

# **TABLE OF CONTENT**

- 3 CEO Statement
- 4 Q4 and FY in Summary
- 5 Business Review Q4
- 6 Financial Review Q4 and FY
- 9 Other Information
- 10 Financial Statements
- 16 Financial Notes
- 18 Definitions and Glossary

# **Financial Calendar**

Q1 2016 27 April 2016

AGM 19 May 2016

Q2 2016 15 July 2016

Q3 2016 27 October 2016

# **CEO Statement**

2015 was a pivotal year for Sobi. We delivered strong financial results, welcomed many new colleagues, expanded our geographic footprint and received important regulatory approvals for our products. The approval of Elocta® (efmoroctocog alfa) in particular — our extended half-life haemophilia A treatment — has the potential to create a true paradigm shift in the treatment of and protection against bleeding and joint damage for people with haemophilia A. We are focused on expanding our reach on the foundation of these achievements going forward.

## Solid financial results

Revenues were at SEK 3,228 M, an increase of 24 per cent (14 per cent at constant exchange rates) with all parts of the portfolio contributing. Kineret® (anakinra) and Orfadin® (nitisinone) delivered growth in existing and new markets; 32 and 45 per cent respectively, and ReFacto® (moroctocog alfa) and the partner portfolio reported high single digit growth. Gross margin was 62 per cent, and our continued positive cash flow has now brought our balance sheet to a net cash position. These results provide a firm foundation from which to further develop our vision of becoming a leading innovative rare disease company.

## Milestones on a transformational journey

Our financial results derive from a transformation over the past several years during which we have returned our core franchises to growth, established operations in key new geographies such as North America and the Middle East, strengthened our partner portfolio, extended our ReFacto manufacturing term, and refocused our R&D organisation on a portfolio of innovative biologics targeting significant rare disease indications.

As part of this journey, we have also welcomed over 100 new colleagues to the Sobi community over the past year, many of whom now comprise a world class, launch-ready platform for our extended half-life factors for haemophilia A and B. These products, Elocta and Alprolix® (rFIXFc), have been marketed in our collaboration partner Biogen's territories over the past 18 months and now exceed USD 600 M in revenue on an annualised basis. We are excited to bring these potentially transformational therapies to patients and families in our territories across Europe, Middle East, and Russia over the coming period.

## **Expanding our reach**

We remain committed to the patient and family communities we have come to know, and we have much to do to contribute to the quality and sustainability of their outcomes in the coming years. The launch of the Orfadin suspension formulation in Europe this year will allow us to offer improved dosing convenience and accuracy in young patients, and we hope to offer this to US families with a potential approval later this year. In addition, the evolution of the autoinflammatory field, specifically IL-1, has inspired us to pursue a much wider set of indications for Kineret. We have a new patent which will allow us to develop and deploy



a new formulation, we are scaling our manufacturing to allow for increased capacity, we are initiating two new pivotal programs to pursue formal indications in Still's disease and acute Gout, and we continue to evaluate several additional areas for development.

As we focus on these areas we are also exploring additional transformational treatments for rare diseases both internally and with partners. Thank you for your support and I hope you will join us for the next part of our journey.

Geoffrey McDonough **CEO** and President

Solna, Sweden, 26 February 2016

# Q4 and FY 2015 in Summary

## **Business Summary Q4 2015**

- Elocta approved in Europe for the treatment of haemophilia A
- New data showed that Elocta and Alprolix may reduce target joint bleeds in people with haemophilia A and B
- Sobi and Biogen initiated deliveries of largest ever donation of haemophilia therapy to World Federation of Hemophilia for patients in the developing world
- Received orphan drug designation for Alprolix in Switzerland
- Xiapex® (collagenase clostridium histolyticum) approved in EU for the treatment of two Dupuytren's contracture cords concurrently
- Xiapex approved for the treatment of Peyronie's disease in Switzerland
- Lars Dreiøe appointed Senior Vice President, Chief Quality
   & Compliance Officer at Sobi

# **Financial Summary Q4 2015 (Q4 2014)**

- Total revenue was SEK 814 M (705), an increase of
   15 per cent (9 per cent at constant exchange rates (CER))
- Product revenue was SEK 698 M (575), an increase of 21 per cent (13 per cent at CER)
- Gross margin was 64 per cent (60)
- EBITA was SEK 90 M (38)

