



**Q1**  
**REPORT**  
**2017**

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## FINANCIAL CALENDAR

AGM	4 May 2017
Q2	19 July 2017
Q3	25 October 2017

## Q1 2017 in summary

### Business highlights

- First patients enrolled in a 24 month real-world study for Eloc-ta®
- EMA approved higher capacity of drug substance manufacturing for Eloc-ta
- New data for Alprolix published in *The Lancet Haematology* and in *Thrombosis and Haemostasis*
- Haemophilia development portfolio expanded by adding rF9Fc-XTEN for subcutaneous treatment of haemophilia B to the col-laboration agreement with Bioverativ
- Health Canada approved Orfadin® capsules for the treatment of hereditary tyrosinaemia type-1 (HT-1)
- EC approved new dosing frequency for Orfadin
- FDA approved in-use storage at room temperature for Orfadin
- The first patient was randomised in the phase 2 study anaGO to evaluate efficacy and safety of anakinra for the treatment of acute gout
- New distribution agreement for Ammonul®

### Financial summary

- Total revenue was SEK 1,396 M (1,273) an increase of 10 per cent (6 per cent at CER)
- Product revenue was SEK 1,269 M (1,108) an increase of 15 per cent (10 per cent at CER)
- Gross margin was 74 per cent (74)
- EBITA was SEK 406 M (502)
- Cash position SEK 1,032 M (SEK 786 M as of 31 December 2016)
- Earnings per share 0.73 SEK (1.12)

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

- Total revenue was USD 156 M
- Product revenue was USD 142 M
- EBITA was USD 46 M
- Ended the quarter with a cash position of USD 116 M

<sup>1</sup>Exchange rate 1USD = 8.9229 SEK

## CEO statement

**The strong first quarter results derive from the entire portfolio, with the launches of Elocta and Alprolix gaining significant momentum. From a development perspective we presented new long-term safety and efficacy data for Elocta and Alprolix, and we elected to include a novel long-acting subcutaneous factor 9 XTEN development candidate in our collaboration with Bioverativ. Orfadin received two important approvals during the quarter.**

### Strong portfolio performance

The revenue for the first quarter 2017 was SEK 1,396 M, an increase of 10 per cent overall, and 47 per cent adjusted for the one-time credit of SEK 322 M received in Q1 2016. Gross margin was 74 per cent. EBITA was SEK 406 M, and we ended the quarter with a cash position of SEK 1,032 M.

Elocta product sales were SEK 250 M, (SEK 20 M) an increase of 85 per cent compared to Q4 2016. Alprolix sales were SEK 50 M, an increase of 28 per cent compared to Q4 2016. Compared to Q1 2016 Kineret® sales increased by 22 per cent to SEK 277 M, and Orfadin sales increased by 9 per cent to SEK 216 M. Sales for the partner products portfolio were SEK 179 M, and ReFacto revenues were SEK 127 M.

### Gathering haemophilia launch momentum

We are beginning to see significant traction for the launch of Elocta, where we now have pricing approvals in 16 markets with the addition of the United Arab Emirates in the quarter. The adoption of Elocta is occurring in several markets, with the combination of global outcomes data and local clinical experience allowing physicians to apply its benefits to a wide variety of pa-

tient cases. We received an approval by the EMA for the manufacturing of Elocta drug substance in 15,000 litre scale bioreactors, an important step in meeting our commitment to the haemophilia community both to ensure reliable supply in our territories and to underpin the ongoing global donation programme which has made an unprecedented level of treatment available to patients and families living in the developing world. While in an earlier phase of launch, Alprolix is now reimbursed in Italy, Denmark, Slovenia and the United Arab Emirates in addition to Germany, Switzerland, the UK, the Republic of Ireland and the Netherlands. Reimbursement dialog is ongoing in several countries.

### Key pipeline developments

New data demonstrating the consistent long-term efficacy and safety for Elocta and Alprolix were presented by Sobi and our partner Bioverativ at the EAHAD meeting in Paris. New data for Alprolix from the B-YOND and the Kids B-LONG studies were also published in Thrombosis and Haemostasis and in Lancet Haematology. We are particularly excited to have expanded our development portfolio by adding the drug product candidate factor 9 XTEN (rF9Fc-XTEN) for subcutaneous treatment of haemophilia B to our collaboration agreement with Bioverativ.

