



 **sobi**  
Pioneer in Rare Diseases

*We've got a story to tell*

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## Financial Calendar

Q3 2015	29 October 2015
Q4 & FY 2015	25 February 2016



# CEO Statement

**The second quarter marks the end of a strong first half year, highlighted by the strength and momentum of Sobi's base business with solid growth across the portfolio, and by significant milestones for our long-acting Haemophilia franchise and for Orfadin®.**

## Strong base business

Total revenues in the second quarter were SEK 764 M, an increase of 15 per cent (4 per cent at constant exchange rates) over the prior year, gross margin was in line with our expectations, and cash flow increased compared to the same period last year.

Orfadin continues to grow, increasing by 35 per cent, following the initiation of direct sales in the US in 2014. This strategic shift has had a positive impact, with several new patients identified and treated over the past year.

Kineret® performed well across our markets with a growth of 15 per cent.

Partner Products increased 10 per cent compared to previous year driven by continued growth for Cometriq® and Xiapex®. We have initiated launch activities for the newly approved indication for Xiapex in Peyronie's Disease, which we expect will contribute to Xiapex sales going forward.

As expected, ReFacto® delivered slightly lower results in the quarter, down 8 per cent compared to the same period last year. Deliveries were unusually high in the first quarter this year.

## Important pipeline developments

Following the positive results of the Kids B-LONG study, Sobi's collaboration partner Biogen submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Alprolix® (rFIXFc). The file was subsequently validated by the EMA, initiating their review process. The MAA filing, coupled with the receipt of the opt-in data package from Biogen, has triggered the formal opt-in right for Sobi to exercise its option in accordance with the collaboration agreement with Biogen. Today, we announced that we have decided to exercise this right.

We continue to anticipate the EU approval and launch of Elocta™ (rFVIII Fc) in Q4 2015. We have a world-class launch-ready haemophilia team in place in our major markets and have completed most of the recruitment and training throughout our territory. We are actively participating in the medical, scientific, and patient association communities, and payer dialog is well underway as we prepare for pricing, reimbursement and patient access.

The European Commission approved the oral suspension formulation of Orfadin for the treatment of Hereditary Tyrosinaemia type-1 (HT-1), a rare genetic disease that affects infants and children. The approval will facilitate accurate dosing for infants and small children, and contribute to improving quality of life for patients and caregivers. We have also reinitiated the filing process with the US Food and Drug Administration (FDA) for this formulation.

We have terminated further development of SOBI002 based on the final evaluation of our Phase 1 trial. However, based on this data, we have identified another development candidate for the



inhibition of complement factor C5 and expect to bring this novel molecule into preclinical development.

I would like to thank our employees for their engagement and achievements during the first half of the year. Their hard work makes a difference in the lives of patients and their families every day. I would also like to thank shareholders for their interest and support for all we do here at Sobi. We realise that the recent speculation around our company has been an external distraction, but I can assure you that we are as devoted and focused as ever on building value through our diverse and growing portfolio.

Geoffrey McDonough  
CEO and President

Solna, Sweden, 16 July 2015

## Q2 in Summary

### Business Summary

- European Commission approved Orfadin oral suspension and 20 mg capsule
- Sobi's collaboration partner Biogen submitted the Marketing Authorisation Application for Alprolix (rFIXFc) in Europe
- New haemophilia data presented with 23 abstracts at the International Society on Thrombosis and Haemostasis (ISTH) 2015 congress
- The European Medicines Agency validated the Marketing Authorisation Application for Alprolix (rFIXFc)
- Received orphan drug designation for Elocta (rFVIII Fc) in Switzerland

### Financial Summary

- Total revenue was SEK 764 M (663), an increase of 15 per cent (4 per cent at CER)
- Product revenue was SEK 593 M (476), an increase of 25 per cent (12 per cent at CER)
- Gross margin was 63 per cent (61)
- EBITA was SEK 74 M (86)
- Ended the quarter with a cash position of SEK 763 M

### Financial Summary in USD<sup>1</sup>

- Total revenue was USD 91 M
- Product revenue was USD 71 M
- EBITA was USD 9 M
- Ended the quarter with a cash position of USD 91 M

<sup>1</sup>Exchange rate 1USD = 8.3781 SEK

## Business Review Q2

### **European Commission approved Orfadin oral suspension and 20 mg capsule**

The European Commission approved the oral suspension formulation of Orfadin for the treatment of Hereditary Tyrosinaemia type-1 (HT-1). The oral suspension of Orfadin will facilitate accurate dosing for infants and small children, and contribute to improving quality of life and patient outcomes.

