%	at CER <sup>2)</sup>	2012
Key Therapeutic Areas									
Inflammation: Kineret	139.5	104.5	33%	41%	256.4	239.2	7%	13%	484.7
Genetics: Orfadin	83.3	89.1	-6%	-2%	192.6	182.7	5%	10%	356.7
Genetics: Other	20.3	20.2	1%	5%	41.4	43.2	-4%	0%	79.6
Total	243.1	213.8	14%	19%	490.4	465.1	5%	10%	921.0
Partner Products									
Current portfolio	128.6	102.3	26%	30%	225.8	204.7	10%	14%	411.3
Co-promotion revenues	0.0	0.0	n/a	n/a	0.0	12.0	-100%	n/a	12.0
Total	128.6	102.3	26%	30%	225.8	216.7	4%	7%	423.3
ReFacto									
Manufacturing revenues	100.7	107.5	-6%	-6%	261.1	224.4	16%	16%	436.0
Royalty revenues	47.8	44.0	9%	15%	71.4	68.1	5%	11%	129.8
Total	148.5	151.5	-2%	0%	332.5	292.5	14%	15%	565.8
Other revenues	-	13.1	-100%	-100%	-	13.1	-100%	n/a	13.1
Total revenues	520.2	480.7	8%	12%	1,048.7	987.4	6%	10%	1,923.2

<sup>&</sup>lt;sup>2)</sup> Constant Exchange Rate.



#### **Partner Products**

Revenue for the Partner Products portfolio for the second quarter was SEK 128.6 M (102.3).

The PharmaSwiss/Valeant portfolio (primarily Megestrol® and Fosinopril®) is now fully integrated into operations.

Sobi began to process requests for named patient access for Cometriq $^{\text{TM}}$  (indicated for medullary thyroid cancer) during second quarter.

# ReFacto® manufacturing and royalties

Revenues related to ReFacto manufacturing and royalty were SEK 148.5 M (151.5). Manufacturing revenue was SEK 100.7 M (107.5), including SEK 17 M from delivery of validation batches, which will continue through year-end 2013. Royalty revenue was SEK 47.8 M (44.0).

### **Product Sales by Region**

Europe <sup>3)</sup> 244.3 223.7 9% 14% 473.4 457.7 3% 7% 8 MENAR <sup>4)</sup> 14.6 7.5 95% 103% 42.3 23.7 78% 86% North America 108.3 76.3 42% 51% 189.8 186.9 2% 7% 3 RoW 4.5 8.6 -48% -45% 10.7 13.5 -21% -16%										
Europe <sup>3)</sup> 244.3 223.7 9% 14% 473.4 457.7 3% 7% 8 MENAR <sup>4)</sup> 14.6 7.5 95% 103% 42.3 23.7 78% 86% North America 108.3 76.3 42% 51% 189.8 186.9 2% 7% 3 RoW 4.5 8.6 -48% -45% 10.7 13.5 -21% -16%		Q2	Q2		Change	H1	H1		Change	FY
MENAR <sup>4)</sup> 14.6 7.5 95% 103% 42.3 23.7 78% 86% North America 108.3 76.3 42% 51% 189.8 186.9 2% 7% 3 RoW 4.5 8.6 -48% -45% 10.7 13.5 -21% -16%	Amounts in SEK M	2013	2012	Change	% at CER	2013	2012	Change	% at CER	2012
North America         108.3         76.3         42%         51%         189.8         186.9         2%         7%         3           RoW         4.5         8.6         -48%         -45%         10.7         13.5         -21%         -16%	Europe <sup>3)</sup>	244.3	223.7	9%	14%	473.4	457.7	3%	7%	895.9
RoW 4.5 8.6 -48% -45% 10.7 13.5 -21% -16%	MENAR <sup>4)</sup>	14.6	7.5	95%	103%	42.3	23.7	78%	86%	38.5
	North America	108.3	76.3	42%	51%	189.8	186.9	2%	7%	383.1
Total product sales 371.7 316.1 18% 23% 716.2 681.8 5% 9% 1,3	RoW	4.5	8.6	-48%	-45%	10.7	13.5	-21%	-16%	26.8
	Total product sales	371.7	316.1	18%	23%	716.2	681.8	5%	9%	1,344.3

