



**sobi**  
Pioneer in Rare Diseases

*A new chapter  
of our story*



Q3 REPORT  
2016

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## FINANCIAL CALENDAR

Q4 and FY 2016	16 February 2017
Q1 2017	28 April 2017
AGM	4 May 2017
Q2 2017	19 July 2017
Q3 2017	25 October 2017

# Q3 2016 in summary

## Business highlights

- Elocta® reimbursed in the UK, Italy, France and Spain
- Alprolix® reimbursed in the UK
- Long term Elocta and Alprolix data presented at WHF 2016 World Congress
- Orfadin® capsule filing validated by Health Canada
- Milan Zdravkovic appointed as SVP, Head of R&D

## Significant events after the quarter

- European Commission grants SOBI003 orphan designation for the treatment of MPS IIIA
- Marketing authorisation holder transfer of Alprolix to Sobi approved by European Commission

## Financial highlights

- Total revenue of SEK 1,171 M (786), an increase of 49 per cent (49 per cent at CER)
- Product revenue of SEK 1,009 M (645), an increase of 56 per cent (57 per cent at CER)
- Gross margin of 67 per cent (62)
- EBITA of SEK 282 M (97)
- Ended the quarter with a cash position of SEK 824 M
- Earnings per share 0.53 SEK (0.02)

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

- Total revenue of USD 139 M
- Product revenue of USD 120 M
- EBITA of USD 34 M
- Ended the quarter with a cash position of USD 98 M

<sup>1</sup>Exchange rate 1USD = 8.3985 SEK [average year rate]



## CEO statement

**The third quarter showed strong growth across our diverse portfolio. We continued laying the foundation for a sustainable haemophilia business in Europe with both Elocta and Alprolix gaining several important reimbursement approvals in major markets.**

### **Solid performance across the portfolio**

Total revenue in the quarter amounted to SEK 1,171 M, an increase of 49 per cent. Gross margin in the quarter was 67 per cent. EBITA was SEK 282 M, and a cash position of SEK 824 M.

Elocta sales were SEK 57 M, reflecting slower conversion over the summer period. Initial Alprolix sales are off to a good start in the quarter following approval in May.

Other highlights in the quarter were Kineret® with a growth of 23 per cent driven by performance in all markets, and the partner products portfolio which grew 13 per cent excluding a one-time payment from Exelixis related to the transfer of Cometriq® to Ipsen.

Orfadin delivered according to expectations but had a slightly lower quarter than last year related to higher Medicaid rebates in the US, and to the approval of a local generic formulation in Turkey.

ReFacto® showed a growth of 15 per cent in the quarter.

### **Laying the foundation for a successful and enduring Haemophilia business in Europe**

We made significant progress in the quarter toward securing timely patient access to our novel extended half-life Haemophilia products Elocta and Alprolix. Our pricing model has been met with a good reception from payers, and we gained several important reimbursement approvals in major markets late in the quarter. We are also working in parallel to further develop the body of literature from our pivotal and extension clinical studies. A growing body of real world evidence can support clinicians and patients when considering the transition process from conventional treatments. This is a process that will take time.

### **Other pipeline developments**

A significant milestone after the quarter was the orphan designation approval by the European Commission for our development candidate SOBI003 for the treatment of MPS IIIA (Sanfilippo A syndrome). The disease is characterised by severe and progressive development delay. Patients rarely survive into their twenties and there is presently no treatment available. We are preparing SOBI003 to enter human testing in 2018.

Milan Zdravkovic has been appointed as Senior Vice President, Head of Research & Development, bringing extensive experience to advancing and expanding our existing and future portfolio of development programs, and to building upon our strong legacy of biologics innovation. It is particularly relevant to welcome Milan as we actively seek to expand our late stage pipeline through external partnerships, licensing, and acquisitions.



Once again, we would like to thank shareholders for your continued interest in and support for Sobi, and to our employees who have made these results possible.