# Financial Summary Q4 2015 in USD<sup>1</sup>

- Total revenue was USD 97 M
- Product revenue was USD 83 M
- EBITA was USD 11 M

# Financial Summary FY 2015 (2014)

- Total revenue was SEK 3,228 M (2,607), an increase of
   24 per cent (14 per cent at constant exchange rates (CER))
- Product revenue was SEK 2,568 M (1,989), an increase of 29 per cent (18 per cent at CER)
- Gross margin was 62 per cent (59)
- EBITA was SEK 433 M (-43)
- Ended the year with a cash position of SEK 904 M (519)

# Financial Summary FY 2015 in USD<sup>1</sup>

- Total revenue was USD 383 M
- Product revenue was USD 304 M
- EBITA was USD 51 M
- Ended the year with a cash position of USD 107 M

<sup>&</sup>lt;sup>1</sup>Exchange rate 1USD = 8.435 SEK

# **Business Review Q4**

# Elocta approved in Europe for the treatment of haemophilia A

The European Commission (EC) approved Elocta for the treatment of haemophilia A in all 28 European Union (EU) member states, as well as Iceland, Liechtenstein and Norway. Elocta, a recombinant factor VIII Fc fusion protein with an extended half-life, is the first haemophilia A treatment in the EU to offer prolonged protection against bleeding episodes with prophylactic injections every three to five days.

# New data showed that Elocta and Alprolix may reduce target joint bleeds in people with haemophilia A and B

New data presented at the 57<sup>th</sup> American Society of Hematology (ASH) Annual Meeting and Exposition in Orlando, Fla. demonstrated that Elocta and Alprolix may effectively manage target joint bleeding and maintain low annualised bleeding rates (ABRs) in people with severe haemophilia A and B.

# Received orphan drug designation for Alprolix in Switzerland

Sobi received orphan drug designation in Switzerland for drug candidate Alprolix developed for the treatment of haemophilia B. An orphan drug designation is to encourage the development of medicines for rare diseases and provides orphan status to drugs and biologics under development.

# Sobi and Biogen initiated deliveries of largest ever donation of haemophilia therapy to World Federation of Hemophilia for patients in the developing world

Sobi, Biogen and the World Federation of Hemophilia (WFH) announced that the first shipments of much-needed haemophilia therapy had 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 the WFH's Humanitarian Aid Program, a 20-year old initiative dedicated to providing treatment and care for people with haemophilia in the developing world.

# Xiapex approved in EU for the treatment of two **Dupuytren's contracture cords**

The European Medicines Agency approved Xiapex for the treatment of two Dupuytren's contracture cords concurrently.

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

Swissmedic, the Swiss Agency for Therapeutic Products, approved Xiapex for the treatment of adult men with Peyronie's disease. The indication is for patients with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy. Peyronie's disease is a condition that involves the development of collagen plaque, or scar tissue, on the shaft of the penis.

# Lars Dreiøe appointed Senior Vice President, Chief **Quality & Compliance Officer at Sobi**

Lars Dreige was appointed Senior Vice President Chief Quality & Compliance Officer (CQCO). Lars Dreiøe joins Sobi from global pharmaceutical company ALK in Denmark where he has been International Head of Quality.

Lars brings 20 years of experience in the Biotech and Pharmaceutical industry in the Quality, Manufacturing, Product Safety and Regulatory Affairs areas, and joined Sobi in January 2016.

# **Financial Review Q4 and FY**

Total revenue for the fourth quarter was SEK 814 M (705), an increase of 15 per cent (9 per cent at constant exchange rates).

Full year revenues were SEK 3,228 M (2,607), an increase of 24 per cent. The increase at constant exchange rates was 14 per cent.

# **Key Therapeutic Areas**

Revenue was SEK 520 M (377) in the quarter, an increase of 38 per cent. Full year revenues were SEK 1,841M (1,307), an increase of 41 per cent.

#### Inflammation

Revenue in the quarter for Kineret was SEK 222 M (163), an increase of 36 per cent driven by growth in major markets, in line with ongoing development of the CAPS and NOMID indications.

Full year revenues were SEK 805 M (609), an increase of 32 per cent.

#### **Genetics & Metabolism**

Revenue for Orfadin was SEK 227 M (169) in the quarter, an increase of 35 per cent, driven by growth in all major markets.

For the full year, revenue was SEK 796 M (548), an increase of 45 per cent. Growth was driven by volume in US, Europe, and South America.

