Q3
2019 report

Continued strong double-digit growth

July—September

- Total revenue of SEK 2,930 M (2,315), 27 per cent revenue growth in the quarter compared with Q3 2018 (22 per cent at constant exchange rates (CER))
- EBITA[1] was SEK 1,099 M (933), an increase of 18 per cent
- Earnings per share (EPS) of SEK 1.84 (2.31)
- Net debt[1] of SEK 7,606 M at 30 September 2019 (net cash of SEK 2,999 M at 31 Dec 2018)
- Sales for Elocta® were SEK 1,156 M (873) and sales for Alprolix® were SEK 341 M (255)
- Sales for Gamifant® amounted to SEK 67 M, Synagis® sales were SEK 124 M and Kineret® sales amounted to SEK 409 M
- Announcement of the intention to acquire Dova Pharmaceuticals™ expanding scope of Haemophilia franchise into the broader area of haematology
- Entered an expanded agreement with Sanofi to exercise early opt-in for the development and commercialisation of BIVV001, a potential once-weekly dosing for people with haemophilia A, and a follow-on product to Elocta
- Completion of acquisition of emapalumab and related assets

January—September

- Total revenue of SEK 9,358 M (6,568), 42 per cent revenue growth in Jan-Sep compared with Jan-Sep 2018 (35 per cent at CER)
- Adjusted EBITA[1,2] was SEK 3,764 M (2,655), an increase of 42 per cent
- EPS of SEK 6.66 (6.77) and adjusted EPS[1,2,3] of SEK 6.98 (6.77)
- Elocta sales were SEK 3,274 M (2,316) and Alprolix sales were SEK 1,059 M (671)
- Gamifant sales amounted to SEK 361 M
- Synagis sales for the period 23 January—30 September were SEK 938 M

Total revenue Q3, SEK M

2,930

+27%

EBITA[1] Q3, SEK M

1,099

+18%

Financial summary

Amounts in SEK M	Q3 2019	Q3 2018	Change	Jan-Sep 2019	Jan-Sep 2018	Change	Full-year 2018
Total revenue	2,930	2,315	27%	9,358	6,568	42%	9,139
Gross profit	2,173	1,741	25%	7,080	4,830	47%	6,723
Gross margin[1]	74%	75%		76%	74%		74%
EBITA[1]	1,099	933	18%	3,645	2,655	37%	3,571
EBITA adjusted[1,2]	1,099	933	18%	3,764	2,655	42%	3,571
EBITA margin[1]	38%	40%		39%	40%		39%
EBITA margin adjusted[1,2]	38%	40%		40%	40%		39%
EBIT (operating profit)	754	820	-8%	2,659	2,320	15%	3,122
Profit for the period	542	623	-13%	1,944	1,823	7%	2,418
Earnings per share, SEK	1.84	2.31	-20%	6.66	6.77	-2%	8.97
Earnings per share, SEK adjusted[1,2,3]	1.84	2.31	-20%	6.98	6.77	3%	8.97

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

[2]EBITA for the nine months of 2019 excluding non-recurring items

[3]EPS for the nine months of 2019 excluding impairment of intangible assets of SEK 18 M related to restructuring in Q2 2019.

CEO statement

Our growth journey continued in the third quarter, strengthening our Haematology franchise with the announcements of the intention to acquire Dova Pharmaceuticals[1] and our decision to opt in early to the development of BIVV001. Revenue growth in the quarter was 27 per cent with revenue of SEK 2,930 M (2,315). EBITA was SEK 1,099 M, resulting in an EBITA margin of 38 per cent.

Haematology – broadening our portfolio

Our Haemophilia products continued to perform strongly, proving yet again that replacement factor therapy is the mainstay of haemophilia treatment. We continue to gain market share in our territories with sales of Elocta amounting to SEK 1,156 M (873) and sales of Alprolix of SEK 341 M (255), up 32 and 34 per cent respectively (29 and 30 per cent at CER). Both have made substantial gains during Q3, which is normally a weaker period.

Total Haematology revenue grew 25 per cent (21 per cent at CER) to SEK 1,932 M including royalties and manufacturing revenue for ReFacto.

The announced intention to acquire Dova Pharmaceuticals[1], when consolidated, is expected to broaden our portfolio in the area of Haematology. The acquisition would provide us with Doptelet® (avatrombopag), a second-generation small-molecule thrombopoietin receptor (TPO) agonist used in the treatment of thrombocytopenia by increasing platelet count. This is a great fit with our current product portfolio and has synergies with the treatment of haemophilia. Doptelet is currently approved for two indications — chronic immune thrombocytopenia (ITP) and thrombocytopenia in chronic liver disease (CLD). Avatrombopag is also being investigated in phase 3 study for chemotherapy-induced thrombocytopenia (CIT). Provided the phase 3 readout is positive, avatrombopag is expected to become the first TPO agonist indicated for CIT in the US. The pace of upcoming launches and approvals across indications and regions that Doptelet would provide will drive further growth in our Haematology franchise.

Immunology – strong performance across the board

The Immunology franchise continued to grow during the quarter with revenue reaching SEK 600 M. The Synagis team has spent much time on premarketing activities and is now up to full speed for the upcoming RSV season. We saw a build-up of normal inventories in the quarter, offsetting the destocking seen at the end of the last season earlier this year. Sales of Synagis for the quarter were SEK 124 M. Sales of Gamifant reached SEK 67 M for the quarter. Gamifant sales were negatively affected by approximately SEK 30-40 M due to inventory shifts in Q3. Sales patterns following launch of products for ultra-rare diseases may be volatile due to the limited number of patients. Gamifant's current label reflects a limited indication whereas the market potential for the product is enhanced and includes a broader HLH population and potential new indications. For example, the interim data in secondary paediatric HLH patients is looking promising. Our current focus is directed towards enabling product access and medical education and awareness of HLH.

Kineret continued to grow strongly with sales amounting to SEK 409 M (347), an increase of 18 per cent (12 per cent at CER). The launch of Kineret for Still's disease in the EMENAR region is ongoing and we see more patients benefitting from treatment with Kineret for this disease.

