Expanding opportunities

Q4/FY 2020 report

October—December

- Total revenue of SEK 4,581 M (4,890), -6 per cent (-2 per cent at CER)
- Adjusted EBITA[1,2] was SEK 2,177 M (2,380), with an adjusted EBITA margin[1,2] of 48 per cent (49). Adjusted EBITA excludes positive impact from reversal of the contingent value right (CVR) liability of SEK 399 M. See page 6 for further information
- Earnings per share (EPS) of SEK 5.09 (4.62), before dilution
- Sales for Elocta® were SEK 1,071 M (1,235) and for Alprolix® SEK 419 M (405)
- Sales for Doptelet® were SEK 191 M (34)
- Sales for Kineret® were SEK 586 M (396), for Synagis® SEK 1,432 M (1,656) and for Gamifant® SEK 263 M (180)
- Cash flow from operations of SEK 858 M (976)
- Sobi and Apellis entered collaboration for global co-development and ex-US commercialisation of systemic pegcetacoplan in rare diseases with urgent need for new treatments

January—December

- Total revenue of SEK 15,261 M (14,248), 7 per cent growth (8 per cent at CER)
- Adjusted EBITA[1,2] was SEK 6,301 M (6,145), an increase of 3 per cent, with an adjusted EBITA margin[1,2] of 41 per cent (43)
- EPS of SEK 11.01 (11.29), before dilution
- Sales for Elocta were SEK 4,585 M (4,508) and for Alprolix SEK 1,705 M (1,463)
- Sales for Doptelet were SEK 587 M (34)
- Sales for Kineret were SEK 2,079 M (1,571), for Synagis SEK 2,726 M (2,594 for the period 23 Jan—31 Dec, 2019) and for Gamifant SEK 609 M (542)
- Cash flow from operations of SEK 5,214 M (3,634)

Outlook 2021

- 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 FY, SEK M

15,261

EBITA margin adjusted[1] FY, SEK M

41%

Haematology FY, growth at CER

13%

Immunology FY, growth at CER

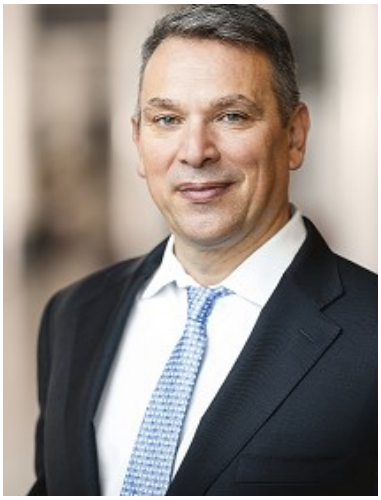
16%

Financial summary

Amounts in SEK M	Q4 2020	Q4 2019	Change	Full-year 2020	Full-year 2019	Change
Total revenue	4,581	4,890	-6%	15,261	14,248	7%
Gross profit	3,718	3,833	-3%	12,036	10,913	10%
Gross margin[1]	81%	78%		79%	77%	
EBITA[1]	2,576	2,288	13%	6,700	5,933	13%
EBITA adjusted[1,2]	2,177	2,380	-9%	6,301	6,145	3%
EBITA margin[1]	56%	47%		44%	42%	
EBITA margin adjusted[1,2]	48%	49%		41%	43%	
Profit for the period	1,502	1,360	10%	3,245	3,304	-2%
Earnings per share, before dilution, SEK	5.09	4.62	10%	11.01	11.29	-2%
Earnings per share, before dilution, SEK adjusted[1,2,3]	3.74	4.90	-24%	9.66	11.89	-19%

[1]Alternative Performance Measures (APMs), see page 13 for further information.
[2]EBITA Q4 and full-year 2020 excluding non-recurring item; other operating income related to the reversal of the CVR liability of SEK 399 M. EBITA 2019 excluding non-recurring items; transaction costs related to the acquisition of Dova in Q4 of SEK 92 M, restructuring costs of SEK 157 M in Q2 and gain from divestment of SOBI005 in Q1 of SEK 37 M.
[3]EPS Q4 and full-year 2020 excluding the reversal of the CVR liability of SEK 399 M. EPS 2019 excluding impairment of intangible assets of SEK 18 M related to restructuring in Q2.

CEO statement



2020 was a year of extreme challenges but also great opportunities. The COVID-19 pandemic created a challenging situation for the whole organisation, which did its utmost to serve customers and ensure supply to patients. At the same time, we entered two important strategic partnerships fuelling our pipeline, strengthening our international footprint and enabling strong future growth. We closed the full year 2020 with solid revenue of SEK 15,261 M, both core areas showing double-digit growth. Adjusted EBITA grew by 3 per cent to SEK 6,301 M.

Haematology – Doptelet continues its strong growth trajectory

Elocta and Alprolix sales for the full year were SEK 4,585 M (4,508) and SEK 1,705 M (1,463) respectively. Sales at CER grew 3 per cent for Elocta and 18 per cent for Alprolix compared with the previous year. We have continued to gain market share and increase the number of patients in most major markets. Patients on Elocta increased by 10 per cent for the full year 2020 and 1 per cent in Q4 vs Q3. Patients on Alprolix increased by 25 per cent and 4 per cent, respectively. The COVID-19 pandemic had a negative impact on consumption per patient, particularly of Elocta at the same time as competition intensified. Market conditions improved in the beginning of the second half of the year, but reverted following the reimposition of lockdowns in Q4.

Doptelet continued its solid performance despite tough market conditions, confirming the differentiation and value that it brings to patients. Sales for 2020 reached SEK 587 M (34) and Q4 at SEK 191 M (34). Next on the agenda is the roll-out in Europe. The CLD indication was launched in the first countries in Europe and preparations continued for launches in ITP in 2021.

Immunology – Kineret generates strong double-digit growth

Kineret continues to consolidate its position and ended the year with strong double-digit growth. Sales reached SEK 2,079 M (1,571) for the full year, an increase of 35 per cent at CER. We are supporting several investigator-initiated studies evaluating Kineret for treatment of hyperinflammation relating to COVID-19. We follow these external studies with great interest as they will be relevant for assessing whether Kineret can be a valuable treatment option for these patients.

Gamifant sales reached SEK 609 M (542), an increase of 16 per cent at CER on the previous year and a strong 56 per cent increase at CER in Q4. There is still a high unmet medical need, and awareness and education continue to be the main drivers of sales and penetration. More patients were treated but total sales were impacted by a lower price compared with last year.

The incidence of RSV was low in Q4 as a consequence of the COVID-19 pandemic, with social distancing and less international travel affecting the RSV season. At the same time, we have further improved our entire value chain, including our distribution setup and in-patient services which resulted in improved treatment compliance, largely compensating for the mild RSV season. Sales of Synagis in Q4 amounted to SEK 1,432 M (1,656).

