sobi
rare strength

Q2
2019 report

Strong performance, sharper focus

April—June

- Total revenue of SEK 3,163 M (2,289). 38 per cent revenue growth in the quarter compared with Q2 2018 (32 per cent at constant exchange rates (CER))
- Adjusted EBITA[1,2] was SEK 1,193 M (951), an increase of 25 per cent
- Earnings per share (EPS) of SEK 1.70 (2.54) and adjusted EPS[1,2,3] of 2.12 SEK (2.54)
- Net debt[1] of SEK 4,403 M at 30 June 2019 (-2,999 at 31 Dec 2018)
- Sales for Elocta® were SEK 1,127 M (794) and sales for Alprolix® were SEK 382 M (263)
- Continued strong performance for Gamifant® with sales amounting to SEK 205 M
- Sales for Synagis® were SEK 148 M
- Purchase agreement of CHF 515 M (SEK 4,897 M) to emapalumab and related assets was signed
- Sharpened strategic focus on core areas of Haematology and Immunology, and on late-stage assets. As a consequence Sobi has the intention to discontinue early research and partner programmes outside core areas, generating annual savings of SEK 200-300 M in 2020. Restructuring costs for the quarter amounted to SEK 175 M, whereof SEK 157 M impacted EBITA and SEK 18 M related to impairment of intangible assets
- New data on emapalumab in patients with macrophage activation syndrome (MAS), a form of secondary HLH complicating systemic juvenile idiopathic arthritis (sJIA), showed that treatment with emapalumab led to a complete response in all six patients with a favourable safety profile
- Outlook 2019 updated, see page 7

January—June

- Total revenue of SEK 6,427 M (4,253). 51 per cent revenue growth in H1 compared with H1 2018 (42 per cent at CER)
- Adjusted EBITA[1,2] was SEK 2,665 M (1,722), an increase of 55 per cent
- EPS of SEK 4.82 (4.45) and adjusted EPS[1,2,3] of SEK 5.14 (4.45)
- Net debt[1] of SEK 4,403 M at 30 June 2019 (-2,999 at 31 Dec 2018)
- Elocta sales were SEK 2,118 M (1,442) and Alprolix sales were SEK 718 M (416)
- Gamifant sales amounted to SEK 294 M
- Synagis sales for the period 23 January - 30 June were SEK 813 M

Total revenue Q2, SEKm

3,163

+38%

Gross margin[1] Q2

76%

Adjusted EBITA[1,2] Q2, SEK M

1,193

+25%

Adjusted EPS[1,2,3] Q2, SEK

2.12

Financial summary

Amounts in SEK M	Q2 2019	Q2 2018	Change	H1 2019	H1 2018	Change	Full-year 2018
Total revenue	3,163	2,289	38%	6,427	4,253	51%	9,139
Gross profit	2,413	1,677	44%	4,907	3,089	59%	6,723
Gross margin[1]	76%	73%		76%	73%		74%
EBITA[1]	1,037	951	9%	2,546	1,722	48%	3,571
EBITA adjusted[1,2]	1,193	951	25%	2,665	1,722	55%	3,571
EBITA margin[1]	33%	42%		40%	40%		39%
EBITA margin adjusted[1,2]	38%	42%		41%	40%		39%
EBIT (operating profit)	677	841	-19%	1,905	1,500	27%	3,122
Profit for the period	499	685	-27%	1,402	1,200	17%	2,418
Earnings per share, SEK	1.70	2.54	-33%	4.82	4.45	8%	8.97
Earnings per share, SEK adjusted[1,2,3]	2.12	2.54	-17%	5.14	4.45	16%	8.97

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

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

CEO statement

Our strong performance continued in the second quarter, with organic growth of 25 per cent taking us to revenue of SEK 3,163 M, adjusted EBITA of SEK 1,193 M and an adjusted EBITA margin of 38 per cent. Announcing the acquisition of emapalumab and related assets, we took further steps to sharpen focus on our core therapeutic areas and on late-stage assets.

Haematology– factor replacement keeps delivering momentum

Within Haematology, Elocta sales amounted to SEK 1,127 M (794) and Alprolix sales to SEK 382 M (263), up 42 and 45 per cent respectively (37 and 40 per cent at CER). Both products continue to make significant progress, as does the shift towards improving care by individualising patients' therapy, something which is only possible with factor replacement.

Total Haematology revenue grew 31 per cent (26 per cent at CER) to SEK 1,950 M including royalties and manufacturing revenues for ReFacto.

Immunology – overall strong performance

Our Immunology franchise – comprising Kineret, Gamifant and Synagis – performed well, with revenue reaching SEK 773 M. The seasonal nature of Synagis, with peak sales in Q4 and Q1, means lower sales in Q2 and Q3. In Q2 Synagis sales were SEK 148 M, due to the fact that the season lasted longer this year as well as our increased focus on achieving full adherence among patients. Sales also include one-offs of SEK 81 M. The Synagis team, now integrated into our North American operations, is working to prepare for an expanded effort in the coming RSV season.

Sales of Gamifant since launch in the US, as the only approved drug for primary HLH, continue to perform strongly, reaching SEK 205 M in Q2 driven by high unmet medical need in HLH. The regulatory dialogue and process is ongoing with the Committee for Medicinal Products for Human Use (CHMP) in Europe for the potential approval of emapalumab for primary HLH. Based on current estimates and anticipated timelines for questions and answers, including what is known as a "clock-stop", we now expect approval around mid-2020.

