A solid third quarter

Q3 2020 report

July—September

- Total revenue of SEK 2,970 M (2,930), up 1 per cent (6 per cent at constant exchange rates (CER))
- EBITA[1] was SEK 933 M (1,099), with an EBITA margin[1] of 31 per cent (38)
- Earnings per share before dilution (EPS) of SEK 0.94 (1.84)
- Net debt[1] of SEK 12,703 M at 30 Sep 2020 (15,404 at 31 Dec 2019)
- Sales for Elocta® were SEK 1,115 M (1,156) and sales for Alprolix® were SEK 435 M (341)
- Continued strong performance for Kineret® with sales of SEK 463 M (409), an increase of 20 per cent at CER
- Sales of Gamifant® were SEK 110 M (67)
- Cash flow from operations of SEK 443 M (995)
- The strategic licensing agreement with Selecta Biosciences, Inc. for the product candidate SEL-212, a potential treatment for chronic refractory gout, was completed
- Topline data for the phase 2 COMPARE study comparing the efficacy of SEL-212 to pegloticase for the treatment of chronic refractory gout was announced
- Outlook 2020 updated, see page 8

January—September

- Total revenue of SEK 10,680 M (9,358), 14 per cent revenue growth (14 per cent at CER)
- Adjusted EBITA[1,2] was SEK 4,124 M (3,764), an increase of 10 per cent, with an EBITA margin[1] of 39 per cent (40)
- EPS of SEK 5.92 (6.66) and adjusted EPS[1,2,3] of SEK 5.92 (6.98), both before dilution
- Elocta sales were SEK 3,514 M (3,274) and Alprolix sales were SEK 1,286 M (1,059)
- Kineret sales amounted to SEK 1,493 M (1,175)
- Gamifant sales amounted to SEK 346 M (361)
- Cash flow from operations of SEK 4,356 M (2,658)

Significant events after the reporting period

- Topline results from the phase 3 study of avatrombopag, in solid tumour cancer patients with CIT were announced

Total revenue Q3, SEK M

2,970

EBITA margin[1] Q3, SEK M

31%

Haematology Q3, growth at CER

16%

Immunology Q3, growth at CER

11%

Financial summary

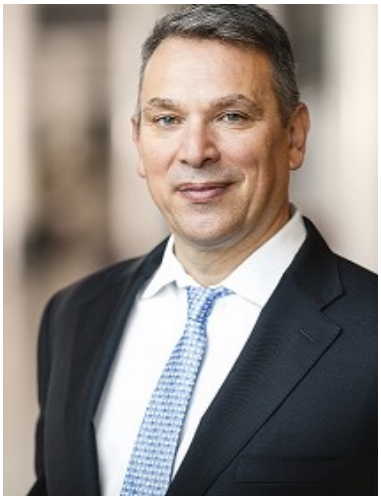
Amounts in SEK M	Q3 2020	Q3 2019	Change	Jan-Sep 2020	Jan-Sep 2019	Change	Full-year 2019
Total revenue	2,970	2,930	1%	10,680	9,358	14%	14,248
Gross profit	2,339	2,173	8%	8,318	7,080	17%	10,913
Gross margin[1]	79%	74%		78%	76%		77%
EBITA[1]	933	1,099	-15%	4,124	3,645	13%	5,933
EBITA adjusted[1,2]	933	1,099	-15%	4,124	3,764	10%	6,145
EBITA margin[1]	31%	38%		39%	39%		42%
EBITA margin adjusted[1,2]	31%	38%		39%	40%		43%
Profit for the period	278	542	-49%	1,743	1,944	-10%	3,304
Earnings per share, SEK	0.94	1.84	-49%	5.92	6.66	-11%	11.29
Earnings per share, SEK adjusted[1,2,3]	0.94	1.84	-49%	5.92	6.98	-15%	11.89

[1]Alternative Performance Measures (APMs), see page 14 for further information.

[2]EBITA Full-year 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 Full-year 2019 excluding impairment of intangible assets of SEK 18 M related to restructuring in Q2.

CEO statement



Q3 has been a productive period for us with the closing of the licensing agreement with Selecta for SEL-212, advancements in our pipeline, participation in virtual congresses and expansion of our footprint into Asia. Total revenue for the third quarter 2020 was SEK 2,970 M and EBITA was SEK 933 M. Despite the continuing COVID-19 challenge, our commercial teams have been able to make progress, generating patient growth even if sales numbers were still negatively impacted by the pandemic.

Haematology – continued positive trend for Doptelet in ITP

Elocta sales for the quarter were SEK 1,115 M (1,156), down 1 per cent (CER), with sales growth January-September of 7 per cent. The number of patients for the year to date was up 15 per cent on 2019. However the volume reduction per patient as a result of COVID-19 affected growth, as did a lack of face-to-face interaction and an increase in competition. Preparations for the launch of Elocta (under the name Eloctate®) in Russia are ongoing, and we plan to submit the pricing and reimbursement dossier to Russian authorities before the end of the year.

Alprolix continued to perform well with sales reaching SEK 435 M (341), up 33 per cent (CER) on Q3 2019. This strong result is evidence of patients and clinicians experiencing predictable bleed control.

Despite a challenging launch climate, Doptelet continues to perform well with quarter-on-quarter growth of 58 per cent CER), driven by the ITP indication. Market share in ITP continues to grow, with Doptelet's adult ITP market share reaching 5 per cent. Sales in Q3 reached SEK 145 M. Leading indicators, such as number of doctors prescribing Doptelet for the first time, and shipments to pharmacies indicate a continuous underlying trend of growth.

Immunology – strong Kineret growth

Kineret continued its strong growth trajectory with sales reaching SEK 463 M (409), an increase of 20 per cent (CER), reflecting strong demand. While field access to healthcare professionals (HCP) continues to be largely virtual, we saw an increase in HCP interactions in Q3 compared with Q2.