Solna, Sweden, 27 October 2016

Geoffrey McDonough  
CEO and President



## Business review Q3

### **Elocta reimbursed in the UK, Italy, France and Spain**

Elocta was approved for reimbursement in the UK, Italy, France and Spain, and is now available on the five largest markets. These countries joined Germany, Sweden, Denmark, Norway, Switzerland, the Netherlands, Slovenia and the Republic of Ireland where Elocta was already available.

### **Alprolix reimbursed in the UK**

Alprolix was approved for reimbursement across the UK. National Health Service (NHS) England confirmed reimbursement alongside Scotland, Wales and Northern Ireland where Alprolix was already reimbursed. Alprolix is also approved for reimbursement in Germany and the Netherlands.

### **Orfadin capsule filing validated by Health Canada**

Health Canada has initiated review of the application for approval of Orfadin (nitisinone) capsules for the treatment of hereditary tyrosinaemia type-1 (HT-1).

### **Data from extended half-life haemophilia therapies presented at WHF 2016 World Congress**

Sobi and Biogen presented updated data on long-term safety and efficacy of the novel extended half-life therapies, Elocta/Eloctate® and Alprolix. The data from the phase 3 extension studies, B-YOND (haemophilia B) and ASPIRE (haemophilia A), was highlighted in oral and poster presentations at the World Federation of Hemophilia (WFH) 2016 World Congress in Orlando, Florida, 24-28 July 2016.

### **Milan Zdravkovic appointed as SVP, Head of R&D**

Milan Zdravkovic was appointed Senior Vice President, Head of Research & Development (R&D).

Milan joins Sobi from Novo Nordisk where he has had an 18 year tenure in the Research and Development organisation responsible for therapeutic areas including diabetes, growth hormone deficiency, obesity and immunology.

### **New number of shares and votes in Swedish Orphan Biovitrum AB (publ)**

The total number of shares and votes as per 31 August 2016 amounted to 272,010,948 shares, whereof 270,389,770 common shares and 1,621,178 class C shares, corresponding to in total 270,551,887.8 votes.

### **The board of directors exercised authorisation for repurchase of shares to secure commitments under incentive programme**

The annual general meeting resolved, for the purpose of ensuring that the company can fulfil its commitments under the long-term incentive programme, a directed share issue of no more than 188,142 redeemable and convertible class C shares.



# Financial review Q3

## Revenues

Total revenue was SEK 1,171 M (786).

## Inflammation

Kineret showed strong volume growth across most major markets as revenue increased by 23 per cent to SEK 265 M (215). Growth in North America was driven by volume and by the newly implemented specialty distribution model and patient support program. Growth in the EMENAR region continued to be driven by the CAPS indication.

## Genetics & Metabolism

Revenue for Orfadin was SEK 193 M (200), a decrease of 3 per cent. The business continued to grow in EMENAR supported by the continued launch of the oral suspension and 20 mg formulations. This was offset by lost sales in Turkey due to the entrance of a local generic. US revenues were negatively affected by higher Medicaid rebates.

## Haemophilia

Total revenue for the Haemophilia franchise was SEK 308 M (29). Royalty revenue amounted to SEK 235 M (29).

Product sales for the quarter were SEK 73 M (0), whereof SEK 57 M (0) was from Elocta and SEK 16 M (0) was from Alprolix. Sales in the quarter derived mainly from Germany followed by the Republic of Ireland and Scotland. The quarter also includes first sales in the Netherlands, Austria, France, Switzerland and Kuwait.

Elocta is now available in the five largest markets in EU.

Reimbursement for Elocta has so far been granted in in the UK,

France, Italy, Germany, Sweden, Denmark, Norway, Switzerland, the Netherlands, Slovenia and the Republic of Ireland.

Alprolix obtained reimbursement in the UK and has so far been granted in three additional markets; Germany, the Netherlands and Ireland.

## Partner Products

Revenue for Partner Products was SEK 217 M (172), an increase of 13 per cent excluding a one-time payment of SEK 24 M from Exelixis related to the transfer of Cometriq to Ipsen.

