Strong first quarter

Q1
2019 report

- Total revenues of SEK 3,265 M (1,964). 66 per cent revenue growth in the quarter compared with Q1 2018 (54 per cent at constant exchange rates (CER))
- EBITA[1] increased by 96 per cent to SEK 1,509 M (771) and adjusted EBITA[2] was SEK 1,471 M, an increase of 91 per cent
- Earnings per share (EPS) of SEK 3.14 (1.91) and adjusted EPS[2] of 3.03 SEK
- Net debt of SEK 5,552 M at 31 March 2019 (-2,999 at 31 Dec 2018)
- Revenues for Elocta® were SEK 991 M (649)
- Revenues for Alprolix® were SEK 337 M (153)
- Early experience of Gamifant® launch has been positive with revenues amounting to SEK 89 M
- The acquisition of Synagis® was completed and sales were consolidated from 23 January, towards the end of the RSV season.
- Revenues for Synagis for the period 23 January—31 March were SEK 665 M
- SOBI003 moved into the second cohort of the phase 1/2 study
- Analysis from the A-LONG/Kids A-LONG/ASPIRE and B-LONG/Kids B-LONG/B-YOND studies confirms the long-term efficacy and safety of rFVIIIFc and rFVIXFc prophylaxis for all types of bleeds in people of all age groups with severe haemophilia A and B respectively
- Financial outlook 2019—unchanged compared to the previously published outlook on 20 February. For more information see page 7
  - Sobi expects revenues for the full year to be in the range of SEK 12,500- 13,000 M
  - EBITA for the full year is expected to be in the range of SEK 5,000 - 5,300 M

Total revenues, SEKm

3,265

+66%

Gross margin[1]

76%

EBITA[1], SEKm

1,509

+96%

Earnings per share, SEK

3.14

Financial summary

Amounts in SEK M[3]	Q1 2019	Q1 2018	Change	Full-year 2018
Total revenues	3,265	1,964	66%	9,139
Gross profit	2,494	1,412	77%	6,723
Gross margin[1]	76%	72%		74%
EBITA[1]	1,509	771	96%	3,571
EBITA adjusted[1,2]	1,471	771	91%	3,571
EBITA margin[1]	46%	39%		39%
EBITA margin adjusted[1,2]	45%	39%		39%
EBIT (operating profit)	1,227	660	86%	3,122
Profit for the period	903	515	75%	2,418
Earnings per share, SEK	3.14	1.91	64%	8.97
Earnings per share, SEK adjusted[1,2]	3.03	1.91	59%	8.97

[1]Alternative Performance Measures (APMs), see page 12 for further information.

[2]EBITA and EPS excluding impact from divestment of SOBI005 in Q1 2019. See Business review page 4 for further information.

[3]The implementation of IFRS 16 has had no material impact on metrics above.

CEO statement

We started 2019 with a strong first quarter, with revenues of SEK 3,265 M and EBITA of SEK 1,509 M, corresponding to an EBITA margin of 46 per cent. We completed the acquisition of Synagis in late January and are in the process of integrating Synagis operations and employees into the organisation. The Haemophilia franchise continued to grow strongly, we have seen positive effects from the Gamifant launch in the US even though it is still in early launch phase, and we see an increasing demand for Synagis.

Haemophilia – individualised therapy gains further momentum

Sales for Elocta were SEK 991 M (649) and SEK 337 M (153) for Alprolix, an increase of 53 and 120 per cent respectively (46 and 110 per cent at CER). I am delighted by the fact that we continue making significant progress with both products. The trend towards improving care by individualising patients' therapy appears to be gaining further momentum. The main countries contributing to the Q1 growth in Haemophilia were France, Germany, Italy and the UK. Elocta and Alprolix have assumed market leadership positions in various geographies including the Nordic region recently. Whilst product sales grew by 66 per cent (58 per cent at CER), total Haemophilia revenues grew by 42 per cent (33 per cent at CER) to SEK 1,731 M including royalties and manufacturing revenues for ReFacto.

Immunology – positive early experience after Gamifant launch

Our Immunology franchise, consisting of Kineret®, Synagis and Gamifant, had a strong first quarter with sales of SEK 1,100 M. Kineret grew 17 per cent (7 per cent at CER) with sales amounting to SEK 346 M (297).

We are still in early launch phase for Gamifant (emapalumab), and our expectation is that there is a true unmet medical need among primary haemophagocytic lymphohistiocytosis (HLH) patients. We believe that Gamifant has the potential to make a real difference for patients with primary HLH, and their carers. Our initial focus in the US has been on education since Gamifant is the only treatment approved by the US Food & Drug Administration (FDA) for HLH. The early experience after launch has been very positive. Revenues for Gamifant amounted to SEK 89 M in Q1 and so far 10 hospitals in the US have treated patients with Gamifant.

With the Synagis transaction finalised on 23 January, our organisation has been strengthened by bringing on board a dedicated workforce of 135 professionals in the US focused on the paediatric sector. The closing date meant that we have not consolidated an important period during the respiratory syncytial virus (RSV) season. As Synagis has been a widely distributed product, there were inventory adjustments as part of the transition. Demand continues to be strong and has not been negatively affected by the ownership change. Underlying demand is up in comparison with

"The Haemophilia franchise continued to grow strongly and we have seen positive effects from the Gamifant launch in the US even though it is still in early launch phase"

Guido Oelkers,
CEO and President

Elocta product sales at CER

+46%

Alprolix product sales at CER

+110%

the previous year. Revenues for the period 23 January–31 March amounted to SEK 665 M.