Orfadin had a significant quarter with the FDA approval for in-use storage at room temperature. We also received the EC approval for once daily dosing, which is a step to improve the lives for people living with HT-1.

Finally, we signed a new agreement for our Partner Products business with Valeant Pharmaceuticals Ireland for the distribu-



tion of Ammonul in Europe, the Middle East and North Africa. We are strengthening this leading speciality platform as we continue to explore the option of divestment.

Thank you for your interest and support for Sobi and we hope that you will continue to follow us on our journey.

Solna, Sweden, 28 April 2017

Geoffrey McDonough, CEO and President

## Business review Q1

### **First patients enrolled in a 24 month real-world study for Elocta**

The first patients were enrolled in the A-SURE study. A-SURE is a 24-month real-world study evaluating the effectiveness of Elocta compared to conventional F8 products in the prophylactic treatment of people living with haemophilia A in Europe.

### **EMA approved higher capacity of drug substance manufacturing for Elocta**

The European Medicines Agency (EMA) approved the type II variation for Elocta. The variation involves several changes, including the approval of Elocta drug substance manufacturing in 15,000 litre scale bioreactors.

### **Sobi and Bioverativ revealed new data for Elocta and Alprolix**

New haemophilia data were presented at the 10th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD), taking place in Paris, France, 1-3 February 2017. Nine posters including data on the long-term safety and efficacy of the companies' extended half-life therapies, Elocta and Alprolix were presented providing an updated analysis of data from the studies ASPIRE and B-YOND.

### **New data for Alprolix published in The Lancet Haematology**

Results from the Kids B-LONG Phase 3 clinical trial, which studied Alprolix in previously-treated children with severe haemophilia B, were published in The Lancet Haematology. The primary outcome measure of the trial was development of inhibitors, and no patients treated with Alprolix in the study developed inhibitors.

### **New data for Alprolix was published in Thrombosis and Haemostasis**

Interim results from the B-YOND extension trial, which studies Alprolix in previously treated subjects with severe haemophilia B,

were published in the March 2017 issue of Thrombosis and Haemostasis. The study results reinforce the long-term safety and efficacy of prophylactic treatment with Alprolix over a median duration of more than three years in adults/adolescents and more than a year and a half in children under 12 years of age.

### **Haemophilia B development portfolio was expanded by adding factor 9 XTEN to the collaboration agreement with Bioverativ**

Sobi elected to add a novel product candidate rF9Fc-XTEN for potential subcutaneous treatment of haemophilia B to the company's collaboration agreement with Bioverativ.

### **Health Canada approved Orfadin capsules for the treatment of hereditary tyrosinaemia type-1 (HT-1)**

Health Canada approved Orfadin capsules for treatment of HT-1 in combination with dietary restriction of tyrosine and phenylalanine. Orfadin is available in Canada in a wide range of dosing forms, where Sobi is the first company to offer Orfadin at the 20 mg dosage option.

### **EC approved new dosing frequency for Orfadin**

The European Commission (EC) approved a reduced dosing frequency for Orfadin from twice daily to once daily, in people with hereditary tyrosinemia type 1 (HT-1) with a body weight >20 kg.

### **FDA approved in-use storage at room temperature for Orfadin**

FDA approved in-use storage at room temperature (25°C or less) for up to 45 days for all strengths of Orfadin capsules. FDA also approved an extended shelf life for Orfadin capsules 20 mg, from 24 to 36 months.

### **First patient randomised in the phase 2 study anaGo**

The first patient was randomised in the phase 2 study anaGO to

evaluate efficacy and safety of Kineret (anakinra) in the treatment of acute gout.

### **New distribution agreement for Ammonul**

Sobi entered into a 3-year agreement with Valeant Pharmaceuticals Ireland for the distribution of Ammonul injection in Europe, the Middle East and North Africa.

### **Armin Reininger joined Sobi as SVP, Head of Global Medical and Scientific Affairs**

Armin Reininger, MD, PhD, was appointed Senior Vice President, Head of Global Medical and Scientific Affairs. Armin is leading Sobi's cross-functional Medical & Scientific Affairs team, supporting Sobi's patient centric approach.

### **CEO succession**

Geoffrey McDonough will leave Sobi on 1 July 2017. A search for a new Chief Executive Officer has been initiated and is ongoing.



