Q3 REPORT 2015

sobi

Pioneer in Rare Diseases

*We've got a story to tell*

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# Financial Calendar

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|---|---|
| Q4 & FY 2015 | 26 February 2016 |
| Q1 2016 | 27 April 2016 |
| AGM | 19 May 2016 |
| Q2 2016 | 15 July 2016 |
| Q3 2016 | 27 October 2016 |

# CEO Statement

**The third quarter results support the themes from the first half year; with solid momentum across the commercial portfolio and achievement of significant additional milestones for our extended half-life Haemophilia franchise.**

## Strong base business

Total revenues in the third quarter were SEK 786 M, an increase of 18 per cent (8 per cent at constant exchange rates) over the prior year. Gross margin was in line with our expectations, and cash flow increased significantly compared to the same period last year.

Orfadin® grew by 22 per cent, with growth across all markets, including South America where we initiated direct sales in the beginning of 2015. An important celebration of 50 years of experience in the global hereditary tyrosinaemia community took place in Quebec in September. Physicians, nurses, and patients from all over the world joined to acknowledge the contributions Orfadin has made to the well being and outcomes of patients with hereditary tyrosinaemia type 1 (HT-1).

Kineret® performed well across our markets with a growth of 23 per cent. A highlight in the quarter was the Australian regulatory approval for use in Systemic Juvenile Idiopathic Arthritis (SJIA).

Partner Products increased 8 per cent driven by continued growth for Cometriq®, Kepivance® and Xiapex®.

ReFacto® delivered slightly higher results in the quarter, up 5 per cent. We continue to expect the second half results for ReFacto to be lower than the first half due to the ordering pattern from Pfizer.

## Important pipeline developments

Our extended half-life haemophilia products in development reached several milestones during the quarter.

Following the positive results of the Kids B-LONG study and the European Medicines Agency (EMA) validation of the Alprolix® (rFIXFc) Market Authorisation Application, we announced on 16 July that we had decided to exercise our opt-in right for the product, as we did for Elocta® (rFVIIIFc) in 2014. We were also glad to publish interim results from the B-YOND study that supported the long-term safety and efficacy of Alprolix in people with severe haemophilia B treated for up to two years. We are now working very hard on supporting the evaluation of the file as we move toward launch in 2016.

On 25 September, we received a positive opinion from EMA's Committee for Medicinal Products for Human Use (CHMP) for Elocta for the treatment of haemophilia A. We continue to anticipate the EU approval of Elocta in Q4 2015, and our team is in place and eager to start securing patient access as soon as possible once approval is granted. Furthermore, data from our extension study ASPIRE were recently published in the scientific journal *Haemophilia,* supporting long-term safety and efficacy of Elocta. We are poised to significantly advance the standard of care in Haemophilia – there has never been a more exciting time in the field.

Finally our Orfadin oral suspension filing was validated by the Food and Drug Administration (FDA) who initiated their review of the new formulation for the treatment of HT1 – we expect the outcome of FDA´s review in Q2 2016. We also submitted an application for

market authorisation of the Orfadin 20 mg capsule to the FDA after the end of the period.

As always thank you to our shareholders for your continued interest in and support for Sobi, and to our employees who have done so much to make these results possible.

Geoffrey McDonough
CEO and President

Solna, Sweden, 29 October 2015

# Q3 2015 in Summary

## Business Summary

- Exercised opt-in right for Alprolix
- Extension study data supporting long-term safety and efficacy of Elocta published in scientific journal *Haemophilia*
- Results from B-YOND study reinforced long-term clinical profile of Alprolix for the treatment of haemophilia B
- Received Australian regulatory approval for Kineret for use in Systemic Juvenile Idiopathic Arthritis
- Opened European and Benelux office in Brussels
- FDA validated Orfadin oral suspension filing
- Received positive opinion from CHMP for Elocta for the treatment of haemophilia A
- Kineret received Orphan Drug Designation for Still´s disease

## Financial Summary

- Total revenue was SEK 786 M (666), an increase of 18 per cent (8 per cent at constant exchange rates (CER))
- Product revenue was SEK 645 M (532), an increase of 21 per cent (10 per cent at CER)
- Gross margin was 62 per cent (59)
- EBITA was SEK 97 M (120)
- Ended the quarter with a cash position of SEK 914 M

## Financial Summary in USD[1]

- Total revenue was USD 93 M
- Product revenue was USD 77 M
- EBITA was USD 12 M
- Ended the quarter with a cash position of USD 109 M

[1] *Exchange rate 1USD = 8.4135 SEK*

# Business Review Q3

### Exercised opt-in right for Alprolix

Sobi announced that the company had exercised its opt-in right to take over final development and commercialisation of Alprolix for the territory composed of Europe, North Africa, Russia and certain Middle Eastern markets. Sobi made a payment to Biogen of USD 10 M, which is held in escrow pending the EU regulatory approval of Alprolix.

