sobi

Pioneer in Rare Diseases

A new chapter of our story

Q1 REPORT 2016

TABLE OF CONTENT

FINANCIAL CALENDAR

Annual General Meeting	24 May 2016
Q2	15 July 2016
Q3	27 October 2016

Q1 2016 in summary

Business summary

- Commercial launch of Elocta® in the first European countries
- Sobi™ and Biogen received CHMP recommendation for Alprolix® for the treatment of haemophilia B
- European Commission approved transfer of marketing authorisation for Elocta to Sobi
- Received commercialisation rights to three products from PharmaSwiss
- European patent granted for Orfadin® oral suspension
- Initiated clinical pipeline programmes for acute gout and Still's disease, and a patent granted for a new formulation of Kineret®
- Håkan Björklund nominated to successor to Bo Jesper Hansen who has decided to step down as Chairman of the Board of Sobi

Financial summary

- Total revenue was SEK 1,273 M (865), an increase of 47 per cent (48 per cent at constant exchange rates (CER))
- Product revenue was SEK 1,108 M (632), an increase of 75 per cent (76 per cent at CER)
- Revenues includes a one-time credit from Biogen of SEK 322 M triggered by the first commercial sales of Elocta
- Gross margin was 74 per cent (60)
- EBITA was SEK 502 M (172)
- Ended the quarter with a cash position of SEK 1,108 M, compared to SEK 904 M as of 31 December 2015
- Earning per share 1.13 SEK (0.28)

Financial summary in USD[1]

- Total revenue was USD 151 M
- Product revenue was USD 131 M
- EBITA was USD 59 M
- Ended the quarter with a cash position of USD 131 M

[1] *Exchange rate 1USD = 8.4567 SEK*

CEO Statement

2016 is off to a strong start with excellent financial results, new products added to our Partner Products portfolio, development of two new programmes for Kineret, the launch of Elocta in Europe, and positive opinions regarding Alprolix from the CHMP and the COMP.

Strong financial results

Revenue increased by 47 per cent to SEK 1,273 M including a one-time credit of SEK 322 M related to the first commercial sales for Elocta. Kineret and Orfadin delivered growth of 15 and 10 per cent respectively in existing and new markets, and our ReFacto business and partner portfolio continued to deliver according to expectations. Gross margin was 74 per cent and we continued to strengthen our net cash position.

Haemophilia launch underway

In January we began the launch of Elocta in the first European countries, enabling people with haemophilia A in the region access to the first extended half-life factor treatment. Revenue from the quarter derives almost exclusively from Germany, the only market in the EU where pharmaceuticals are immediately reimbursed upon EU approval. The initial market feedback there has been encouraging, with 14 percent of centres having prescribed Elocta so far. We received positive reimbursement decisions late in the quarter in both the Netherlands and Ireland, and continue to advance discussions in Denmark, Sweden and the UK. We continue to believe that Elocta has the potential to create a true paradigm shift for people with haemophilia A.

It has also been an active period for Alprolix, with a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMA) recommending that marketing authorisation be granted for Alprolix for the treatment of haemophilia B. After the quarter ended we also received a positive opinion from the Committee for Orphan Medicinal Products (COMP) at EMA recommending the European Commission (EC) to maintain the orphan designation for Alprolix. The CHMP and COMP recommendations are now referred to the EC which is responsible for granting marketing authorisation for medicines in the EU and we expect a decision very shortly.

New development programmes

We continue to advance our early portfolio, and in addition we announced this quarter our intention to initiate two clinical programmes for Kineret in Still's disease and Acute Gout – indications where a significant need exists for alternative treatment options.

Finally, we received a patent for the oral suspension formulation of Orfadin in Europe, as well as a patent for our new citrate-free formulation of Kineret.

Thank you for your interest in our work at Sobi. We are energised by our progress so far and even more so by our future.

Geoffrey McDonough
CEO and President

Solna, 27 April 2016

Business review Q1

Commercial launch of Elocta in the first European countries

Sobi initiated the commercial launch of Elocta in the first European countries. Following the first commercial sales in January, Sobi received a one-time credit of SEK 322 M, corresponding to 10 per cent of Biogen's total sales of Eloctate® in its territories since the launch in 2014.