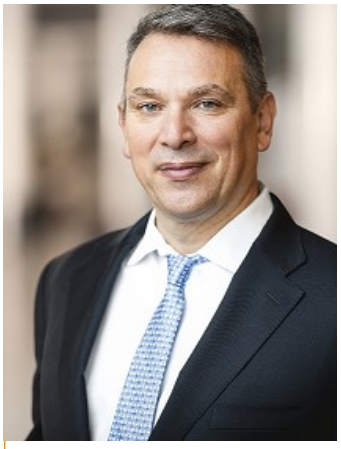
Pipeline – opt-in to BIVV001 to strengthen haematology pipeline

With the addition of BIVV001 for the treatment of haemophilia A, Sobi is well positioned to continue its growth trajectory in haemophilia into the future. BIVV001 is an investigational once-weekly haemophilia A replacement therapy with the potential to deliver a new standard of care in personalised treatment. The accelerated opt-in is driven by our conviction of the potential of this breakthrough innovation and the strength of the data. We expect that our early involvement will improve the probability of success in our territories and will enable us to shape the development programme more directly. This step tangibly underlines our commitment to the patient and medical community in haemophilia. Encouraged by the early results in the clinical programme, we look forward to taking this important project into phase 3 together with our partner Sanofi by year end.

Pre-market assets, potential to deliver more value than current portfolio

The third quarter has been a significant milestone for strengthening our portfolio of pre-market assets. BIVV001 and the follow on product in RSV, MEDI8897, have the potential to affect our mid-term sales materially. The launch of the different indications of Doptelet and Gamifant in the different geographies will be pivotal to continue driving double-digit growth in our two business areas Haematology and Immunology.

Guido Oelkers
Solna, Sweden, 31 October 2019



"The addition of BIVV001 to our development portfolio as well as Doptelet, a commerically available product with potential for exiciting new indications have the possibility to accelerate the transformation of the company."

Guido Oelkers,
CEO and President

Elocta product sales at CER

+29%

Alprolix product sales at CER

+30%

[1]Offer of Dova Pharmaceuticals conditional upon the tender of a majority of the outstanding shares of Dova's common stock, as well as customary conditions.

Business Review Q3

Haematology

Sobi expanded the scope of its haemophilia franchise into the broader area of haematology with the announcement of the intention to acquire Dova Pharmaceuticals. The acquisition, if completed, would provide Sobi with Doptelet (avatrombopag), a differentiated on-market product in chronic immune thrombocytopenia (ITP), a well-established and growing market. Doptelet is also indicated for thrombocytopenia in chronic liver disease (CLD) and is currently under investigation for chemotherapy-induced thrombocytopenia (CIT) in an ongoing phase 3 study. The thrombopoietin receptor (TPO) market is currently estimated at USD 2.0 billion, growing by 5 per cent, and represents an attractive commercial opportunity. Doptelet's recent launch in ITP in the US is a first step in capturing significant market share in the mid-term. In addition, Doptelet has the potential to become the first-to-market drug to treat CIT. The transaction is valued at up to USD 915 million (approximately SEK 9.0 billion) on a fully diluted basis. The consideration consists of an upfront payment of USD 27.50 per share in cash and one non-tradeable Contingent Value Right (CVR). The CVR entitles Dova shareholders to an additional USD 1.50 per share upon approval of Doptelet for use in CIT by the US Food & Drug Administration (FDA). The upfront cash component of the offer represents a premium of 36 per cent based on Dova's closing price before the announcement, of USD 20.19 per share.

Sobi and the Republic of Ireland's Haemophilia Product Selection and Monitoring Advisory Board have extended the contract for the supply of Elocta for another 12 months , until 31 January 2021, which means that every person with Haemophilia A requiring factor replacement therapy in the Republic of Ireland will continue to be treated with Elocta.

Results from several ongoing studies were presented at ISTH 2019, the 27th Congress of the International Society on Thrombosis and Haemostasis, in Melbourne, Australia, on 7-9 July 2019:

- Clinical study data on switching haemophilia A and B patients from on-demand treatment to extended half-life (EHL) prophylaxis showed a positive impact on clinical outcomes, with improvements in quality of life (QoL) and reduced annual bleeding rates (ABR), with improved joint health.
- Positive results from the interim analysis from verITI-8 — an ongoing prospective, phase 4 study evaluating the efficacy of Elocta for first-time immune tolerance induction (ITI) for people with severe haemophilia A with inhibitors, including 15 patients with a history of high titre inhibitors and no prior ITI therapy — were presented. The patients received ITI treatment which included administration of 200 IU/kg/day of Elocta until tolerisation or up to 48 weeks. At the data cut-off, on 23 January, six patients had been successfully tolerised, with a median time to tolerisation of 11.7 weeks. Eight subjects in the study continue to receive Elocta ITI therapy and one has failed.
- People with haemophilia have an increased risk of acute and chronic pain, and long-term disability, associated with bleeds. Anxiety and depression are other factors negatively affecting their quality of life. These were among the results of the MIND study, which aims to identify patterns of prescribed pain, anti-depressive and anti-anxiety medication and management of pain, depression and anxiety in people with haemophilia in four Nordic countries. This is further evidence of a strong medical need for haemophilia treatment with extended half-life products and to be able to personalise treatment.

Immunology

The acquisition announced on 12 June of emapalumab and related assets was completed on 18 July. The acquisition means that the previously announced exclusive licence agreement with Novimmune is superseded. Through the acquisition of emapalumab, Sobi gained access to all assets relating to emapalumab including intellectual property, patent rights, data and know-how; all relevant employees involved in the clinical and biopharmaceutical development of emapalumab; options for the shared financial rights to NI-1701 and NI-1801, two product candidates in the field of immuno-oncology; and a priority review voucher (PRV) within the US Food & Drug Administration's priority review programme.

The PRV was sold for a total cash consideration of USD 95 M during the quarter.

Specialty Care

In line with the sharpened focus on Haematology and Immunology and on products where Sobi controls the whole value chain, certain contracts in the Specialty Care portfolio were terminated. The impact from the terminations is expected to be insignificant on future recurring earnings.

R&D pipeline

Sobi entered an expanded agreement with Sanofi to exercise an early opt-in for the development and commercialisation of BIVV001, an investigational extended half-life factor VIII therapy with the potential to provide extended protection from bleeds with once-weekly dosing for people with haemophilia A. Sobi will make a payment to Sanofi of USD 50 million and become a development partner in this programme. Upon potential approval in the EU, Sobi will pay a royalty on revenues in Sobi's territories and receive royalties on Sanofi revenue in its territories. The early opt-in will enable Sobi to take a greater role in the development of BIVV001. The phase 3 trial is expected to start by year end. 2019. As part of the extended Sanofi agreement, a new supply agreement is now in place until 2027.