Pipeline

New encouraging data for emapalumab highlighting post-transplant treatment outcomes in primary HLH was presented during Q1. The data supports our commitment to further investigate emapalumab for other indications and pursue life-cycle management studies for primary HLH.

In April 2018, Kineret was approved by the European Medicines Agency (EMA) for the treatment of Still's disease. A study, anaSTILLs, is ongoing in the US for a potential approval in Still's disease for US patients. Only 12 out of 81 patients have so far been enrolled. We have therefore after careful consideration and evaluation decided to end enrolment and discontinue the study. The study will be completed according to plan for the patients enrolled.

The SOBI003 phase 1/2 study moved into the second cohort after review of safety data collected to date for the first three mucopolysaccharidosis type IIIA (MPS IIIA) in the first cohort.

Continued focus on M&A

Our strategy for growth remains in place and we are continuously evaluating external opportunities to further strengthen our business and our late-stage pipeline with products that fulfil an unmet medical need in the rare disease space. Our short-term focus is on the launch of Gamifant, Synagis sales activities and continued growth for our Haemophilia franchise.

Solna, Sweden, 25 April 2019

Guido Oelkers, President & CEO

SOBI003 moved into the second cohort of the phase 1/2 study

We are continuously evaluating opportunities to further strengthen our business and our late-stage pipeline with products that fulfil an unmet medical need in the rare disease space

Business review Q1

Haemophilia

Our haemophilia products are performing well throughout Europe. During the quarter, Alprolix was approved for reimbursement in Croatia, Finland and Romania. Elocta and Alprolix are now reimbursed in a total of 26 and 22 countries respectively. Both products have assumed market leadership positions in various geographies including the Nordic region recently.

Data on the long-term safety and efficacy of prophylactic treatment with Elocta and Alprolix in adults, adolescents and children, with haemophilia A and B respectively, was presented at the European Association for Haemophilia and Allied Disorders (EAHAD) Congress, based on a longitudinal analysis of the final data from the A-LONG/Kids A-LONG/ASPIRE and B-LONG/Kids B-LONG/B-YOND studies. The analysis confirms long-term efficacy and safety of rFVIIIFc and rFVIXFc prophylaxis for all types of bleeds in people of all age groups with severe haemophilia A and B respectively.

Interim data on the incidence of inhibitors in previously untreated patients (PUPs) with severe haemophilia A treated with Elocta — the PUPs A-LONG study — was also presented at EAHAD. Data demonstrates that rFVIIIFc was well tolerated and efficacious for prevention of bleeds in a PUP population. This interim analysis is the first data reported on PUPs for an extended half-life product. The study is still ongoing and the final results will be presented at a future conference.

Immunology

The acquisition of Synagis was completed on 23 January. The 135 AstraZeneca employees working with Synagis in the US all joined Sobi. Integration of the employees is currently ongoing as well as value creation activities and preparation for coming RSV seasons.

R&D pipeline

New emapalumab data highlighting post-transplant treatment outcomes in primary HLH was presented at the Transplantation and Cellular Therapy (TCT) Meeting. In the phase 2/3 study, most patients treated with emapalumab proceeded to haematopoietic stem cell transplantation (HSCT): 64.7 per cent of all patients treated and 70.4 per cent of patients treated after failing prior conventional HLH therapy. The median time to transplant was 100 days for the full cohort and 83 days for the cohort failing prior conventional HLH therapy. Of the full cohort, 90.9 per cent survived post-HSCT, as did 89.5 per cent of the cohort failing prior conventional HLH therapy.

The SOBI003 Safety Review Committee has reviewed safety data collected to date for the first three MPS IIIA patients who had received a dose of 3 mg/kg. The dose level was considered safe and the decision was taken to proceed with recruitment and dosing of three additional MPS IIIA patients to receive a dose of 10 mg/kg.

The anaSTILLs study was initiated to meet the regulatory requirements for an approval of Kineret in Still's disease in the US. Recruitment has been challenging and only 12 out of 81 patients have been enrolled. Sobi has therefore after careful consideration and evaluation decided to end enrolment and discontinue the study. The study will be completed for the patients enrolled.

Sobi is currently evaluating options to study other indications for Kineret. In line with this, Sobi has also carefully evaluated the opportunity for Kineret in acute gout, along with other potential indications, and has decided to prioritise other Kineret indications before acute gout. Sobi will complete the extension phase of the phase 2 study anaGO in acute gout and continue to collect efficacy and safety data from additional gout flares. These results are expected in the beginning of 2020.

In March, Sobi divested SOBI005, in pre-clinical phase, to a US based start-up company. Sobi will receive a total consideration of USD 5 M (SEK 46 M) over a period of up to two years. Sobi will also receive additional milestones and royalties related to progress in the development and commercialisation of SOBI005. The capital gain for the transaction amounted to SEK 37 M in Q1.