Kineret had a strong performance with sales amounting to SEK 419 M (340), an increase of 23 per cent (16 per cent at CER).

Pipeline – future potential for emapalumab

At the European League Against Rheumatism (EULAR) / Paediatric Rheumatology European Society (PReS) Scientific Congress in Madrid, clinical data from a study involving emapalumab was presented, with an interim analysis of the first six enrolled patients with macrophage activation syndrome (MAS), a form of secondary haemophagocytic lymphohistiocytosis (HLH) complicating systemic juvenile idiopathic arthritis (sJIA). The study showed that treatment with emapalumab led to a complete response in all six patients with a favourable safety profile.

As part of our focused strategy we announced that we will look to divest two early research projects: the SOBI006 programme in pre-clinical phase and the SOBI003 programme for the potential treatment of Sanfilippo syndrome type A (MPS type IIIA), currently in phase 1/2.

Tighter focus on core areas and late-stage assets

We announced in June our intention to complete the acquisition of emapalumab and all related assets, and our plan to discontinue Sobi early-stage research projects. We believe we can make the most meaningful impact for rare disease patients by providing the competence and infrastructure needed to bring products all the way to patients – through late-stage clinical development, patient access and commercialisation. This is where we will focus our efforts going forward.

As part of the subsequent planned reorganisation, we will establish two centres of excellence – for Haematology in Stockholm, and for Immunology in Switzerland. The planned reorganisation is expected to free up SEK 200-300 M on a full-year basis from 2020, which will increase our financial flexibility to allocate future investments into late-stage development projects. Restructuring costs of SEK 175 M were charged in Q2 relating to the reorganisation and redundancies corresponding to approximately 90 positions.

With our sharper focus I am convinced that we can achieve our vision of becoming a global leader in rare diseases.

Solna, Sweden, 17 July 2019

Guido Oelkers, President & CEO

"Announcing the acquisition of emapalumab and related assets, we took further steps to sharpen focus on our core therapeutic areas and on late-stage assets"

Guido Oelkers,
CEO and President

Elocta product sales at CER

+37%

Alprolix product sales at CER

+40%

Business Review Q2

Haematology

Sobi and Sanofi presented data demonstrating that Elocta and Alprolix can provide perioperative haemostatic control across a wide spectrum of major and minor surgeries in patients of all ages with severe haemophilia A and B respectively. Recurrent bleeding into joints and subsequent deteriorating joint health is a major complication for people living with haemophilia. Joint surgery can improve quality of life but people with haemophilia are at risk during surgery due to the increased risk of bleeding during the procedure and the reduced clotting of the blood which characterises haemophilia. Blood loss during surgery can be minimised by treating patients with individualised and optimal factor replacement therapy to control the haemostasis. The risk of bleeding in a haemophilia patient is inversely proportional to the factor level activity in the blood and treatment guidelines recommend monitoring factor levels post-surgery.

Sobi launched Liberate Life™, a vision of living life beyond haemophilia, on World Haemophilia Day, 17 April. Through this long-term commitment, Sobi is seeking to shape new standards, optimise treatment, build evidence, create sustainable access and provide community support in haemophilia care. As well as working with the haemophilia community, Sobi is dedicated to delivering treatments that allow people living with haemophilia to feel safe, provide them protection from all bleeds, protect their long-term joint health, and reduce their pain and the mental burden of their condition. As the first initiative in showcasing the Liberate Life vision, Sobi is reaching out to the broader haemophilia community across Europe through social media, encouraging and motivating people to expect more from life and reach for the many possibilities that advances in care have made possible.

Immunology

Sobi strengthened its focus on Immunology through the intended acquisition announced on 12 June of emapalumab and related assets, giving Sobi access to world-class R&D capabilities in the field of Immunology. The acquisition also includes a priority review voucher, which can be sold, as well as options for the shared financial rights to NI-1701 and NI-1801, two products in the field of immuno-oncology. The acquisition means that the previously announced exclusive licence agreement with Novimmune will be superseded. The consideration for the acquisition is CHF 515 M (SEK 4,897 M), of which CHF 400 M was previously committed in the exclusive licence agreement for emapalumab. The acquisition is expected to be earnings-neutral in 2019 and completed during Q3 2019, subject to customary closing conditions.

R&D pipeline

The regulatory dialogue and process is ongoing with the Committee for Medicinal Products for Human Use (CHMP) in Europe for the potential approval of emapalumab for primary HLH. Based on current estimates and anticipated timelines for questions and answers, including what is known as a "clock-stop", we now expect approval around mid-2020.

New data was presented at the European League Against Rheumatism (EULAR) / Paediatric Rheumatology European Society (PReS) Scientific Congress in Madrid. The data presented was an interim analysis of the first six patients with macrophage activation syndrome (MAS), a form of secondary haemophagocytic lymphohistiocytosis (HLH) complicating systemic juvenile idiopathic arthritis (sJIA). The study showed that treatment with emapalumab led to rapid neutralisation of interferon gamma (IFN_{γ}) and a complete response in all six patients thus far. Furthermore, emapalumab demonstrated a favourable safety profile. The data was also recognised with the Gold PReS KOURIR Award during the conference. A meeting is planned with the US FDA to discuss a potential way forward for this additional indication for emapalumab in the US.

