



## **Financial Calendar**

Capital Markets Day, Stockholm 5 November 2013

Capital Markets Day, New York 7 November 2013

Q4 and Full Year results 2013 20 February 2014

Q1 2014 8 May 2014

AGM 8 May 2014

Q2 2014 18 July 2014

Q3 2014 30 October 2014

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### **CEO Statement**

The third quarter for Sobi demonstrated solid progress in operational performance, business development, and in the advancement of our pipeline.

Revenue for the overall portfolio grew by 12 per cent compared to last year, with Kineret® and Partner Products showing strong performance in the quarter. Our margins are evolving as expected and we are making good progress financially with a stable cash position and improved profitability from operations.

A key achievement during the quarter was the acquisition of the full rights to develop and commercialize Kineret from Amgen for all therapeutic indications. This reflects a long-standing ambition for Sobi to fully explore Kineret's potential, and we are actively formulating our plans in this area.

We also acquired additional data for Kepivance® from two completed phase III trials performed by Amgen. These two positive studies demonstrate the potential for Kepivance to significantly reduce the incidence of severe oral mucositis in patients undergoing treatment for advanced head and neck cancer. We plan to engage with the US Food and Drug Administration (FDA) to establish a filing strategy in the near future.

In addition, just after the close of the quarter we announced that we have been granted the exclusive rights by Hyperion Therapeutics Inc. to distribute Ravicti® (glycerol phenylbutyrate) Oral Liquid on a named patient basis for the chronic treatment of Urea Cycle Disorders (UCD) in the Middle East.

Our pipeline programs have also continued to advance.

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion for the use of Kineret for the treatment of patients with Cryopyrin-Associated Periodic Syndromes (CAPS). This follows the FDA's approval earlier this year of Kineret for the treatment of children and adults with neonatal-onset multisystem inflammatory disease (NOMID), the most severe form of CAPS.

Further, our application for Orfadin® oral suspension was accepted by the EMA. This new dosage form has been developed to facilitate the ease and accuracy of administration of Orfadin to paediatric patients.

Finally, I am looking forward to welcoming the investor community to our capital market events on 5 November 2013 in Stockholm and on 7 November 2013 in New York City to give some perspectives on our on-going and early stage pipeline programs.

Thank you for your interest in our work here at Sobi.

Solna, 30 October 2013

Geoffrey McDonough **CEO** and President





## **Business Highlights Q3 2013**

- Auxilium Pharmaceuticals, Inc. and Sobi entered into a collaboration agreement for XIAPEX® in 71 European, Asian and African countries
- Acquired full rights for Kineret and additional clinical data for Kepivance from Amgen
- Received positive CHMP opinion for Kineret for treatment of rare disease CAPS
- Submitted application for Orfadin oral suspension to EMA
- Dennis Schmidt Pedersen appointed Senior Vice President Human Resources

## Financial Highlights Q3 2013 (Q3 2012)

- Total revenues were SEK 517.3 M (463.8)
- Product revenues were SEK 393.5 M (306.4)
- Gross margin was 59 per cent (57)
- Ended the quarter with a cash position of SEK 449.3 M
- Earnings per share: SEK -0.21 (-0.17)



#### **Business Review**

# Auxilium Pharmaceuticals, Inc. and Sobi entered into a collaboration agreement for XIAPEX in 71 European, Asian and African countries

Auxilium Pharmaceuticals, Inc. and Sobi announced that they entered into a long-term collaboration for the development, supply and commercialization of XIAPEX (collagenase clostridium histolyticum), for the treatment of 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.

Auxilium will remain primarily responsible for the global development of XIAPEX in Dupuytren's contracture and Peyronie's disease and will be responsible for drug manufacturing and supply. Sobi will be responsible for clinical development and regulatory activities and associated costs corresponding to any additional trials required in its licensed territories.

## Acquired full rights for Kineret and additional clinical data for Kepivance from Amgen

Sobi acquired the full rights to develop and commercialize Kineret (anakinra) from Amgen for all therapeutic indications. Sobi also acquired the right to additional data for Kepivance allowing the company to explore a potential new therapeutic indication. The data demonstrates the potential for Kepivance to reduce the incidence of severe oral mucositis in patients undergoing treatment for advanced head and neck cancer.

