

Investing in growth

January—March

- Total revenue of SEK 3,661 M (4,639), -21 per cent and -13 per cent at CER
- EBITA¹ was SEK 1,484 M (2,173), with an EBITA margin¹ of 41 per cent (47)
- Earnings per share (EPS) before dilution of SEK 2.36 (4.02)
- Haematology sales were SEK 1,877 M (2,394), Doptelet[®] grew by 222 per cent at CER to SEK 180 M
- Sales for Elocta[®] was SEK 857 M (1,359), for Alprolix[®] SEK 413 M (488), with patient growth of 6 and 16 per cent
- Immunology sales were SEK 1,554 M (1,800), Gamifant[®] grew by 47 per cent at CER to SEK 133 M
- Cash flow from operating activities of SEK 1,699 M (1,886)
- Doptelet (avatrombopag) was approved in the EU for treatment of ITP
- Kineret[®] (anakinra) was approved in Russia for the treatment of CAPS

Outlook 2021—unchanged

- Revenue for the full-year 2021 is expected to be in the range of SEK 14,000–15,000 M
- EBITA margin is expected to be in the range of 30–35 per cent of revenue

Total revenue, SEK M

3,661

EBITA margin¹

41%

Financial summary

Amounts in SEK M	Q1 2021	Q1 2020	Change	Full-year 2020
Total revenue	3,661	4,639	-21%	15,261
Gross profit	2,935	3,598	-18%	12,036
Gross margin ¹	80%	78%		79%
EBITA ¹	1,484	2,173	-32%	6,700
EBITA adjusted ^{1,2}	1,484	2,173	-32%	6,301
EBITA margin ¹	41%	47%		44%
EBITA margin adjusted ^{1,2}	41%	47%		41%
Profit for the period	696	1,182	-41%	3,245
Earnings per share, before dilution, SEK	2.36	4.02	-41%	11.01
Earnings per share, before dilution, SEK adjusted ^{1,2,3}	2.36	4.02	-41%	9.66

¹Alternative Performance Measures (APMs), see page 17 for further information.

²EBITA full-year 2020 excluding non-recurring items; other operating income related to the reversal of the CVR liability of SEK 399 M.

³EPS full-year 2020 excluding the reversal of the CVR liability of SEK 399 M.

CEO statement

The COVID-19 pandemic, with its related restrictions and lockdowns, has continued to impact our markets and operations. Both Synagis and Elocta saw tougher market environments in the first quarter than the same period last year. However, post COVID-19 we expect market conditions to go back to normal with consumption of Elocta and Synagis also returning to normal levels. I believe that we will be able to recover many of the adverse effects of COVID-19 over time. Despite this unfavourable environment we have been able to strategically progress our core portfolio. We have advanced key products, such as pegcetacoplan and efanesoctocog alfa, in our R&D portfolio, and we are exploring new opportunities for anakinra for the treatment of hyperinflammation related to COVID-19.

We closed the quarter with revenue of SEK 3,661 M, with both core areas affected by COVID-19. EBITA was SEK 1,484 M.

Within business area **Haematology**, Doptelet tripled its revenues versus last year at CER. Elocta® and Alprolix® showed steady patient growth – up 6 per cent for Elocta and 16 per cent for Alprolix compared with the same period last year, and 1 per cent and 3 per cent compared with Q4 2020. Consumption was low as a consequence of lockdowns and reduced activity among patients. However, the patient gains in Haemophilia underscore the competitiveness of our products. Sales for Haematology reached SEK 1,877 M (2,394) for the first quarter, with unfavourable exchange rates and price reductions affecting sales. In addition a one-time retroactive price adjustment in Germany negatively impacted Elocta sales in the first quarter. As communicated in 2020, we foresee double-digit price erosion for Elocta for full-year 2021, primarily driven by mandated pricing changes.

During the quarter the European Commission approved Doptelet (avatrombopag) for treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments such as corticosteroids and immunoglobulins. Our key focus for Doptelet is the launch of both ITP and CLD (chronic liver disease) indications throughout Europe.

Within our business area **Immunology**, Kineret (anakinra) continues to deliver, with double-digit growth at constant exchange rates (CER). Sales reached SEK 542 M (501) for the first quarter. Sales have been positively impacted by COVID-19 and we continue to support and closely follow several investigator-initiated studies evaluating anakinra for treatment of hyperinflammation related to COVID-19. In the first quarter, Kineret was approved in Russia for the treatment of cryopyrin-associated periodic syndromes (CAPS).

The incidence of respiratory syncytial virus (RSV) is low as a consequence of social distancing measures and reduced international travel stemming from COVID-19. This impacted Synagis® sales, which reached SEK 879 M (1,196).

Gamifant sales reached SEK 133 M (104), an increase of 47 per cent at CER. The number of patients treated increased in the quarter, but sales continue to fluctuate depending on the weight and treatment period of patients. Awareness and education are remain drivers of sales and penetration, which is why we continue to strengthen those areas.

Our international expansion is making good progress. We are paving the way for Elocta in Russia and continue to build our teams in Japan, China and Australia.