Sobi further announced the full acquisition of emapalumab as well as a sharpened focus on late-stage development projects. Accordingly, Sobi will look to divest two projects: the SOBI006 programme in pre-clinical phase as well as the SOBI003 programme for the potential treatment of MPSIIIA, currently in phase 1/2.

Based on encouraging data from the phase 3 study with Orfadin (nitisinone) for the treatment of alkaptonuria, Sobi expects to submit a marketing authorisation application to the EMA for this potential indication in the first half of 2020.

Corporate

Sobi's focus on two core areas – Haematology and Immunology – as well as plans to increase investments in late-stage development led to the intention to reorganise R&D and to discontinue discovery/early research and partner R&D programmes outside core focus areas. The new focus of the R&D organisation is expected to lead to annual savings of SEK 200–300 M on a full-year basis in 2020, which will increase the company's financial flexibility to allocate future investments into late-stage development projects. Restructuring costs of SEK 175 M were charged in Q2 relating to the reorganisation and redundancies corresponding to approximately 90 positions.

On 14 May, Sobi hosted a Capital Markets Day close to its premises in Solna, Stockholm. Sixty investors, financial analysts and media representatives attended the event which aimed to give external stakeholders an opportunity to meet senior management, get more information about Sobi in general as well as get an update on our products, strategy and financial targets.

Amy Pott was appointed new Head of Sobi North America. As Sobi North America is entering a new phase in line with Sobi's strategy and with two new products in the portfolio, Synagis and Gamifant, Amy Pott will be key to the development of this business.

Financial Review

Total revenue

Total revenue for the quarter amounted to SEK 3,163 M (2,289), up 38 per cent compared with the second quarter 2018 (32 per cent at CER). Organic growth (adjusted for Synagis and measured at CER) amounted to 25 per cent compared with Q2 2018.

Half-year revenue was SEK 6,427 M (4,253), an increase of 51 per cent. Organic growth (adjusted for Synagis and measured at CER) amounted to 25 per cent compared with the first half of 2018.

Revenue by business area

Haematology

Total Haemophilia revenue reached SEK 1,950 M (1,493) for the quarter, an increase of 31 per cent (26 per cent at CER). Half-year revenue amounted to SEK 3,681 M (2,714), up 36 per cent (29 per cent at CER).

Product sales rose 43 per cent for the quarter (38 per cent at CER) to SEK 1,509 M (1,057). Most of this growth derived from France, Italy and Germany. Elocta sales reached SEK 1,127 M (794) for the quarter, up 42 percent (37 per cent at CER). Elocta sales were also positively impacted by order patterns in the Middle East. Alprolix sales reached SEK 382 M (263) for the quarter, up 45 per cent (40 per cent at CER). Half-year sales totalled SEK 2,836 M (1,859), with Elocta up 47 per cent (41 per cent at CER) and Alprolix up 73 per cent (66 per cent at CER).

Estimated royalty revenue was SEK 345 M (335) for the quarter and SEK 679 M (636) for the half year.

ReFacto manufacturing revenue was SEK 97 M (100) for the quarter, down 3 per cent. Half-year manufacturing revenue was SEK 166 M (220), down 25 per cent compared with the same period last year.

Immunology

Total Immunology revenue for the quarter was SEK 773 M. Half-year revenue was SEK 1,873 M.

Gamifant sales amounted to SEK 205 M. Growth was driven by strong demand confirming high unmet medical need in HLH. Half-year Gamifant sales were SEK 294 M.

Due to seasonality effects, with peak sales in Q4 and Q1, Synagis sales are lower in Q2 and Q3. Sales for the quarter were SEK 148 M, due to the fact that the season lasted longer this year, as well as Sobi's focus on achieving full adherence among patients with subsequent dosing of all five doses. Sales also include one-offs of SEK 81 M, relating mainly to rebate adjustments. Half-year sales of Synagis were SEK 813 M (23 January-30 June).

Kineret sales for the quarter were SEK 419 M (340), an increase of 23 per cent (16 per cent at CER). Double-digit growth was seen across all regions. High demand in the US is related to more patients continuing on treatment, new patient enrolments, improved prescription fill rates and a new distribution channel provider. Half-year sales were SEK 765 M (637), an increase of 20 per cent (12 per cent at CER) driven by higher demand.

Specialty Care

Total Specialty Care revenue for the quarter was SEK 440 M (456), a decrease of 4 per cent (-8 per cent at CER). Half-year sales were SEK 873 M (901), a decrease of 3 per cent (-8 per cent at CER).

Orfadin sales for the quarter were SEK 215 M (236), a decrease of 9 per cent (-14 per cent at CER). The decrease is mainly explained by the introduction of generic competition to Orfadin. Half-year sales were SEK 404 M (461), a decrease of 12 per cent (-18 per cent at CER).

Q2 sales for the other Specialty Care products amounted to SEK 225 M (220), an increase of 2 per cent (-1 per cent at CER). Half-year revenue was SEK 469 M (440), an increase of 7 per cent (2 per cent at CER).