<sup>3)</sup> Including the Nordic region

<sup>&</sup>lt;sup>4)</sup> Middle East, North Africa and Russia



### **Gross profit**

Gross profit was SEK 316.7 M (246.9), corresponding to a gross margin of 61 percent (51). The gross margin increase continues to be derived from productivity improvements following the scale-up of the downstream production process for ReFacto, and improved margins for Kineret.

# **Operating profit**

Overall operating expenses excluding amortizations increased to SEK 275.9 M (260.3).

Operating expenses for sales and administration of SEK 154.9 M (151.8) were in line with the same period last year. Research and development costs were SEK 121.0 M (108.5) reflecting on-going investment in the phase III program for Kiobrina, and preparation for the expected launch of the Haemophilia programs.

Adjusted EBITA was SEK 37.8 M (-5.6).

Amortization of intangible assets amounted to SEK 69.7 M (64.2).

Operating profit (EBIT) amounted to SEK -31.9 M (-69.8).

# Detailed Operating Profit/Loss<sup>5)</sup>

Detailed Operating Profit/Loss					
	Q2	Q2	H1	H1	FY
Amounts in SEK M	2013	2012	2013	2012	2012
Total revenues	520.2	480.7	1,048.7	987.4	1,923.2
Total cost of goods and services sold	-203.5	-233.8	-429.1	-481.1	-882.8
Gross profit	316.7	246.9	619.6	506.3	1,040.4
Gross Margin	61%	51%	59%	51%	54%
Sales and administration expenses	-154.9	-151.8	-278.9	-279.5	-539.6
less amortizations and write-downs					
Research and development expenses	-121.0	-108.5	-240.2	-205.9	-401.6
less amortizations and write-downs					
Total opex less amortizations and write-downs	-275.9	-260.3	-519.1	-485.4	-941.2
Other operating revenues/expenses	-3.0	7.8	-1.5	8.2	-2.6
Adjusted EBITA	37.8	-5.6	99.0	29.1	96.6
Non-recurring revenues <sup>6)</sup>	_	_	_	307.5	307.5
Non-recurring expenses	_	_	_	-34.0	-37.1
less amortizations and write-downs					
Net non-recurring revenue and expenses	0.0	0.0	0.0	273.5	270.4
EBITA	37.8	-5.6	99.0	302.6	367.0
Amortizations and write-downs relating to					
Sales and administration expenses	-69.7	-64.2	-134.3	-129.8	-421.6
Research and development expenses	-	-	-	-	-
Non-recurring items	-	-	-	-	-
Amortizations and write-downs	-69.7	-64.2	-134.3	-129.8	-421.6
EBIT	-31.9	-69.8	-35.3	172.8	-54.6

<sup>&</sup>lt;sup>5)</sup> The statement is a non-IFRS statement. For IFRS purpose please see Group Income Statement.

<sup>&</sup>lt;sup>6)</sup> Previously reported as part of Other operating revenues/expenses.



#### Net financial items and tax

Net financial items amounted to SEK 11.1 M (-5.5), including unrealised exchange gains. Tax amounted to SEK 9.9 M (7.6).

### Profit/loss for the period

Profit/loss amounted to SEK -10.9 M (-67.7). Earnings per share amounted to SEK -0.04 (-0.26).

#### Cash flow and investments

Cash flow from operations before changes in working capital amounted to SEK 38.9 M (-4.3).

Non-cash items amounted to SEK 49.8 M (63.4).

Working capital impacted cash flow positively by SEK 6.0 M (-25.1).

Cash flow from investing activities amounted to SEK -8.4 M (-42.1).

#### Cash

Sobi ended the quarter with a cash position of SEK 438.1 M.

#### **Net Debt**

Sobi ended the quarter with a net debt of SEK 366.3 M.