# Financial review Q1

## Key therapeutic areas

Total revenues amounted to SEK 1,396 M, an increase of 10 per cent compared to Q1 2016. Total revenue growth was 47 per cent adjusted for the one-time credit of SEK 322 M received in Q1 2016. Product sales amounted to SEK 1,269 M, an increase of 15 per cent, (61 per cent adjusted).

## Haemophilia

Total revenue for the Haemophilia franchise amounted to SEK 571 M (466). Haemophilia product sales were SEK 300 M (20), whereof SEK 250 M (20) were from Elocta, and SEK 50 M (0) were from Alprolix. Product sales derived mainly from France, Germany and the UK, followed by Italy and Switzerland.

Estimated royalty revenue amounted to SEK 270 M (445). Excluding the one-time credit of SEK 322 M in Q1 2016, estimated royalty revenue increased by SEK 147 M.

Reimbursement for Elocta has so far been granted in 16 countries and for Alprolix in 8 countries.

## Inflammation

Kineret showed volume growth across all major markets, reaching revenues of SEK 277 M (227), an increase of 22 percent.

The performance was enabled by the fully established new US patient support program in North America, and by growth in EMENAR where highlights were Turkey, France, Germany and Italy.

## Genetics & Metabolism

Orfadin revenue was SEK 216 M (198), an increase of 9 per cent.

Revenues in North America were strong, partially offset by lost sales due to the approval of a generic formulation in Canada. The

EMENAR business was negatively impacted by loss of sales due to the approval of a generic formulation in Turkey, and to order phasing in the Middle East and North Africa.

## Partner Products

Partner Products revenue was SEK 179 M (187), a decrease of 5 per cent, resulting from order phasing from Ammonul and Ravicti®. We continue to see solid growth for the base business, led by Xiapex.

## ReFacto

ReFacto manufacturing revenue and royalty were SEK 127 M (165), a decrease of 23 per cent due to phasing effects.

Manufacturing revenue was SEK 121 M (137). Royalty revenue was SEK 6 M (28). Royalty to Sobi from ReFacto AF sales outside of the US ceased 1 June 2016.

## Gross profit

Gross profit was SEK 1,028 M (944), representing a gross margin of 74 per cent (74). Gross margin was impacted positively in Q1 2017 by a one-time adjustment to inventory due to delayed release of

Kineret drug substance manufactured in 2016, and positively in Q1 2016 by a one-time credit following the first commercial sales of Elocta. Adjusting for these factors the gross margin in Q1 2017 was 69 per cent compared to 65 per cent in Q1 2016.

## Operating expenses

Overall operating expenses less amortisations and write-downs were SEK 601 M (453).

Operating expenses for sales and administration less amortisations amounted to SEK 382 M (315). The increase mainly relates to restructuring of the Partner Products business, a one time cost for CEO succession, and continued investment to support the launch of Elocta and Alprolix.

Research and development costs increased to SEK 218 M (138). Costs reflect Sobi assuming its 50 per cent share of Bioverativ's ongoing development costs, as of 1 March 2016 for Elocta, and as of 1 August 2016 for Alprolix.

## Financial summary

Amounts in SEK M	Q1 2017	Q1 2016	Change	Full year 2016
Total revenues <sup>1</sup>	1,396	1,273	10%	5,204
Gross profit <sup>2</sup>	1,028	944	9%	3,651
Gross margin	74%	74%		70%
EBITA	406	502	-19%	1,543
EBIT (Operating profit/loss)	284	409	-31%	1,133
Profit for the period	196	301	-35%	809

<sup>1</sup>Q1 2016 revenues include a one time credit of SEK 322 M relating to the first commercial sales of Elocta.

<sup>2</sup>Q1 2017 includes a one-time inventory adjustment of SEK 59 M due to delayed release of Kineret drug substance manufactured in 2016

**Operating profit**

EBITA was SEK 406 M (502). 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 122 M (92).

EBIT (operating profit) amounted to SEK 284 M (409).

**Net financial items and tax**

Net financial items amounted to SEK -15 M (-23), including exchange rate gains/losses of SEK 4 M (-2). Tax amounted to SEK -74 M (-86).

**Profit/loss**

Profit was SEK 196 M (301).

**Cash flow and investments**

Cash flow from operations before change in working capital amounted to SEK 400 M (192).

Working capital impacted cash flow by SEK -77 M (43), mainly due to the one-time adjustment to inventory.

Cash flow from investing activities amounted to SEK -76 M (-9).