## Received positive CHMP opinion for Kineret for treatment of rare disease CAPS

Sobi announced that the Committee for Medicinal Products for Human Use (CHMP) of EMA has adopted a positive opinion for the use of Kineret for the treatment of patients with Cryopyrin-Associated Periodic Syndromes (CAPS).

## Submitted application for Orfadin oral suspension to EMA

Sobi announced that the company's application for Orfadin oral suspension has been accepted by EMA. The new dosage form has been developed to facilitate the ease and accuracy in administration of the desired Orfadin dose to paediatric patients and to increase convenience for the patients and their caregivers.

### Dennis Schmidt Pedersen appointed Senior Vice President Human Resources

Dennis Schmidt Pedersen was appointed Senior Vice President Human Resources at Sobi.

Schmidt Pedersen joined Sobi from Takeda where he held the position of Director Human Resources, Northern Europe.

## New number of shares and votes in Swedish Orphan Biovitrum AB (publ)

The company announced that as per 30 September 2013 the total numbers of shares in Swedish Orphan Biovitrum AB (publ) amounts to 270,389,770 shares. The increase in the number of shares and votes results from an issue of 754,912 class C shares. The class C shares are intended to ensure fulfilment of commitments under the long-term incentive programs. The company in total holds 5,163,172 class C shares.



## **Financial Review**

Total revenues for the third quarter 2013 were SEK 517.3 M (463.8), an increase of 12 per cent.

### **Key Therapeutic Areas**

Revenues for Key Therapeutic Areas for the third quarter were SEK 246.7 M (213.8), an increase of 15 per cent.

#### Inflammation: Kineret

Revenue for Kineret for the third quarter was SEK 141.8 M (114.4), an increase of 24 per cent. The growth was attributed to both volume and price.

#### **Genetics: Orfadin**

Revenue for Orfadin for the third quarter was SEK 81.9 M (82.6), a decrease of 1 per cent. The business showed consistent volume increase in all geographies, balanced by higher rebates in the US Affordable Care Act (Obama Care).

### **Financial Summary**

	Q3	Q3		Jan-Sep	Jan-Sep		FY
Amounts in SEK M	2013	2012	Change	2013	2012	Change	2012
Total revenues	517.3	463.8	12%	1,566.0	1,451.3	8%	1,923.2
Gross profit	306.2	266.6	15%	925.8	773.0	20%	1,040.4
Gross margin	59%	57%		59%	53%		54%
Adjusted EBITA <sup>1)</sup>	46.9	29.8	57%	145.9	366.5	-60%	404.1
Operating profit/loss	-26.3	-34.7	24%	-61.6	138.2	<-100%	-54.6
Profit/loss for the period	-56.4	-45.4	-24%	-79.5	41.8	<-100%	-100.9
Earnings/loss per share, SEK	-0.21	-0.17	-24%	-0.30	0.16	<-100%	-0.38

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

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

	Q3	Q3	Change	Change %	Jan-Sep	Jan-Sep	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	141.8	114.4	24%	26%	398.2	353.9	13%	17%	484.7
Genetics: Orfadin	81.9	82.6	-1%	-1%	274.7	265.4	3%	6%	356.7
Genetics: Other	22.9	16.9	36%	33%	64.4	58.7	10%	12%	79.6
Total	246.7	213.8	15%	16%	737.3	678.0	9%	12%	921.0
Partner Products									
Current portfolio	146.8	92.6	59%	59%	372.5	298.2	25%	28%	411.3
Co-promotion revenues	0.0	0.0	n/a	n/a	0.0	12.0	-100%	-100%	12.0
Total	146.8	92.6	59%	59%	372.5	310.2	20%	23%	423.3
ReFacto									
Manufacturing revenues	84.4	118.9	-29%	-29%	345.6	343.3	1%	1%	436.0
Royalty revenues	39.3	38.5	2%	4%	110.7	106.6	4%	4%	129.8
Total	123.7	157.4	-21%	-21%	456.2	449.9	1%	1%	565.8
Other revenues	-	-	n/a	n/a	-	13.1	-100%	-100%	13.1
Total revenues	517.3	463.8	12%	12%	1,566.0	1,451.3	8%	10%	1,923.2

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



#### **Partner Products**

Revenue for the Partner Products portfolio for the third quarter was SEK 146.8 M (92.6), an increase of 59 per cent.

