



# **Financial Calendar**

Q1 6 May 2015

Annual General Meeting 6 May 2015

Q2 17 July 2015

Q3 29 October 2015

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Photo: Ralph Skorge (cover) and Martin Botvidsson



## **CEO Statement**

2014 was a pivotal year for Sobi marked by excellent commercial performance across the portfolio. Total revenues were SEK 2,607 million, an increase of 20 per cent over the prior year. Cash flow increased year over year and gross margin was stable. Our development portfolio had several successes as well as some setbacks.

Operational highlights include initiating direct sales of Orfadin® in North America in conjunction with strengthening the local organisation in the US and establishing our own organisation in Canada.

Our portfolio in Europe, Middle East, North Africa and Russia was also dynamic and successful, with 7 product launches in 21 countries in these territories. Of particular note has been the ongoing launch of Kineret® in CAPS, Xiapex® in Dupuytren's Contracture, ChondroCelect® for the repair of cartilage defects of the knee, and Cometriq® in Medullary Thyroid Cancer. The integrated commercialisation in the Partner Products business is approaching that of our proprietary portfolio. To highlight this convergence, we will launch Xiapex as Marketing Authorisation Holder this year in a new indication, Peyronie's Disease — representing a significant unmet medical need and growth opportunity for Sobi as well as for our partner.

ReFacto® delivered solid results and it continues to be a stable and important contributor to Sobi's results.

The positive results of the Kids A-LONG study paved the way for the European filing of Elocta™ (rFVIIIFc) in October 2014, making EU approval possible before the end of 2015. As a result we formally exercised our optin right to take over final development and commercialisation in our territories. During 2014 we have been focused on building a world class haemophilia organisation to support launch and commercialisation and this will be expanded in 2015. We also elected to include a longer-acting Factor VIII-Fc candidate with XTEN technology in our collaboration with Biogen Idec. Finally, the launches of Eloctate® [Antihemophilic Factor (Recombinant), Fc Fusion Protein] and Alprolix® [Coagulation Factor IX (Recombinant), Fc Fusion Protein] by our partner Biogen Idec are under way in North America and other territories.

In our development portfolio, the phase 3 results unfortunately failed to demonstrate benefit of Kiobrina® for neonatal growth and development, and we also decided not to pursue an additional indication for Kepivance®. We remain interested and engaged in the neonatology and supportive oncology fields and will build on these experiences in the field. Finally we are further investigating SOBI002, our biologic inhibitor of complement factor C5 after observing adverse events in its first-in-human study.



Thanks to our employees for their commitment, engagement, and achievements this year, and to our shareholders for their support for the company. We envision a world where rare diseases can be diagnosed at birth and addressed with sustainable, specific therapy that restores health for a lifetime. This is the vision which inspires our work inside Sobi and with our partners every day.

Thank you.

Geoffrey McDonough CEO and President

Solna, Sweden, 19 February 2015



# **Business Highlight Q4 2014**

- Received positive opinion by the Committee for Medicinal Products for Human Use (CHMP) regarding Xiapex for the treatment of Peyronie's disease, which was followed by an approval by the EU Commission in January 2015
- Exercised opt-in right for Elocta
- Marketing Authorisation Application (MAA) for Elocta filed and validated for review by European Medicines Agency (EMA)
- Orfadin approved in Japan

# Financial Highlights Q4 2014 (Q4 2013)

- Total revenues were SEK 705.3 M (610.8)
- Product revenues were SEK 575.3 M (448.0)
- Gross margin was 60 per cent (59)
- EBITA was SEK 38.2 M (65.2)
- EBITA excluding write-downs (Multiferon) was SEK 63.4 M (65.2)

# Financial Highlights FY 2014 (FY 2013)

- Total revenues were SEK 2,607.0 M (2,176.7)
- Product revenues were SEK 1,988.8 M (1,557.7)
- Gross margin was 59 per cent (59)
- EBITA was SEK -43.4 M (211.0)
- EBITA excluding write-downs (Kiobrina/Multiferon) was SEK 306.7 M (211.0)
- Ended the year with a cash position of SEK 519.1 M (445.1). The
  decisions to add XTEN to the company's collaboration with Biogen
  Idec and to exercise the opt-in right for Elocta impacted the cashflow by SEK -124.7 M.