I am proud that our substantial R&D pipeline continues to deliver various endpoints. In March, the New England Journal of Medicine published a positive phase 3 PEGASUS study results comparing pegcetacoplan to eculizumab for paroxysmal nocturnal haemoglobinuria (PNH). Marketing applications for pegcetacoplan for the treatment of PNH are under review in the US and the EU. For Doptelet, the first patient was dosed with avatrombopag for treatment of ITP in paediatric patients in the first phase 3 study to evaluate avatrombopag in children.

2021 is a year of investment for Sobi, with a view to accelerate our pipeline, propel our international launches of Doptelet and Gamifant, whilst preparing the commercialisation of pegcetacoplan. This will lay the foundation for future double-digit growth and secure Sobi's long-term interests.

I am proud of our team on how we are able to manage the ambiguities and challenges of today's environment and hold course to systematically build our company for an exciting future.

Solna, Sweden, 4 May 2021

Guido Oelkers, President & CEO



Financial performance

Total revenue

Total revenue amounted to SEK 3,661 M (4,639), -21 per cent compared with the same period last year and -13 per cent at CER. The decrease was mainly driven by reduced sales of Synagis and Elocta due to the ongoing pandemic and price reductions for Elocta.

Amounts in SEK M	Q1	Q1	Change	Change at CER ¹	Full-year 2020
	2021	2020			
Haematology	1,877	2,394	-22%	-15%	8,660
Immunology	1,554	1,800	-14%	-2%	5,415
Specialty Care	230	445	-48%	-44%	1,186
Total	3,661	4,639	-21%	-13%	15,261

¹Constant exchange rates.

Gross profit

Gross profit was SEK 2,935 M (3,598), representing a gross margin of 80 per cent (78). The margin increase was driven by favourable product and country mix, lowered distribution costs, ceased royalty obligation and a retroactive adjustment of royalty costs related to Synagis. This was partially offset by price reductions and a retroactive price adjustment for Elocta.

Operating expenses

Sales and administrative expenses, excluding amortisation and write-downs, amounted to SEK 981 (1,061), corresponding to an 8 per cent decrease, mainly related to a lower activity level across all business areas due to COVID-19, slightly off-set by increased investments in new product launches and continued geographic expansion in Asia and Russia.

Research and development expenses amounted to SEK 471 M (359). The increase reflects mainly spending related to the new programmes for pegcetacoplan and SEL-212.

Operating profit

EBITA was SEK 1,484 M (2,173), corresponding to a margin of 41 per cent (47). Amortisation of intangible assets amounted to SEK 450 M (475), resulting in an EBIT of SEK 1,034 M (1,698).

Operating profit

Amounts in SEK M	Q1	Q1	Full-year 2020
	2021	2020	
Total revenue	3,661	4,639	15,261
Cost of goods sold	-726	-1,042	-3,225
Gross profit	2,935	3,598	12,036
<i>Gross margin</i>	<i>80%</i>	<i>78%</i>	<i>79%</i>
Selling and administrative expenses before amortisation and write-downs	-981	-1,061	-4,099
Research and development expenses	-471	-359	-1,594
Total opex less amortisation and write-downs	-1,452	-1,419	-5,693
Other operating income/expenses	0	-5	357
EBITA	1,484	2,173	6,700
Non-recurring items	-	-	-399
<i>EBITA adjusted¹</i>	<i>1,484</i>	<i>2,173</i>	<i>6,301</i>
Amortisation and write-downs related to Sales and administrative expenses	-450	-475	-1,882
EBIT (Operating profit)	1,034	1,698	4,818

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

¹EBITA full-year 2020 excluding non-recurring items; other operating income related to the reversal of the CVR liability of SEK 399 M.

Net financial items

Net financial items amounted to SEK -115 M (-141), reflecting lower debt compared with 2020.

Tax

Income tax amounted to SEK -223 M (-375), corresponding to an effective tax rate of 24.2 per cent (24.1).

Profit

Profit for the period totalled SEK 696 M (1,182).

Cash flow

Cash flow from operating activities before changes in working capital amounted to SEK 756 M (1,780). Changes in working capital affected cash flow by SEK 943 M (106), mainly attributable to collection of receivables from previous quarter, lower sales during the period and timing of payment of sales-related accruals.

Cash flow from investing activities was SEK -91 M (-24) and from financing activities SEK -1,384 M (-1,773).

Cash and net debt

At the end of the quarter, cash and cash equivalents amounted to SEK 633 M (SEK 404 M at 31 Dec 2020). Sobi ended the quarter with undrawn committed credit facilities totalling SEK 5,665 M (SEK 4,320 M at 31 Dec 2020) and drawn credit facilities totalling SEK 13,307 M (SEK 14,234 M at 31 Dec 2020). Net debt at the end of the quarter amounted to SEK 12,674 M (SEK 13,748 M at 31 Dec 2020). The decrease in net debt was mainly driven by operating cash flow generated in the period.

Equity

At 31 March 2021, consolidated shareholders' equity was SEK 20,864 M, compared with SEK 20,206 M at 31 Dec 2020.

Personnel

At 31 March 2021, the number of full-time equivalents was 1,508 (1,509 at 31 Dec 2020).

Parent Company

Net sales for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 2,463 M (4,201). The decrease was driven by the transfer of the Synagis sales to the US subsidiary during 2020. Group companies sales amounted to SEK 1,397 M (1,657). Profit for the period amounted to SEK 264 M (1,164). Investing activities affecting cash flow amounted to SEK 25 M (14).

