

#### **INTERIM REPORT**

JANUARY-MARCH 2018



# 2018 off to a strong start

- Total revenues of SEK 1,964 M (1,396)
- 41 per cent sales growth in the quarter compared to Q1 2017
   (43 per cent at constant exchange rates, CER)
- EBITA increased by 90 per cent to SEK 771 M (406)
- Net cash position of SEK 1,744 M (1,472 as of 31 December 2017)
- New contract signed for Elocta® with Health Services Executive in the Republic of Ireland
- Kineret® received a positive CHMP opinion for the treatment of Still's
  disease in the EU, followed by the European Commission approval after
  the reporting period
- Continued solid growth for Orfadin®
- Ravicti® launched in major European markets
- FDA accepted Investigational New Drug application and granted Fast Track status for SOBI003
- Outlook revised, see page 9

## Financial summary

	Q1	Q1		Full-year
Amounts in SEK M	2018	2017	Change	2017
Total revenues	1,964	1,396	41%	6,511
Gross profit <sup>1</sup>	1,412	1,028	37%	4,657
Gross margin <sup>2</sup>	72%	74%		72%
EBITA <sup>2</sup>	771	406	90%	2,053
EBITA margin <sup>2</sup>	39%	29%		32%
EBIT (Operating profit/loss)	660	284	132%	1,600
Profit for the period <sup>3</sup>	515	202	155%	1,149
Earnings per share, SEK	1.91	0.75	154%	4.27

 $<sup>^{1}</sup>$ 2017 included a one-time inventory adjustment of SEK 59 M in Q1 due to delayed release of Kineret drug substance manufactured in 2016.

REVENUES

+41%

GROSS MARGIN<sup>2</sup>

**72**%

EBITA<sup>2</sup>

SEK **771** M

<sup>&</sup>lt;sup>2</sup>Alternative performance measures (APMs), see page 14 for further information.

<sup>&</sup>lt;sup>3</sup>Deferred tax has been adjusted during 2017, affecting profit for the period Q1 2017 with SEK 6 M.

<sup>1</sup> SOBI INTERIM REPORT / JANUARY-MARCH 2018

## **CEO** statement



2017 was a great year and 2018 is off to a strong start, with total revenue growth of 41 per cent, leading to revenues of SEK 1,964 M for the quarter. Elocta and Alprolix® continued to deliver impressive results in Haemophilia, and both Kineret and Orfadin showed solid growth in Specialty Care. The FDA accepted an Investigational New Drug (IND) application for SOBI003 and granted Fast Track status. Kineret received a positive opinion for the treatment of Still's disease in the EU, followed by the European Commission (EC) approval after the end of the quarter.

Haemophilia

In the Haemophilia business area, revenues rose 75 per cent to SEK 1,222 M (698), including royalties. Elocta sales amounted to SEK 649 M (250) and Alprolix sales to SEK 153 M (50), up 159 and 204 per cent respectively. The main drivers for growth were France, Germany, Italy and the UK.

We received pricing and reimbursement approvals for both products in several European countries, including France for Alprolix. The approvals were partly based on a wealth of real-world data from an extensive study programme, as well as over four years on the market. Alprolix is now the first extended half-life (EHL) treatment for haemophilia B available in France, and we are the first company in France to provide EHL products for both haemophilia A and B.

The new supply contracts for Elocta and Alprolix in the Republic of Ireland, will result in a switch for all people with haemophilia A and B from treatment with conventional replacement clotting factors to Sobi's EHL therapies.

Our ReFacto manufacturing business is contributing to our overall Haemophilia offering and will support the long-term growth in this business area. Accordingly, ReFacto will be reported in the Haemophilia business area as of 2018.

"We have successfully developed a solid Haemophilia organisation that is delivering strong financial growth"

Guido Oelkers, CEO and Presiden

ELOCTA PRODUCT SALES

+159%

ALPROLIX PRODUCT SALES

+204%

#### **Specialty Care**

The first quarter saw organic growth in our Specialty Care business area, driven by Kineret and Orfadin. Total revenues rose 6 per cent to SEK 742 M (698). Kineret sales amounted to SEK 297 M (277) and Orfadin sales to SEK 224 M (216), up 7 per cent and 4 per cent respectively.

Another highlight was the launch of Ravicti in a number of major European markets. Ravicti, a treatment within our partnered product portfolio, is a new therapy option for patients with urea-cycle disorders. Our strength and experience in enabling patient access to treatments in complex market environments has helped us obtain reimbursement approval for Ravicti in several EU member states. Austria, Denmark, Germany and Sweden will be the first countries to launch, followed by the Netherlands, Spain and the UK.