**Cash**

Cash position at the end of quarter was SEK 1,032 M, compared to SEK 786 M as of 31 December 2016.

**Net cash/debt**

Sobi ended the quarter with a net cash of SEK 529 M, compared to a net cash of SEK 282 M as of 31 December 2016.

**Equity**

Consolidated shareholders' equity as of 31 March 2017 amounted

**Revenues by business line**

Amounts in SEK M	Q1 2017	Q1 2016	Change %	Change % at CER <sup>1</sup>	Full year 2016
<b>Key therapeutic areas</b>					
Haemophilia: Elocta	250	20	>100%	>100%	267
Haemophilia: Alprolix	50	0	>100%	>100%	60
Haemophilia: Estimated royalty <sup>2</sup>	270	445	-39%	-43%	1,525
Inflammation: Kineret	277	227	22%	17%	1,001
Inflammation: Other	26	29	-9%	-13%	105
Genetics & Metabolism: Orfadin	216	198	9%	6%	770
<b>Total</b>	<b>1,090</b>	<b>920</b>	<b>19%</b>	<b>13%</b>	<b>3,729</b>
<b>Partner Products</b>					
	<b>179</b>	<b>187</b>	<b>-5%</b>	<b>-6%</b>	<b>820</b>
<b>ReFacto</b>					
Manufacturing revenues	121	137	-12%	-12%	569
Royalty revenues	6	28	-78%	-79%	88
<b>Total</b>	<b>127</b>	<b>165</b>	<b>-23%</b>	<b>-24%</b>	<b>656</b>
<b>Total revenues</b>	<b>1,396</b>	<b>1,273</b>	<b>10%</b>	<b>6%</b>	<b>5,204</b>

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

<sup>2</sup>Q1 2016 revenues include a one time credit of SEK 322 M relating to the first commercial sales of Elocta.

to SEK 5,592 M compared to SEK 5,354 M as of 31 December 2016.

**Parent company**

Net sales in Q1 2017 for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 1,270 M (1,093) of which SEK 589 M (275) referred to sales to Group companies. Profit after financial items amounted to SEK 338 M (433). Investments in tangible and intangible assets amounted to SEK 71 M (8).

**Operating profit/loss**

Amounts in SEK M	Q1 2017	Q1 2016	Full year 2016
Total revenues	1,396	1,273	5,204
Total cost of goods and services sold	-368	-329	-1,554
<b>Gross profit</b>	<b>1,028</b>	<b>944</b>	<b>3,651</b>
<i>Gross Margin*</i>	74%	74%	70%
Sales and administration expenses less amortisations and write-downs	-382	-315	-1,366
Research and development expenses	-218	-138	-778
<b>Total opex less amortisations and write-downs</b>	<b>-601</b>	<b>-453</b>	<b>-2,144</b>
<b>Other operating revenues/expenses</b>	<b>-21</b>	<b>11</b>	<b>36</b>
<b>EBITA</b>	<b>406</b>	<b>502</b>	<b>1,543</b>
Amortisations relating to Sales and administration expenses	-122	-92	-410
<b>Amortisations</b>	<b>-122</b>	<b>-92</b>	<b>-410</b>
<b>EBIT</b>	<b>284</b>	<b>409</b>	<b>1,133</b>

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

\*Gross margin was impacted positively in Q1 2017 by a one-time adjustment to inventory due to delayed release of Kineret drug substance manufactured in 2016, and positively in Q1 2016 by a one-time credit following the first commercial sales of Elocta. Adjusting for these factors the gross margin

**Outlook 2017\***

Sobi expects revenues for the full year to be in the range of SEK 5,800 to 6,000 M.

Gross margin is expected to be in the range of 66 to 68 per cent.

Sobi expects EBITA for the full year to be in the range of SEK 1,600 to 1,700 M.

*\*The outlook was first published on 16 February 2017 and is based on the exchange rate as of that date.*





# Other information

## Personnel

As of 31 March 2017, the number of full-time equivalents was 760 (760, as of 31 December 2016).

## Significant events after the reporting period

### Theresa Heggie resigned from the Board of Directors

Theresa Heggie resigned from Sobi's Board of Directors since she will take up an executive position that will not be possible to combine with a role as Member of the Board of Sobi.

## Annual General Meeting 2017

The Annual General Meeting (AGM) of Swedish Orphan Biovitrum AB (publ) will be held on Thursday, 4 May 2017 at 3 pm, at Kungliga Ingenjörsvetenskapsakademin (IVA), Stockholm, Sweden.