Haematology

Revenue is generated from sales of the products Elocta, Alprolix and Doptelet. Revenue is also derived from manufacturing of the drug substance for ReFacto AF®/Xyntha® for Pfizer and royalty of Sanofi's sales of Eloctate® and Alprolix.

Revenue Haematology

Amounts in SEK M	Q1 2021	Q1 2020	Change	Change at CER ¹	Full-year 2020
Elocta	857	1,359	-37%	-33%	4,585
Alprolix	413	488	-15%	-10%	1,705
Royalty	298	335	-11%	1%	1,301
Doptelet	180	65	179%	222%	587
Manufacturing	130	148	-12%	-12%	481
Total	1,877	2,394	-22%	-15%	8,660

¹Constant exchange rates.

The pandemic posed a challenge to Haematology sales in the quarter. With prolonged lockdowns and restrictions, people with haemophilia reduced their levels of activity, and consequently their factor consumption. Lower number of surgical procedures also impacted sales for all factor treatment. Elocta and Alprolix showed continued positive patient uptake despite increased competition and impact of COVID lockdowns across Europe.

Revenue

Haematology revenue amounted to SEK 1,877 M (2,394), a decline of 22 per cent and 15 per cent at CER.

Elocta sales were SEK 857 M (1,359), -37 per cent and -33 per cent at CER. Patient growth continued but the decline was driven by lower consumption per patient due to the COVID-19 pandemic and unfavourable price adjustments, primarily driven by mandated pricing changes. In addition, a one-time retroactive price adjustment in Germany negatively impacted sales in the first quarter by SEK 92 M. Sales in the first quarter 2020 were impacted by a positive stocking effect due to the pandemic. Patient growth for Elocta was 6 per cent compared with the same period last year and 1 per cent compared with the previous quarter.

Alprolix sales were SEK 413 M (488), -15 per cent and -10 per cent at CER. Lower sales reflect reduced consumption per patient, largely due to COVID-19 restrictions, somewhat offset by continued patient growth. Sales in the first quarter 2020 were impacted by a positive stocking effect due to the COVID-19 pandemic. Patient growth for Alprolix was 16 per cent compared with the same period last year and 3 per cent compared with previous quarter.

Doptelet sales were SEK 180 M (65), showing steady launch progress in the quarter although impacted by slight inventory reductions at the wholesale level.

Royalty revenue was SEK 298 M (335), and ReFacto manufacturing revenue totalled SEK 130 M (148), corresponding to a reduction of 12 per cent explained by ordering patterns.

Events

- Doptelet was approved for the ITP indication in Europe, with expected launch in Germany as the first market.

Immunology

Revenue is generated from sales of the products Kineret, Synagis and Gamifant.

Revenue Immunology

Amounts in SEK M	Q1 2021	Q1 2020	Change	Change at CER ¹	Full-year 2020
Kineret	542	501	8%	20%	2,079
Synagis	879	1,196	-26%	-16%	2,726
Gamifant	133	104	28%	47%	609
Total	1,554	1,800	-14%	-2%	5,415

¹Constant exchange rates.

Kineret continued to show strong underlying demand driven by new indications, patient growth and demand relating to COVID-19. Synagis faced lower demand with almost no RSV virology across the US as a result of social distancing and fewer children in school.

Revenue

Immunology revenue amounted to SEK 1,554 M (1,800) a decline of 14 per cent and 2 per cent at CER.

Kineret sales were SEK 542 M (501), an increase of 8 per cent and 20 per cent at CER. Kineret continued to perform well, driven by strong underlying demand. Sales were also positively impacted by use in treatment of COVID-19 patients.

Synagis sales were SEK 879 M (1,196), a decrease of 26 per cent and 16 per cent at CER. Synagis sales have been highly affected by the very low RSV virology in the first quarter and stocking in Q4 2020.

Gamifant sales were SEK 133 M (104), an increase of 28 per cent and 47 per cent at CER, reflecting increased demand and continued patient growth.

Events

- Kineret (anakinra) was approved in Russia for the treatment of CAPS.

Specialty Care

Revenue is generated from sales of Orfadin®, Kepivance® and other products in the Specialty Care portfolio.

Revenue Specialty Care

Amounts in SEK M	Q1 2021	Q1 2020	Change	Change at CER ¹	Full-year 2020
Orfadin	97	196	-51%	-46%	665
Other Specialty Care	133	248	-47%	-43%	521
Total	230	445	-48%	-44%	1,186

¹Constant exchange rates.

Revenue

Specialty Care revenue amounted to SEK 230 M (445), a decrease of 48 per cent and 44 per cent at CER.

Orfadin sales were SEK 97 M (196), -51 per cent and -46 per cent at CER, explained by generic competition and associated price erosion as well as ordering patterns. Sales for other Specialty Care products were SEK 133 M (248), -47 per cent and -43 per cent at CER related to the discontinuation of products.

Events

- Through an agreement with US-based Akcea Therapeutics, Sobi is commercialising Tegsedi® and Waylivra® in Europe, CEER and the Middle East from January 2021. Since April 2021, Sobi is commercialising Tegsedi in North America.