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

- Total revenues were USD 380.2 M (317.4)
- Product revenues were USD 290.0 M (227.1)
- EBITA was USD -6.3 M (30.8)
- Ended the quarter with a cash position of USD 66.5 M

<sup>\*</sup>The statement is a non-IFRS statement. For the Income Statement we have used an exchange rate of 6.8577 (average rate for the period) and for the Balance Sheet 7.8117 (closing rate for the period)



## **Business Review Q4 2014**

Received positive opinion by the CHMP regarding Xiapex for the treatment of Peyronie's disease

The CHMP of the EMA adopted a positive opinion for the use of Xiapex for the treatment of adult men with Peyronie's disease.

### **Exercised opt-in right for Elocta**

The company decided to exercise its opt-in right to take over final development and commercialisation of Elocta (the European trade name for rFVIIIFc which is also known as Eloctate) for the territory essentially composed of Europe, North Africa, Russia and most Middle Eastern markets. Elocta is a recombinant factor VIII Fc fusion protein product candidate for the treatment of haemophilia A. Sobi has made a payment to Biogen Idec of USD 10 million, which will be held in escrow pending the EU regulatory approval of Elocta. For more information see note 4.

MAA for Elocta filed and validated for review by EMA Sobi's partner Biogen Idec submitted a MAA for Elocta to EMA. The EMA subsequently validated the MAA of Elocta. The validation of the MAA initiates the EMA's review process.

## Orfadin approved in Japan

Orfadin was approved in Japan in December, triggering a milestone payment from Sobi's distribution partner Astellas of SEK 4.8 M.



## **Financial Review Q4 and FY**

Total revenues were SEK 705.3 M (610.8), an increase of 15 per cent. The increase at constant exchange rates was 9 per cent.

Full year revenues were SEK 2,607.0 M (2,176.7), an increase of 20 per cent. The increase at constant exchange rates was 15 per cent.

#### **Key Therapeutic Areas**

Revenues for Key Therapeutic Areas were SEK 376.9 M (274.8), an increase of 37 per cent.

Full year revenues were SEK 1,306.6 M (1,012.0), an increase of 29 per cent.

## Inflammation

Revenue for Kineret was SEK 163.3 M (163.6), unchanged versus prior year. US sales in Q4 2013 were positively impacted by a change of wholesaler.

Full year revenue was SEK 609.3 M (561.7), an increase of 8 per cent. Growth was driven primarily by price in the US and volume in Europe

#### Genetics & Metabolism

Revenue for Orfadin was SEK 168.5 M (91.2), an increase of 85 per cent. The Q4 revenue includes a one-time milestone payment following the registration of Orfadin in Japan of SEK 4.8 M.

For the full year, revenue was SEK 547.9 M (365.9), an increase of 50 per cent. The increase is related to initiation <sup>1</sup>Constant Exchange Rate. of direct sales in North America in the second quarter in combination with continued growth in the Middle East, North Africa, and Russia.

## **Financial Summary**

	Q4	Q4		Full year	Full year	
Amounts in SEK M	2014	2013	Change	2014	2013	Change
Total revenues	705.3	610.8	15%	2,607.0	2,176.7	20%
Gross profit	426.6	358.3	19%	1,547.8	1,284.0	21%
Gross margin	60%	59%	-	59%	59%	-
EBITA <sup>1</sup>	38.2	65.2	-41%	-43.4	211.0	<-100%
EBITA excluding write-offs	63.4	65.2	-3%	306.7	211.0	45%
EBIT (Operating profit/loss)	-32.7	-4.9	<-100%	-325.0	-66.6	<-100%
Profit/loss for the period	-17.4	-13.4	-30%	-267.8	-93.0	<-100%

<sup>&</sup>lt;sup>1</sup> 2014 FY includes write-offs relating to Kiobrina of SEK 324.9 M and Multiferon of SEK 25.2 M. Multiferon is also included in the quarter.

