Significant progress with launches

Q4 and FY 2021 report

October – December 2021

- **Total revenue** SEK 4,896 M (4,581), +7 per cent, +9 per cent at constant exchange rates (CER)
- **Haematology** revenue SEK 2,242 M (2,081), +8 per cent at CER of which Elocta® SEK 1,063 M (1,071), unchanged at CER, Alprolix® SEK 482 M (419), +16 per cent at CER, and Doptelet® SEK 306 M (191), +60 per cent at CER. First shipment of Empaveli™ achieved
- **Immunology** revenue SEK 2,330 M (2,281), +6 per cent at CER of which Kineret® SEK 682 M (586), +16 per cent at CER, Synagis® SEK 1,364 M (1,432), +1 per cent at CER, and Gamifant® SEK 284 M (263), +10 per cent at CER
- **EBITA**[1] SEK 2,002 M (2,576), EBITA margin[1] 41 per cent (56, adjusted 48)
- **Earnings per share** (EPS) before dilution SEK 4.21 (5.09)
- **Cash flow** from operating activities SEK 2,121 M (716)
- **Aspaveli®** EU approval and **Kineret** EU approval extension

January – December 2021

- **Total revenue** SEK 15,529 M (15,261), +2 per cent, +7 per cent at CER
- **Haematology** revenue SEK 8,536 M (8,660), +3 per cent at CER of which Elocta SEK 3,960 M (4,585), -11 per cent at CER, Alprolix SEK 1,764 M (1,705), +7 per cent at CER, and Doptelet SEK 1,116 M (587), +104 per cent at CER
- **Immunology** revenue SEK 5,780 M (5,415), +15 per cent at CER of which Kineret SEK 2,290 M (2,079), +16 per cent at CER, Synagis SEK 2,650 M (2,726), +6 per cent at CER, and Gamifant SEK 840 M (609), +48 per cent at CER
- **EBITA**[1] SEK 5,575 M (6,700), EBITA margin[1] 36 per cent (44, adjusted 41)
- **EPS** before dilution SEK 9.08 (11.01)
- **Cash flow** from operating activities SEK 5,470 M (4,926)

2022 outlook

- Revenue is anticipated to grow by a mid to high single-digit percentage at CER
- EBITA margin is anticipated to be at a low 30s percentage of revenue

Total revenue Q4, SEK M

4,896

Total revenue growth Q4, CER

9%

Launch medicines* growth Q4, CER

31%

EBITA margin[1] Q4

41%

Financial summary

SEK M	Q4 2021	Q4 2020	Change	Full-year 2021	Full-year 2020	Change
Total revenue	4,896	4,581	7%	15,529	15,261	2%
Gross profit	3,880	3,718	4%	12,045	12,036	0%
Gross margin[1]	79%	81%		78%	79%	
EBITA[1]	2,002	2,576	-22%	5,575	6,700	-17%
EBITA adjusted[1,2]	2,002	2,177	-8%	5,575	6,301	-12%
EBITA margin[1]	41%	56%		36%	44%	
EBITA margin adjusted[1,2]	41%	48%		36%	41%	
Profit for the period	1,241	1,502	-17%	2,679	3,245	-17%
Earnings per share, before dilution, SEK	4.21	5.09	-17%	9.08	11.01	-18%
Earnings per share, before dilution, SEK adjusted[1,2,3]	4.21	3.74	12%	9.08	9.66	-6%

[1]Alternative Performance Measures (APMs), see page 21 for further information.

[2]EBITA in 2020 excluding non-recurring items; other operating income related to the reversal of the CVR liability of SEK 399 M, see page 22 for further information.

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

* Launch medicines include Doptelet and Gamifant.

CEO statement

Closing 2021, it is a pleasure to look back on a year of some great achievements, in our pipeline, in our geographic expansion, in sales figures, and in our overall performance.

We are returning to sustainable revenue growth and delivered a strong quarter. The fourth quarter closed with revenue of SEK 4,896 M and growth of 9 per cent at CER, including extraordinary sales of Kineret for use in COVID-19 patients at risk of developing severe respiratory failure. Our launch medicines, Doptelet and Gamifant, combined grew by 31 per cent in the quarter and by 75 per cent in the year. EBITA in the quarter was SEK 2,002 M, with a margin of 41 per cent.

