Building our future

Q4 and full-year report 2018

- Total revenues of SEK 2,571 M (1,875) in Q4 and SEK 9,139 M (6,511) for the full year
- 37 per cent sales growth in Q4 compared with Q4 2017 (29 per cent at constant exchange rates (CER))
- EBITA[1] increased 48 per cent to SEK 916 M (619) in Q4 and 74 per cent to SEK 3,571 M (2,053) for the full year
- Earnings per share of SEK 2.20 (1.33) in Q4 and SEK 8.97 (4.27) for the full year
- Net cash position of SEK 2,995 M at 31 December 2018 (1,472 at 31 Dec 2017)
- Revenues for Elocta® were SEK 945 M (540) for Q4 and SEK 3,261 M (1,557) for the full year
- Revenues for Alprolix® were SEK 303 M (131) for Q4 and SEK 974 M (363) for the full year
- Sobi™ entered into agreements to acquire the perpetual rights to Synagis® in the US from AstraZeneca and to participate in 50 per cent of future earnings from the candidate drug MEDI8897 in the US. The closing of the acquisition was announced on 24 January 2019
- The US Food and Drug Administration (FDA) approved Gamifant® for the treatment of primary HLH
- Late-breaking abstract on emapalumab was presented—first approved treatment in primary HLH
- Impressive data from the phase 1/2a study with BIVV001 were presented
- Financial outlook 2019: for more details, see page 8
  - Sobi expects revenue 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

Full-year revenues, SEKm

9,139

+40%

Full-year gross margin[1]

74%

Full-year EBITA[1], SEKm

3,571

+74%

Full-year earnings per share, SEK

8.97

Financial summary

Amounts in SEK M	Q4 2018	Q4 2017	Change	Full-year 2018	Full-year 2017	Change
Total revenues	2,571	1,875	37%	9,139	6,511	40%
Gross profit	1,894	1,337	42%	6,723	4,657	44%
Gross margin[1]	74%	71%		74%	72%	
EBITA[1]	916	619	48%	3,571	2,053	74%
EBITA margin[1]	36%	33%		39%	32%	
EBIT (operating profit)	802	509	58%	3,122	1,600	95%
Profit for the period	595	357	67%	2,418	1,149	110%
Earnings per share, SEK	2.20	1.33	66%	8.97	4.27	110%

[1]Alternative performance measures (APMs), see page 13 for further information.

CEO statement

2018 was a significant year for Sobi. Revenues grew 40 per cent, totalling SEK 9,139 M (6,511) for the full year. We generated operating leverage and grew earnings by 74 per cent, with EBITA of SEK 3,571 M (2,053). Gross margin rose to 74 per cent (72). We made transformational changes to our business building the company's future with the help of substantial M&A activities. We also made significant progress in our pipeline.

Haemophilia – product sales more than doubled

In 2018, full-year sales for Elocta were SEK 3,261 M (1,557) and SEK 974 M (363) for Alprolix, up 109 and 168 per cent respectively. This is an outstanding development and reflects the value these treatments bring to people with haemophilia. The main countries contributing to this growth were France, Germany, Italy and the UK. Whilst our product sales in Haemophilia have more than doubled (SEK 4.2 B vs. SEK 1.9 B), total Haemophilia revenues grew by 63 per cent to SEK 6,012 M (3,682), including royalties and manufacturing revenues for ReFacto.

Specialty Care – solid double-digit growth

Specialty Care continued to perform favourably during 2018, with year-on-year growth at 11 per cent and revenues of SEK 3,127 M (2,829). Growth was mainly driven by strong underlying progress for Kineret in both North America and the EMENAR region with sales reaching SEK 1,320 M (1,142), up 16 per cent. In EMENAR we started to see first impact from the ongoing launch of the Still's disease indication, for which Kineret is now available to patients in nine EU markets.

Orfadin sales reached SEK 899 M (862), an increase of 4 per cent for the full year. There was a minor impact on sales due to generics entering the market during the second half of 2018.

Pipeline advances

Emapalumab (Gamifant®) was approved in the US for treatment of primary HLH, and the regulatory review is ongoing in Europe. Beyond primary HLH, a clinical study is ongoing in secondary HLH and additional indications are being considered.

The acquisitions of Synagis® and emapalumab broadened our pipeline. MEDI8897, a follow-on compound to Synagis, is being developed for the passive immunisation of a broad infant population; it has been engineered to have a long half-life so that only one dose will be needed for the entire respiratory syncytial virus (RSV) season. Primary analysis from the pivotal, phase 2b study to evaluate the safety and efficacy of MEDI8897 showed that the study met its primary endpoint. The current development plan includes a proposed phase 3 study in late preterm and healthy full-term infants. Based on the results from the phase 2b study, the FDA has granted Breakthrough

"We have made significant progress towards taking Sobi to a leadership position in the rare disease market, building on strong organic growth and thoughtful strategic acquisitions."