Our new formulations, which are gaining increasing acceptance from patients and treating physicians, are driving organic growth for Orfadin. Our strategy in Specialty Care includes ensuring that Orfadin meets the evolving needs of patients as well as continuing to develop Kineret through active life-cycle management and the exploration and approval of new indications. Following the recent EC approval, Kineret will soon be available in Europe for patients with Still's disease beginning with Germany, the Netherlands, the Nordic region and the UK.

#### **Pipeline advances**

In parallel with the EC approval of Kineret for Still's disease, the phase 3 programme for Still's in the US is ongoing.

The FDA accepted the IND application for our in-house-developed candidate drug SOBI003 for the treatment of MPS IIIA, allowing studies to proceed, and also granted a request for Fast Track status. The first patient is expected to be included in the study in mid-2018.

#### **Delivering on our strategy**

We have taken advantage of our extensive competence in launching rare disease and specialty care products on the complex European market to launch our EHL treatments for haemophilia. We have successfully developed a solid Haemophilia organisation that is delivering strong financial growth and, in turn, allowing us to reinvest in Specialty Care.

We will continue our evaluation of external opportunities to expand our commercial portfolio through in-licensing, acquisitions or partnerships in EMENAR and North America, and to expand our R&D pipeline with new late-stage assets. We will ensure that potential new assets, partnerships and agreements will support the delivery of our established strategy for growth.

Solna, Sweden, 26 April 2018

Guido Oelkers, CEO and President

Ravicti, a new therapy option for the treatment of urea-cycle disorders, was launched in major European markets

SOBI003 was approved as an IND for the treatment of MPS IIIA

## **Business review Q1**

#### Haemophilia

Sobi's Haemophilia business continued to show strong growth, with several pricing and reimbursement approvals for both Elocta and Alprolix. Elocta is now reimbursed in 24 countries including Poland, Portugal and Slovakia added in the first quarter, and Alprolix in 16 countries including Austria and France in the first quarter. The reimbursement approval of Alprolix in France makes Sobi the only company in that country to offer EHL treatments for both haemophilia A and B.

A new contract to supply Elocta for the treatment of haemophilia A was signed between the Health Services Executive in the Republic of Ireland and Sobi. This follows an earlier contract for the supply of Alprolix for the treatment of haemophilia B. With both of these two-year contracts in place, the Republic of Ireland is the first country in Europe to switch an entire population undergoing treatment from conventional short-acting therapies to EHL therapies for haemophilia A and B.

Sobi presented new data at the 11th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD), in Madrid, Spain, 7-9 February 2018:

- The first real-world comparison of prophylactic treatment in patients with haemophilia A, before and after switching from conventional rFVIII therapy to Elocta (rFVIIIFc), was presented. The data, gathered from the UK National Haemophilia Database, demonstrate a significant reduction of injection frequency and clotting factor consumption, and provides further evidence that EHL rFVIIIFc products can reduce treatment burden.
- Results of pharmacokinetic simulations for different prophylactic treatments and dosing regimens for haemophilia A in Germany suggest that, by using rFVIIIFc instead of conventional rFVIII therapy, it is possible to achieve better bleed protection and extend the dosing interval, lower factor consumption and reduce healthcare costs.

#### **Specialty Care**

Ravicti, a new therapy option for the treatment of patients with urea-cycle disorders (UCDs), obtained reimbursement approval in the EU. UCDs are very rare, serious and life-threatening disorders. For patients with UCDs, early treatment and adequate ammonia control are critical for maintaining intellectual function, preventing neurologic damage and reducing the frequency of hyperammonaemic crises. The introduction of Ravicti offers a new alternative for managing ammonia levels, and will contribute to the further advancement of care of patients with UCDs.



Orfadin was approved by Health Canada for once-daily dosing for the treatment of hereditary tyrosinaemia type 1 (HT-1). Orfadin is the first and only nitisinone product in Canada approved for once-daily use, designed to meet the needs of HT-1 patients entering older childhood, adolescence and adulthood.

The Swedish reimbursement agency (TLV) approved reimbursement for Xiapex® in Peyronie's Disease. Treatment with Xiapex is an alternative to surgery and the approval will increase patient access to this treatment and may contribute to improved quality of life.

#### **R&D** pipeline

The FDA accepted our IND application for Sobi's in-house-developed drug candidate SOBI003 for the treatment of MPS IIIA, and granted Fast Track status. Both of these approvals are key steps towards the initiation of the first clinical study with SOBI003 in children affected by MPS IIIA. The clinical study is expected to start around mid-2018.

Kineret received a positive CHMP opinion the treatment of Still's disease in the EU, followed by the EC approval after the quarter. This is an important milestone for patients with Still's disease, offering an alternative to treatment with steroids. The Still's programme in the US is ongoing.