Gamifant sales reached SEK 110 M (67), an increase of 83 per cent (CER) for the quarter versus previous year. There is continued progress in patient uptake. However, the financial impact is not as favourable due to a lower price in 2020 as well as lower consumption per patient due to lower bodyweight and treatment duration.

We are just in the beginning of the respiratory syncytial virus (RSV) season and the team has made significant efforts during the off-season to build a strong foundation for Synagis in a challenging environment. Sales for the year to date are up 34 per cent, while sales for the quarter were SEK 46 M (124), down due to higher levels of inventory stocking during Q3 2019. We see strong underlying demand while the overall virology is uncertain.

R&D – new leadership strengthening focus

It is a great pleasure to welcome Ravi Rao as our new Head of R&D in September. Ravi will spearhead the development of our R&D strategy and his experience, particularly in the broader area of Immunology, will help us to progress a variety of projects.

During Q3 we announced the phase 2 results of the COMPARE study of SEL-212, the newly in-licensed project for the treatment of chronic refractory gout. During this challenging pandemic, this was one of very few studies that could be completed. Even if the primary endpoint was not met, our conviction regarding SEL-212 was strengthened by the endpoints in serum uric acid removal and tophi patients. We are very positive about the progress in the ongoing phase 3 programme with SEL-212.

The read-out from the phase 3 study of avatrombopag for chemotherapy-induced thrombocytopenia (CIT) was announced in October and the primary endpoint unfortunately was not met. We are obviously disappointed by the outcome of the study. Even though the product demonstrated efficacy levels in line with our expectations, the high level of efficacy in the placebo group was surprising for us and for the external specialists consulted. We continue to believe in the efficacy of avatrombopag in this indication based on the entire body of evidence and will perform further investigations to clarify the underlying reasons for the results. In the meantime, we continue to drive the penetration of Doptelet in CLD and ITP in the US, Europe and other markets, with exciting launches in Europe over the coming 12 months. Given the potential of the product in its approved indications our peak sales estimate remains above USD 500 M.

Expanding international footprint

Our expansion into Asia will be a significant long-term promise for Sobi moving forward. There is a huge unmet medical need within rare diseases in China, Japan and other countries outside Sobi's traditional territories. We are working hard to make our treatments available to patients in these parts of the world. Moving into these markets is an opportunity for products such as Gamifant, Doptelet, Kineret and Orfadin.

These have indeed been challenging times, and they still are, but I feel confident in my team and in our product portfolio. I am very proud to work with such talented people staying focused and doing their outmost to ensure that our treatments reach all of our patients.

Solna, Sweden, 22 October 2020

Guido Oelkers, President & CEO

Business Review Q3

Haematology

Sobi had a strong presence at the ISTH virtual congress in July, with a satellite symposium and two product theatres focused on Elocta and Alprolix.

The Sobi Haemophilia Virtual Meeting was held successfully in September, with 250 healthcare professionals (HCP) across Europe and the Middle East registered and top key opinion leaders taking part as speakers.

Sales of Elocta and Alprolix continued to be impacted by COVID-19, with levels of factor use lower and significant numbers of surgical procedures being cancelled. Italy is one market where the pandemic has created a lot of uncertainty, with a subsequent negative impact on sales. Overall, however, we continued to see patient growth for both products.

In Germany, new regulations for distribution channels became effective on 1 September. As a result of this price cuts are expected however it also means new market opportunities since plasma based products will not be offering the same advantages to the treatment centres.

The COVID-19 situation has slowed launches of new products in general in almost every country, although we are starting to see an impact from non-factor products in certain markets. Standard half-life products comprise the segment where Sobi sees the greatest opportunity to gain market share. Pricing erosion is mainly being seen in tender markets, either through mandatory price cuts or individual agreements.

In Russia, preparations for the launch of Elocta (marketed as Elocate in Russia) are ongoing and a dossier for pricing and reimbursement is planned for submission to the authorities before the end of 2020.

We continue to see progress for Doptelet in the US even though the launch remains challenging due to the pandemic. In Europe we are planning for launch in the CLD indication during Q4; preparations for the ITP indication are ongoing pending expected approval by the European Commission in 2021.

Immunology

The in-licensing agreement for SEL-212, a unique phase 3-ready therapy for the treatment of chronic refractory gout, announced in June was completed. Sobi will take on development, regulatory and commercial activities in all markets outside China while Selecta will run the phase 3 studies on behalf of Sobi.

We have seen strong underlying demand for Kineret, as well as some demand in the US related to COVID-19, even if this demand decreased in Q3 compared to Q2. The number of patients benefiting from Kineret continued to grow. Most interactions with healthcare professionals continue to be virtual, but an increase in physical HCP interactions was seen in Q3.

The launch of Gamifant continues in the US and important disease awareness activities continue to raise awareness of primary HLH. There was continued progress in patient uptake, but after Sobi's price reduction in 2020, together with lower consumption by patients due to lower bodyweight and treatment duration, sales were negatively impacted.

RSV season is just beginning, and as usual, sales were limited during Q3. Higher stocking levels in 2019 meant that sales this year were down quarter on quarter. A new enhanced distribution system is operating well as we begin the RSV season. Significant efforts have been made during the off-season to put measures in place to mitigate the impact of COVID-19 but there is still some uncertainty due to the current healthcare environment.

Specialty Care

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for Orfadin® (nitisinone) for the treatment of adult patients with alkaptonuria (AKU), the first described human genetic disease. The opinion is now referred to the European Commission for a decision.

AKU is 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 due to the disease characteristics, it is an extremely rare genetic condition, which can cause significant damage to the bones, cartilage and tissue which eventually leads to joint disease. The medical need is high as there is currently no pharmacological treatment available.

A long-term follow-up study of Orfadin, the OPAL study, in patients with hereditary tyrosinemia type 1 (HT-1) was completed. The OPAL study is a non-interventional post-authorisation safety study to evaluate long-term safety of Orfadin treatment in hereditary tyrosinemia type 1 (HT-1) patients in standard clinical care. The results of the study confirm the long-term safety profile of Orfadin. Over the 15-year study follow-up period, Orfadin treatment in HT-1 patients with a mean treatment duration of 12.0 years (range 0.7–28.4 years) was safe and well tolerated with sustained efficacy. Further, the results of the study add significant value by demonstrating that optimal management of HT-1 patients is maintained over life.