## **Revenues by Business Line**

	Q4	Q4	Change	Change %	Full year	Full year	Change	Change %
Amounts in SEK M	2014	2013	%	at CER <sup>1</sup>	2014	2013	%	at CER <sup>1</sup>
Key Therapeutic Areas								
Inflammation: Kineret	163.3	163.6	0%	-9%	609.3	561.7	8%	3%
Genetics & Metabolism: Orfadin	168.5	91.2	85%	73%	547.9	365.9	50%	42%
Genetics & Metabolism: Other <sup>2</sup>	33.1	20.0	66%	58%	118.5	84.4	40%	33%
Haemophilia: Royalties <sup>3</sup>	12.0	0.0	n/a	n/a	30.9	0.0	n/a	n/a
Total	376.9	274.8	37%	27%	1,306.6	1,012.0	29%	22%
Partner Products	198.4	173.2	15%	9%	682.2	545.7	25%	21%
ReFacto								
Manufacturing revenues	98.9	146.4	-32%	-32%	465.9	491.9	-5%	-5%
Royalty revenues	31.1	16.4	90%	73%	152.2	127.1	20%	14%
Total	130.0	162.8	-20%	-22%	618.2	619.0	0%	-1%
Total revenues	705.3	610.8	15%	9%	2,607.0	2,176.7	20%	15%
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<sup>&</sup>lt;sup>2</sup> Includes a one-time milestone payment for the approval of Orfadin in Japan.

<sup>&</sup>lt;sup>3</sup> Royalties on commercial sales, Biogen Idec. Note that YTD includes a one-time milestone payment.



## Haemophilia

Revenue for the Haemophilia franchise was SEK 12.0 M (0) representing royalties equal to 2 per cent from the sales of Eloctate and Alprolix in Biogen Idec territories during the fourth quarter.

For the full year, revenue was SEK 30.9 M (0) including a milestone payment to Sobi of SEK 10.7 M.

#### **Partner Products**

Revenue for Partner Products was SEK 198.4 M (173.2), an increase of 15 per cent.

Full year revenue was SEK 682.2 M (545.7), an increase of 25 per cent. The increase was driven by new partnerships and by growth of the base portfolio.

#### ReFacto

ReFacto manufacturing revenues and royalty were SEK 130.0 M (162.8), a decrease of 20 per cent. Manufacturing revenue was SEK 98.9 M (146.4). Q4 last year included validation batches of SEK 43.0 M. Royalty revenue was SEK 31.1 M (16.4).

Full year revenues related to ReFacto manufacturing and royalty were SEK 618.2 M (619.0), unchanged versus prior year. Manufacturing revenue was SEK 465.9 M (491.9). 2013 revenue included validation batches of SEK 65.8 M. Royalty revenue was SEK 152.2 M (127.1).

## Gross profit Q4 and FY

Gross profit for the fourth quarter was SEK 426.6 M (358.3), equivalent to a gross margin of 60 per cent (59).

For the full year, gross profit was SEK 1,547.8 M (1,284.0), equal to a gross margin of 59 per cent (59).

## **Operating Profit/Loss**

Q4	Q4	Full year	Full year
2014	2013	2014	2013
705.3	610.8	2,607.0	2,176.7
-278.7	-252.5	-1,059.2	-892.7
426.6	358.3	1,547.8	1,284.0
60%	59%	59%	59%
-213.7	-192.2	-749.9	-620.7
-149.3	-102.4	-500.5	-455.7
-363.0	-294.6	-1,250.4	-1,076.4
-25.4	1.5	-340.8	3.4
38.2	65.2	-43.4	211.0
-70.9	-70.1	-281.6	-277.6
-70.9	-70.1	-281.6	-277.6
-32.7	-4.9	-325.0	-66.6
	2014 705.3 -278.7 426.6 60% -213.7 -149.3 -363.0 -25.4 38.2 -70.9 -70.9	2014       2013         705.3       610.8         -278.7       -252.5         426.6       358.3         60%       59%         -213.7       -192.2         -149.3       -102.4         -363.0       -294.6         -25.4       1.5         38.2       65.2         -70.9       -70.1         -70.9       -70.1	2014         2013         2014           705.3         610.8         2,607.0           -278.7         -252.5         -1,059.2           426.6         358.3         1,547.8           60%         59%         59%           -213.7         -192.2         -749.9           -149.3         -102.4         -500.5           -363.0         -294.6         -1,250.4           -25.4         1.5         -340.8           38.2         65.2         -43.4           -70.9         -70.1         -281.6           -70.9         -70.1         -281.6

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

## Operating profit Q4

Overall operating expenses excluding amortisations and write-downs were SEK 363.0 M (294.6).