#### **Corporate**

An enhanced corporate sustainability initiative was launched. The programme has a strong connection to Sobi's strategy of providing access to treatments for rare diseases. A sustainable business entails a commitment to responsibility for patients and employees, reduced environmental impact from operations and treatment, as well as long-term sustainable profitability so that we can continue to reinvest in developing new therapies for rare diseases and serve our communities for many years to come.

Two new senior recruitments will provide invaluable experience and competence to support our strategy for growth. Henrik Stenqvist was announced new Chief Financial Officer (CFO) in February and will join in late spring. Just after the end of the quarter, Sobi announced that Fredrik Wetterlundh would become Head of Human Resources. Both have extensive experience in the pharmaceutical industry.

# Financial review Q1

#### **Total revenues**

Total revenues for the guarter amounted to SEK 1,964 M (1,396), up 41 per cent compared to the first quarter 2017.

#### Revenues by business area

#### Haemophilia

Total revenues for Haemophilia were SEK 1,222 M (698), including estimated royalty revenue of SEK 301 M (277). Product sales amounted to SEK 801 M (300), of which SEK 649 M (250) pertained to Elocta and SEK 153 M (50) to Alprolix. France, Germany, Italy and the UK accounted for approximately 70 per cent of this growth.

ReFacto manufacturing revenues were SEK 120 M (121), down 1 per cent due to phasing effects.

Royalty to Sobi on sales of ReFacto AF outside of the US ceased on 1 June 2016 and for the US on 1 February 2018.

As of 2018, ReFacto is reported under the Haemophilia business area.

#### Specialty Care

Revenues for Specialty Care were SEK 742 M (698), up 6 per cent. Kineret and Orfadin showed solid growth.

Ravicti obtained reimbursement in a number of EU member states and was launched in first-wave countries.

Revenues for Orfadin were SEK 224 M (216), up 4 per cent. Growth across EMENAR and North America was driven by the new formulations. The impact of generics has not yet been realised.

Kineret revenues amounted to SEK 297 M (277), up 7 per cent. Growth was mainly driven by North America, and high interest in the IL-1 field.

Xiapex revenues amounted to SEK 47 M (45) representing a solid growth for the quarter, with an increase of more than 4 per cent.

Following a recommendation by the National Institute for Health and Care Excellence (NICE) in 2017 to make Xiapex available in England for people with Dupuytren's disease, the uptake in that region as increased.

## Revenues by business area

Amounts in SEK M	Q1 2018	Q1 2017	Change	Change at CER <sup>1</sup>	Full-year 2017
Haemophilia					
Elocta	649	250	159%	150%	1,557
Alprolix	153	50	204%	190%	363
Manufacturing revenues <sup>2</sup>	120	121	-1%	-1%	559
Royalty <sup>3,4</sup>	301	277	9%	22%	1,203
Total	1,222	698	75%	77%	3,682
Specialty Care					
Orfadin	224	216	4%	7%	862
Kineret	297	277	7%	12%	1,142
Xiapex	47	45	4%	2%	164
Other	174	160	9%	7%	661
Total	742	698	6%	9%	2,829
Total revenues	1,964	1,396	41%	43%	6,511

<sup>&</sup>lt;sup>1</sup>Constant exchange rates.

<sup>&</sup>lt;sup>2</sup>Previously reported under the ReFacto business area.

<sup>&</sup>lt;sup>3</sup>Includes royalty revenues from ReFacto as of Q1 2018.

<sup>&</sup>lt;sup>4</sup> Royalty in Q1 2018, based on estimated numbers.

#### **Gross profit**

Gross profit for the quarter was SEK 1,412M (1,028), representing a gross margin of 72 per cent (74).

#### **Operating expenses**

Operating expenses for sales and administrative excluding amortisation and write-downs amounted to SEK 433 M (382). This increase was primarily driven by continued investment in marketing activities and building up the Haemophilia organisation.

Research and development expenses were SEK 233 M (218). The increase was driven by the phasing of Sobi's share of Bioverativ's development costs for Elocta and Alprolix, early-stage development programmes.

#### **Operating profit**

EBITA was SEK 771 M (406).

Amortisation and write-downs of intangible assets for the quarter amounted to SEK 111 M (122). Last year included a write-down of one of the clinical programmes in early phase of SEK 12 M.

EBIT for the quarter amounted to SEK 660 M (284) representing a year-on-year increase of SEK 376 M.

#### Net financial items and tax

Net financial items amounted to SEK 3 M (-15) for the quarter, including exchange rate gains of SEK 15 M (3). The difference was mainly attributable to lower interest expense for the debt to Bioverativ and higher exchange rate gains. For more information regarding the agreement with Bioverativ se note 17 in the Annual Report 2017.

Tax amounted to SEK -148 M (-67) for the quarter.