## ReFacto

ReFacto manufacturing revenue and royalty were SEK 162 M (140), an increase of 15 per cent. Manufacturing revenue was SEK 145 M (109). Royalty revenue was SEK 17 M (31). As of 1 June 2016 Sobi does not receive royalty on ReFacto sales outside of the US.

## Gross profit

Gross profit for the third quarter 2016 was SEK 782 M (486), representing a gross margin of 67 per cent (62).

## Operating expenses

Overall operating expenses excluding amortisations and write-offs were SEK 507 M (392).

Operating expenses for sales and administration excluding amortisations amounted to SEK 327 M (272). The increase primarily reflects the increased investment to support the launch of Elocta and Alprolix.

Research and development costs excluding amortisation increased to SEK 179 M (120), reflecting Sobi assuming its 50 per cent share of Biogen's ongoing development costs for Elocta from 1 March, and for Alprolix from 1 August, 2016. Increased investments were also driven early development programs and the initiation of the Kineret development programs for acute gout and Still's disease.

EBITA was SEK 282 M (97).

Amortisations of intangible assets amounted to SEK 110 M (72).

EBIT (operating profit) amounted to SEK 171 M (25).

## Financial summary

Amounts in SEK M	Q3 2016	Q3 2015	Change	Jan-Sep 2016	Jan-Sep 2015	Change	Full year 2015
Total revenues <sup>1</sup>	1,171	786	49%	3,913	2,414	62%	3,228
Gross profit	782	486	61%	2,791	1,486	88%	2,007
Gross margin	67%	62%		71%	62%		62%
EBITA	282	97	>100%	1,334	343	>100%	433
EBIT (Operating profit/loss)	171	25	>100%	1,034	129	>100%	146
Profit/loss for the period	143	5	>100%	710	77	>100%	68

<sup>1</sup>Jan-Sep 2016 revenues include a one time credit in Q1 of SEK 322 M relating to the first commercial sales of Elocta, and a one time credit in Q2 of SEK 386 M relating to first commercial sales of Alprolix.

### Net financial items and tax

Net financial items amounted to SEK -22 M (-14), including exchange rate loss of SEK -4 M (-3).

Tax amounted to SEK -6 M (-5).

### Profit/loss

Profit was SEK 143 M (5).

### Cash flow and investments

Cash flow from operations before change in working capital amounted to SEK 218 M (93).

Working capital impacted cash flow by SEK -136 M (152), mainly due to an increase in operating receivables.

Cash flow from investing activities amounted to SEK -30 M (-95).

### Cash

At the end of quarter the company had SEK 824 M in cash, compared to SEK 904 M as of 31 December 2015.

### Net cash/debt

Sobi ended the quarter with a net cash position of SEK 319 M, compared to SEK 82 M as of 31 December 2015.

### Revenues by Business Line

	Q3	Q3	Change	Change %	Jan-Sep	Jan-Sep	Change	Change %	FY
Amounts in SEK M	2016	2015	%	at CER <sup>1</sup>	2016	2015	%	at CER <sup>1</sup>	2015
<b>Key Therapeutic Areas</b>									
Inflammation: Kineret	265	215	23%	23%	735	583	26%	27%	805
Inflammation: Other <sup>2</sup>	26	29	-13%	-13%	79	75	4%	5%	99
Genetics & Metabolism: Orfadin	193	200	-3%	-3%	573	568	1%	2%	796
Haemophilia: Elocta	57	-	n/a	n/a	132	-	n/a	n/a	1
Haemophilia: Alprolix	16	-	n/a	n/a	21	-	n/a	n/a	1
Haemophilia: Royalty <sup>3</sup>	235	29	>100%	>100%	1,248	65	>100%	>100%	95
<b>Total</b>	<b>791</b>	<b>473</b>	<b>67%</b>	<b>68%</b>	<b>2,787</b>	<b>1,292</b>	<b>&gt;100%</b>	<b>&gt;100%</b>	<b>1,797</b>
<b>Partner Products<sup>4, 5, 6</sup></b>	<b>217</b>	<b>172</b>	<b>26%</b>	<b>28%</b>	<b>617</b>	<b>578</b>	<b>7%</b>	<b>8%</b>	<b>771</b>
<b>ReFacto</b>									
Manufacturing revenues	145	109	33%	31%	424	415	2%	2%	504
Royalty revenues	17	31	-47%	-57%	84	129	-35%	-33%	156
<b>Total</b>	<b>162</b>	<b>140</b>	<b>15%</b>	<b>11%</b>	<b>508</b>	<b>544</b>	<b>-7%</b>	<b>-6%</b>	<b>660</b>
<b>Total revenues</b>	<b>1,171</b>	<b>786</b>	<b>49%</b>	<b>49%</b>	<b>3,913</b>	<b>2,414</b>	<b>62%</b>	<b>64%</b>	<b>3,228</b>