### Extension study data supporting long-term safety and efficacy of Elocta published in *Haemophilia*

Sobi and Biogen announced that newly published clinical data demonstrated that people on extended-interval prophylaxis regimens with Elocta experienced low bleeding rates. The interim results of the phase 3, open-label extension study of Elocta called ASPIRE were published in the online edition of *Haemophilia*, the journal of the World Federation of Hemophilia, the European Association for Haemophilia and Allied Disorders, and the Hemostasis & Thrombosis Research Society.

### Results from B-YOND study reinforced long-term clinical profile of Alprolix for the treatment of haemophilia B

Sobi and Biogen released interim results from the B-YOND study that supported the long-term safety and efficacy of Alprolix in people with severe haemophilia B treated for up to two years. Participants in the phase 3, open-label long-term study maintained low bleeding rates with one to two week prophylaxis regimens.

### Received Australian regulatory approval for Kineret for use in Systemic Juvenile Idiopathic Arthritis

Sobi received marketing authorisation in Australia for Kineret for the treatment of SJIA, which is a rare form of juvenile chronic arthritis.

### Opened European and Benelux office in Brussels

Sobi formally opened its new European and Benelux office in Brussels, Belgium. The inauguration results from Sobi's expanding international presence and further strengthens the company's platform in Europe as well as in the Benelux Region.

### FDA validated Orfadin oral suspension filing

Sobi announced that the FDA initiated the review of the oral suspension formulation of Orfadin for the treatment of HT-1. HT-1 is a rare genetic disease characterised by signs and symptoms that begin in the first few months of life. In affected infants the disease may result in liver and kidney failure, and can be fatal if not diagnosed and treated early in life.

### Received positive opinion from CHMP for Elocta for the treatment of haemophilia A

Sobi and Biogen received a positive recommendation from CHMP for the marketing authorisation of Elocta. If Elocta is approved by the European Commission, it will be the first haemophilia A treatment with extended half-life available in the EU.

### Kineret received Orphan Drug Designation for Still´s disease

FDA approved Sobi´s application for an Orphan Drug Designation of Kineret for treatment of Still's disease.

# Financial Review Q3

## Key Therapeutic Areas

Revenue was SEK 472 M (372), an increase of 27 per cent (13 per cent at constant exchange rates).

### Inflammation

Revenue for Kineret was SEK 215 M (174), an increase of 23 per cent.

There was good volume growth across most European markets, with the continued launch of the CAPS indication. The US market also performed well, driven by price and to a lesser extent by demand.

### Genetics & Metabolism

Revenue for Orfadin was SEK 200 M (164), an increase of 22 per cent.

Orfadin grew in all major markets, including South America where Sobi initiated sales in January 2015 with partner Innovative Medicines.

### Haemophilia

Revenue for the Haemophilia franchise was SEK 29 M (8). SEK 25 M (7) represent royalties equal to 2 per cent from the sales of Eloctate and Alprolix in Biogen territories during the third quarter, and SEK 4 M (1) from sales in the second quarter not previously reported.

## Partner Products

Revenue for Partner Products was SEK 173 M (160), an increase of 8 per cent. The increase was mainly driven by growth of Cometriq and Xiapex.

## ReFacto

ReFacto manufacturing revenues and royalty were SEK 140 M (134), an increase of 5 per cent. Manufacturing revenue was SEK 109 M (92). Royalty revenue was SEK 31 M (42).

## Gross Profit

Gross profit for the third quarter was SEK 486 M (395), representing a gross margin of 62 per cent (59). Favourable product mix and currency effects were the main contributors.

## Operating Expenses

Operating expenses excluding amortisations and write-offs were SEK 392 M (278).

Operating expenses for sales and administration excluding amortisations amounted to SEK 272 M (187). The increase reflects new employees hired to support the build-up of the Haemophilia organisation. Unfavourable exchange rates increased costs by approximately 5 per cent.

Research and development costs excluding amortisation and write-offs were SEK 120 M (91), reflecting increased investments in early programs, Haemophilia launch activities and study programs for Xiapex.

EBITA was SEK 97 M (120).

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

EBIT (operating profit) amounted to SEK 25 M (50).

## Net financial items and tax

Net financial items amounted to SEK -14 M (7), including exchange rate losses (gains) of SEK -3 M (21). The variance is mainly due to the larger positive exposure in USD denominated items during Q3 2014 compared to Q3 2015 and the substantial appreciation of the USD during the same period.