#### **Profit**

Profit totalled SEK 515 M (202).

#### **Cash flow and investments**

Cash flow from operations before change in working capital amounted to SEK 508 M (400).

Working capital impacted cash flow by SEK -231 M (-77).

Cash flow from investing activities was SEK -16 M (-76).

#### Cash

At the end of the quarter, cash and cash equivalents amounted to SEK 1,750 M, compared with SEK 1,478 M, at 31 December 2017.

## Operating profit/loss

	Q1	Q1	Full-year
Amounts in SEK M	2018	2017	2017
Total revenues	1,964	1,396	6,511
Total cost of goods and services sold	-552	-368	-1,854
Gross profit	1,412	1,028	4,657
Gross margin <sup>1</sup>	72%	74%	72%
Sales and administrative expenses before amortisation and write-downs	-433	-382	-1,644
Research and development expenses	-233	-218	-908
Total opex less amortisation and write-downs	-666	-601	-2,551
Other operating revenue/expenses	25	-21	-52
ЕВІТА	771	406	2,053
Amortisation related to Sales and administrative expenses	-111	-122	-453
EBIT	660	284	1.600

The statement is a non-IFRS statement. For an IFRS income statement, please refer to the Consolidated statement of comprehensive income

<sup>&</sup>lt;sup>1</sup>The gross margin for Q1 2017 was impacted by a one-time adjustment of inventory of SEK 59 M due to a delayed release of the drug substance for Kineret manufactured in 2016.

#### Net cash/debt

Sobi ended the quarter with a net cash position of SEK 1,744 M, compared with SEK 1,472 M, at 31 December 2017.

#### **Equity**

Consolidated shareholders' equity at 31 March 2018, was to SEK 7,215 M compared to SEK 6,701 M at 31 December 2017.

#### **Parent Company**

Net sales in the first quarter of 2018, for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 1,833 M (1,270) of which SEK 1,008 M (589) referred to sales to Group companies.

Profit after financial items amounted to SEK 821 M (338). Investments in tangible and intangible assets affecting cash amounted to SEK 11 M (71).

# Financial calendar

**AGM** 9 May 2018

Q2 2018 18 July 2018

Q3 2018 31 October 2018

## Other information

#### Personnel

At 31 March 2018, the number of full-time equivalents was 816 (800 at 31 December 2017).

#### Pharmaceutical taxes update in France

New market data were received from the pharmaceutical industry association in France during the first quarter 2018 which indicates that the provision made by Sobi's French subsidiary in 2017 for pharmaceutical tax may be too high. One component in the calculation of pharmaceutical tax is based on the development of the French market. Preliminary prognoses from an independent organisation in France are submitted to the industry body during the financial year, and provide a foundation for pharmaceutical tax provisions. In February 2018, the industry body reported that the growth figure on which the received forecasts potentially could be too high. A final figure for pharmaceutical tax will be received during the second quarter of 2018, at which point the provision will be adjusted, if required, and reported.

#### Significant events after the reporting period

- Kineret received EC approval for the treatment of Still's disease.
- Fredrik Wetterlundh was appointed as Head of Human Resources.

#### Financial outlook 2018<sup>1,2</sup>- revised

Sobi now expects total revenues for the full-year to be in the range of SEK 7,900 - 8,100 M (7,500 - 7,700).

The gross margin is expected to be at least 70 per cent (unchanged).

Sobi now expects EBITA for the full-year to be in the range of SEK 2,800 - 3,000 M (2,500 - 2,700).

#### **Annual General Meeting 2018**

The Annual General Meeting (AGM) of Swedish Orphan Biovitrum AB (publ) will be held on Wednesday, 9 May 2018 at 15:00, at Näringslivets Hus, Stockholm, Sweden.

Notice of the Annual General Meeting is available on www.sobi.com.

This report has not been audited.

Solna, Sweden, 26 April 2018

Guido Oelkers, CEO and President

#### **Forward-looking statements**

This report includes forward-looking statements. Actual results may differ from those stated. Internal factors such as the successful management of research programmes and intellectual property rights may affect future results. There are also external conditions such as the economic climate, political changes and competing research programmes that may affect Sobi's results.

This information is information that Swedish Orphan Biovitrum AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of Linda Holmström, Senior Communications Manager, at 08:00 CET on 26 April 2018.

<sup>&</sup>lt;sup>1</sup>At current exchange rates as of 26 April 2018.

<sup>&</sup>lt;sup>2</sup>The original outlook was published on 22 February 2018.