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

<sup>2</sup>Reported under Partner Products until 31 December 2015. Numbers for previous years have been adjusted accordingly.

<sup>3</sup>Jan-Sep 2016 revenues include a one time credit in Q1 of SEK 322 M relating to the first commercial sales of Elocta, and a one time credit in Q2 of SEK 386 M relating to first commercial sales of Alprolix.

<sup>4</sup>Jan-Sep 2015 figures includes a one-time revenue milestone and a service fee for Cometriq of SEK 22 M received in Q1 2015.

<sup>5</sup>Partner Products now also include sales of Ammonaps, Ammonul and Ravicti which until 31 December 2015 were reported as Genetics & Metabolism: Other. Numbers for previous years have been adjusted accordingly.

<sup>6</sup>Jan-Sep 2016 and Q3 2016 revenues includes a one-time payment of SEK 24 M related to the transfer of Cometriq to Ipsen.



## Equity

Consolidated shareholders' equity as of 30 September 2016 amounted to SEK 5,370 M compared to SEK 4,689 M as of 31 December 2015.

## Parent company

Net sales in Q3 2016 for the Parent company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 1,177 M (584) of which SEK 536 M (222) referred to sales to Group companies. Income after financial items amounted to SEK 310 M (23). Investments in tangible and intangible assets amounted to SEK 29 M (91).

## Outlook 2016<sup>1</sup> guidance raised

For the full-year 2016, Sobi now expects revenues of SEK 5,125–5,200 M (4,800-5,000). Revenues include one time credits for Elocta of SEK 322 M and for Alprolix SEK 386 M, which do not impact cash.

Gross margin is expected to be 70 per cent (68-70).

EBITA for the full-year is now expected to be in the range of SEK 1,475–1,525 M (1,200-1,300).

<sup>1</sup>The original outlook was published on 29 February 2016.

## Operating Profit/Loss

	Q3 2016	Q3 2015	Jan-Sep 2016	Jan-Sep 2015	Full year 2015
<b>Amounts in SEK M</b>					
Total revenues	1,171	786	3,913	2,414	3,228
Total cost of goods and services sold	-389	-300	-1,122	-928	-1,221
<b>Gross profit</b>	<b>782</b>	<b>486</b>	<b>2,791</b>	<b>1,486</b>	<b>2,007</b>
<i>Gross Margin</i>	67%	62%	71%	62%	62%
Sales and administration expenses less amortisations and write-	-327	-272	-967	-764	-1,057
Research and development expenses less amortisations and write-	-179	-120	-520	-379	-513
<b>Total opex excl. amortisations and write-downs</b>	<b>-507</b>	<b>-392</b>	<b>-1,487</b>	<b>-1,143</b>	<b>-1,571</b>
<b>Other operating revenues/expenses</b>	<b>6</b>	<b>3</b>	<b>29</b>	<b>0</b>	<b>-3</b>
<b>EBITA</b>	<b>282</b>	<b>97</b>	<b>1,334</b>	<b>343</b>	<b>433</b>
Amortisations relating to					
Sales and administration expenses	-110	-72	-300	-214	-287
<b>Amortisations</b>	<b>-110</b>	<b>-72</b>	<b>-300</b>	<b>-214</b>	<b>-287</b>
<b>EBIT</b>	<b>171</b>	<b>25</b>	<b>1,034</b>	<b>129</b>	<b>146</b>

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



## Other information

### Personnel

As of September 2016, the number of full-time equivalents was 758 (702, December 2015).

