



# **Financial Calendar**

 Q4 & FY 2014
 19 February 2015

 Q1
 6 May 2015

 Annual General Meeting
 6 May 2015

 Q2
 17 July 2015

 Q3
 29 October 2015

# **Table of Contents**

CEO Statement	3
Highlights Q3	4
Financial Review	5
Other Information	7
Auditor Report	8
Financial Statements	9
Financial Notes	15
Business Glossary	16
Financial Glossary	17

Photo: Ralph Skorge (cover) and Martin Botvidsson



### **CEO Statement**

The third quarter results come at an exciting time for Sobi, marked by excellent operating momentum and by a key transition in our pipeline as the launches of Eloctate™ and Alprolix® continue. Elocta™, as Eloctate will be known in Europe, is potentially entering its approval year following the submission of the Marketing Authorization Application (MAA) to the European Medicines Agency by our partner Biogen Idec.

Revenues grew 29 percent to SEK 666 M compared to Q3 2013, with product sales growing 35 percent to SEK 532 M and sales from the manufacturing and royalties for ReFacto® increasing by 8 per cent to SEK 134 M. Gross margin is stable and operating profit reached SEK 50 M. Cash flow continues to be positive and we ended the quarter with a cash position of SEK 611 M.

Orfadin® has been a highlight in the quarter with a doubling of revenue to Sobi following initiation of direct sales in North America. Kineret® grew 23 per cent in the quarter with many European markets continuing to show volume growth, and US volumes recovering after a slow start in the first quarter. Our Partner Products portfolio grew 9 per cent, with growth across the portfolio.

The transition of Elocta from the pipeline to launch preparation has several implications for Sobi. The MAA filing for Elocta, together with the receipt of certain information from Biogen Idec, triggers our opt-in right to complete development and to commercialise in our territories. We have been building our capabilities and

presence over the past two years and we are now fully focused on the launch of Elocta. Upon opt-in for Elocta, Sobi will make a one-time payment to Biogen Idec of USD 10 M.

Over the longer term, by recently electing to add the preclinical rFVIIIFc-XTEN construct to the company's collaboration with Biogen Idec, we hope to offer a potentially next generation rFVIIIFc molecule in our territory. This early stage program offers an exciting path forward for us in the Haemophilia area.

We have also taken several difficult decisions in this period.

We will cease manufacturing of Multiferon® and withdraw it from the market at the end of 2015. Multiferon is primarily used for treatment of malignant melanoma and revenues year to date are SEK 5 M. We expect that current patients will be able to complete their treatment and we will work during this period to support the redeployment or relocation of the 16 employees at our facility in Umeå.

We have placed the phase 1 study of SOBI002 on hold after adverse events were observed in this first-in-human study. The events were transient and all subjects are well. SOBI002 is an investigational molecule that is a novel biological inhibitor of complement factor C5 based on the Affibody® technology platform. We are working to understand the observed findings in more detail.



Finally, we have decided not to pursue an additional indication for Kepivance® to reduce the incidence and duration of severe oral mucositis in patients with head and neck cancer undergoing radiochemotherapy. After thorough exposition and analysis of the available data we have concluded that the benefit/risk for Kepivance is not supported well enough to pursue a filing.

Although difficult, these decisions will allow us to focus our activities even further on our business and on the upcoming launch of Elocta while we reset our development portfolio.

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

Solna, 30 October 2014

Geoffrey McDonough CEO and President



# **Business Highlights Q3 2014**

- Sobi expanded its Haemophilia development portfolio by electing to include a potentially longer-acting Haemophilia A candidate (rFVIIIFc-XTEN) in collaboration agreement with Biogen Idec
- Sobi opened North American headquarters office in Waltham,
   Massachusetts with a ribbon cutting ceremony arranged in
   collaboration with the Massachusetts Life Sciences Center (MLSC)
   on 22 September

# Financial Highlights Q3 2014 (Q3 2013)

- Total revenues were SEK 665.9 M (517.3)
- Product revenues were SEK 532.3 M (393.5)
- Gross margin was 59 per cent (59)
- EBITA was SEK 119.9 M (46.9)
- Ended the quarter with a cash position of SEK 611.3 M

# Financial Highlights Q3 2014 (Q3 2013) in USD\*

- Total revenues were USD 99.8 M (77.5)
- Product revenues were USD 79.7 M (60.0)
- Gross margin was 59 per cent (59)
- EBITA was USD 18.0 M (7.0)
- Ended the quarter with a cash position of USD 84.5 M

<sup>\*</sup> The statement is a non-IFRS statement. For the Income Statement we have used an exchange rate of 6.6757 (average rate for the period) and for the Balance Sheet 7.2383 (closing rate for the period)



# **Financial Review Q3 2014**

Total revenues for the third quarter were SEK 665.9 M (517.3), an increase of 29 per cent compared to the same quarter last year. The increase at constant exchange rates was 23 per cent.