# Financial statements – Group Statement of comprehensive income

	Q1	Q1	Full-year
Amounts in SEK M	2018	2017	2017
Total revenues <sup>1</sup>	1,964	1,396	6,511
Total cost of goods and services sold	-552	-368	-1,854
Gross profit	1,412	1,028	4,657
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Sales and administrative expenses <sup>2</sup>	-544	-504	-2,096
Research and development expenses	-233	-218	-908
Other operating revenue/expenses	25	-21	-52
Operating profit	660	284	1,600
Ft	2	1.5	60
Financial income/expenses <sup>3</sup>	3	-15	-68
Profit before tax	662	269	1,532
la sense have avances	1.40	-67	204
Income tax expenses	-148		-384
Profit for the period	515	202	1,149
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
Items that may be reclassified subsequently to profit/loss			
Translation difference	11	-1	-1
Cash flow hedge (net of tax)	-21	36	150
Comprehensive income for the period	505	237	1,296
<sup>1</sup> See page 6 for split by business area.			
<sup>2</sup> Amortisation and write-downs of intangible assets included in Sales and administrative expenses.	-111	-122	-453
<sup>3</sup> Including financing costs amounting to:	0	0	1
	_	_	_
Earnings per share, SEK	1.91	0.75 0.75	4.27 4.25
Earnings per share after dilution, SEK	1.90	0.75	4.25

### **Balance** sheet

	Mar	Dec	Mar
Amounts in SEK M	2018	2017	2017
ASSETS			
Non-current assets			
Intangible fixed assets <sup>1</sup>	6,343	6,445	6,747
Tangible fixed assets	133	134	126
Other non-current assets	200	167	155
Total non-current assets	6,676	6,746	7,028
Current assets			
Inventories	1,064	1,053	988
Accounts receivable	1,439	1,129	888
Current receivables, non-interest bearing	458	496	396
Cash and cash equivalents	1,750	1,478	1,032
Total current assets	4,710	4,157	3,304
Total assets	11,386	10,903	10,332
EQUITY AND LIABILITIES			
Shareholders' equity	7,215	6,701	5,609
Long-term liabilities			
Long-term liabilities <sup>2</sup>	5	5	502
Long-term liabilities, non-interest bearing	1,675	1,832	2,199
Total long-term liabilities	1,680	1,838	2,701
Current liabilities			
Current liabilities	1	2	2
Current liabilities, non-interest bearing	2,490	2,363	2,020
Total current liabilities	2,491	2,365	2,022
Total equity and liabilities	11,386	10,903	10,332
1. I I I GENERAL SEANA			

<sup>&</sup>lt;sup>1</sup>Including goodwill of SEK 1,554 M.

## Changes in equity

	Jan-Mar	Full-year	Jan-Mar
Amounts in SEK M	2018	2017	2017
Opening balance <sup>1</sup>	6,701	5,365	5,365
Share-based compensation to employees	10	40	7
Comprehensive income for the period <sup>2</sup>	505	1,296	237
Equity at end of period	7,215	6,701	5,609

 $<sup>^{1}\</sup>mbox{Adjustment}$  of deferred tax affected the opening balance 2017 with SEK 11 M.

<sup>&</sup>lt;sup>2</sup>External bank loan of SEK 500 M was repaid in Q4 2017.

 $<sup>^{2}\</sup>mbox{Whereof}$  changes in cash flow hedges amounted to SEK -21 M (36).

## Cash flow statement

	Q1	Q1	Full-year
Amounts in SEK M	2018	2017	2017
	-4-		
Profit for the period	515	202	1,149
Adjustment for non-cash items <sup>1</sup>	-7	198	283
Cash flow from operations before change in working capital	508	400	1,431
Change in working capital	-231	-77	-98
Cash flow from operations	277	323	1,333
Investment in intangible fixed assets	-8	-63	-92
Investment in tangible fixed assets	-8	-13	-48
Divestment of tangible fixed assets	1	0	1
Investment in financial assets	_	_	-1
Cash flow from investing activities	-16	-76	-139
Loans - Raising/Amortisation	_	_	-500
Net finance lease	-1		
Cash flow from financing activities	-1	_	-500
Change in cash and cash equivalents	260	247	694
Cash and cash equivalents at the beginning of the period	1,478	786	786
Translation difference in cash flow and cash and cash equivalents	11	-1	-1
Cash and cash equivalents at the end of the period	1,750	1,032	1,478
<sup>1</sup> Adjustment for non-cash items:			
Depreciation tangible fixed assets	9	8	33
Amortisation and write-downs intangible assets	111	122	453
Deferred tax	-31	9	164
Other, whereof SEK -116 M (47) in Q1 2018 and SEK -438 M in full year 2017 reflect Elocta and Alprolix non-cash transactions, see also Sobi's 2017 Annual Report for more information on the agreement with Bioverativ in Note 17	-95	59	-367
Non-cash items	-7	198	283