### Significant events after the reporting period

#### European Commission grants SOBI003 orphan designation for the treatment of MPS IIIA

Sobi was granted orphan designation by the European Commission (EC) for the company's development candidate SOBI003, a modified human recombinant sulfamidase for the treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome).

#### MAH transfer of Alprolix to Sobi approved by European Commission (EC)

The European Commission (EC) approved the transfer of the marketing authorisation for Alprolix from Biogen to Sobi.

### 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.

Solna, Sweden 27 October 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 October 2016.*







# Auditors' review report

## Introduction

We have reviewed the condensed interim report for Swedish Orphan Biovitrum AB (publ) as at September 30, 2016 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

## Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 Review of Interim Financial Statements Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

## Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act regarding the Group, and in accordance with the Swedish Annual Accounts Act regarding the Parent Company.

Stockholm, 27 October 2016

Ernst & Young AB

Björn Ohlsson

Authorised Public Accountant



# Financial statements

## Group Statement of comprehensive income

Amounts in SEK M	Q3 2016	Q3 2015	Jan-Sep 2016	Jan-Sep 2015	Full year 2015
Total revenues <sup>1</sup>	1,171	786	3,913	2,414	3,228
Total cost of goods and services sold	-389	-300	-1,122	-928	-1,221
<b>Gross profit</b>	<b>782</b>	<b>486</b>	<b>2,791</b>	<b>1,486</b>	<b>2,007</b>
Sales and administration expenses	-438	-344	-1,267	-979	-1,344
Research and development expenses	-179	-120	-520	-379	-513
Other operating revenues/expenses	6	3	29	0	-3
<b>Operating profit/loss</b>	<b>171</b>	<b>25</b>	<b>1,034</b>	<b>129</b>	<b>146</b>
Financial income/expenses	-22	-14	-73	-33	-58
<b>Profit before tax</b>	<b>149</b>	<b>11</b>	<b>961</b>	<b>96</b>	<b>88</b>
Income tax expense	-6	-5	-251	-19	-19
<b>Profit for the period</b>	<b>143</b>	<b>5</b>	<b>710</b>	<b>77</b>	<b>68</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	0	–	–	-1	-3
<i>Items that may be reclassified subsequently to profit/loss</i>					
Translation difference	2	0	3	1	-2
Cash flow hedge (net of tax)	-28	–	-81	4	58
<b>Comprehensive income for the period</b>	<b>118</b>	<b>5</b>	<b>632</b>	<b>82</b>	<b>122</b>
Amortisation and write-down of intangible assets included in Sales and administration expenses	-110	-72	-300	-214	-287
Earning per share	0.53	0.02	2.65	0.29	0.26
Earning per share after dilution	0.53	0.02	2.64	0.29	0.26