Research and Development

Highlights within late-stage projects in the first quarter:

- The first patient was dosed with avatrombopag for treatment of immune thrombocytopenia (ITP) in paediatric patients. The phase 3 study is the first to evaluate avatrombopag in children.
- The New England Journal of Medicine published results from the phase 3 PEGASUS study, which demonstrated the superiority of pegcetacoplan in improving haemoglobin levels, and showed improvements in key clinical outcomes compared with eculizumab in adults with paroxysmal nocturnal haemoglobinuria (PNH) at 16 weeks.
- In May, Sobi and Hellenic Institute for the Study of Sepsis reported that use of anakinra improved overall clinical outcomes by 64% in hospitalised patients with COVID-19 pneumonia.

Research and Development expenses

Amounts in SEK M	Q1 2021	Q1 2020	Full-year 2020
Research and development expenses	-471	-359	-1,594
Total revenue	3,661	4,639	15,261
Research and development expenses in relation to total revenue	13%	8%	10%

Other information

Significant events after the reporting period

The first patient was dosed in the phase 3 interventional study of efanesoctocog alfa in children with severe haemophilia A.

Nirsevimab MELODY Phase III trial met primary endpoint of reducing RSV lower respiratory tract infections in healthy infants.

In May, Sobi and Hellenic Institute for the Study of Sepsis reported that use of anakinra improved overall clinical outcomes by 64% in hospitalised patients with COVID-19 pneumonia.

Sustainability

Sobi continues to deliver on its primary contribution to social sustainability—access to medicine—with expanded access to rare disease treatments. Responsible behaviour in operations and the supply chain is continuously promoted, and Sobi engages in dialogue with internal and external stakeholders on areas covering labour rights, ethics and responsible sourcing. In the first quarter, all employees were invited to provide input in a follow-up survey on the effects of the pandemic to staff.

Financial outlook 2021—unchanged

The outlook for 2021 is expressed at January 2021 closing exchange rates. The negative currency impact on 2021 performance is expected to be 5-7 per cent on revenues and 6-8 per cent on EBITA compared with average full-year 2020 exchange rates.

Revenue for the full-year 2021 is expected to be in the range of SEK 14,000–15,000 M. At constant exchange rates this range corresponds to a revenue growth between -2.5 and 4.5 per cent.

EBITA margin is expected to be in the range of 30–35 per cent of revenue.

R&D expenses as a share of revenue are expected to grow to 13–15 per cent reflecting increased investments in SEL-212 and pegcetacoplan, and support for our late-stage programmes.

Forward-looking statements

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

Financial calendar

AGM	4 May 2021
Q2 2021	21 July 2021
Q3 2021	28 October 2021
Q4 2021	10 February 2022

Annual General Meeting 2021

The Annual General Meeting (AGM) of Swedish Orphan Biovitrum AB (publ) will be held on Tuesday, 4 May 2021 at 15:00 CET. Due to the COVID-19 pandemic and in order to reduce the risk of spreading the virus, the Board has decided that the Meeting should be conducted by way of postal vote pursuant to temporary legislation being in effect in 2021. This means that the Meeting will be held without the physical presence of shareholders, representatives or third parties. Shareholders will therefore only be able to exercise their voting rights by postal voting in advance of the Meeting. Further information regarding the AGM is available on Sobi's website.

The Annual Report for 2020 is published on www.sobi.com and is available at Sobi's head office in Solna.

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

Solna, Sweden, 4 May 2021

Guido Oelkers, CEO and President

Financial statements – Group

Consolidated statement of comprehensive income

Amounts in SEK M	Q1	Q1	Full-Year
	2021	2020	2020
Total revenue ¹	3,661	4,639	15,261
Cost of goods sold	-726	-1,042	-3,225
Gross profit	2,935	3,598	12,036
Selling and administrative expenses ²	-1,431	-1,536	-5,981
Research and development expenses	-471	-359	-1,594
Other operating income/expenses	0	-5	357
Operating profit	1,034	1,698	4,818
Net financial items ³	-115	-141	-601
Profit before tax	919	1,557	4,217
Income tax	-223	-375	-972
Profit for the period	696	1,182	3,245
<i>All earnings are attributable to Parent Company shareholders</i>			
Other comprehensive income			
<i>Items that cannot be reclassified into profit or loss</i>			
Remeasurement on defined-benefit plans (net of tax)	8	–	-3
Fair value of equity instruments (net of tax)	7	–	9
Total	15	–	6
<i>Items that can be reclassified into profit or loss</i>			
Translation differences	138	794	-434
Net investment hedges (net of tax)	-147	-40	246
Cash flow hedges (net of tax)	-62	-241	130
Total	-71	513	-58
Other comprehensive income	-56	513	-52
Comprehensive income for the period	640	1,695	3,193
<i>All comprehensive income is attributable to Parent Company shareholders</i>			
Earnings per share, SEK	2.36	4.02	11.01
Earnings per share, SEK, adjusted ⁴	2.36	4.02	9.66
Earnings per share after dilution, SEK	2.33	3.98	10.90
Earnings per share after dilution, SEK, adjusted ⁴	2.33	3.98	9.56
¹ See page 3 for split by business area.			
² Amortisation and write-downs of intangible assets included in Sales and administrative expenses.	-450	-475	-1,882
³ Including financing costs.	-9	-7	-32
⁴ Alternative Performance Measures (APMs), see page 17 for further information.			