# Key ratios and other information

	Q1	Q1	Full-year
Amounts in SEK M	2018	2017	2017
Profit measures			
Gross profit	1,412	1,028	4,657
EBITDA <sup>1</sup>	779	415	2,086
EBITA <sup>1</sup>	771	406	2,053
EBIT (Earnings before interest and tax)	660	284	1,600
Profit/loss	515	202	1,149
Per share data (SEK)			
Earnings per share	1.91	0.75	4.27
Earnings per share after dilution	1.90	0.75	4.25
Shareholders' equity per share <sup>1</sup>	26.5	20.7	24.6
Shareholders' equity per share after dilution <sup>1</sup>	26.3	20.6	24.5
Other information			
Gross margin <sup>1</sup>	72%	74%	72%
EBITA margin <sup>1</sup>	39%	29%	32%
Equity ratio <sup>1</sup>	63%	54%	61%
Net cash (-)/debt (+) <sup>1</sup>	-1,744	-529	-1,472
Number of ordinary shares	272,507,708	270,389,770	272,507,708
Number of C-shares (in treasury)	_	1,621,178	_
Number of ordinary shares (in treasury)	3,249,870	1,610,086	3,249,870
Average number of ordinary shares (excluding shares in treasury)	269,257,838	268,779,684	269,020,363
Number of shares after dilution	273,938,320	271,797,411	273,458,932
Average number of ordinary shares after dilution (excluding shares in treasury)	270,332,138	269,720,104	270,003,546

 $<sup>^1\!\</sup>mbox{Alternative}$  performance measures (APMs), see next page for further information.

# 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 these measures to 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:

All amounts are stated in SEK M unless otherwise stated.

	Q1 2018	Q1 2018	Full-year 2017
Operating revenue	1,964	1,396	6,511
Cost of goods and services sold	-552	-368	-1,854
Gross profit	1,412	1,028	4,657
Gross margin, %	72 %	74%	72%
Gross profit - Net sales less cost of goods and services sold.			
Gross margin - Gross profit as a percentage of sales.			
Operating profit	660	284	1,600
Add back amortisation and write-downs of intangible assets	111	122	453
EBITA	771	406	2,053
Add back depreciation of tangible assets	9	8	33
EBITDA	779	415	2,086
EBITA - Earnings before interest, tax and amortisation.			
EBITDA - Earnings before interest, tax, depreciation and amortisation.			
Liabilities to credit institutions			
– Long-term	5	502	5
- Current	1	2	2
Interest bearing liability	6	504	7
Cash and cash equivalents	1,750	1,032	1,478
Net debt (+)/Net cash (-)	-1,744	-529	-1,472
Interest bearing liability - Credit facilities and other liabilities to credit institutions.			
Net debt/net cash - Interest-bearing long-term and current liabilities less cash at bank.			
Equity	7,215	5,609	6,701
Total assets	11,386	10,332	10,903
Equity ratio, %	63 %	54%	61%
Number of shares	272,507,708	270,389,770	272,507,708
Equity per share, SEK	26.5	20.7	24.6
Equity ratio - Shareholders' equity as a proportion of total assets.			
Equity per share - Equity divided by the number of shares.			

# Financial statements – Parent Company

### Income statement

	Q1	Q1	Full-year
Amounts in SEK M	2018	2017	2017
Total revenues	1,833	1,270	5,756
Total cost of goods and services sold	-524	-387	-1,861
Gross profit	1,309	883	3,895
Sales and administrative expenses <sup>1</sup>	-298	-306	-1,400
Research and development expenses	-221	-207	-855
Other operating revenue/expenses	27	-18	-40
Operating profit	817	352	1,600
Result from participation in Group companies <sup>2</sup>	-	-	-1,000
Financial income/expenses	4	-14	-65
Profit/loss after financial items	821	338	535
Appropriations	_	_	-911
Profit/loss before tax	821	338	-376
Income tax expenses	-154	-43	-132
Profit/loss for the period	667	295	-508

# Statement of other comprehensive income

	Q1	Q1	Full-year
Amounts in SEK M	2018	2017	2017
Profit/loss for the period	667	295	-508
Items that may be subsequently reclassified to profit/loss			
Cash flow hedge (net of tax)	-21	36	150
Comprehensive income for the period	646	331	-358
<sup>1</sup> Amortisation and write-downs of intangible assets included in Sales and administrative expenses.	-72	-83	-296

<sup>&</sup>lt;sup>2</sup>The Parent Company wrote down the value of the shares in the subsidiary Swedish Orphan Biovitrum International AB in the fourth quarter of 2017 with SEK