### **Key Therapeutic Areas**

Revenues for Key Therapeutic Areas were SEK 372.0 M (246.7), an increase of 51 per cent.

### Inflammation

Revenue for Kineret was SEK 174.1 M (141.8), an increase of 23 per cent. US volumes have recovered after lower volumes in the first quarter.

### Genetics & Metabolism

Revenue for Orfadin was SEK 163.5 M (81.9), an increase of 100 per cent. The increase is mainly related to initiation of direct sales in North America in the second quarter in combination with continued growth in the Middle East, North Africa, and Russia.

### Haemophilia

Revenue for the Haemophilia franchise was SEK 8.2 M. SEK 6.8 M (0) represent royalties equal to 2 per cent from the sales of Eloctate and Alprolix respectively in Biogen Idec territories during the third quarter, and SEK 1.4 M (0) from sales in the second quarter not previously reported.

### **Partner Products**

Revenue for Partner Products was SEK 160.3 M (146.8), an increase of 9 per cent. The increase was driven by continued growth across the portfolio.

### **Financial Summary**

·							
	Q3	Q3		Jan-Sep	Jan-Sep		Full year
Amounts in SEK M	2014	2013	Change	2014	2013	Change	2013
Total revenues	665.9	517.3	29%	1,901.7	1,566.0	21%	2,176.7
Gross profit	395.3	306.2	29%	1,121.2	925.8	21%	1,284.0
Gross margin	59%	59%		59%	59%		59%
EBITA	119.9	46.9	>100%	-81.6	145.9	<-100%	211.0
EBITA excluding Kiobrina write-off <sup>1</sup>	119.9	46.9	>100%	243.3	145.9	67%	211.0
EBIT (Operating profit/loss)	49.7	-26.3	>100%	-292.3	-61.6	<-100%	-66.6
Profit/loss for the period	52.7	-56.4	>100%	-250.4	-79.5	<-100%	-93.0

<sup>&</sup>lt;sup>1</sup>2014 YTD includes write-off relating to Kiobrina of SEK 324.9 M.

### **Revenues by Business Line**

nevenues by business zine									
	Q3	Q3	Change	Change %	Jan-Sep	Jan-Sep	Change	Change %	Full year
Amounts in SEK M	2014	2013	%	at CER <sup>1</sup>	2014	2013	%	at CER <sup>1</sup>	2013
Key Therapeutic Areas									
Inflammation: Kineret	174.1	141.8	23%	16%	446.0	398.2	12%	8%	561.7
Genetics & Metabolism: Orfadin	163.5	81.9	100%	91%	379.3	274.7	38%	33%	365.9
Genetics & Metabolism: Other	26.1	22.9	14%	7%	85.4	64.4	33%	26%	84.4
Haemophilia: Royalties <sup>2</sup>	8.2	0.0	n/a	n/a	19.0	0.0	n/a	n/a	0.0
Total	372.0	246.7	51%	43%	929.7	737.3	26%	21%	1,012.0
Partner Products	160.3	146.8	9%	4%	483.9	372.5	30%	26%	545.7
ReFacto									
Manufacturing revenues	91.7	84.4	9%	9%	367.0	345.6	6%	6%	491.9
Royalty revenues	41.9	39.3	7%	-3%	121.1	110.6	9%	5%	127.0
Total	133.5	123.7	8%	5%	488.1	456.2	7%	6%	619.0
Total revenues	665.9	517.3	29%	23%	1,901.7	1,565.9	21%	18%	2,176.7

Constant Exchange Rate

 $<sup>^{2}</sup>$  Royalties on commercial sales, Biogen Idec. Note that YTD includes a one-time milestone payment.



### ReFacto

Revenues from ReFacto manufacturing and royalty were SEK 133.5 M (123.7), an increase of 8 per cent.