Revenue growth in Partner Products was primarily driven by the three new deals in Europe (PharmaSwiss, Exelixis and Auxilium). Base business excluding these new products grew 8 per cent. In August, Sobi and Exelixis expanded the territories in which Sobi is responsible for managing unsolicited request for the use of Cometriq® in named patient situations, to include all countries outside the US.

#### ReFacto® manufacturing and royalties

Revenues related to ReFacto manufacturing and royalty were SEK 123.7 M (157.4), a decrease of 21 per cent. The revenues reflect variation of quarterly deliveries to Pfizer. Manufacturing revenue was SEK 84.4 M (118.9), including SEK 5.7 M from delivery of validation batches, which will continue through year-end 2013. Royalty revenue was SEK 39.3 M (38.5).

#### **Product Sales by Region**

	Q3	Q3		Change	Jan-Sep	Jan-Sep		Change	FY
Amounts in SEK M	2013	2012	Change	% at CER	2013	2012	Change	% at CER	2012
Europe <sup>3)</sup>	267.8	205.0	31%	29%	741.1	662.7	12%	15%	896.0
MENAR <sup>4)</sup>	5.0	0.0	>100%	>100%	47.3	23.8	99%	>100%	38.5
North America	113.3	94.6	20%	24%	303.1	281.5	8%	12%	383.1
RoW	7.5	6.7	12%	20%	18.3	20.2	-10%	-4%	26.8
Total product sales	393.5	306.4	28%	29%	1,109.7	988.3	12%	16%	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 306.2 M (266.6), corresponding to a gross margin of 59 per cent (57).

#### **Operating profit**

Overall operating expenses excluding amortizations increased to SEK 262.7 M (227.1).

Operating expenses for sales and administration amounted to SEK 149.6 M (130.0). Research and development costs were SEK 113.1 M (97.1) reflecting on-going investment in the phase III program for Kiobrina, and preparation for the expected launch of the Haemophilia programs. The operating expenses also reflect increased costs for long-term incentive programs related to share price appreciation during the period. The cash flow impact of these programs is hedged.

Adjusted EBITA was SEK 46.9 M (29.8).

Amortization of intangible assets amounted to SEK 73.2 M (64.5).

Operating profit (EBIT) amounted to SEK -26.3 M (-34.7).

#### Net financial items and tax

Net financial items amounted to SEK -25.7 M (-14.9), including unrealised exchange losses. Tax amounted to SEK -4.4 M (4.2).

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

	Q3	Q3	Jan-Sep	Jan-Sep	FY
Amounts in SEK M	2013	2012	2013	2012	2012
Total revenues	517.3	463.8	1,566.0	1,451.3	1,923.2
Total cost of goods and services sold	-211.1	-197.2	-640.2	-678.3	-882.8
Gross profit	306.2	266.6	925.8	773.0	1,040.4
Gross Margin	59%	57%	59%	53%	54%
Sales and administration expenses	-149.6	-130.0	-428.5	-409.5	-539.6
Research and development expenses less amortizations and write-downs	-113.1	-97.1	-353.3	-303.0	-401.6
Total opex less amortizations and write-downs	-262.7	-227.1	-781.8	-712.5	-941.2
Other operating revenues/expenses	3.4	-9.7	1.9	306.0	304.9
Adjusted EBITA	46.9	29.8	145.9	366.5	404.1
Non-recurring expenses	_	_	_	-34.0	-37.1
ЕВІТА	46.9	29.8	145.9	332.5	367.0
Amortizations and write-downs relating to					
Sales and administration expenses	-73.2	-64.5	-207.5	-194.3	-421.6
Amortizations and write-downs	-73.2	-64.5	-207.5	-194.3	-421.6
EBIT	-26.3	-34.7	-61.6	138.2	-54.6

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

## Profit/loss for the period

Profit/loss amounted to SEK -56.4 M (-45.4). Earnings per share amounted to SEK -0.21 (-0.17).

#### Cash flow and investments

Cash flow from operations before changes in working capital amounted to SEK 37.2 M (19.6).

Non-cash items amounted to SEK 93.6 M (65.0).

Working capital impacted cash flow by SEK -12.0 M (-46.0).