We had positive developments across our portfolio throughout the year. A major accomplishment was the approval of Aspaveli in the EU, as was the extension of the Kineret approval in the EU to cover COVID-19 in patients at risk of developing severe respiratory failure.

For haemophilia, we saw a stabilisation of the business as we moved through the year. We remain optimistic that our pipeline medicine efanesoctocog alfa (formerly BIVV001) has the potential to be a transformative treatment for people with haemophilia A.

We continued to expand our geographic footprint in 2021, including new presence in a large part of Latin America through a distribution agreement. With that included, Sobi medicines will now be present in countries with an estimated 90 per cent of rare disease patients globally, supporting our strategy of becoming a leader in rare diseases.

In September 2021, Sobi shareholders received a public cash offer to sell their shares. The offer was withdrawn in December as the acceptance level condition was not met. Today's results show the performance during this period, and I would like to thank every employee for their commitment and resilience and the dedication to patients.

We enter 2022 from a position of strength, with continued and consistent revenue growth. We will continue to reinforce the foundation for Sobi's future growth, through investment in our pipeline and launches – taking newly licensed or acquired medicines through clinical development to the patient and taking existing medicines into new indications and new markets.

I am committed to accelerate the delivery of medicines to patients in need and to ensure an inspiring workplace to make it happen.

Solna, Sweden, 10 February 2022

Guido Oelkers, President & CEO

Financial performance

Total revenue

Total revenue for October to December ('the quarter') amounted to SEK 4,896 M (4,581), an increase of 7 per cent compared with the same period a year ago and 9 per cent at CER. Growth was mainly driven by increased uptake of Doptelet in the US and strong demand for Kineret, related to COVID-19 in Russia, Romania and Turkey. Tegsedi® and Waylivra® that were in-licensed recently also contributed.

Revenue for January to December ('the full year') was SEK 15,529 M (15,261), an increase of 2 per cent compared to the prior year and 7 per cent at CER.

SEK M	Q4 2021	Q4 2020	Change	Change at CER	Full-year 2021	Full-year 2020	Change	Change at CER
Haematology	2,242	2,081	8%	8%	8,536	8,660	-1%	3%
Immunology	2,330	2,281	2%	6%	5,780	5,415	7%	15%
Specialty Care	324	218	48%	46%	1,213	1,186	2%	8%
Total	**4,896**	**4,581**	**7%**	**9%**	**15,529**	**15,261**	**2%**	**7%**

Gross profit

Gross profit for the quarter was SEK 3,880 M (3,718), representing a gross margin of 79 per cent (81). The margin decrease was driven mainly by a mandatory price reduction for Elocta in Germany and unfavourable product and country mix driven by Kineret, Tegsedi and Waylivra. Full-year gross profit was SEK 12,045 M (12,036), representing a gross margin of 78 per cent (79).

Operating expenses

Selling and administrative expenses, excluding amortisation and impairment, amounted to SEK 1,346 M (1,092) for the quarter, and full year to SEK 4,453 M (4,099). For the quarter, expenses increased by 23 per cent at CER, reflecting launch preparations for Aspaveli and activities related to Tegsedi and Waylivra.

Research and development expenses amounted to SEK 554 M (486) for the quarter, and for the full year to SEK 1,994 M (1,594). The increase in the quarter reflected spending related to development programmes for Aspaveli and SEL-212.

SEK M	Q4 2021	Q4 2020	Full-year 2021	Full-year 2020
Total revenue	4,896	4,581	15,529	15,261
Cost of goods sold	-1,016	-863	-3,484	-3,225
Gross profit	**3,880**	**3,718**	**12,045**	**12,036**
Gross margin	*79%*	*81%*	*78%*	*79%*
Selling and administrative expenses before amortisation and impairment of intangible assets	-1,346	-1,092	-4,453	-4,099
Research and development expenses	-554	-486	-1,994	-1,594
Operating expenses less amortisation and impairment of intangible asset	**-1,900**	**-1,578**	**-6,446**	**-5,693**
Other operating income/expenses	23	435	-24	357
EBITA	**2,002**	**2,576**	**5,575**	**6,700**
Non-recurring items	–	-399	–	-399
EBITA adjusted [1]	***2,002***	***2,177***	***5,575***	***6,301***
Amortisation and impairment of intangible assets related to Selling and administrative expenses	-477	-460	-1,841	-1,882
EBIT (Operating profit)	**1,525**	**2,116**	**3,733**	**4,818**

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

[1]EBITA in full-year 2020 excluding non-recurring items; other operating income related to the reversal of the CVR liability of SEK 399 M, see page 22 for further information.