#### Haemophilia

Revenue for the Haemophilia franchise in the fourth quarter was SEK 32 M (12), representing royalties equal to 2 per cent of the sales of Eloctate® and Alprolix in Biogen's territories during the fourth quarter.

For the full year, revenues were SEK 96 M (31).

#### **Partner Products**

Revenue for Partner Products was SEK 178 M (198) in the quarter, a decrease of 10 per cent, due to lower sales of Kepivance® and the PharmaSwiss portfolio compared to last year.

Full year revenues were SEK 727 M (682), an increase of 7 per cent, mainly driven by the growth of Cometriq®, Yondelis® and Xiapex.

#### ReFacto

ReFacto manufacturing revenue and royalty for the fourth quarter were SEK 116 M (130), a decrease of 11 per cent due to phasing. Manufacturing revenue was SEK 89 M (99). Royalty revenue was SEK 27 M (31).

Full year revenues related to ReFacto manufacturing and royalty were SEK 660 M (618), an increase of 7 per cent. Manufacturing

revenues were SEK 504 M (466). Royalty revenues were SEK 156 M (152).

## **Gross Profit**

Gross profit for the fourth quarter was SEK 520 M (427), representing a gross margin of 64 per cent (60).

For the full year, gross profit was SEK 2,007 M (1,548), equal to a gross margin of 62 per cent (59). Favourable product mix and currency effects were the main contributors.

## **Operating profit Q4**

Operating expenses excluding amortisations and write-offs were SEK 427 M (363).

Operating expenses for sales and administration excluding amortisations amounted to SEK 293 M (214). The increase reflects new employees hired to staff the haemophilia organisation. Unfavourable exchange rates also increased costs by 5 per cent compared to prior year.

Financial Summary						
	Q4	Q4		Full year	Full year	
Amounts in SEK M	2015	2014	Change	2015	2014	Change
Total revenues	814	705	15%	3,228	2,607	24%
Gross profit	520	427	22%	2,007	1,548	30%
Gross margin	64%	60%		62%	59%	
EBITA <sup>1</sup>	90	38	>100%	433	-43	>100%
EBITA excluding write-offs	90	63	41%	433	307	41%
EBIT (Operating profit/loss)	17	-33	>100%	146	-325	>100%
Profit/loss for the period	-9	-17	48%	68	-268	>100%

<sup>1</sup>2014 FY includes write-offs relating to Kiobrina of SEK 325 M (Q1) and Multiferon of SEK 25M (Q4).

Research and development costs excluding amortisation and writeoffs were SEK 135 M (149), reflecting the closure of the Kiobrina® program early 2015.

EBITA was SEK 90 M (38). 2014 included an one-time write-down for Multiferon® of SEK 25 M.

Amortisations of intangible assets amounted to SEK 73 M (71).

EBIT (operating profit) amounted to SEK 17 M (-33).

# **Operating profit FY**

Operating expenses excluding amortisations and write-downs were SEK 1,571 M (1,250).

Operating expenses for sales and administration excluding amortisations amounted to SEK 1,057 M (750). The increase relates to Elocta and Alprolix launch preparations and increased investments in the North American operations. There was also an unfavourable exchange rate impact of 6 per cent versus prior year, driven by the EUR and USD.

Research and development costs excluding amortisation and write-downs were SEK 513 M (501). Spending within the Haemophilia franchise increased during 2015, partly offset by lower spending for the closed Kiobrina and SOBI002 programs.

EBITA was SEK 433 M (-43). 2014 included one-time write-downs for Kiobrina of SEK 325 M and for Multiferon SEK 25 M.

Amortisations of intangible assets amounted to SEK 287 M (282).

EBIT (operating profit) amounted to SEK 146 M (-325).