The notice of annual general meeting is available on [www.sobi.com](http://www.sobi.com).

## Audit

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

Solna, Sweden, 28 April 2017

Geoffrey McDonough  
CEO and President

## Forward-looking statements

*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.*

*This information is information that Swedish Orphan Biovitrum AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of Linda Holmström, Senior Communications Manager, at 08:00 am CET on 28 April 2017.*





## Vision

We are inspired to pioneer a world in which rare disease patients are diagnosed at birth, receive effective and sustainable therapy, and go on to live full and healthy lives.

## Mission

To develop and deliver innovative therapies and services to improve the lives of patients.

## Sobi's value creation

True availability and access to treatment for patients is what brings long-term value to the patients we serve, our employees, partners and shareholders. The capabilities that make this possible are our knowledge of biologics manufacturing and industrialisation, our in-house research and development competencies within protein characterisation, and our ability to provide access to treatments for rare disease patients. We believe that our ability to partner and to pioneer with different stakeholders and bring together all the opportunities that exist to facilitate effective and timely rare disease therapy development creates unique opportunities to add value to the rare disease field.

## Objectives for 2017

- Exercise personal leadership by taking crisp decisions and acting with urgency in serving patients.
- Meet or exceed operational targets:
  - expand market shares for Elocta, Alprolix, and Orfadin Oral Suspension and 20 mg capsule;
  - exceed contract delivery for ReFacto.
- Expand portfolio through synergistic new indications, partnerships and acquisitions.
- Ensure key pipeline inflection points are met:
  - complete enrolment to anaGo study;
  - initiate anaStill's study;
  - initiate two Elocta immune tolerance studies in collaboration with Bioverativ; and
  - SOBI003 on track for first patient in clinical trials in early 2018.

# Financial statements

## Group Statement of comprehensive income

Amounts in SEK M	Q1 2017	Q1 2016	Full year 2016
Total revenues <sup>1</sup>	1,396	1,273	5,204
Total cost of goods and services sold	-368	-329	-1,554
<b>Gross profit</b>	<b>1,028</b>	<b>944</b>	<b>3,651</b>
Sales and administration expenses <sup>2</sup>	-504	-407	-1,776
Research and development expenses	-218	-138	-778
Other operating revenues/expenses	-21	11	36
<b>Operating profit</b>	<b>284</b>	<b>409</b>	<b>1,133</b>
Financial income/expenses	-15	-23	-85
<b>Profit before tax</b>	<b>269</b>	<b>387</b>	<b>1,048</b>
Income tax expenses	-74	-86	-239
<b>Profit for the period</b>	<b>196</b>	<b>301</b>	<b>809</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>			
Remeasurements of post employment benefit obligations	–	–	1
<i>Items that may be reclassified subsequently to profit/loss</i>			
Translation difference	-1	-1	5
Cash flow hedge (net of tax)	36	11	-176
<b>Comprehensive income for the period</b>	<b>230</b>	<b>311</b>	<b>639</b>
<sup>1</sup> See page 6 for split by business line			
<sup>2</sup> Amortisation and write-downs of intangible assets included in Sales and administration	-122	-92	-410
Earnings per share	0.73	1.12	3.01
Earnings per share after dilution	0.73	1.12	3.01

**Group  
Balance sheet**

Amounts in SEK M	Mar 2017	Dec 2016	Mar 2016
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible fixed assets <sup>1</sup>	6,747	6,806	5,661
Tangible fixed assets	126	121	105
Other long-term assets	155	136	93
<b>Total non-current assets</b>	<b>7,028</b>	<b>7,063</b>	<b>5,858</b>
<b>Current assets</b>			
Inventories	988	870	810
Accounts receivable	888	769	505
Current receivables, non-interest bearing	396	487	260
Cash and cash equivalents	1,032	786	1,108
<b>Total current assets</b>	<b>3,304</b>	<b>2,911</b>	<b>2,684</b>
<b>Total assets</b>	<b>10,332</b>	<b>9,974</b>	<b>8,542</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>	<b>5,592</b>	<b>5,354</b>	<b>4,987</b>
<b>Long-term liabilities</b>			
Long-term debt	502	502	802
Long-term liabilities, non-interest bearing	2,216	2,360	1,491
<b>Total long-term liabilities</b>	<b>2,718</b>	<b>2,862</b>	<b>2,292</b>
<b>Current liabilities</b>			
Short term debt	2	2	1
Current liabilities, non-interest bearing	2,020	1,756	1,261
<b>Total short-term liabilities</b>	<b>2,022</b>	<b>1,758</b>	<b>1,263</b>
<b>Total equity and liabilities</b>	<b>10,332</b>	<b>9,974</b>	<b>8,542</b>

<sup>1</sup>Including goodwill SEK 1,554 M.