Tax amounted to SEK -5 M (-4). An adjustment relating to deferred tax has been made for Q1 and Q2 2015, see note 4 for more information.

## Financial Summary

| Amounts in SEK M | Q3 2015 | Q3 2014 | Change | Jan-Sep 2015 | Jan-Sep 2014 | Change | Full year 2014 |
|---|---|---|---|---|---|---|---|
| Total revenues | 786 | 666 | 18% | 2,414 | 1,902 | 27% | 2,607 |
| Gross profit | 486 | 395 | 23% | 1,486 | 1,121 | 33% | 1,548 |
| Gross margin | 62% | 59% | | 62% | 59% | | 59% |
| EBITA[1] | 97 | 120 | -19% | 343 | -82 | >100% | -43 |
| EBITA excluding write-offs | 97 | 120 | -19% | 343 | 243 | 41% | 307 |
| EBIT (Operating profit/loss) | 25 | 50 | -50% | 129 | -292 | >100% | -325 |
| Profit/loss for the period | 5 | 53 | -90% | 77 | -250 | >100% | -268 |

[1]Jan-Sep 2014 includes write-offs relating to Kiobrina® of SEK 325 M in Q1.

## Profit/Loss

Profit was SEK 5 M (53).

## Cash flow and investments

Cash flow from operations before change in working capital amounted to SEK 93 M (83).

Working capital impacted cash flow by SEK 152 M (41), due to increase in operating liabilities.

Cash flow from investing activities amounted to SEK -95 M (-16). The decision to exercise Sobi´s opt-in right to take over final development and commercialisation of Alprolix in Sobi´s territories was the largest investment during the quarter.

## Cash

Cash position at the end of quarter was SEK 914 M, compared to SEK 519 M as of 31 December 2014.

## Net Cash/Debt

Sobi ended the quarter with a net cash of SEK 92 M, compared to a net debt of SEK 298 M as of 31 December 2014.

## Equity

Consolidated shareholders' equity as of 30 of September 2015 amounted to SEK 4,640 M compared to 4,523 M as of 31 December 2014.

## Revenues by Business Line

| Amounts in SEK M | Q3 2015 | Q3 2014 | Change % | Change % at CER[1] | Jan-Sep 2015 | Jan-Sep 2014 | Change % | Change % at CER[1] | Full Year 2014 |
|---|---|---|---|---|---|---|---|---|---|
| **Key Therapeutic Areas** | | | | | | | | | |
| Inflammation: Kineret | 215 | 174 | 23% | 9% | 583 | 446 | 31% | 14% | 609 |
| Genetics & Metabolism: Orfadin | 200 | 164 | 22% | 9% | 568 | 379 | 50% | 34% | 548 |
| Genetics & Metabolism: Other | 28 | 26 | 8% | 3% | 104 | 85 | 22% | 16% | 118 |
| Haemophilia: Royalties[2] | 29 | 8 | >100% | >100% | 65 | 19 | >100% | >100% | 31 |
| **Total** | **472** | **372** | **27%** | **13%** | **1,320** | **930** | **42%** | **25%** | **1,307** |
| **Partner Products[3]** | **173** | **160** | **8%** | **3%** | **549** | **484** | **14%** | **7%** | **682** |
| **ReFacto** | | | | | | | | | |
| Manufacturing revenues | 109 | 92 | 19% | 19% | 415 | 367 | 13% | 13% | 466 |
| Royalty revenues | 31 | 42 | -25% | -35% | 129 | 121 | 7% | -16% | 152 |
| **Total** | **140** | **134** | **5%** | **2%** | **544** | **488** | **12%** | **6%** | **618** |
| **Total revenues** | **786** | **666** | **18%** | **8%** | **2,414** | **1,902** | **27%** | **16%** | **2,607** |

[1]Constant Exchange Rate.

[2]Royalties on commercial sales, Biogen. Note that Jan-Sep 2014 includes a one-time milestone payment of SEK 11 M.

[3]Jan-Sep 2015 includes a one-time revenue milestone for Cometriq of SEK 18 M in Q1.

## Parent Company

Net sales in Q3 2015 for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 584 M (544) of which SEK 222 M (220) referred to sales to Group companies. Income after financial items amounted to SEK 23 M (87). Investments in tangible and intangible assets amounted to SEK 91 M (67).

## Outlook 2015 - EBITA range revised

Sobi expects total revenues for the full year to be in the range of SEK 3,000 to 3,200 M, and gross margin to be in the range of 59 to 61 per cent. Operating costs are projected to increase as the company continues to prepare for the planned launch of Elocta.

Based on the results for the first three quarters Sobi now expects EBITA for the full year to be in the range of SEK 350-400 M (previously SEK 325-400 M).