R&D – pipeline boosted by new partnerships

In the second half of 2020, we entered two strategically important partnerships which significantly strengthen our late-stage pipeline and enable continued expansion in international markets. The partnership with Selecta Biosciences added a potential new treatment for chronic refractory gout, SEL-212, in phase 3; our partnership with Apellis Pharmaceuticals for systemic pegcetacoplan brings five potential new indications including a possible launch this year. We now have 12 late-stage programmes in our portfolio, and we are well positioned for future growth.

International

Our international expansion is a key priority and we have now established a Sobi presence in China, Japan and Australia. Emapalumab and nitisinone have both been submitted in China, with potential approval in 2021.

I am proud of what Sobi employees achieved in 2020. Despite challenges, patients have remained our focus: we have continued to support our patients and to ensure supply. The strengthening of the pipeline, together with increased investments in R&D and the commercial organisation, will take Sobi to the next level. We have accordingly increased our mid-term ambition to reach revenue of SEK 25 billion by 2025.

Solna, Sweden, 18 February 2021

Guido Oelkers, President & CEO

Business Review

Haematology

Sobi had strong participation at the annual meeting of the American Society of Hematology (ASH) in the beginning of December. Twelve abstracts featuring five treatments were accepted for presentation during ASH.

Sobi launched Doptelet in Q4 in Europe, with the United Kingdom as the first country for launch. Doptelet is a thrombopoietin receptor agonist (TPO-RA) approved for the treatment of severe thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo an invasive procedure.

Following approval by the European Commission for the chronic immune thrombocytopenia (ITP) indication in Europe in January 2021, we are preparing to launch in this indication. We continue to see strong progress for Doptelet in the US even though the challenging environment remains.

Sales of Elocta in particular continued to be impacted by COVID-19, with reduced factor consumption as well as postponed surgeries. We are still seeing patient growth but the expected normalisation of market conditions in Q4 was offset by reinstated measures relating to the COVID-19 pandemic. Sales of Alprolix, with less frequent dosing than Elocta, have not been impacted to the same extent. There is in addition a more intense competitive environment within haemophilia with continued price pressure.

Immunology

Kineret continues to show strong underlying demand driven by new indications, patient growth and demand relating to COVID-19. At the end of December the FDA (US Food & Drug Administration) granted Kineret a new indication for DIRA (deficiency of the interleukin-1 receptor antagonist), an ultra-rare autoinflammatory disease. Earlier in the year the indication familial Mediterranean fever (FMF) was approved in the EU.

Awareness of primary haemophagocytic lymphohistiocytosis (HLH) is increasing, driving demand for Gamifant. There has been continued progress in patient uptake, and Q4 saw strong growth in new patients and increased duration of therapy. For the full year, the number of patients grew by 67 per cent compared with 2019.

The RSV season was very mild with almost no RSV reported across the US in Q4, largely thought to be a result of COVID-19 measures such as social distancing and travel restrictions, resulting in weak underlying demand for Synagis. However, previously implemented efficiency measures, improved dose adherence and a new distribution system partly offset the negative effects of the milder RSV season.

Specialty Care

On 22 October a European Commission decision was adopted regarding the indication extension for Orfadin to include treatment of adult patients with alkaptonuria (AKU). The decision followed the positive opinion adopted by the Committee for Medicinal Products for Human Use (CHMP) in September. AKU, also known as black bone disease or black urine disease, is an extremely rare genetic condition affecting approximately 1 in every 250,000 to 1 million people. The medical need is high as there has been no pharmacological treatment available.

Through an agreement with US-based Akcea Therapeutics, Sobi will continue the commercialisation of the products Tegsedi and Waylivra in Europe, CEER and the Middle East from January 2021. Tegsedi (inotersen) is a self-administered subcutaneous treatment for the polyneuropathy of hATTR amyloidosis in adults. Waylivra (volanesorsen) is a treatment for genetically confirmed familial chylomicronaemia syndrome (FCS).

R&D pipeline

In October Sobi entered a partnership with Apellis Pharmaceuticals and obtained global co-development and exclusive ex-US commercialisation rights for systemic pegcetacoplan, a targeted C3 therapy. Sobi and Apellis will jointly advance systemic pegcetacoplan in five parallel registrational programmes including two new haematological studies that are planned to start in 2021: cold agglutinin disease (CAD) and HSCT-associated thrombotic microangiopathy (HSCT-TMA). Ongoing programmes are within haematology (paroxysmal nocturnal haemoglobinuria, PNH), nephrology (IC-MPGN/C3 glomerulopathy) and neurology (ALS).

In November, the first patients were dosed in the potentially registrational phase 2 MERIDIAN study of pegcetacoplan, in approximately 200 adults with sporadic amyotrophic lateral sclerosis (ALS).

In December, positive top-line results at week 48 from the phase 3 PEGASUS study were reported, which demonstrated sustained haematological and clinical improvements in patients with PNH who were treated with pegcetacoplan. The safety profile of pegcetacoplan was consistent with previously reported data and no new safety signals were identified. Marketing applications for pegcetacoplan for PNH are under review by the FDA, which has granted the application Priority Review designation, and by the European Medicines Agency (EMA).

The five programmes target rare diseases with high unmet need that impact more than 275,000 patients globally.

Sobi presented results from a sensitivity analysis from the pivotal phase 2/3 study (NCT01818492) of emapalumab in patients with primary HLH at the 19th meeting of the European Society of Immunodeficiencies (ESID) in October. Analyses of the efficacy of emapalumab in primary HLH, utilising various definitions of treatment response, all support the study primary endpoint of a 63 per cent overall response rate in patients with insufficient response to standard of care, as published in NEJM in May 2020.

The Marketing Authorisation Application for emapalumab has been accepted for review in China. The targeted indication is for treatment of adult and paediatric (newborn and older) patients with primary HLH with refractory, recurrent or progressive disease, or intolerance for conventional HLH therapy. Emapalumab has also been submitted in the United Arab Emirates for the treatment of primary HLH; approval is expected by the end of 2021.

Sobi filed for a re-examination of emapalumab in Europe following a negative opinion by CHMP recommending a refusal of marketing authorisation for emapalumab for the treatment of primary HLH in children under 18 years of age in Europe. The CHMP adopted a final negative opinion in November.

In October, topline results from the phase 3 study of avatrombopag in solid tumour cancer patients with chemotherapy-induced thrombocytopenia (CIT) was announced. Although avatrombopag increased platelet counts relative to placebo as expected, the study

did not meet the composite primary endpoint of avoiding platelet transfusions, chemotherapy dose reductions by 15 per cent or greater, and chemotherapy dose delays by four days or more.