## **Balance** sheet

	Mar	Dec	Mar
Amounts in SEK M	2018	2017	2017
ASSETS			
Non-current assets			
Intangible fixed assets	3,994	4,058	4,243
Tangible fixed assets	110	114	105
Other non-current assets	2,918	2,915	3,882
Total non-current assets	7,023	7,087	8,230
Current assets			050
Inventories	891	894	853
Current receivables, non-interest bearing	2,161	1,779	1,487
Cash and cash equivalents	1,589	1,381	932
Total current assets	4,642	4,054	3,272
Total assets	11,664	11,140	11,502
EQUITY AND LIABILITIES			
Shareholders' equity	6,092	5,436	6,093
Untaxed reserves	2,124	2,124	1,154
Long-term liabilities			
Long-term liabilities <sup>1</sup>	_	_	497
Long-term liabilities, non-interest bearing	978	1,159	1,680
Total long-term liabilities	978	1,159	2,177
Current liabilities			
Current liabilities, non-interest bearing	2,470	2,421	2,077
Total current liabilities	2,470	2,421	2,077
Total equity and liabilities	11,664	11,140	11,502

<sup>&</sup>lt;sup>1</sup>External bank loan of SEK 500 M was repaid in Q4 2017

# Change in shareholders' equity

Amounts in SEK M	Jan-Mar	Full-year	Jan-Mar 2017
	2018	2017	
Opening balance <sup>1</sup>	5 436	5 755	5 755
Share-based compensation to employees	10	40	7
Comprehensive income for the period <sup>2</sup>	646	-358	331
Equity at end of period	6 092	5 436	6 093

 $<sup>^{1}\</sup>mbox{Adjustment}$  of deferred tax affected the opening balance 2017 with SEK 11 M.

 $<sup>^{2}\</sup>mbox{Whereof}$  changes in cash flow hedges amounted to SEK -21 M (36).

## Financial notes

## Note 1 – Accounting policies and measurement bases and other information

#### Significant accounting policies

This report has been prepared in accordance with IAS 34 and the Swedish Annual Accounts Act. The consolidated financial statements for the period January-March 2018 have been prepared in accordance with International Financial Reporting Standards (IFRS) and the International Financial Reporting Interpretations Committee (IFRIC) interpretations as adopted by the EU and the Swedish Annual Accounts Act.

The Parent Company applies the Annual Accounts Act and the Swedish Financial Reporting Board's Recommendation RFR 2 Accounting for Legal Entities.

The consolidated financial statements have been prepared according to the historical cost convention, except in the case of financial assets and certain financial assets and liabilities (including derivative instruments) which are measured at fair value through profit and loss.

The accounting policies applied, except for the changes listed below, are in accordance with those described in the 2017 Annual Report. More detailed information about the Group's accounting policies and measurement bases can be found in the 2017 Annual Report, available on www.sobi.com.

#### Change in accounting policies

The new accounting standards IFRS 9 Financial Instruments and IFRS 15 Revenue from Contracts with Customers, came into effect on 1 January 2018. Preparations continue for the implementation of new accounting standard IFRS 16 Leasing, which will apply for the financial year beginning on or after 1 January 2019.

IFRS 9 Financial Instruments replaces IAS 39 Financial Instruments: Recognition and Measurement.

The standard contains rules for the classification and measurement of financial assets and liabilities, impairment of financial instruments and hedge accounting. One of the changes relates to liabilities reported at fair value. The part of the change relating to fair value attributable to the own credit risk should be reported in other compre-

hensive income instead of in the result, unless this causes inconsistency in the accounting. Sobi has no liabilities valued at fair value and is therefore not affected by the change. Another change relates to hedge accounting and requires increased disclosure of risk management and the effect of hedge accounting. Sobi's hedge accounting is made in accordance with IAS 39 with disclosures in accordance with IFRS 9, the new hedge requirements have no material impact on current hedge activities. Finally, new principles have been introduced regarding impairment of financial assets, where the model is based on expected losses. Sobi has applied the retrospective transition method which has no material impact on either earnings or the financial position. In accordance with IFRS 9, Sobi has chosen not to recalculate comparative figures.

IFRS 15 contains a comprehensive accounting model for revenues from customer contracts and replaces the existing standards for revenue accounting, such as IAS 18.

Sobi has conducted a thorough analysis of the effects that the introduction of IFRS 15 may have on the Group's financial statements, and it will not have any material impact on either earnings or the financial position. To reach this conclusion, agreements and transactions have been reviewed and tested against the standard's five-step model for revenue recognition. Consequently, revenue recognition according to IFRS 15 has been applied in its entirety and remains unchanged from the present standard. As a transition method, Sobi has chosen full retrospective application, which means that the company applies IFRS 15 prospectively for contracts in place on the transition date. As revenue recognition remains unchanged on transition to the new standard, the choice of transition method is not of importance.