Sobi and Biogen received CHMP recommendation for Alprolix for the treatment of haemophilia B

The CHMP recommended that Alprolix be granted marketing authorisation in EU. If approved, Alprolix will be one of the first therapies in the EU to offer people with haemophilia B prolonged protection against bleeding episodes with prophylactic injections.

European Commission approved transfer of marketing authorisation for Elocta to Sobi

The European Commission approved the transfer of the marketing authorisation for Elocta from Biogen to Sobi, making Sobi the marketing authorisation holder (MAH) of Elocta in the EU.

Received commercialisation rights to three products from PharmaSwiss

Sobi received commercialisation rights from the Swiss company PharmaSwiss to distribute Relistor®, Deflux® and Solesta® in major parts of Europe, including Western Europe, the Czech Republic, Slovakia and Hungary, as well as Russia for Relistor.

European patent granted for Orfadin oral suspension

The European Patent Office (EPO) decided to grant a European patent for the Orfadin oral suspension formulation, which was approved by the European Commission in 2015 for the treatment of hereditary tyrosinaemia type 1 (HT-1).

Clinical pipeline programmes for acute gout and Still's disease, and a new patent for a new formulation of Kineret

Sobi announced the intent to initiate two clinical pipeline programmes for Kineret, with the goal of evaluating two new potential indications: acute gout and Still's disease. Sobi was also granted a patent for a citrate-free formulation of Kineret in the US, which extends until 2032. The corresponding European patent was granted in April. The European patent extends until 2032.

Håkan Björklund nominated as successor to Bo Jesper Hansen who has decided to step down as Chairman of the Board of Sobi

Bo Jesper Hansen informed Sobi's Nomination Committee that he will not be standing for re-election at the 2016 AGM. Bo Jesper Hansen has served as Chairman since the merger of Biovitrum and Swedish Orphan International in 2010. The Nomination Committee has proposed that shareholders elect Håkan Björklund, former CEO of Nycomed who currently serves as an Industry Executive at Avista Capital Partners, as the new Chairman of Sobi.

Financial review Q1

Key Therapeutic Areas

Revenue was SEK 920 M (421).

Inflammation

Kineret showed solid volume growth across all major markets. Revenue increased by 15 percent to SEK 227 M (198). The main contributors were the continued launch of the CAPS indication in Europe and the new specialty distribution model in the North America.

Total revenue for Inflammation now also include sales of Kepivance®, reported as *Inflammation: Other*. Kepivance was previously reported as part of Partner Products. Numbers for previous years have been adjusted accordingly.

Genetics & Metabolism

Revenue for Orfadin was SEK 198 M (180), an increase of 10 per cent. Orfadin continued to grow in major as well as new markets. The oral suspension formulation of Orfadin has now been launched in first countries in Europe.

Haemophilia

Revenue for the Haemophilia franchise was SEK 465 M (17). Royalty revenue amounted to SEK 445 M (17) of which SEK 322 M (0) was a one-time royalty credit triggered by first commercial sales of Elocta in Sobi's territory. The credit had no cash effect but has been deducted against Sobi's liability to Biogen for Elocta according to the agreement.

Product sales for the quarter totalled SEK 20 M (0). Revenue from the quarter derives almost exclusively from Germany, the only market in the EU where pharmaceuticals are immediately reimbursed upon EU approval. Reimbursement was granted in the Netherlands and Ireland at the end of the quarter and is pending in Denmark, Sweden and the UK.

First commercial sales in the Sobi territory have affected the royalty structure between Sobi and Biogen. Sobi will now in essence record a royalty rate of 12 per cent from Biogen on Eloctate sales compared to the previous 2 per cent. At the same time, Sobi will record a royalty rate of 12 per cent to Biogen on Sobi's Elocta sales. For more information on the agreement with Biogen, please see Sobi's Annual Report 2015.

Partner Products

Revenue for Partner Products was SEK 187 M (212), a decrease of 11 per cent. Q1 2015 included a revenue milestone and a service fee for Cometriq of in total SEK 22 M, and income from products that have been returned to partners during the year in the amount of SEK 10 M. The underlying business continued to show solid growth especially driven by Xiapex.

Revenue for Partner Products now also include sales of Ammonaps, Ammonul and Ravicti which were previously reported as *Genetics & Metabolism: Other*. Numbers for previous years have been adjusted accordingly.