## **Equity**

Consolidated shareholders' equity as of 30 June 2013 amounted to SEK 4,826.7 M compared to SEK 4,837.9 M as of 31 December 2012.

#### **Outlook for 2013**

The outlook for 2013 remains unchanged with the total revenues for the full year expected to be in the range of SEK 2,000 to 2,200 M.

Revenues for Key Therapeutic Areas are expected to show high single-digit growth, whereas the Partner Products portfolio is expected to grow by 30 percent, and ReFacto manufacturing and royalty revenues are expected to show low single-digit growth.

Gross margin is expected to be in the range of 57-59 percent.

# **Other Information**

#### **Personnel**

As of June 2013, the number of full-time equivalents was 491 (476).

#### Significant events after the reporting period

Shortly after the quarter closed Sobi announced that the company had been selected by Auxilium of Pennsylvania, US to be the exclusive partner for the on-going commercialization of XIAPEX, a biological therapy for Dupuytren's contracture. This new partnership further strengthens the Partner Product portfolio through Europe, Middle East, Africa and Russia.

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

	Stockholm, 18 July 2013	
Bo Jesper Hansen Chairman of the Board	Adine Grate Axén	Helena Saxon
Lennart Johansson	Matthew Gantz	Hans GCP Schikan
	Hans Wigzell	
Bo-Gunnar Rosenbrand Employee representative		Catarina Larsson Employee representative
	Geoffrey McDonough President and CEO	

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



# **Financial Statements**

Group
Statement of Comprehensive Income

statement of comprehensive meanic					
	Q2	Q2	H1	H1	FY
Amounts in SEK M	2013	2012	2013	2012	2012
Total revenues	520.2	480.7	1,048.7	987.4	1,923.2
Total cost of goods and services sold	-203.5	-233.8	-429.1	-481.1	-882.8
Gross profit	316.7	246.9	619.6	506.3	1,040.4
Sales and administration expenses	-224.6	-216.0	-413.2	-409.3	-961.2
Research and development expenses	-121.0	-108.5	-240.2	-205.9	-401.6
Non-recurring items	_	_	_	-34.0	-37.1
Other operating revenues/expenses	-3.0	7.8	-1.5	315.7	304.9
Operating profit/loss	-31.9	-69.8	-35.3	172.8	-54.6
Financial income/expenses	11.1	-5.5	-25.2	-18.8	-50.5
Income tax benefit/expense	9.9	7.6	37.4	-66.9	4.2
Profit/loss for the period	-10.9	-67.7	-23.1	87.1	-100.9
Other comprehensive income					
Items that will not be reclassified to profit/loss					
Actuarial gain/loss on defined benefit plan	-3.9	_	3.5	_	_
Items that may be reclassified subsequently to profit/loss					
Translation difference	1.1	-0.2	_	-0.3	0.9
Cash flow hedge (net of tax)	-1.3	12.1	5.2	12.1	-6.5
Comprehensive income for the period	-15.0	-55.8	-14.4	98.9	-106.5
Amortization and write-down of intangible assets included in Sales and administration expenses	-69.7	-64.2	-134.3	-129.8	-421.6