Operating profit

EBITA for the quarter was SEK 2,002 M (2,576) and full year SEK 5,575 M (6,700), corresponding to a margin of 41 per cent (56, adjusted 48) and 36 per cent (44, adjusted 41), respectively. EBITA for 2020 included a positive impact from reversal of a contingent value right (CVR) liability of SEK 399 M. Amortisation of intangible assets for the quarter amounted to SEK 477 M (460) and for the full year to SEK 1,841 M (1,882). EBIT for the quarter amounted to SEK 1,525 M (2,116) and for the full year SEK 3,733 M (4,818).

Net financial items

Net financial items amounted to SEK -102 M (-180) for the quarter and full year to SEK -438 M (-601). The quarter and full-year improvement reflected lower debt in 2021 and negative exchange rate effects in 2020.

Tax

Income tax amounted to SEK -182 M (-434) for the quarter, corresponding to an effective tax rate of 12.7 per cent (22.4), and full year to SEK -616 M (-972), corresponding to an effective tax rate of 18.7 per cent (23.1). The lower tax rates were mainly due to capitalisation of losses from prior years.

Profit

Profit totalled SEK 1,241 M (1,502) for the quarter and SEK 2,679 M (3,245) for the full year.

Cash flow

Cash flow from operating activities before changes in working capital amounted to SEK 1,856 M (2,047) for the quarter and SEK 4,356 M (5,367) for the full year. Changes in working capital affected cash flow by SEK 265 M (-1,331) for the quarter and by SEK 1,114 M (-441) for the full year, reflecting decreased receivables, followed by timing of payments due to the early start of the RSV season. Further, the comparative periods in 2020 was negatively impacted by inventory build-up.

Cash flow from investing activities was SEK -245 M (-2,528) for the quarter and SEK -367 M (-3,964) for the full year. The 2020 figures included the investments in SEL-212 and Aspaveli.

Cash and net debt

On 31 December 2021, cash and cash equivalents amounted to SEK 1,045 M (404) with undrawn committed credit facilities totalling SEK 4,336 M (4,320) and drawn credit facilities totalling SEK 10,597 M (14,234). Net debt at the end of December 2021 amounted to SEK 9,500 M (13,748). The decrease in net debt was mainly driven by the strong operating cash flow generated in the period.

Equity

On 31 December 2021, consolidated shareholders' equity was SEK 23,203 M (20,206).

Personnel

On 31 December 2021, the number of full-time equivalents was 1,559 (1,509).

Parent Company

In the fourth quarter, total revenue for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 5,031 M (3,565), of which Group companies accounted for SEK 3,806 M (2,453). Total revenue for the full year amounted to SEK 12,401 M (13,968) of which SEK 7,967 M (8,349) referred to Group companies' sales. The full-year decrease reflected the transfer of the Synagis sales to the US subsidiary during 2020.

Profit/loss amounted to SEK -96 M (-772) for the quarter and to SEK 1,790 M (3,406) for the full year. Investing activities affecting cash flow amounted to SEK -233 M (-2,348) for the quarter and for the full year to SEK -288 M (-3,760).