Guido Oelkers,
CEO and President

Elocta product sales

+109%

Alprolix product sales

+168%

Therapy Designation (BTD) for MEDI8897, which will help bring MEDI8897 as quickly as possible to all infants at risk for RSV.

In December, data from the phase 1/2a study of BIVV001 were presented at the 60th Annual Meeting of the American Society of Hematology (ASH). The data showed that a single 65 IU/kg dose of BIVV001 extended the half-life of factor VIII to an unprecedented 44 hours with high factor activity levels and was generally well tolerated. These are very encouraging results, which suggest that BIVV001 has the potential to markedly improve the treatment paradigm for patients and physicians. As the study continues we look forward to learning more about the potential of BIVV001.

Encouraging results from the study with BIVV001

In 2018, we also made significant advances in our R&D pipeline. SOBI003, a potential treatment for MPS IIIA, moved into clinical phase. All patients have now been recruited to the first cohort in the study.

Business transformation based on exponential growth in Haemophilia and M&A

Sobi's growth is a result of successful launches of Elocta and Alprolix as well as double-digit growth for Kineret. However, with the new acquisitions of emapalumab (approved as Gamifant in the US) and Synagis, the company is now entering a new phase. We are creating a second leg in Immunology comprising Kineret, Gamifant and Synagis, to diversify the company beyond our Haemophilia franchise. The investment into Immunology is on its way to build scale and critical mass to our US business. Our immediate focus for Gamifant is directed towards commercialisation in the US. Pending approval by the European Medicines Agency (EMA) is expected by the end of 2019. Clinical development activities to expand indications for emapalumab, are ongoing. The closing of the acquisition of the US rights to Synagis was announced on 24 January, 2019.

A second leg in Immunology was created, consisting of Kineret, Gamifant and Synagis.

In 2018, we made significant progress towards taking Sobi to a leadership position in the rare disease market, building on strong organic growth and thoughtful strategic acquisitions. The company is well positioned to expand in our core businesses Haemophilia and Immunology in the years to come.

Solna, Sweden, 20 February 2019

Guido Oelkers, President & CEO

Business review Q4

Haemophilia

During the quarter, Elocta was approved for reimbursement in the Czech Republic and Alprolix in Hungary. The products are now reimbursed in a total of 26 and 19 countries respectively.

Sobi and Sanofi (formerly Bioverativ) announced the final results of ASPIRE and B-YOND, the most comprehensive long-term studies of extended half-life factor therapies in haemophilia, at the 60th Annual Meeting of the American Society of Hematology (ASH) in December. The data from both studies confirm the established safety and sustained efficacy of Elocta and Alprolix over four years of treatment in previously treated adult, adolescent and paediatric patients with severe haemophilia A and B, respectively.

Specialty Care

On 20 November, the US Food and Drug Administration approved Gamifant for the treatment of paediatric (newborn and older) and adult patients with primary haemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance to conventional HLH therapy. Primary HLH is an ultra-rare syndrome of hyperinflammation with high morbidity and mortality, and for which no approved drug was previously available. Gamifant represents a major advance in the treatment of these patients through a targeted mode of action. An application was submitted to the European Medicines Agency in August 2018.

Orfadin capsules were approved in Argentina and Jordan (5 and 10 mg). The oral suspension formulation was approved in Tunisia.

R&D pipeline

At ASH, Sobi's collaboration partner Sanofi presented new data from the EXTEN-A phase 1/2a trial of BIVV001 (rFVIIIFc-VWF-XTEN) showing that a single 65 IU/kg dose of BIVV001 extended the half-life of factor VIII to an unprecedented 44 hours with high factor activity levels and was generally well tolerated. Seven days post infusion, the factor activity level was 18.5 per cent, which is an unprecedented level of protection in factor VIII therapy. BIVV001 is a novel and investigational von Willebrand factor (VWF)-independent factor VIII therapy for people with haemophilia A. Factor replacement therapy is the cornerstone of effective treatment of haemophilia A, as it naturally provides what is missing in the body (clotting factor VIII), and has a consistent and well-characterised safety and efficacy profile.

The abstract "Safety and efficacy of emapalumab in paediatric patients with primary hemophagocytic lymphohistiocytosis" was accepted as a late-breaking abstract at ASH in December 2018, for oral presentation by Sobi and Novimmune. Data from the pivotal phase 2/3 clinical study of emapalumab in primary haemophagocytic lymphohistiocytosis demonstrated that the study achieved its primary endpoint, with 64.7 per cent of all patients treated (22 of 34; p=0.0031) and 63 per cent of the patients who had failed prior conventional HLH therapy (17 of 27; p=0.0134) demonstrating an overall response at the end of treatment, defined as achievement of either a complete or partial response, or HLH improvement. This demonstrated that emapalumab treatment helped patients control HLH activity and reach stem cell transplant, which is the only cure for this devastating disease, potentially without the side effects of prolonged chemotherapy.