Group	
Ralance	sheet

Dalatice Stiect					
	Jun	Mar	Dec	Sep	Jun
Amounts in SEK M	2013	2013	2012	2012	2012
ASSETS					
Non-current assets					
Intangible fixed assets 1)	4,766.5	4,834.4	4,533.4	4,741.6	4,802.9
Tangible fixed assets	123.2	123.9	125.6	135.8	140.3
Financial fixed assets	30.6	1.9	4.4	7.3	7.6
Total fixed assets	4,920.3	4,960.2	4,663.3	4,884.7	4,950.8
Current assets					
Inventories	703.4	681.2	700.4	742.3	810.5
Accounts receivable	382.5	401.7	343.2	367.1	350.6
Current receivables, non-interest bearing	143.3	123.5	154.5	243.5	248.9
Cash and cash equivalents	438.1	401.2	457.0	319.2	350.0
Total current assets	1,667.3	1,607.6	1,655.1	1,672.1	1,760.0
Total assets	6,587.6	6,567.8	6,318.4	6,556.8	6,710.8
EQUITY AND LIABILITIES					
Shareholders equity	4,826.7	4,840.1	4,837.9	4,986.4	5,040.4
Long-term liabilities					
Long-term debt	800.0	800.0	600.0	600.0	600.0
Long-term liabilities, non-interest bearing	317.5	313.1	371.6	452.4	461.5
Total long-term liabilities	1,117.5	1,113.1	971.6	1,052.4	1,061.5
Current liabilities					
Short term debt	1.3	0.7	1.1	14.3	13.7
Current liabilities, non-interest bearing	642.1	613.9	507.8	503.7	595.2
Total short-term liabilities	643.4	614.6	508.9	518.0	608.9
Total equity and liabilities	6,587.6	6,567.8	6,318.4	6,556.8	6,710.8

<sup>1)</sup> Including goodwill MSEK 1,605.3

# Group Changes in Equity

	Jun	Jun	Dec
Amounts in SEK M	2013	2012	2012
Opening balance	4,837.9	4,963.4	4,963.4
Change in accounting principle	_	-24.6	-24.6
Opening balance	4,837.9	4,938.8	4,938.8
Sharebased compensation to employees	4.2	2.7	5.7
Translation difference	-1.0	_	-0.1
Actuarial gain		_	-1.2
Comprehensive income for the period	-14.4	98.9	-105.3
Equity, end of period	4,826.7	5,040.4	4,837.9



Group
Cash Flow Statement

Cash Flow Statement					
	Q2	Q2	H1	H1	FY
Amounts in SEK M	2013	2012	2013	2012	2012
Net result	-10.9	-67.7	-23.1	87.1	-100.9
Non-cash items <sup>1)</sup>	49.8	63.4	98.6	245.2	468.6
Cash flow from operations before change in working capital	38.9	-4.3	75.5	332.3	367.7
Change in working capital	6.0	-25.1	100.6	-57.6	37.9
Cash flow from operations	44.9	-29.4	176.1	274.7	405.6
Investment in intangible fixed assets	-2.0	-40.9	-367.6	-41.0	-62.8
Investment in tangible fixed assets	-7.1	-1.2	-12.9	-2.5	-5.5
Divestment of tangible fixed assets	0.7	_	0.7	-	4.6
Investment/Divestment of financial assets	-	_	2.5	-	-
Short-term investments	-	_	2.9	-	-3.6
Cash flow from investing activities	-8.4	-42.1	-374.4	-43.5	-67.3
Loans - Raising/Amortization	_	107.5	200.0	-100.0	-100.0
Reclassification to short-term investment	_	-	-19.8	-	_
Cash flow from financing activities	-	107.5	180.2	-100.0	-100.0
Net change in cash	36.5	36.0	-18.1	131.2	238.3
Liquid funds at the beginning of the period	401.2	314.1	457.0	219.1	219.0
Translation difference in cash flow and liquid funds	0.4	-0.1	-0.8	-0.3	-0.3
Liquid funds at the end of the period	438.1	350.0	438.1	350.0	457.0
1) Depreciations, amortization and deferred tax:					
Depreciation tangible fixed assets	7.0	8.3	14.5	16.8	32.7
Amortization intangible assets	69.7	64.2	134.3	129.8	421.6
Deferred tax	-10.8	-12.1	-39.6	59.6	-25.2