R&D pipeline

Sobi has been granted a re-examination of emapalumab in Europe following a negative opinion by CHMP recommending a refusal of the marketing authorisation for emapalumab for the treatment of primary HLH in children under 18 years of age in Europe. Given the significant unmet medical need that emapalumab addresses in patients with primary HLH, and the lack of any approved treatments in Europe, Sobi has requested a re-examination and the CHMP has agreed to conduct one. The decision is expected in November.

Top-line data from the phase 2 COMPARE study with SEL-212 was announced. The study compared the efficacy of SEL-212 to pegloticase (Krystexxa®), the currently approved uricase in the US, for the treatment of chronic refractory gout. All data was consistent with a stronger performance of SEL-212 versus pegloticase. Although the primary endpoint was not met, the underlying data is positive and supports the commencement of the phase 3 DISSOLVE programme.

The first patient was randomised in the first phase 3 study with SEL-212. The phase 3 clinical programme consists of two double-blind, placebo-controlled studies of SEL-212: DISSOLVE I and II.

Business Review Q3 cont.

Top-line data from the phase 3 clinical programme is expected in the second half of 2022. The biologics licence application (BLA) filing to the US FDA for SEL-212 is expected in Q1 2023. On commencement of the phase 3 programme, Sobi will pay a milestone of USD 5 million to Selecta.

The New England Journal of Medicine published positive final results from a phase 1/2a study of BIVV001 in people with severe haemophilia A. BIVV001 is the first investigational factor VIII therapy independent of von Willebrand factor and has the potential to transform replacement therapy for people with haemophilia A. Results from the phase 1/2a study showed that a single dose of BIVV001 achieved high sustained factor activity and a three- to four -fold increase in half-life when compared with conventional factor VIII replacement therapies.

A study assessing the effect of blocking IL-1 or IFN-γ with anakinra and emapalumab respectively in patients with hyperinflammation and respiratory complications following SARS-Cov-2 infection is ongoing. While more sites have been added in Italy, enrolment has been affected by a lower rate of intensive care patients, additional sites have been opened in the US to add further enrolment capacity. There are many patients being treated with anakinra for cytokine storm syndrome in numerous investigator-sponsored studies all over Europe and some very encouraging results have been published in prestigious medical publications.

Sustainability

Environment

Emission limits were sharpened in the corporate car policy and the price base amount increased in Sweden to include electric cars.

Social

Two employee surveys were conducted, a smaller survey looking at the COVID situation and a larger Global Engagement Survey.

Sobi in the US presented a focused Diversity, Equity & Inclusion workstream including a Diversity and Inclusion Employee Resource Group (ERG), Team Inclusion and Belonging Discussion Guide for all managers, and an Unconscious Bias training for all employees.

Governance

A renewed Code of Conduct was approved by the Board of Directors. The Code of Conduct has been fully digitalised and is externally available.

Sobi launched the Responsible Sourcing Programme, including the introduction of a Partner Code of Conduct and sustainability screening, in January 2020: 57 per cent of Sobi's current top 100 partners have been screened for sustainability criteria.

Corporate

Ravi Rao was appointed Head of Research & Development and Chief Medical Officer, joining Sobi on 1 September. He replaces Milan Zdravkovic who left the company to pursue other opportunities. Ravi's vast experience from early development through to launch will be instrumental for Sobi as we enter the next phase of our transformational journey. Amy Pott, Head of Sobi North America, left Sobi during the third quarter.

Financial Review

Total revenue

Total revenue for the quarter amounted to SEK 2,970 M (2,930), up 1 per cent compared with the third quarter 2019 (6 per cent at CER).

Revenues for the period January—September were SEK 10,680 M (9,358), an increase of 14 per cent (14 per cent at CER). Organic growth amounted to 11 per cent at CER.

Revenue by business area

Haematology

Haematology revenue reached SEK 2,147 M (1,932) for the quarter, an increase of 11 per cent (16 per cent at CER) and increased by 17 per cent to SEK 6,578 M (5,613) for the period January—September.

Elocta sales were SEK 1,115 M (1,156) for the quarter, down 4 per cent (-1 per cent at CER). There was continued patient growth, however sales continued to be negatively impacted by the ongoing COVID-19 pandemic, which resulted in overall lower consumption per patient. In Q3 2019, sales were positively impacted by SEK 35 M related to pharmaceutical taxes in France.

Elocta sales for the period January-September were SEK 3,514 M (3,274), a growth of 7 per cent (7 per cent at CER).

Alprolix sales were SEK 435 M (341) for the quarter, up 28 per cent (33 per cent at CER). Sales growth was driven by underlying patient growth although negatively impacted by reduced consumption per patient due to the ongoing pandemic.

Alprolix sales for January-September were SEK 1,286 M (1,059), growth of 21 per cent (22 per cent at CER).

Doptelet revenue reached SEK 145 M (–) for the quarter. Doptelet revenue for the first nine months was SEK 396 M (–) including a milestone revenue related to the approval of the CLD indication in China of SEK 87 M in the second quarter.

Estimated royalty revenue was SEK 314 M (342) for the quarter. January—September revenue amounted to SEK 985 M (1,021).

ReFacto manufacturing revenue totalled SEK 138 M (94) for the quarter, up 46 per cent driven by ordering patterns. January—September manufacturing revenue totalled SEK 398 M (260), up 53 per cent.

Immunology

Immunology revenue for the quarter was SEK 619 M (600) an increase of 3 percent (11 per cent at CER). January—September revenue was SEK 3,133 M (2,473), up 27 per cent (25 per cent at CER).