<sup>1</sup>See page 6 for split by business line


**Group  
Balance sheet**

Amounts in SEK M	Sep 2016	Dec 2015	Sep 2015
<b>ASSETS</b>			
<i>Non-current assets</i>			
Intangible fixed assets <sup>1</sup>	6,893	5,787	4,145
Tangible fixed assets	107	109	105
Other long-term assets	146	99	80
<b>Total non-current assets</b>	<b>7,147</b>	<b>5,995</b>	<b>4,330</b>
<i>Current assets</i>			
Inventories	798	776	758
Accounts receivable	628	451	498
Current receivables, non-interest bearing	398	185	172
Cash and cash equivalents	824	904	914
<b>Total current assets</b>	<b>2,647</b>	<b>2,316</b>	<b>2,343</b>
<b>Total assets</b>	<b>9,794</b>	<b>8,311</b>	<b>6,672</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>	<b>5,370</b>	<b>4,689</b>	<b>4,640</b>
<i>Long-term liabilities</i>			
Long-term debt	502	800	820
Long-term liabilities, non-interest bearing	2,432	1,501	308
<b>Total long-term liabilities</b>	<b>2,934</b>	<b>2,301</b>	<b>1,127</b>
<i>Current liabilities</i>			
Short term debt	2	22	2
Current liabilities, non-interest bearing	1,488	1,298	904
<b>Total short-term liabilities</b>	<b>1,490</b>	<b>1,320</b>	<b>906</b>
<b>Total equity and liabilities</b>	<b>9,794</b>	<b>8,311</b>	<b>6,672</b>

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

**Group  
Changes in equity**

Amounts in SEK M	Jan - Sep 2016	Jan - Sep 2015	Full year 2015
<b>Opening balance</b>	<b>4,689</b>	<b>4,523</b>	<b>4,523</b>
Sharebased compensation to employees	25	13	23
Sale of own shares	24	22	22
Comprehensive income for the period	632	82	122
<b>Equity, end of period</b>	<b>5,370</b>	<b>4,640</b>	<b>4,689</b>

Whereof cash-flow hedges amounted to SEK -27 M as of 30 September 2016 and SEK 54 M in Full Year 2015



**Group  
Cash flow statement**

Amounts in SEK M	Q3 2016	Q3 2015	Jan-Sep 2016	Jan-Sep 2015	Full year 2015
Net result	143	5	710	77	68
Non-cash items <sup>1</sup>	75	88	-204	268	343
<b>Cash flow from operations before change in working capital</b>	<b>218</b>	<b>93</b>	<b>505</b>	<b>346</b>	<b>411</b>
Change in working capital	-136	152	-189	148	96
<b>Cash flow from operations</b>	<b>81</b>	<b>245</b>	<b>316</b>	<b>494</b>	<b>507</b>
Investment in intangible fixed assets	-27	-89	-70	-108	-119
Investment in tangible fixed assets	-4	-5	-28	-14	-27
Divestment of tangible fixed assets	1	-1	6	0	3
<b>Cash flow from investing activities</b>	<b>-30</b>	<b>-95</b>	<b>-92</b>	<b>-122</b>	<b>-143</b>
Loans - Raising/Amortization	0	-	-331	-	-
Sale of own shares	-	-	24	22	22
<b>Cash flow from financing activities</b>	<b>0</b>	<b>-</b>	<b>-308</b>	<b>22</b>	<b>22</b>
<b>Net change in cash</b>	<b>51</b>	<b>151</b>	<b>-83</b>	<b>394</b>	<b>386</b>
Liquid funds at the beginning of the period	770	763	904	519	519
Translation difference in cash flow and liquid funds	2	0	3	1	-2
<b>Liquid funds at the end of the period</b>	<b>824</b>	<b>914</b>	<b>824</b>	<b>914</b>	<b>904</b>
<sup>1</sup> Non-cash items:					
Depreciation tangible fixed assets	7	8	22	24	32
Amortization intangible assets	110	72	300	214	287
Deferred tax	-7	3	206	14	13
Other, whereof SEK -42 M in Q3 2016 reflects Elocta and Alprolix (SEK -770 M in Jan-Sep 2016), see also page 5 under Haemophilia	-36	5	-733	16	11
<b>Total non-cash items</b>	<b>75</b>	<b>88</b>	<b>-204</b>	<b>268</b>	<b>343</b>