Group Quarterly data

Quarterly data								
Amounts in SEK million	Q2-13	Q1-13	Q4-12	Q3-12	Q2-12	Q1-12	Q4-11	Q3-11
Total Revenues	520.2	528.5	471.9	463.8	480.7	506.7	436.4	447.1
COGS	-203.5	-225.6	-204.5	-197.2	-233.8	-247.3	-256.1	-213.1
Gross profit	316.7	302.9	267.4	266.6	246.9	259.4	180.3	233.9
Gross margin	61%	57%	57%	57%	51%	51%	41%	52%
Sales and administration expenses	-154.9	-124.0	-130.1	-130.0	-151.8	-127.8	-192.5	-130.4
Research and development expenses	-121.0	-119.2	-98.6	-97.1	-108.5	-97.4	-103.7	-97.3
OPEX	-275.9	-243.2	-228.7	-227.1	-260.3	-225.1	-296.2	-227.7
% of sales	-53%	-46%	-48%	-49%	-54%	-44%	-68%	-51%
Other operating revenues/expenses	-3.0	1.5	-1.1	-9.7	7.8	0.4	0.2	-3.2
Non-recurring revenues <sup>1)</sup>	-	_	-	-	-	307.5	-	0.3
Non-recurring expenses	-	-	-3.1	-	-	-34.0	-8.0	-
Net non-recurring revenue and expenses	0.0	0.0	-3.1	0.0	0.0	273.5	-8.0	0.3
EBITA	37.8	61.2	34.5	29.8	-5.6	308.2	-123.7	3.3
% of sales	7%	12%	7%	6%	-1%	61%	-28%	1%
Amortizations	-69.7	-64.6	-227.3	-64.5	-64.2	-65.6	-203.9	-57.7
EBIT	-31.9	-3.4	-192.8	-34.7	-69.8	242.6	-327.7	-54.4
EBIT margin	-6%	-1%	-41%	-7%	-15%	48%	-75%	-12%
EBITDA	44.8	68.7	42.3	37.9	2.7	316.7	-78.6	13.3

<sup>1)</sup> Previously reported as part of Other operating revenues/expenses.



# **Key ratios and Other Information**

	Q2	Q2	H1	H1	FY
Amounts in SEK M	2013	2012	2013	2012	2012
Return on					
Shareholders' equity	-0.2%	-1.3%	-0.5%	1.7%	-2.1%
Total capital	-0.4%	-1.0%	-0.4%	2.6%	-0.4%
Profit numbers					
Gross profit	316.7	246.9	619.6	506.3	1,040.4
EBITDA	44.8	2.7	113.5	319.4	399.7
Adjusted EBITA	37.8	-5.6	99.0	336.6	404.1
Adjusted EBIT	-31.9	-69.8	-35.3	206.8	-17.5
EBITA	37.8	-5.6	99.0	302.6	367.0
EBIT	-31.9	-69.8	-35.3	172.8	-54.6
Profit/loss	-10.9	-67.7	-23.1	87.1	-100.9
Per share data (SEK)					
Earning/loss per share	-0.04	-0.26	-0.09	0.33	-0.38
Earning/loss per share after dilution	-0.04	-0.26	-0.09	0.33	-0.38
Shareholders' equity per share	18.2	19.0	18.2	19.0	18.2
Shareholders' equity per share after dilution	18.2	19.0	18.2	19.0	18.2
Cash flow per share	0.1	0.1	-0.1	0.5	0.9
Cash flow per share after dilution	0.1	0.1	-0.1	0.5	0.9
Other information					
Gross margin	61%	51%	59%	51%	54%
Equity ratio	73.3%	75.1%	73.3%	75.1%	76.6%
Net debt	366.3	251.2	366.3	251.2	146.5
Number of ordinary shares	265,226,598	265,226,598	265,226,598	265,226,598	265,226,598
Number of C-shares (In treasury)	4,408,260	2,753,124	4,408,260	2,753,124	4,408,260
Average number of ordinary shares	265,226,598	265,226,598	265,226,598	265,226,598	265,226,598
Number of shares after dilution	265,226,598	265,226,598	265,226,598	265,226,598	265,226,598
Average number of ordinary shares after dilution	265,226,598	265,226,598	265,226,598	265,226,598	265,226,598