Kineret sales for the quarter were SEK 463 M (409), an increase of 13 per cent (20 per cent at CER). Kineret continues to perform well with double-digit growth. Growth is mainly driven by increased underlying demand across all regions. Kineret sales for the first nine months were SEK 1,493 M (1,175), an increase of 27 per cent (27 per cent at CER).

Revenue by business area

Amounts in SEK M	Q3 2020	Q3 2019	Change	Change at CER[1]	Jan-Sep 2020	Jan-Sep 2019	Change	Change at CER[1]	Full-year 2019
Haematology									
Elocta	1,115	1,156	-4%	-1%	3,514	3,274	7%	7%	4,508
Alprolix	435	341	28%	33%	1,286	1,059	21%	22%	1,463
Royalty	314	342	-8%	0%	985	1,021	-4%	-4%	1,373
Doptelet	145	–	N/A	N/A	396	–	N/A	N/A	34
Manufacturing revenue	138	94	46%	46%	398	260	53%	53%	376
Total	**2,147**	**1,932**	**11%**	**16%**	**6,578**	**5,613**	**17%**	**17%**	**7,755**
Immunology									
Kineret	463	409	13%	20%	1,493	1,175	27%	27%	1,571
Synagis	46	124	-63%	-61%	1,294	938	38%	34%	2,594
Gamifant	110	67	64%	83%	346	361	-4%	-4%	542
Total	**619**	**600**	**3%**	**11%**	**3,133**	**2,473**	**27%**	**25%**	**4,706**
Specialty Care									
Specialty Care	204	398	-49%	-45%	968	1,271	-24%	-24%	1,787
Total	**204**	**398**	**-49%**	**-45%**	**968**	**1,271**	**-24%**	**-24%**	**1,787**
Total revenue	**2,970**	**2,930**	**1%**	**6%**	**10,680**	**9,358**	**14%**	**14%**	**14,248**

[1]Constant exchange rates.

Gamifant sales for the quarter amounted to SEK 110 M (67) an increase of 64 per cent (83 per cent at CER). The number of patients continued to grow, however sales were slightly offset by a lower price as well as lower consumption and treatment duration. Year-to-date Gamifant sales were SEK 346 M (361) a decrease of 4 per cent (-4 per cent at CER).

Synagis sales for the quarter were SEK 46 M (124), a decrease of 63 per cent (-61 per cent at CER), explained by the timing of wholesalers´ pre-season inventory build-up. Sales of Synagis for first nine months were SEK 1,294 M (SEK 938 M for the period 23 January-30 September 2019).

Specialty Care

Specialty Care revenue for the quarter was SEK 204 M (398), a decrease of 49 per cent (-45 per cent at CER). January—September sales were SEK 968 M (1,271), a decrease of 24 per cent (-24 per cent at CER).

Orfadin sales for the quarter were SEK 155 M (193), a decrease of 19 per cent (-14 per cent at CER). The decrease is mainly explained by generic competition and associated price erosion. Sales for the period January—September were SEK 519 M (596), a decrease of 13 per cent (-13 per cent at CER).

Third quarter sales for other Specialty Care products amounted to SEK 49 M (205), a decrease of 76 per cent (-75 per cent at CER) related to the discontinuation of products. Year-to-date sales were SEK 449 M (675), a decrease of 33 per cent (-34 per cent at CER).

Gross profit

Gross profit for the quarter was SEK 2,339 M (2,173), representing a gross margin of 79 per cent (74). Nine-month gross profit was SEK 8,318 M (7,080) representing a gross margin of 78 per cent (76). 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 947 (792) for the quarter and SEK 3,007 M (2,356) for the period January—September. The increase is mainly driven by the consolidation of Dova, launch preparations for Doptelet as well as geographic expansion in Japan and China. This was partially offset by a lower activity level due to COVID-19.

Research and development expenses amounted to SEK 405 M (293) for the quarter and to SEK 1,108 M (1,138) for the first nine months. The increase reflects increased spending related to programmes for emapalumab, avatrombopag and SEL-212.

Operating profit

EBITA for the quarter was SEK 933 M (1,099) corresponding to a margin of 31 per cent (38). Year-to-date EBITA amounted to SEK 4,124 M (3,645). Adjusted EBITA for the period January—September was SEK 4,124 M (3,764).

Amortisation and write-downs of intangible assets for the quarter amounted to SEK 469 M (345) and SEK 1,422 M (986) for the first nine months, including write-downs of SEK—M (18) . The increase relates mainly to product rights acquired during 2019.

EBIT for the quarter decreased to SEK 464 M (754). EBIT for the nine months increased to SEK 2,702 M (2,659).

Operating profit/loss

Amounts in SEK M	Q3 2020	Q3 2019	Jan-Sep 2020	Jan-Sep 2019	Full-year 2019
Total revenue	2,970	2,930	10,680	9,358	14,248
Total cost of goods sold	-632	-757	-2,362	-2,278	-3,335
Gross profit	**2,339**	**2,173**	**8,318**	**7,080**	**10,913**
Gross margin	*79%*	*74%*	*78%*	*76%*	*77%*
Sales and administrative expenses before amortisation and write-downs	-947	-792	-3,007	-2,356	-3,535
Research and development expenses	-405	-293	-1,108	-1,138	-1,495
Total opex less amortisation and write-downs	**-1,351**	**-1,084**	**-4,115**	**-3,494**	**-5,029**
Other operating income/expenses	-54	10	-78	59	50
EBITA	933	1,099	4,124	3,645	5,933
Non-recurring items	–	–	–	119	211
EBITA adjusted[1]	*933*	*1,099*	*4,124*	*3,764*	*6,145*
Amortisation and write-downs related to Sales and administrative expenses	-469	-345	-1,422	-986	-1,401
EBIT	464	754	2,702	2,659	4,533

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

[1]EBITA Full-year 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 and tax

Net financial items amounted to SEK -98 M (-57) for the quarter, including exchange rate gains/losses of SEK 12 M (-3). The increase in costs compared with the previous year is mainly attributable to the additional borrowings and liabilities from the acquisitions made in 2019. Net financial items for the nine months amounted to SEK -421 M (-175), including exchange rate losses of SEK -27 M (-25).