Manufacturing revenue was SEK 91.7 M (84.4). Royalty revenue was SEK 41.9 M (39.3). Q3 last year included validation batches of SEK 5.7 M.

### **Gross profit**

Gross profit was SEK 395.3 M (306.2), corresponding to a gross margin of 59 per cent (59). The gross profit was impacted by product mix for the quarter with a lower percentage of ReFacto sales compared to total sales, offset by the addition of haemophilia royalties and increased sales of Orfadin.

### **Operating profit**

Overall operating expenses excluding amortisations and write-downs were SEK 278.1M (262.7).

Operating expenses for sales and administration excluding amortisation amounted to SEK 187.3 M (149.6). The increase relates to additional resources in marketing, medical and patient access to support the current portfolio and to prepare for planned launch of the haemophilia programmes as well as to increased investments in the North American operations.

Research and development costs excluding amortisation and write-downs were SEK 90.8 M (113.1), reflecting the discontinuation of the Kiobrina programme.

EBITA was SEK 119.9 M (46.9).

Amortisation of intangible assets amounted to SEK 70.2 M (73.2).

### **Operating Profit/Loss**

	Q3	Q3	Jan-Sep	Jan-Sep	Full year
Amounts in SEK M	2014	2013	2014	2013	2013
Total revenues	665.9	517.3	1,901.7	1,566.0	2,176.7
Total cost of goods and services sold	-270.6	-211.1	-780.5	-640.2	-892.7
Gross profit	395.3	306.2	1,121.2	925.8	1,284.0
Gross Margin	59%	59%	59%	59%	59%
Sales and administration expenses	-187.3	-149.6	-536.2	-428.5	-620.7
less amortisations and write-downs					
Research and development expenses	-90.8	-113.1	-351.2	-353.3	-455.7
less amortisations and write-downs					
Total opex less amortisations and write-downs	-278.1	-262.7	-887.4	-781.8	-1,076.4
Other operating revenues/expenses	2.7	3.4	-315.4	1.9	3.4
EBITA	119.9	46.9	-81.6	145.9	211.0
Amortisations and write-downs relating to					
Sales and administration expenses	-70.2	-73.2	-210.7	-207.5	-277.6
Amortisations and write-downs	-70.2	-73.2	-210.7	-207.5	-277.6
EBIT	49.7	-26.3	-292.3	-61.6	-66.6

The statement is a non-IFRS statement. For IFRS purpose please see Group Income Statement.

EBIT (operating profit) amounted to SEK 49.7 M (-26.3).

### Net financial items and tax

Net financial items amounted to SEK 6.8 M (-25.7), including unrealised exchange gains. Tax amounted to SEK -3.8 M (-4.4).

### Profit/loss

Profit/loss amounted to SEK 52.7 M (-56.4).

Earnings per share amounted to SEK 0.20 (-0.21).

#### Cash flow and investments

Cash flow from operations before changes in working capital amounted to SEK 133.8 M (37.2), reflecting better results for the company.

Working capital impacted cash flow by SEK 40.8 M (-12.0).

Cash flow from investing activities amounted to SEK -67.0 M (-14.7). The election to add the XTEN programme to the company's collaboration with Biogen Idec was the largest investment during the quarter.



### Cash

Cash position at quarter end was SEK 611.3 M, compared to SEK 445.1 M as of 31 December 2013.

### **Net Debt**

Sobi ended the quarter with a net debt of SEK 205.9 M, compared to SEK 352.5 M as of 31 December 2013.

### **Equity**

Consolidated shareholders' equity as of 30 September 2014 amounted to SEK 4,532.9 M compared to SEK 4,769.2 M as of 31 December 2013.

### Outlook 2014 (unchanged)

For 2014, Sobi expects total revenues for the full year to be in the range of SEK 2,300 to 2,500 M.

The company expects the gross margin will be in the range of 58-60 per cent.

Operating costs are expected to increase as the company continues to prepare for the planned launch of the haemophilia programmes.

### Other Information

#### Personnel

As of September 2014, the number of full-time equivalents in personnel was 569 (540, Dec 2013).