In addition, a 20 mg capsule to facilitate treatment regimens that support adherence in adolescent and adult patients was also approved in the same period.

HT-1 is a rare genetic disease that affects infants and children. It is progressive and may result in liver and kidney failure and can be fatal if untreated.

### **Sobi's collaboration partner Biogen submitted the marketing authorisation application for Alprolix (rFIXFc) in Europe**

Biogen submitted a Marketing Authorisation Application (MAA) for Alprolix to the European Medicines Agency (EMA). Sobi has an opt-in right to assume final development and commercialisation of Alprolix in Europe, Russia, certain countries in the Middle East, and North Africa. The MAA filing with the EMA coupled with the receipt of the opt-in data package, triggered the formal opt-in right, for Sobi to exercise its option in accordance with the collaboration agreement.

### **New haemophilia data presented at International Society on Thrombosis and Haemostasis (ISTH) congress**

Sobi and collaboration partner Biogen presented 23 company-sponsored platform and poster presentations at the ISTH 2015 congress which took place in Toronto, Canada, 20-25 June 2015. The data presented included a presentation from the Kids B-LONG study detailing the safety and efficacy of Alprolix in children with haemophilia B. It was the first time full results from the Kids B-LONG study were publicly presented.

### **EMA validated the MAA for Alprolix**

Sobi and Biogen announced that the EMA accepted the MAA of Alprolix. The validation signified the initiation of EMA's review process.

### **Received orphan drug designation for Elocta (rFVIII Fc) in Switzerland**

Sobi received orphan drug designation in Switzerland for the long-acting haemophilia drug candidate Elocta for the treatment of haemophilia A. An orphan drug designation is granted to encourage the development of medicines for rare diseases.

# Financial Review Q2

## Key Therapeutic Areas

Revenue was SEK 418 M (317), an increase of 32 per cent (16 per cent at constant exchange rates).

### Inflammation

Revenue for Kineret was SEK 171 M (148), an increase of 15 per cent.

There was good volume growth across most European markets and US demand continues to be steady through the shift to a specialty distribution model.

### Genetics & Metabolism

Revenue for Orfadin was SEK 189 M (140), an increase of 35 per cent versus prior year.

Orfadin has continued to show good growth in all major markets.

In January 2015, Sobi initiated sales in South America with partner Innovative Medicines following the termination of the distribution agreement with RDT (Rare Disease Therapeutics, Inc.) for this territory. South American revenues have been positively impacted by the shift in our sales model.

### Haemophilia

Sobi has estimated revenue from royalties, equal to 2 per cent of the Biogen analyst consensus from 10 April 2015, to make an accrual of SEK 18 M (0) for expected sales of Eloctate and Alprolix in Biogen territories during the second quarter. Sobi will update this accrual when Biogen actuals are available later this month.

## Partner Products

Revenue for Partner Products was SEK 175 M (159), an increase of 10 per cent versus prior year. The increase was mainly driven by growth of Cometriq, Yondelis®, and Xiapex.

## ReFacto

ReFacto manufacturing revenues and royalty were SEK 172 M (187), a decrease of 8 per cent. Phasing effects are caused by unusually high deliveries in the first quarter 2015. Manufacturing revenue was SEK 99 M (134). Royalty revenue was SEK 73 M (53).

## Gross Profit

Gross profit for the second quarter was SEK 482 M (406), representing a gross margin of 63 per cent (61), due to product mix, favourable currency effects, and higher royalty revenues for ReFacto.

## Operating Expenses

Operating expenses excluding amortisations and write-offs were SEK 401 M (327).

Operating expenses for sales and administration excluding amortisations amounted to SEK 274 M (193). The increase reflects new employees hired to support the build-up of the Haemophilia organisation and the geographic expansion. Costs were impacted by unfavourable exchange rates increasing costs by approximately 7 per cent compared to prior year.