ReFacto

ReFacto manufacturing revenue and royalty were SEK 165 M (232), a decrease of 29 per cent. During 2015, 41 per cent of manufacturing deliveries were recorded in Q1.

Manufacturing revenue was SEK 137 M (208). Royalty revenue was SEK 28 M (25).

Financial Summary

Amounts in SEK M	Q1 2016	Q1 2015	Change	Full year 2015
Total revenues[1]	1,273	865	47%	3,228
Gross profit	944	519	82%	2,007
Gross margin	74%	60%		62%
EBITA	502	172	>100%	433
EBIT (Operating profit/loss)	410	102	>100%	146
Profit/loss for the period	301	75	>100%	68

[1] Q1 2016 revenues include a one time credit of SEK 322 M relating to first commercial sales of Elocta.

Gross Profit

Gross profit for the first quarter 2016 was SEK 944 M (519), representing a gross margin of 74 per cent (60). The one-time credit following first commercial sales of Elocta was the main contributor.

Operating Expenses

Overall operating expenses excluding amortisations and write-offs were SEK 453 M (351).

Operating expenses for sales and administration excluding amortisations amounted to SEK 315 M (219). The increase reflects new employees hired to support the build-up of the Haemophilia organisation in launch markets.

Research and development costs excluding amortisation and write-downs increased to SEK 138 M (132). Costs reflect Sobi assuming its 50 per cent share of Biogen's ongoing development costs, as of 1 March for Elocta.

EBITA was SEK 502 M (172). Q1 2016 revenues include a one-time credit of SEK 322 M relating to first commercial sales of Elocta in Sobi's territory.

Amortisations of intangible assets amounted to SEK 92 M (71).

EBIT (operating profit) amounted to SEK 410 M (102).

Net financial items and tax

Net financial items amounted to SEK –23 M (–1), including exchange rate losses of SEK –2 M (14). Tax amounted to SEK –86 M (–26), see Note 5.

Revenues by Business Line

Amounts in SEK M	Q1 2016	Q1 2015	Change %	Change % at CER[1]	Full year 2015
Key Therapeutic Areas					
Inflammation: Kineret	227	198	15%	15%	805
Inflammation: Other[2]	29	26	9%	8%	99
Genetics & Metabolism: Orfadin	198	180	10%	10%	796
Haemophilia: Elocta	20	0	n/a	n/a	1
Haemophilia: Alprolix	0	0	n/a	n/a	1
Haemophilia: Royalty[3]	445	17	>100%	>100%	95
Total	**920**	**421**	**>100%**	**>100%**	**1,797**
Partner Products[4, 5]	**187**	**212**	**-11%**	**-10%**	**771**
ReFacto					
Manufacturing revenues	137	208	-34%	-34%	504
Royalty revenues	28	25	14%	15%	156
Total	**165**	**232**	**-29%**	**-29%**	**660**
Total revenues	**1,273**	**865**	**47%**	**48%**	**3,228**

[1] Constant Exchange Rate.

[2] Previuosly reported under Partner Products. Numbers for previous years have been adjusted accordingly.

[3] 2016 includes a one-time credit of SEK 322 M, triggered by Sobi's first commercial sales of Elocta.

[4] Q1 2015 includes a one-time revenue milestone and a service fee for Cometriq of SEK 22 M.

[5] Partner Products now also include sales of Ammonaps, Ammonul and Ravicti which were previously reported as *Genetics & Metabolism: Other*. Numbers for previous years have been adjusted accordingly.

Profit/Loss

Profit was SEK 301 M (75).

Cash flow and investments

Cash flow from operations before change in working capital amounted to SEK 192 M (181).

Working capital impacted cash flow by SEK 43 M (–12), mainly due to increase in operating liabilities.

Cash flow from investing activities amounted to SEK –9 M (–17).

Cash

Cash position at the end of quarter was SEK 1,108 M, compared to SEK 904 M as of 31 December 2015.

Net Cash/Debt

Sobi ended the quarter with a net cash of SEK 305 M, compared to a net cash of SEK 82 M as of 31 December 2015.

Equity

Consolidated shareholders' equity as of 31 March 2016 amounted to SEK 5,016 M compared to SEK 4,689 M as of 31 December 2015.