In December, the CHMP adopted a positive opinion of Doptelet for the treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). The opinion was referred to the European Commission for a decision and was approved in January 2021.

Doptelet was submitted in Russia for both ITP and CLD in December, targeting approval in H1 2022.

Sustainability

Social

All employees were assigned the annual mandatory Patient Safety training in Q4.

Governance

The renewed Code of Conduct and training was rolled out. 97 per cent of all employees completed the training in 2020.

Sobi launched the Responsible Sourcing Programme in January 2020; 85 per cent of Sobi's current top 100 partners have been screened for sustainability criteria.

Corporate

Duane H. Barnes was appointed Head of North America and started on 15 January 2021. Duane has a strong background in the US healthcare sector with experience from both the biotechnology and healthcare services sectors. His background and experience will be instrumental as Sobi North America enters its next growth phase and continues to build the organisation.

Financial Review

Total revenue

Total revenue for the quarter amounted to SEK 4,581 M (4,890), down 6 per cent compared with the fourth quarter 2019 (-2 per cent at CER).

Full-year revenue was SEK 15,261 M (14,248), an increase of 7 per cent (8 per cent at CER). Organic growth amounted to 7 per cent at CER.

Revenue by business area

Haematology

Haematology revenue reached SEK 2,081 M (2,142) for the quarter, a decline of 3 per cent (2 per cent at CER). Full-year revenue amounted to SEK 8,660 M (7,755), an increase of 12 per cent (13 per cent at CER).

Elocta sales were SEK 1,071 M (1,235) for the quarter, down 13 per cent (-10 per cent at CER). Patient growth continued, but was off-set by lower consumption per patient due to the COVID-19 pan-demic, unfavourable price adjustments and order patterns. Full-year sales were SEK 4,585 M (4,508).

Alprolix sales were SEK 419 M (405) for the quarter, up 3 per cent (8 per cent at CER). Sales growth was driven by underlying patient growth but impacted by reduced consumption per patient due to the pandemic. Full-year Alprolix sales were SEK 1,705 M (1,463).

Doptelet sales reached SEK 191 M (34, period 12 November–31 December) for the quarter and market share strengthened. Full-year Doptelet revenue was SEK 587 M (34) including a milestone revenue related to the approval of the CLD indication in China of SEK 87 M in the second quarter.

Royalty revenue was SEK 316 M (352) for the quarter. Full-year revenue amounted to SEK 1,301 M (1,373).

ReFacto manufacturing revenue totalled SEK 84 M (116) for the quarter, down 28 per cent explained by ordering patterns. Full-year manufacturing revenue totalled SEK 481 M (376).

Immunology

Immunology revenue for the quarter was SEK 2,281 M (2,233) an increase of 2 percent (6 per cent at CER). Full-year revenue was SEK 5,415 M (4,706), up 15 per cent (16 per cent at CER).

Kineret sales for the quarter were SEK 586 M (396), an increase of 48 per cent (59 per cent at CER). Kineret continued to perform well with double-digit growth driven by strong underlying demand across all regions. Sales were also positively impacted by use in treatment of COVID-19 patients. Full-year sales were SEK 2,079 M (1,571).

Gamifant sales for the quarter amounted to SEK 263 M (180) an increase of 46 per cent (56 per cent at CER). Number of patients continued to grow, however sales were slightly offset by a lower price. Full-year sales were SEK 609 M (542).

Synagis sales for the quarter were SEK 1,432 M (1,656), a decrease of 14 per cent (-11 per cent at CER). The decrease is a result of a lower RSV infection rate during the COVID-19 pandemic. Full-year sales of Synagis were SEK 2,726 M (2,594 for the period 23 January -31 December 2019).

Revenue by business area

Amounts in SEK M	Q4 2020	Q4 2019	Change	Change at CER[1]	Full-year 2020	Full-year 2019	Change	Change at CER[1]
Haematology								
Elocta	1,071	1,235	-13%	-10%	4,585	4,508	2%	3%
Alprolix	419	405	3%	8%	1,705	1,463	17%	18%
Royalty	316	352	-10%	-1%	1,301	1,373	-5%	-3%
Doptelet	191	34	>100%	>100%	587	34	>100%	>100%
Manufacturing revenue	84	116	-28%	-28%	481	376	28%	28%
Total	**2,081**	**2,142**	**-3%**	**2%**	**8,660**	**7,755**	**12%**	**13%**
Immunology								
Kineret	586	396	48%	59%	2,079	1,571	32%	35%
Synagis	1,432	1,656	-14%	-11%	2,726	2,594	5%	5%
Gamifant	263	180	46%	56%	609	542	12%	16%
Total	**2,281**	**2,233**	**2%**	**6%**	**5,415**	**4,706**	**15%**	**16%**
Specialty Care								
Specialty Care	218	516	-58%	-54%	1,186	1,787	-34%	-33%
Total	**218**	**516**	**-58%**	**-54%**	**1,186**	**1,787**	**-34%**	**-33%**
Total revenue	**4,581**	**4,890**	**-6%**	**-2%**	**15,261**	**14,248**	**7%**	**8%**

[1]Constant exchange rates.

Specialty Care

Specialty Care revenue for the quarter was SEK 218 M (516), a decrease of 58 per cent (-54 per cent at CER). Full-year sales were SEK 1,186 M (1,787), a decrease of 34 per cent (-33 per cent at CER).

Orfadin sales for the quarter were SEK 146 M (231), a decrease of 37 per cent (-31 per cent at CER). The decrease is explained by generic competition and associated price erosion. Full-year sales were SEK 665 M (827).

Fourth quarter sales for other Specialty Care products amounted to SEK 72 M (285), a decrease of 75 per cent (-73 per cent at CER) related to the discontinuation of products. Year-to-date sales were SEK 521 M (959).

Gross profit

Gross profit for the quarter was SEK 3,718 M (3,833), representing a gross margin of 81 per cent (78). Full-year gross profit was SEK 12,036 M (10,913) representing a gross margin of 79 per cent (77). The increase in gross margin was driven by a favourable product mix and ceased royalty obligations.

Operating expenses

Sales and administrative expenses, excluding amortisation and write-downs, amounted to SEK 1,092 (1,179) for the quarter, corresponding to a 7 per cent decrease, mainly related to a lower activity level across all business areas due to COVID-19. Full-year expenses increased to SEK 4,099 M (3,535) due to the inclusion of the Dova business, launch preparations for Doptelet and geographic expansion in Asia.

Research and development expenses amounted to SEK 486 M (357) for the quarter and to SEK 1,594 M (1,495) for the full-year. The increase reflects spending related to programmes for emapalumab, avatrombopag, SEL-212 and pegcetacoplan.