Research and development costs excluding amortisation and write-offs were SEK 127 M (133).

EBITA was SEK 74 M (86).

Amortisations of intangible assets amounted to SEK 72 M (70).

EBIT (operating profit) amounted to SEK 3 M (16).

## FINANCIAL SUMMARY

<i>Amounts in SEK M</i>	Q2 2015	Q2 2014	Change	H1 2015	H1 2014	Change	Full year 2014
Total revenues	764	663	15%	1,629	1,236	32%	2,607
Gross profit	482	406	19%	1,001	726	38%	1,548
Gross margin	63%	61%		61%	59%		59%
EBITA <sup>1</sup>	74	86	-14%	247	-202	>100%	-43
EBITA excluding write-offs	74	86	-14%	247	123	100%	307
EBIT (Operating profit/loss)	3	16	-83%	105	-342	>100%	-325
Profit/loss for the period	9	26	-66%	115	-303	>100%	-268

<sup>1</sup> H1 2014 includes write-offs relating to Kiobrina of SEK 325 M in Q1

### Net financial items and tax

Net financial items amounted to SEK -17 M (3), including exchange rate losses (gains) of SEK -4 M (+17). Tax amounted to SEK 24 M (6).

### Profit

Profit was SEK 9 M (26).

### Cash flow and investments

Cash flow from operations before change in working capital amounted to SEK 71 M (101).

Working capital impacted cash flow by SEK 8 M (-178), due to decrease in inventory and receivables.

Cash flow from investing activities amounted to SEK -10 M (-14).

### Cash

Cash position at the end of quarter was SEK 763 M, compared to SEK 519 M as of 31 December 2014.

### Net Debt

Sobi ended the quarter with a net debt of SEK 57 M, compared to SEK 298 M as of 31 December 2014.

### Equity

Consolidated shareholders' equity as of 30 of June 2015 amounted to SEK 4,672 M compared to 4,523 M as of 31 December 2014.

### REVENUES BY BUSINESS LINE

<i>Amounts in SEK M</i>	Q2 2015	Q2 2014	Change %	Change % at CER <sup>1</sup>	H1 2015	H1 2014	Change %	Change % at CER <sup>1</sup>	FY 2014
<b>Key Therapeutic Areas</b>									
Inflammation: Kineret	171	148	15%	0%	369	272	36%	17%	609
Genetics & Metabolism: Orfadin	189	140	35%	19%	369	216	71%	52%	548
Genetics & Metabolism: Other	40	29	38%	33%	76	59	28%	21%	118
Haemophilia: Royalties <sup>2</sup>	18	0	>100%	>100%	35	11	>100%	>100%	31
<b>Total</b>	<b>418</b>	<b>317</b>	<b>32%</b>	<b>16%</b>	<b>848</b>	<b>558</b>	<b>52%</b>	<b>34%</b>	<b>1,307</b>
<b>Partner Products<sup>3</sup></b>	<b>175</b>	<b>159</b>	<b>10%</b>	<b>3%</b>	<b>376</b>	<b>324</b>	<b>16%</b>	<b>9%</b>	<b>682</b>
<b>ReFacto</b>									
Manufacturing revenues	99	134	-26%	-26%	306	275	11%	11%	466
Royalty revenues	73	53	37%	7%	98	79	23%	-7%	152
<b>Total</b>	<b>172</b>	<b>187</b>	<b>-8%</b>	<b>-16%</b>	<b>404</b>	<b>355</b>	<b>14%</b>	<b>7%</b>	<b>618</b>
<b>Total revenues</b>	<b>764</b>	<b>663</b>	<b>15%</b>	<b>4%</b>	<b>1,629</b>	<b>1,236</b>	<b>32%</b>	<b>20%</b>	<b>2,607</b>

<sup>1</sup> Constant Exchange Rates.

<sup>2</sup> Royalties on commercial sales, Biogen. Note that H1 2014 includes a one-time milestone payment of SEK 11 M.

<sup>3</sup> H1 2015 includes a one-time revenue milestone for Cometriq of SEK 18 M.