Consolidated balance sheet

Amounts in SEK M	Mar 2021	Dec 2020	Mar 2020
ASSETS			
Non-current assets			
Intangible assets ¹	38,978	38,791	38,018
Tangible assets	516	534	514
Financial assets	188	179	50
Deferred tax assets	541	611	369
Total non-current assets	40,223	40,115	38,952
Current assets			
Inventories	3,076	3,053	1,755
Accounts receivable	3,336	3,756	4,076
Other receivables, non-interest bearing	923	955	805
Cash and cash equivalents	633	404	842
Total current assets	7,969	8,168	7,479
Total assets	48,192	48,283	46,430
EQUITY AND LIABILITIES			
Shareholders' equity	20,864	20,206	18,616
Non-current liabilities			
Borrowings	9,212	10,137	15,040
Deferred tax liabilities	3,517	3,464	3,599
Lease liabilities	289	308	304
Other liabilities, non-interest bearing	3,979	3,725	3,107
Total non-current liabilities	16,997	17,634	22,050
Current liabilities			
Borrowings	4,095	4,015	–
Accounts payable	392	569	487
Lease liabilities	113	111	102
Other liabilities, non-interest bearing	5,730	5,748	5,175
Total current liabilities	10,330	10,443	5,764
Total equity and liabilities	48,192	48,283	46,430

¹Including goodwill of SEK 6,099 M (SEK 5,873 M at 31 Dec 2020).

Changes in equity

Amounts in SEK M	Jan-Mar 2021	Full-year 2020	Jan-Mar 2020
Opening balance	20,206	16,930	16,930
Adjusted opening balance for post employment-benefits from prior years ¹	–	-38	-38
Share-based compensation to employees	26	114	26
Share-based compensation to employees tax effect ²	-9	7	4
Comprehensive income for the period ³	640	3,193	1,695
Equity at end of period	20,864	20,206	18,616

¹Refers to post employment-benefits, mainly in Switzerland not previously included at Dec 2019 (net of tax).

²The change relates to difference between the market value of vested shares and recognised IFRS 2 cost.

³Whereof changes in cash-flow hedges (net of tax) amounted to SEK -62 M (SEK 130 M at 31 Dec 2020) and net investment hedges (net of tax) amounted to SEK -147 M (SEK 246 M at 31 Dec 2020).

Consolidated cash flow statement

Amounts in SEK M	Q1 2021	Q1 2020	Full-year 2020
Profit before tax ¹	919	1,557	4,217
Amortization and depreciation	485	507	2,023
Other, including non-cash items	-14	142	45
Income tax paid	-634	-426	-918
Cash flow from operating activities before changes in working capital	756	1,780	5,367
Changes in working capital	943	106	-442
Cash flow from operating activities	1,699	1,886	4,925
Investments in intangible assets ²	-85	-14	-3,811
Investments in tangible assets	-6	-9	-41
Investments in financial assets ²	–	–	-120
Disposal of tangible assets	–	–	8
Cash flow from investing activities	-91	-24	-3,964
Borrowings/repayment of borrowings	-1,163	-1,862	-1,452
Hedging arrangement for financing	-191	115	288
Repayment of leasing	-30	-26	-118
Cash flow from financing activities	-1,384	-1,773	-1,282
Change in cash and cash equivalents	224	90	-320
Cash and cash equivalents at the beginning of the period	404	737	737
Exchange difference in cash and cash equivalents	5	15	-13
Cash and cash equivalents at the end of the period	633	842	404

¹As of 2021, Sobi has changed the form of presentation for the cash flow statement, see Note 1 for more information.

²2020 investments refer mainly to SEL-212 and pegcetacoplan.

Key ratios and other information

Amounts in SEK M	Q1 2021	Q1 2020	Full-year 2020
Profit measures			
Gross profit	2,935	3,598	12,036
EBITDA ¹	1,519	2,206	6,830
EBITA ¹	1,484	2,173	6,700
EBITA adjusted ^{1,2}	1,484	2,173	6,301
EBIT (operating profit)	1,034	1,698	4,818
Profit/loss	696	1,182	3,245
Per share data (SEK)			
Earnings per share	2.36	4.02	11.01
Earnings per share, adjusted ^{2,3}	2.36	4.02	9.66
Earnings per share after dilution	2.33	3.98	10.90
Earnings per share after dilution, adjusted ^{2,3}	2.33	3.98	9.56
Shareholders' equity per share ¹	68.7	62.1	66.5
Shareholders' equity per share after dilution ¹	67.8	61.5	65.9
Other information			
Gross margin ¹	80%	78%	79%
EBITA margin ¹	41%	47%	44%
EBITA margin adjusted ^{1,2}	41%	47%	41%
Equity ratio ¹	43%	40%	42%
Net debt (+)/Net cash (-) ¹	12,674	14,198	13,748
Number of ordinary shares ⁴	303,815,511	299,977,839	303,815,511
Number of ordinary shares (in treasury)	8,916,033	5,678,099	8,918,672
Number of ordinary shares (excluding shares in treasury)	294,899,478	294,299,740	294,896,839
Number of ordinary shares after dilution	307,650,103	302,811,887	306,797,549
Average number of ordinary shares (excluding shares in treasury)	294,899,097	294,299,740	294,658,136
Average number of ordinary shares after dilution (excluding shares in treasury)	298,733,689	297,133,788	297,640,174

¹Alternative performance measures (APMs), see page 17 for further information.