Revenue by business area

Amounts in SEK M	Q2 2019	Q2 2018	Change	Change at CER[1]	H1 2019	H1 2018	Change	Change at CER[1]	Full-year 2018
Haematology									
Elocta	1,127	794	42%	37%	2,118	1,442	47%	41%	3,261
Alprolix	382	263	45%	40%	718	416	73%	66%	974
Manufacturing	97	100	-3%	-3%	166	220	-25%	-25%	436
Royalty	345	335	3%	-6%	679	636	7%	-4%	1,341
Total	**1,950**	**1,493**	**31%**	**26%**	**3,681**	**2,714**	**36%**	**29%**	**6,012**
Immunology									
Kineret	419	340	23%	16%	765	637	20%	12%	1,320
Synagis	148	-	N/A	N/A	813	-	-	-	-
Gamifant	205	-	N/A	N/A	294	-	-	-	-
Total	**773**	**340**	**127%**	**111%**	**1,873**	**637**	**194%**	**169%**	**1,320**
Specialty Care									
Speciality Care	440	456	-4%	-8%	873	901	-3%	-8%	1,807
Total	**440**	**456**	**-4%**	**-8%**	**873**	**901**	**-3%**	**-8%**	**1,807**
Total revenue	**3,163**	**2,289**	**38%**	**32%**	**6,427**	**4,253**	**51%**	**42%**	**9,139**

[1]Constant exchange rates.

Gross profit

Gross profit for the quarter was SEK 2,413 M (1,677), representing a gross margin of 76 per cent (73). Half-year gross profit was SEK 4,907 M (3,089) representing a gross margin of 76 percent (73).

The increase was due to a favourable product mix from increased sales of Elocta, Alprolix and Gamifant as well as the acquisition of Synagis.

Operating expenses

Sales and administrative expenses excluding amortisation and write-downs amounted to SEK 860 M (483) for the quarter and SEK 1,564 M (916) for the half year. The main increase was in Immunology, related to the transition of Synagis and US launch activities for Gamifant. In Haematology, the increase was driven by continued investments in the EMENAR region to strengthen our market position.

Research and development expenses amounted to SEK 513 M (241) for the quarter. Expenses reflect increased spending in emapalumab as well as restructuring costs of SEK 157 M relating to the reorganisation of R&D. Half-year R&D expenses were SEK 845 M (475).

Operating profit

EBITA for the quarter was SEK 1,037 M (951) corresponding to a margin of 38 per cent (42). Half-year EBITA amounted to SEK 2,546 M (1,722).

Adjusted EBITA was SEK 1,193 M (951). Adjusted EBITA for the half year was SEK 2,665 M (1,772).

The net impact of IFRS 16 was insignificant in the quarter and for the half year.

Amortisation and write-downs of intangible assets for the quarter amounted to SEK 359 M (111), whereof SEK 18 M related to the restructuring of R&D. Amortisations and write-downs for the half year amount to SEK 641 M (221).

EBIT for the quarter decreased to SEK 677 M (841). EBIT for the half year increased to SEK 1,905 M (1,500).

Net financial items and tax

Net financial items amounted to SEK -45 M (-6) for the quarter, including exchange rate gains/losses of SEK 5 M (6).

Net financial items for the half year amounted to SEK -118 M (-4), including exchange rate gains/losses of SEK -21 M (22). The difference was mainly attributable to increased interest costs for the financing related to the acquisition of the US rights to Synagis.

Income tax amounted to SEK -133 M (-149) for the quarter and SEK -385 M (-297) for the half year, corresponding to an effective tax rate of 21.1 (17.9) and 21.5 (19.8) per cent respectively.

Profit

Profit totalled SEK 499 M (685) for the quarter and SEK 1,402 M (1,200) for the half year.

Cash flow and investments

Cash flow from operations before change in working capital amounted to SEK 1,091 M (679) for the quarter and to SEK 2,398 M (1,187) for the half year.

Working capital impacted cash flow by SEK 184 M (-115) for the quarter and by SEK -735 M (-346) for the half year. The negative cash flow effect for the half year was primarily attributable to increased accounts receivable as a result of the sales growth.

Cash flow from investing activities was SEK -29 M (-19) for the quarter and SEK -8,901 M (-35) for the half year. The largest investment during the half year was SEK 13,869 M related to Synagis, with a cash flow impact of SEK -8,860 M.

Operating profit/loss

Amounts in SEK M	Q2 2019	Q2 2018	H1 2019	H1 2018	Full-year 2018
Total revenue	3,163	2,289	6,427	4,253	9,139
Total cost of goods sold	-750	-612	-1,521	-1,164	-2,415
Gross profit	2,413	1,677	4,907	3,089	6,723
Gross margin	*76%*	*73%*	*76%*	*73%*	*74%*
Sales and administrative expenses before amortisation and write-downs	-860	-483	-1,564	-916	-2,062
Research and development expenses	-513	-241	-845	-475	-1,090
Total opex less amortisation and write-downs	-1,373	-725	-2,410	-1,391	-3,153
Other operating income/expenses	-3	-1	49	24	0
EBITA	1,037	951	2,546	1,722	3,571
Non-recurring items	157	-	119	-	-
EBITA adjusted[1]	*1,193*	*951*	*2,665*	*1,722*	*3,571*
Amortisation and write-down related to Sales and administrative expenses	-359	-111	-641	-221	-449
EBIT	677	841	1,905	1,500	3,122

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

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

Cash flow from financing activities amounted to SEK -523 M (—) for the quarter and SEK 5,421 M (—) for the half year, impacted by the acquisition of Synagis that took place during the first quarter. Rental payments according to IFRS 16 are presented on page 11, cash flow statement, financing activities.