Parent Company

Net sales in Q1 2016 for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 1,093 M (724) of which SEK 275 M (256) referred to sales to Group companies. Income after financial items amounted to SEK 433 M (179). Investments in tangible and intangible assets amounted to SEK 8 M (16).

Operating Profit/Loss

Amounts in SEK M	Q1 2016	Q1 2015	Full year 2015
Total revenues	1,273	865	3,228
Total cost of goods and services sold	-329	-346	-1,221
Gross profit	**944**	**519**	**2,007**
Gross Margin	*74%*	*60%*	*62%*
Sales and administration expenses less amortisations and write-downs	-315	-219	-1,057
Research and development expenses less amortisations and write-downs	-138	-132	-513
Total opex excl. amortisations and write-downs	**-453**	**-351**	**-1,571**
Other operating revenues/expenses	**11**	**4**	**-3**
EBITA	**502**	**172**	**433**
Amortisations relating to Sales and administration expenses	-92	-71	-287
Amortisations	**-92**	**-71**	**-287**
EBIT	**410**	**102**	**146**

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

Outlook for 2016[1]

For the full-year 2016, Sobi expects revenues of between SEK 4,800 and 5,000 M. Revenues will include one time credits for Elocta of SEK 300-325 M, and for Alprolix SEK 300-325 M, which will not impact cash.

Gross margin is expected to be in the range of 68–70 per cent. Sobi will continue to invest in the launches of Elocta and Alprolix and will also take on incremental cost of SEK 250–300 M, reflecting its 50 per cent share of Biogen's ongoing development costs for the products. Sobi will assume these costs when it becomes marketing authorisation holder for Elocta expected in Q1 2016; and for Alprolix in the second half of the year. These incremental costs are included in this outlook.

EBITA for the full-year is expected to be in the range of SEK 1,200–1,300 M.

[1] *The outlook was published on 29 February 2016.*

Other information

Personnel

As of March 2016, the number of full-time equivalents was 700 (702, December 2015).

Significant events after the reporting period

COMP recommended maintained orphan designation for Alprolix

The Committee for Orphan Medicinal Products (COMP) of EMA recommended the European Commission to maintain the orphan designation for Alprolix.

European patent granted on new formulation of Kineret

The company was granted a European patent for a new, citrate free formulation for Kineret. The patents will expire in February 2032.

Signed licensing agreement with Affibody for IL-1

Sobi exercised its option to sign a licensing agreement with Swedish biotech company Affibody AB for the development of novel treatments for inflammatory diseases where interleukin-1 (IL-1) is involved.

Orfadin Oral Suspension approved in the US

The US Food and Drug Administration (FDA) approved Orfadin Oral Suspension for the treatment of hereditary tyrosinaemia type-1 (HT -1) in combination with dietary restriction of tyrosine and phenylanine.

Annual general Meeting 2016

The Annual General Meeting (AGM) of Swedish Orphan Biovitrum AB (publ) will be held on Tuesday, 24 May 2016, at 3 pm, at ”Wallenbergsalen”, Kungliga Ingenjörsvetenskapsakademien (IVA), Grev Turegatan 16, Stockholm, Sweden.

The notice of annual general meeting is available on www.sobi.com.

Audit

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

Solna, Sweden, 27 April 2016

Geoffrey McDonough
CEO and President

The information in this interim report is that which Swedish Orphan Biovitrum AB (publ) is required to disclose under Sweden’s Securities Market Act. It was published at 08.00 (CET) on 27 April 2016.

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

Amounts in SEK M	Q1 2016	Q1 2015	Full year 2015
Total revenues[1]	1,273	865	3,228
Total cost of goods and services sold	-329	-346	-1,221
Gross profit	**944**	**519**	**2,007**
Sales and administration expenses	-407	-289	-1,344
Research and development expenses	-138	-132	-513
Other operating revenues/expenses	11	4	-3
Operating profit/loss	**410**	**102**	**146**
Financial income/expenses	-23	-1	-58
Profit before tax	**387**	**101**	**88**
Income tax expense[2]	-86	-26	-19
Profit for the period	**301**	**75**	**68**
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	–	–	-3
Items that may be reclassified subsequently to profit/loss			
Translation difference	-1	0	-2
Cash flow hedge (net of tax)	11	2	58
Comprehensive income for the period	**312**	**76**	**122**
Amortisation and write-down of intangible assets included in Sales and administration expenses	-92	-71	-287
Earning per share	1.13	0.28	0.26
Earning per share after dilution	1.12	0.28	0.26

[1] See page 6 for split by business line
[2] See Note 5.