### Significant events after the reporting period

- Sobi announced that Biogen Idec submitted a Marketing Authorisation Application (MAA) for Elocta (rFVIIIFc) to the European Medicines Agency (EMA), on 9 October 2014. The MAA filing with the EMA, combined with the receipt of certain information from Biogen Idec, triggers the formal opt-in right, giving Sobi approximately two months to exercise its option. If Sobi decides to opt to take over final regulatory development and commercialisation activities in the Sobi territory, the company will make a one-time payment to Biogen Idec of USD 10 M.
- Sobi will cease manufacturing of Multiferon, a product indicated for treatment of malignant melanoma. As a consequence the company will also close its Multiferon production site in Umeå, which currently has a staff of 16. Sobi will provide Multiferon for patients until the end of 2015, allowing time for physicians to complete ongoing treatment courses with Multiferon and/or to switch patients to alternative treatments. At present there are 63 patients on treatment. The company expects that the discontinuation and closure will result in a write-down in the fourth quarter of approximately SEK 25 to 30 M with a minor cash flow effect. The revenue for Multiferon YTD was SEK 5 M.

- Sobi has placed the phase 1 study of SOBI002 on hold after adverse events were observed in the first-inhuman study. The events were transient and all subjects dosed in the study are well. SOBI002 is an investigational molecule, a biological inhibitor of complement factor C5 based on the novel Affibody technology platform. Sobi is working to understand the observed findings in more detail.
- Sobi has decided not to pursue an expanded label for Kepivance to reduce the incidence and duration of severe oral mucositis in patients with head and neck cancer undergoing radiochemotherapy. After thorough exposition and analysis of the available data the company has concluded that the benefit/risk for Kepivance is not supported well enough to pursue a filing.

### Forward-looking statement

This report includes forward-looking statements. Actual results may differ from those stated. Internal factors such as the successful management of research programmes and intellectual property rights may affect future results. There are also external conditions such as the economic climate, political changes and competing research programmes that may affect Sobi's results.



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

### Introduction

We have reviewed the condensed interim report for Swedish Orphan Biovitrum AB (publ) as at 30 September 2014 and for the nine months period then ended. The Board of Directors and the Managing Director 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 International Standard on Review Engagements, ISRE 2410 Review of Interim Financial Statements 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 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.

### Other matters

The review of the condensed interim report as at 30 September 2013 and for the nine months period then ended was performed by another auditor who submitted an auditor's review report 30 October 2013, with unmodified opinions in the condensed interim report.

### 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 2014

**Ernst & Young AB** 

Björn Ohlsson Authorised Public Accountant



# **Financial Statements**

**Group Statement of Comprehensive Income** 

	Q3	Q3	Jan-Sep	Jan-Sep	Full year
Amounts in SEK M	2014	2013	2014	2013	2013
Total revenues	665.9	517.3	1,901.7	1,566.0	2,176.7
Total cost of goods and services sold	-270.6	-211.1	-780.5	-640.2	-892.7
Gross profit	395.3	306.2	1,121.2	925.8	1,284.0
Sales and administration expenses	-257.5	-222.8	-746.9	-636.0	-898.3
Research and development expenses	-90.8	-113.1	-351.2	-353.3	-455.7
Other operating revenues/expenses	2.7	3.4	-315.4	1.9	3.4
Operating profit/loss	49.7	-26.3	-292.3	-61.6	-66.6
Financial income/expenses	6.8	-25.7	-3.7	-50.9	-56.9
Income tax benefit/expense	-3.8	-4.4	45.6	33.0	30.5
Profit/loss for the period	52.7	-56.4	-250.4	-79.5	-93.0
Other comprehensive income					
Items that will not be reclassified to profit/loss					
Remeasurements of post employment benefit obligations	_	-	1.6	3.5	2.0
Items that may be reclassified subsequently to profit/loss					
Translation difference	-1.0	_	_	_	-
Cash flow hedge (net of tax)	0.3	-0.2	-0.7	5.0	1.9
Comprehensive income for the period	52.0	-56.6	-249.5	-71.0	-89.1
Amortisation and write-down of intangible assets included in Sales and					
administration expenses	-70.2	-73.2	-210.7	-207.5	-277.6
Earning/loss per share	0.20	-0.21	-0.94	-0.30	-0.35