Cash

At the end of the quarter, cash and cash equivalents amounted to SEK 1,189 M, compared with SEK 2,999 M at 31 December 2018. The change is an effect of the financing of the Synagis acquisition.

Net debt

Sobi ended the quarter with net debt of SEK 4,403 M, compared with a net cash position of SEK 2,999 M at 31 December 2018.

Equity

At 30 June 2019, consolidated shareholders' equity was SEK 14,972 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 June 2019, the number of full-time equivalents was 1,185 (902 at 31 December 2018).

Parent Company

In the second quarter of 2019, net sales for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 2,938 M (1,897), of which Group companies accounted for SEK 1,716 M (971). Half-year sales amounted to SEK 6,039 M (3,730) of which SEK 3,197 M (1,979) referred to sales to Group companies.

Profit after financial items amounted to SEK 1,035 M (760) for the quarter and to SEK 2,515 M (1,581) for the half year.

Investments in tangible and intangible assets affecting cash flows amounted to SEK 48 M (20) for the quarter and SEK 56 M (32) for the half year.

Total assets have increased due to the acquisition of Synagis.

Other information

Significant events after the reporting period

- Data presented at the 27th Congress of the International Society on Thrombosis and Haemostasis (ISTH) in Melbourne:
  - Encouraging interim results from verITI-8, an ongoing prospective, phase 4 study evaluating the efficacy of Elocta for first-time ITI for people with severe haemophilia A with inhibitors
  - Results of the MIND study showed that 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
  - Clinical study data on switching haemophilia A and B patients from on-demand treatment to extended half-life prophylaxis showed a positive impact on clinical outcomes, with improvements in quality of life (QoL) and reduced annual bleeding rates (ABR)
- The Board of Directors exercised authorisation for repurchase of shares for the purpose of securing the company's commitments under the incentive programme on a directed share issue of no more than 2,462,630 redeemable and convertible class C-shares

Financial outlook 2019 — updated

Sobi expects revenue for the full year to be in the range of SEK 13,000 - 13,500 M[1] (12,500 - 13,000)[2].

EBITA for the full year is expected to be in the range of SEK 5,300 - 5,500 M[1] (5,000 - 5,300)[2], excluding restructuring costs.

The updated outlook reflects the continued strong product sales in Haemophilia and the promising uptake of Gamifant in the US.

[1]At current exchange rates.
[2]The initial outlook was first published on 20 February 2019.

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

Solna, Sweden, 17 July 2019

Guido Oelkers, CEO and President

Financial calendar

Q3 2019 report	31 October 2019
Q4 and FY 2019 report	13 February 2020

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 CEST on 17 July 2019.

The Board of Directors and the CEO of Swedish Orphan Biovitrum AB (publ) provide their assurance that the interim report provides a fair and true overview of the Parent Company's and the Group's operations, financial position and results, and describes material risks and uncertainties faced by the Parent Company and the companies in the Group. See page 18, Financial notes, Operating risks.

Stockholm, 17 July 2019

Håkan Björklund
Chairman

David Allsop
Board Member

Annette Clancy
Board Member

Matthew Gantz
Board Member

Lennart Johansson
Board Member

Helena Saxon
Board Member

Hans GCP Schikan
Board Member

Elisabeth Svanberg
Board Member

Pia Axelson
Employee Representative

Bo-Gunnar Rosenbrand
Employee Representative

Guido Oelkers
CEO and President

Financial statements – Group

Statement of comprehensive income

Amounts in SEK M	Q2 2019	Q2 2018	H1 2019	H1 2018	Full-Year 2018
Total revenue[1]	3,163	2,289	6,427	4,253	9,139
Total cost of goods sold	-750	-612	-1,521	-1,164	-2,415
Gross profit	**2,413**	**1,677**	**4,907**	**3,089**	**6,723**
Sales and administrative expenses[2]	-1,219	-594	-2,205	-1,138	-2,511
Research and development expenses	-513	-241	-845	-475	-1,090
Other operating income/expenses	-3	-1	49	24	0
Operating profit	**677**	**841**	**1,905**	**1,500**	**3,122**
Financial income/expenses[3]	-45	-6	-118	-4	-40
Profit before tax	**632**	**834**	**1,787**	**1,497**	**3,082**
Income tax expenses	-133	-149	-385	-297	-664
Profit for the period	**499**	**685**	**1,402**	**1,200**	**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	3	3	3	3	0
Items that may be reclassified subsequently to profit/loss					
Translation difference	8	10	29	22	9
Cash flow hedge (net of tax)	-34	-70	-46	-92	-133
Comprehensive income for the period	**476**	**628**	**1,387**	**1,133**	**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.	-359	-111	-641	-221	-449
[3]Including financing costs amounting to:	-4	0	-7	1	-2
Earnings per share, SEK	1.70	2.54	4.82	4.45	8.97
Earnings per share, SEK, adjusted	2.12	2.54	5.14	4.45	8.97
Earnings per share after dilution, SEK	1.69	2.53	4.80	4.43	8.93
Earnings per share after dilution, SEK, adjusted	2.11	2.53	5.12	4.43	8.93