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

### Operating Profit/Loss

| Amounts in SEK M | Q3 2015 | Q3 2014 | Jan-Sep 2015 | Jan-Sep 2014 | Full year 2014 |
|---|---|---|---|---|---|
| Total revenues | 786 | 666 | 2,414 | 1,902 | 2,607 |
| Total cost of goods and services sold | -300 | -271 | -928 | -781 | -1,059 |
| **Gross profit** | **486** | **395** | **1,486** | **1,121** | **1,548** |
| *Gross Margin* | *62%* | *59%* | *62%* | *59%* | *59%* |
| Sales and administration expenses less amortisations and write-downs | -272 | -187 | -764 | -536 | -750 |
| Research and development expenses less amortisations and write-downs | -120 | -91 | -379 | -351 | -501 |
| **Total opex less amortisations and write-downs** | **-392** | **-278** | **-1,143** | **-887** | **-1,250** |
| **Other operating revenues/expenses** | **3** | **3** | **0** | **-315** | **-341** |
| **EBITA** | **97** | **120** | **343** | **-82** | **-43** |
| Amortisations and write-downs relating to Sales and administration expenses | -72 | -70 | -214 | -211 | -282 |
| **EBIT** | **25** | **50** | **129** | **-292** | **-325** |

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

# Other Information

## Personnel

As of September 2015, the number of full-time equivalents in personnel was 667 (584, December 2014).

## Significant events after the reporting period

**Haemophilia therapy from largest multi-year donation now available to patients in developing world**

Sobi, Biogen, and the World Federation of Hemophilia (WFH) announced that the first shipments of haemophilia therapy have started to arrive at treatment centres across the developing world. These shipments are part of the largest humanitarian aid pledge of its kind to help people with haemophilia in developing countries.

The donation will provide up to 500 million units of haemophilia therapy over five years to the WFH and represents a significant contribution to the expansion of their *Humanitarian Aid Program*, a 20-year old initiative dedicated to providing treatment and care for people with haemophilia in the developing world. This donation is the first phase of Biogen and Sobi's ten-year commitment to produce 1 billion International Units (IUs) of haemophilia therapy for humanitarian use.

**Xiapex approved for the treatment of Peyronie's disease in Switzerland**

Sobi received approval from Swissmedic, the Swiss Agency for Therapeutic Products, for Xiapex (collagenase clostridium histolyticum) for the treatment of adult men with Peyronie's disease.

*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.*

# Auditors´ Review Report

## Introduction

We have reviewed the condensed interim report for Swedish Orphan Biovitrum AB (publ) as at September 30, 2015 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, 29 October 2015

Ernst & Young AB

Björn Ohlsson
Authorised Public Accountant

# Financial Statements

**Group**
**Income Statement**

| Amounts in SEK M | Q3 2015 | Q3 2014 | Jan-Sep 2015 | Jan-Sep 2014 | Full Year 2014 |
|---|---|---|---|---|---|
| Total revenues | 786 | 666 | 2,414 | 1,902 | 2,607 |
| Total cost of goods and services sold | -300 | -271 | -928 | -781 | -1,059 |
| **Gross profit** | **486** | **395** | **1,486** | **1,121** | **1,548** |
| Sales and administration expenses | -344 | -258 | -979 | -747 | -1,032 |
| Research and development expenses | -120 | -91 | -379 | -351 | -501 |
| Other operating revenues/expenses | 3 | 3 | 0 | -315 | -341 |
| **Operating profit/loss** | **25** | **50** | **129** | **-292** | **-325** |
| Financial income/expenses | -14 | 7 | -33 | -4 | 6 |
| Income tax benefit/expense | -5 | -4 | -19 | 46 | 51 |
| **Profit/loss for the period** | **5** | **53** | **77** | **-250** | **-268** |
| *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 | – | – | -1 | 2 | 1 |
| *Items that may be reclassified subsequently to profit/loss* | | | | | |
| Translation difference | 0 | 1 | 1 | 2 | 4 |
| Cash flow hedge (net of tax) | – | 0 | 4 | -1 | 1 |
| **Comprehensive income for the period** | **6** | **53** | **82** | **-248** | **-263** |
| Amortisation and write-down of intangible assets included in Sales and administration expenses | -72 | -70 | -214 | -211 | -282 |
| Earning/loss per share before and after dilution | 0.02 | 0.20 | 0.29 | -0.94 | -1.01 |