Revenues by Business Line								
Amounts in SEK M	Q4 2015	Q4 2014	Change %	Change % at CER <sup>1</sup>	Full year 2015	Full Year 2014	Change %	Change % at CER <sup>1</sup>
Key Therapeutic Areas								
Inflammation: Kineret	222	163	36%	26%	805	609	32%	17%
Genetics & Metabolism: Orfadin	227	169	35%	23%	796	548	45%	30%
Genetics & Metabolism: Other	40	33	19%	17%	144	118	21%	16%
Haemophilia <sup>2</sup>	32	12	>100%	>100%	96	31	>100%	>100%
Total	520	377	38%	27%	1,841	1,307	41%	26%
Partner Products <sup>3</sup>	178	198	-10%	-13%	727	682	7%	1%
ReFacto								
Manufacturing revenues	89	99	-10%	-10%	504	466	8%	8%
Royalty revenues	27	31	-13%	-21%	156	152	3%	-17%
Total	116	130	-11%	-13%	660	618	7%	2%
Total revenues	814	705	15%	9%	3,228	2,607	24%	14%

<sup>&</sup>lt;sup>1</sup>Constant Exchange Rate.

## Net financial items and tax for Q4 and FY

Net financial items amounted to SEK -26 M (10), including exchange rate losses of SEK -10 M (24). The remaining part consisted of interest. The variance was mainly due to the larger positive exposure in USD denominated items during Q4 2014 compared to Q4 2015, and the appreciation of the USD during the same period.

Tax amounted to SEK 0 M (5), due to the current tax being offset by deferred tax.

Net financial items for the full year amounted to SEK -58 M (6), including exchange losses of SEK -4 M (63). The remaining part consisted of interest.

Tax amounted to SEK -19 M (51), due to a better result.

<sup>&</sup>lt;sup>2</sup>Jan-Dec 2014 includes a one-time milestone payment of SEK 11 M relating to Alprolix in Q1.

<sup>&</sup>lt;sup>3</sup>Jan-Dec 2015 includes a one-time revenue milestone for Cometriq of SEK 18 M in Q1.

# Profit/Loss Q4 and FY

Loss for the quarter was SEK -9 M (-17), and loss per share was SEK -0.03 (-0.07).

For the full year profit was SEK 68 M (-268), and earnings per share was SEK 0.26 (-1,01).

#### Cash flow and investments Q4

Cash flow from operations before change in working capital amounted to SEK 66 M (113).

Working capital impacted cash flow by SEK -52 M (-61), mainly due to a decrease in operating liabilities.

Cash flow from investing activities was SEK -21 M (-147). 2014 included investments for opt-in of Elocta and the XTEN programme.

#### Cash

Cash position at the end of quarter was SEK 904 M, compared to SEK 519 M as of 31 December 2014.

#### Cash flow and investments FY

Cash flow from operations before change in working capital amounted to SEK 411 M (299).

Working capital impacted cash flow by SEK 96 M (-66), mainly due to an increase in liabilities.

Cash flow from investing activities were SEK -143 M (-184). The decision to exercise Sobi's opt-in right to take over final development and commercialisation of Alprolix in Sobi's

Operating Profit/Loss				
	Q4	Q4	Full year	Full year
Amounts in SEK M	2015	2014	2015	2014
Total revenues	814	705	3,228	2,607
Total cost of goods and services sold	-293	-279	-1,221	-1,059
Gross profit	520	427	2,007	1,548
Gross Margin	64%	60%	62%	59%
Sales and administration expenses less amortisations and write-downs	-293	-214	-1,057	-750
Research and development expenses less amortisations and write-downs	-135	-149	-513	-501
Total opex less amortisations and write-downs	-427	-363	-1,571	-1,250
Other operating revenues/expenses	-3	-25	-3	-341
EBITA	90	38	433	-43
Amortisations relating to				
Sales and administration expenses	-73	-71	-287	-282
Amortisations	-73	-71	-287	-282
EBIT	17	-33	146	-325

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

territories was the largest investment in the year, amounting to SEK 82  $\,\mathrm{M}.$ 

The investment in Elocta of SEK 1,704 M had no cash flow impact (see note 4 for more information).

# Net Cash/Debt

Sobi ended the year with net cash of SEK 82 M, compared to a net debt of SEK 298 M as of 31 December 2014. The Elocta liability is

non interest bearing and therefore not included in net cash/debt.

# **Equity**

Consolidated shareholders' equity as of 31 of December 2015 amounted to SEK 4,689 M compared to 4,523 M as of 31 December 2014.

# **Parent Company**

Net sales in 2015 for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 2,750 M (2,328) of which SEK 1,136 M (964) referred to sales to Group companies. Income after financial items amounted to SEK 276 M (59). Investments in tangible and intangible assets amounted to SEK 139 M (177). The investment in Elocta of SEK 1,704 M had no cash flow impact.