Haematology

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

Revenue Haematology

SEK M	Q4 2021	Q4 2020	Change	Change at CER	Full-year 2021	Full-year 2020	Change	Change at CER
Elocta	1,063	1,071	-1%	0%	3,960	4,585	-14%	-11%
Alprolix	482	419	15%	16%	1,764	1,705	3%	7%
Royalty	317	316	0%	-1%	1,251	1,301	-4%	3%
Doptelet	306	191	60%	60%	1,116	587	90%	104%
Aspaveli/Empaveli	1	–	n/a	n/a	1	–	n/a	n/a
Manufacturing	72	84	-13%	-13%	445	481	-8%	-8%
Total	**2,242**	**2,081**	**8%**	**8%**	**8,536**	**8,660**	**-1%**	**3%**

Haematology revenue amounted to SEK 2,242 M (2,081) for the quarter, an increase of 8 per cent and 8 per cent at CER. Full-year revenue amounted to SEK 8,536 M (8,660), down by 1 per cent and up by 3 per cent at CER.

Elocta sales were SEK 1,063 M (1,071) for the quarter, down by 1 per cent and unchanged at CER. The negative impact from price adjustments, including the mandatory reduction in Germany, was offset by low single-digit percentage growth in patients and higher factor consumption. Full-year sales amounted to SEK 3,960 M (4,585), down by 14 per cent and by 11 per cent at CER.

Alprolix sales were SEK 482 M (419) for the quarter, an increase of 15 per cent and 16 per cent at CER. Sales grew mainly from underlying patient growth. Full-year sales amounted to SEK 1,764 M (1,705), an increase of 3 per cent and 7 per cent at CER.

Royalty revenue was SEK 317 M (316) for the quarter and SEK 1,251 M (1,301) for the full year.

Doptelet sales were SEK 306 M (191) for the quarter, an increase of 60 per cent and 60 per cent at CER. Growth was driven mainly by continued launch progress in the US, launch in Europe and higher sales to the partner in China. Full-year sales amounted to SEK 1,116 M (587), an increase of 90 per cent and 104 per cent at CER.

Empaveli sales started in the quarter with initial supply in Saudi Arabia.

ReFacto AF/Xyntha manufacturing revenue totalled SEK 72 M (84) for the quarter and SEK 445 M (481) for the full year.

Immunology

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

Revenue Immunology

SEK M	Q4 2021	Q4 2020	Change	Change at CER	Full-year 2021	Full-year 2020	Change	Change at CER
Kineret	682	586	16%	16%	2,290	2,079	10%	16%
Synagis	1,364	1,432	-5%	1%	2,650	2,726	-3%	6%
Gamifant	284	263	8%	10%	840	609	38%	48%
Total	**2,330**	**2,281**	**2%**	**6%**	**5,780**	**5,415**	**7%**	**15%**

Immunology revenue for the quarter amounted to SEK 2,330 M (2,281), an increase of 2 per cent and 6 per cent at CER. Full-year revenue was SEK 5,780 M (5,415), an increase of 7 per cent and 15 per cent at CER.

Kineret sales for the quarter were SEK 682 M (586), an increase of 16 per cent and 16 per cent at CER. While Kineret continued to perform well, driven by new uses and patient growth, most of the sales growth came from supplies in Russia, Romania and Turkey related to COVID-19. This was partly offset by lower demand in the US. Full-year sales were SEK 2,290 M (2,079), an increase of 10 per cent and 16 per cent at CER.

Synagis sales for the quarter were SEK 1,364 M (1,432), down by 5 per cent and up by 1 per cent at CER driven by continued good demand. The comparative period in 2020 was positively impacted by stocking effects. Full-year sales were SEK 2,650 M (2,726), down by 3 per cent and up by 6 per cent at CER.

Gamifant sales for the quarter amounted to SEK 284 M (263), an increase of 8 per cent and 10 per cent at CER, reflecting continued patient growth, increased volume per patient and longer duration of therapy. Full-year sales were SEK 840 M (609), an increase of 38 per cent and 48 per cent at CER.

Specialty Care

Revenue is generated from sales of Orfadin®, Tegsedi, Waylivra and other medicines in specialty care.

Revenue Specialty Care

SEK M	Q4 2021	Q4 2020	Change	Change at CER	Full-year 2021	Full-year 2020	Change	Change at CER
Orfadin	121	146	-17%	-19%	459	665	-31%	-28%
Tegsedi	123	–	n/a	n/a	427	–	n/a	n/a
Waylivra	30	–	n/a	n/a	121	–	n/a	n/a
Other Specialty Care	50	72	-31%	-32%	207	521	-60%	-58%
Total	**324**	**218**	**48%**	**46%**	**1,213**	**1,186**	**2%**	**8%**

Specialty Care revenue for the quarter was SEK 324 M (218), an increase of 48 per cent and 46 per cent at CER. The increase was driven by Tegsedi and Waylivra that were in-licensed recently, while Orfadin sales continued to be negatively impacted by generic competition and associated price erosion. Full-year sales were SEK 1,213 M (1,186), an increase of 2 per cent and 8 per cent at CER.