## Group
## Balance sheet

| Amounts in SEK M | Sep 2015 | Jun 2015 | Mar 2015 | Dec 2014 | Sep 2014 |
|---|---|---|---|---|---|
| **ASSETS** | | | | | |
| ***Non-current assets*** | | | | | |
| Intangible fixed assets[1] | 4,145 | 4,128 | 4,192 | 4,248 | 4,231 |
| Tangible fixed assets | 105 | 107 | 110 | 115 | 116 |
| Financial fixed assets | 80 | 92 | 79 | 73 | 67 |
| **Total non-current assets** | **4,330** | **4,327** | **4,380** | **4,436** | **4,414** |
| ***Current assets*** | | | | | |
| Inventories | 758 | 742 | 765 | 764 | 726 |
| Accounts receivable | 498 | 523 | 647 | 480 | 451 |
| Current receivables, non-interest bearing | 172 | 194 | 133 | 172 | 169 |
| Cash and cash equivalents | 914 | 763 | 682 | 519 | 611 |
| **Total current assets** | **2,343** | **2,222** | **2,226** | **1,935** | **1,957** |
| **Total assets** | **6,672** | **6,549** | **6,606** | **6,371** | **6,371** |
| **EQUITY AND LIABILITIES** | | | | | |
| ***Shareholders´ equity***[2] | **4,640** | **4,630** | **4,614** | **4,523** | **4,533** |
| ***Long-term liabilities*** | | | | | |
| Long-term debt | 820 | 819 | 817 | 816 | 815 |
| Long-term liabilities, non-interest bearing[2] | 308 | 316 | 313 | 285 | 292 |
| **Total long-term liabilities** | **1,127** | **1,135** | **1,130** | **1,101** | **1,108** |
| ***Current liabilities*** | | | | | |
| Short term debt | 2 | 2 | 2 | 2 | 2 |
| Current liabilities, non-interest bearing | 904 | 783 | 861 | 745 | 729 |
| **Total short-term liabilities** | **906** | **784** | **862** | **747** | **730** |
| **Total equity and liabilities** | **6,672** | **6,549** | **6,606** | **6,371** | **6,371** |

[1]Including goodwill SEK 1,554 M, as per 30 September 2015.
[2]An adjustment relating to deferred tax has been made for Q1 and Q2 2015, see note 4 for more information.

## Group
## Changes in Equity

| Amounts in SEK M | Jan-Sep 2015 | Jan-Sep 2014 | Full year 2014 |
|---|---|---|---|
| **Opening balance** | **4,523** | **4,769** | **4,769** |
| Sharebased compensation to employees | 13 | 12 | 16 |
| Transfer of own shares | 22 | – | – |
| Comprehensive income for the period | 82 | -248 | -263 |
| **Equity, end of period** | **4,640** | **4,533** | **4,523** |

## Group
## Cash Flow Statement

| Amounts in SEK M | Q3 2015 | Q3 2014 | Jan-Sep 2015 | Jan-Sep 2014 | Full year 2014 |
|---|---|---|---|---|---|
| Net result | 5 | 53 | 77 | -250 | -268 |
| Non-cash items[1] | 88 | 30 | 268 | 437 | 567 |
| **Cash flow from operations before change in working capital** | **93** | **83** | **346** | **186** | **299** |
| Change in working capital | 152 | 41 | 148 | -5 | -66 |
| **Cash flow from operations** | **245** | **124** | **494** | **181** | **234** |
| Investment in intangible fixed assets | -89 | -10 | -108 | -22 | -160 |
| Investment in tangible fixed assets | -5 | -6 | -14 | -14 | -23 |
| Divestment of tangible fixed assets | -1 | -1 | 0 | – | – |
| **Cash flow from investing activities** | **-95** | **-16** | **-122** | **-36** | **-184** |
| Loans - Raising/Amortisation | – | – | – | 20 | 20 |
| Transfer of own shares | – | – | 22 | – | – |
| **Cash flow from financing activities** | **–** | **–** | **22** | **20** | **20** |
| **Net change in cash** | **151** | **108** | **394** | **165** | **70** |
| Liquid funds at the beginning of the period | 763 | 503 | 519 | 445 | 445 |
| Translation difference in cash flow and liquid funds | 0 | 1 | 1 | 2 | 4 |
| **Liquid funds at the end of the period** | **914** | **611** | **914** | **611** | **519** |
| **[1]Non-cash items:** | | | | | |
| Depreciation tangible fixed assets | 8 | 8 | 24 | 24 | 32 |
| Amortisation intangible assets | 72 | 70 | 214 | 211 | 282 |
| Deferred tax | 3 | -2 | 14 | -59 | -71 |
| Other, whereof Kiobrina write-off amounts to SEK 268 M in 2014 | 5 | -46 | 16 | 261 | 325 |