### Parent Company

Net sales in Q2 2015 for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 720 M (567) of which SEK 331 M (213) referred to sales to Group companies. Income after financial items amounted to SEK 59 M (69). Investments in tangible and intangible assets amounted to SEK 7 M (13).

**Outlook 2015 - raised guidance**

Based on the results for the first two quarters 2015, Sobi now expects total revenues for the full year to be in the range of SEK 3,000 to 3,200 M (previously 2,800 to 3,000), and gross margin to be in the range of 59 to 61 per cent (previously 58 to 60 per cent).

Operating costs are projected to increase as the company continues to prepare for the planned launch of Elocta. Sobi expects EBITA to be in the range of SEK 325-400 M.<sup>1</sup>

The outlook excludes revenue from the potential European launch of Elocta.

<b>OPERATING PROFIT/LOSS</b>					
<i>Amounts in SEK M</i>	<b>Q2 2015</b>	<b>Q2 2014</b>	<b>H1 2015</b>	<b>H1 2014</b>	<b>Full year 2014</b>
Total revenues	764	663	1,629	1,236	2,607
Total cost of goods and services sold	-282	-256	-628	-510	-1,059
<b>Gross profit</b>	<b>482</b>	<b>406</b>	<b>1,001</b>	<b>726</b>	<b>1,548</b>
<i>Gross Margin</i>	63%	61%	61%	59%	59%
Sales and administration expenses less amortisations and write-downs	-274	-193	-493	-349	-750
Research and development expenses less amortisations and write-downs	-127	-133	-259	-260	-501
<b>Total opex less amortisations and write-downs</b>	<b>-401</b>	<b>-327</b>	<b>-751</b>	<b>-609</b>	<b>-1,250</b>
<b>Other operating revenues/expenses</b>	<b>-7</b>	<b>7</b>	<b>-3</b>	<b>-318</b>	<b>-341</b>
<b>EBITA</b>	<b>74</b>	<b>86</b>	<b>247</b>	<b>-202</b>	<b>-43</b>
Amortisations and write-downs relating to sales and administration expenses	-72	-70	-142	-141	-282
<b>Amortisations and write-downs</b>	<b>-72</b>	<b>-70</b>	<b>-142</b>	<b>-141</b>	<b>-282</b>
<b>EBIT</b>	<b>3</b>	<b>16</b>	<b>105</b>	<b>-342</b>	<b>-325</b>

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

<sup>1</sup>The original outlook presented on 19 February 2015 stated that "Sobi expects EBITA to be in line with the adjusted 2014 level".



## Other Information

### Personnel

As of June 2015, the number of full-time equivalents in personnel was 648 (584, December 2014).

### Significant events after the reporting period

#### Exercised opt-in right for Alprolix

Sobi announced that the company has decided to exercise its opt-in right to take over final development and commercialisation of Alprolix (rFIXFc) for the territory composed of Europe, North Africa, Russia and most Middle Eastern markets. Sobi will make a payment to Biogen of USD 10 M, which will be held in escrow pending the EU regulatory approval of Alprolix.

#### 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.*

The Board of Directors and the CEO of Swedish Orphan Biovitrum AB (publ) provide their assurance that the interim report provides a fair and true overview of the Parent Company's and the Group's operations, financial position and results, and describes material risks and uncertainties faced by the parent Company and the companies in the Group. See under the heading "Accounting and valuation principles and in other information" for a description of the operational risks.