Operating profit

EBITA for the quarter was SEK 2,576 M (2,288), corresponding to a margin of 56 per cent (47). Adjusted EBITA for the quarter was SEK 2,177 M (2,380) corresponding to a margin of 48 per cent (49). Adjusted EBITA excludes a positive impact from reversal of the CVR liability of SEK 399 M. Full-year EBITA amounted to SEK 6,700 M (5,933) and adjusted EBITA amounted to SEK 6,301 M (6,145).

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.

Amortisation and write-downs of intangible assets for the quarter amounted to SEK 460 M (415) and SEK 1,882 M (1,401) for the full year. The increase relates mainly to product rights acquired during 2019.

EBIT for the quarter was SEK 2,116 M (1,874). EBIT for the full year was SEK 4,818 M (4,533).

Operating profit

Amounts in SEK M	Q4 2020	Q4 2019	Full-year 2020	Full-year 2019
Total revenue	4,581	4,890	15,261	14,248
Total cost of goods sold	-863	-1,057	-3,225	-3,335
Gross profit	**3,718**	**3,833**	**12,036**	**10,913**
Gross margin	*81%*	*78%*	*79%*	*77%*
Sales and administrative expenses excluding amortisation and write-downs	-1,092	-1,179	-4,099	-3,535
Research and development expenses	-486	-357	-1,594	-1,495
Total opex excluding amortisation and write-downs	**-1,578**	**-1,536**	**-5,693**	**-5,029**
Other operating income/expenses	435	-9	357	50
EBITA	**2,576**	**2,288**	**6,700**	**5,933**
Non-recurring items	-399	92	-399	211
EBITA adjusted[1]	***2,177***	***2,380***	***6,301***	***6,145***
Amortisation and write-downs related to Sales and administrative expenses	-460	-415	-1,882	-1,401
EBIT	**2,116**	**1,874**	**4,818**	**4,533**

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

[1]EBITA Q4 and full-year 2020 excluding non-reccuring items; other operating income related to the reversal of the CVR liability of SEK 399 M. EBITA 2019 excluding non-recurring items; transaction costs related to the acquisition of Dova in Q4 of SEK 92 M, restructuring costs of SEK 157 M in Q2 and gain from divestment of SOBI005 in Q1 of SEK 37 M.

Net financial items

Net financial items amounted to SEK -180 M (-111) for the quarter, including exchange rate losses of SEK -88 M (-7) driven by high volatility in currency rates. Net financial items for the full year amounted to SEK -601 M (-286), including exchange rate losses of SEK -115 M (-31).

Tax

Income tax amounted to SEK -434 M (-402) for the quarter, corresponding to an effective tax rate of 22.4 per cent (22.8), and to SEK -972 M (-942) for the full-year, corresponding to an effective tax rate of 23.1 per cent (22.2). The lower effective tax rate in the quarter relates mainly to the reversal of the CVR liability.

Profit

Profit totalled SEK 1,502 M (1,360) for the quarter and SEK 3,245 M (3,304) for the full year.

Cash flow

Cash flow from operations before change in working capital amounted to SEK 1,917 (1,928) for the quarter and to SEK 5,398 M (5,300) for the full-year.

Change in working capital affected cash flow by SEK -1,059 M (-952) for the quarter, mainly attributable to inventory build-up and increased receivables driven by seasonal sales. Full-year change in working capital amounted to SEK -184 M (-1,666), driven by inventory build-up partially offset by sales related accruals.

Cash flow from investing activities for the quarter was SEK -2,528 M (-8,737) including cash flow from the upfront payment related to pegcetacoplan of SEK -2,198 M. Full-year cash flow from investing activities amounted to SEK -3,964 M (-21,685) also including the investment in SEL-212 of SEK -977 M. The 2019 figure includes the acquisition of Synagis and Dova.

Cash flow from financing activities amounted to SEK 1,925 M (7,428) for the quarter and SEK -1,570 M (15,780) for the full-year. The increased borrowings during the quarter relate to the financing of the pegcetacoplan agreement.

Cash and net debt

At the end of the year, cash and cash equivalents amounted to SEK 404 M (737). At 31 December 2020 undrawn committed credit facilities totalled SEK 4,320 M (3,959) and drawn totalled SEK 14,234 M (16,243). Net debt at year-end amounted to SEK 13,748 M (15,404).

Equity

At 31 Dec 2020, consolidated shareholders' equity was SEK 20,206 M (16,930).

Personnel

At 31 Dec 2020, the number of full-time equivalents was 1,509 (1,335).

Parent Company

In the fourth quarter, net sales for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 3,565 M (4,252), of which Group companies accounted for SEK 2,453 M (1,399). Full-year sales amounted to SEK 13,968 M (12,991) of which SEK 8,349 M (6,154) referred to sales to Group companies.

Profit for the period amounted to SEK -772 M (-2,384) for the quarter and to SEK 3,406 M (1,118) for the full year.

Investing activities affecting cash flow amounted to SEK -2,348 M (-572) for the quarter and SEK -3,760 M (-673) for the full year, whereof SEK -2,198 M refers to pegcetacoplan and SEK -977 M refers to SEL-212.

Other information

Significant events after the reporting period

Doptelet (avatrombopag) was approved in the EU for treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments. ITP is an autoimmune disorder characterised by low numbers of platelets.

Financial outlook 2021

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 to 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 12 late-stage programmes.

Dividend

The Board of Directors proposes that no dividend will be paid for the 2020 financial year.

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. Further information regarding the AGM will be available on Sobi's website.

The Annual Report for 2020 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 reviewed by the Company's auditors.