**Group  
Changes in equity**

Amounts in SEK M	Jan - Mar 2017	Jan - Mar 2016	Full year 2016
<b>Opening balance</b>	<b>5,354</b>	<b>4,660</b>	<b>4,660</b>
Sharebased compensation to employees	7	15	32
Sale of own shares	–	–	24
Comprehensive income for the period	230	311	639
<b>Equity, end of period</b>	<b>5,592</b>	<b>4,987</b>	<b>5,354</b>

Whereof changes in cash-flow hedges amounted to SEK 36 M (11).

**Group**  
**Cash flow statement**

Amounts in SEK M	Q1 2017	Q1 2016	Full year 2016
Net result	196	301	809
Non-cash items <sup>1</sup>	205	-109	-167
<b>Cash flow from operations before change in working capital</b>	<b>400</b>	<b>192</b>	<b>642</b>
Change in working capital	-77	43	-300
<b>Cash flow from operations</b>	<b>324</b>	<b>235</b>	<b>343</b>
Investment in intangible fixed assets	-63	-8	-119
Investment in tangible fixed assets	-13	-5	-46
Divestment of tangible fixed assets	0	4	7
<b>Cash flow from investing activities</b>	<b>-76</b>	<b>-9</b>	<b>-158</b>
Loans - Raising/Amortisation	–	-20	-331
Sale of own shares	–	–	24
<b>Cash flow from financing activities</b>	<b>–</b>	<b>-20</b>	<b>-308</b>
<b>Net change in cash</b>	<b>247</b>	<b>205</b>	<b>-123</b>
Liquid funds at the beginning of the period	786	904	904
Translation difference in cash flow and liquid funds	-1	-1	5
<b>Liquid funds at the end of the period</b>	<b>1,032</b>	<b>1,108</b>	<b>786</b>
<sup>1</sup> Non-cash items:			
Depreciation tangible fixed assets	8	8	31
Amortisation intangible assets	122	92	410
Deferred tax	16	86	158
Other, whereof SEK 47 M in Q1 2017 (SEK -312 M in Q1 2016 and SEK -812 M in full year 2016) reflects Elocta and Alprolix, see also page 5 under Haemophilia	59	-296	-765
<b>Total non-cash items</b>	<b>205</b>	<b>-109</b>	<b>-167</b>



## Group

### Key ratios and other information

Amounts in SEK M	Q1 2017	Q1 2016	Full year 2016
<b>Profit numbers</b>			
Gross profit	1,028	944	3,651
EBITDA <sup>1</sup>	415	510	1,574
EBITA <sup>1</sup>	406	502	1,543
EBIT <sup>1</sup>	284	409	1,133
Profit/loss	196	301	809
<b>Per share data (SEK)</b>			
Earnings per share	0.73	1.12	3.01
Earnings per share after dilution	0.73	1.12	3.01
Shareholders' equity per share <sup>3</sup>	20.7	18.4	19.8
Shareholders' equity per share after dilution <sup>3</sup>	20.7	18.5	19.7
<b>Other information</b>			
Gross margin	74%	74%	70%
Equity ratio <sup>3</sup>	54%	58%	54%
Net cash (-)/debt (+) <sup>2</sup>	-529	-305	-282
Number of ordinary shares	270,389,770	270,389,770	270,389,770
Number of C-shares (in treasury)	1,621,178	1,433,036	1,621,178
Number of ordinary shares (in treasury)	1,610,086	2,763,768	1,610,086
Average number of ordinary shares (excluding shares in treasury)	268,779,684	267,626,002	268,362,041
Average number of ordinary shares after dilution (excluding shares in treasury)	269,720,104	269,547,965	269,252,883

<sup>1,2,3</sup>Sobi presents certain financial measures in the interim report that are not defined according to IFRS, so called alternative performance measures (APMs). Where APMs are not directly identifiable from the financial statements and in need of an explanation, the parameters used to calculate these key ratios have been specified below. Further information on why these are considered important can be found in Definitions at the end of this report.