Operating expenses for sales and administration excluding amortisation amounted to SEK 213.7 M (192.2). The increase is due to staffing and preparation within the Haemophilia franchise and investments made in North American operations. Q4 costs were also impacted by unfavourable exchange rates of

approximately 5 per cent versus prior year.

Research and development costs excluding amortisation and write-downs were SEK 149.3 M (102.4). Increased investment mainly for Haemophilia launch preparations were partially offset by the discontinuation of the Kiobrina programme.

EBITA was SEK 38.2 M (65.2). 2014 includes one-time write-down for Multiferon of SEK 25.2 M, with a minor cash-flow effect.



Amortisation of intangible assets amounted to SEK 70.9 M (70.1).

EBIT (operating profit) amounted to SEK -32.7 M (-4.9).

## **Operating profit FY**

Overall operating expenses excluding amortisations and write-downs were SEK 1,250.4 M (1,076.4).

Operating expenses for sales and administration excluding amortisation amounted to SEK 749.9 M (620.7). The increase relates to additional resources in marketing, medical and patient access to support the current portfolio and to prepare for the planned launch of the haemophilia programmes, and increased investments in the North American operations. There was also an unfavourable exchange rate impact of about 4 per cent versus prior year, driven by the Euro and USD.

Research and development costs excluding amortisation and write-downs were SEK 500.5 M (455.7), reflecting the discontinuation of the Kiobrina programme and preparation of the expected launch of the Elocta.

The operating expenses were affected by costs relating to the long-term incentive programs of SEK 51 M. There is no cash flow impact of these programmes.

EBITA was SEK -43.4 M (211.0). 2014 includes one-time write-downs for Kiobrina of SEK 324.9 M and for Multiferon of SEK 25.2 M.

Amortisation of intangible assets amounted to SEK 281.6 M (277.6).

EBIT (operating profit) amounted to SEK -325.0 M (-66.6).

## Net financial items and tax for Q4 and FY

Net financial items amounted to SEK 10.1 M (-6.0), including exchange gains of SEK 24.1 M (7.0). Tax amounted to SEK 5.2 M (-2.5).

Net financial items for the full year amounted to SEK 6.4 M (-56.9), including exchange gains of SEK 62.6 M Cash flow from investing activities amounted to (1.0). Tax amounted to SEK 50.8 M (30.5). SEK -183.5 M (-404.6). As for the fourth quarter

## Profit/loss for Q4 and FY

The loss amounted to SEK -17.4 M (-13.4), and earnings per share was SEK -0.07 (-0.05).

For the full year the loss amounted to SEK -267.8 M (-93.0), and earnings per share was SEK -1.01 (-0.35).

#### Cash flow and investments Q4

Cash flow from operations before changes in working capital amounted to SEK 113.3 M (53.0).

Working capital impacted cash flow by SEK -60.7 M (-48.9).

Cash flow from investing activities amounted to SEK -147.1 M (-15.5). The decision to exercise Sobi's optin right to take over final development and commercialisation of Elocta in Sobi's territories and the election to add the XTEN programme to the company's collaboration with Biogen Idec was the largest investments during the quarter.

#### Cash flow and investments FY

Cash flow from operations before changes in working capital amounted to SEK 299.4 M (165.5), reflecting better results for the company, adjusted for write-downs of non-cash items.

Working capital impacted cash flow by SEK -65.7 M (19.9).

Cash flow from investing activities amounted to SEK -183.5 M (-404.6). As for the fourth quarter the largest investments during the year relate to the XTEN programme and the opt-in for Elocta.

#### Cash

Cash position at quarter end was SEK 519.1 M, compared to SEK 445.1 M as of 31 December 2013.

#### **Net Debt**

Sobi ended the quarter with a net debt of SEK 298.4 M, compared to SEK 352.5 M as of 31 December 2013.

## Equity

Consolidated shareholders' equity as of 31 December 2014 amounted to SEK 4,522.9 M compared to SEK 4,769.2 M as of 31 December 2013.

## **Parent Company**

Net sales in 2014 for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 2,328.3 M (1,841.9), of which SEK 963.8 M (629.9) referred to sales to Group companies. Income after financial items amounted to SEK 58.6 M (-43.7). Investments in tangible and intangible assets amounted to SEK 176.5 M (403.2).



#### Outlook 2015

For 2015, Sobi expects total revenues for the full year to be in the range of SEK 2,800 to 3,000 M, and gross margin to be in the range of 58-60 percent.