Upon EU regulatory approval of BIVV001, Sobi will be liable to pay the balance of the development costs incurred for BIVV001. The total payment obligation is currently estimated to reach approximately USD 280-290 million (including the USD 50 million payment). The royalty structure under the agreement states that Sobi will pay Sanofi 9 per cent of direct sales in the Sobi territory, and Sanofi will pay Sobi 8 per cent of direct sales in North America and 13 per cent of direct sales in other markets.

Financial Review

Total revenue

Total revenue for the quarter amounted to SEK 2,930 M (2,315), up 27 per cent compared with the third quarter 2018 (22 per cent at CER). Organic growth (adjusted for Synagis at CER) amounted to 17 per cent compared with Q3 2018.

Revenue for the period January—September was SEK 9,358 M (6,568), an increase of 42 per cent. Organic growth (adjusted for Synagis at CER) amounted to 22 per cent.

Revenue by business area

Haematology

The Haemotology franchise continues to deliver strong double-digit growth, 25 per cent (21 per cent at CER) to SEK 1,932 M (1,545) for the quarter and 32 per cent growth (26 per cent at CER) to SEK 5,613 M (4,260) for the period January—September.

Total product sales reached SEK 1,497 M (1,128) for the quarter, up 33 per cent (29 per cent at CER). The majority of this growth derived from the continued strong performance in Germany, France, Italy and Spain. Elocta sales rose 32 percent (29 per cent at CER) to SEK 1,156 M (873) and Alprolix rose 34 per cent (30 per cent at CER) to SEK 341 M (255). Elocta sales in Q3 2019 and Q3 2018 were positively affected by one-off revenue adjustments related to adjusted pharmaceutical taxes in France, SEK 35 M in Q3 2019 and SEK 52 M in Q3 2018. Year-to-date sales totalled SEK 4,333 M (2,987), with Elocta up 41 per cent (37 per cent at CER) and Alprolix up 58 per cent (53 per cent at CER).

Estimated royalty revenue were SEK 342 M (338) for the quarter and SEK 1,021 M (974) for the first nine months of 2019.

ReFacto manufacturing revenue was SEK 94 M (79) for the quarter, up 19 per cent. Manufacturing revenue for the period of January—September was SEK 260 M (299), down 13 per cent.

Immunology

Total Immunology revenue for the quarter was SEK 600 M, and SEK 2,473 M for the period of January—September.

Gamifant sales for the quarter amounted to SEK 67 M. The volatile sales pattern from quarter to quarter is normal for an ultra-rare disease product in launch phase. In addition, Gamifant sales were negatively affected by approximately SEK 30 M due to inventory shifts in Q3. We continue with disease awareness activities to ensure accurate and timely diagnosis of primary HLH. Year-to-date Gamifant sales were SEK 361 M.

Synagis sales for the quarter amounted to SEK 124 M, and SEK 938 M for the first nine months, reflecting an early stock build-up ahead of the upcoming RSV season.

Kineret sales for the quarter were SEK 409 M (347), an increase of 18 per cent (12 per cent at CER). Double-digit growth was seen across all regions driven by increased underlying demand. Kineret sales for the first nine months were SEK 1,175 M (985), an increase of 19 per cent (12 per cent at CER), driven by higher demand.

Specialty Care

Total Specialty Care revenue for the quarter was SEK 398 M (422), a decrease of 6 per cent (-9 per cent at CER). Sales for the first nine months were SEK 1,271 M (1,323), a decrease of 4 per cent (-9 per cent at CER).

Orfadin sales for the quarter were SEK 193 M (217), a decrease of 11 per cent (-15 per cent at CER). The decrease is mainly explained by price erosion due to generic competition for Orfadin. Sales for the period January—September were SEK 596 M (678), a decrease of 12 per cent (-17 per cent at CER).

Q3 sales for the other Specialty Care products amounted to SEK 205 M (205), -3 per cent at CER. Year-to-date sales amounted to SEK 675 M (645), an increase of 5 per cent (0 per cent at CER).

Revenue by business area

Amounts in SEK M	Q3 2019	Q3 2018	Change	Change at CER[1]	Jan-Sep 2019	Jan-Sep 2018	Change	Change at CER[1]	Full-year 2018
Haematology									
Elocta	1,156	873	32%	29%	3,274	2,316	41%	37%	3 261
Alprolix	341	255	34%	30%	1,059	671	58%	53%	974
Manufacturing	94	79	19%	19%	260	299	-13%	-13%	436
Royalty	342	338	1%	-6%	1,021	974	5%	-4%	1 341
Total	**1,932**	**1,545**	**25%**	**21%**	**5,613**	**4,260**	**32%**	**26%**	**6 012**
Immunology									
Kineret	409	347	18%	12%	1,175	985	19%	12%	1 320
Synagis	124	–	N/A	N/A	938	–	N/A	N/A	–
Gamifant	67	–	N/A	N/A	361	–	N/A	N/A	–
Total	**600**	**347**	**73%**	**62%**	**2,473**	**985**	**151%**	**133%**	**1 320**
Specialty Care									
Speciality Care	398	422	-6%	-9%	1,271	1,323	-4%	-9%	1 807
Total	**398**	**422**	**-6%**	**-9%**	**1,271**	**1,323**	**-4%**	**-9%**	**1 807**
Total revenues	**2,930**	**2,315**	**27%**	**22%**	**9,358**	**6,568**	**42%**	**35%**	**9 139**

[1]Constant exchange rates.

Gross profit

Gross profit for the quarter was SEK 2,173 M (1,741), representing a gross margin of 74 per cent (75). The decrease was due to more favourable one-off revenue adjustments in Q3 2018, lower proportion of royalty revenues and continued price pressure on Orfadin due to generic competition. Nine-month gross profit was SEK 7,080 M (4,830) representing a gross margin of 76 per cent (74). The increase was due to a favourable product mix from increased sales of Elocta, Alprolix, Gamifant and Synagis as well as from favourable exchange rates.

Operating expenses

Sales and administrative expenses excluding amortisation and write-downs amounted to SEK 791 M (509) for the quarter and SEK 2 356 M (1 425) for the period January—September. The main increase was in Immunology, related to the Synagis business and US launch of Gamifant. There were also continued investments in the Haematology business to further strengthen the market position.