Stockholm, 16 July 2015

Bo Jesper Hansen  
Chairman of the Board

Lennart Johansson  
Board member

Adine Grate Axén  
Board member

Annette Clancy  
Board member

Matthew Gantz  
Board member

Helena Saxon  
Board member

Hans GCP Schikan  
Board member

Hans Wigzell  
Board member

Catarina Larsson  
Employee representative

Bo-Gunnar Rosenbrand  
Employee representative

Geoffrey McDonough  
President and CEO

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

# Financial Statements

<b>GROUP</b>					
<b>STATEMENT OF COMPREHENSIVE INCOME</b>					
<i>Amounts in SEK M</i>	<b>Q2 2015</b>	<b>Q2 2014</b>	<b>H1 2015</b>	<b>H1 2014</b>	<b>FY 2014</b>
Total revenues	764	663	1,629	1,236	2,607
Total cost of goods and services sold	-282	-256	-628	-510	-1,059
<b>Gross profit</b>	<b>482</b>	<b>406</b>	<b>1,001</b>	<b>726</b>	<b>1,548</b>
Sales and administration expenses	-346	-264	-635	-489	-1,032
Research and development expenses	-127	-133	-259	-260	-501
Other operating revenues/expenses	-7	7	-3	-318	-341
<b>Operating profit/loss</b>	<b>3</b>	<b>16</b>	<b>105</b>	<b>-342</b>	<b>-325</b>
Financial income/expenses	-17	3	-19	-11	6
Income tax benefit/expense	24	6	29	49	51
<b>Profit/loss for the period</b>	<b>9</b>	<b>26</b>	<b>115</b>	<b>-303</b>	<b>-268</b>
<i>All earnings are attributable to parent company shareholders</i>					
<b>Other comprehensive income</b>					
<i>Items that will not be reclassified to profit/loss</i>					
Re-measurements of post employment benefit obligations	-1	2	-1	2	1
<i>Items that may be reclassified subsequently to profit/loss</i>					
Translation difference	0	1	0	1	4
Cash flow hedge (net of tax)	3	0	4	-1	1
<b>Comprehensive income for the period</b>	<b>11</b>	<b>28</b>	<b>118</b>	<b>-302</b>	<b>-263</b>
Amortisation and write-down of intangible assets	-72	-70	-142	-141	-282
Earning/loss per share before and after dilution	0.03	0.10	0.43	-1.14	-1.01

<b>GROUP BALANCE SHEET</b>					
<i>Amounts in SEK M</i>	Jun 2015	Mar 2015	Dec 2014	Sep 2014	Jun 2014
<b>ASSETS</b>					
<b>Non-current assets</b>					
Intangible fixed assets <sup>1</sup>	4,128	4,192	4,248	4,231	4,241
Tangible fixed assets	107	110	115	116	118
Financial fixed assets	92	79	73	67	43
<b>Total non-current assets</b>	<b>4,327</b>	<b>4,380</b>	<b>4,436</b>	<b>4,414</b>	<b>4,402</b>
<b>Current assets</b>					
Inventories	742	765	764	726	729
Accounts receivable	523	647	480	451	448
Current receivables, non-interest bearing	194	133	172	169	164
Cash and cash equivalents	763	682	519	611	503
<b>Total current assets</b>	<b>2,222</b>	<b>2,226</b>	<b>1,935</b>	<b>1,957</b>	<b>1,844</b>
<b>Total assets</b>	<b>6,549</b>	<b>6,606</b>	<b>6,371</b>	<b>6,371</b>	<b>6,246</b>
<b>EQUITY AND LIABILITIES</b>					
<b>Shareholders' equity</b>					
<b>Long-term liabilities</b>					
Long-term debt	819	817	816	815	815
Long-term liabilities, non-interest bearing	274	282	285	292	270
<b>Total long-term liabilities</b>	<b>1,093</b>	<b>1,099</b>	<b>1,101</b>	<b>1,108</b>	<b>1,085</b>
<b>Current liabilities</b>					
Short term debt	2	2	2	2	2
Current liabilities, non-interest bearing	783	861	745	729	684
<b>Total short-term liabilities</b>	<b>784</b>	<b>862</b>	<b>747</b>	<b>730</b>	<b>686</b>
<b>Total equity and liabilities</b>	<b>6,549</b>	<b>6,606</b>	<b>6,371</b>	<b>6,371</b>	<b>6,246</b>

<sup>1</sup> Including goodwill SEK 1,554 M, as per 30 June 2015

<b>GROUP CHANGES IN EQUITY</b>			
<i>Amounts in SEK M</i>	Jan - Jun 2015	Jan - Jun 2014	Full year 2014
<b>Opening balance</b>	<b>4,523</b>	<b>4,769</b>	<b>4,769</b>
Share-based compensation to employees	9	8	16
Transfer of own shares	22	–	–
Comprehensive income for the period	118	-302	-263
<b>Equity, end of period</b>	<b>4,672</b>	<b>4,475</b>	<b>4,523</b>