Corporate

After a long period of preparation Sobi is serialising the first MAH (marketing authorisation holder) products for Europe, which means that we are in compliance with the Falsified Medicines Directive legislation which came into force on 9 February 2019. All medications require unique serial numbers in order to combat the risk of counterfeit medicines.

Sobi and Novimmune were selected as honourees by the National Organization for Rare Disorders (NORD) for the 2019 Rare Impact Awards. The companies were nominated in the category of Industry Innovation in recognition of the FDA approval in November 2018 of Gamifant (emapalumab). The Rare Impact Awards recognise individuals, organisations and industry innovators for outstanding work in support of the rare disease community.

Sobi Middle East opened its new corporate offices in Dubai in late February.

Sobi UK and Republic of Ireland has taken measures to ensure continuity of supply for patients in the United Kingdom ahead of all potential scenarios flowing from the exit of the UK from the European Union.

Financial review

Total revenues

Total revenues for the quarter amounted to SEK 3,265 M (1,964), up 66 per cent compared with the first quarter of 2018 (54 per cent at CER). Organic growth (adjusted for Synagis and measured at CER) amounted to 24 per cent compared with Q1 2018.

Revenues by business area

As of 1 January 2019 the former business area Specialty Care is divided into two business areas: Immunology and Specialty Care.

Haemophilia

Total Haemophilia revenues increased by 42 per cent (33 per cent at CER) to SEK 1,731 M (1,222). Product sales rose 66 per cent (58 per cent at CER) to SEK 1,328 M (801). The growth primarily derived from the continued strong performance in the EU5 markets which accounted for more than 70 per cent of this growth. Elocta sales reached SEK 991 M (649) and Alprolix sales reached SEK 337 M (153).

Royalty revenues totalled SEK 334 M (301). ReFacto manufacturing revenues were SEK 69 M (120), down 43 per cent.

Immunology

Revenues for the Immunology franchise were SEK 1,100 M. Gamifant is still in early launch phase and positive results were seen in Q1 when sales in the US amounted to SEK 89 M, positively affected by initial stocking effects. Synagis sales for the period of 23 January to 31 March amounted to SEK 665 M, which excluded an important part of the RSV season in the quarter. Kineret revenues were SEK 346 M (297 M) for the quarter, an increase of 17 per cent (7 per cent at CER) supported by growth in Europe. A Market Authorisation Application (MAA) for Kineret in Russia was submitted in March.

Specialty Care

Revenues for the remaining Specialty Care products were SEK 434 M (445), a decrease of 3 per cent (-9 per cent at CER). Revenues for Orfadin, the main Specialty Care product, were SEK 189 M (224) a decrease of 16 per cent (-23 per cent at CER). The decrease is mainly explained by the introduction of generic competition to Orfadin in certain markets, leading to requests for lower prices and mandatory price cuts.

Revenues for other products amounted to SEK 245 M (221), an increase of 11 per cent (5 per cent at CER).

Gross profit

Gross profit for the quarter was SEK 2,494 M (1,412), representing a gross margin of 76 per cent (72).

The increase was due to a favourable product mix, increased sales of Elocta and Alprolix as well as the acquisition of Synagis.

Operating expenses

Sales and administrative expenses before amortisation and write-downs amounted to SEK 703 M (433) for the quarter. In Immunology, the increase was driven mainly by the transition of Synagis and by launch activities for Gamifant in the US. In Haemophilia the increase was driven by continued investments in the EMENAR region to increase market penetration.

Research and development expenses amounted to SEK 332 M (233) for the quarter. The expenses reflect increased spending in emapalumab and investments within Haemophilia.

Revenues by business area

Amounts in SEK M	Q1 2019	Q1 2018	Change	Change at CER[1]	Full-year 2018
Haemophilia					
Elocta	991	649	53%	46%	3,261
Alprolix	337	153	120%	110%	974
Manufacturing	69	120	-43%	-43%	436
Royalty	334	301	11%	-2%	1,341
Total	**1,731**	**1,222**	**42%**	**33%**	**6,012**
Immunology					
Kineret	346	297	17%	7%	1,320
Synagis	665	-	N/A	N/A	-
Gamifant	89	-	N/A	N/A	-
Total	**1,100**	**297**	**-**	**-**	**1,320**
Specialty Care					
Specialty Care	434	445	-3%	-9%	1,807
Total	**434**	**445**	**-3%**	**-9%**	**1,807**
Total revenues	**3,265**	**1,964**	**66%**	**54%**	**9,139**

[1]Constant exchange rates.

Operating profit

EBITA was SEK 1,509 M (771) corresponding to a margin of 46 (39) per cent.

Adjusted EBITA, excluding impact from divestment of SOBI005 in the first quarter 2019, was SEK 1,471 M (771). See Business Review page 4 for further information.

IFRS 16 impact on operating profit was SEK 19 M in increased depreciations and SEK 20 M in decreased other operating expenses.

Amortisation and write-downs of intangible assets amounted to SEK 282 M (111).

EBIT amounted to SEK 1,227 M (660) representing a year-on-year increase of SEK 567 M.

Net financial items and tax

Net financial items amounted to SEK -73 M (3), including exchange rate gains/losses of SEK -27 M (15). The difference was mainly attributable to increased costs for the financing related to the acquisition of the US rights to Synagis.