Group
Balance sheet

Amounts in SEK M	Mar 2016	Dec 2015	Mar 2015
ASSETS			
Non-current assets			
Intangible fixed assets[1]	5,661	5,787	4,192
Tangible fixed assets	101	109	110
Other long-term assets[2]	93	99	79
Total non-current assets	**5,854**	**5,995**	**4,380**
Current assets			
Inventories	810	776	765
Accounts receivable	505	451	647
Current receivables, non-interest bearing	260	185	133
Cash and cash equivalents	1,108	904	682
Total current assets	**2,684**	**2,316**	**2,226**
Total assets	**8,538**	**8,311**	**6,606**
EQUITY AND LIABILITIES			
Shareholders´ equity	**5,016**	**4,689**	**4,614**
Long-term liabilities			
Long-term debt	802	800	817
Long-term liabilities, non-interest bearing[2]	1,457	1,501	313
Total long-term liabilities	**2,259**	**2,301**	**1,130**
Current liabilities			
Short term debt	1	22	2
Current liabilities, non-interest bearing	1,261	1,298	861
Total short-term liabilities	**1,263**	**1,320**	**862**
Total equity and liabilities	**8,538**	**8,311**	**6,606**

[1] Including goodwill SEK 1,554 M.
[2] See Note 5.

Group
Changes in Equity

Amounts in SEK M	Jan - Mar 2016	Jan - Mar 2015	Full year 2015
Opening balance	**4,689**	**4,523**	**4,523**
Sharebased compensation to employees	15	5	23
Sale of own shares	–	10	22
Comprehensive income for the period	312	76	122
Equity, end of period	**5,016**	**4,614**	**4,689**

Whereof cash-flow hedges amounted to SEK 66 M as of 31 March 2016.

Group
Cash Flow Statement

Amounts in SEK M	Q1 2016	Q1 2015	Full year 2015
Net result	301	75	68
Non-cash items[1]	-109	106	343
Cash flow from operations before change in working capital	**192**	**181**	**411**
Change in working capital	43	-12	96
Cash flow from operations	**235**	**169**	**507**
Investment in intangible fixed assets	-8	-15	-119
Investment in tangible fixed assets	-5	-2	-27
Divestment of tangible fixed assets	4	–	2
Cash flow from investing activities	**-9**	**-17**	**-144**
Loans - Raising/Amortization	-20	–	–
Sale of own shares	–	10	22
Cash flow from financing activities	**-20**	**10**	**22**
Net change in cash	**205**	**163**	**386**
Liquid funds at the beginning of the period	904	519	519
Translation difference in cash flow and liquid funds	-1	0	-2
Liquid funds at the end of the period	**1,108**	**682**	**904**
[1] **Non-cash items:**			
Depreciation tangible fixed assets	8	8	32
Amortization intangible assets	92	71	287
Deferred tax	86	23	13
Other, whereof SEK -312 M in 2016 reflects Elocta, see also page 5 under Haemophilia.	-296	5	11
Total non-cash items	**-109**	**106**	**343**

Group
Key Ratios and Other Information

Amounts in SEK M	Q1 2016	Q1 2015	Full year 2015
Profit numbers			
Gross profit	944	519	2,007
EBITDA	510	180	465
EBITA	502	172	433
EBIT	410	102	146
Profit/loss	301	75	68
Per share data (SEK)			
Earning/loss per share	1.13	0.28	0.26
Earning/loss per share after dilution	1.12	0.28	0.26
Shareholders' equity per share	18.6	17.1	17.3
Shareholders' equity per share after dilution	18.6	17.1	17.3
Other information			
Gross margin	74%	60%	62%
Equity ratio	59%	70%	56%
Net cash (-)/debt (+)	-305	136	-82
Number of ordinary shares	270,389,770	270,389,770	270,389,770
Number of C-shares (in treasury)	1,433,036	396,180	1,433,036
Number of ordinary shares (in treasury)	2,763,768	4,688,948	2,763,768
Average number of ordinary shares (excluding shares in treasury)	267,626,002	266,842,738	267,278,339
Average number of ordinary shares after dilution (excluding shares in treasury)	269,547,965	266,842,738	267,278,339