#### Outlook 2016

Sobi expects total revenues for the full year to be in the range of SEK 4,300 to 4,500 M.

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

EBITA for the full year is expected to be in the range of SEK 700 to 800 M.

Note: 2016 will be impacted by a one-time credit for Elocta estimated to be SEK 300 to 325 M. This one-time credit will be reported in the Profit and Loss statement but will not impact cash.

OPEX includes Sobi share of ongoing costs for Elocta, estimated to be SEK 200 to 250 M.

This outlook excludes the impact of an anticipated Alprolix approval and launch in 2016.

# Other Information

#### Personnel

As of December 2015, the number of full-time equivalents in personnel was 702 (584, December 2014).

#### Other

Opened affiliate in Toronto, Canada, in November 2015.

# Significant events after the reporting period

Gained commercial rights for 3 products from PharmaSwiss Sobi gained commercial rights from the Swiss based company PharmaSwiss SA, to distribute Relistor®, Deflux® and Solesta® in a territory including Western Europe, Czech Republic, Slovakia, Hungary and for Relistor also in Russia.

Announced commercial launch of Elocta in first countries in EU Sobi announced the commercial launch of Elocta in first countries in EU. Following the first commercial sales of Elocta in January 2016 Sobi received a preliminary one-time credit of USD 38 M, equal to 10 per cent of the total accumulated sales for Eloctate in Biogen territories.

#### Orfadin oral suspension granted European patent

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

Chief Medical Officer Birgitte Volck to leave Sobi Sobi announced that Birgitte Volck, SVP of Development and Chief Medical Officer, will leave Sobi.

Announced initiation of clinical development programs in acute gout and Still's disease, and new patent on new formulation for Kineret

Sobi announced that the company has decided to initiate two clinical programs with Kineret, with the aim of evaluating two new potential indications: acute gout and Still's disease.

In addition, Sobi has been granted a US patent for a citrate-free formulation of Kineret which will expire in 2032. A corresponding patent has recently been allowed in Europe and may be granted in 2016.

## **Annual general Meeting 2016**

The Annual General Meeting (AGM) of Swedish Orphan Biovitrum AB (publ) will be held on Thursday, 19 May 2016, at 2 pm, at Näringlivets Hus, Stockholm, Sweden.

The Board of Directors proposes that no dividend will be paid for the 2015 financial year.

The Annual Report for 2015 will be published on www.sobi.com three weeks before the AGM. It will also be available at Sobi's headquarter in Solna.

The Nomination Committee will in due time before the AGM 2016 prepare further proposals, including proposals for the Chairman of the AGM, Board members, remuneration for Board members and auditor, and to the extent deemed necessary, tasks for and the composition of the Nomination Committee for the AGM in 2017.

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

Geoffrey McDonough **CEO** and President

Solna, Sweden, 26 February 2016

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.

# **Financial Statements**

Group				
Income Statement	Q4	Q4	Full year	Full year
Amounts in SEK M	2015	2014	2015	2014
Total revenues	814	705	3,228	2,607
Total cost of goods and services sold	-293	-279	-1,221	-1,059
Gross profit	520	427	2,007	1,548
Sales and administration expenses	-366	-285	-1,344	-1,032
Research and development expenses	-135	-149	-513	-501
Other operating revenues/expenses	-3	-25	-3	-341
Operating profit/loss	17	-33	146	-325
Financial income/expenses	-26	10	-58	6
Income tax benefit/expense	0	5	-19	51
Profit/loss for the period	-9	-17	68	-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	-3	-1	-3	1
Items that may be reclassified subsequently to profit/loss				
Translation difference	-2	2	-2	4
Cash flow hedge (net of tax)	54	1	58	1
Comprehensive income for the period	40	-15	122	-263
Amortisation and write-down of intangible assets included in	-73	-71	-287	-282
Sales and administration expenses Earning/loss per share before and after dilution	-0.03	-0.07	0.26	-1.01