Tax amounted to SEK -251 M (-148) corresponding to an effective tax rate of 21.8 per cent. The Swedish corporate tax rate for 2019 has been reduced to 21.4 per cent.

Profit

Profit totalled SEK 903 M (515).

Cash flow and investments

Cash flow from operations before change in working capital amounted to SEK 1,307 M (508).

Working capital had a negative impact of SEK -919 M (-231) on cash flow. This was primarily attributable to increased accounts receivable as a result of the sales growth in the quarter and to 2018 income taxes paid in the quarter.

The largest investment during the quarter was SEK 13,869 M related to Synagis, with a cash flow impact of SEK -8,860 M.

Cash flow from financing activities amounted to SEK 5,943 M (-1). This was mainly related to the acquisition of Synagis. Rental payments according to IFRS 16 is presented under the heading financing activities.

Cash

At the end of the quarter, cash and cash equivalents amounted to SEK 463 M, compared with SEK 2,999 M at 31 December 2018. The change is an effect of the financing of the Synagis acquision.

Net debt/cash

Sobi ended the quarter with net debt of SEK 5,552 M, compared with a net cash position of SEK 2,999 M at 31 December 2018.

Equity

At 31 March 2019, consolidated shareholders' equity was SEK 14,481 M compared with SEK 9,040 M at 31 December 2018. Equity has increased by SEK 4,513 M due to financing of the acquisition of Synagis.

Personnel

At 31 Mars 2019, the number of full-time equivalents was 1,077 (902 at 31 December 2018).

Parent Company

In the first quarter of 2019, net sales for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 3,101 M (1,833), of which Group companies accounted for SEK 1,481 M (1,008).

Profit after financial items amounted to SEK 1,480 M (821).

Investments in tangible and intangible assets affecting cash flows amounted to SEK 7 M (11).

Total assets have increased due to the acquisition of Synagis.

Operating profit/loss

Amounts in SEK M	Q1 2019	Q1 2018	Full-year 2018
Total revenues	3,265	1,964	9,139
Total cost of goods sold	-771	-552	-2 415
Gross profit	2,494	1,412	6,723
Gross margin	*76%*	*72%*	*74%*
Sales and administrative expenses before amortisation and write-downs	-703	-433	-2,062
Research and development expenses	-332	-233	-1,090
Total opex less amortisation and write-downs	-1,035	-666	-3,153
Other operating income/expenses	50	25	0
EBITA	1,509	771	3,571
Non-recurring items[1]	-37	–	–
EBITA adjusted[1]	*1,471*	*771*	*3,571*
Amortisation and write-down related to Sales and administrative expenses	-282	-111	-449
EBIT	1,227	660	3,122

This is non-IFRS financial information. For an IFRS income statement, please refer to the Consolidated statement of comprehensive income.
[1]Impact from divestment of SOBI005 in Q1 2019, see Business review page 4 for further information.

Other information

Significant events after the reporting period
None.

Financial outlook 2019[1,2] — unchanged
Sobi expects revenue for the full year to be in the range of SEK 12,500 - 13,000 M.

Main drivers of revenue growth are: continued market share growth of our Haemophilia franchise with Elocta and Alprolix, the acquisition of Synagis and growth of this franchise in the US and the continuing launch of Gamifant in the US.

EBITA for the full year is expected to be in the range of SEK 5,000 - 5,300 M.

In 2019, we will increase market investments in the Haemophilia franchise and in the commercial launch of Gamifant (emapalumab). Furthermore, we will expand clinical activities for emapalumab.

[1]At current exchange rates as of 20 February 2019.
[2]Outlook published for the first time on 20 February 2019

Annual General Meeting 2019
The Annual General Meeting (AGM) of Swedish Orphan Biovitrum AB (publ) will be held on Thursday, 9 May 2019 at 15:00 CEST, at Grand Hôtel, S. Blasieholmshamnen 8, Stockholm, Sweden.

This report has not been audited by the Company's auditors.

Solna, Sweden, 25 April 2019

Guido Oelkers, CEO and President

Financial calendar

AGM	9 May 2019
Capital Markets Day	14 May 2019
Q2 2019 report	17 July 2019
Q3 2019 report	31 October 2019

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, Corporate Communications and Investor Relations, at 08:00 CEST on 25 April 2019.

Financial statements – Group

Statement of comprehensive income

Amounts in SEK M	Q1 2019	Q1 2018	Full-year 2018
Total revenues[1]	3,265	1,964	9,139
Total cost of goods sold	-771	-552	-2,415
Gross profit	**2,494**	**1,412**	**6,723**
Sales and administrative expenses[2]	-985	-544	-2,511
Research and development expenses	-332	-233	-1,090
Other operating income/expenses	50	25	0
Operating profit	**1,227**	**660**	**3,122**
Financial income/expenses[3]	-73	3	-40
Profit before tax	**1,154**	**662**	**3,082**
Income tax expenses	-251	-148	-664
Profit for the period	**903**	**515**	**2,418**
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	–	–	0
Items that may be reclassified subsequently to profit/loss			
Translation difference	21	11	9
Cash flow hedge (net of tax)	-13	-21	-133
Comprehensive income for the period	**911**	**505**	**2,294**
[1]See page 5 for split by business area.			
[2]Amortisation and write-downs of intangible assets included in Sales and administrative expenses.	-282	-111	-449
[3]Including financing costs amounting to:	-3	0	-2
Earnings per share, SEK	3.14	1.91	8.97
Earnings per share, SEK, adjusted	3.03[4]	1.91	8.97
Earnings per share after dilution, SEK	3.12	1.90	8.93
Earnings per share after dilution, SEK, adjusted	3.02[4]	1.90	8.93
[4]Excluding impact from divestment of SOBI005.			