Cash flow from investing activities amounted to SEK -14.7 M (-4.6).



#### Cash

Sobi ended the quarter with a cash position of SEK 449.3 M.

#### **Net Debt**

Sobi ended the quarter with a net debt of SEK 346.5 M.

#### Equity

Consolidated shareholders' equity as of 30 September 2013 amounted to SEK 4,774.6 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 per cent, 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 per cent.

#### Other Information

#### Personnel

As of September 2013, the number of full-time equivalents was 519 (483).

#### Significant events after the reporting period

Shortly after the quarter closed Sobi announced that the company had been granted the exclusive right by Hyperion to distribute Ravicti (glycerol phenylbutyrate) Oral Liquid on a named patient basis for the chronic treatment of Urea Cycle Disorders (UCD) in the Middle East.

In addition Sobi announced that the company's application for Orfadin oral suspension has been submitted to FDA. This new dosage form has been developed to facilitate the ease and accuracy in administration of the desired Orfadin dose to paediatric patients and to increase convenience for the patients and their caregivers.

On 29 October 2013 Sobi's partner Biogen Idec gave an update on the regulatory process for the companies' long-lasting recombinant factor VIII product candidate, rFVIIIFc. The FDA has raised some questions pertaining to the validation of certain steps in the manufacturing process which could potentially cause a delay in US approval. Sobi believes that any potential delay in FDA approval would be unlikely to impact planned European approval timelines.

Solna, 30 October 2013

Geoffrey McDonough CEO and President

### **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.



## **Auditor Report: Review of Interim Financial Information**

#### Introduction

We have reviewed this report for the period 1 January 2013 to 30 September 2013 for Swedish Orphan Biovitrum AB (publ). The Board of Directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

#### **Scope of Review**

We conducted our review in accordance with the Swedish Standard on Review Engagements SÖG 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance

that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

#### Conclusion

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

Stockholm, 30 October 2013

PricewaterhouseCoopers AB

Mikael Winkvist Authorized Public Accountant



## **Financial Statements**

Group
Statement of Profit or Loss and other Comprehensive Income

	Q3	Q3	Jan-Sep	Jan-Sep	FY
Amounts in SEK M	2013	2012	2013	2012	2012
Total revenues	517.3	463.8	1,566.0	1,451.3	1,923.2
Total cost of goods and services sold	-211.1	-197.2	-640.2	-678.3	-882.8
Gross profit	306.2	266.6	925.8	773.0	1,040.4
Sales and administration expenses	-222.8	-194.5	-636.0	-603.8	-961.2
Research and development expenses	-113.1	-97.1	-353.3	-303.0	-401.6
Non-recurring items	_	_	_	-34.0	-37.1
Other operating revenues/expenses	3.4	-9.7	1.9	306.0	304.9
Operating profit/loss	-26.3	-34.7	-61.6	138.2	-54.6
Financial income/expenses	-25.7	-14.9	-50.9	-33.7	-50.5
Income tax benefit/expense	-4.4	4.2	33.0	-62.7	4.2
Profit/loss for the period	-56.4	-45.4	-79.5	41.8	-100.9
Other comprehensive income					
Items that will not be reclassified to profit/loss					
Actuarial gain/loss on defined benefit plan	_	_	3.5	_	_
Items that may be reclassified subsequently to profit/loss					
Translation difference	_	0.2	_	-0.1	0.9
Cash flow hedge (net of tax)	-0.2	-11.9	5.0	0.2	-6.5
Comprehensive income for the period	-56.6	-57.1	-71.0	41.9	-106.5
Amortization and write-down of intangible assets included in Sales and administration expenses	-73.2	-64.5	-207.5	-194.3	-421.6