<sup>1</sup> Amortisations	-122	-92	-410
<sup>1</sup> Depreciations	-8	-8	-31
<sup>2</sup> Long term liabilities interest-bearing	502	802	502
<sup>2</sup> Short term liabilities interest-bearing	2	2	2
<sup>2</sup> Cash	1,032	1,108	786
<sup>3</sup> Equity	5,592	4,987	5,354
<sup>3</sup> Total assets	10,332	8,542	9,974

**Parent company  
Income statement**

<b>Amounts in SEK M</b>	<b>Q1 2017</b>	<b>Q1 2016</b>	<b>Full year 2016</b>
Total revenues	1,270	1,093	4,594
Total cost of goods and services sold	-387	-301	-1,470
<b>Gross profit</b>	<b>883</b>	<b>792</b>	<b>3,124</b>
Sales and Administration expenses <sup>1</sup>	-306	-227	-1,218
Research and Development expenses	-207	-128	-729
Other operating revenues/expenses	-18	14	30
<b>Operating profit</b>	<b>352</b>	<b>451</b>	<b>1,206</b>
Financial income/expenses	-14	-18	-73
<b>Profit after financial items</b>	<b>338</b>	<b>433</b>	<b>1,133</b>
Appropriations	—	—	-1,049
<b>Profit before tax</b>	<b>338</b>	<b>433</b>	<b>85</b>
Income tax expenses	-49	-86	-26
<b>Profit for the period</b>	<b>289</b>	<b>347</b>	<b>59</b>

**Parent company statement of other comprehensive income**

<b>Amounts in SEK M</b>	<b>Q1 2017</b>	<b>Q1 2016</b>	<b>Full year 2016</b>
Profit/loss for the period	289	347	59
<i>Items that may be reclassified subsequently to profit/loss</i>			
Cash flow hedge (net of tax)	36	11	-176
<b>Comprehensive income for the period</b>	<b>325</b>	<b>358</b>	<b>-117</b>

<sup>1</sup>Amortisation and write-downs of intangible assets included in Sales and admin-

## Parent company

## Balance sheet

	Mar	Dec	Mar
Amounts in SEK M	2017	2016	2016
<b>ASSETS</b>			
<i>Non-current assets</i>			
Intangible fixed assets	4,243	4,262	2,658
Tangible fixed assets	105	103	88
Other long-term assets	3,882	3,882	3,882
<b>Total non-current assets</b>	<b>8,229</b>	<b>8,247</b>	<b>6,628</b>
<i>Current assets</i>			
Inventories	853	766	728
Current receivables, non-interest bearing	1,487	1,460	1,098
Cash and cash equivalents	932	662	1,001
<b>Total current assets</b>	<b>3,272</b>	<b>2,888</b>	<b>2,827</b>
<b>Total assets</b>	<b>11,502</b>	<b>11,136</b>	<b>9,455</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>	<b>6,076</b>	<b>5,744</b>	<b>6,177</b>
<i>Untaxed reserves</i>	<i>1,154</i>	<i>1,154</i>	–
<i>Long-term liabilities</i>			
Long-term debt	497	497	796
Long-term liabilities, non-interest bearing	1,697	1,878	1,237
<b>Total long-term liabilities</b>	<b>2,194</b>	<b>2,374</b>	<b>2,033</b>
<i>Current liabilities</i>			
Current liabilities, non-interest bearing	2,077	1,863	1,245
<b>Total short-term liabilities</b>	<b>2,078</b>	<b>1,863</b>	<b>1,245</b>
<b>Total equity and liabilities</b>	<b>11,502</b>	<b>11,136</b>	<b>9,455</b>

## Parent company

## Change in shareholders' equity

	Jan-Mar	Jan-Mar	Full year
Amounts in SEK M	2017	2016	2016
<b>Opening balance</b>	<b>5,744</b>	<b>5,803</b>	<b>5,803</b>
Share based compensation to employees	7	15	35
Sale of own shares	–	–	24
Comprehensive income for the period	325	358	-117
<b>Equity, end of period</b>	<b>6,076</b>	<b>6,177</b>	<b>5,744</b>

Whereof changes in cash-flow hedges amounted to SEK 36 M (11).

# Definitions

## **CER**

Constant exchange rates.

## **Earnings per share**

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

## **Full-time equivalents**

Unit that indicates the workload of an employed person in a way that makes workloads comparable.