Income tax amounted to SEK -88 M (-155) for the quarter, corresponding to an effective tax rate of 24.0 per cent (22.3), and to SEK -538 M (-540) for January—September, corresponding to an effective tax rate of 23.6 per cent (21.7). The higher effective tax rate in the quarter was mainly driven by an increased impact from higher tax jurisdictions.

Profit

Profit totalled SEK 278 M (542) for the quarter and SEK 1,743 M (1,944) for the nine months.

Cash flow

Cash flow from operations before change in working capital amounted to SEK 933 M (973) for the quarter and to SEK 3,481 M (3,371) for the nine months.

Change in working capital affected cash flow by SEK -490 M (22) for the quarter, primarily attributable to seasonal inventory build-up. Year-to-date change in working capital amounted to SEK 875 M (-713). The positive cash flow year-to-date effect was primarily attributable to collection of receivables following high sales at the end of 2019 partially offset by increased inventories.

Cash flow from investing activities for the quarter was SEK -1,289 M (-4,047) including cash flow impact from SEL-212 of SEK -933 M and the repayment of the remaining liability attributable to Alprolix of SEK -315 M. Year-to-date cash flow amounted to SEK -1,436 M (-12,948). The amount from 2019 reflects the investment in Synagis.

Cash flow from financing activities amounted to SEK 802 M (2,931) for the quarter and SEK -3,495 M (8,352) for the period January—September. The increased borrowings during the quarter relate to the financing of SEL-212.

Cash

At the end of the quarter, cash and cash equivalents amounted to SEK 164 M, compared with SEK 737 M at 31 Dec 2019. The decrease is mainly attributable to repayments of borrowings. At 30 Sep 2020 undrawn committed credit facilities totalled SEK 6,513 M (3,959) and drawn totalled SEK 12,985 M (16,243).

Net debt

Sobi ended the quarter with a net debt of SEK 12,703 M compared with SEK 15,404 M at 31 Dec 2019. Net debt decreased mainly due to a strong operating cash flow during the period.

Equity

At 30 Sep 2020, consolidated shareholders' equity was SEK 18,784 M compared with SEK 16,930 M at 31 Dec 2019.

Personnel

At 30 Sep 2020, the number of full-time equivalents was 1,471 (1,335 at 31 Dec 2019).

Parent Company

In the third quarter of 2020, net sales for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 2,951 M (2,700), of which Group companies accounted for SEK 1,982 M (1,558). Nine-month sales amounted to SEK 10,403 M (8,739) of which SEK 5,796 M (4,755) referred to sales to Group companies.

Profit for the period amounted to SEK 1,477 M (1,082) for the quarter and to SEK 4,178 M (3,502) for the nine months.

Investing activities affecting cash flow amounted to SEK 1,296 M (41) for the quarter and SEK 1,412 M (91) for the nine months, whereof SEK 933 M refers to SEL-212.

Other information

Significant events after the reporting period

The results from the phase 3 data of avatrombopag for the treatment of CIT were announced. Avatrombopag increased platelet counts relative to placebo as expected; however, 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. Sobi is investigating the result of the study, the path forward in this indication and any potential effects on the consolidated financial statements.

Financial outlook 2020[1]—Updated

Revenue for the full-year 2020 is expected to be in the range of SEK 15,000—15,500 M.

EBITA is expected to be in the range of SEK 5,700—6,200 M.

[1]Assuming exchange rates as of September 30 remain stable during the fourth quarter of 2020.

Solna, Sweden, 22 October 2020

Guido Oelkers, CEO and President

Financial calendar

Q4 & FY 2020 report	18 February 2021
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.

This information is information that Swedish Orphan Biovitrum AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of Linda Holmström, Corporate Communication and Investor Relations, at 08:00 CET on 22 October 2020.

Auditor's review report

Swedish Orphan Biovitrum AB (publ), corp. reg. no. 556038-9321

Introduction

We have reviewed the condensed interim report for Swedish Orphan Biovitrum AB (publ) as of 30 September 2020, and for the nine-month period then ended. The Board of Directors and the Chief Executive Officer are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 *Review of Interim Financial Statements Performed by the Independent Auditor of the Entity.* A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden.

The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act regarding the Group, and in accordance with the Swedish Annual Accounts Act regarding the Parent Company.

Stockholm, 22 October 2020

Ernst & Young AB

Jonatan Hansson

Authorised Public Accountant

Financial statements – Group

Consolidated Statement of comprehensive income

Amounts in SEK M	Q3 2020	Q3 2019	Jan-Sep 2020	Jan-Sep 2019	Full-Year 2019
Total revenue[1]	2,970	2,930	10,680	9,358	14,248
Total cost of goods sold	-632	-757	-2,362	-2,278	-3,335
Gross profit	**2,339**	**2,173**	**8,318**	**7,080**	**10,913**
Sales and administrative expenses[2]	-1,416	-1,137	-4,429	-3,342	-4,935
Research and development expenses	-405	-293	-1,108	-1,138	-1,495
Other operating income/expenses	-54	10	-78	59	50
Operating profit	**464**	**754**	**2,702**	**2,659**	**4,533**
Financial income/expenses[3]	-98	-57	-421	-175	-286
Profit before tax	**366**	**697**	**2,281**	**2,484**	**4,247**
Income tax expenses	-88	-155	-538	-540	-942
Profit for the period	**278**	**542**	**1,743**	**1,944**	**3,304**
Profit for the period is attributable to Parent Company shareholders					
Other comprehensive income					
Items that will not be reclassified to profit/loss					
Remeasurements of post-employment benefit obligations	-5	0	1	3	-4
Items that may be reclassified subsequently to profit/loss					
Translation difference	-133	221	17	250	-97
Hedge of net investment (net of tax)	10	–	48	–	2
Cash flow hedges (net of tax)	15	-73	-13	-120	42
Comprehensive income for the period	**165**	**690**	**1,796**	**2,078**	**3,247**
Comprehensive income for the period is attributable to Parent Company shareholders					
Earnings per share, SEK	0.94	1.84	5.92	6.66	11.29
Earnings per share, SEK, adjusted[4]	0.94	1.84	5.92	6.98	11.89
Earnings per share after dilution, SEK	0.93	1.83	5.87	6.62	11.22
Earnings per share after dilution, SEK, adjusted[4]	0.93	1.83	5.87	6.93	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. -469 -345 -1,422 -986 -1,401

[3]Including financing costs -8 -5 -22 -12 -18

[4]Alternative Performance Measures (APMs), see page 14 for further information.