Solna, Sweden, 18 February 2021

Guido Oelkers, CEO and President

Financial calendar

AGM	4 May 2021
Q1 2021	4 May 2021
Q2 2021	21 July 2021
Q3 2021	28 October 2021

Forward-looking statements

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

Financial statements – Group

Consolidated Statement of comprehensive income

Amounts in SEK M	Q4 2020	Q4 2019	Full-Year 2020	Full-Year 2019
Total revenue[1]	4,581	4,890	15,261	14,248
Total cost of goods sold	-863	-1,057	-3,225	-3,335
Gross profit	**3,718**	**3,833**	**12,036**	**10,913**
Sales and administrative expenses[2]	-1,552	-1,593	-5,981	-4,935
Research and development expenses	-486	-357	-1,594	-1,495
Other operating income/expenses	435	-9	357	50
Operating profit	**2,116**	**1,874**	**4,818**	**4,533**
Financial income/expenses[3]	-180	-111	-601	-286
Profit before tax	**1,936**	**1,763**	**4,217**	**4,247**
Income tax expenses	-434	-402	-972	-942
Profit for the period	**1,502**	**1,360**	**3,245**	**3,304**
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	-4	-7	-3	-4
Fair value of financial investment (net of tax)	9	–	9	–
Items that may be reclassified subsequently to profit/loss				
Translation difference	-450	-347	-434	-97
Hedge of net investment (net of tax)	198	42	246	42
Cash flow hedges (net of tax)	143	121	130	2
Comprehensive income for the period	**1,398**	**1,169**	**3,193**	**3,247**
All comprehensive income are attributable to Parent Company shareholders				
Earnings per share, SEK	5.09	4.62	11.01	11.29
Earnings per share, SEK, adjusted[4]	3.74	4.90	9.66	11.89
Earnings per share after dilution, SEK	5.04	4.59	10.90	11.22
Earnings per share after dilution, SEK, adjusted[4]	3.69	4.86	9.56	11.81
[1]See page 5 for split by business area.				
[2]Amortisation and write-downs of intangible assets included in Sales and administrative expenses.	-460	-415	-1,882	-1,401
[3]Including financing costs.	-10	-7	-32	-18

[4]Alternative Performance Measures (APMs), see page 13 for further information.

Consolidated Balance sheet

Amounts in SEK M	Dec 2020	Dec 2019
ASSETS		
Non-current assets		
Intangible assets[1]	38,791	37,412
Tangible assets	534	518
Financial assets	179	50
Deferred tax assets	611	354
Total non-current assets	40,115	38,335
Current assets		
Inventories	3,053	1,772
Accounts receivable	3,756	3,736
Other receivables, non-interest bearing	955	1,078
Cash and cash equivalents	404	737
Total current assets	8,168	7,323
Total assets	48,283	45,658
EQUITY AND LIABILITIES		
Shareholders´ equity	20,206	16,930
Non-current liabilities		
Borrowings	10,137	16,141
Deferred tax liabilites	3,464	3,726
Lease liabilities	308	320
Other liabilities, non-interest bearing	3,725	2,800
Total non-current liabilities	17,634	22,987
Current liabilities		
Borrowings	4,015	–
Accounts payable	569	681
Lease liabilities	111	99
Other liabilities, non-interest bearing	5,748	4,961
Total current liabilities	10,443	5,741
Total equity and liabilities	48,283	45,658

[1]Including goodwill of SEK 5,873 M (6,678), the decrease is related to the adjusted PPA for Dova with SEK -313 M (see Note 5 for more information) and currency effects.

Changes in equity

Amounts in SEK M	Full-year 2020	Full-year 2019
Opening balance	16,930	9,040
Adjusted opening balance for post employment-benefits from previous years[1]	-38	–
Share-based compensation to employees	114	80
Share-based compensation to employees tax effect[2]	7	50
Issue of shares	–	4,513
Comprehensive income for the period[3]	3,193	3,247
Equity at end of period	20,206	16,930

[1]Refers to post employment-benefits, mainly in Switzerland not previously included at Dec 2019.

[2]The parent company has during 2019 been granted additional deductions for tax purposes related to incentive programmes vested in 2013-2018. The additional deductions relate to difference between the market value of vested shares and recognised IFRS 2 cost.

[3]Whereof changes in cash flow hedges (net of tax) amounted to SEK 130 M (2) and net investment hedges (net of tax) amounted to SEK 246 M (42).

Consolidated Cash flow statement

Amounts in SEK M	Q4 2020	Q4 2019	Full-year 2020	Full-year 2019
Profit for the period	1,502	1,360	3,245	3,304
Adjustment for non-cash items[1]	415	568	2,153	1,995
Cash flow from operations before change in working capital	**1,917**	**1,928**	**5,398**	**5,300**
Change in working capital	-1,059	-952	-184	-1,666
Cash flow from operations	**858**	**976**	**5,214**	**3,634**
Acquisition of business, net of cash[2]	–	-7,969	–	-12,880
Investment in intangible assets[3,4]	-2,523	-758	-3,811	-9,709
Investment in tangible assets[3]	-13	-10	-41	-37
Investment in financial assets[3]	–	–	-120	–
Divestment of tangible assets	8	–	8	–
Divestment of intangible assets[5]	–	0	–	941
Cash flow from investing activities	**-2,528**	**-8,737**	**-3,964**	**-21,685**
Loans - Raising/Amortisation	1,955	7,455	-1,452	15,875
Lease payments	-30	-26	-118	-94
Cash flow from financing activities	**1,925**	**7,428**	**-1,570**	**15,780**
Change in cash and cash equivalents	**255**	**-332**	**-320**	**-2,271**
Cash and cash equivalents at the beginning of the period	164	1,077	737	2,999
Translation difference in cash flow and cash and cash equivalents	-14	-7	-13	9
Cash and cash equivalents at the end of the period	**404**	**737**	**404**	**737**
[1] Adjustment for non-cash items:				
Depreciation of tangible assets	37	57	141	188
Amortisation and write-downs of intangible assets	460	415	1,882	1,401
Deferred tax	102	109	-153	411
Other	-184	-12	283	-4
Non-cash items	**415**	**568**	**2,153**	**1,995**

[2]Relates to the acquisitions of Dova and emapalumab in 2019.

[3]Whereof SEK -2,198 M of intangible assets relates to pegcetacoplan, SEK -857 M of intangible assets and SEK -120 M of financial assets relates to SEL-212.

[4]Relates mainly to the acquisition of Synagis and BIV001 in 2019.

[5]2019 relates to the divestments of Priority Review Voucher (PRV).

Key ratios and other information

Amounts in SEK M	Q4 2020	Q4 2019	Full-year 2020	Full-year 2019
Profit measures				
Gross profit	3,718	3,833	12,036	10,913
EBITDA[1]	2,613	2,345	6,830	6,121
EBITA[1]	2,576	2,288	6,700	5,933
EBITA adjusted[1,2]	2,177	2,380	6,301	6,145
EBIT (operating profit)	2,116	1,874	4,818	4,533
Profit/loss	1,502	1,360	3,245	3,304
Per share data (SEK)				
Earnings per share	5.09	4.62	11.01	11.29
Earnings per share, adjusted[2,3]	3.74	4.90	9.66	11.89
Earnings per share after dilution	5.04	4.59	10.90	11.22
Earnings per share after dilution, adjusted[2,3]	3.69	4.86	9.56	11.81
Shareholders' equity per share[1]	66.5	56.4	66.5	56.4
Shareholders' equity per share after dilution[1]	65.9	56.1	65.9	56.1
Other information				
Gross margin[1]	81%	78%	79%	77%
EBITA margin[1]	56%	47%	44%	42%
EBITA margin adjusted[1,2]	48%	49%	41%	43%
Equity ratio[1]	42%	37%	42%	37%
Net cash (-)/debt (+)[1]	13,748	15,404	13,748	15,404
Number of ordinary shares[4]	303,815,511	299,977,839	303,815,511	299,977,839
Number of ordinary shares (in treasury)	8,918,672	5,678,099	8,918,672	5,678,099
Number of ordinary shares (excluding shares in treasury)	294,896,839	294,299,740	294,896,839	294,299,740
Number of ordinary shares after dilution	306,797,549	301,857,247	306,797,549	301,857,247
Average number of ordinary shares (excluding shares in treasury)	294,896,839	294,299,740	294,658,136	292,649,020
Average number of ordinary shares after dilution (excluding shares in treasury)	297,878,877	296,179,148	297,640,174	294,528,428