²EBITA full-year 2020 excluding non-recurring items; other operating income related to the reversal of the CVR liability of SEK 399 M.

³EPS full-year 2020 excluding the reversal of the CVR liability of SEK 399 M.

⁴The increase in the number of shares results from an issue of 3,837,672 shares issued for the purpose of ensuring fulfilment of commitments under incentive programmes.

Financial statements – Parent Company

Income statement

Amounts in SEK M	Q1	Q1	Full-year
	2021	2020	2020
Total revenue	2,463	4,201	13,968
Cost of goods sold	-617	-1,005	-3,134
Gross profit	1,846	3,195	10,834
Selling and administrative expenses ¹	-1,058	-1,448	-4,174
Research and development expenses	-311	-210	-923
Other operating income/expenses	58	-10	96
Operating profit	535	1,528	5,833
Net financial items	-190	-55	194
Profit after financial items	345	1,473	6,027
Appropriations	–	–	-1,690
Profit before tax	345	1,473	4,337
Income tax expenses	-81	-309	-931
Profit for the period	264	1,164	3,406
¹ Amortisation and write-downs of intangible assets included in Sales and administrative expenses.	-83	-79	-328

Statement of comprehensive income

Amounts in SEK M	Q1	Q1	Full-year
	2021	2020	2020
Profit for the period	264	1,164	3,406
<i>Items that cannot be reclassified into profit or loss</i>			
Fair value of equity instruments (net of tax)	7	–	9
<i>Items that can be reclassified into profit or loss</i>			
Cash flow hedges (net of tax)	-62	-241	130
Comprehensive income for the period	209	923	3,545

Balance sheet

Amounts in SEK M	Mar 2021	Dec 2020	Mar 2020
ASSETS			
<i>Non-current assets</i>			
Intangible assets	10,127	10,205	5,505
Tangible assets	61	64	63
Financial assets	22,234	23,164	26,561
Deferred tax assets	17	24	27
Total non-current assets	32,439	33,457	32,155
<i>Current assets</i>			
Inventories	2,487	2,527	1,387
Accounts receivable	979	731	2,192
Receivables Group companies	2,872	3,947	1,660
Other receivables, non-interest bearing	798	835	722
Cash and cash equivalents	472	240	676
Total current assets	7,608	8,280	6,636
Total assets	40,047	41,737	38,791
EQUITY AND LIABILITIES			
<i>Shareholders' equity</i>	17,427	17,200	14,483
Untaxed reserves	3,091	3,091	2,984
<i>Non-current liabilities</i>			
Borrowings	9,212	10,137	15,040
Liabilities Group companies	–	157	187
Other liabilities, non-interest bearing	2,739	2,557	1,475
Total non-current liabilities	11,951	12,851	16,702
<i>Current liabilities</i>			
Borrowings	4,095	4,015	–
Accounts payable	271	398	392
Liabilities Group companies	1,376	1,674	1,748
Other liabilities, non-interest bearing	1,836	2,508	2,482
Total current liabilities	7,578	8,595	4,623
Total equity and liabilities	40,047	41,737	38,791

Change in shareholders' equity

Amounts in SEK M	Jan-Mar 2021	Full-year 2020	Jan-Mar 2020
Opening balance	17,200	13,534	13,534
Share-based compensation to employees	26	114	22
Share-based compensation to employees tax effect	-8	7	4
Comprehensive income for the period ¹	209	3,545	923
Equity at end of period	17,427	17,200	14,483

¹Whereof changes in cash-flow hedges (net of tax) amounted to SEK -62 M (SEK 130 M at 31 Dec 2020).

Notes

Note 1 Accounting policies and measurement bases and other information

Accounting policies

This interim report has been prepared in accordance with IAS 34 and the Swedish Annual Accounts Act. The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) and the International Financial Reporting Interpretations Committee (IFRIC) as adopted by the EU. The Parent Company applies the Annual Accounts Act and the Swedish Financial Reporting Board's Recommendation RFR 2 Accounting for Legal Entities. The accounting policies apply with those described in the 2020 Annual and Sustainability Report. IASB has published amendments of standards that are effective as of 1 January 2021 or later. The standards have not had any material impact on the consolidated financial statements.

More detailed information about the Group's accounting policies and measurement bases can be found in the 2020 Annual and Sustainability Report, available at www.sobi.com.

Cash flow statement

As of 2021, Sobi has changed the form of presentation for the cash flow statement and reclassified hedging arrangements for financing from cash flow from operating activities to cash flow from financing activities. Comparative figures for 2020 have been recalculated, whereby the cash flow from operating activities for the period January-March 2020 has been adjusted from SEK 2,001 M to SEK 1,886 M and for the full-year 2020 from SEK 5,214 M to SEK 4,925 M. Cash-flow from financing activities has been adjusted for the corresponding periods from SEK -1,888 M to SEK -1,773 M and from SEK -1,570 M to -1,282, respectively.

Risks and uncertainties

Sobi is exposed to a number of risks in its operations. Effective risk management aligns Sobi's business opportunities and profit with shareholders' and other stakeholders' demands for stable, long-term value growth and control. Key risk areas are summarised below:

- Pandemics and other external events
- Strategic and operational risk
- Commercialisation and business environment
- Financial and reporting risk
- Compliance risk

More information about risk exposure and risk management is included in Sobi's 2020 Annual and Sustainability Report.