Group					
Balance sheet					
	Dec	Sep	Jun	Mar	Dec
Amounts in SEK M	2015	2015	2015	2015	2014
ASSETS					
Non-current assets					
Intangible fixed assets <sup>1,2</sup>	5,787	4,145	4,128	4,192	4,248
Tangible fixed assets	109	105	107	110	115
Financial fixed assets	99	80	92	79	73
Total non-current assets	5,995	4,330	4,327	4,380	4,436
Current assets					
Inventories	776	758	742	765	764
Accounts receivable	451	498	523	647	480
Current receivables, non-interest bearing	185	172	194	133	172
Cash and cash equivalents	904	914	763	682	519
Total current assets	2,316	2,343	2,222	2,226	1,935
Total assets	8,311	6,672	6,549	6,606	6,371
EQUITY AND LIABILITIES					
Shareholders' equity <sup>2</sup>	4,689	4,640	4,630	4,614	4,523
Long-term liabilities					
Long-term debt	800	820	819	817	816
Long-term liabilities, non-interest bearing <sup>2</sup>	1,501	308	316	313	285
Total long-term liabilities	2,301	1,127	1,135	1,130	1,101
Current liabilities					
Short term debt	22	2	2	2	2
Current liabilities, non-interest bearing <sup>2</sup>	1,298	904	783	861	745
Total short-term liabilities	1,320	906	784	862	747
Total equity and liabilities	8,311	6,672	6,549	6,606	6,371
<sup>1</sup> Including goodwill SEK 1,554 M. <sup>2</sup> Elocta approval, see note 4					

Group Changes in Equity Amounts in SEK M	Full year 2015	Full year 2014
Opening balance	4,523	4,769
Sharebased compensation to employees	23	16
Divestment of own shares	22	_
Comprehensive income for the period	122	-263
Equity, end of period	4,689	4,523

Group				
Cash Flow Statement				
Cash Flow Statement				
	Q4	Q4	Full year	Full year
Amounts in SEK M	2015	2014	2015	2014
Net result	-9	-17	68	-268
Non-cash items <sup>1</sup>	75	131	343	567
Cash flow from operations before change in working capital	66	113	411	299
Change in working capital	-52	-61	96	-66
Cash flow from operations	13	53	507	234
Investment in intangible fixed assets	-11	-138	-119	-160
Investment in tangible fixed assets	-13	-9	-27	-23
Divestment of tangible fixed assets	2	_	2	_
Cash flow from investing activities	-21	-147	-143	-184
Loans - Raising/Amortization	_	_	_	20
Transfer of own shares	_	_	22	_
Cash flow from financing activities	-	-	22	20
Net change in cash	-8	-94	386	70
Liquid funds at the beginning of the period	914	611	519	445
Translation difference in cash flow and liquid funds	-2	2	-2	4
Liquid funds at the end of the period	904	519	904	519
<sup>1</sup> Non-cash items:				
Depreciation tangible fixed assets	8	8	32	32
Amortization intangible assets	73	71	287	282
Deferred tax	-1	-13	13	-71
Other, whereof SEK 268 M in 2014 reflects Kiobrina write-off that was non cash related	-5	64	11	325

Group  Key Paties and Other Information				
Key Ratios and Other Information	Q4	Q4	Full year	Full year
Amounts in SEK M	2015	2014	2015	2014
Profit numbers				
Gross profit	520	427	2,007	1,548
EBITDA	97	46	465	-12
EBITA	90	38	433	-43
EBIT	17	-33	146	-325
Profit/loss	-9	-17	68	-268
Per share data (SEK)				
Earning/loss per share	-0.03	-0.07	0.26	-1.01
Earning/loss per share after dilution	-0.03	-0.07	0.26	-1.01
Shareholders' equity per share	17.3	16.7	17.3	16.7
Shareholders' equity per share after dilution	17.3	16.7	17.3	16.7
Other information				
Gross margin	64%	60%	62%	59%
Equity ratio	56%	71%	56%	71%
Net cash (-)/debt (+)	-82	298	-82	298
Number of ordinary shares	270 389 770	270,389,770	270,389,770	270,389,770
Number of C-shares (in treasury)	1,433,036		1,433,036	396,180
Number of ordinary shares (in treasury)	2,763,768	,	2,763,768	,
Average number of ordinary shares (excluding shares in treasury)	267,626,002			
Number of shares after dilution	270,389,770	, ,	, ,	, ,
Average number of ordinary shares after dilution (excluding shares in treasury)	267,626,002	, ,	267,278,339	