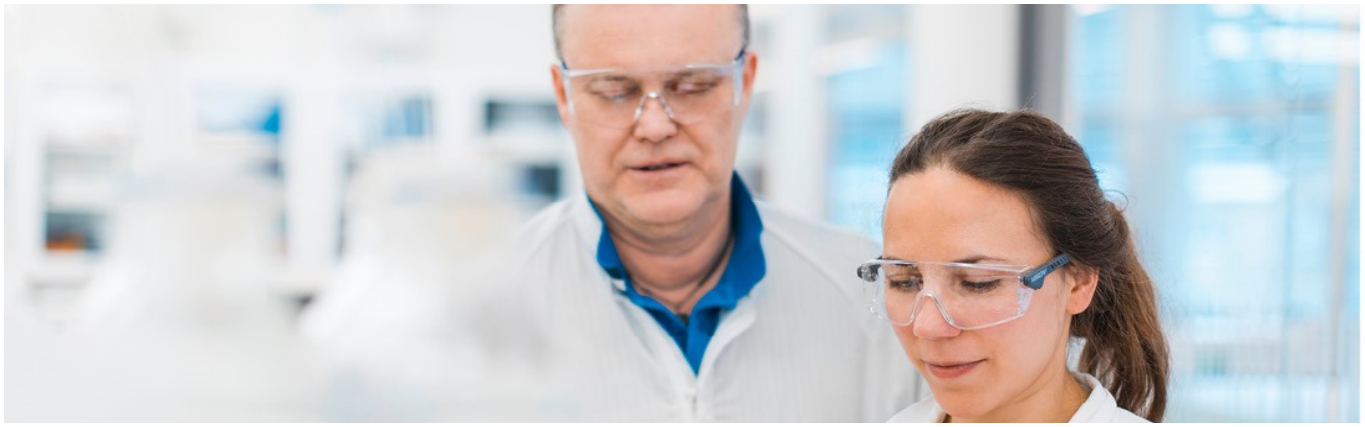
Primary efficacy results from the phase 2 study with anakinra in patients with acute gout were released in October. For the primary endpoint of patient-assessed pain intensity in the most affected joint there was a substantial reduction from baseline, both following treatment with anakinra and the comparator triamcinolone. There was a clinically meaningful pain reduction with anakinra of around 50 per cent, in line with expectations of IL-1 blockade in this disease. No statistically significant difference between the two treatments was obtained (primary endpoint). Sobi will continue to collect data from the extension phase of the phase 2 study to obtain further data in this patient population where further gout flares will be studied.

All three patients in the first cohort of the study to the SOBI003 phase 1/2 study were recruited and dosed.

AstraZeneca released the primary efficacy results for the Phase 2b study to evaluate the safety and efficacy of MEDI8897. The trial met its primary endpoint, defined as a statistically-significant reduction in the incidence of medically-attended lower respiratory tract infection (LRTI) caused by reverse transcriptase polymerase chain reaction-confirmed RSV for 150 days after dosing.

Corporate

Sobi appointed Paula Treutiger as Head of Communications and Investor Relations. Paula joined Sobi on 1 January 2019.



Financial review

Total revenues

Total revenues for the quarter amounted to SEK 2,571 M (1,875), up 37 per cent compared with the fourth quarter of 2017 (29 per cent at CER).

Revenues for the full year were SEK 9,139 M (6,511), an increase of 40 per cent (35 per cent at CER).

Revenues by business area

Haemophilia

Total Haemophilia revenues rose 57 per cent (48 per cent at CER) to SEK 1,752 M (1,114) for the quarter. Full-year revenues amounted to SEK 6,012 M (3,682), an increase of 63 per cent (57 per cent at CER). Full-year revenues for Elocta were positively affected by SEK 52 M, in Q3 2018, related to adjusted pharmaceutical taxes in France from 2017.

Product sales increased 86 per cent (76 per cent at CER) to SEK 1,248 M (671) for the quarter. The growth primarily derived from the continued strong performance in France, Germany, Italy and the UK. Elocta sales reached SEK 945 M (540) for the quarter and Alprolix sales SEK 303 M (131). Full-year product sales totalled SEK 4,235 M (1,920) of which Elocta accounted for SEK 3,261 M (1,557) and Alprolix for SEK 974 M (363).

Royalty revenues amounted to SEK 367 M (323) for the quarter and SEK 1,341 M (1,203) for the full year.