Note 2 Segment reporting

Amounts in SEK M

Q1 2021	Haematology	Immunology	Specialty Care	Group - other	Total
Revenue	1 877	1 554	230	–	3 661
EBITA ¹	823	732	72	-143	1 484
Adjusted EBITA ^{1,2}	823	732	72	-143	1 484
Q1 2020	Haematology	Immunology	Specialty Care	Group - other	Total
Revenue	2 394	1 800	445	–	4 639
EBITA ¹	1 197	864	241	-129	2 173
Adjusted EBITA ^{1,2}	1 197	864	241	-129	2 173
Full-year 2020	Haematology	Immunology	Specialty Care	Group - other	Total
Revenue	8 660	5 415	1 187	–	15 261
EBITA ¹	4 377	1 902	564	-143	6 700
Adjusted EBITA ^{1,2}	3 978	1 902	564	-142	6 301

There are no intersegment transactions.

¹Alternative Performance Measures (APMs), see page 17 for further information.

²EBITA 2020 excluding non-recurring items; other operating income related to Contingent Value Right (CVR) of SEK 399 M.

³The category Group-other mainly refers to costs for central functions such as finance, legal, communication, human resources and other items that cannot be allocated by segment.

Note 3 Fair value of financial instruments

The following table shows financial instruments measured at fair value, based on their classification in the fair value hierarchy. Sobi's financial instruments at fair value at the end of the quarter consist of equity instruments, derivatives held for trading and endowment policies.

Equity instruments are categorised within level 1 and consist of the Group's holding of quoted shares in Selecta Biosciences, Inc. Fair value measurement is based on quoted prices in active markets. Derivatives held for trading are categorised within level 2 and consist of currency derivatives forward contracts. Fair value measurement is based on published forward prices. Endowment insurances are categorised within level 3. No transfers have been made between the levels during the period.

At 31 March 2021, all other financial instruments on the balance sheet had reported values that are in all material aspects equivalent to fair value.

The contingent consideration in Q1 2020 refers to the CVR which was reversed during the fourth quarter in 2020. See page 18 for more information.

Q1 2021	Level 1	Level 2	Level 3	Total
<i>Financial assets and liabilities measured at fair value through profit or loss</i>				
Derivatives held for trading	–	-42	–	-42
Endowment policies	–	–	44	44
<i>Financial assets measured at fair value through other comprehensive income</i>				
Equity instruments	140	–	–	140
Total	140	-42	44	142

Q1 2020	Level 1	Level 2	Level 3	Total
<i>Financial assets and liabilities measured at fair value through profit or loss</i>				
Derivatives held for trading	–	16	–	16
Endowment policies	–	–	47	47
Contingent considerations	–	–	-427	-427
Total	–	16	-380	-364

Full-year 2020	Level 1	Level 2	Level 3	Total
<i>Financial assets and liabilities measured at fair value through profit or loss</i>				
Derivatives held for trading	–	-151	–	-151
Endowment policies	–	–	44	44
<i>Financial assets measured at fair value through other comprehensive income</i>				
Equity instruments	131	–	–	131
Total	131	-151	44	24

Alternative performance measures—Financial measures not defined according to IFRS

Sobi uses certain financial measures (alternative performance measures, APM) 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 2021	Q1 2020	Full-year 2020
Total revenue	3,661	4,639	15,261
Cost of goods sold	-726	-1,042	-3,225
Gross profit	2,935	3,598	12,036
Gross margin	80%	78%	79%
EBIT (operating profit)	1,034	1,698	4,818
Plus amortisation and write-downs of intangible assets	450	475	1,882
EBITA	1,484	2,173	6,700
Plus depreciations and write-downs of tangible assets	35	32	130
EBITDA	1,519	2,206	6,830
EBITA margin	41%	47%	44%
Non-recurring items	–	–	-399
EBITA adjusted	1,484	2,173	6,301
EBITA margin adjusted	41%	47%	41%
Profit for the period	696	1,182	3,245
Non-recurring items	–	–	-399
Profit for the period, adjusted	696	1,182	2,846
Average number of ordinary shares (excluding shares in treasury)	294,899,097	294,299,740	294,658,136
Average number of ordinary shares after dilution (excluding shares in treasury)	298,733,689	297,133,788	297,640,174
EPS, SEK adjusted	2.36	4.02	9.66
Borrowings	13,307	15,040	14,152
Cash and cash equivalents	633	842	404
Net debt (+)/Net cash (-)	12,674	14,198	13,748
Shareholders' equity	20,864	18,616	20,206
Total assets	48,192	46,430	48,283
Equity ratio	43%	40%	42%
Number of ordinary shares	303,815,511	299,977,839	303,815,511
Number of ordinary shares after dilution	307,650,103	302,811,887	306,797,549
Equity per share, SEK	68.7	62.1	66.5
Equity per share after dilution, SEK	67.8	61.5	65.9