Operating costs are projected to increase as the company continues to prepare for the planned launch of Elocta. Sobi expects EBITA to be in line with the adjusted 2014 level.

The outlook for 2015 is based on current exchange rates, and excludes revenue from the European launch of Elocta.

## Other Information

#### Personnel

As of December 2014, the number of full-time equivalents in personnel was 584 (540).

As of 1 October Kirsti Gjellan officially took on the responsibility of Senior Vice President, Head of Manufacturing Operations as part of the Executive Leadership Team.

## Significant events after the reporting period

- Sobi announced that the company's agreement with Exelixis, Inc. regarding the commercialisation and distribution of Cometriq has been restructured and extended to 31 December 2019. The companies established the collaboration in February 2013, which was initially structured to expire 31 December 2015.
- The EU Commission approved Xiapex for the treatment of adult men with Peyronie's disease.

The Nomination Committee will in due time before the AGM 2015 prepare further proposals, including proposals for the Chairman of the AGM, Board members, remuneration for Board members and auditor, and to the extent deemed necessary, tasks for and the composition of the Nomination Committee for the AGM in 2016.

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

Geoffrey McDonough CEO and President

Solna, Sweden, 19 February 2015

## **Annual general Meeting 2015**

The Annual General Meeting (AGM) of Swedish Orphan Biovitrum AB (publ) will be held on Wednesday, 6 May 2015, at 4 pm, at Näringlivets Hus, Stockholm, Sweden.

The Board of Directors propose that no dividend will be paid for the 2014 financial year.

The Annual Report for 2014 will be published on www.sobi.com three weeks before the AGM. It will also be available at Sobi's headquarter in Solna.

#### 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.



# **Financial Statements**

**Group Statement of Comprehensive Income** 

	Q4	Q4	Full year	Full year
Amounts in SEK M	2014	2013	2014	2013
Total revenues	705.3	610.8	2,607.0	2,176.7
Total cost of goods and services sold	-278.7	-252.5	-1,059.2	-892.7
Gross profit	426.6	358.3	1,547.8	1,284.0
Sales and administration expenses	-284.6	-262.3	-1,031.5	-898.3
Research and development expenses	-149.3	-102.4	-500.5	-455.7
Other operating revenues/expenses	-25.4	1.5	-340.8	3.4
Operating profit/loss	-32.7	-4.9	-325.0	-66.6
Financial income/expenses	10.1	-6.0	6.4	-56.9
Income tax benefit/expense	5.2	-2.5	50.8	30.5
Profit/loss for the period	-17.4	-13.4	-267.8	-93.0
All earnings are attributable to parent company shareholders				
Other comprehensive income				
Items that will not be reclassified to profit/loss				
Remeasurements of post employment benefit obligations	-0.8	-1.5	0.8	2.0
Items that may be reclassified subsequently to profit/loss				
Translation difference	2.3	0.8	3.8	0.5
Cash flow hedge (net of tax)	1.3	-3.1	0.6	1.9
Comprehensive income for the period	-14.6	-17.2	-262.6	-88.6
Amortisation and write-down of intangible assets included in Sales and				
administration expenses	-70.9	-70.1	-281.6	-277.6
	-0.07			-0.35