ReFacto manufacturing revenues were SEK 137 M (120) for the quarter, up 14 per cent. Full-year manufacturing revenues totalled SEK 436 M (559), down 22 per cent due to the lower year-on-year order pattern.

Specialty Care

Revenues for Specialty Care were SEK 819 M (761) for the quarter, an increase of 8 per cent (1 per cent at CER). Revenues for the full year were SEK 3,127 M (2,829), an increase of 11 per cent (7 per cent at CER).

There was a strong performance across the Specialty Care portfolio. Solid growth for Kineret continued across all regions for the full year. The commercial launch of Kineret for Still's disease in the EU is ongoing. The Still's indication has been launched in nine EU countries and the price and reimbursement process throughout Europe is proceeding. For Orfadin generics have entered certain markets and a first sign of price erosion has been observed. In 2018, however, patient support programmes and new formulations defended our market position, even though we saw some impact affecting mainly price.

Kineret revenue growth slowed down in Q4, reflecting phasing of sales after the strong performance in Q3. Revenues amounted to SEK 335 M (307) for the quarter, an increase of 9 per cent (2 per cent at CER) . Revenues for the full year were SEK 1,320 M (1,142), an increase of 16 per cent (12 per cent at CER).

Revenues for Orfadin were SEK 221 M (223) for the quarter, a decrease of 1 per cent (7 per cent at CER). Revenues for the full year were SEK 899 M (862), an increase of 4 per cent (1 per cent at CER).

Gross profit

Gross profit for the quarter was SEK 1,894 M (1,337), representing a gross margin of 74 per cent (71).

Gross profit for the full year was SEK 6,723 M (4,657), representing a gross margin of 74 per cent (72). A favourable product mix, a positive one-time impact of pharmaceutical taxes in France and currency effects were the main contributors.

Revenues by business area

Amounts in SEK M	Q4 2018	Q4 2017	Change	Change at CER[1]	Full-year 2018	Full-year 2017	Change	Change at CER[1]
Haemophilia								
Elocta	945	540	75%	65%	3,261	1,557	109%	98%
Alprolix	303	131	131%	118%	974	363	168%	153%
Manufacturing	137	120	14%	14%	436	559	-22%	-22%
Royalty	367	323	14%	4%	1,341	1,203	12%	11%
Total	1,752	1,114	57%	48%	6,012	3,682	63%	57%
Specialty Care								
Orfadin	221	223	-1%	-7%	899	862	4%	1%
Kineret	335	307	9%	2%	1,320	1,142	16%	12%
Other	263	231	14%	8%	908	825	10%	5%
Total	819	761	8%	1%	3,127	2,829	11%	7%
Total revenues	2,571	1,875	37%	29%	9,139	6,511	40%	35%

[1]Constant exchange rates.

Operating expenses

Sales and administrative expenses before amortisation and write-downs amounted to SEK 637 M (477) for the quarter. The increase was mainly driven by continued investments in Haemophilia. In Specialty Care, the increase was mainly driven by launch activities for Gamifant in the US.

Sales and administrative expenses before amortisation and write-downs amounted to SEK 2,062 M (1,644) for the full year. The increase reflects activities in the Haemophilia franchise in EMENAR, including marketing and personnel increases as well as investments in the North American region.

Research and development expenses amounted to SEK 329 M (228) for the quarter, and SEK 1,090 M (908) for the full year.

The increased expenses reflect activities for programmes for Kineret, SOBI003, and phasing of Sobi's 50 per cent share of Sanofi Genzyme's ongoing development costs for haemophilia, as well as expenses related to the acquisition of the global rights to emapalumab.

Operating profit

EBITA was SEK 916 M (619) for the quarter and SEK 3,571 M (2,053) for the full year, corresponding to a margin of 36 (33) and 39 (32) per cent respectively.

Amortisation and write-downs of intangible assets amounted to SEK 114 M (110) for the quarter and SEK 449 M (453) for the full year. Full-year 2017 included a write-down for one of the early-stage pipeline programmes amounting to SEK 12 M.

EBIT amounted to SEK 802 M (509) for the quarter and SEK 3,122 M (1,600) for the full year. EBIT increased by SEK 293 M for the quarter and SEK 1,522 M for the full year.

Net financial items and tax

Net financial items amounted to SEK -23 M (-15) for the quarter, including exchange-rate losses of SEK 9 M (0).

Net financial items for the full year amounted to SEK -40 M (-68), including exchange-rate gains of SEK 17 M (-3). The difference was mainly attributable to lower interest expense for the debt to Sanofi and higher exchange-rate gains. For more information regarding the agreement with Sanofi, see Note 17 in the 2017 Annual Report.