Balance sheet

Amounts in SEK M	Mar 2019	Dec 2018	Mar 2018
ASSETS			
Non-current assets			
Intangible assets[1,2]	23,840	10,159	6,343
Tangible assets[3]	539	136	133
Financial assets	242	286	200
Total non-current assets	24,621	10,581	6,676
Current assets			
Inventories	1,445	1,284	1,064
Accounts receivable	2,361	1,665	1,439
Other receivables, non-interest bearing	1,082	654	458
Cash and cash equivalents	463	2,999	1,750
Total current assets	5,351	6,602	4,710
Total assets	29,973	17,183	11,386
EQUITY AND LIABILITIES			
Shareholders' equity	14,481	9,040	7,215
Non-current liabilities			
Borrowings	6,015	–	–
Lease liabilities	314	3	5
Other liabilities, non-interest bearing	1,560	1,189	1,675
Total non-current liabilities	7,889	1,192	1,680
Current liabilities			
Accounts payable	743	487	231
Lease liabilities	82	1	1
Other liabilities, non-interest bearing	6,778	6,463	2,259
Total current liabilities	7,603	6,951	2,491
Total equity and liabilities	29,973	17,183	11,386

[1]Including goodwill of SEK 1,554 M.

[2]The increase is mainly related to the acquisition of the rights to Synagis.

[3]Right-of-use assets related to IFRS 16 are classified as tangible assets. Amounts to SEK 403 M as of Q1 2019.

Changes in equity

Amounts in SEK M	Jan-Mar 2019	Full-year 2018	Jan-Mar 2018
Opening balance	9,040	6,701	6,701
Share-based compensation to employees	16	46	10
Issue of shares	4,513	–	–
Comprehensive income for the period[1]	911	2,294	505
Equity at end of period	14,481	9,040	7,215

[1]Whereof changes in cash flow hedges amounted to SEK -13 M (-21).

Cash flow statement

Amounts in SEK M	Q1 2019	Q1 2018	Full-year 2018
Profit for the period	903	515	2,418
Adjustment for non-cash items[1]	405	-7	-77
Cash flow from operations before change in working capital	**1,307**	**508**	**2,341**
Change in working capital	-919	-231	-250
Cash flow from operations	**388**	**277**	**2,090**
Investment in intangible assets[2]	-8,864	-8	-537
Investment in tangible assets	-8	-8	-41
Divestment of tangible assets	–	1	3
Investment in financial assets	–	–	-1
Cash flow from investment activities	**-8,872**	**-16**	**-575**
Loans - Raising/Amortisation	5,965	–	–
Lease payments	-22	–	–
Net finance lease	–	-1	-1
Cash flow from financing activities	**5,943**	**-1**	**-1**
Change in cash and cash equivalents	**-2,541**	**260**	**1,514**
Cash and cash equivalents at the beginning of the period	2,999	1,478	1,478
Translation difference in cash flow and cash and cash equivalents	5	11	7
Cash and cash equivalents at the end of the period	**463**	**1,750**	**2,999**
[1] Adjustment for non-cash items:			
Depreciation of tangible assets	30	9	36
Amortisation and write-downs of intangible assets	282	111	449
Deferred tax	136	-31	-103
Other, whereof mainly non-cash transactions including revaluation of loans	-43	-95	-459
Non-cash items	**405**	**-7**	**-77**

[2]Investments intangible assets	
Investments during the period, whereof Synagis SEK 13,869 M	-13,873
Issue of shares	4,513
Deferred purchase consideration	496
Cash paid	-8,864

Key ratios and other information

Amounts in SEK M	Q1 2019	Q1 2018	Full-year 2018
Profit measures			
Gross profit	2,494	1,412	6,723
EBITDA[1]	1,538	779	3,607
EBITA[1]	1,509	771	3,571
EBITA adjusted[1,2]	1,471	771	3,571
EBIT (operating profit)	1,227	660	3,122
Profit/loss	903	515	2,418
Per share data (SEK)			
Earnings per share	3.14	1.91	8.97
Earnings per share, adjusted[2]	3.03	1.91	8.97
Earnings per share after dilution	3.12	1.90	8.93
Earnings per share after dilution, adjusted[2]	3.02	1.90	8.93
Shareholders' equity per share[1]	48.7	26.5	33.1
Shareholders' equity per share after dilution[1]	48.5	26.3	32.9
Other information			
Gross margin[1]	76%	72%	74%
EBITA margin[1]	46%	39%	39%
EBITA margin adjusted[1,2]	45%	39%	39%
Equity ratio[1]	48%	63%	53%
Net debt (+)/cash (-)[1]	5,552	-1,750	-2,999
Number of ordinary shares[3]	297,515,209	272,507,708	273,322,117
Number of ordinary shares (in treasury)	3,423,726	3,249,870	3,423,726
Number of ordinary shares (excluding shares in treasury)	294,091,483	269,257,838	269,898,391
Number of ordinary shares after dilution	298,872,610	273,938,320	274,365,601
Average number of ordinary shares (excluding shares in treasury)	287,908,804	269,257,838	269,523,784
Average number of ordinary shares after dilution (excluding shares in treasury)	289,266,205	270,332,138	270,603,665

[1]Alternative performance measures (APMs), see next page for further information.