Group Balance sheet

	Sep	Jun	Mar	Dec	Sep
Amounts in SEK M	2013	2013	2013	2012	2012
ASSETS					
Non-current assets					
Intangible fixed assets 1)	4,700.8	4,766.5	4,834.4	4,533.4	4,741.6
Tangible fixed assets	119.6	123.2	123.9	125.6	135.8
Financial fixed assets	28.6	30.6	1.9	4.4	7.3
Total fixed assets	4,849.0	4,920.3	4,960.2	4,663.3	4,884.7
Current assets					
Inventories	693.3	703.4	681.2	700.4	742.3
Accounts receivable	369.9	382.5	401.7	343.2	367.1
Current receivables, non-interest bearing	144.2	132.7	112.2	142.6	230.9
Cash and cash equivalents	449.3	438.1	401.2	457.0	319.2
Total current assets	1,656.7	1,656.7	1,596.3	1,643.2	1,659.5
Total assets	6,505.7	6,577.0	6,556.5	6,306.5	6,544.2
<b>EQUITY AND LIABILITIES</b>					
Shareholders equity	4,774.6	4,826.7	4,840.1	4,837.9	4,986.4
Long-term liabilities					
Long-term debt <sup>2)</sup>	794.2	789.4	788.7	588.1	587.4
Long-term liabilities, non-interest bearing	317.3	317.5	313.1	371.6	452.4
		1 100 0			
Total long-term liabilities	1,111.5	1,106.9	1,101.8	959.7	1,039.8
Total long-term liabilities  Current liabilities	1,111.5	1,106.9	1,101.8	959.7	1,039.8
•	<b>1,111.5</b> 1.6	<b>1,106.9</b> 1.3	<b>1,101.8</b> 0.7	9 <b>59.7</b> 1.1	<b>1,039.8</b> 14.3
Current liabilities	·	·	·		•
Current liabilities Short term debt	1.6	1.3	0.7	1.1	14.3

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

## Group Changes in Equity

Changes in Equity			
	Sep	Sep	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	8.0	5.7	5.7
Translation difference	-0.3	-	-0.1
Actuarial gain	<del>-</del> -	-	_
Comprehensive income for the period	-71.0	41.9	-106.5
Equity, end of period	4,774.6	4,986.4	4,837.9

 $<sup>^{2)}</sup>$  Net accounting of the long term debt, see note 1



Group **Cash Flow Statement** 

Cash flow Statement	Q3	Q3	Jan-Sep	Jan-Sep	FY
Amounts in SEK M	2013	2012	2013	2012	2012
Net result	-56.4	-45.4	-79.5	41.8	-100.9
Non-cash items <sup>1)</sup>	93.6	65.0	192.1	310.1	468.6
Cash flow from operations before change in working capital	37.2	19.6	112.6	351.9	367.7
Change in working capital	-12.0	-46.0	68.8	-103.6	37.9
Cash flow from operations	25.2	-26.4	181.4	248.3	405.6
Investment in intangible fixed assets	-10.1	-2.7	-377.7	-43.7	-62.8
Investment in tangible fixed assets	-3.9	-1.9	-16.8	-4.4	-5.5
Divestment of tangible fixed assets	-0.7	_	_	_	4.6
Investment/Divestment of financial assets	_	_	2.5	_	_
Short-term investments	_	-	2.9	-	-3.6
Cash flow from investing activities	-14.7	-4.6	-389.1	-48.1	-67.3
Loans - Raising/Amortization	_	_	200.0	-100.0	-100.0
Cash flow from financing activities	-	-	200.0	-100.0	-100.0
Net change in cash	10.5	-31.0	-7.7	100.2	238.3
Liquid funds at the beginning of the period	438.1	350.0	457.0	219.1	219.0
Translation difference in cash flow and liquid funds	0.7	0.2	-	-0.1	-0.3
Liquid funds at the end of the period	449.3	319.2	449.3	319.2	457.0
1) Depreciations, amortization and deferred tax:					
Depreciation tangible fixed assets	7.9	8.1	22.4	24.9	32.7
Amortization intangible assets	73.2	64.5	207.5	194.3	421.6
Deferred tax	2.9	-12.4	-36.7	47.5	-25.2