Definitions—financial terms

CER	Constant exchange rates
CVR	Following the completion of Sobi's acquisition of Dova Pharmaceuticals, Inc. (Dova) on 12 November 2019, Dova shareholders were provided one non-transferrable Contingent Value Right (CVR) to an additional USD 1.50 per share to be paid upon approval of Doptelet for use in chemotherapy-induced thrombocytopenia (CIT) by the FDA. On 9 October 2020, Sobi announced topline results for phase 3 CIT study of avatrombopag. The primary endpoints were not met and Sobi estimates that the conditions of the CVR will not be met. Consequently, the corresponding liability on the balance sheet was reversed, positively impacting other operating income by SEK 399 M.
Earnings per share	The portion of a company's profit allocated to each outstanding share of common stock
EBIT (Operating profit)	Earnings before interest and tax
EBITA	Earnings before interest, tax and amortisation
EBITA margin, %	EBITA as a percentage of total revenue
EBITA adjusted	EBITA less non-recurring items
EBITA margin adjusted, %	EBITA adjusted as a percentage of total revenue
EBITDA	Earnings before interest, tax, depreciation, amortisation and write-downs
EPS, adjusted	Profit for the period, adjusted, divided by average number of ordinary shares
EPS after dilution, adjusted	Profit for the period, adjusted, divided by average number of ordinary shares after dilution
Equity ratio	Shareholders' equity as a proportion of total assets
Equity per share	Equity divided by the number of ordinary shares
Equity per share after dilution	Equity divided by the number of ordinary shares after dilution
Full-time equivalents	Unit that indicates the workload of an employed person in a way that makes workloads comparable
Gross profit	Total revenue less cost of goods sold
Gross margin	Gross profit as a percentage of total revenue
IFRS	International Financial Reporting Standards
Net debt (+)/Net cash (-)	Borrowings less Cash and cash equivalents
Non-recurring items	Refers to items that have no clear connection with the ordinary operations and are of such a type that it cannot be expected to occur often or regularly and that it is an item of significant value. This may, for example, refer to capital gains/losses from divestments, restructuring initiatives, impairments and other unusual one-time income and expenses.

Glossary

Alprolix (eftrenonacog alfa)	A recombinant, extended half-life (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.
BIVV001, efanesoctocog alfa	A novel, investigational factor VIII therapy designed to extend protection from bleeds with prophylactic dosing of once weekly or longer intervals 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.
Chronic immune thrombocytopenia (ITP)	A rare autoimmune bleeding disorder characterised by a low number of platelets, affecting approximately 60,000 adults in the United States.
Chronic liver disease (CLD)	Liver disease becomes chronic when it has been present for more than 6-12 months without signs of resolution. Chronic liver disease can be inherited (genetic) or caused by a variety of factors such as viruses, auto-immunity, obesity and alcohol use.
COVID-19	The infectious disease caused by a coronavirus discovered in 2019, declared a pandemic by WHO.
Doptelet (avatrombopag)	A second-generation small-molecule thrombopoietin receptor (TPO) agonist used in the treatment of thrombocytopenia by increasing platelet count.
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. 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.
FDA	The US Food & Drug Administration.
Gamifant (emapalumab)	An anti-interferon-gamma (IFN- γ) monoclonal antibody (mAb), approved by the FDA for the treatment of primary haemophagocytic lymphohistiocytosis (pHLH), a life-threatening syndrome of immune activation.
Gout	An autoinflammatory disease that causes intensely painful flares and debilitating inflammatory arthritis due to deposition of pro-inflammatory monosodium urate (MSU) crystals in synovial fluid and other tissues.
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 can 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-1 α and IL-1 β) 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.
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. Orfadin was approved in the EU in October 2020 for the treatment of adult patients with alkaptonuria (AKU).

Pegcetacoplan	An investigational, targeted C3 therapy designed to regulate excessive complement activation, which can lead to the onset and progression of many serious diseases. Pegcetacoplan is a synthetic cyclic peptide conjugated to a polyethylene glycol polymer that binds specifically to C3 and C3b.
PNH—paroxysmal nocturnal haemoglobinuria	A rare, chronic, life-threatening blood disorder characterised by the destruction of oxygen-carrying red blood cells through extravascular and intravascular haemolysis. Persistently low haemoglobin can result debilitating symptoms such as severe fatigue, haemoglobinuria, and difficulty breathing (dyspnoea), and the need for frequent transfusions.
RSV	Respiratory syncytial virus. A common virus and the most common cause of lower respiratory tract infections (LRTI) in young children.
SEL-212	SEL-212 is a novel combination product candidate designed to sustain control of serum uric acid levels in patients with chronic refractory gout. SEL-212 consists of pegadricase, co-administered with ImmTOR, designed to mitigate the formation of anti-drug antibodies.
Synagis (palivizumab)	Indicated for the prevention of serious lower respiratory tract infection (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.
Tegsedi (inotersen)	Tegsedi (inotersen) is a self-administered subcutaneous treatment for the polyneuropathy of hATTR amyloidosis in adults.
Waylivra (volanesorsen)	Waylivra (volanesorsen) is a treatment for genetically confirmed familial chylomicronaemia syndrome (FCS).

Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Sobi is providing sustainable access to innovative therapies in the areas of haematology, immunology and specialty indications. Today, Sobi employs approximately 1,500 people across Europe, North America, the Middle East, Russia and Asia. In 2020, Sobi's revenue amounted to SEK 15.3 billion.

Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm.

You can find more information about Sobi at [sobi.com](https://www.sobi.com)



Swedish Orphan Biovitrum AB (publ)

SE-112 76 Stockholm, Sweden | Street address: Tomtebodavägen 23 A

Telephone: +46 8-697 20 00 | Fax: +46 8-697 23 30

www.sobi.com