Full year

4,837.9

13.2

-88.6

4,769.2

6.7

Full year

4,769.2

16.3

-262.6

4,522.9

	D		 D	
Balance sheet				<b>Changes in Equity</b>
Group				Group

Balance Sirect						Changes in Equity
	Dec	Sep	Jun	Mar	Dec	
Amounts in SEK M	2014	2014	2014	2014	2013	Amounts in SEK M
ASSETS						Opening balance
Non-current assets						Sharebased compensation to employees
Intangible fixed assets <sup>1</sup>	4,247.5	4,231.0	4,240.5	4,302.7	4,637.0	Transfer of own shares
Tangible fixed assets	115.2	115.8	118.2	120.1	125.7	
Financial fixed assets	72.8	67.4	43.2	38.9	26.4	Equity, end of period
Total non-current assets	4,435.5	4,414.2	4,401.9	4,461.7	4,789.1	•
Current assets						
Inventories	763.9	725.5	728.9	678.4	726.0	
Accounts receivable	480.0	451.1	447.7	376.6	414.5	
Current receivables, non-interest bearing	172.2	168.6	164.3	133.4	144.6	
Cash and cash equivalents	519.1	611.3	503.2	573.7	445.1	
Total current assets	1,935.2	1,956.5	1,844.1	1,762.1	1,730.2	
Total assets	6,370.7	6,370.7	6,246.0	6,223.8	6,519.3	
EQUITY AND LIABILITIES						
Shareholders' equity	4,522.9	4,532.9	4,475.4	4,443.1	4,769.2	
Long-term liabilities						
Long-term debt	815.8	815.4	814.8	794.0	795.7	
Long-term liabilities, non-interest bearing	285.1	292.2	269.8	274.2	306.9	_
Total long-term liabilities	1,100.9	1,107.6	1,084.6	1,068.2	1,102.6	
Current liabilities						
Short term debt	1.7	1.7	1.9	1.8	1.9	
Current liabilities, non-interest bearing	745.2	728.5	684.1	710.7	645.6	
Total short-term liabilities	746.9	730.2	686.0	712.5	647.5	
Total equity and liabilities	6,370.7	6,370.7	6,246.0	6,223.8	6,519.3	

 $<sup>^{\</sup>rm 1}$  Including goodwill MSEK 1,554.2, as per 31 December 2014



Group
Cash Flow Statement

Cash Flow Statement				
	Q4	Q4	Full year	Full year
Amounts in SEK M	2014	2013	2014	2013
Net result	-17.4	-13.4	-267.8	-93.0
Non-cash items <sup>1</sup>	130.7	66.4	567.2	258.5
Cash flow from operations before change in working capital	113.3	53.0	299.4	165.5
Change in working capital	-60.7	-48.9	-65.7	19.9
Cash flow from operations	52.6	4.1	233.7	185.4
Investment in intangible fixed assets	-138.1	-6.5	-160.3	-384.2
Investment in tangible fixed assets	-8.5	-9.2	-22.9	-26.0
Divestment of tangible fixed assets	_	0.2	_	0.2
Investment/Divestment of financial assets	-0.5	_	-0.3	2.5
Short-term investments	_	_	_	2.9
Cash flow from investing activities	-147.1	-15.5	-183.5	-404.6
Loans - Raising/Amortization	_	_	20.0	200.0
Transfer of own shares	_	6.7	_	6.7
Cash flow from financing activities	-	6.7	20.0	206.7
Net change in cash	-94.5	-4.7	70.2	-12.5
Liquid funds at the beginning of the period	611.3	449.3	445.1	457.0
Translation difference in cash flow and liquid funds	2.3	0.5	3.8	0.6
Liquid funds at the end of the period	519.1	445.1	519.1	445.1
<sup>1</sup> Depreciations, amortization, deferred tax and other:				
Depreciation tangible fixed assets	8.2	7.7	31.7	30.1
Amortization intangible assets	70.9	70.1	281.6	277.6
Deferred tax	-12.6	-8.2	-71.2	-44.9
Other, whereof Kiobrina write-off amounts to SEK 268.3 M in full year.	64.2	-3.2	325.1	-4.3



# **Key Ratios and Other Information**

	Q4	Q4	Full year	Full year
Amounts in SEK M	2014	2013	2014	2013
Profit numbers				
Gross profit	426.6	358.3	1,547.8	1,284.0
EBITDA	46.4	72.9	-11.7	241.1
EBITA	38.2	65.2	-43.4	211.0
EBIT	-32.7	-4.9	-325.0	-66.6
Profit/loss	-17.4	-13.4	-267.8	-93.0
Per share data (SEK)				
Earning/loss per share	-0.07	-0.05	-1.01	-0.35
Earning/loss per share after dilution	-0.07	-0.05	-1.01	-0.35
Shareholders' equity per share	16.7	17.6	16.7	17.6
Shareholders' equity per share after dilution	16.7	17.6	16.7	17.6
Other information				
Gross margin	60%	59%	59%	59%
Equity ratio	71.0%	73.2%	71.0%	73.2%
Net debt	298.4	352.5	298.4	352.5
Number of ordinary shares	270,389,770	270,389,770	270,389,770	270,389,770
Number of C-shares (in treasury)	396,180	_	396,180	_
Number of ordinary shares (in treasury)	3,674,140	4,688,948	3,674,140	4,688,948
Average number of ordinary shares (excluding shares in treasury)	266,636,545	265,384,673	266,158,798	265,266,117
Number of shares after dilution	270,389,770	270,389,770	270,389,770	270,389,770
Average number of ordinary shares after dilution (excluding shares in treasury)	266,636,545	265,384,673	266,158,798	265,266,117