Group Quarterly data

Amounts in SEK million	Q3-13	Q2-13	Q1-13	Q4-12	Q3-12	Q2-12	Q1-12	Q4-11
Total Revenues	517.3	520.2	528.5	471.9	463.8	480.7	506.7	436.4
COGS	-211.1	-203.5	-225.6	-204.5	-197.2	-233.8	-247.3	-256.1
Gross profit	306.2	316.7	302.9	267.4	266.6	246.9	259.4	180.3
Gross margin	59%	61%	57%	57%	57%	51%	51%	41%
Sales and administration expenses	-149.6	-154.9	-124.0	-130.1	-130.0	-151.8	-127.8	-192.5
Research and development expenses	-113.1	-121.0	-119.2	-98.6	-97.1	-108.5	-97.4	-103.7
OPEX	-262.7	-275.9	-243.2	-228.7	-227.1	-260.3	-225.1	-296.2
% of sales	-51%	-53%	-46%	-48%	-49%	-54%	-44%	-68%
Other operating revenues/expenses	3.4	-3.0	1.5	-1.1	-9.7	7.8	307.9	0.2
Non-recurring expenses	-	-	-	-3.1	-	-	-34.0	-8.0
ЕВІТА	46.9	37.8	61.2	34.5	29.8	-5.6	308.2	-123.7
% of sales	9%	7%	12%	7%	6%	-1%	61%	-28%
Amortizations	-73.2	-69.7	-64.6	-227.3	-64.5	-64.2	-65.6	-203.9
EBIT	-26.3	-31.9	-3.4	-192.8	-34.7	-69.8	242.6	-327.7
EBIT margin	-5%	-6%	-1%	-41%	-7%	-15%	48%	-75%
EBITDA	54.8	44.8	68.7	42.3	37.9	2.7	316.7	-78.6



## **Key ratios and Other Information**

	Q3	Q3	Jan-Sep	Jan-Sep	FY
Amounts in SEK M	2013	2012	2013	2012	2012
Return on					
Shareholders' equity	-1.2%	-0.9%	-1.7%	0.8%	-2.1%
Total capital	-0.5%	-0.5%	-1.0%	2.1%	-0.4%
Profit numbers					
Gross profit	306.2	266.6	925.8	773.0	1,040.4
EBITDA	54.8	37.9	168.3	357.4	399.7
Adjusted EBITA	46.9	29.8	145.9	366.5	404.1
Adjusted EBIT	-26.3	-34.7	-61.6	172.2	-17.5
EBITA	46.9	29.8	145.9	332.5	367.0
EBIT	-26.3	-34.7	-61.6	138.2	-54.6
Profit/loss	-56.4	-45.4	-79.5	41.8	-100.9
Per share data (SEK)					
Earning/loss per share	-0.21	-0.17	-0.30	0.16	-0.38
Earning/loss per share after dilution	-0.21	-0.17	-0.30	0.16	-0.38
Shareholders' equity per share	18.0	18.8	18.0	18.8	18.2
Shareholders' equity per share after dilution	18.0	18.8	18.0	18.8	18.2
Cash flow per share	0.0	-0.1	-0.0	0.4	0.9
Cash flow per share after dilution	0.0	-0.1	-0.0	0.4	0.9
Other information					
Gross margin	59%	57%	59%	53%	54%
Equity ratio	73.4%	76.2%	73.4%	76.2%	76.7%
Net debt	346.5	271.3	346.5	271.3	134.6
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)	5,163,172	4,408,260	5,163,172	4,408,260	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 Profit or Loss and other Comprehensive Income

	Q3	Q3	Jan-Sep	Jan-Sep	FY
Amounts in SEK M	2013	2012	2013	2012	2012
Total revenues	435.3	584.1	1,358.3	1253.1	1,640.5
Total cost of goods and services sold	-204.3	-239.9	-640.2	-612.7	-813.2
Gross profit	231.0	344.2	718.1	640.4	827.3
Sales and Administration expenses	-121.4	-111.0	-353.0	-320.6	-446.0
Research and Development expenses	-109.2	-96.5	-355.1	-290.7	-390.4
Non recurring items	_	-34.0	_	-34.0	-37.1
Other operating revenues/expenses	0.8	-8.9	0.4	312.0	311.6
Operating profit/loss	1.2	93.8	10.4	307.1	265.4
Result from participation in Group companies	_	1.3	_	1.1	-0.2
Financial income	4.4	3.8	24.7	23.9	61.9
Financial expenses	-19.0	-13.2	-51.4	-28.5	-75.0
Profit/loss after financial items	-13.4	85.7	-16.3	303.6	252.1
Income tax benefit/expenses	1.0	-33.1	36.2	-109.6	-220.5
Profit/loss for the period	-12.4	52.6	19.9	194.0	31.6
Other comprehensive income					
Items that may be reclassified subsequently to profit/loss					
Cash flow hedge (net of tax)	-0.1	-11.9	5.1	0.2	-6.5
Comprehensive income for the period	-12.5	40.7	25.0	194.2	25.1
Amortization and write-down of intangible assets included in Sales & Adm					
expenses	-24.7	-13.6	-63.0	-40.9	-53.8