<b>GROUP</b>					
<b>CASH FLOW STATEMENT</b>					
<i>Amounts in SEK M</i>	<b>Q2 2015</b>	<b>Q2 2014</b>	<b>H1 2015</b>	<b>H1 2014</b>	<b>Full year 2014</b>
Net result	9	26	115	-303	-268
Non-cash items <sup>1</sup>	63	75	138	406	567
<b>Cash flow from operations before change in working capital</b>	<b>71</b>	<b>101</b>	<b>252</b>	<b>103</b>	<b>299</b>
Change in working capital	8	-178	-4	-46	-66
<b>Cash flow from operations</b>	<b>79</b>	<b>-78</b>	<b>249</b>	<b>57</b>	<b>234</b>
Investment in intangible fixed assets	-4	-8	-19	-12	-160
Investment in tangible fixed assets	-7	-6	-9	-9	-23
Divestment of tangible fixed assets	1	0	1	1	-
<b>Cash flow from investing activities</b>	<b>-10</b>	<b>-14</b>	<b>-27</b>	<b>-20</b>	<b>-184</b>
Loans - Raising/Amortization	-	20	-	20	20
Transfer of own shares	12	-	22	-	-
<b>Cash flow from financing activities</b>	<b>12</b>	<b>20</b>	<b>22</b>	<b>20</b>	<b>20</b>
<b>Net change in cash</b>	<b>81</b>	<b>-72</b>	<b>244</b>	<b>57</b>	<b>70</b>
Liquid funds at the beginning of the period	682	574	519	445	445
Translation difference in cash flow and liquid funds	0	1	0	1	4
<b>Liquid funds at the end of the period</b>	<b>763</b>	<b>503</b>	<b>763</b>	<b>503</b>	<b>519</b>
<sup>1</sup> <b>Depreciations, amortization, deferred tax and other:</b>					
Depreciation tangible fixed assets	8	8	16	16	32
Amortization intangible assets	72	70	142	141	282
Deferred tax	-23	-12	-31	-57	-71
Other, whereof Kiobrina write-off amounts to SEK 268 M in 2014.	6	9	11	307	325



<b>GROUP</b>					
<b>KEY RATIOS AND OTHER INFORMATION</b>					
<i>Amounts in SEK M</i>	<b>Q2 2015</b>	<b>Q2 2014</b>	<b>H1 2015</b>	<b>H1 2014</b>	<b>Full year 2014</b>
<b>Profit numbers</b>					
Gross profit	482	406	1,001	726	1,548
EBITDA	83	94	263	-186	-12
EBITA	74	86	247	-202	-43
EBIT	3	16	105	-342	-325
Profit/loss	9	26	115	-303	-268
<b>Per share data (SEK)</b>					
Earning/loss per share	0.03	0.10	0.43	-1.14	-1.01
Earning/loss per share after dilution	0.03	0.10	0.43	-1.14	-1.01
Shareholders' equity per share	17.3	16.8	17.3	16.8	16.7
Shareholders' equity per share after dilution	17.3	16.8	17.3	16.8	16.7
<b>Other information</b>					
Gross margin	63%	61%	61%	59%	59%
Equity ratio	71%	72%	71%	72%	71%
Net debt	57	314	57	314	298
Number of ordinary shares	270,389,770	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)	2,848,980	4,688,948	2,848,980	4,688,948	4,688,948
Average number of ordinary shares	267,075,422	265,700,822	266,959,080	265,700,822	265,993,723
Number of shares after dilution	270,389,770	270,389,770	270,389,770	270,389,770	270,389,770
Average number of ordinary shares after dilution	267,075,422	265,700,822	266,959,080	265,700,822	265,993,723