[2]EBITA and EPS excluding impact from divestment of SOBI005 in Q1 2019, see Business review page 4 for further information.

[3]The increase in the number of shares results from an issue of 24,193,092 ordinary shares in connection with the acquisition from AstraZeneca of rights to Synagis (palivizumab) in the US.

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 not, therefore, be regarded as substitutes for measures defined according to IFRS. The following metrics are not defined according to IFRS:

All amounts in SEK M unless otherwise stated.

	Q1 2019	Q1 2018	Full-year 2018
Total revenues	3,265	1,964	9,139
Total cost of goods sold	-771	-552	-2,415
Gross profit	**2,494**	**1,412**	**6,723**
Gross margin, %	**76%**	**72%**	**74%**

Gross profit - Total revenue less cost of goods sold
Gross margin - Gross profit as a percentage of total revenue

EBIT (operating profit)	1,227	660	3,122
Plus amortisation and write-downs of intangible assets	282	111	449
EBITA	**1,509**	**771**	**3,571**
Plus depreciations of tangible assets	30	9	36
EBITDA	**1,538**	**779**	**3,607**
EBITA margin, %	**46%**	**39%**	**39%**
Non-recurring item	-37	–	–
EBITA adjusted	**1,471**	**771**	**3,571**
EBITA margin adjusted, %	**45%**	**39%**	**39%**

EBITA - Earnings before interest, tax and amortisation
EBITDA - Earnings before interest, tax, depreciation and amortisation
EBITA margin, % - EBITA as a percentage of total revenue
Non-recurring item - impact from divestment of SOBI005
EBITA adjusted - EBITA less divestment of SOBI005
EBITA margin adjusted, % - EBITA adjusted as a percentage of total revenue

Profit for the period	903	515	2,418
Impact from divestment of SOBI005, after tax	-29	–	–
Profit for the period, adjusted	873	515	2,418
Average number of ordinary shares	287,908,804	269,257,838	269,523,784
Average number of ordinary shares after dilution	289,266,205	270,332,138	270,603,665
EPS adjusted	**3.03**	**1.91**	**8.97**
EPS after dilution, adjusted	**3.02**	**1.90**	**8.93**

EPS adjusted - Profit for the period, adjusted, divided by the average number of ordinary shares

EPS after dilution, adjusted - Profit for the period, adjusted, divided by the average number of ordinary shares after dilution

Borrowings	6,015	–	–
Cash and cash equivalents	463	1,750	2,999
Net debt (+)/Net cash (-)	**5,552**	**-1,750**	**-2,999**

Net debt (+)/Net cash (-) - Borrowings less cash and cash equivalents

Shareholder's equity	14,481	7,215	9,040
Total assets	29,973	11,386	17,183
Equity ratio, %	**48%**	**63%**	**53%**
Number of ordinary shares	297,515,209	272,507,708	273,322,117
Equity per share, SEK	**48.7**	**26.5**	**33.1**

Equity ratio - Shareholders' equity as a proportion of total assets
Equity per share - Equity divided by the number of ordinary shares

Financial statements – Parent Company income statement

Amounts in SEK M	Q1 2019	Q1 2018	Full-year 2018
Total revenues	3,101	1,833	8,221
Total cost of goods sold	-786	-524	-2,349
Gross profit	**2,315**	**1,309**	**5,872**
Sales and administrative expenses[1]	-558	-298	-1,445
Research and development expenses	-243	-221	-932
Other operating income/expenses	50	27	-2
Operating profit	**1,564**	**817**	**3,492**
Financial income/expenses	-84	4	-35
Profit after financial items	**1,480**	**821**	**3,457**
Appropriations	–	–	-397
Profit before tax	**1,480**	**821**	**3,060**
Income tax expenses	-80	-154	-678
Profit for the period	**1,400**	**667**	**2,382**

Statement of other comprehensive income

Amounts in SEK M	Q1 2019	Q1 2018	Full-year 2018
Profit/loss for the period	1,400	667	2,382
Items that may be subsequently reclassified to profit/loss			
Cash flow hedge (net of tax)	-13	-21	-133
Comprehensive income for the period	**1,387**	**646**	**2,248**
[1]Amortisation and write-downs of intangible assets included in Sales and administrative expenses.	-75	-72	-292