## Group

### Key ratios and other information

Amounts in SEK M	Q3 2016	Q3 2015	Jan-Sep 2016	Jan-Sep 2015	Full year 2015
<b>Profit numbers</b>					
Gross profit	782	486	2,791	1,486	2,007
EBITDA <sup>1</sup>	289	105	1,356	367	465
EBITA <sup>1</sup>	282	97	1,334	343	433
EBIT <sup>1</sup>	171	25	1,034	129	146
Profit/loss	143	5	710	77	68
<b>Per share data (SEK)</b>					
Earning/loss per share	0.53	0.02	2.65	0.29	0.26
Earning/loss per share after dilution	0.53	0.02	2.64	0.29	0.26
Shareholders' equity per share	19.9	17.2	19.9	17.2	17.3
Shareholders' equity per share after dilution	19.8	17.2	19.8	17.2	17.3
<b>Other information</b>					
Gross margin	67%	62%	71%	62%	62%
Equity ratio	55%	70%	55%	70%	56%
Net cash (-)/debt (+) <sup>2</sup>	-319	57	-319	57	-82
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)	1,621,178	1,433,036	1,621,178	1,433,036	1,433,036
Number of ordinary shares (in treasury)	1,640,735	2,763,768	1,640,735	2,763,768	2,763,768
Average number of ordinary shares (excluding shares in treasury)	268,749,035	267,569,194	268,226,232	267,162,451	267,278,339
Average number of ordinary shares after dilution (excluding shares in treasury)	269,035,680	267,569,194	269,273,995	267,162,451	267,278,339

<sup>1,2</sup>Sobi presents certain financial measures in the interim report that are not defined according to IFRS, so called alternative performance measures. These have been noted in the table above and the parameters used to calculate these key ratios have been further specified below. Further information on why these are considered important can be found in Definitions at the end of this report.

<sup>1</sup> Amortizations	-110	-72	-300	-214	-287
<sup>1</sup> Depreciations	-7	-8	-22	-24	-32
<sup>2</sup> Long term liabilities interest-bearing	502	820	502	820	800
<sup>2</sup> Short term liabilities interest-bearing	2	2	2	2	22
<sup>2</sup> Cash	824	914	824	914	904


**Parent company  
Income statement**

Amounts in SEK M	Q3 2016	Q3 2015	Jan-Sep 2016	Jan-Sep 2015	Full year 2015
Total revenues	1,177	584	3,510	2,028	2,750
Total cost of goods and services sold	-362	-275	-1,045	-875	-1,168
<b>Gross profit</b>	<b>815</b>	<b>309</b>	<b>2,465</b>	<b>1,153</b>	<b>1,582</b>
Sales and Administration expenses	-323	-171	-810	-525	-814
Research and Development expenses	-168	-110	-479	-352	-472
Other operating revenues/expenses	8	3	31	-2	13
<b>Operating profit/loss</b>	<b>332</b>	<b>31</b>	<b>1,207</b>	<b>274</b>	<b>309</b>
Financial income/expenses	-22	-8	-63	-13	-33
<b>Profit/loss after financial items</b>	<b>310</b>	<b>23</b>	<b>1,144</b>	<b>261</b>	<b>276</b>
Income tax benefit/expenses <sup>1</sup>	-	-	-26	-6	-58
<b>Profit/loss for the period</b>	<b>310</b>	<b>23</b>	<b>1,118</b>	<b>255</b>	<b>218</b>

<sup>1</sup>The parent company applies accelerated depreciation on an annual basis which has been considered in the reported tax expense in 2016.

**Parent company statement  
of other comprehensive income**

Amounts in SEK M	Q3 2016	Q3 2015	Jan-Sep 2016	Jan-Sep 2015	Full year 2015
Profit/loss for the period	310	23	1,118	255	218
<i>Items that may be reclassified subsequently to profit/loss</i>					
Cash flow hedge (net of tax)	-28	-	-81	4	58
<b>Comprehensive income for the period</b>	<b>282</b>	<b>23</b>	<b>1,037</b>	<b>259</b>	<b>276</b>
Amortisation and write-down of intangible assets included in Sales & Adm expenses	-71	-24	-173	-70	-94