Parent Company
Income Statement

Amounts in SEK M	Q1 2016	Q1 2015	Full year 2015
Total revenues	1,093	724	2,750
Total cost of goods and services sold	-301	-282	-1,168
Gross profit	**792**	**442**	**1,582**
Sales and Administration expenses	-227	-145	-814
Research and Development expenses	-128	-125	-472
Other operating revenues/expenses	14	1	13
Operating profit/loss	**451**	**173**	**309**
Financial income/expenses	-18	6	-33
Profit/loss after financial items	**433**	**179**	**276**
Income tax benefit/expenses	-86	-6	-58
Profit/loss for the period	**347**	**173**	**218**
Other comprehensive income			
Items that may be reclassified subsequently to profit/loss			
Cash flow hedge (net of tax)[2]	11	2	58
Comprehensive income for the period	**358**	**175**	**276**
Amortization and write-down of intangible assets included in Sales & Administration expenses	-47	-22	-94

Parent Company
Balance Sheet

Amounts in SEK M	Mar 2016	Dec 2015	Mar 2015
ASSETS			
Non-current assets			
Intangible fixed assets	2,658	2,739	999
Tangible fixed assets	84	92	99
Other long-term assets	3,882	3,899	3,914
Total non-current assets	**6,624**	**6,730**	**5,012**
Current assets			
Inventories	728	674	708
Current receivables, non-interest bearing	1,098	1,012	1,113
Cash and cash equivalents	1,001	750	578
Total current assets	**2,827**	**2,436**	**2,399**
Total assets	**9,451**	**9,166**	**7,411**
EQUITY AND LIABILITIES			
Shareholders´ equity	**6,206**	**5,832**	**5,700**
Long-term liabilities			
Long-term debt	796	795	813
Long-term liabilities, non-interest bearing	1,204	1,238	–
Total long-term liabilities	**2,000**	**2,033**	**813**
Current liabilities			
Short term debt	–	20	–
Current liabilities, non-interest bearing	1,245	1,281	898
Total short-term liabilities	**1,245**	**1,301**	**898**
Total equity and liabilities	**9,451**	**9,166**	**7,411**

Parent Company
Change in Shareholders´ Equity

Amounts in SEK M	Jan-Mar 2016	Jan-Mar 2015	Full year 2015
Opening balance	**5,832**	**5,510**	**5,510**
Sharebased compensation to employees	15	5	23
Sale of own shares	–	10	22
Comprehensive income for the period	358	175	276
Equity, end of period	**6,206**	**5,700**	**5,832**

Whereof cash-flow hedges amounted to SEK 66 M as of 31 March 2016.

Financial notes

Note 1 – Accounting and valuation principles and other information

Important accounting principles

This report has been prepared in accordance with IAS 34 and with the Annual Accounts Act. The consolidated financial statements for the period January—March 2016 have been prepared in accordance with the Financial Reporting Standards (IFRS) and International Financial Reporting Interpretations Committee (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 except certain 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 2015 Annual Report. More detailed information about the Group's accounting and valuation principles can be found in the 2015 Annual Report which is available on www.sobi.com.

Change in accounting principles From fiscal year 2016 a number of new and revised standards came 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 2015 Annual Report (see the Directors' Report). The positive recommendations from the CHMP and the COMP regarding Alprolix in February and April 2016 respectively has reduced the company's risk exposure compared to 2015. In all other aspects, there are no major changes in the Group's risk exposure and risk management in 2016 compared to the previous year.

Note 2 – Fair values of financial instruments

The Group carries derivatives. Refer to the 2015 Annual Report 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 31 March 2016, the reported value in the balance sheet for derivatives was SEK 2 M (-6).