## Parent Company Balance Sheet

Balance Sheet					
	Sep	Jun	Mar	Dec	Sep
Amounts in SEK M	2013	2013	2013	2012	2012
ASSETS					
Fixed assets					
Intangible fixed assets	950.3	967.6	987.9	638.5	633.2
Tangible fixed assets	111.6	116.6	118.9	120.0	130.7
Financial fixed assets	4,095.7	4,094.5	4,089.7	4,063.7	4,101.8
Total fixed assets	5,157.6	5,178.7	5,196.5	4,822.2	4,865.7
Current assets					
Inventories	620.1	627.7	600.3	617.9	671.1
Current receivables, non-interest bearing	1,119.5	1,149.5	1,169.8	1,267.7	1,331.3
Cash and cash equivalents	364.5	384.1	311.6	276.5	239.4
Total current assets	2,104.1	2,161.3	2,081.7	2,162.1	2,241.8
Total assets	7,261.7	7,340.0	7,278.2	6,984.3	7,107.5
EQUITY AND LIABILITIES					
Shareholders' equity	5,640.4	5,649.2	5,658.3	5,607.4	5,776.3
Untaxed reserves	1.1	1.1	1.1	1.1	3.6
Long-term liabilities					
Long-term debt 1)	790.1	789.4	788.7	588.1	587.4
Long-term liabilities, non-interest bearing	-	-	-	19.8	19.5
Total long-term liabilities	790.1	789.4	788.7	607.9	606.9
Current liabilities					
Current liabilities, non-interest bearing	830.1	900.3	830.1	767.9	720.7
Total short-term liabilities	830.1	900.3	830.1	767.9	720.7
Total equity and liabilities	7,261.7	7,340.0	7,278.2	6,984.3	7,107.5

 $<sup>^{1)}</sup>$  Net accounting of the long term debt, see note 1

## Parent Company Change in Shareholder's Equity

Equity, end of period	5,640.4	5,776.3	5,607.4
Comprehensive income for the period	25.0	194.2	25.1
Merger gain	_	46.4	46.4
Sharebased compensation to employees	8.0	5.7	5.9
Opening balance	5,607.4	5,530.0	5,530.0
Amounts in SEK M	2013	2012	2012
	Sep	Sep	Dec



#### **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>.

As of Q3 2013 the long-term debt is reported as the net after deduction of accrued borrowing costs. The numbers for prior periods have been restated.

#### 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.

#### 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 requires 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.



- 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 sha	are capital and number	No of shares	Share capital, SEK
December 2012		269,634,858	147,947,800
September 2013	Rights issue of Class C shares	754,912	415,201
September 2013		270,389,770	148,363,001

A share issue of C shares was completed in September 2013, after which the total number of shares is 270,389,770. 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 5,163,172 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 (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	395,146
Share based incentative program 2011	578,187
Share based incentative program 2012, Leadership	649,120
Share based incentative program 2012, Personell	24,000
Share based incentative program 2013	974,928
Share based incentative program CEO	500,000
Total shares	3,121,381

#### 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 September 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 September 2013 the reported value in the balance sheet for the bond is SEK 790 M. Fair value of the bond is deemed to be SEK 837 M. The fair value is based on the average of the bid-ask-spread at the balance sheet date.



## **Business Glossary**

#### CHMP

The Committee for Medicinal Products for Human Use of the European Medicines Agency

#### Dupuytren's contracture

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

#### **EMA**

**European Medicines Agency** 

#### **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

#### Kineret

Kineret (anakinra) is a recombinant protein drug which locks 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

#### Peyronie's Disease

Peyronie's Disease the development of collagen plaque, or scar tissue, on the shaft of the penis that may harden and reduce flexibility, thus occasionally causing pain and causing the penis to deform in a bend or arc during erection. It can be a physically and psychosocially devastating disorder that results in varying degrees of penile curvature deformity and disease bother associated with painful erections, erection appearance, impact on intercourse, and intercourse frequency



## **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.