Parent Company
Statement of Comprehensive Income

	Q4	Q4	Full year	Full year
Amounts in SEK M	2014	2013	2014	2013
Total revenues	591.6	483.6	2,328.3	1,841.9
Total cost of goods and services sold	-263.3	-249.7	-973.8	-889.9
Gross profit	328.3	233.9	1,354.5	952.0
Sales and Administration expenses	-181.9	-179.7	-623.7	-532.7
Research and Development expenses	-140.9	-95.5	-469.9	-450.6
Other operating revenues/expenses	-23.4	13.0	-64.1	13.4
Operating profit/loss	-17.9	-28.3	196.8	-17.9
Result from participation in Group companies <sup>1</sup>	-0.1	2.3	-174.7	2.3
Financial income/expenses	16.8	-1.4	36.5	-28.1
Profit/loss after financial items	-1.2	-27.4	58.6	-43.7
Group contribution	-158.8	_	-158.8	_
Income tax benefit/expenses	0.2	-0.1	-20.5	36.1
Profit/loss for the period	-159.8	-27.5	-120.7	-7.6
Other comprehensive income				
Items that may be reclassified subsequently to profit/loss				
Cash flow hedge (net of tax)	1.2	-3.2	0.5	1.9
Comprehensive income for the period	-158.6	-30.7	-120.2	-5.7
Amortization and write-down of intangible assets included in Sales & Adm				
expenses	-22.7	-22.0	-88.5	-85.0

 $<sup>^{\</sup>rm 1}$  2014 includes write-down in value of ownership of Arexis relating to Kiobrina, of SEK 177.4 M



## Parent Company Balance Sheet

	Dec	Sep	Jun	Mar	Dec
Amounts in SEK M	2014	2014	2014	2014	2013
ASSETS					
Non-current assets					
Intangible fixed assets	1,006.5	941.8	903.0	917.0	934.8
Tangible fixed assets	104.0	106.0	107.7	109.4	115.6
Financial fixed assets	3,918.8	3,918.2	3,917.8	3,916.4	4,096.1
Total non-current assets	5,029.3	4,966.0	4,928.5	4,942.8	5,146.5
Current assets					
Inventories	680.3	655.9	655.6	612.4	664.6
Current receivables, non-interest bearing	1,038.3	1,166.3	1,210.4	1,120.9	1,042.2
Cash and cash equivalents	392.4	517.4	431.8	512.5	373.5
Total current assets	2,111.0	2,339.6	2,297.8	2,245.8	2,080.3
Total assets	7,140.3	7,305.6	7,226.3	7,188.6	7,226.8
EQUITY AND LIABILITIES					
Shareholders' equity	5,510.4	5,664.6	5,580.2	5,511.2	5,621.6
Long-term liabilities					
Long-term debt	811.8	810.9	810.1	789.2	790.8
Total long-term liabilities	811.8	810.9	810.1	789.2	790.8
Current liabilities					
Current liabilities, non-interest bearing	818.1	830.1	836.0	888.2	814.4
Total short-term liabilities	818.1	830.1	836.0	888.2	814.4
Total equity and liabilities	7,140.3	7,305.6	7,226.3	7,188.6	7,226.8

# **Parent Company**

# Change in Shareholders' Equity

	Full year	Full Year
Amounts in SEK M	2014	2013
Opening balance	5,621.6	5,607.4
Sharebased compensation to employees	9.0	13.2
Transfer of shares	_	6.7
Comprehensive income for the period	-120.2	-5.7
Equity, end of period	5,510.4	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 October—December 2014 and year end has been prepared in accordance with the 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). There are no major changes in the Group's risk exposure and risk management in 2014.

#### 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). All derivatives are measured at fair value based on market data in accordance with IFRS. At 31 December 2014 the reported value in the balance sheet for the derivatives was SEK -8 M (-6).

As of 31 December 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 31 December 2014 the reported value in the balance sheet for the bond was SEK 792 M (791). Fair value of the bond is deemed to be SEK 838 M (848). The fair value is based on the average of the bid-ask-spread at the balance sheet date.