## Group
## Key Ratios and Other Information

| Amounts in SEK M | Q3 2015 | Q3 2014 | Jan-Sep 2015 | Jan-Sep 2014 | Full year 2014 |
|---|---|---|---|---|---|
| **Profit numbers** | | | | | |
| Gross profit | 486 | 395 | 1,486 | 1,121 | 1,548 |
| EBITDA | 105 | 128 | 367 | -58 | -12 |
| EBITA | 97 | 120 | 343 | -82 | -43 |
| EBIT | 25 | 50 | 129 | -292 | -325 |
| Profit/loss | 5 | 53 | 77 | -250 | -268 |
| **Per share data (SEK)** | | | | | |
| Earning/loss per share | 0.02 | 0.20 | 0.29 | -0.94 | -1.01 |
| Earning/loss per share after dilution | 0.02 | 0.20 | 0.29 | -0.94 | -1.01 |
| Shareholders' equity per share | 17.2 | 17.0 | 17.2 | 17.0 | 16.7 |
| Shareholders' equity per share after dilution | 17.2 | 17.0 | 17.2 | 17.0 | 16.7 |
| **Other information** | | | | | |
| Gross margin | 62% | 59% | 62% | 59% | 59% |
| Equity ratio | 70% | 71% | 70% | 71% | 71% |
| Net cash (-)/debt (+) | -92 | 206 | -92 | 206 | 298 |
| Number of ordinary shares | 270,389,770 | 270,389,770 | 270,389,770 | 270,389,770 | 270,389,770 |
| Number of C-shares (in treasury) | 1,433,036 | 396,180 | 1,433,036 | 396,180 | – |
| Number of ordinary shares (in treasury) | 2,763,768 | 4,188,948 | 2,763,768 | 4,188,948 | 4,688,948 |
| Average number of ordinary shares (excluding shares in treasury) | 267,569,194 | 266,200,822 | 267,162,451 | 265,867,489 | 265,993,723 |
| Number of shares after dilution | 270,389,770 | 270,389,770 | 270,389,770 | 270,389,770 | 270,389,770 |
| Average number of ordinary shares after dilution (excluding shares in treasury) | 267,569,194 | 266,200,822 | 267,162,451 | 265,867,489 | 265,993,723 |

## Parent Company
## Income Statement

| Amounts in SEK M | Q3 2015 | Q3 2014 | Jan-Sep 2015 | Jan-Sep 2014 | Full year 2014 |
|---|---|---|---|---|---|
| Total revenues | 584 | 544 | 2,028 | 1,737 | 2,328 |
| Total cost of goods and services sold | -275 | -231 | -875 | -711 | -974 |
| **Gross profit** | **309** | **314** | **1,153** | **1,026** | **1,355** |
| Sales and Administration expenses | -171 | -162 | -525 | -442 | -624 |
| Research and Development expenses | -110 | -88 | -352 | -329 | -470 |
| Other operating revenues/expenses | 3 | 7 | -2 | -41 | -64 |
| **Operating profit/loss** | **31** | **71** | **274** | **215** | **197** |
| Result from participation in Group companies[1] | – | 2 | – | -175 | -175 |
| Financial income/expenses | -8 | 15 | -13 | 20 | 37 |
| **Profit/loss after financial items** | **23** | **87** | **261** | **60** | **59** |
| Group contribution | – | – | – | – | -159 |
| Income tax benefit/expenses | – | – | -6 | -21 | -21 |
| **Profit/loss for the period** | **23** | **87** | **255** | **39** | **-121** |
| **Other comprehensive income** | | | | | |
| *Items that may be reclassified subsequently to profit/loss* | | | | | |
| Cash flow hedge (net of tax) | – | 0 | 4 | -1 | 1 |
| **Comprehensive income for the period** | **23** | **88** | **259** | **38** | **-120** |
| Amortisation and write-down of intangible assets included in Sales & Adm expenses | -24 | -22 | -70 | -66 | -89 |

[1]2014 includes write-down in value of ownership of Arexis relating to Kiobrina of SEK 177 M.