Research and development expenses amounted to SEK 293 M (287) for the quarter and to SEK 1,138 M (762) for the first nine months. The increase reflects spending relating to investments in emapalumab and restructuring costs of SEK 157 M in the second quarter.

Operating profit

EBITA for the quarter was SEK 1,099 M (933) corresponding to a margin of 38 per cent (40). Year-to-date EBITA amounted to SEK 3,645 M (2,655).

Adjusted EBITA was SEK 1,099 M (933). Adjusted EBITA for the period January-September was SEK 3,764 M (2,655).

The net impact of IFRS 16 was insignificant in the quarter and for the first nine months.

Amortisation and write-downs of intangible assets for the quarter amounted to SEK 345 M (113). Year-to-date amortisations and write-downs amounted to SEK 986 M (335). The increase relates to amortisation of the US rights to Synagis and emapamulab.

EBIT for the quarter decreased to SEK 754 M (820). EBIT for the nine months increased to SEK 2,659 M (2,320).

Net financial items and tax

Net financial items amounted to SEK -57 M (-13) for the quarter, including exchange rate gains/losses of SEK -3 M (4).

Net financial items for the nine months amounted to SEK -175 M (-17), including exchange rate gains/losses of SEK -25 M (25). The difference was mainly attributable to increased interest costs for the financing related to the acquisition of the US rights to Synagis and the acquisition of emapamulab and related assets.

Income tax amounted to SEK -155 M (-183) for the quarter and SEK -540 M (-480) for the nine months, corresponding to an effective tax rate of 22.3 (22.7) and 21.7 (20.9) per cent respectively.

Profit

Profit totalled SEK 542 M (623) for the quarter and SEK 1,944 M (1,823) for the nine months.

Cash flow and investments

Cash flow from operations before change in working capital amounted to SEK 973 M (613) for the quarter and to SEK 3,371 M (1,800) for the first nine months.

Working capital impacted cash flow by SEK 22 M (98) for the quarter and by SEK -713 M (-248) for the first nine months. The increase in working capital for the nine months was mainly attributable to inventory build-up and increased accounts receivable as a result of sales growth.

Cash flow from investing activities was SEK -4,047 M (-512) for the quarter and SEK -12,948 M (-547) for the first nine months. Sobi

Operating profit/loss

Amounts in SEK M	Q3 2019	Q3 2018	Jan-Sep 2019	Jan-Sep 2018	Full-year 2018
Total revenues	2,930	2,315	9,358	6,568	9,139
Total cost of goods sold	-757	-574	-2,278	-1,738	-2,415
Gross profit	2,173	1,741	7,080	4,830	6,723
Gross margin	*74%*	*75%*	*76%*	*74%*	*74%*
Sales and administrative expenses before amortisation and write-downs	-792	-509	-2,356	-1,425	-2,062
Research and development expenses	-293	-287	-1,138	-762	-1,090
Total opex before amortisation and write-downs	-1,084	-796	-3,494	-2,187	-3,153
Other operating income/expenses	10	-12	59	12	0
EBITA	1,099	933	3,645	2,655	3,571
Non-recurring items[1]	-	-	119	-	-
EBITA adjusted[1]	*1,099*	*933*	*3,764*	*2,655*	*3,571*
Amortisation and write-downs related to Sales and administrative expenses	-345	-113	-986	-335	-449
EBIT	754	820	2,659	2,320	3,122

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

[1]EBITA Jan-Sept 2019 excluding non-recurring items; restructuring costs of SEK 157 M in Q2 2019 and gain from divestment of SOBI005 in Q1 2019 of SEK 37 M, see further page 13.

completed the acquisition of emapalumab and related assets in the third quarter, which impacted cash flow negatively by SEK 4,911 M. As part of the acquisition, Sobi acquired a Priority Review Voucher (PRV), which was sold during the quarter and impacted cash flow positively by SEK 914 M.

The largest investment in intangible assets during the first nine months was SEK 13,869 M related to Synagis, with a cash flow impact of SEK -8,860 M. In the third quarter, Sobi acquired an intangible asset related to BIVV001 of SEK 1,817 M with no cash flow impact.

Cash flow from financing activities amounted to SEK 2,931 M (-1) for the quarter and SEK 8,352 M (-1) for the period January-September. The increased borrowings during the quarter relates to the financing of the acquisition of emapalumab and related assets. The increase in the first nine months' cash flow from financing was related to the acquisition of the US rights to Synagis during the first quarter and emapalumab and related assets in the third quarter. The rental payments according to IFRS 16 are presented on page 11, cash flow from financing activities.

Cash

At the end of the quarter, cash and cash equivalents amounted to SEK 1,077 M, compared with SEK 2,999 M at 31 December 2018. The cash consumed is mainly related to the acquisitions made in the period.

Net debt

Sobi ended the quarter with net debt of SEK 7,606 M, compared with a net cash position of SEK 2,999 M at 31 December 2018.

Equity

At 30 September 2019, consolidated shareholders' equity was SEK 15,686 M compared with SEK 9,040 M at 31 December 2018. Equity has increased by SEK 4,513 M due to the issue of shares related to the acquisition of Synagis.

Personnel

At 30 September 2019, the number of full-time equivalents was 1,275 (902 at 31 December 2018).

Parent Company

In the third quarter of 2019, net sales for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 2,700 M (2,141), of which Group companies accounted for SEK 1,558 M (1,262). Nine-month sales amounted to SEK 8,739 M (5,871) of which SEK 4,755 M (3,241) referred to sales to Group companies.

Profit after financial items amounted to SEK 1,140 M (936) for the quarter and to SEK 3,653 M (2,517) for the nine months.

Investments in tangible and intangible assets affecting cash flows amounted to SEK 41 M (14) for the quarter and SEK 91 M (46) for the first nine months.

Total assets have increased mainly due to the acquisition of Synagis and emapamulab and related assets.

Other information

Significant events after the reporting period

- On 11 October Sobi announced the initiation of a tender offer for all outstanding shares of Dova Pharmaceuticals through its indirect wholly owned subsidiary Dragonfly Acquisition Corp. to purchase all outstanding shares of Dova Pharmaceuticals, Inc.

Financial outlook 2019

Sobi reiterates the financial outlook for 2019 published on 17 July, 2019.

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

EBITA for the full year is expected to be in the range of SEK 5,300 - 5,500 M[1,2] excluding restructuring costs.