Parent Company
Statement of Comprehensive Income

	Q2	Q2	H1	H2	FY
Amounts in SEK M	2013	2012	2013	2012	2012
Total revenues	455.7	372.8	923.0	669.0	1,640.5
Total cost of goods and services sold	-224.7	-220.8	-435.9	-372.8	-813.2
Gross profit	231.0	152.0	487.1	296.2	827.3
Sales and Administration expenses	-133.9	-123.2	-231.6	-209.6	-446.0
Research and Development expenses	-126.2	-103.2	-245.9	-194.2	-390.4
Non recurring items	_	_	_	_	-37.1
Other operating revenues/expenses	-2.1	11.3	-0.4	320.9	311.6
Operating profit/loss	-31.2	-63.1	9.2	213.3	265.4
Result from participation in Group companies	_	-0.2	-	-0.2	-0.2
Financial income	14.0	22.1	20.3	20.1	61.9
Financial expenses	2.4	-3.0	-32.4	-15.3	-75.0
Profit/loss after financial items	-14.8	-44.2	-2.9	217.9	252.1
Income tax benefit/expenses	4.5	-7.1	35.2	-76.5	-220.5
Profit/loss for the period	-10.3	-51.3	32.3	141.4	31.6
Other comprehensive income					
Items that may be reclassified subsequently to profit/loss					
Cash flow hedge (net of tax)	-1.3	12.1	5.2	12.1	-6.5
Comprehensive income for the period	-11.6	-39.2	37.5	153.5	25.1
Amortization and write-down of intangible assets included in Sales & Adm					
expenses	-22.1	-13.1	-38.3	-27.3	-53.8



# Parent Company Balance Sheet

	Jun	Mar	Dec	Sep	Jun
Amounts in SEK M	2013	2013	2012	2012	2012
ASSETS					
Fixed assets					
Intangible fixed assets	967.6	987.9	638.5	633.2	643.5
Tangible fixed assets	116.6	118.9	120.0	130.7	137.3
Financial fixed assets	4,094.5	4,089.7	4,063.7	4,101.8	4,173.8
Total fixed assets	5,178.7	5,196.5	4,822.2	4,865.7	4,954.6
Current assets					
Inventories	627.7	600.3	617.9	671.1	766.5
Current receivables, non-interest bearing	1,160.1	1,181.1	1,279.6	1,343.9	1,306.9
Cash and cash equivalents	384.1	311.6	276.5	239.4	305.5
Total current assets	2,171.9	2,093.0	2,174.0	2,254.4	2,378.9
Total assets	7,350.6	7,289.5	6,996.2	7,120.1	7,333.5
EQUITY AND LIABILITIES					
Shareholders' equity	5,649.2	5,658.3	5,607.4	5,776.3	5,732.6
Untaxed reserves	1.1	1.1	1.1	3.6	-
Long-term liabilities					
Long-term debt	800.0	800.0	600.0	600.0	600.0
Long-term liabilities, non-interest bearing	-	-	19.8	19.5	19.0
Total long-term liabilities	800.0	800.0	619.8	619.5	619.0
Current liabilities					
Current liabilities, non-interest bearing	900.3	830.1	767.9	720.7	981.9
Total short-term liabilities	900.3	830.1	767.9	720.7	981.9
Total equity and liabilities	7,350.6	7,289.5	6,996.2	7,120.1	7,333.5

# Parent Company Change in Shareholder's Equity

	Jun	Jun	Dec
Amounts in SEK M	2013	2012	2012
Opening balance	5,607.4	5,530.0	5,530.0
Sharebased compensation to employees	4.2	2.7	5.9
Merger gain	_	46.4	46.4
Comprehensive income for the period	37.5	153.5	25.1
Equity, end of period	5,649.2	5,732.6	5,607.4



#### **Financial Notes**

# Note 1 – Accounting and valuation principles and other information

#### Important accounting principles

Sobi 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) which are measured at fair value in comprehensive income. The parent company applies the Annual Accounts Act and RFR 2 Reporting for legal entities. This interim report has been prepared in accordance with IAS 34, Interim Financial Reporting.

Accounting principles applied, except for the changes listed below, are in accordance with those described in the 2012 Annual Report. More detailed information about the Group's accounting and valuation principles can be found in the 2012 Annual Report which is available on <a href="https://www.sobi.com">www.sobi.com</a>.