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

[2]EBITA Q4 and full-year 2020 excluding non-reccuring item; other operating income related to the reversal of the CVR liability of SEK 399 M. EBITA 2019 excluding non-recurring items; transaction costs related to the acquisition of Dova in Q4 of SEK 92 M, restructuring costs of SEK 157 M in Q2 and gain from divestment of SOBI005 in Q1 of SEK 37 M.
[3]EPS Q4 and full-year 2020 excluding the reversal of the CVR liability of SEK 399 M. EPS 2019 excluding impairment of intangible assets of SEK 18 M related to restructuring in Q2.

[4]The 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 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

	Q4 2020	Q4 2019	Full-year 2020	Full-year 2019
Total revenue	4,581	4,890	15,261	14,248
Total cost of goods sold	-863	-1,057	-3,225	-3,335
Gross profit	**3,718**	**3,833**	**12,036**	**10,913**
Gross margin	**81%**	**78%**	**79%**	**77%**

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

Total revenue	4,581	4,890	15,261	14,248
Total revenue adjusted for Synagis[1]	4,581	4,890	15,007	14,248
Organic growth	-6%	24%	5%	27%
Organic growth, CER	**-2%**	**20%**	**7%**	**21%**

[1]Jan-Dec 2020 excluding sales of SEK 254 M for Synagis period 1-22 January 2020. Synagis was acquired on 23 January 2019.

Organic growth, % CER - Total revenues adjusted for Synagis measured at CER compared to previous period.

EBIT (operating profit)	2,116	1,874	4,818	4,533
Plus amortisation and write-downs of intangible assets	460	415	1,882	1,401
EBITA	**2,576**	**2,288**	**6,700**	**5,933**
Plus depreciations and write-downs of tangible assets	36	57	130	188
EBITDA	**2,613**	**2,345**	**6,830**	**6,121**
EBITA margin	**56%**	**47%**	**44%**	**42%**
Non-recurring items	-399	92	-399	211
EBITA adjusted	**2,177**	**2,380**	**6,301**	**6,145**
EBITA margin adjusted	**48%**	**49%**	**41%**	**43%**

EBITA - Earnings before interest, tax and amortisation
EBITDA - Earnings before interest, tax, depreciation, amortisation and write-downs
EBITA margin, % - EBITA as a percentage of total revenue
Non-recurring item in Q4 and full-year 2020; other operating income related to the reversal of the CVR liability. Full-year 2019 - impact from divestment of SOBI005 in Q1, restructuring costs in Q2 and transaction costs related to the acquisition of Dova in Q4.
EBITA adjusted - EBITA less non-recurring items
EBITA margin adjusted, % - EBITA adjusted as a percentage of total revenue

Financial measures not defined according to IFRS, cont.

	Q4 2020	Q4 2019	Full-year 2020	Full-year 2019
Profit for the period	1,502	1,360	3,245	3,304
Impact 2020 from the reversal of the CVR liability. Impact 2019 from divestment of SOBI005, restructuring costs and transaction costs related to the acquisition of Dova Pharmaceuticals, after tax	-399	81	-399	174
Profit for the period, adjusted	1,103	1,441	2,846	3,479
Average number of ordinary shares (excluding shares in treasury)	294,896,839	294,299,740	294,658,136	292,649,020
Average number of ordinary shares after dilution (excluding shares in treasury)	297,878,877	296,179,148	297,640,174	294,528,428
EPS, SEK adjusted	**3.74**	**4.90**	**9.66**	**11.89**
EPS after dilution, SEK adjusted	**3.69**	**4.86**	**9.56**	**11.81**

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

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

Borrowings	14,152	16,141	14,152	16,141
Cash and cash equivalents	404	737	404	737
Net debt (+)/Net cash (-)	**13,748**	**15,404**	**13,748**	**15,404**

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

Shareholders' equity	20,206	16,930	20,206	16,930
Total assets	48,283	45,658	48,283	45,658
Equity ratio	**42%**	**37%**	**42%**	**37%**
Number of ordinary shares	303,815,511	299,977,839	303,815,511	299,977,839
Number of ordinary shares after dilution	306,797,549	301,857,247	306,797,549	301,857,247
Equity per share, SEK	**66.5**	**56.4**	**66.5**	**56.4**
Equity per share after dilution, SEK	**65.9**	**56.1**	**65.9**	**56.1**

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

Financial statements – Parent Company

Income statement

Amounts in SEK M	Q4 2020	Q4 2019	Full-year 2020	Full-year 2019
Total revenue	3,565	4,252	13,968	12,991
Total cost of goods sold	-763	-1,002	-3,134	-3,177
Gross profit	**2,802**	**3,251**	**10,834**	**9,814**
Sales and administrative expenses[1]	-1,543	-2,096	-4,174	-4,220
Research and development expenses	-317	-231	-923	-1,110
Other operating income/expenses	76	-6	96	52
Operating profit	**1,018**	**918**	**5,833**	**4,536**
Financial income/expenses	185	26	194	61
Profit after financial items	**1,203**	**944**	**6,027**	**4,597**
Appropriations	-1,690	-3,166	-1,690	-3,166
Profit before tax	**-487**	**-2,222**	**4,337**	**1,431**
Income tax expenses	-285	-162	-931	-313
Profit for the period	**-772**	**-2,384**	**3,406**	**1,118**
[1]Amortisation and write-downs of intangible assets included in Sales and administrative expenses.	-82	-79	-328	-323

Statement of other comprehensive income

Amounts in SEK M	Q4 2020	Q4 2019	Full-year 2020	Full-year 2019
Profit for the period	-772	-2,384	3,406	1,118
Items that will not be reclassified to profit/loss				
Fair value of financial investment (net of tax)	9	–	9	–
Items that may be subsequently reclassified to profit/loss				
Cash flow hedge (net of tax)	144	163	130	44
Fair value of financial investment (net of tax)	9	–	9	–
Comprehensive income for the period	**-619**	**-2,221**	**3,545**	**1,161**