Balance sheet

Amounts in SEK M	Mar 2019	Dec 2018	Mar 2018
ASSETS			
Non-current assets			
Intangible assets	3,720	3,801	3,994
Tangible assets	413	112	110
Financial assets	3,539	3,537	2,918
Total non-current assets	7,672	7,450	7,023
Current assets			
Inventories	1,165	1,071	891
Accounts receivable	1,169	590	636
Other receivables[1]	13,728	–	–
Other receivables, non-interest bearing	2,442	2,054	1,525
Cash and cash equivalents	372	2,762	1,589
Total current assets	18,877	6,476	4,642
Total assets	26,548	13,926	11,664
EQUITY AND LIABILITIES			
Shareholders´ equity	13,647	7,731	6,092
Untaxed reserves	2,584	2,584	2,124
Non-current liabilities			
Borrowings	6,056	–	–
Lease liability	244	–	–
Other liabilities, non-interest bearing	455	508	978
Total non-current liabilities	6,755	508	978
Current liabilities			
Accounts payable	283	376	193
Lease liability	53	–	–
Other liabilities, non-interest bearing	3,227	2,727	2,277
Total current liabilities	3,563	3,103	2,470
Total equity and liabilities	26,548	13,926	11,664

[1]Receivables from subsidiaries has increased due to the acqusition of Synagis.

Change in shareholders' equity

Amounts in SEK M	Jan-Mar 2019	Full-year 2018	Jan-Mar 2018
Opening balance	7,731	5,436	5,436
Share-based compensation to employees	16	46	10
Issue of shares	4,513	–	–
Comprehensive income for the period[1]	1,387	2,248	646
Equity at end of period	13,647	7,731	6,092

[1]Whereof changes in cash flow hedges amounted to SEK -13 M (-21).

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 2019 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 using the historical cost convention, except in the case of financial assets and liabilities (including derivative instruments) that are measured at fair value through profit or loss.

The accounting policies applied, except for the changes listed below, are in accordance with those described in the 2018 Annual Report. More detailed information about the Group's accounting policies and measurement bases can be found in the 2018 Annual Report, available at www.sobi.com.

Changes in accounting policies

The new accounting standard IFRS 16 Leases came into force on 1 January 2019, replacing IAS 17 Leases. The standard involves new accounting requirements for lessees and stipulates that all lease contracts be reported in the lessee's balance sheet as liabilities, and as corresponding right-to use assets. Previous operational leasing fees will be replaced by depreciation and interest expenses. Leasing payments are allocated between the liability and interest expense. The right-of-use asset is depreciated over the expected lease term on a straight-line basis.

Sobi has chosen to adopt the modified retrospective approach, without any impact on the Group's equity at 1 January 2019. The modified retrospective approach requires that right-of-use assets, primarily comprising the leasing contract regarding premises and vehicles, matches the leasing liability at the time of transition, 1 January 2019, prepaid rent taken into consideration. In conjunction with the transition, Sobi has chosen to apply the exception rules for short-term leases and low-value leases. Short-term leases have been defined as leasing agreements maturing within one year. Low-value leases comprise predominantly computers, printers and photocopiers.

The liabilities were measured at the net present value of the remaining lease payments. The weighted average discounting rate (incremental borrowing rate as per transition date) applied was 1,6 %, based on the estimated borrowing rates Sobi would have obtained from financial institution for the relevant tenors. Options to renew contracts are taken into account when the Group considers it reasonable certain that the option will be exercised.

As an effect of the transition, the Group's total assets at the transition date, 1 January 2019, have increased by SEK 397 M, which represents 2 per cent of the balance sheet. The Group's financial liabilities have increased by SEK 397 M, also representing 2 per cent of the balance sheet.

Amounts in SEK M	2018-12-31	IFRS 16 adjustment	2019-01-01
ASSETS			
Non-current assets			
Intangible assets	10,159		10,159
Tangible assets	136	412	548
Financial assets	286		286
Total non-current assets	**10,581**	**412**	**10,993**
Current assets			
Current assets	*6,602*	*-15*	6,587
Total current assets	**6,602**	**-15**	**6,587**
Total assets	**17,183**	**397**	**17,580**
EQUITY AND LIABILITIES			
Shareholders´ equity	**9,040**		**9,040**
Non-current liabilities			
Lease liabilities	3	320	323
Other liabilities, non-interest bearing	1,189	-2	1 187
Total non-current liabilities	**1,192**	**318**	**1,510**
Current liabilities			
Lease liabilities	1	81	82
Other liabilities, non-interest bearing	6,950	-2	6,948
Total current liabilities	**6,951**	**79**	**7,030**
Total equity and liabilities	**17,183**	**397**	**17,580**

IFRS 16 impact on operating profit was SEK 19 M in increased depreciations and SEK 20 M in decreased other operating expenses. Thus, no material impact on operating profit and EPS. However, the alternative performance measure EBITDA has increased by SEK 20 M due to decrease in other operating expenses according to IFRS 16.

Summary of the new accounting policies of the group upon adoption of IFRS 16:

Leased assets (right-of use assets) are capitalised at the commencement date of the lease, i.e. the date when the underlying asset is available for use. The leased assets comprise of the initial lease liability including lease payments made at or before commencement date. The leased assets are measured at cost, less any accumulated depreciations, impairment losses and remeasurements of lease liabilities. Leased assets are depreciated over the expected lease term on a straight-line basis.

The leased liability is measured at the present value of fixed pay-

ments less any lease incentives receivable and variable lease payments that depend on an index or rate, not paid at commencement date. Lease payment are discounted using the interest rate implicit in the lease contract or the lessee´s incremental borrowing rate when discount rate used can´t be readily determined. The carrying value of the lease liability is remeasured when there is a modification or change in lease terms.