Change in accounting principles

#### **IAS 19**

"Employee Benefits" was amended in June 2011 and the amendments have been adopted by the group as of the

first quarter 2013. Since the group from 1 January 2012 stopped applying the "corridor method" for defined benefit plans in the previous version of IAS 19, it has recognized all actuarial gains and losses in other comprehensive income as incurred (refer to the annual report 2012, page 72). Thus, that change in IAS 19 has not resulted in material changes to equity or profit/loss in this interim report or in the comparative period. However other amendments in IAS 19 has resulted in changed accounting principles compared to those described and applied in the annual report 2012. Interest cost and expected return on plan assets have been replaced by a net interest calculated using the discount rate, based on the net surplus or net deficit in the defined benefit plan. Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are charged or credited in other comprehensive income in the period which they arise.

During 2013, Sobi replaced a defined benefit pension plan covering approximately 50 employees with a premium determined pension plan. The defined benefit plan was redeemed using the assets held by Skandia and making a single payment, leaving Sobi with no remaining pension obligations under this plan. The measure has led to a gain of SEK 18.3 M in Q2.

#### IAS 1

IAS 1 has been amended. This affects the group's presentation in Other Comprehensive Income. The amended IAS 1 requires entities to group items in other comprehensive income on the basis of whether they are potentially re-classifiable to profit/loss subsequently.

Thus the group has inserted two new headings in the Group's statement of comprehensive income: "Items that will not be reclassified to profit/loss" (at present actuarial changes are reported under this heading) and "Items that may be reclassified subsequently to profit/loss" (at present the change in fair value of derivative hedging instruments and translation differences are reported under this heading).

#### IFRS 13

The introduction of the new standard IFRS 13 (which was described in the 2012 annual report on page 72) has amended IAS 34 Interim reporting now requiring the group to disclose information about fair values of financial instruments in interim reporting. Thus a new note about fair values of financial instruments has been included in the interim report.

#### 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. Sobi is exposed to three main risk categories:

 External risks such as patent infringements, competition within product concepts and decisions by authorities regarding product use and prices.

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- Operational risk, e.g. due to the capital-intensive and risky nature of new drug development, dependence on external partners in various collaborations, product liability claims and 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 Sobi's 2012 Annual Report (see the Directors' Report).

Note 2 – Shares

Development in share capital and number	No of shares	Share capital, SEK
December 2012	269 634 858	147 947 800
June 2013	269 634 858	147 947 800

The total number of shares is 269,634,858. The class C shares are intended to ensure fulfilment of commitments under the company's long-term share based incentive programs. Issued shares break down as 265,226,598 ordinary shares and 4,408,260 class C shares. The ordinary shares carry one vote per share and the class C shares carry 1/10 of a vote per share. All class C shares are treasury shares.

#### Share based incentive programs

Sobi currently has five share programs. The 2010-2012 programs as well as the CEO program are described in detail in Sobi's 2012 Annual Report (see note 14).

The 2013 program is a long-term, performance-based share program which was adopted at the Annual General Meeting on 26 April 2013. The program covers all permanent employees in Sobi. 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 Sobi's share performance over a three-year benchmark period.

	Total maximum
Share Program	allocation of shares
Share based incentative program 2010	427,033
Share based incentative program 2011	578,187
Share based incentative program 2012, Leadership	661,118
Share based incentative program 2012, Personell	24,600
Share based incentative program 2013	974,928
Share based incentative program CEO	500,000
Total shares	3,165,866

#### Note 3 – Contingencies

Sobi has an on-going dispute with the Swedish Tax Agency regarding the real estate Paradiset 14. The case is currently under consideration by the Administrative Court of Appeal (please see Annual Report 2012 for more information). During the period, there have been no relevant developments in the proceedings.

On 29 March 2012, Sobi amended its share purchase agreement regarding the acquisition in 2005 of the pharmaceutical Company Arexis AB. Under the agreement Sobi has paid SEK 36 M in connection with the signing of the agreement and an additional

SEK 20 M during the first quarter in 2013 and will pay SEK 21 M in 2014 (please see Annual Report 2012 for more information).