Group						Group			
Balance sheet						Changes in Equity			
	Sep	Jun	Mar	Dec	Sep		Jan-Sep	Jan-Sep	Full year
Amounts in SEK M	2014	2014	2014	2013	2013	Amounts in SEK M	2014	2013	2013
ASSETS						Opening balance	4,769.2	4,837.9	4,837.9
Non-current assets						Sharebased compensation to employees	11.7	8.0	13.2
Intangible fixed assets <sup>1</sup>	4,231.0	4,240.5	4,302.7	4,637.0	4,700.8	Transfer of own shares	_	_	6.7
Tangible fixed assets	115.8	118.2	120.1	125.7	119.6	Translation difference	1.5	-0.3	0.5
Financial fixed assets	67.4	43.2	38.9	26.4	28.6	Comprehensive income for the period	-249.5	-71.0	-89.1
Total fixed assets	4,414.2	4,401.9	4,461.7	4,789.1	4,849.0	Equity, end of period	4,532.9	4,774.6	4,769.2
Current assets									
Inventories	725.5	728.9	678.4	726.0	693.3				
Accounts receivable	451.1	447.7	376.6	414.5	369.9				
Current receivables, non-interest bearing	168.6	164.3	133.4	144.6	144.2				
Cash and cash equivalents	611.3	503.2	573.7	445.1	449.3				
Total current assets	1,956.5	1,844.1	1,762.1	1,730.2	1,656.7				
Total assets	6,370.7	6,246.0	6,223.8	6,519.3	6,505.7				
EQUITY AND LIABILITIES									
Shareholders' equity	4,532.9	4,475.4	4,443.1	4,769.2	4,774.6				
Long-term liabilities									
Long-term debt	815.4	814.8	794.0	795.7	794.2				
Long-term liabilities, non-interest bearing	292.2	269.8	274.2	306.9	317.3				
Total long-term liabilities	1,107.6	1,084.6	1,068.2	1,102.6	1,111.5				
Current liabilities									
Short term debt	1.7	1.9	1.8	1.9	1.6				
Current liabilities, non-interest bearing	728.5	684.1	710.7	645.6	618.0				
Total short-term liabilities	730.2	686.0	712.5	647.5	619.6				
Total equity and liabilities	6,370.7	6,246.0	6,223.8	6,519.3	6,505.7				

<sup>&</sup>lt;sup>1</sup> Including goodwill MSEK 1,554.2



Group
Cash Flow Statement

Cash Flow Statement					
	Q3	Q3	Jan-Sep	Jan-Sep	Full year
Amounts in SEK M	2014	2013	2014	2013	2013
Net result	52.7	-56.4	-250.4	-79.5	-93.0
Non-cash items <sup>1</sup>	81.1	93.6	487.2	192.1	258.5
Cash flow from operations before change in working capital	133.8	37.2	236.8	112.6	165.5
Change in working capital	40.8	-12.0	-5.0	68.8	19.9
Cash flow from operations	174.6	25.2	231.8	181.4	185.4
Investment in intangible fixed assets	-60.7	-10.1	-72.9	-377.7	-384.2
Investment in tangible fixed assets	-5.8	-3.9	-14.4	-16.8	-26.0
Divestment of tangible fixed assets	-0.5	-0.7	_	_	0.2
Investment/Divestment of financial assets	_	_	0.2	2.5	2.5
Short-term investments	_	-	_	2.9	2.9
Cash flow from investing activities	-67.0	-14.7	-87.1	-389.1	-404.6
Loans - Raising/Amortization	_	_	20.0	200.0	200.0
Transfer of own shares	_	-	_	-	6.7
Cash flow from financing activities	-	-	20.0	200.0	206.7
Net change in cash	107.6	10.5	164.7	-7.7	-12.5
Liquid funds at the beginning of the period	503.2	438.1	445.1	457.0	457.0
Translation difference in cash flow and liquid funds	0.5	0.7	1.5	-	0.6
Liquid funds at the end of the period	611.3	449.3	611.3	449.3	445.1
<sup>1</sup> Depreciations, amortization, deferred tax and other:					
Depreciation tangible fixed assets	7.8	7.9	23.5	22.4	30.1
Amortization intangible assets	70.2	73.2	210.7	207.5	277.6
Deferred tax	-1.8	2.9	-58.6	-36.7	-44.9