Consolidated Balance sheet

Amounts in SEK M	Sep 2020	Dec 2019	Sep 2019
ASSETS			
Non-current assets			
Intangible assets[1]	37,240	37,412	26,377
Tangible assets	564	518	508
Deferred tax assets	698	354	393
Financial assets	170	50	51
Total non-current assets	38,672	38,335	27,329
Current assets			
Inventories	2,542	1,772	1,623
Accounts receivable	2,136	3,736	1,983
Other receivables, non-interest bearing	620	1,078	783
Cash and cash equivalents	164	737	1,077
Total current assets	5,462	7,323	5,466
Total assets	44,134	45,658	32,794
EQUITY AND LIABILITIES			
Shareholders´ equity	18,784	16,930	15,686
Non-current liabilities			
Borrowings	10,759	16,141	8,683
Lease liabilities	336	320	296
Deferred tax liabilities	3,476	3,726	1,779
Other liabilities, non-interest bearing	3,775	2,800	2,189
Total non-current liabilities	18,346	22,987	12,947
Current liabilities			
Accounts payable	414	681	347
Borrowings	2,108	–	–
Lease liabilities	111	99	90
Other liabilities, non-interest bearing	4,370	4,961	3,724
Total current liabilities	7,004	5,741	4,161
Total equity and liabilities	44,134	45,658	32,794

[1]Including goodwill of SEK 6,256 M (6,678 at 31 Dec 2019), see Note 5 for more information.

Changes in equity

Amounts in SEK M	Jan-Sep 2020	Full-year 2019	Jan-Sep 2019
Opening balance	16,930	9,040	9,040
Adjusted opening balance for post-employment benefits from previous years[1]	-38	–	–
Share-based compensation to employees	85	80	56
Share-based compensation to employees tax effect	12	50	–
Issue of shares	–	4,513	4,513
Comprehensive income for the period[2]	1,796	3,247	2,078
Equity at end of period	18,784	16,930	15,686

[1]Refers to post employment-benefits, mainly in Switzerland not previously included at Dec 2019. Comparative periods have not been adjusted, the effect on the statement of comprehensive income for comparative periods would not been material.
[2]Whereof changes in cash flow hedges (net of tax) amounted to SEK -13 M (2 at 31 Dec 2019) and net investment hedges (net of tax) amounted to SEK 48 M (42 at 31 Dec 2019).

Consolidated Cash flow statement

Amounts in SEK M	Q3 2020	Q3 2019	Jan-Sep 2020	Jan-Sep 2019	Full-year 2019
Profit for the period	278	542	1,743	1,944	3,304
Adjustment for non-cash items[1]	655	431	1,738	1,427	1,995
Cash flow from operations before change in working capital	**933**	**973**	**3,481**	**3,371**	**5,300**
Change in working capital	-490	22	875	-713	-1,666
Cash flow from operations	**443**	**995**	**4,356**	**2,658**	**3,634**
Acquisition of business, net of cash[2]	–	-4,911	–	-4,911	-12,880
Investment in intangible assets[3, 4]	-1,164	-41	-1,288	-8,951	-9,709
Investment in tangible assets[3]	-5	-10	-28	-27	-37
Investment in financial assets[3]	-120	–	-120	–	–
Divestment of intangible assets[5]	–	914	–	941	941
Cash flow from investing activities	**-1,289**	**-4,047**	**-1,436**	**-12,948**	**-21,686**
Borrowings - Raising/Amortisation	831	2,956	-3,407	8,420	15,875
Payment of lease liabilities	-29	-24	-88	-68	-94
Cash flow from financing activities	**802**	**2,931**	**-3,495**	**8,352**	**15,780**
Change in cash and cash equivalents	**-43**	**-121**	**-575**	**-1,938**	**-2,271**
Cash and cash equivalents at the beginning of the period	213	1,189	737	2,999	2,999
Translation difference in cash flow and cash and cash equivalents	-6	9	1	16	9
Cash and cash equivalents at the end of the period	**164**	**1,077**	**164**	**1,077**	**737**
[1] Adjustment for non-cash items:					
Depreciation of tangible assets	32	34	104	131	188
Amortisation and write-downs of intangible assets	469	345	1,422	986	1,401
Deferred tax	-124	86	-256	303	411
Other	278	-34	468	8	-4
Non-cash items	655	431	1,738	1,427	1,995

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

[3] Whereof SEK 813 M of intangible assets and SEK 120 M of financial assets relates to the acquisition of SEL-212.