#### Note 4 - Fair values of financial instruments

The group carries derivatives. Refer to the annual report 2012 for a narrative description of the purpose of the holdings. The derivatives (under the heading "other current receivables") are all level 2 instruments in the fair value hierarchy in the standard IFRS 13 (inputs other than quoted prices that are observable for the instruments, either directly or indirectly, are used in the fair value measurement). The fair value of the derivative is based on the net present value of the expected difference between the expected market rate and Sobi's fixed swap rate for the remaining duration of the swap discounted with current market rate.

As of 30 June 2013 all other financial instruments in the balance sheet, with the exception of the group's bond, have reported values that are in all material aspects equivalent to fair value. At 30 June 2013 the reported value in the balance sheet for the bond is SEK 800 M. Fair value of the bond is deemed to be SEK 835 M. The fair value is based on the average of the bid-ask-spread at the balance sheet date.



# **Business Glossary**

#### BLA

**Biologics License Application** 

#### Dupuytren's contracture

A fixed flexion contracture of the hand where the fingers bend towards the palm and cannot be fully extended (straightened).

### **Efficacy**

The capacity for beneficial change (or therapeutic effect) of a given intervention

#### **FDA**

**US Food and Drug Administration** 

#### Haemophilia

A group of hereditary genetic disorders that impair the body's ability to control blood clotting or coagulation. Haemophilia A (clotting factor VIII deficiency) is the most common form of the disorder, present in about 1 in 5,000–10,000 male births. Haemophilia B (factor IX deficiency) occurs in around 1 in about 20,000–34,000 male births.

#### KIDS A-LONG and KIDS B-LONG

Two global paediatric clinical trials of rFVIIIFc (Kids A-LONG) and rFIXFc (Kids B-LONG) in haemophilia A and haemophilia B, respectively.

#### Kineret

A recombinant protein drug. Kineret (anakinra) blocks the biological activity of IL-1 by binding to the interleukin-1 type 1 receptor, which is expressed in a wide variety of tissues and organs. IL-1 is a key mediator of inflammation and driver of autoinflammatory diseases in both adults and children

#### Kiobrina

Kiobrina is a recombinant human bile-salt-stimulated lipase (rhBSSL) developed by Sobi for enzyme replacement therapy to improve growth and development in preterm infants receiving pasteurized breast milk and/or formula.

#### Orfadin

Pharmaceutical used for the treatment of hereditary tyrosinemia type 1 (HT-1), a rare genetic disorder which can cause liver failure, kidney dysfunction and neurological problems

#### **XTEN**

Half-life extension Technology, developed by Amunix. Protein-based technology to extend the serum's half-life

# **Financial Glossary**

#### **Adjusted EBIT**

Operating profit/loss before non-recurring items

#### Adjusted EBITA

Operating profit/loss before non-recurring items and amortizations

#### Cash flow per share

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

#### **EBIT**

Operating profit/loss

#### **EBITA**

Operating profit/loss before amortization

#### **EBITDA**

Operating profit/loss before depreciation and amortization.

#### **Equity ratio**

Shareholders' equity as a proportion of total assets

#### **Full-time equivalents**

Unit that indicates the workload of an employed person in a way that makes workloads comparable across various contexts

#### **Gross margin**

Gross profit as a percentage of sales



# **Gross profit**

Net sales less cost of goods and services sold

#### Net debt

Interest bearing long term and short term debt less cash at bank

# Non-recurring items

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

## Profit/loss

Profit/loss for the period

# Return on shareholders' equity

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

# Return on total capital

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

# 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 ordinary shares after dilution



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#### **About Sobi**

Sobi is an international specialty healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on Inflammation and Genetic diseases, with three late stage biological development projects within Haemophilia and Neonatology. We also market a portfolio of specialty and rare disease products for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2012, Sobi had total revenues of SEK 1.9 billion (€ 215 M) and about 500 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.