Balance sheet

Amounts in SEK M	Dec 2020	Dec 2019
ASSETS		
Non-current assets		
Intangible assets	10,205	5,572
Tangible assets	64	65
Financial assets	23,164	26,113
Deferred tax assets	24	22
Total non-current assets	33,457	31,772
Current assets		
Inventories	2,527	1,533
Accounts receivable	731	2,402
Receivables Group companies	3,947	1,286
Other receivables, non-interest bearing	835	949
Cash and cash equivalents	240	431
Total current assets	8,280	6,601
Total assets	41,737	38,373
EQUITY AND LIABILITIES		
Shareholders´ equity	17,200	13,534
Untaxed reserves	3,091	2,984
Non-current liabilities		
Borrowings	10,137	16,141
Liabilities Group companies	157	–
Other liabilities, non-interest bearing	2,557	1,357
Total non-current liabilities	12,851	17,499
Current liabilities		
Borrowings	4,015	–
Accounts payable	398	574
Liabilities Group companies	1,674	1,358
Other liabilities, non-interest bearing	2,508	2,424
Total current liabilities	8,595	4,356
Total equity and liabilities	41,737	38,373

Change in shareholders' equity

Amounts in SEK M	Full-year 2020	Full-year 2019
Opening balance	13,534	7,731
Share-based compensation to employees	114	80
Share-based compensation to employees tax effect[1]	7	50
Issue of shares	–	4,513
Comprehensive income for the period[2]	3,545	1,161
Equity at end of period	17,200	13,534

[1]The parent company has during 2019 been granted additional deductions for tax purposes related to incentive programmes vested in 2013-2018. The additional deductions relate to difference between the market value of vested shares and recognised IFRS 2 cost.

[2]Whereof changes in cash flow hedges (net of tax) amounted to SEK 130 M (44).

Financial notes

Note 1 – Accounting policies and measurement bases and other information

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 2020 have been prepared in accordance with International Financial Reporting Standards (IFRS) and the International Financial Reporting Interpretations Committee (IFRIC) 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 accounting policies apply with those described in the 2019 Annual and Sustainability Report, with exception for below. More detailed information about the Group's accounting policies and measurement bases can be found in the 2019 Annual and Sustainability Report, available at www.sobi.com.

As from 1 January 2020 segment reporting is reported according to IFRS 8.

The definition of business combinations in IFRS 3 'Business Combinations' has been changed and applied from 2020. The changes had no impact on Sobi's full-year report but may affect future periods if Sobi makes acquisitions. The amendments clarify that to be considered a business, an integrated set of activities and assets must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output. It also makes clear that this must be based on what has been acquired in its current state and condition and not what could be replaced by a market participant. Further, the amendments introduced an optional concentration test to perform a simplified assessment, to determine whether an acquired set of activities and assets is not a business.

There are no other amendments to IFRS during 2020 that have any material effect on the consolidated financial statements.

COVID-19 impact on the consolidated financial statements

Due to the COVID-19 pandemic Sobi has performed an assessment of its assets and liabilities where estimates and assumptions about the future and judgements form the basis for the carrying amounts in the consolidated financial statements. The assessment has not had any impact on the consolidated financial statements for the period.

Risks and uncertainties

Sobi is exposed to a number of risks in its operations which have been divided into three main 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.

More information about risk exposure and risk management is included in Sobi's 2019 Annual and Sustainability Report. An update to these risks has been assessed by management during 2020 to also include pandemics, such as the COVID-19 pandemic. Sobi has put actions in place to mitigate the effects of a pandemic, however the pandemic may have material adverse effects on Sobi's business and financial position.

Note 2 – Segment reporting

Segment information

Sobi's operations are organised into three business areas - Haematology, Immunology and Specialty Care. As from 1 January 2020 these business areas form the basis for the Group's segment reporting.

A new strategy together with integration of acquisitions and implementation of organisational changes in 2019 led to a clearer division and refinement of the business into the three business areas. Sobi has three independent business areas, which naturally entails the introduction of business reporting in the three segments. These operating segments are regularly reviewed by the Group's chief operating decision maker and strategic decisions are made on the basis of adjusted segment reporting results.

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

Segment Immunology: Revenue are generated from the sale of the products Kineret, Synagis and Gamifant.

Segment Specialty Care: Revenue are generated from the sale of Orfadin, Kepivance® and partner products in the Specialty Care portfolio.

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

Comparative figures for 2019 is presented by segment. The same accounting principles are applied in the segment reporting as for the Group. Revenue, EBITA and adjusted EBITA for each segment represent their contribution to the groups revenue, EBITA and adjusted EBITA. There are no intersegment transactions. See page 19 for segment table.

Note 3 – Fair value of financial instruments

The group carries financial instruments that are measured at fair value. See the 2019 Annual and Sustainability Report for more information and a narrative description of the purposes of the holdings.

Quoted shares are categorized within Level 1 of the fair value hierarchy in the IFRS 13 standard. These consist of the groups holding of shares in Selecta Biosciences, Inc. At 31 December 2020 the reported value on the balance sheet was SEK 131 M (-), included in the balance sheet under financial assets.

Currency derivatives forward contracts are categorized within Level 2. Fair value measurement is based on published forward prices. At 31 December 2020, the net reported value on the balance sheet was SEK -151 M (-4).

Endowment insurances are categorized within level 3. At 31 December 2020 the reported value on the balance sheet was SEK 44 M (47), included in the balance sheet under financial assets.

Liabilities measured at fair value are categorized within Level 3 and consist of a contingent purchase price related to the Dova acquisition (CVR). At 31 December 2020 the reported value on the balance sheet was SEK - M (388), se page 6 for further information.

At 31 December 2020, all other financial instruments on the balance sheet had reported values that are in all material aspects equivalent to fair value.

Note 4 – Restructuring reserve

Restructuring costs of SEK 175 M were charged in Q2 2019 relating to the reorganisation of R&D and redundancies corresponding to approximately 90 positions. In the Statement of comprehensive income this was mainly recognised as research and development expenses. At 31 December 2020 the remaining provision on the balance sheet recognised under Other liabilities, non-interest bearing was SEK 13 M.

During 2020 Sobi signed agreements to sell assets for which an impairment was done in connection with the reorganisation in 2019. The sales price totaled SEK 11 M which was recognised as a reduction of research and development expenses in the Statement of comprehensive income.

Note 5 – Acquisitions

Apellis - collaboration agreement

During the fourth quarter 2020 Sobi and Apellis entered collaboration for global co-development and ex-US commercialisation of systemic pegcetacoplan in rare diseases with urgent need for new treatments.