[1]At exchange rates as of 17 July.

[2]Excluding impact from the potential acquisition of Dova Pharmaceuticals

Solna, Sweden, 31 October 2019

Guido Oelkers, CEO and President

Forward-looking statements

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

This information is information that Swedish Orphan Biovitrum AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of Linda Holmström, Corporate Communication and Investor Relations, at 08:00 CET on 31 October 2019.

Financial calendar

Q4 and FY 2019 report	13 February 2020
Q1 2020	29 April 2020
AGM	13 May 2020
Q2 2020	16 July 2020
Q3 2020	22 October 2020

Auditor's review

Introduction

We have reviewed the condensed interim report for Swedish Orphan Biovitrum AB (publ) as of 30 September 2019, 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, 31 October 2019

Ernst & Young AB

Björn Ohlsson

Authorised Public Accountant

Financial statements – Group

Statement of comprehensive income

Amounts in SEK M	Q3 2019	Q3 2018	Jan-Sep 2019	Jan-Sep 2018	Full-Year 2018
Total revenues[1]	2,930	2,315	9,358	6,568	9,139
Total cost of goods sold	-757	-574	-2,278	-1,738	-2,415
Gross profit	**2,173**	**1,741**	**7,080**	**4,830**	**6,723**
Sales and administrative expenses[2]	-1,137	-622	-3,342	-1,760	-2,511
Research and development expenses	-293	-287	-1,138	-762	-1,090
Other operating income/expenses	10	-12	59	12	0
Operating profit	**754**	**820**	**2,659**	**2,320**	**3,122**
Financial income/expenses[3]	-57	-13	-175	-17	-40
Profit before tax	**697**	**807**	**2,484**	**2,303**	**3,082**
Income tax expenses	-155	-183	-540	-480	-664
Profit for the period	**542**	**623**	**1,944**	**1,823**	**2,418**
All earnings are attributable to Parent Company shareholders					
Other comprehensive income					
Items that will not be reclassified to profit/loss					
Remeasurements of post-employment benefit obligations	0	–	3	3	0
Items that may be reclassified subsequently to profit/loss					
Translation difference	221	-6	250	16	9
Cash flow hedge (net of tax)	-73	16	-120	-75	-133
Comprehensive income for the period	**690**	**634**	**2,078**	**1,766**	**2,294**
[1]See page 4 for split by business area.					
[2]Amortisation and write-downs of intangible assets included in Sales and administrative expenses.	-345	-113	-986	-335	-449
[3]Including financing costs amounting to:	-5	0	-12	-1	-2
Earnings per share, SEK	1.84	2.31	6.66	6.77	8.97
Earnings per share, SEK, adjusted[1]	1.84	2.31	6.98	6.77	8.97
Earnings per share after dilution, SEK	1.83	2.30	6.62	6.74	8.93
Earnings per share after dilution, SEK, adjusted[1]	1.83	2.30	6.93	6.74	8.93

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

Balance sheet

Amounts in SEK M	Sep 2019	Dec 2018	Sep 2018
ASSETS			
Non-current assets			
Intangible assets[1,2]	26,377	10,159	10,242
Tangible assets[3]	508	136	135
Financial assets	444	286	227
Total non-current assets	27,329	10,581	10,604
Current assets			
Inventories	1,623	1,284	1,174
Accounts receivable	1,983	1,665	1,511
Other receivables, non-interest bearing	783	654	488
Cash and cash equivalents	1,077	2,999	2,488
Total current assets	5,466	6,602	5,662
Total assets	32,794	17,183	16,266
EQUITY AND LIABILITIES			
Shareholders' equity	15,686	9,040	8,499
Non-current liabilities			
Borrowings	8,683	–	–
Lease liabilities	296	3	4
Other liabilities, non-interest bearing	3,967	1,189	1,213
Total non-current liabilities	12,947	1,192	1,217
Current liabilities			
Accounts payable	347	487	240
Lease liabilities	90	1	1
Other liabilities, non-interest bearing	3,724	6,463	6,308
Total current liabilities	4,161	6,951	6,550
Total equity and liabilities	32,794	17,183	16,266

[1]Including goodwill of SEK 2,551 M.
[2]The increase is mainly related to the acqusition of the US rights to Synagis and the acquisition relatad to BIV-V001 in Q3 2019.

[3]The Right-of-use assets related to IFRS 16 are classified as tangible assets and amount to SEK 363 M.

Changes in equity

Amounts in SEK M	Jan-Sep 2019	Full-year 2018	Jan-Sep 2018
Opening balance	9,040	6,701	6,701
Share-based compensation to employees	56	46	32
Issue of shares	4 513	–	–
Comprehensive income for the period[1]	2,078	2,294	1,766
Equity at end of period	15,686	9,040	8,499

[1]Whereof changes in cash flow hedges amounted to SEK -120 M (-75).

Cash flow statement

Amounts in SEK M	Q3 2019	Q3 2018	Jan-Sep 2019	Jan-Sep 2018	Full-year 2018
Profit for the period	542	623	1,944	1,823	2,418
Adjustment for non-cash items[1]	431	-10	1,427	-23	-77
Cash flow from operations before change in working capital	**973**	**613**	**3,371**	**1,800**	**2,341**
Change in working capital	22	98	-713	-248	-250
Cash flow from operations	**995**	**712**	**2,658**	**1,553**	**2,090**
Acquisition of business, net of cash acquired[2]	-4,911	–	-4,911	–	–
Investment in intangible assets[3]	-41	-503	-8,951	-523	-537
Investment in tangible assets	-10	-10	-27	-29	-41
Divestment of tangible assets	–	1	–	2	3
Divestment of intangible assets[4]	914	–	941	–	–
Investment in financial assets	–	0	–	3	-1
Cash flow from investing activities	**-4,047**	**-512**	**-12,948**	**-547**	**-575**
Loans - Raising/Amortisation	2,956	–	8,420	–	–
Lease payments	-24	–	-68	–	–
Net finance lease	–	-1	–	-1	-1
Cash flow from financing activities	**2,931**	**-1**	**8,352**	**-1**	**-1**
Change in cash and cash equivalents	**-121**	**198**	**-1,938**	**1,005**	**1,514**
Cash and cash equivalents at the beginning of the period	1,189	2,306	2,999	1,478	1,478
Translation difference in cash flow and cash and cash equivalents	9	-16	16	6	7
Cash and cash equivalents at the end of the period	**1,077**	**2,488**	**1,077**	**2,488**	**2,999**
[1] Adjustment for non-cash items:					
Depreciation of tangible assets	34	9	131	27	36
Amortisation and write-downs of intangible assets	345	113	986	335	449
Restructuring reserve	–	–	120	–	–
Deferred tax	86	-23	303	-77	-103
Other, whereof mainly non-cash transactions including revaluation of loans	-34	-110	-112	-308	-459
Non-cash items	**431**	**-10**	**1,427**	**-23**	**-77**