<b>PARENT COMPANY</b>					
<b>STATEMENT OF COMPREHENSIVE INCOME</b>					
<i>Amounts in SEK M</i>	<b>Q2 2015</b>	<b>Q2 2014</b>	<b>H1 2015</b>	<b>H1 2014</b>	<b>Full year 2014</b>
Total revenues	720	567	1,444	1,192	2,328
Total cost of goods and services sold	-318	-240	-600	-480	-974
<b>Gross profit</b>	<b>402</b>	<b>327</b>	<b>844</b>	<b>712</b>	<b>1,355</b>
Sales and Administration expenses	-209	-155	-354	-280	-624
Research and Development expenses	-117	-123	-242	-241	-470
Other operating revenues/expenses	-6	8	-5	-47	-64
<b>Operating profit/loss</b>	<b>70</b>	<b>57</b>	<b>243</b>	<b>144</b>	<b>197</b>
Result from participation in Group companies <sup>1</sup>	-	-	-	-177	-175
Financial income/expenses	-11	11	-5	5	37
<b>Profit/loss after financial items</b>	<b>59</b>	<b>68</b>	<b>238</b>	<b>-27</b>	<b>59</b>
Group contribution	-	-	-	-	-159
Income tax benefit/expenses	-	-3	-6	-21	-21
<b>Profit/loss for the period</b>	<b>59</b>	<b>65</b>	<b>232</b>	<b>-48</b>	<b>-121</b>
<b>Other comprehensive income</b>					
<i>Items that may be reclassified subsequently to profit/loss</i>					
Cash flow hedge (net of tax)	2	0	4	-1	1
<b>Comprehensive income for the period</b>	<b>61</b>	<b>65</b>	<b>236</b>	<b>-49</b>	<b>-120</b>
Amortization and write-down of intangible assets included in Sales & Adm expenses	-24	-22	-46	-44	-89

<sup>1</sup> 2014 includes write-down in value of ownership of Arexis relating to Kiobrina of SEK 177 M

<b>PARENT COMPANY BALANCE SHEET</b>					
<i>Amounts in SEK M</i>	Jun 2015	Mar 2015	Dec 2014	Sep 2014	Jun 2014
<b>ASSETS</b>					
<i>Non-current assets</i>					
Intangible fixed assets	983	999	1,007	942	903
Tangible fixed assets	94	99	104	106	108
Financial fixed assets	3,912	3,914	3,919	3,918	3,918
<b>Total non-current assets</b>	<b>4,989</b>	<b>5,012</b>	<b>5,029</b>	<b>4,966</b>	<b>4,929</b>
<i>Current assets</i>					
Inventories	648	708	680	656	656
Current receivables, non-interest bearing	1,117	1,113	1,038	1,166	1,210
Cash and cash equivalents	665	578	392	517	432
<b>Total current assets</b>	<b>2,430</b>	<b>2,399</b>	<b>2,111</b>	<b>2,340</b>	<b>2,298</b>
<b>Total assets</b>	<b>7,419</b>	<b>7,411</b>	<b>7,140</b>	<b>7,306</b>	<b>7,226</b>
<b>EQUITY AND LIABILITIES</b>					
<i>Shareholders' equity</i>					
<i>Long-term liabilities</i>					
Long-term debt	814	813	812	811	810
<b>Total long-term liabilities</b>	<b>814</b>	<b>813</b>	<b>812</b>	<b>811</b>	<b>810</b>
<i>Current liabilities</i>					
Current liabilities, non-interest bearing	823	898	818	830	836
<b>Total short-term liabilities</b>	<b>823</b>	<b>898</b>	<b>818</b>	<b>830</b>	<b>836</b>
<b>Total equity and liabilities</b>	<b>7,419</b>	<b>7,411</b>	<b>7,140</b>	<b>7,306</b>	<b>7,226</b>

<b>PARENT COMPANY CHANGE IN SHAREHOLDERS' EQUITY</b>			
<i>Amounts in SEK M</i>	Jan-Jun 2015	Jan-Jun 2014	Full Year 2014
<b>Opening balance</b>	<b>5,510</b>	<b>5,622</b>	<b>5,622</b>
Share-based compensation to employees	14	8	9
Transfer of shares	22	–	–
Comprehensive income for the period	236	-49	-120
<b>Equity, end of period</b>	<b>5,782</b>	<b>5,580</b>	<b>5,510</b>

# 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 2015 have 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 2014 Annual Report. More detailed information about the Group's accounting and valuation principles can be found in the 2014 Annual Report which is available on [www.sobi.com](http://www.sobi.com).

### *Change in accounting principles*

From fiscal year 2015 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:

- Operational risks, 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.
- External risks such as patent infringements, competition within product concepts and decisions by authorities regarding product use and prices.
- 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 2014 Annual Report (see the Directors' Report). There are no major changes in the Group's risk exposure and risk management in 2015.