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

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

Key ratios and other information

Amounts in SEK M	Q3 2020	Q3 2019	Jan-Sep 2020	Jan-Sep 2019	Full-year 2019
Profit measures					
Gross profit	2,339	2,173	8,318	7,080	10,913
EBITDA[1]	971	1,133	4,228	3,776	6,121
EBITA[1]	933	1,099	4,124	3,645	5,933
EBITA adjusted[1,2]	933	1,099	4,124	3,764	6,145
EBIT (operating profit)	464	753	2,702	2,659	4,533
Profit/loss	278	542	1,743	1,944	3,304
Per share data (SEK)					
Earnings per share	0.94	1.84	5.92	6.66	11.29
Earnings per share, adjusted[2,3]	0.94	1.84	5.92	6.98	11.89
Earnings per share after dilution	0.93	1.83	5.87	6.62	11.22
Earnings per share after dilution, adjusted[2,3]	0.93	1.83	5.87	6.93	11.81
Shareholders' equity per share[1]	61,8	52,3	61,8	52,3	56,4
Shareholders' equity per share after dilution[1]	61,3	52,0	61,3	52,0	56,1
Other information					
Gross margin[1]	79%	74%	78%	76%	77%
EBITA margin[1]	31%	38%	39%	39%	42%
EBITA margin adjusted[1,2]	31%	38%	39%	40%	43%
Equity ratio[1]	43%	48%	43%	48%	37%
Net cash (-)/debt (+)[1]	12,703	7,606	12,703	7,606	15,404
Number of ordinary shares[4]	303,815,511	299,977,839	303,815,511	299,977,839	299,977,839
Number of ordinary shares (in treasury)	8,918,672	5,886,356	8,918,672	5,886,356	5,678,099
Number of ordinary shares (excluding shares in treasury)	294,896,839	294,091,483	294,896,839	294,091,483	294,299,740
Number of ordinary shares after dilution	306,369,328	301,785,687	306,369,328	301,785,687	301,857,247
Average number of ordinary shares (excluding shares in treasury)	294,896,839	294,278,857	294,577,987	292,116,382	292,649,020
Average number of ordinary shares after dilution (excluding shares in treasury)	297,450,656	295,899,331	297,131,804	293,924,229	294,528,428

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

[2]EBITA Full-year 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 Full-year 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

	Q3 2020	Q3 2019	Jan-Sep 2020	Jan-Sep 2019	Full-year 2019
Total revenue	2,970	2,930	10,680	9,358	14,248
Total cost of goods sold	-632	-757	-2,362	-2,278	-3,335
Gross profit	**2,339**	**2,173**	**8,318**	**7,080**	**10,913**
Gross margin	**79%**	**74%**	**78%**	**76%**	**77%**

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

Total revenue	2,970	2,930	10,680	9,358	14,248
Total revenue adjusted for Synagis[1]	2,970	2,930	10,426	9,358	14,248
Organic growth	1%	21%	11%	28%	27%
Organic growth, CER	**6%**	**17%**	**11%**	**22%**	**21%**

[1]Jan-Sept 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)	464	754	2,702	2,659	4,533
Plus amortisation and write-downs of intangible assets	469	345	1,422	986	1,401
EBITA	**933**	**1,099**	**4,124**	**3,645**	**5,933**
Plus depreciations of tangible assets	38	34	104	131	188
EBITDA	**971**	**1,133**	**4,228**	**3,776**	**6,121**
EBITA margin	**31%**	**38%**	**39%**	**39%**	**42%**
Non-recurring items	–	–	–	119	211
EBITA adjusted	**933**	**1,099**	**4,124**	**3,764**	**6,145**
EBITA margin adjusted	**31%**	**38%**	**39%**	**40%**	**43%**

EBITA - Earnings before interest, tax and amortisation
EBITDA - Earnings before interest, tax, depreciation and amortisation
EBITA margin, % - EBITA as a percentage of total revenue
Non-recurring items Jan-Sep and Full-year 2019 - impact from divestment of SOBI005 in Q1, restructuring costs in Q2 and transaction costs related to the acquisition of Dova Pharmaceuticals 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.

	Q3 2020	Q3 2019	Jan-Sep 2020	Jan-Sep 2019	Full-year 2019
Profit for the period	278	542	1,743	1,944	3,304
Impact of divestment of SOBI005, restructuring costs and transaction costs related to the acquisition of Dova Pharmaceuticals in 2019, after tax	–	–	–	94	174
Profit for the period, adjusted	278	542	1,743	2,038	3,479
Average number of ordinary shares (excluding shares in treasury)	294,896,839	294,278,857	294,577,987	292,116,382	292,649,020
Average number of ordinary shares after dilution (excluding shares in treasury)	297,450,656	295,899,331	297,131,804	293,924,229	294,528,428
EPS, SEK adjusted	**0.94**	**1.84**	**5.92**	**6.98**	**11.89**
EPS after dilution, SEK adjusted	**0.93**	**1.83**	**5.87**	**6.93**	**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	12,867	8,683	12,867	8,683	16,141
Cash and cash equivalents	164	1,077	164	1,077	737
Net debt (+)/Net cash (-)	**12,703**	**7,606**	**12,703**	**7,606**	**15,404**

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

Shareholders' equity	18,784	15,686	18,784	15,686	16,930
Total assets	44,134	32,794	44,134	32,794	45,658
Equity ratio	**43%**	**48%**	**43%**	**48%**	**37%**
Number of ordinary shares	303,815,511	299,977,839	303,815,511	299,977,839	299,977,839
Number of ordinary shares after dilution	306,369,328	301,785,687	306,369,328	301,785,687	301,857,247
Equity per share, SEK	**61.8**	**52.3**	**61.8**	**52.3**	**56.4**
Equity per share after dilution, SEK	**61.3**	**52.0**	**61.3**	**52.0**	**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	Q3 2020	Q3 2019	Jan-Sep 2020	Jan-Sep 2019	Full-year 2019
Total revenue	2,951	2,700	10,403	8,739	12,991
Total cost of goods sold	-626	-716	-2,371	-2,175	-3,177
Gross profit	**2,325**	**1,984**	**8,032**	**6,564**	**9,814**
Sales and administrative expenses[1]	-531	-657	-2,631	-2,124	-4,220
Research and development expenses	-198	-219	-606	-879	-1,110
Other operating income/expenses	13	5	20	58	52
Operating profit	**1,608**	**1,113**	**4,815**	**3,618**	**4,536**
Financial income/expenses	7	25	9	35	61
Profit after financial items	**1,616**	**1,137**	**4,824**	**3,653**	**4,597**
Appropriations	–	–	–	–	-3,166
Profit before tax	**1,616**	**1,137**	**4,824**	**3,653**	**1,431**
Income tax expenses	-138	-55	-646	-151	-313
Profit for the period	**1,477**	**1,082**	**4,178**	**3,502**	**1,118**
[1]Amortisation and write-downs of intangible assets included in Sales and administrative expenses.	-86	-75	-246	-244	-323