Tax amounted to SEK -184 M (-137) for the quarter and SEK -664 M (-384) for the full-year, corresponding to an effective tax rate of 23.6 and 21.5 per cent respectively. On 14 June 2018, the corporate tax rate in Sweden was reduced to 21.4 per cent effective 1 January 2019, and to 20.6 per cent effective 1 January 2021. The Group's deferred tax was revalued in Q2, which resulted in a lower effective tax rate for full-year 2018 compared with full-year 2017.

Profit

Profit totalled SEK 595 M (357) for the quarter and SEK 2,418 M (1,149) for the full year.

Cash flow and investments

Cash flow from operations before change in working capital amounted to SEK 541 M (467) for the quarter and to SEK 2,341 M (1,431) for the full year.

Working capital had a negative impact of SEK -3 M (-210) on cash flow for the quarter and SEK -250 M (-98) for the full year.

Cash flow from investing activities was SEK –28 M (-42) for the quarter and SEK -575 M (-139) for the full year. The largest investment during the year was the acquisition of the global rights to emapalumab, whereof cash flow impact amounted to SEK 497 M.

Operating profit/loss

Amounts in SEK M	Q4 2018	Q4 2017	Full-year 2018	Full-year 2017
Total revenues	2,571	1,875	9,139	6,511
Total cost of goods and services sold	-678	-538	-2,415	-1,854
Gross profit	1,894	1,337	6,723	4,657
Gross margin	*74%*	*71%*	*74%*	*72%*
Sales and administrative expenses before amortisation and write-downs	-637	-477	-2,062	-1,644
Research and development expenses	-329	-228	-1,090	-908
Total opex less amortisation and write-downs	-966	-705	-3,153	-2,551
Other operating revenue/expenses	-12	-13	0	-52
EBITA	916	619	3,571	2,053
Amortisation and write-down related to Sales and administrative expenses	-114	-110	-449	-453
EBIT	802	509	3,122	1,600

This is non-IFRS financial information. For an IFRS income statement, please refer to the Consolidated statement of comprehensive income.

Cash

At the end of the quarter, cash and cash equivalents amounted to SEK 2,999 M, compared with SEK 1,478 M at 31 December 2017.

Net cash/debt

Sobi ended the quarter with a net cash position of SEK 2,995 M, compared with SEK 1,472 M at 31 December 2017.

Equity

At 31 December 2018, consolidated shareholders' equity was SEK 9,040 M compared with SEK 6,701 M at 31 December 2017.

Personnel

At 31 December 2018, the number of full-time equivalents was 902 (800 at 31 December 2017).

Parent Company

In the fourth quarter of 2018, net sales for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 2,350 M (1,605), of which Group companies accounted for SEK 1,313 M (762). Full-year sales amounted to SEK 8,221 M (5,756) of which Group companies accounted for SEK 4,554 M (2,732).

Profit after financial items amounted to SEK 957 M (-594) for the quarter and SEK 3,457 M (535) for the full year. Profit after financial items 2017 was affected by a write-down of the value of the shares in the subsidiary Swedish Orphan Biovitrum International AB by SEK 1,000 M.

Investments in tangible and intangible assets affecting cash flows amounted to SEK 23 M (39) for the quarter and SEK 68 M (129) for the full year.

Other information

Significant events after the reporting period

Sobi completed the acquisition of the Synagis US rights from AstraZeneca and exercised authorisation to issue shares. The upfront consideration payable at closing of the acquisition, announced on January 24, 2019, corresponds to approximately USD 1.5 B (SEK 13.8 B) consisting of cash and 24,193,092 newly issued Sobi common shares.

Sobi announced a new number of shares and votes in connection with the acquisition from AstraZeneca of the rights to Synagis in the US. At 31 January 2019, the company held 3,423,726 common shares.

The FDA granted Breakthrough Therapy Designation (BTD) for MEDI8897.

Financial outlook 2018 and outcome

Total revenues for the full year in the range of SEK 8,900 - 9,000 M.
Outcome: SEK 9,139 M

Gross margin in the range of 73 - 74 per cent.
Outcome: 74 per cent

EBITA for the full year in the range of SEK 3,400 - 3,500 M, including development and commercialisation costs for emapalumab of around SEK 200 M.
Outcome: SEK 3,571 M

Dividend

The Board of Directors proposes that no dividend will be paid for the 2018 financial year.

Financial outlook 2019[1]

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 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. Furthermore, we will expand clinical activities for emapalumab.

[1]At current exchange rates as of 20 February 2019.

Financial calendar

Annual report 2018	18 April 2019
Q1 2019	25 April 2019
AGM	9 May 2019
Capital markets day	14 May 2019
Q2 2019	17 July 2019
Q3 2019	31 October 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 CET, at Grand Hôtel, S. Blasieholmshamnen 8, Stockholm, Sweden.