Balance sheet

Amounts in SEK M	Jun 2019	Dec 2018	Jun 2018
ASSETS			
Non-current assets			
Intangible assets[1,2]	23,611	10,159	6,240
Tangible assets[3]	488	136	135
Financial assets	447	286	193
Total non-current assets	24,546	10,581	6,567
Current assets			
Inventories	1,482	1,284	1,185
Accounts receivable	2,267	1,665	1,555
Other receivables, non-interest bearing	686	654	512
Cash and cash equivalents	1,189	2,999	2,306
Total current assets	5,624	6,602	5,558
Total assets	30,170	17,183	12,124
EQUITY AND LIABILITIES			
Shareholders' equity	14,972	9,040	7,851
Non-current liabilities			
Borrowings	5,592	–	–
Lease liabilities	297	3	5
Other liabilities, non-interest bearing	1,792	1,189	1,489
Total non-current liabilities	7,681	1,192	1,493
Current liabilities			
Accounts payable	419	487	308
Lease liabilities	84	1	2
Other liabilities, non-interest bearing	7,014	6,463	2,470
Total current liabilities	7,517	6,951	2,780
Total equity and liabilities	30,170	17,183	12,124

[1]Including goodwill of SEK 1,554 M.

[2]The increase is mainly related to the acquisition of the US rights to Synagis.

[3]The Right-of-use assets related to IFRS 16 are classified as tangible assets and amount to SEK 359 M.

Changes in equity

Amounts in SEK M	Jan-Jun 2019	Full-year 2018	Jan-Jun 2018
Opening balance	9,040	6,701	6,701
Share-based compensation to employees	32	46	18
Issue of shares	4,513	–	–
Comprehensive income for the period[1]	1,387	2,294	1,133
Equity at end of period	14,972	9,040	7,851

[1]Whereof changes in cash flow hedges amounted to SEK -46 M (-92).

Cash flow statement

Amounts in SEK M	Q2 2019	Q2 2018	H1 2019	H1 2018	Full-year 2018
Profit for the period	499	685	1,402	1,200	2,418
Adjustment for non-cash items[1]	592	-6	996	-12	-77
Cash flow from operations before change in working capital	**1,091**	**679**	**2,398**	**1,187**	**2,341**
Change in working capital	184	-115	-735	-346	-250
Cash flow from operations	**1,275**	**564**	**1,663**	**841**	**2,090**
Investment in intangible assets[2]	-46	-12	-8,910	-21	-537
Investment in tangible assets	-9	-11	-18	-19	-41
Divestment of tangible assets	–	1	–	1	3
Divestment of intangible assets	28	–	28	–	–
Investment in financial assets	-1	3	-1	3	-1
Cash flow from investing activities	**-29**	**-19**	**-8,901**	**-35**	**-575**
Loans - Raising/Amortisation	-501	–	5 464	–	–
Lease payments	-22	–	-43	–	–
Net finance lease	–	–	–	–	-1
Cash flow from financing activities	**-523**	**–**	**5,421**	**–**	**-1**
Change in cash and cash equivalents	**724**	**546**	**-1,817**	**806**	**1,514**
Cash and cash equivalents at the beginning of the period	463	1,750	2,999	1,478	1,478
Translation difference in cash flow and cash and cash equivalents	2	10	7	22	7
Cash and cash equivalents at the end of the period	**1,189**	**2,306**	**1 189**	**2,306**	**2,999**
[1] Adjustment for non-cash items:					
Depreciation of tangible assets	67	9	97	18	36
Amortisation and write-downs of intangible assets	359	111	641	221	449
Restructuring reserve	120	–	120	–	–
Deferred tax	79	-23	217	-54	-103
Other, whereof mainly non-cash transactions including revaluation of loans	-34	-103	-79	-198	-459
Non-cash items	**592**	**-6**	**996**	**-12**	**-77**

[2]Investments intangible assets	
Investments during H1 2019, whereof Synagis SEK 13,869 M in Q1	-13,919
Issue of shares	4,513
Deferred purchase consideration	496
Cash paid	-8,910

Key ratios and other information

Amounts in SEK M	Q2 2019	Q2 2018	H1 2019	H1 2018	Full-year 2018
Profit measures					
Gross profit	2,413	1,677	4,907	3,089	6,723
EBITDA[1]	1,104	961	2,643	1,740	3,607
EBITA[1]	1,037	951	2,546	1,722	3,571
EBITA adjusted[1,2]	1,193	951	2,665	1,722	3,571
EBIT (operating profit)	677	841	1,905	1,500	3,122
Profit/loss	499	685	1,402	1,200	2,418
Per share data (SEK)					
Earnings per share	1.70	2.54	4.82	4.45	8.97
Earnings per share, adjusted[2,3]	2.12	2.54	5.14	4.45	8.97
Earnings per share after dilution	1.69	2.53	4.80	4.43	8.93
Earnings per share after dilution, adjusted[2,3]	2.11	2.53	5.12	4.43	8.93
Shareholders' equity per share[1]	50.3	28.8	50.3	28.8	33.1
Shareholders' equity per share after dilution[1]	50.1	28.6	50.1	28.6	32.9
Other information					
Gross margin[1]	76%	73%	76%	73%	74%
EBITA margin[1]	33%	42%	40%	40%	39%
EBITA margin adjusted[1,2]	38%	42%	41%	40%	39%
Equity ratio[1]	50%	65%	50%	65%	53%
Net cash (-)/debt (+)[1]	4,403	-2,300	4,403	-2,300	-2,999
Number of ordinary shares[4]	297,515 209	272,507,708	297,515,209	272,507,708	273,322,117
Number of ordinary shares (in treasury)	3,423,726	3,249,870	3,423,726	3,249,870	3,423,726
Number of ordinary shares (excluding shares in treasury)	294,091,483	269,257,838	294,091,483	269,257,838	269,898,391
Number of ordinary shares after dilution	298,912,075	274,138,213	298,912,075	274,138,213	274,365,601
Average number of ordinary shares (excluding shares in treasury)	294,091,483	269,257,838	291,017,223	269,257,838	269,523,784
Average number of ordinary shares after dilution (excluding shares in treasury)	295,488,349	270,788,396	292,414,088	270,788,396	270,603,665