IFRS 16 replaces IAS 17 Leases, with new accounting requirements for lessees. All leasing contracts, except short-term and minor leases, must be reported as assets with the right of use, and as a corresponding liability in the lessee's balance sheet. Lease payments must be reported as repayment, depreciation and interest expenses. The accounting requirements for lessors are unchanged. IFRS 16 will have effect on Sobi's accounts, primarily in terms of fixed assets and long-term liabilities, but the full extent has yet to be determined.

#### **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 2017 Annual Report (see the Directors' Report). There are no major changes in the Group's risk exposure and risk management in 2018 compared to the previous year.

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

The Group carries derivatives (see the 2017 Annual Report for a narrative description of the purpose of the holdings). The derivatives (under the heading "current assets/ liabilities") are all level 2 instruments in the fair value hierarchy in the standard IFRS 13 (inputs other than quoted prices that are observable for the instruments, either directly or indirectly, are used in the fair value measurement). All derivatives are measured at fair value based on market data in accordance with IFRS. At 31 March 2018, the net reported value in the balance sheet for derivatives was SEK -14 M (-3).

At 31 March 2018, all other financial instruments in the balance sheet had reported values that are in all material aspects equivalent to fair value.



## Mission

We transform the lives of people with rare diseases by providing innovative therapies in our focus areas.

We are growing our haemophilia business to become a leading player in the EMENAR region.

We look to become the preferred partner for the development and commercialisation of products in specialty care.

We continue to identify and develop innovative treatments through a self-sustained R&D organisation funded by growth in our business areas.

# Value creation

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

# Operational and pipeline targets 2018

#### Strengthen commercial focus

- Increase sales of Elocta and Alprolix in existing and new markets
- Increase sales of Kineret in existing markets and in applications

Expand our commercial portfolio through new in-licensing, acquisitions or partnerships focused on Europe and North America

Progress development towards a self-sustained R&D pipeline

- Begin SOBI003 first in human phase 1/2 study
- Complete enrolment into the RelTlrate study
- Phase 2 Gout (anakinra) key results for phase 3 decision

Expand R&D pipeline with new late-stage assets

# Definitions and glossary

Alprolix (eftrenonacog alfa) A recombinant, EHL clotting factor IX therapy approved in the EU, Iceland, Kuwait,

Liechtenstein, Norway, Saudi Arabia and Switzerland, as well as in Australia, Brazil,

Canada, Japan, New Zealand and the United States, for the treatment of

haemophilia B, and can be used by people of all ages.

anaSTILLs A randomised, double-blind, multicentre study being conducted in North America

studying two dose levels of anakinra, administrated subcutaneously, in comparison

to placebo for the treatment of Still's disease.

**CER** Constant Exchange Rate

**CHMP** Committee for Medicinal Products for Human Use

**Dupuytren's contracture** Also known as "Viking disease", is a condition that affects the connective tissue in

the palm of the hand and the inside surface of the fingers. It occurs when a collagen nodule forms in the palm of the hand resulting in a small lump.

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

stock.

The European Commission

**EHL** Extended half-life

Elocta (efmoroctocog alfa) A recombinant, EHL clotting factor VIII therapy approved in the EU, Iceland,

Kuwait, Liechtenstein, Norway, Saudi Arabia and Switzerland, for the treatment of haemophilia A and can be used by people of all ages. It is also approved in Australia, Brazil, Canada, Japan, New Zealand and the United States, where it is

known as ELOCTATE®.

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

**FDA** The US Food and Drug Administration.

Full-time equivalents

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

workloads comparable.

**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.

Hereditary tyrosinemia type 1

(HT-1)

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

renal and neurological complications.

IND Investigational New Drug

**Kineret (anakinra)** A drug used to treat inflammatory diseases.

# Definitions and glossary

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).

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

**Peyronie's disease**A condition in which men develop plaques of fibrous, scar-like tissue in their

penis, causing it to become abnormally curved when erect.

SOBI003 A Sobi product candidate. A chemically modified variant of a recombinant human

sulfamidase 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).

Xiapex (collagenase clostridium

histolyticum)

Used to treat Dupuytren's contracture and Peyronie's disease in adults.

Sobi™ is an international speciality healthcare company dedicated to rare diseases.

Our vision is to be recognised as a global leader in providing access to innovative treatments that make a significant difference for individuals with rare diseases.

The product portfolio is primarily focused on treatments in Haemophilia and Specialty Care. Partnering in the development and commercialisation of products in specialty care is a key element of our strategy. Sobi has pioneered in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2017, Sobi had total revenues of SEK 6.5 billion and approximately 850 employees. The share (STO:SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.



#### Swedish Orphan Biovitrum AB (publ)

SE-112 76 Stockholm, Sweden | Street address: Tomtebodavägen 23 A Telephone: +46 8-697 20 00 | Fax: +46 8-697 23 30

www.sobi.com