The Annual Report for 2018 will be published on www.sobi.com three weeks before the AGM. It will also be available at Sobi's head office in Solna.

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

Solna, Sweden, 20 February 2019

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 20 February 2019.

Financial statements – Group

Statement of comprehensive income

Amounts in SEK M	Q4 2018	Q4 2017	Full-year 2018	Full-year 2017
Total revenues[1]	2,571	1,875	9,139	6,511
Total cost of goods and services sold	-678	-538	-2,415	-1,854
Gross profit	**1,894**	**1,337**	**6,723**	**4,657**
Sales and administrative expenses[2]	-751	-587	-2,511	-2,096
Research and development expenses	-329	-228	-1,090	-908
Other operating revenue/expenses	-12	-13	0	-52
Operating profit	**802**	**509**	**3,122**	**1,600**
Financial income/expenses[3]	-23	-15	-40	-68
Profit before tax	**779**	**494**	**3,082**	**1,532**
Income tax expenses	-184	-137	-664	-384
Profit for the period	**595**	**357**	**2,418**	**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	-3	-3	0	-1
Items that may be reclassified subsequently to profit/loss				
Translation difference	-6	6	9	-1
Cash flow hedge (net of tax)	-58	-23	-133	150
Comprehensive income for the period	**528**	**337**	**2,294**	**1,296**
[1]See page 5 for split by business area.				
[2]Amortisation and write-downs of intangible assets included in Sales and administrative expenses.	-114	-110	-449	-453
[3]Including financing costs amounting to:	-1	0	-2	-1
Earnings per share, SEK	2.20	1.33	8.97	4.27
Earnings per share after dilution, SEK	2.20	1.32	8.93	4.25

Balance sheet

Amounts in SEK M	Dec 2018	Dec 2017
ASSETS		
Non-current assets		
Intangible assets[1,2]	10,159	6,445
Tangible assets	136	134
Financial assets	286	167
Total non-current assets	10,581	6,746
Current assets		
Inventories	1,284	1,053
Accounts receivable	1,665	1,129
Current receivables, non-interest bearing	654	496
Cash and cash equivalents	2,999	1,478
Total current assets	6,602	4,157
Total assets	17,183	10,903
EQUITY AND LIABILITIES		
Shareholders' equity	9,040	6,701
Long-term liabilities		
Long-term liabilities	3	5
Long-term liabilities, non-interest bearing	1,189	1,832
Total long-term liabilities	1,192	1,838
Current liabilities		
Current liabilities	1	2
Current liabilities, non-interest bearing[2]	6,950	2,363
Total current liabilities	6,951	2,365
Total equity and liabilities	17,183	10,903

[1]Including goodwill of SEK 1,554 M (1,554).
[2]The increase is related to the acquisition of the global rights to ema-palumab of CHF 450 M. The liability is classified as short-term since the additional payments may be accelerated by either party any time after 1 July 2019.

Changes in equity

Amounts in SEK M	Full-year 2018	Full-year 2017
Opening balance[1]	6,701	5,365
Share-based compensation to employees	46	40
Comprehensive income for the period[2]	2,294	1,296
Equity at end of period	9,040	6,701

[1]Adjustment of deferred tax affected the 2017 opening balance in an amount of SEK 11 M.
[2]Whereof changes in cash flow hedges amounted to SEK -133 M (150).

Cash flow statement

Amounts in SEK M	Q4 2018	Q4 2017	Full-year 2018	Full-year 2017
Profit for the period	595	357	2,418	1,149
Adjustment for non-cash items[1]	-55	110	-77	283
Cash flow from operations before change in working capital	**541**	**467**	**2,341**	**1,431**
Change in working capital	-3	-210	-250	-98
Cash flow from operations	**538**	**257**	**2,090**	**1,333**
Investment in intangible assets	-14	-20	-537	-92
Investment in tangible assets	-12	-21	-41	-48
Divestment of tangible assets	2	0	3	1
Investment in financial assets	-4	-1	-1	-1
Cash flow from investing activities	**-28**	**-42**	**-575**	**-139**
Loans - Raising/Amortisation	–	-500	–	-500
Net finance lease	-1	–	-1	–
Cash flow from financing activities	**-1**	**-500**	**-1**	**-500**
Change in cash and cash equivalents	**508**	**-285**	**1,514**	**694**
Cash and cash equivalents at the beginning of the period	2,488	1,758	1,478	786
Translation difference in cash flow and cash and cash equivalents	2	6	7	-1
Cash and cash equivalents at the end of the period	**2,999**	**1,478**	**2,999**	**1,478**
[1] Adjustment for non-cash items:				
Depreciation of tangible assets	9	8	36	33
Amortisation and write-downs of intangible assets	114	110	449	453
Deferred tax	-27	75	-103	164
Other, whereof SEK -166 M (-98) in Q4 2018 and SEK -485 M in full-year 2018 reflect Elocta and Alprolix non-cash transactions, see also Note 17 in Sobi's 2017 Annual Report for more information about the agreement with Sanofi Genzyme	-150	-84	-459	-367
Non-cash items	**-55**	**110**	**-77**	**283**