Statement of other comprehensive income

Amounts in SEK M	Q3 2020	Q3 2019	Jan-Sep 2020	Jan-Sep 2019	Full-year 2019
Profit for the period	1,477	1,082	4,178	3,502	1,118
Items that may be subsequently reclassified to profit/loss					
Cash flow hedge (net of tax)	20	-85	-13	-120	44
Comprehensive income for the period	**1,497**	**997**	**4,164**	**3,382**	**1,161**

Balance sheet

Amounts in SEK M	Sep 2020	Dec 2019	Sep 2019
ASSETS			
Non-current assets			
Intangible assets	7,107	5,572	6,132
Tangible assets	68	65	90
Deferred tax assets	35	22	9
Financial assets	25,254	26,113	3,523
Total non-current assets	32,464	31,772	9,754
Current assets			
Inventories	2,018	1,533	1,345
Accounts receivable	640	2,402	662
Receivables Group companies	2,868	1,286	19,940
Other receivables, non-interest bearing	484	949	680
Cash and cash equivalents	0	431	872
Total current assets	6,010	6,601	23,500
Total assets	38,474	38,373	33,254
EQUITY AND LIABILITIES			
Shareholders´ equity	17,796	13,534	15,682
Untaxed reserves	2,984	2,984	2,584
Non-current liabilities			
Borrowings	10,759	16,141	8,736
Other liabilities, non-interest bearing	2,451	1,357	2,346
Total non-current liabilities	13,210	17,499	11,082
Current liabilities			
Accounts payable	327	574	242
Borrowings	2,108	–	–
Other liabilities, non-interest bearing	2,050	3,782	3,664
Total current liabilities	4,484	4,356	3,906
Total equity and liabilities	38,474	38,373	33,254

Change in shareholders' equity

Amounts in SEK M	Jan-Sep 2020	Full-year 2019	Jan-Sep 2019
Opening balance	13,534	7,731	7,731
Share-based compensation to employees	85	80	56
Share-based compensation to employees tax effect	12	50	–
Issue of shares	–	4,513	4,513
Comprehensive income for the period[1]	4,164	1,161	3,382
Equity at end of period	17,796	13,534	15,682

[1]Whereof changes in cash flow hedges (net of tax) amounted to SEK -13 M (SEK 44 M at Dec 2019).

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-September 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 Sobis interim 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 asset is or is not a business combination.

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.

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 30 September 2020 the reported value on the balance sheet was SEK 120 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

30 September 2020, the net reported value on the balance sheet was SEK -13 M (-4 at 31 Dec 2019).

Liabilities measured at fair value are categorized within Level 3. These consist of a contingent purchase price related to the Dova acquisition, a liability to Sanofi for BIVV001, Selecta for SEL-212 and endowment insurances. At 30 September 2020 the reported value on the balance sheet was SEK 389 M (388 at Dec 2019), SEK 1,264 (1,273 at Dec 2019), SEK 977 M (- at Dec 2019) and SEK 47 M (47 at Dec 2019).

At 30 September 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 30 September the remaining provision on the balance sheet recognised under Other liabilities, non-interest bearing was SEK 33 M and the remaining part as impairment of assets.

During the second and third quarter 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 10 M which was recognised as a reduction of research and development expenses in the Statement of comprehensive income.

Note 5 – Acquisitions

Licensing agreement SEL-212

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, including an up-front license fee and shares in Selecta Biosciences, Inc. Selecta is eligible to receive potential milestone payments of up to USD 630 M, and additional royalties on net sales.

Balance sheet at acquisition date

Amounts in SEK M	
Intangible assets	1,767
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.

Note 6 – Impairment

Gamifant

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

Revenue and EBITA by segment

Amounts in SEK M Q3 2020	Haematology	Immunology	Specialty Care	Group - other	Total
Revenue	2,147	619	204	–	2,970
EBITA[1]	1,154	-139	82	-164	933
Adjusted EBITA[1,2]	1,154	-139	82	-164	933
Q3 2019	**Haematology**	**Immunology**	**Specialty Care**	**Group - other**	**Total**
Revenue	1,932	600	398	–	2,930
EBITA[1]	1,166	-77	106	-96	1,099
Adjusted EBITA[1,2]	1,166	-77	106	-96	1,099
Jan-Sep 2020	**Haematology**	**Immunology**	**Specialty Care**	**Group - other**	**Total**
Revenue	6,578	3,133	968	–	10,680
EBITA[1]	3,397	637	505	-415	4,124
Adjusted EBITA[1,2]	3,397	637	505	-415	4,124
Jan-Sep 2019	**Haematology**	**Immunology**	**Specialty Care**	**Group - other**	**Total**
Revenue	5,613	2,473	1,271	–	9,358
EBITA[1]	3,366	309	368	-398	3,645
Adjusted EBITA[1,2]	3,366	309	368	-279	3,764
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 14 for further information.
[2]EBITA Full-year 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.
BIVV001	A novel, investigational factor VIII therapy designed to extend protection from bleeds with prophylaxis dosing of once weekly or longer for people with haemophilia A. Builds on the Fc fusion technology by adding a region of von Willebrand factor and XTEN polypeptides to potentially extend its time in circulation.
CER	Constant exchange rates.
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.
COVID-19	The infectious disease caused by the most recently discovered coronavirus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019.
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.
Gamifant (emapalumab)	An anti-interferon-gamma (IFN-γ) monoclonal antibody (mAb), approved by the FDA and currently under EMA review for the treatment of primary haemophagocytic lymphohistiocytosis (pHLH), a life-threatening syndrome of immune activation.
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.

Definitions and Glossary

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.
HCP	Health Care Professional
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.
PPA	Purchase Price Allocation.
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 North Africa. In 2019, Sobi's revenues amounted to SEK 14.2 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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