## Note 2 – Fair values of financial instruments

The group carries derivatives. Refer to the annual report 2014 for a narrative description of the purpose of the holdings. The derivatives (under the heading "current assets/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 30 June 2015 the reported value in the balance sheet for the derivatives was SEK 13 M (-7).

As of 30 June 2015 all other financial instruments in the balance sheet, with the exception of the group's bond, have reported values that are in all material aspects equivalent to fair value. At 30 June 2015 the reported value in the balance sheet for the bond was SEK 793 M (790). Fair value of the bond is deemed to be SEK 825 M (847). The fair value is based on the average of the bid-ask-spread at the balance sheet date.

**Note 3 – Contractual commitments for the acquisition of intangible assets**

In October 2014, Sobi's partner Biogen submitted an MAA for Elocta (rFVlllFc) to the EMA. This application for marketing approval to the EMA, together with the delivery of data from Biogen to Sobi, triggered Sobi's exclusive opt-in right to assume final development and commercialisation of Elocta in Europe, North Africa, Russia and most countries in the Middle East. On 21 November, Sobi exercised its opt-in right and paid, in accordance with the agreement, a deposit of USD 10 M. The deposit has been recognised in the balance sheet as an advance payment under intangible fixed assets.

Following the EU regulatory approval of Elocta, Sobi will be liable to reimburse Biogen for 50 per cent of the total production costs for clinical manufacture of the product, development costs for the product from 1 October 2009 until the date on which Sobi is registered as the Marketing Authorisation Holder, or 90 days after the approval, and certain shared expenses related to regulatory approval, costs for final development and commercialisation, and 100 per cent of some development costs that only benefitted Sobi's territory. Total payment is estimated to be about USD 233 M.

(See note 19 in the 2014 Annual Report for more information.)



# Definitions and Glossary

## Definitions

### Capital employed

Total assets less non-interest-bearing responsibilities.

### Cash flow per share

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

### CER

Constant exchange rates

### Debt/Equity ratio

Relative proportion of shareholders equity and debt used to finance the company's assets.

### EBIT

Earnings Before Interest and Taxes (Operating profit/loss).

### EBITA

Operating profit/loss before amortisation.

### EBITDA

Operating profit/loss before depreciation and amortisation.

### Earnings per share

The portion of a company's profit allocated to each outstanding share of common stock.

### Equity per share

The value of the company's common stock adjusted for any outflow (dividends and stock buy backs) and inflow (retained earnings) related to amount of shares outstanding.

### 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.

### Return on shareholders' equity

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

### Return on capital employed

Earnings Before Interest and Tax (EBIT)/Capital Employed.

### 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.

## Glossary

### Alprolix (rFIXFc)

rFIXFc is a long-acting recombinant factor IX Fc fusion protein product candidate in the EU 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.

### Cometriq

Cometriq (cabozantinib) is a therapy for the treatment of adult patients with progressive, unresectable, locally advanced or metastatic medullary thyroid carcinoma (MTC).

### Elocta (rFVIII Fc)

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 rFVIII Fc, also known as Eloctate [Antihemophilic Factor VIII (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 EMA.

### EMA

European Medicines Agency.

### EMENAR

A business region including Europe, Middle East, North Africa and Russia.

### FDA

Food and Drug Administration

### Haemophilia

Haemophilia is 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 male births.

Haemophilia B (clotting factor IX deficiency) occurs in around 1 in about 25,000 male births.

### Kineret

Kineret (anakinra) is a recombinant protein drug which blocks the biological activity of IL-1 by binding to the interleukin-1 (IL-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

Orfadin (nitisinone) is a 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 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. Peyronie's disease can result in varying degrees of penile curvature deformity and disease "bother" (encompassing concern about erection appearance, erection pain and the impact of Peyronie's disease on intercourse and on frequency of intercourse).

### Xiapex

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





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**About Sobi**

Sobi is an international speciality 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 primary focused on Haemophilia, Inflammation and Genetic diseases. We also market a portfolio of speciality 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 [www.sobi.com](http://www.sobi.com)