Key ratios and other information

Amounts in SEK M	Q4 2018	Q4 2017	Full-year 2018	Full-year 2017
Profit measures				
Gross profit	1,894	1,337	6,723	4,657
EBITDA[1]	924	628	3,607	2,086
EBITA[1]	916	619	3,571	2,053
EBIT (operating profit)	802	509	3,122	1,600
Profit/loss	595	357	2,418	1,149
Per share data (SEK)				
Earnings per share	2.20	1.33	8.97	4.27
Earnings per share after dilution	2.20	1.32	8.93	4.25
Shareholders' equity per share[1]	33.1	24.6	33.1	24.6
Shareholders' equity per share after dilution[1]	32.9	24.5	32.9	24.5
Other information				
Gross margin[1]	74%	71%	74%	72%
EBITA margin[1]	36%	33%	39%	32%
Equity ratio[1]	53%	61%	53%	61%
Net cash (-)/debt (+)[1]	-2,995	-1,472	-2,995	-1,472
Number of ordinary shares[2]	273,322,117	272,507,708	273,322,117	272,507,708
Number of ordinary shares (in treasury)	3,423,726	3,249,870	3,423,726	3,249,870
Number of ordinary shares (excluding shares in treasury)	269,898,391	269,257,838	269,898,391	269,257,838
Number of ordinary shares after dilution	274,365,601	273,458,932	274,365,601	273,458,932
Average number of ordinary shares (excluding shares in treasury)	269,898,391	269,168,592	269,523,784	269,020,363
Average number of ordinary shares after dilution (excluding shares in treasury)	270,418,933	269,913,933	270,603,665	270,003,546

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

[2]The increase in the number of shares results from an issue of 814,409 class C shares which have been converted to ordinary shares.

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.

	Q4 2018	Q4 2017	Full-year 2018	Full-year 2017
Total revenues	2,571	1,875	9,139	6,511
Total cost of goods and services sold	-678	-538	-2,415	-1,854
Gross profit	**1,894**	**1,337**	**6,723**	**4,657**
Gross margin, %	**74%**	**71%**	**74%**	**72%**

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

EBIT (operating profit)	802	509	3,122	1,600
Plus amortisation and write-downs of intangible assets	114	110	449	453
EBITA	**916**	**619**	**3,571**	**2,053**
Plus depreciations of tangible assets	9	8	36	33
EBITDA	**924**	**628**	**3,607**	**2,086**
EBITA margin, %	**36%**	**33%**	**39%**	**32%**

EBITA - Earnings before interest, tax and amortisation
EBITDA - Earnings before interest, tax, depreciation and amortisation
EBITA margin - EBITA as a percentage of total revenue

Liabilities to credit institutions				
- Long-term	3	5	3	5
- Current	1	2	1	2
Interest-bearing liability	**4**	**7**	**4**	**7**
Cash and cash equivalents	2,999	1,478	2,999	1,478
Net debt (+)/Net cash (-)	**-2,995**	**-1,472**	**-2,995**	**-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

Shareholder's equity	9,040	6,701	9,040	6,701
Total assets	17,183	10,903	17,183	10,903
Equity ratio, %	**53%**	**61%**	**53%**	**61%**
Number of ordinary shares	273,322,117	272,507,708	273,322,117	272,507,708
Equity per share, SEK	**33.1**	**24.6**	**33.1**	**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

Amounts in SEK M	Q4 2018	Q4 2017	Full-year 2018	Full-year 2017
Total revenues	2,350	1,605	8,221	5,756
Total cost of goods and services sold	-677	-510	-2,349	-1,861
Gross profit	**1,673**	**1,095**	**5,872**	**3,895**
Sales and administrative expenses[1]	-468	-453	-1,445	-1,400
Research and development expenses	-234	-210	-932	-855
Non recurring items				
Other operating revenue/expenses	-11	-12	-2	-40
Operating profit	**959**	**420**	**3,492**	**1,600**
Result from participation in Group companies[2]	–	-1,000	–	-1,000
Financial income/expenses	-20	-14	-35	-65
Profit/loss after financial items	**939**	**-594**	**3,457**	**535**
Appropriations	-397	-911	-397	-911
Profit/loss before tax	**542**	**-1,505**	**3,060**	**-376**
Income tax expenses	-196	-30	-678	-132
Profit/loss for the period	**346**	**-1,535**	**2,382**	**-508**