Income Statement				
	Q4	Q4	Full year	Full yea
Amounts in SEK M	2015	2014	2015	201
Total revenues	722	592	2,750	2,32
Total cost of goods and services sold	-293	-263	-1,168	-97
Gross profit	429	328	1,582	1,35
Sales and Administration expenses	-289	-182	-814	-62
Research and Development expenses	-120	-141	-472	-47
Other operating revenues/expenses	15	-23	13	-6
Operating profit/loss	35	-18	309	19
Result from participation in Group companies <sup>1</sup>	_	_	_	-17
Financial income/expenses	-20	17	-33	3
Profit/loss after financial items	15	-1	276	5
Group contribution	_	-159	_	-15
Income tax benefit/expenses	-52	-	-58	-2
Profit/loss for the period	-37	-160	218	-12
Other comprehensive income				
Items that may be reclassified subsequently to profit/loss				
Cash flow hedge (net of tax) <sup>2</sup>	54	1	58	
Comprehensive income for the period	17	-159	276	-12
Amortisation and write-down of intangible assets included in Sales & Adm expenses	-24	-22	-94	-8

 $^{1}$ 2014 includes write-down in value of ownership of Arexis relating to Kiobrina, of SEK 177 M.

<sup>2</sup>Elocta approval, see note 4.

Parent Company Balance Sheet					
butuitee street	Dec	Sep	Jun	Mar	Dec
Amounts in SEK M	2015	2015	2015	2015	2014
ASSETS					
Non-current assets					
Intangible fixed assets <sup>1</sup>	2,739	1,048	983	999	1,007
Tangible fixed assets	92	89	94	99	104
Financial fixed assets	3,899	3,911	3,912	3,914	3,919
Total non-current assets	6,730	5,048	4,989	5,012	5,029
Current assets					
Inventories	674	665	648	708	680
Current receivables, non-interest bearing	1,012	1,034	1,117	1,113	1,038
Cash and cash equivalents	750	733	665	578	392
Total current assets	2,436	2,432	2,430	2,399	2,111
Total assets	9,166	7,480	7,419	7,411	7,140
EQUITY AND LIABILITIES					
Shareholders' equity	5,832	5,809	5,782	5,700	5,510
Long-term liabilities					
Long-term debt	795	814	814	813	812
Long-term liabilities, non-interest bearing <sup>1</sup>	1,238	_	_	_	-
Total long-term liabilities	2,033	814	814	813	812
Current liabilities					
Short term debt	20	_	_	_	-
Current liabilities, non-interest bearing <sup>1</sup>	1,281	857	823	898	818
Total short-term liabilities	1,301	857	823	898	818
Total equity and liabilities	9,166	7,480	7,419	7,411	7,140
¹Elocta approval, see note 4.					

Parent Company Change in Shareholders' Equity		
	Full year	Full Year
Amounts in SEK M	2015	2014
Opening balance	5,510	5,622
Share based compensation to employees	23	9
Divestment of own shares	22	_
Comprehensive income for the period	276	-120
Equity, end of period	5,832	5,510

# **Financial Notes**

# Note 1 – Accounting and valuation principles and other information

#### Important accounting principles

This report has been prepared in accordance with IAS 34 and with the Annual Accounts Act. The consolidated financial statements for the period January—December 2015 have been prepared in accordance with the Financial Reporting Standards (IFRS) and International Financial Reporting Interpretations Committee (IFRIC) interpretations as adopted by the EU and the Swedish Annual Act. The parent company applies the Annual Accounts Act and Council for Financial Reporting, RFR 2 Reporting for legal entities. The consolidated financial statements have been prepared according to the historical cost convention, except in the case of financial assets and 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 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 2014 Annual Report (see the Directors' Report). The EU approval of Elocta in November 2015 has reduced the company's risk exposure compared to 2014. In all other aspects, there are no major changes in the Group's risk exposure and risk management in 2015 compared to the previous year.

#### Note 2 – Fair values of financial instruments

The Group carries derivatives. Refer to the 2014 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 December 2015, the reported value in the balance sheet for the derivatives was SEK 9 M (-8).

As of 31 December 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 31 December 2015, the reported value in the balance sheet for the bond was SEK 795 M (792). Fair value of the bond is deemed to be SEK 823 M (838). The fair value is based on the average of the bid-ask-spread at the balance sheet date.