# **Key Ratios and Other Information**

key katios and other information	Q3	Q3	Jan-Sep	Jan-Sep	Full year
Amounts in SEK M	2014	2013	2014	2013	2013
Profit numbers					
Gross profit	395.3	306.2	1,121.2	925.8	1,284.0
EBITDA	127.7	54.8	-58.1	168.3	241.1
EBITA	119.9	46.9	-81.6	145.9	211.0
EBIT	49.7	-26.3	-292.3	-61.6	-66.6
Profit/loss	52.7	-56.4	-250.4	-79.5	-93.0
Per share data (SEK)					
Earning/loss per share	0.20	-0.21	-0.94	-0.30	-0.35
Earning/loss per share after dilution	0.20	-0.21	-0.94	-0.30	-0.35
Shareholders' equity per share	17.0	18.0	17.0	18.0	17.6
Shareholders' equity per share after dilution	17.0	18.0	17.0	18.0	17.6
Other information					
Gross margin	59%	59%	59%	59%	59%
Equity ratio	71.2%	73.4%	71.2%	73.4%	73.2%
Net debt	205.9	346.5	205.9	346.5	352.5
Number of ordinary shares	270,785,950	265,226,598	270,785,950	265,226,598	270,389,770
Number of C-shares (in treasury)	<u>-</u>	5,163,172	_	5,163,172	_
Number of ordinary shares (in treasury)	4,188,948	_	4,188,948	_	4,688,948
Average number of ordinary shares (excluding shares in treasury)	266,597,002	265,226,598	265,999,549	265,226,598	265,266,117
Number of shares after dilution	270,785,950	265,226,598	270,785,950	265,226,598	270,389,770
Average number of ordinary shares after dilution (excluding shares in treasury)	266,597,002	265,226,598	265,999,549	265,226,598	265,266,117



Parent Company
Statement of Comprehensive Income

	Q3	Q3	Jan-Sep	Jan-Sep	Full year
Amounts in SEK M	2014	2013	2014	2013	2013
Total revenues	544.3	435.3	1,736.7	1,358.3	1,841.9
Total cost of goods and services sold	-230.5	-204.3	-710.5	-640.2	-889.9
Gross profit	313.8	231.0	1,026.2	718.1	952.0
Sales and Administration expenses	-161.5	-121.4	-441.8	-353.0	-532.7
Research and Development expenses	-88.0	-109.2	-329.0	-355.1	-450.6
Other operating revenues/expenses	6.5	0.8	-40.7	0.4	13.4
Operating profit/loss	70.8	1.2	214.7	10.4	-17.9
Result from participation in Group companies <sup>1</sup>	1.9	_	-174.6	_	2.3
Financial income/expenses	14.5	-14.6	19.7	-26.7	-28.1
Profit/loss after financial items	87.2	-13.4	59.8	-16.3	-43.7
Income tax benefit/expenses	_	1.0	-20.7	36.2	36.1
Profit/loss for the period	87.2	-12.4	39.1	19.9	-7.6
Other comprehensive income					
Items that may be reclassified subsequently to profit/loss					
Cash flow hedge (net of tax)	0.3	-0.1	-0.7	5.1	1.9
Comprehensive income for the period	87.5	-12.5	38.4	25.0	-5.7
Amortization and write-down of intangible assets included in Sales & Adm					
expenses	-21.9	-24.7	-65.8	-63.0	-85.0

 $<sup>^{1}</sup>$  2014 includes write-down in value of ownership of Arexis relating to Kiobrina.



# Parent Company Balance Sheet

24.4					
	Sep	Jun	Mar	Dec	Sep
Amounts in SEK M	2014	2014	2014	2013	2013
ASSETS					
Fixed assets					
Intangible fixed assets	941.8	903.0	917.0	934.8	950.3
Tangible fixed assets	106.0	107.7	109.4	115.6	111.6
Financial fixed assets	3,918.2	3,917.8	3,916.4	4,096.1	4,095.7
Total fixed assets	4,966.0	4,928.5	4,942.8	5,146.5	5,157.6
Current assets					
Inventories	655.9	655.6	612.4	664.6	620.1
Current receivables, non-interest bearing	1,166.3	1,210.4	1,120.9	1,042.2	1,119.5
Cash and cash equivalents	517.4	431.8	512.5	373.5	364.5
Total current assets	2,339.6	2,297.8	2,245.8	2,080.3	2,104.1
Total assets	7,305.6	7,226.3	7,188.6	7,226.8	7,261.7
EQUITY AND LIABILITIES					
Shareholders' equity	5,664.6	5,580.2	5,511.2	5,621.6	5,640.4
Untaxed reserves	-	-	-	-	1.1
Long-term liabilities					
Long-term debt	810.9	810.1	789.2	790.8	790.1
Total long-term liabilities	810.9	810.1	789.2	790.8	790.1
Current liabilities					
Current liabilities, non-interest bearing	830.1	836.0	888.2	814.4	830.1
Total short-term liabilities	830.1	836.0	888.2	814.4	830.1
Total equity and liabilities	7,305.6	7,226.3	7,188.6	7,226.8	7,261.7