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

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

[3]EPS excluding impairment of intangible assets of SEK 18 M related to the 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 in the US.

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

	Q2 2019	Q2 2018	H1 2019	H1 2018	Full-year 2018
Total revenue	3,163	2,289	6,427	4,253	9,139
Total cost of goods sold	-750	-612	-1,521	-1,164	-2,415
Gross profit	**2,413**	**1,677**	**4,907**	**3,089**	**6,723**
Gross margin, %	**76%**	**73%**	**76%**	**73%**	**74%**

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

Total revenue	3,163	2,289	6,427	4,253	9,139
Total revenue, measured at CER	3,017	2,292	6,031	4,242	9,065
Sales for Synagis	148	-	813	-	-
Sales for Synagis, measured at CER	136	-	735	-	-
Total revenue adjusted for Synagis	3,014	2,289	5,614	4,253	9,139
Total revenue adjusted for Synagis, measured at CER	2,881	2,292	5,296	4,242	9,065
Organic growth	725	N/A	1,362	N/A	N/A
Organic growth at CER	589	N/A	1,054	N/A	N/A
Organic growth, %	32%	N/A	32%	N/A	N/A
Organic growth, % CER	**25%**	N/A	**25%**	N/A	N/A

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

EBIT (operating profit)	677	841	1,905	1,500	3,122
Plus amortisation and write-downs of intangible assets	359	111	641	221	449
EBITA	**1,036**	**951**	**2,546**	**1,722**	**3,571**
Plus depreciations of tangible assets	67	9	97	18	36
EBITDA	**1,104**	**961**	**2,643**	**1,740**	**3,607**
EBITA margin, %	**33%**	**42%**	**40%**	**40%**	**39%**
Non-recurring items	157	-	119	-	-
EBITA adjusted	**1,194**	**951**	**2,665**	**1,740**	**3,571**
EBITA margin adjusted, %	**38%**	**42%**	**41%**	**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 - impact from divestment of SOBI005 in Q1 2019 and restructuring expenses in Q2 2019
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.

	Q2 2019	Q2 2018	H1 2019	H1 2018	Full-year 2018
Profit for the period	499	685	1,402	1,200	2,418
Impact of divestment of SOBI005 and restructuring expenses, after tax	123	-	94	-	-
Profit for the period, adjusted	623	685	1,496	1,200	2,418
Average number of ordinary shares	294,091,483	269,257,838	291,017,223	269,257,838	269,523,784
Average number of ordinary shares after dilution	295,488,349	270,788,396	292,414,088	270,788,396	270,603,665
EPS, SEK adjusted	2.12	2.54	5.14	4.45	8.97
EPS after dilution, SEK adjusted	2.11	2.53	5.12	4.43	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	5,592	0	5,592	0	0
Cash and cash equivalents	1,189	2,306	1,189	2,306	2,999
Net debt (+)/Net cash (-)	4,403	-2,306	4,403	-2,306	-2,999

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

Shareholders' equity	14,972	7,851	14,972	7,851	9,040
Total assets	30,170	12,124	30,170	12,124	17,183
Equity ratio, %	50%	65%	50%	65%	53%
Number of ordinary shares	297,515,209	272,507,708	297,515,209	272,507,708	273,322,117
Equity per share, SEK	50.3	28.8	50.3	28.8	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	Q2 2019	Q2 2018	H1 2019	H1 2018	Full-year 2018
Total revenue	2,938	1,897	6,039	3,730	8,221
Total cost of goods sold	-673	-545	-1,459	-1,069	-2,349
Gross profit	**2,265**	**1,353**	**4,580**	**2,662**	**5,872**
Sales and administrative expenses[1]	-909	-350	-1,467	-648	-1,445
Research and development expenses	-417	-228	-660	-449	-932
Other operating income/expenses	3	-6	53	21	-2
Operating profit	**942**	**768**	**2,506**	**1,585**	**3,492**
Financial income/expenses	93	-8	10	-4	-35
Profit after financial items	**1,035**	**760**	**2,516**	**1,581**	**3,457**
Appropriations	–	–	–	–	-397
Profit before tax	**1,035**	**760**	**2,516**	**1,581**	**3,060**
Income tax expenses	-16	-147	-96	-301	-678
Profit for the period	**1,019**	**613**	**2,420**	**1,280**	**2,382**
[1]Amortisation and write-downs of intangible assets included in Sales and administrative expenses.	-93	-71	-168	-143	-292