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-rate risk, credit risk and liquidity risk.

A more detailed description of the Group's risk exposure and risk management is included in Sobi's 2018 Annual Report (see the Directors' Report). There are no major changes in the Group's risk exposure and risk management in 2019 compared with the previous year.

Note 2 – Fair value of financial instruments

The Group carries derivatives (see the 2018 Annual Report for a narrative description of the purpose of the holdings). The derivatives (under the heading "current assets/liabilities") are all categorised within Level 2 of the fair value hierarchy in the IFRS 13 standard (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 2019, the net reported value of derivatives on the balance sheet was SEK -18 M (-14).

At 31 March 2019, all other financial instruments on the balance sheet had reported values that are in all material aspects equivalent to fair value.

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, the United States and other countries, for the treatment of haemophilia B, which can be used by people of all ages.
Acute gout	An autoinflammatory disease and intensely painful and disabling inflammatory arthritis involving one or several joints. Gout is also a disease associated with multiple comorbidities, which may limit the use of some conventional treatment regimens.
AnaGO	A randomised double-blind, multicentre phase 2 study being conducted in North America studying two dose levels of anakinra in comparison to intramuscular triamcinolone for the treatment of acute gout.
CER	Constant exchange rates.
EAHAD	The European Association for Haemophilia and Allied Disorders
Earnings per share	The portion of a company's profit allocated to each outstanding share of common stock.
EHL	Extended half-life, which means that the circulation in the body is prolonged. Sobi's haemophilia treatments, Elocta and Alprolix, are EHL products.
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, which can be used by people of all ages. It is also approved in Australia, Brazil, Canada, Japan, New Zealand, the United States and other countries, where it is known as ELOCTATE®.
EMA	European Medicines Agency.
EMENAR	Abbreviation for business region including Europe, Middle East, North Africa and Russia.
FDA	The US Food & Drug Administration.
Full-time equivalents	Unit that indicates the workload of an employed person in a way that makes workloads comparable.
Gamifant (emapalumab)	An anti-interferon-gamma (IFN-γ) monoclonal antibody (mAb), approved by the FDA and currently under EMA review for the treatment of primary haemophagocytic lymphohistiocytosis (pHLH), a life-threatening syndrome of immune activation. An application to the EMA was submitted in August 2018.
Haemophagocytic lymphohistiocytosis (HLH)	A rare and life-threatening syndrome of extreme immune activation. The primary form of the disease (pHLH, inherited) mainly occurs in infants and young children while the secondary form of the disease (sHLH, acquired) is acquired from or associated with infection, autoimmune diseases or malignancy.
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, limited mobility, irreversible joint damage and life-threatening haemorrhages.
Kineret (anakinra)	A recombinant protein drug that blocks the biological activity of interleukin-1 α and β (IL-1α and IL -1β) by binding to IL-1 type 1 receptors (IL-R 1), expressed in a variety of tissues and organs, thereby blocking the IL-1 signalling. IL-1 is a key mediator of inflammation and a significant contributor to autoinflammatory diseases.
Mucopolysaccharidosis (MPS) type IIIA (Sanfilippo A syndrome)	A progressive, life-threatening and rare inherited metabolic disorder affecting children from a young age. Belongs to a group of diseases called lysosomal storage disorders (LSDs).

Definitions and Glossary

Orfadin (nitisinone)	A drug used to treat hereditary tyrosinaemia type 1 (HT-1). It blocks the breakdown of tyrosine, thereby reducing the amount of toxic tyrosine by-products in the body. Patients must maintain a special diet in combination with Orfadin treatment as tyrosine is not adequately broken down.
RSV	Respiratory syncytial virus. A common virus and the most common cause of lower respiratory tract infections (LRTI) in young children.
SOBI003	A product candidate and a chemically modified variant of a recombinant human sulfamidase, using Sobi's proprietary glycan modification technology Modifa™, intended as an enzyme-replacement therapy in the lysosomal storage disease MPS IIIA, aimed at reducing heparan sulfate storage materials in affected cells.
SOBI005	A novel biopharmaceutical product candidate based on the Affibody platform that works as an inhibitor of complement protein C5. SOBI005 is formatted as an Fc fusion protein and is intended to be administered by subcutaneous injection.
Still's disease	An autoinflammatory disease that affects both children and adults, 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).
Synagis (palivizumab)	Indicated for the prevention of serious LRTI caused by RSV in infants and young children at high risk of RSV disease. RSV is the most prevalent cause of LRTI among infants and young children. Synagis is a RSV F protein inhibitor monoclonal antibody that acts as a prophylaxis against serious RSV disease. It is the only medicine approved for the prevention of serious RSV disease.

At Sobi, we are transforming the lives of people affected by rare diseases. As a specialised international biopharmaceutical company, we provide sustainable access to innovative therapies in the areas of haematology, immunology and specialty care. We bring something rare to rare diseases – a belief in the strength of focus, the power of agility and the potential of the people we are dedicated to serving.

The hard work and dedication of our approximately 1,050 employees around the globe has been instrumental in our success across Europe, North America, the Middle East, Russia and North Africa, leading to total revenues of SEK 9.1 billion in 2018. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm.

You can find more information about Sobi at www.sobi.com.

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