**Parent company  
Balance sheet**

Amounts in SEK M	Sep 2016	Dec 2015	Sep 2015
<b>ASSETS</b>			
<i>Non-current assets</i>			
Intangible fixed assets	4,310	2,739	1,048
Tangible fixed assets	89	92	89
Other long-term assets	3,882	3,899	3,911
<b>Total non-current assets</b>	<b>8,281</b>	<b>6,730</b>	<b>5,048</b>
<i>Current assets</i>			
Inventories	719	674	665
Current receivables, non-interest bearing	1,334	1,012	1,034
Cash and cash equivalents	661	750	733
<b>Total current assets</b>	<b>2,714</b>	<b>2,436</b>	<b>2,432</b>
<b>Total assets</b>	<b>10,995</b>	<b>9,166</b>	<b>7,480</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>	<b>6,920</b>	<b>5,832</b>	<b>5,809</b>
<i>Long-term liabilities</i>			
Long-term debt	497	795	814
Long-term liabilities, non-interest bearing	1,919	1,238	–
<b>Total long-term liabilities</b>	<b>2,416</b>	<b>2,033</b>	<b>814</b>
<i>Current liabilities</i>			
Short term debt	–	20	–
Current liabilities, non-interest bearing	1,659	1,281	857
<b>Total short-term liabilities</b>	<b>1,659</b>	<b>1,301</b>	<b>857</b>
<b>Total equity and liabilities</b>	<b>10,995</b>	<b>9,166</b>	<b>7,480</b>

**Parent company**

**Change in shareholders' equity**

Amounts in SEK M	Jan-Sep 2016	Jan-Sep 2015	Full year 2015
<b>Opening balance</b>	<b>5,832</b>	<b>5,510</b>	<b>5,510</b>
Sharebased compensation to employees	28	18	23
Sale of own shares	24	22	22
Comprehensive income for the period	1,037	259	276
<b>Equity, end of period</b>	<b>6,920</b>	<b>5,809</b>	<b>5,832</b>

Whereof cash-flow hedges amounted to SEK -27 M as of 30 September 2016 and SEK 54 M in Full Year 2015



# 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—September 2016 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 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](http://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 EU approval of Alprolix in May 2016 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 (see 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 30 September 2016, the net reported value in the balance sheet for derivatives was SEK -4 M (1).

As of 30 September 2016, all other financial instruments in the balance sheet have reported values that are in all material aspects equivalent to fair value.

## Note 3 — Financial impact of Alprolix approval

The final purchase price will be determined in Q4 2016 and is expected to be USD 186 M.





# 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.

## **Gross profit**

Net sales less cost of goods and services sold.

## **Interest bearing liability**

Credit facilities and other liabilities to credit institutions.

## **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.

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

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



# Glossary

## Acute gout

An autoinflammatory 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.

## Alprolix

Alprolix (eftrenonacog alfa) is a recombinant, extended half-life clotting factor IX 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.

## 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 of the European Medicines Agency.

## EC

European Commission.

## Elocta

Elocta (efmoroctocog alfa) is a recombinant, extended half-life clotting factor VIII 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

## GMP

Good Manufacturing Practice

## 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.

## Kineret

Kineret (anakinra) is a drug used to treat inflammatory diseases.

## MAH

Marketing authorisation holder. Regulatory responsible.

## Mucopolysaccharidosis (MPS) type IIIA (Sanfilippo A syndrome)

A progressive, life-threatening and rare inherited metabolic disorder affecting children already from a young age. Belongs to a group of diseases called Lysosomal Storage Disorders (LSDs).

## NHS

National Health Service

## Orfadin

A drug used to treat Hereditary Tyrosinaemia type 1 (HT1-).

## SOBI003

A chemically modified variant of a recombinant human sulfamidase product candidate intended as an enzyme replacement therapy in lysosomal storage disease MPS IIIA, aimed to reduce heparan sulfate storage materials in affected cells.

## Still's disease

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).



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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 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 Stockholm. More information is available at [www.sobi.com](http://www.sobi.com)