## Parent Company
## Balance Sheet

| Amounts in SEK M | Sep 2015 | Jun 2015 | Mar 2015 | Dec 2014 | Sep 2014 |
|---|---|---|---|---|---|
| **ASSETS** | | | | | |
| ***Non-current assets*** | | | | | |
| Intangible fixed assets | 1,048 | 983 | 999 | 1,007 | 942 |
| Tangible fixed assets | 89 | 94 | 99 | 104 | 106 |
| Financial fixed assets | 3,911 | 3,912 | 3,914 | 3,919 | 3,918 |
| **Total non-current assets** | **5,048** | **4,989** | **5,012** | **5,029** | **4,966** |
| ***Current assets*** | | | | | |
| Inventories | 665 | 648 | 708 | 680 | 656 |
| Current receivables, non-interest bearing | 1,034 | 1,117 | 1,113 | 1,038 | 1,166 |
| Cash and cash equivalents | 733 | 665 | 578 | 392 | 517 |
| **Total current assets** | **2,432** | **2,430** | **2,399** | **2,111** | **2,340** |
| **Total assets** | **7,480** | **7,419** | **7,411** | **7,140** | **7,306** |
| **EQUITY AND LIABILITIES** | | | | | |
| ***Shareholders´ equity*** | ***5,809*** | ***5,782*** | ***5,700*** | ***5,510*** | ***5,665*** |
| ***Long-term liabilities*** | | | | | |
| Long-term debt | 814 | 814 | 813 | 812 | 811 |
| **Total long-term liabilities** | **814** | **814** | **813** | **812** | **811** |
| ***Current liabilities*** | | | | | |
| Current liabilities, non-interest bearing | 857 | 823 | 898 | 818 | 830 |
| **Total short-term liabilities** | **857** | **823** | **898** | **818** | **830** |
| **Total equity and liabilities** | **7,480** | **7,419** | **7,411** | **7,140** | **7,306** |

## Parent Company
## Change in Shareholders´ Equity

| Amounts in SEK M | Jan-Sep 2015 | Jan-Sep 2014 | Full Year 2014 |
|---|---|---|---|
| **Opening balance** | **5,510** | **5,622** | **5,622** |
| Sharebased compensation to employees | 18 | 5 | 9 |
| Transfer of shares | 22 | – | – |
| Comprehensive income for the period | 259 | 38 | -120 |
| **Equity, end of period** | **5,809** | **5,665** | **5,510** |

# Financial Notes

## Note 1 – Accounting and valuation principles and other information

**Important accounting principles**

This interim report has been prepared in accordance with IAS 34 and with the Annual Accounts Act. The consolidated financial statements for the period January—September 2015 have been prepared in accordance with the Financial Reporting Standards (IFRS) and IFRIC interpretations as adopted by the EU and the Swedish Annual Act. The parent company applies the Annual Accounts Act and Council for Financial Reporting, RFR 2 Reporting for legal entities. The consolidated financial statements have been prepared according to the historical cost convention, except in the case of financial assets and financial assets and liabilities (including derivative instruments) which are measured at fair value through profit and loss.

Accounting principles applied, except for the changes listed below, are in accordance with those described in the 2014 Annual Report. More detailed information about the Group's accounting and valuation principles can be found in the 2014 Annual Report which is available on www.sobi.com.

*Change in accounting principles*

From fiscal year 2015 comes a number of new and revised standards in force. These standards have had no material impact on the consolidated financial statements.

**Operating risks**

All business operations involve risk. Managed risk-taking is necessary to maintain good profitability. Risk may be due to events in the external environment and may affect a certain industry or market. Risk may also be specific to a certain company.

Sobi is exposed to three main risk categories:

- Operational risks, e.g. due to the capital-intensive and risky nature of new drug development, dependence on external partners in various collaborations, product liability claims and laws and rules on the treatment of hazardous materials.
- External risks such as patent infringements, competition within product concepts and decisions by authorities regarding product use and prices.
- Financial risks, such as currency risk, interest risk, credit risk and liquidity risk.

A more detailed description of the Group's risk exposure and risk management is included in Sobi's 2014 Annual Report (see the Directors' Report). There are no major changes in the Group's risk exposure and risk management in 2015.

## Note 2 – Fair values of financial instruments

The group carries derivatives. Refer to the annual report 2014 for a narrative description of the purpose of the holdings. The derivatives (under the heading "current assets/liabilities") are all level 2 instruments in the fair value hierarchy in the standard IFRS 13 (inputs other than quoted prices that are observable for the instruments, either directly or indirectly, are used in the fair value measurement). All derivatives are measured at fair value based on market data in accordance with IFRS. At 30 September 2015 the reported value in the balance sheet for the derivatives was SEK 1 M (-6).

As of 30 September 2015 all other financial instruments in the balance sheet, with the exception of the group's bond, have reported values that are in all material aspects equivalent to fair value. At 30 September 2015 the reported value in the balance sheet for the bond was SEK 794 M (791). Fair value of the bond is deemed to be SEK 825 M (842). The fair value is based on the average of the bid-ask-spread at the balance sheet date.

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

In October 2014, Sobi's partner Biogen submitted an MAA for Elocta and in June 2015 they submitted an MAA for Alprolix to the EMA. These applications for marketing approval, together with the delivery of data from Biogen to Sobi, triggered Sobi's exclusive opt-in rights to assume final development and commercialisation of Elocta and Alprolix in Europe, North Africa, Russia and most countries in the Middle East. On 21 November 2014 (for Elocta) and 16 July 2015 (for Alprolix) respectively, Sobi exercised these opt-in rights and paid, in accordance with the agreements, USD 10 M for each opt-in, which will be kept in escrow until approval. These payments have been recognised in the balance sheet as advanced payments under intangible fixed assets.