[2]Relates to the acquistion of emapalumab and related assets and liabilities. Please refer to Note 4 under Financial notes

[3]Investments intangible assets	Q3 2019	Jan-Sep 2019
Investment intangible assets during 2019 YTD; whereof Synagis SEK 13,869 M in Q1 and BIVV001 SEK 1,817 M in Q3	-1,911	-15,830
Other liabilities, non-interest bearing	1,817	1,817
Reported as part of acquistion of business	53	53
Issue of shares	–	4,513
Deferred purchase consideration	–	496
Cash paid	-41	-8,951

[4]Divestments of intangible assets comprise during the quarter of the sale of Priority Review Voucher (PRV), acquired in the acquistion of the emapalumab related assets and liabilities. For the nine month period the sale of SOBI005 is included as well.

Key ratios and other information

Amounts in SEK M	Q3 2019	Q3 2018	Jan-Sep 2019	Jan-Sep 2018	Full-year 2018
Profit measures					
Gross profit	2,173	1,741	7,080	4,830	6,723
EBITDA[1]	1,133	942	3,776	2,682	3,607
EBITA[1]	1,099	933	3,645	2,655	3,571
EBITA adjusted[1,2]	1,099	933	3,764	2,655	3,571
EBIT (operating profit)	753	820	2,659	2,320	3,122
Profit/loss	542	623	1,944	1,823	2,418
Per share data (SEK)					
Earnings per share	1.84	2.31	6.66	6.77	8.97
Earnings per share, adjusted[2,3]	1.84	2.31	6.98	6.77	8.97
Earnings per share after dilution	1.83	2.30	6.62	6.74	8.93
Earnings per share after dilution, adjusted[2,3]	1.83	2.30	6.93	6.74	8.93
Shareholders' equity per share[1]	52.3	31.1	52.3	31.1	33.1
Shareholders' equity per share after dilution[1]	52.0	31.0	52.0	31.0	32.9
Other information					
Gross margin[1]	74%	75%	76%	74%	74%
EBITA margin[1]	38%	40%	39%	40%	39%
EBITA margin adjusted[1,2]	38%	40%	40%	40%	39%
Equity ratio[1]	48%	52%	48%	52%	53%
Net cash (-)/debt (+)[1]	7,606	-2,488	7,606	-2,488	-2,999
Number of ordinary shares[4]	299,977,839	273,322,117	299,977,839	273,322,117	273,322,117
Number of ordinary shares (in treasury)	5,886,356	3,429,430	5,886,356	3,429,430	3,423,726
Number of ordinary shares (excluding shares in	294,091,483	269,892,687	294,091,483	269,892,687	269,898,391
Number of ordinary shares after dilution	301,785,687	274,159,143	301,785,687	274,159,143	274,365,601
Average number of ordinary shares (excluding shares in treasury)	294,278,857	269,681,071	292,116,382	269,398,916	269,523,784
Average number of ordinary shares after dilution (excluding shares in treasury)	295,899,331	270,601,711	293,924,229	270,630,624	270,603,665

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

[2]EBITA Jan-Sep 2019 excluding non-recurring items; restructuring costs of SEK 157 M in Q2 2019 and gain from divestment of SOBI005 in Q1 2019 of SEK 37 M.

[3]EPS Jan-Sep 2019 excluding impairment of intangible assets of SEK 18 M related to restructuring in Q2 2019.

[4]The increase in the number of shares results from an issue of 24,193,092 ordinary shares in connection with the acquisition from AstraZeneca of rights to Synagis (palivizumab) in the US and from an increase in the number of shares resulting from an issue of 2,462,630 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 2019	Q3 2018	Jan-Sep 2019	Jan-Sep 2018	Full-year 2018
Total revenue	2,930	2,315	9,358	6,568	9,139
Total cost of goods sold	-757	-574	-2,278	-1,738	-2,415
Gross profit	**2,173**	**1,741**	**7,080**	**4,830**	**6,723**
Gross margin, %	**74%**	**75%**	**76%**	**74%**	**74%**

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

Total revenue	2,930	2,315	9,358	6,568	9,139
Total revenue, measured at CER	2,820	2,318	8,867	6,559	9,065
Sales for Synagis	124	-	938	-	-
Sales for Synagis, measured at CER	113	-	861	-	-
Total revenue adjusted for Synagis	2,806	2,315	8,420	6,568	9,139
Total revenue adjusted for Synagis, measured at CER	2,707	2,318	8,007	6,559	9,065
Organic growth	491	N/A	1,852	N/A	N/A
Organic growth, measured at CER	388	N/A	1,448	N/A	N/A
Organic growth, %	21%	N/A	28%	N/A	N/A
Organic growth, % CER	**17%**	N/A	**22%**	N/A	N/A

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

EBIT (operating profit)	754	820	2,659	2,320	3,122
Plus amortisation and write-downs of intangible assets	345	113	986	335	449
EBITA	**1,099**	**933**	**3,645**	**2,655**	**3,571**
Plus depreciations of tangible assets	34	9	131	27	36
EBITDA	**1,133**	**942**	**3,776**	**2,682**	**3,607**
EBITA margin, %	**38%**	**40%**	**39%**	**40%**	**39%**
Non-recurring items	-	-	119	-	-
EBITA adjusted	**1,099**	**933**	**3,764**	**2,682**	**3,571**
EBITA margin adjusted, %	**38%**	**40%**	**40%**	**40%**	**39%**