## **Profit/loss**

Profit/loss for the period.

## **FINANCIAL MEASURES NOT DEFINED ACCORDING TO IFRS**

Sobi uses certain financial measures in the interim report that are not defined according to IFRS. The company considers that these measures provide valuable supplementary information for investors and company management, as they enable an assessment and benchmarking of the company's reporting. Since not all companies calculate financial measures in the same way, these are not always comparable to measures used by other companies. These financial measures should therefore not be regarded as substitutes for measures defined according to IFRS. The following key ratios are not defined according to IFRS.

### **EBIT**

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

### **EBITA**

Operating profit/loss before amortisation.

### **EBITDA**

Operating profit/loss before depreciation and amortisation.

### **Equity per share**

Equity divided by the number of shares.

### **Equity ratio**

Shareholders' equity as a proportion of total assets.

### **Gross margin**

Gross profit as a percentage of sales.

### **Gross profit**

Net sales less cost of goods and services sold.

### **Interest bearing liability**

Credit facilities and other liabilities to credit institutions.

### **Net debt/net cash**

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

# 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 Swedish Annual Accounts Act. The consolidated financial statements for the period January—March 2017 have been prepared in accordance with the International 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 2016 Annual Report. More detailed information about the Group's accounting and valuation principles can be found in the 2016 Annual Report which is available on [www.sobi.com](http://www.sobi.com).

### Change in accounting principles

From fiscal year 2017 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 2016 Annual Report (see the Directors' Report). There are no major changes in the Group's risk exposure and risk management in 2017 compared to the previous year.

## Note 2 – Fair values of financial instruments

The Group carries derivatives (see the 2016 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 2017, the net reported value in the balance sheet for derivatives was SEK -3 M (2).

As of 31 March 2017, all other financial instruments in the balance sheet have reported values that are in all material aspects equivalent to fair value.



# Glossary

## Acute gout

An auto inflammatory disease and an intensely painful and disabling inflammatory arthritis involving one or several joints. Gout is also a disease that is associated with multiple comorbidities, which may limit the use of some conventional treatment regimens.

## anaGO

A randomised, double-blind, multicentre study being conducted in North America studying two dose levels of anakinra in comparison to intramuscular triamcinolone.

## A-SURE

A multicentre, non-interventional study to evaluate the effectiveness of Elocta compared to conventional factor products in the prophylactic treatment of patients with haemophilia A.

## Alprolix (eftrenonacog alfa)

A recombinant, extended half-life clotting factor 9 therapy approved in Australia, Canada, the EU, Japan, New Zealand, and the US for the treatment of haemophilia B, which can be used by people of all ages.

## Ammonul (sodium phenyl acetate and sodium benzoate)

Approved by the FDA for the treatment of acute Urea Cycle Disorders (UCDs). Ammonul is not registered in the European Union, Middle East or North Africa but is only available under named patients use (NPU) programmes.

## EC

European Commission.

## Elocta (efmoroctocog alfa)

A recombinant, extended half-life clotting factor 8 therapy approved in the EU and Switzerland for the treatment of

haemophilia A and can be used by people of all ages. It is also approved in Australia, Canada, Japan, New Zealand, and the US where it is known as Eloctate.

## EMA

European Medicines Agency.

## EMENAR

Abbreviation for Europe, Middle East, North Africa and Russia.

## FDA

Food and Drug Administration.

## F9-XTEN (rFIXFc-XTEN)

A novel factor 9 fusion protein that combines Fc dimer and XTEN half-life extension technology for the treatment of haemophilia B and has been designed to enable subcutaneous administration.

## Haemophilia

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.

## Health Canada

Department of the government of Canada with responsibility for national public health.

## Hereditary tyrosinemia type 1 (HT-1)

People with HT-1 have problems breaking down an amino acid called tyrosine. Toxic by-products are formed and accumulate in the body, which can cause liver, renal and neurological complications.

## Kineret (anakinra)

Kineret is a drug used to treat inflammatory diseases.

## Orfadin (nitisinone)

A drug used to treat hereditary tyrosinaemia type 1 (HT-1).

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 2016, Sobi had total revenues of SEK 5.2 billion (USD 608 M) and approximately 760 employees. The share (STO:SOBI) is listed on Nasdaq Stockholm. More information is available at [www.sobi.com](http://www.sobi.com).



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