#### Note 3 – Transactions with Related Parties

In January 2014 the company prolonged its employment agreement with Bo Jesper Hansen, unrelated to his position as Chairman for the company. The new agreement entered into effect on 1 May 2014 and is valid until 1 May 2015.



# Note 4 – Contractual commitments for the acquisition of intangible assets

In October 2014 Sobi's partner Biogen Idec submitted a MAA to the EMA for Elocta (rFVIIIFc). The MAA filing with the EMA, together with the delivery of a data package from Biogen Idec to Sobi, triggered Sobi's exclusive optin right to assume final development and commercialisation of Elocta for the territory essentially composed of Europe, North Africa, Russia and most Middle Eastern markets.

On November 21, Sobi exercised its opt-in right and paid, in accordance with the agreement, a deposit of USD 10.0 million. The deposit has been recorded in the balance sheet as an advance payment under intangible assets.

Upon EU regulatory approval of Elocta, Sobi will be liable to reimburse Biogen Idec 50 percent of the sum of the manufacturing expenses for clinical supplies of the product, the development expenses for the product from 1 October 2009 through the date on which Sobi is registered as the Marketing Authorisation Holder or 90 days after receipt of approval and certain shared expenses for final regulatory approval, final development and commercialisation activities, and 100 percent of certain development expenses. Total reimbursement is estimated to be approximately USD 245 million.



# **Business Glossary**

## Alprolix (rFIXFc)

rFIXFc is a long-acting recombinant factor IX Fc fusion protein product candidate for people with haemophilia B. rFIXFc is also known as Alprolix [Coagulation Factor IX (Recombinant), Fc Fusion Protein], in the US, Canada, Australia, and Japan, where it is approved for the treatment of haemophilia B

#### **CAPS**

Cryopyrin-Associated Periodic Syndromes, CAPS, constitutes a group of rare autoinflammatory diseases with an incidence estimated to be 1:1,000,000 worldwide. CAPS is characterised by uncontrolled overproduction of Interleukin-1 (IL-1 which induces a number of inflammatory responses such as fevers, rash, joint pain, headaches, conjunctivitis and many other symptoms

#### ChondroCelect

A cell-based medicinal product for the repair of cartilage defects of the knee

#### **CHMP**

The Committee for Medicinal Products for Human at the European Medicines Agency, responsible for preparing opinions on questions concerning medicines for human use.

## Cometriq

Therapy for the treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma (MTC)

## **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

## Elocta (rFVIIIFc)

Elocta is a long-acting recombinant factor VIII Fc fusion protein product candidate in the EU for people with haemophilia A. Elocta is the trade name in Europe for rFVIIIFc, also known as Eloctate [Antihemophilic Factor (Recombinant), Fc Fusion Protein] in the US, Canada, Australia, and Japan, where it is approved for the treatment of haemophilia A. A MAA for Elocta is currently under review by the 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

#### **Kepivance**

Kepivance (palifermin) 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

#### MAA

Marketing Authorisation Application

#### 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

#### Peyronie's Disease

Peyronie's Disease (PD) is a condition that involves the development of collagen plaque, or scar tissue, on the shaft of the penis. The scar tissue, known as a Peyronie's plaque, may harden and reduce flexibility, which may cause bending or arching of the penis during erection



#### **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

#### Xiapex

Xiapex (collagenase clostridium histolyticum), is a pharmacological treatment for Peyronie's disease and Dupuytren's contracture and may be an alternative to invasive and often complicated surgery for patients

#### **XTEN**

XTEN is a DNA-based hydrophilic polymer that increases the hydrodynamic radius of target proteins with the goal of extending the half-life of those proteins

# **Financial Glossary**

#### CER

**Constant Exchange Rates** 

## Earnings/loss per share

Earnings/loss divided by the average number of shares

#### **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

#### **Product revenues**

Sobi revenues excluding ReFacto revenues

## Profit/loss

Profit/loss for the period

## Shareholders' equity per share

Shareholders' equity divided by the number of shares



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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 Haemophilia, Inflammation and Genetic diseases. We also market a portfolio of specialty and rare disease products for partner companies across Europe, Middle East, North Africa and Russia. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2014, Sobi had total revenues of SEK 2.6 billion (USD 380 M) and about 600 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>.