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

In June 2015, Sobi's collaboration partner Biogen submitted an MAA for Alprolix to the EMA. The application for marketing approval, together with the delivery of data from Biogen to Sobi, triggered Sobi's exclusive opt-in right to assume final development and commercialisation of Alprolix in Europe, North Africa, Russia and most countries in the Middle East. On 16 July 2015, Sobi exercised the opt-in right and paid, in accordance with the agreements, USD 10 M for the opt-in right, which will be kept in escrow until EU approval. The payment has been recognised in the balance sheet as advanced payment under intangible fixed assets. Following the EU regulatory approval of Alprolix, Sobi will be liable to reimburse Biogen for:

- 50 per cent of the total production costs for clinical manufacture;
- development costs from 1 October 2009 until the date on which Sobi is registered as the Marketing Authorisation Holder, or 90 days after the EU approval;
- certain shared expenses related to regulatory approval;
- costs for final development and commercialisation; and
- 100 per cent of some development costs that only benefitted Sobi's territory.

Total payment is estimated to be about USD 187 M for Alprolix. (See note 19 in the 2014 Annual Report for more information.)

## Note 4 – Financial impact of Elocta approval

Following the EU regulatory approval of Elocta, Sobi acquired the right to market the product in certain markets. The cost for the market rights corresponds to 50 per cent of Biogen's development costs for Elocta. The nominal amount is USD 206 M, but as the liability will be paid during a number of years it is the discounted value of the liability that is reflected in the balance sheet. The intangible asset representing the right to market the product in certain markets is accounted for at the same value as when the debt was accounted for. The acquisition cost corresponding to an amount equal to the discounted liability and the difference compared to nominal amount leads to deferred tax in the financial statements. The risk related to foreign exchange effects of the liability is mitigated by applying hedge accounting to the debt, securing future highly probable inflows in USD via a cash flow

hedge, and the effect from revaluing the debt is a consequence reflected in other comprehensive income (OCI). If full reimbursement has not been achieved within six years of Biogen's first commercial sale for the programme, Biogen is entitled to request that Sobi pay the remaining amount within 90 days from the sixth anniversary of the date of the first commercial sale.

The liability and the corresponding intangible fixed asset, including the advance payments from 2014 in the financial statements in Q4 2015, are presented below.

		Impact in	
Amounts in SEK M	OB 2015-01-01	Q4 2015	FY 2015
Balance sheet			
Intangible fixed assets	81	1,704	1,785
Total assets	81	1,704	1,785
Equity (cash flow hedge reserve, excluding tax)		69	69
Long-term debt (related to Elocta approval)		1,179	1,179
Short-term debt (related to Elocta approval)		460	460
Total equity and liabilities		1,709	1,709
Income Statement			
Interest costs (related to Elocta approval)		5	5
P&L effect of Elocta approval in 2015		-5	-5

# **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

## Acute gout

Acute gout is 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 (rFIXFc) is a long-acting recombinant factor IX Fc fusion protein product candidate for people with haemophilia B. Alprolix [Coagulation Factor IX (Recombinant), Fc Fusion Protein], is the first recombinant, clotting factor therapy with prolonged circulation in the body for adults and children with haemophilia B, approved in the United States, Canada, Australia and Japan. Alprolix was submitted to the EMA for regulatory approval in Europe in June 2015.

## Cometriq

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

#### Elocta

Elocta (efmoroctocog alfa) is the first recombinant clotting factor VIII therapy in the EU that offers an extended half-life in the body. It is indicated for the treatment and prophylaxis of bleeding episodes in patients with haemophilia A (factor VIII deficiency) and can be used by people of all ages.

#### **EMA**

European Medicines Agency

#### **EMENAR**

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

#### FDA

Food and Drug Administration

### Haemophilia

Haemophilia is a group of hereditary genetic disorders that impair the body's ability to control blood clotting or coagulation.

Haemophilia A (clotting factor VIII deficiency) is the most common form of the disorder, present in about 1 in 5,000 male births.

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

#### Kineret

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

#### 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.

#### Still's disease

Still's disease is an autoinflammatory disease that affects both children and adults, and is characterised by high spiking fevers, intermittent rash and arthritis. Still's disease is also referred to as systemic juvenile idiopathic arthritis or adult-onset Still's 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.



## Swedish Orphan Biovitrum AB (publ)

SE-112 76 Stockholm, Sweden Visiting address: Tomtebodavägen 23 A Telephone: +46 8-697 20 00

Fax: +46 8-697 23 30 www.sobi.com

#### About Sobi™

Sobi™ is an international speciality healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is 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 2015, Sobi had total revenues of SEK 3.2 billion (USD 385 M) and about 700 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com