EBITA - Earnings before interest, tax and amortisation
EBITDA - Earnings before interest, tax, depreciation and amortisation
EBITA margin, % - EBITA as a percentage of total revenue
Non-recurring items from divestment of SOBI005 in Q1 2019 of SEK 37 M and restructuring expenses in Q2 2019 of SEK 157 M.
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 2019	Q3 2018	Jan-Sep 2019	Jan-Sep 2018	Full-year 2018
Profit for the period	542	623	1,944	1,823	2,418
Impact of divestment of SOBI005 and restructuring expenses, after tax	-	-	94	-	-
Profit for the period, adjusted	542	623	2,038	1,823	2,418
Average number of ordinary shares	294,278,857	269,681,071	292,116,382	269,398,916	269,523,784
Average number of ordinary shares after dilution	295,899,331	270,601,711	293,924,229	270,630,624	270,603,665
EPS, SEK adjusted	1.84	2.31	6.98	6.77	8.97
EPS after dilution, SEK adjusted	1.83	2.30	6.93	6.74	8.93

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	8,683	0	8,683	0	0
Cash and cash equivalents	1,077	2,488	1,077	2,488	2,999
Net debt (+)/Net cash (-)	7,606	-2,488	7,606	-2,488	-2,999

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

Shareholders' equity	15,686	8,499	15,686	8,499	9,040
Total assets	32,794	16,266	32,794	16,266	17,183
Equity ratio, %	48%	52%	48%	52%	53%
Number of ordinary shares	299,977,839	273,322,117	299,977,839	273,322,117	273,322,117
Equity per share, SEK	52.3	31.1	52.3	31.1	33.1

Equity ratio - Shareholders' equity as a proportion of total assets

Equity per share - Equity divided by the number of ordinary shares

Financial statements – Parent Company

Income statement

Amounts in SEK M	Q3 2019	Q3 2018	Jan-Sep 2019	Jan-Sep 2018	Full-year 2018
Total revenues	2,700	2,141	8,739	5,871	8,221
Total cost of goods sold	-716	-603	-2,175	-1,672	-2,349
Gross profit	**1,984**	**1,538**	**6,564**	**4,199**	**5,872**
Sales and administrative expenses[1]	-657	-329	-2,124	-977	-1,445
Research and development expenses	-219	-249	-879	-698	-932
Other operating income/expenses	5	-12	58	9	-2
Operating profit	**1,113**	**948**	**3,618**	**2,533**	**3,492**
Financial income/expenses	25	-11	35	-15	-35
Profit after financial items	**1,137**	**936**	**3,653**	**2,517**	**3,457**
Appropriations	–	–	–	–	-397
Profit before tax	**1,137**	**936**	**3,653**	**2,517**	**3,060**
Income tax expenses	-55	-181	-151	-482	-678
Profit for the period	**1,082**	**755**	**3,502**	**2,035**	**2,382**
[1]Amortisation and write-downs of intangible assets included in Sales and administrative expenses.	-75	-74	-244	-225	-292

Statement of other comprehensive income

Amounts in SEK M	Q3 2019	Q3 2018	Jan-Sep 2019	Jan-Sep 2018	Full-year 2018
Profit/loss for the period	1,082	755	3,502	2,035	2,382
Items that may be subsequently reclassified to profit/loss					
Cash flow hedge (net of tax)	-85	17	-120	-75	-133
Comprehensive income for the period	**997**	**772**	**3,382**	**1,960**	**2,248**

Balance sheet

Amounts in SEK M	Sep 2019	Dec 2018	Sep 2018
ASSETS			
Non-current assets			
Intangible assets	6,132	3,801	3,862
Tangible assets	90	112	112
Financial assets	3,531	3,537	2,915
Total non-current assets	9,754	7,450	6,889
Current assets			
Inventories	1,345	1,071	994
Accounts receivable	662	590	453
Receivables Group companies[1]	19,940	1,465	1,831
Other receivables, non-interest bearing	680	589	433
Cash and cash equivalents	872	2,762	2,340
Total current assets	23,500	6,476	6,050
Total assets	33,254	13,926	12,939
EQUITY AND LIABILITIES			
Shareholders' equity	15,682	7,731	7,428
Untaxed reserves	2,584	2,584	2,124
Non-current liabilities			
Borrowings	8,736	–	–
Other liabilities, non-interest bearing	2,346	508	546
Total non-current liabilities	11,082	508	546
Current liabilities			
Accounts payable	242	376	196
Other liabilities, non-interest bearing	3,664	2,727	2,645
Total current liabilities	3,906	3,103	2,841
Total equity and liabilities	33,254	13,926	12,939

[1]Receivables from Group companies have increased due to the acquisition of the US rights to Synagis.

Change in shareholders' equity

Amounts in SEK M	Jan-Sep 2019	Full-year 2018	Jan-Sep 2018
Opening balance	7,731	5,436	5,436
Share-based compensation to employees	56	46	32
Issue of shares	4,513	–	–
Comprehensive income for the period[1]	3,382	2,248	1,960
Equity at end of period	15,682	7,731	7,428

[1]Whereof changes in cash flow hedges amounted to SEK -120 M (-75).

Financial notes

Note 1 – Accounting policies and measurement bases and other information

Significant accounting policies

This report has been prepared in accordance with IAS 34 and the Swedish Annual Accounts Act. The consolidated financial statements for the period January-September 2019 have been prepared in accordance with International Financial Reporting Standards (IFRS) and the International Financial Reporting Interpretations Committee (IFRIC) interpretations as adopted by the EU and the Swedish Annual Accounts Act.

The Parent Company applies the Annual Accounts Act and the Swedish Financial Reporting Board's Recommendation RFR 2 Accounting for Legal Entities.

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

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

Changes in accounting policies

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

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

The liabilities are measured at the net present value of the remaining lease payments. The weighted average discounting rate (incremental borrowing rate as per transition date) applied at 1 January 2019 was 1.6 per cent, based on the estimated borrowing rates Sobi would have obtained from financial institutions for the relevant tenors. Options to renew contracts are taken into account when the Group considers it reasonably certain that the option will be exercised.

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

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

IFRS 16's impact on operating profit as per September 2019 was SEK 2 M, consisting of a SEK 97 M decrease in other operating expenses and a SEK 95 M increase in depreciations. In summary, no material impact on operating profit and EPS.

However, the alternative performance measure EBITDA has increased by SEK 97 M due to a decrease in other operating expenses according to IFRS 16.

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

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

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

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

Operating risks

All business operations involve risk. Managed risk-taking is necessary to maintain good profitability. Risk may be due to events in the external environment and may affect a certain industry or market. Risk may also be specific to a certain company.