Statement of other comprehensive income

Amounts in SEK M	Q2 2019	Q2 2018	H1 2019	H1 2018	Full-year 2018
Profit/loss for the period	1,019	613	2,420	1,280	2,382
Items that may be subsequently reclassified to profit/loss					
Cash flow hedge (net of tax)	-22	-70	-35	-92	-133
Comprehensive income for the period	**997**	**543**	**2,385**	**1,189**	**2,248**

Balance sheet

Amounts in SEK M	Jun 2019	Dec 2018	Jun 2018
ASSETS			
Non-current assets			
Intangible assets	3,673	3,801	3,931
Tangible assets	98	112	110
Financial assets	3,541	3,537	2,915
Total non-current assets	7,312	7,450	6,956
Current assets			
Inventories	1,241	1,071	1,042
Accounts receivable	838	590	564
Receivables Group companies[1]	15,948	1,465	1,175
Other receivables, non-interest bearing	651	589	460
Cash and cash equivalents	1,000	2,762	2,170
Total current assets	19,678	6,476	5,411
Total assets	26,989	13,926	12,366
EQUITY AND LIABILITIES			
Shareholders' equity	14,660	7,731	6,643
Untaxed reserves	2,584	2,584	2,124
Non-current liabilities			
Borrowings	5,649	–	–
Other liabilities, non-interest bearing	395	508	836
Total non-current liabilities	6,044	508	836
Current liabilities			
Accounts payable	314	376	268
Other liabilities, non-interest bearing	3,387	2,727	2,495
Total current liabilities	3,701	3,103	2,763
Total equity and liabilities	26,989	13,926	12,366

[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-June 2019	Full-year 2018	Jan-June 2018
Opening balance	7,731	5,436	5,436
Share-based compensation to employees	32	46	18
Issue of shares	4,513	–	–
Comprehensive income for the period[1]	2,385	2,248	1,189
Equity at end of period	14,660	7,731	6,643

[1]Whereof changes in cash flow hedges amounted to SEK -35 M (-92).

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-June 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 will be 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 were measured at the net present value of the remaining lease payments. The weighted average discounting rate (incremental borrowing rate as per transition date) applied 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 June 2019 was SEK 1 M, consisting of a SEK 73 M decrease in other operating expenses and a SEK 72 M increase in depreciations. In summary, no material impact on operating profit and EPS.

However, the alternative performance measure EBITDA has increased by SEK 73 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 June 2019, the net reported value of derivatives on the balance sheet was SEK -23 M (-8).

At 30 June 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 are charged in Q2 2019 relating to the planned 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.

Definitions and Glossary

Alprolix (eftrenonacog alfa)	A recombinant, EHL clotting factor IX therapy approved in the EU, Iceland, Kuwait, Liechtenstein, Norway, Saudi Arabia and Switzerland, as well as in Australia, Brazil, Canada, Japan, New Zealand, the United States and other countries, for the treatment of haemophilia B, and which can be used by people of all ages.
CER	Constant exchange rates.
Clock stop	A period during which the evaluation of a medicine is officially stopped, while the applicant prepares responses to questions from the regulatory authority. The clock resumes when the applicant has sent its responses.
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.
EULAR/PReS	European League Against Rheumatism / Paediatric Rheumatology European Society.
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 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
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.
Macrophage activation syndrome (MAS)	A rare, life-threatening condition characterised by uncontrolled hyperinflammation which may develop on a background of rheumatic diseases such as sJIA. It is classified as a secondary form of HLH and is caused by excessive activation and expansion of T cells and macrophages. MAS is characterised by fever, hepatosplenomegaly, liver dysfunction, cytopenias, coagulation abnormalities and hyperferritinaemia, possibly progressing to multiple organ failure and death.

Definitions and Glossary

Mucopolysaccharidosis (MPS) type IIIA (Sanfilippo A syndrome)	A progressive, life-threatening and rare inherited metabolic disorder affecting children from a young age. Belongs to a group of diseases called lysosomal storage disorders (LSDs).
Orfadin (nitisinone)	A drug used to treat hereditary tyrosinaemia type 1 (HT-1). It blocks the breakdown of tyrosine, thereby reducing the amount of toxic tyrosine by-products in the body. Patients must maintain a special diet in combination with Orfadin treatment as tyrosine is not adequately broken down.
Systemic juvenile idiopathic arthritis (sJIA)	A rare systemic disorder of auto-inflammatory nature with common clinical manifestations such as daily spiking fever, typical transient cutaneous rash, arthritis, lymphadenopathy, hepatosplenomegaly and serositis.
RSV	Respiratory syncytial virus. A common virus and the most common cause of lower respiratory tract infections (LRTI) in young children.
SOBI003	A product candidate and a chemically modified variant of a recombinant human sulfamidase, using Sobi's proprietary glycan modification technology Modifa™, intended as an enzyme-replacement therapy in the lysosomal storage disease MPS IIIA, aimed at reducing heparan sulfate storage materials in affected cells.
SOBI005	A novel biopharmaceutical product candidate based on the Affibody platform that works as an inhibitor of complement protein C5. SOBI005 is formatted as an Fc fusion protein and is intended to be administered by subcutaneous injection.
SOBI006	A novel biopharmaceutical product candidate based on the Affibody platform that works as an antagonist of the IL-1 receptor, blocking the actions of both IL-1alpha and IL-1beta. SOBI006 is formatted as an Fc fusion protein and is intended to be administered by subcutaneous injection.
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 1,050 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.

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