As of 31 March 2016, 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 March 2016, the reported value in the balance sheet for the bond was SEK 796 M (792). Fair value of the bond is deemed to be SEK 815 M (832). 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 June 2015, Sobi's collaboration partner Biogen submitted an MAA for Alprolix to the EMA. The application for marketing approval, together with the delivery of data from Biogen to Sobi, triggered Sobi's exclusive opt-in right to assume final development and commercialisation of Alprolix in Europe, North Africa, Russia and most countries in the Middle East. On 16 July 2015, Sobi exercised the opt-in right and paid, in accordance with the agreements, USD 10 M for the opt-in right, which will be kept in escrow until EU approval. The payment has been recognised in the balance sheet as advance payment under intangible fixed assets. Following the EU regulatory approval of Alprolix, Sobi will be liable to reimburse Biogen for:

- 50 per cent of the total production costs for clinical manufacture;
- development costs from 1 October 2009 until the date on which Sobi is registered as the Marketing Authorisation Holder, or 90 days after the EU approval;
- 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 185 M for Alprolix. (See note 19 in the 2015 Annual Report for more information.)

Note 4—Adjusted purchase price for Elocta

The anticipated purchase price to Biogen for Elocta has been estimated to be USD 5 M lower than previously reported which is reflected in the accounts at 31 March 2016. The final purchase price will be determined in Q2 2016 and is expected to be USD 210 M.

Note 5 — Adjustment of deferred tax previously reported

An adjustment relating to deferred tax has been made for Q1 2015, previously reported in Q3 2015.

Group

	Previously reported		Adjusted numbers	
Amounts in SEK M	Q2 2015	Q1 2015	Q2 2015	Q1 2015
Balance sheet				
Equity	4,672	4,645	4,630	4,614
Long-term liabilities, non-interest bearing	274	282	316	313
Total equity and liabilities	**6,549**	**6,606**	**6,549**	**6,606**
Income Statement				
Income tax benefit expenses	24	5	13	-26
Profit/loss for the period	9	106	-2	75
P&L effect of adjusted deferred tax			**-11**	**-31**

Definitions

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.

Interest bearing liability

Bond loans and liabilities to credit institutions

Net debt

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

Profit/loss

Profit/loss for the period.

Return on 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.

Glossary

Glossary

Acute gout

Acute gout is an autoinflammatory disease and an intensely painful and disabling inflammatory arthritis involving one or several joints. The goal of therapy in acute gout is prompt and safe termination of pain and disability. Gout is also a disease that is associated with multiple comorbidities, which may limit the use of some conventional treatment regimens.

Alprolix

Alprolix (eftrenonacog alfa) is a recombinant, extended half-life clotting factor therapy under development for people with haemophilia B. Alprolix is the first recombinant, clotting factor therapy with prolonged circulation in the body, that has been approved for adults and children with haemophilia B in the US, Canada, Australia, New Zealand and Japan. A marketing authorisation application for Alprolix in EU was submitted to the EMA in June 2015.

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.

CHMP

The Committee for Medicinal Products for Human Use at the European Medicines Agency.

COMP

The Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency.

Elocta

Elocta (efmoroctocog alfa) is the first recombinant, clotting factor VIII therapy with prolonged circulation in the body. The product is approved in the EU for the treatment and prophylaxis of bleeding episodes in patients with haemophilia A (factor VIII deficiency) and can be used by people of all ages.

EMA

European Medicines Agency.

Haemophilia

Haemophilia is a rare, genetic disorder in which the ability of a person's blood to clot is impaired. Haemophilia A occurs in about one in 5,000 male births annually, and haemophilia B occurs in about one in 25,000 male births annually. Both occur more rarely in females. People with haemophilia experience bleeding episodes that may cause pain, irreversible joint damage and life-threatening haemorrhages.

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 drug used to treat inflammatory diseases.

Orfadin

Orfadin (nitisinone) is a drug used to treat hereditary tyrosinaemia type 1 (HT1-).

Still's disease

Still's disease is an autoinflammatory disease that affects both children and adults, and is characterised by persistent high spiking fevers, recurring rashes and arthritis. Still's disease is also known as systemic-onset juvenile idiopathic arthritis (SJIA) or adult-onset Still's disease (AOSD).

Xiapex

Xiapex (collagenase clostridium histolyticum), is a pharmacological treatment for Dupuytren's contracture and Peyronie's disease.

Swedish Orphan Biovitrum AB (publ)
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 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 primarily focused on Haemophilia, Inflammation and Genetic diseases. We also market a portfolio of speciality and rare disease products across Europe, Middle East, North Africa and Russia for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2015, Sobi had total revenues of SEK 3.2 billion (USD 385 M) and approximately 700 employees. The share (STO:SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com