# Parent Company Change in Shareholders' Equity

	Jan-Sep	Jan-Sep	Full Year
Amounts in SEK M	2014	2013	2013
Opening balance	5,621.6	5,607.4	5,607.4
Sharebased compensation to employees	4.6	8.0	13.2
Transfer of shares	_	_	6.7
Comprehensive income for the period	38.4	25.0	-5.7
Equity, end of period	5,664.6	5,640.4	5,621.6



### **Financial Notes**

# Note 1 – Accounting and valuation principles and other information

Important accounting principles

This interim report has been prepared in accordance with IAS 34 and with the Annual Accounts Act. The consolidated financial statements for the period January—June 2014 has been prepared in accordance with the year end for 2013 in accordance with Financial Reporting Standards (IFRS) and IFRIC interpretations as adopted by the EU and the Swedish Annual Act.

The parent company applies the Annual Accounts Act and Council for Financial Reporting, RFR 2 Reporting for legal entities. 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 through profit and loss.

Accounting principles applied, except for the changes listed below, are in accordance with those described in the 2013 Annual Report. More detailed information about the Group's accounting and valuation principles can be found in the 2013 Annual Report which is available on www.sobi.com.

Change in accounting principles
From fiscal year 2014 comes a number of new and
revised standards in force. These standards have
had no material impact on the consolidated financial

statements.

### 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 risks, e.g. due to the capitalintensive 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 2013 Annual Report (see the Directors' Report).

#### Note 2 - Fair values of financial instruments

The group carries derivatives. Refer to the annual report 2013 for a narrative description of the purpose of the holdings. The derivatives (under the heading "current liabilities") 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 2014 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 2014 the reported value in the balance sheet for the bond was SEK 791 M (790). Fair value of the bond is deemed to be SEK 842 M (837). The fair value is based on the average of the bid-ask-spread at the balance sheet date.

### Note 3 – Transactions with Related Parties

There were no significant transactions with related parties during the reporting period, compared to Sobi's annual report 2013.



# **Business Glossary**

### **Alprolix**

Alprolix is the first recombinant, clotting factor therapy with prolonged circulation in the body. In the US it is indicated for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis in adults and children with hemophilia B. Alprolix is also approved in Canada, Australia and Japan

### **EMA**

**European Medicines Agency** 

### Elocta

Elocta is a long-acting recombinant factor VIIIFc fusion protein product candidate for people with haemophilia A. Elocta is the approved European trade name for rFVIIIFc, also known as Eloctate in the U.S., Canada, and Australia, where it is approved for the treatment of hemophilia A

#### **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

### Kepivance

Kepivance is indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy requiring hematopoietic stem cell support

### Kineret

Kineret (anakinra) is a recombinant protein drug which 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

### Orfadin

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

#### SOBI002

A small biologic molecule based on the Affibody platform that works as a potent and selective inhibitor of complement protein C5, a key protein in human immunological and inflammatory processes and central to a number of important diseases



# **Financial Glossary**

### **EBIT**

Earnings Before Interest and Taxes (Operating profit/loss)

### **EBITA**

Operating profit/loss before amortisation

### **EBITDA**

Operating profit/loss before depreciation and amortisation

# **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

### **Profit/loss**

Profit/loss for the period

# Shareholders' equity per share

Shareholders' equity divided by the number of shares



Swedish Orphan Biovitrum AB SE-112 76 Stockholm, Sweden Visiting address: Tomtebodavägen 23 A Telephone: +46 8-697 20 00

Fax: +46 8-697 23 30 www.sobi.com

### **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 two late stage biological development projects within haemophilia. 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 2013, Sobi had total revenues of SEK 2.2 billion (USD 334 M) and about 550 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at <a href="https://www.sobi.com">www.sobi.com</a>.