Sobi has paid USD 250 M to Apellis at the close of the collaboration and has committed to pay, to Apellis, potential milestone payments of up to USD 915 M upon achievement of certain regulatory and commercial milestones. The initial payment together with the liability (the probability-weighted and discounted value) for future payments of potential milestone payments constitutes the purchase price of SEK 3,060 M for the acquired intangible asset. The debt is included in the other liabilities, not interest-bearing. Furthermore, Apellis is entitled to tiered double-digit royalties on future sales.

Sobi will contribute USD 80 M to Apellis in reimbursement payments over a four-year period for research and development to support the initial development plan. These will be expensed when occurred.

Balance sheet at acquisition date, pegcetacoplan

Amounts in SEK M	
Intangible assets	3,060
Other liabilities, non interest bearing	851

Selecta - licensing agreement

During the third quarter 2020 Sobi and Selecta closed the strategic licensing agreement for SEL-212. Sobi will assume responsibility for development, regulatory and commercial activities in all markets outside of China, while Selecta will run the phase 3 study on behalf of Sobi.

Sobi has paid USD 100 M to Selecta at the close of the agreement and has committed to pay, to Selecta, potential milestone payments of up to USD 630 M upon achievement of certain regulatory and commercial milestones. The initial payment together with the liability (the probability-weighted and discounted value) for future payments of potential milestone payments constitutes the purchase price of SEK 1,896 M for the acquired intangible asset and the financial asset. The debt is included in the other liabilities, not interest-bearing. Furthermore, Selecta is entitled to tiered double-digit royalties on future sales. During the fourth quarter Sobi paid, to Selecta, a milestone payment of USD 5 M related to randomisation of the first patient in phase 3 clinical program of SEL-212.

Balance sheet at acquisition date, SEL-212

Amounts in SEK M	
Intangible assets	1,776
Financial assets	120
Other liabilities, non-interest bearing	954

Dova

During the fourth quarter 2019 Sobi completed the acquisition of Dova. The PPA for Dova was adjusted in the first quarter 2020, where the change, SEK 320 M, was recognised as a deferred tax asset (related to the liability to Eisai), SEK -7 M on other liabilities and SEK -313 M on goodwill.

As a result of the phase 3 study regarding Doptelet for use in CIT, Sobi estimates that the conditions for the CVR will not be met. Therefore the CVR liability was reversed positively impacting the profit for the period of SEK 399 M. For further information see page 6.

Note 6 – Impairment

Doptelet

Following the result from the phase 3 study of avatrombopag and its effect in the treatment of CIT, an impairment test was performed, the test showed no impairment need.

Gamifant

Following the negative opinion in July by CHMP for emapalumab in Europe, an impairment test was performed. The test showed no impairment need.

Note 2 - Segment reporting

Amounts in SEK M

Q4 2020	Haematology	Immunology	Specialty Care	Group - other	Total
Revenue	2,081	2,281	218	–	4,581
EBITA[1]	980	1,265	59	272	2,576
Adjusted EBITA[1,2]	582	1,265	59	272	2,177

Q4 2019	Haematology	Immunology	Specialty Care	Group - other	Total
Revenue	2,142	2,233	516	–	4,890
EBITA[1]	1,084	1,220	196	-211	2,289
Adjusted EBITA[1,2]	1,084	1,220	196	-119	2,380

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

Full-year 2019	Haematology	Immunology	Specialty Care	Group - other	Total
Revenue	7,755	4,706	1,787	–	14,248
EBITA[1]	4,451	1,529	563	-610	5,933
Adjusted EBITA[1,2]	4,451	1,529	563	-398	6,145

[1]Alternative Performance Measures (APMs), see page 13 for further information.

[2]EBITA Q4 and full-year 2020 excluding non-reccuring items; other operating income related to the reversal of the CVR liability of SEK 399 M. EBITA 2019 excluding non-recurring items; transaction costs related to the acquisition of Dova in Q4 of SEK 92 M, restructuring costs of SEK 157 M in Q2 and gain from divestment of SOBI005 in Q1 of SEK 37 M.

Definitions and Glossary

Alkaptonuria (AKU)	A serious, multifaceted, debilitating and slowly progressive disease affecting approximately 1 in every 250 000 to 1 million people. Also known as black bone disease or black urine disease.
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.
ALS—amyotrophic lateral sclerosis	A devastating neurodegenerative disease that results in progressive muscle weakness and paralysis due to the death of nerve cells, called motor neurons, in the brain and spinal cord.
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.
CAD—cold agglutinin disease	A severe, chronic, rare blood disorder that currently has no approved therapies and impacts around 10,500 people across the United States and Europe. People living with CAD may suffer from chronic anaemia, transfusion requirements, and an increased risk of life-threatening thrombotic events such as stroke.
CER	Constant exchange rates.
Chemotherapy-induced thrombocytopenia (CIT)	A common side effect of chemotherapy that results in a low number of platelets.
CHMP	Committee for Medicinal Products for Human Use.
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.
CVR	Contingent Value Right.
COVID-19	The infectious disease caused by a coronavirus discovered in 2019, declared a pandemic by WHO.
Deficiency of interleukin-1 receptor antagonist (DIRA)	An ultra-rare autoinflammatory disease.
Doptelet (avatrombopag)	A second-generation small-molecule thrombopoietin receptor (TPO) agonist used in the treatment of thrombocytopenia by increasing platelet count.
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. 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.
Full-time equivalents	Unit that indicates the workload of an employed person in a way that makes workloads comparable.

Familial Mediterranean fever (FMF)	An inherited disorder manifested by episodic fevers, often with pain in the abdomen, joints or chest, and rash in the lower extremities.
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.
HSCT-TMA	A rare blood disease that can be a fatal complication of a bone-marrow transplant or HSCT (hemopoietic stem cell transplantation). In HSCT-TMA, microscopic blood clots form in small blood vessels, leading to organ damage.
IC-MPGN/C3G	IC-MPGN and C3G are rare, debilitating kidney diseases that affect around 18,000 people in the United States and Europe. There are no approved therapies for the diseases, and symptoms include blood in the urine, dark foamy urine due to the presence of protein, swelling, and high blood pressure.
IFRS	International Financial Reporting Standards.
ISTH	International Society on Thrombosis and Haemostasis.
Kineret (anakinra)	A recombinant protein drug that blocks the biological activity of interleukin-1 α and β (IL-1α and IL -1β) by binding to IL-1 type 1 receptors (IL-R 1), expressed in a variety of tissues and organs, thereby blocking the IL-1 signalling. IL-1 is a key mediator of inflammation and a significant contributor to autoinflammatory diseases.
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 in frequent transfusions and debilitating symptoms such as severe fatigue, haemoglobinuria, and difficulty breathing (dyspnoea).
PPA	Purchase Price Allocation.
Randomised study	A random division of test subjects into predetermined treatment groups or placebo groups in a clinical trial.
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.

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

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