Statement of other comprehensive income

Amounts in SEK M	Q4 2018	Q4 2017	Full-year 2018	Full-year 2017
Profit/loss for the period	346	-1,535	2,382	-508
Items that may be subsequently reclassified to profit/loss				
Cash flow hedge (net of tax)	-58	-23	-133	150
Comprehensive income for the period	**288**	**-1,558**	**2,248**	**-358**
[1]Amortisation and write-downs of intangible assets included in Sales and administrative expenses.	-75	-71	-292	-296

[2]The Parent Company wrote down the value of the shares in the subsidiary Swedish Orphan Biovitrum International AB in 2017 by SEK 1,000 M.

Balance sheet

Amounts in SEK M	Dec 2018	Dec 2017
ASSETS		
Non-current assets		
Intangible assets	3,801	4,058
Tangible assets	112	114
Financial assets	3,537	2,915
Total non-current assets	7,450	7,087
Current assets		
Inventories	1,071	894
Current receivables, non-interest bearing	2,643	1,779
Cash and cash equivalents	2,762	1,381
Total current assets	6,476	4,054
Total assets	13,926	11,140
EQUITY AND LIABILITIES		
Shareholders' equity	7,731	5,436
Untaxed reserves	2,584	2,124
Long-term liabilities		
Long-term liabilities, non-interest bearing	508	1,159
Total long-term liabilities	508	1,159
Current liabilities		
Current liabilities, non-interest bearing	3,103	2,421
Total current liabilities	3,103	2,421
Total equity and liabilities	13,926	11,140

Change in shareholders' equity

Amounts in SEK M	Full-year 2018	Full-year 2017
Opening balance[1]	5,436	5,755
Share-based compensation to employees	46	40
Comprehensive income for the period[2]	2,248	-358
Equity at end of period	7,731	5,436

[1]Adjustment of deferred tax affected the 2017 opening balance by SEK 11 M.
[2]Whereof changes in cash flow hedges amounted to SEK -133 M (150).

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-December 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 using the historical cost convention, except in the case of financial assets and certain 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 2017 Annual Report. More detailed information about the Group's accounting policies and measurement bases can be found in the 2017 Annual Report, available at www.sobi.com.

Changes 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. The new accounting standard IFRS 16 Leases, will apply for financial periods 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 measured at fair value. The part of the change relating to fair value of liabilities due to changes in own credit risk should be reported in other comprehensive income instead of in profit or loss, unless this causes inconsistency in the accounting. Sobi has no liabilities measured 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 done in accordance with IAS 39 with disclosures in accordance with IFRS 7; 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 future losses. Sobi has applied the retrospective transition method which has no material impact on either earnings or 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 these have no 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 the financial effects for Sobi remains unchanged from the previous standard, IAS 18. 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.

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-of-use assets. Previous leasing fees will be replaced by depreciation and interest expenses.

Sobi has chosen to adopt the simplified transition method (modified retrospective approach), without any impact on the Group's equity at 1 January 2019. The simplified transition method 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 rule 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 discounting rates used when discounting the leasing liabilities are based on the actual borrowing rates Sobi would have obtained from financial institutions for the relevant tenors. Options to renew contracts are taken into account when the Group considers it likely 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. The impact of the transition on the reported key indicators, involving these parameters (total assets/financial liabilities), is judged to be insignificant. The main impact will be seen in the non-IFRS measurement EBITDA.

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 2017 Annual Report (see the Directors' Report). There are no major changes in the Group's risk exposure and risk management in 2018 compared with 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 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 December 2018, the net reported value of derivatives on the balance sheet was SEK 7 M (2).

At 31 December 2018, 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.
ASH	Annual Meeting of the American Society of Hematology.
BIVV001	A novel, investigational factor VIII therapy designed to extend protection from bleeds with prophylaxis dosing of once weekly or longer for people with haemophilia A. Builds on the Fc fusion technology by adding a region of von Willebrand factor and XTEN polypeptides to potentially extend its time in circulation.
CER	Constant exchange rates.
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 and 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 and 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.
LRTI	Lower respiratory tract infections.

Definitions and Glossary

Hereditary tyrosinaemia 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.
Kineret (anakinra)	A recombinant protein drug that blocks the biological activity of interleukin-1 a and b (IL-1a and IL -1b) 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.
MEDI8897	A single dose extended half-life anti-RSV F monoclonal antibody being developed for the prevention of lower respiratory tract infections (LRTI) caused by RSV in all infants entering their first RSV season and children with chronic lung disease or congenital heart disease entering their first and second RSV season. Engineered to have a long half-life so that only one dose will be needed for the entire RSV season.
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).
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.
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 1050 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.

sobi
rare strength

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