Following the EU regulatory approval of Elocta and Alprolix, Sobi will be liable to reimburse Biogen for 50 per cent of the total production costs for clinical manufacture of each product, development costs for each product from 1 October 2009 until the date on which Sobi is registered as the Marketing Authorisation Holder, or 90 days after the approval, and certain shared expenses related to regulatory approval, costs for final development and commercialisation, and 100 per cent of some development costs that only benefitted Sobi's territory. Total payment is estimated to be about USD 228 M for Elocta and USD 204 M for Alprolix.

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

## Note 4 – Adjustment of deferred tax previously reported

Deferred tax has been adjusted year to date 30 September due to an earlier calculation error, resulting in adjustments, to the previously reported quarters in 2015, listed in the table below.

**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 and Glossary

## Definitions

**Capital employed**
Total assets less non-interest-bearing responsibilities.

**Cash flow per share**
Changes in cash and cash equivalents divided by the weighted average number of outstanding shares.

**CER**
Constant exchange rates

**Debt/Equity ratio**
Relative proportion of shareholders equity and debt used to finance the company's assets.

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

**EBITA**
Operating profit/loss before amortisation.

**EBITDA**
Operating profit/loss before depreciation and amortisation.

**Earnings per share**
The portion of a company´s profit allocated to each outstanding share of common stock.

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

**Equity ratio**
Shareholders' equity as a proportion of total assets.

**Full-time equivalents**
Unit that indicates the workload of an employed person in a way that makes workloads comparable across various contexts.

**Gross margin**
Gross profit as a percentage of sales.

**Gross profit**
Net sales less cost of goods and services sold.

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

**Profit/loss**
Profit/loss for the period.

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

**Return on capital employed**
Earnings Before Interest and Tax (EBIT)/Capital Employed.

**Return on total capital**
Profit/loss after financial items plus financial expenses as a percentage of average total assets.

**Shareholders' equity per share**
Shareholders' equity divided by the number of shares.

## Glossary

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

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

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

**EMA**
European Medicines Agency

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

**FDA**
Food and Drug Administration

**Haemophilia**
Haemophilia is a group of hereditary genetic disorders that impair the body's ability to control blood clotting or coagulation. Haemophilia A (clotting factor VIII deficiency) is the most common form of the disorder, present in about 1 in 5,000 male births. Haemophilia B (clotting factor IX deficiency) occurs in around 1 in about 25,000 male births.

**Kepivance**
Kepivance (palifermin) is indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy requiring hematopoietic stem cell support.

**Kineret**
Kineret (anakinra) is a recombinant protein drug which blocks the biological activity of IL-1 by binding to the interleukin-1 (IL-1) type 1 receptor, which is expressed in a wide variety of tissues and organs. IL-1 is a key mediator of inflammation and driver of autoinflammatory diseases in both adults and children.

**MAA**
Marketing Authorisation Application

**Orfadin**
Orfadin (nitisinone) is a pharmaceutical used for the treatment of hereditary tyrosinaemia type 1 (HT-1), a rare genetic disorder which can cause liver failure, kidney dysfunction and neurological problems.

**Peyronie's disease**
Peyronie's disease is a condition that involves the development of collagen plaque, or scar tissue, on the shaft of the penis. The scar tissue, known as a Peyronie's plaque, may harden and reduce flexibility, which may cause bending or arching of the penis during erection. Peyronie's disease can result in varying degrees of penile curvature deformity and disease "bother" (encompassing concern about erection appearance, erection pain and the impact of Peyronie's disease on intercourse and on frequency of intercourse).

**Still´s disease**
Still's disease is a rare form of chronic arthritis which can occur during childhood or later in life with an adult-onset. The disease is characterized by severe manifestations with fever, rash, lymph node and liver swelling, serositis sometimes, as well as widespread and severe joint pain.

**Systemic juvenile idiopathic arthritis (SJIA)**
A rare form of chronic arthritis in children up to 16 years of age. About 100 of 100,000 children are affected by child arthritis, and of these 10-20 percent have the SJIA form, today classified as an autoinflammatory disease.

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


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**About Sobi**

Sobi is an international speciality healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primary focused on Haemophilia, Inflammation and Genetic diseases. We also market a portfolio of speciality and rare disease products for partner companies across Europe, Middle East, North Africa and Russia. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2014, Sobi had total revenues of SEK 2.6 billion (USD 380 M) and about 600 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com