Sobi is exposed to three main risk categories:

- Operational risks, e.g. due to the capital-intensive and risky nature of new drug development, dependence on external partners in various collaborations, product liability claims, and laws and rules on the treatment of hazardous materials.
- External risks, such as patent infringements, competition within product concepts and decisions by authorities regarding product use and prices.
- Financial risks, such as currency risk, interest-rate risk, credit risk and liquidity risk.

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

Note 2 – Fair value of financial instruments

The Group carries derivatives (see the 2018 Annual Report for a narrative description of the purpose of the holdings). The derivatives (under the heading "current assets/liabilities") are all categorised within Level 2 of the fair value hierarchy in the IFRS 13 standard (inputs other than quoted prices that are observable for the instruments, either directly or indirectly, are used in the fair value measurement). All derivatives are measured at fair value based on market data in accordance with IFRS. At 30 September 2019, the net reported value of derivatives on the balance sheet was SEK 22 M (1).

At 30 September 2019, all other financial instruments on the balance sheet had reported values that are in all material aspects equivalent to fair value.

Note 3 – 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 is mainly recognised as research and development expenses. In the Balance sheet a provision of SEK 120 M is recognised under Other liabilities non-interest bearing and the remaining part as impairment of assets.

Note 4 – Acquisitions 2019

During the third quarter 2019 Sobi completed the acquisition of emapalumab and related assets and liabilities.

Through the acquisition of emapalumab, Sobi gains access to:

- All assets relating to emapalumab including intellectual property, patent rights, data and know-how
- All relevant employees involved in the clinical and biopharmaceutical development of emapalumab
- Options for the shared financial rights to NI-1701 and NI-1801, two product candidates in the field of immuno-oncology
- A priority review voucher within the US Food & Drug Administration's priority review programme, which offers companies investing in orphan drugs a cost reduction for the application fee for future products and shortens the review period. The PRV was sold for a total cash consideration of USD 95 M during the quarter.

The consideration for the acquisition is CHF 515 M (SEK 4,911 M), of which CHF 400 M was previously committed in the exclusive licence agreement for emapalumab. The transaction was completed on July 18 2019.

Amounts in SEK M	Q3 2019	Jan-Sep 2019
Agreed purchase price	4,914	4,914
Redemption of previous commitment[1]	-3,802	-3,802
Deferred tax	469	469
Net consideration	**1,581**	**1,581**
Assets		
Intangible assets	88	88
Tangible assets	19	19
Inventory	34	34
Priority Review Voucher (PRV)[2]	892	892
Cash	3	3
Total assets	**1,037**	**1,037**
Liabilities		
Other liabilities and provisions	-188	-188
Accrued expenses	-45	-45
Deferred tax	-182	-182
Total liabilities	**-415**	**-415**
Total identifiable net assets at fair value	**622**	**622**
Goodwill arising on acquistion[3]	959	959
Purchase consideration transferred	**1,581**	**1,581**
Analysis of cash flows in acquisition		
Net cash acquired	-3	-3
Cash paid	4,914	4,914
Acquisition of business, net of cash	**4,911**	**4,911**

1. Refers to CHF 400 M previously committed in the exclusive licence agreement for emapalumab and reported as a short-term liability
2. Priority Review Voucher (PRV) was sold in September 2019
3. The goodwill recognised is primarily related to securing the know-how and highly experienced employees for the future development and related earning potential from follow-on indications of emapamulab.

The acquisition of emapalumab and related assets and liabilities does not increase Sobi´s expenses compared to the periods following the acquisition of the global rights.

Transaction costs of SEK 18 M have been expensed and are included in administrative expenses in income statement and is part of operating cash flow in the statement of cash flows.

Definitions and Glossary

Alprolix (eftrenonacog alfa)	A recombinant, extended half-life (EHL) clotting factor IX therapy approved in the EU, Iceland, Kuwait, Liechtenstein, Norway, Saudi Arabia and Switzerland, as well as in Australia, Brazil, Canada, Japan, New Zealand, the United States and other countries, for the treatment of haemophilia B, and which can be used by people of all ages.
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.
Chronic immune thrombocytopenia (ITP)	A rare autoimmune bleeding disorder characterised by 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.
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, which can be used by people of all ages. It is also approved in Australia, Brazil, Canada, Japan, New Zealand, the United States and other countries, where it is known as ELOCTATE®.
EMA	European Medicines Agency.
EMENAR	Abbreviation for business region including Europe, Middle East, North Africa and Russia.
FDA	The US Food & Drug Administration.
Full-time equivalents	Unit that indicates the workload of an employed person in a way that makes workloads comparable.
Gamifant (emapalumab)	An anti-interferon-gamma (IFN-γ) monoclonal antibody (mAb), approved by the FDA and currently under EMA review for the treatment of primary haemophagocytic lymphohistiocytosis (pHLH), a life-threatening syndrome of immune activation. An application to the EMA was submitted in August 2018.
Haemophagocytic lymphohistiocytosis (HLH)	A rare and life-threatening syndrome of extreme immune activation. The primary form of the disease (pHLH, inherited) mainly occurs in infants and young children while the secondary form of the disease (sHLH, acquired) is acquired from or associated with infection, autoimmune diseases or malignancy.
Haemophilia	A rare, genetic disorder in which the ability of a person's blood to clot is impaired. Haemophilia A occurs in about one in 5,000 male births annually, and haemophilia B occurs in about one in 25,000 male births annually. Both occur more rarely in females. People with haemophilia can experience bleeding episodes that may cause pain, limited mobility, irreversible joint damage and life-threatening haemorrhages.
ISTH	Congress of the International Society on Thrombosis and Haemostasis.

Definitions and Glossary

Immune tolerance induction (ITI)	A therapy used when haemophilia patients develop inhibitors to treatment. Factor concentrate is given regularly and at high doses over a period of time until the body learns to recognise the medicine without reacting to it.
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
RSV	Respiratory syncytial virus. A common virus and the most common cause of lower respiratory tract infections (LRTI) in young children.
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. It is the only medicine approved for the prevention of serious RSV disease.

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

The hard work and dedication of our approximately 1,300 employees around the globe has been instrumental in our success across Europe, North America, the Middle East, Russia and North Africa, leading to total revenues of SEK 9.1 billion in 2018. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm.

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

Swedish Orphan Biovitrum AB (publ)
SE-112 76 Stockholm, Sweden | Street address: Tomtebodavägen 23 A
Telephone: +46 8-697 20 00 | Fax: +46 8-697 23 30
www.sobi.com