Pipeline

Pipeline milestones since the previous quarterly report

(Abbreviations used in the table are explained in the text below)

Regulatory approval	Aspaveli/Empaveli – PNH: approval EU, Saudi Arabia, Australia Kineret – COVID-19: approval EU Kineret – familial Mediterranean fever, Still's disease: approval Russia
Other significant milestones	Aspaveli/Empaveli – TA-TMA: phase 2 study start Gamifant – MAS in rheumatological diseases: EMERALD phase 3 study start SEL-212 – CRG: DISSOLVE I phase 3 study enrolment completed

Haematology

Aspaveli/Empaveli

Aspaveli/Empaveli, a recently approved medicine for the treatment of paroxysmal nocturnal haemoglobinuria (PNH), is in phase 2 and phase 3 clinical development for several new indications.

In December, Aspaveli, the trade name in the EU, was approved by the European Commission for the treatment of adult patients with PNH who are anaemic after treatment with a C5 inhibitor for at least 3 months. With the approval, Aspaveli became the first new medicine in the EU since 2007 for the treatment of PNH with a novel mechanism of action, providing expanded choice to treating physicians and patients. The first EU country is currently initiating a launch of the medicine.

At the 63rd American Society of Hematology (ASH) annual meeting and exposition in Atlanta, Georgia, US in December, Sobi and the US collaborator Apellis Pharmaceuticals, Inc. provided new data for Aspaveli/Empaveli, including a presentation of the PRINCE phase 3 study in treatment-naïve patients with PNH, four posters covering various aspects from the clinical development programme in PNH as well as additional data for publication only.

Outside the approved indication in PNH, Sobi and Apellis are developing Aspaveli/Empaveli in collaboration for potential use in several new indications. A Sobi-sponsored phase 2 study in transplant-associated thrombotic microangiopathy after allogenic haematopoietic stem cell transplantation (TA-TMA) recently achieved the first patient dosed. A phase 3 study in cold agglutinin disease (CAD) is currently awaiting the first patient to be dosed. Apellis is advancing the medicine in immune complex-mediated membranoproliferative glomerulonephritis (IC-MPGN) and C3 glomerulopathy (C3G) where a phase 3 study is currently awaiting the first patient to be dosed. In addition, Apellis has the ongoing MERIDIAN phase 2 study, potentially registrational, in amyotrophic lateral sclerosis (ALS) with anticipated completion of enrolment in the first half of 2022.

Efanesoctocog alfa

Efanesoctocog alfa (formerly BIVV001), a potential new treatment for haemophilia A, is in phase 3 clinical development with the collaborator Sanofi. The first data readout from the XTEND-1 phase 3 study in adults and adolescences is anticipated during the first half of 2022. Enrolment and dosing were initiated in the XTEND-Kids phase 3 paediatric study in patients younger than 12 years of age in early 2021 with the paediatric study data readout anticipated in 2023. If results are positive, efanesoctocog alfa could provide high sustained factor VIII activity and near-normal factor levels for the majority of the week.

At the ASH medical meeting (see above), new data were shared for efanesoctocog alfa from the phase 1/2a studies supporting its profile as being independent of von Willebrand factor, a key component of the blood clotting cascade.

Immunology

Kineret

In December, Kineret was approved by the European Commission for the treatment of coronavirus disease 2019 (COVID-19) in adult patients with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure determined by plasma concentration of soluble urokinase plasminogen activator receptor (suPAR) ≥ 6ng/ml. suPAR is a biomarker which can be measured in the blood of patients. The EU approval followed a positive opinion by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency which was issued just one day ahead. In the US, Sobi anticipates making a regulatory submission for emergency use authorisation with agency validation expected during the first half of 2022.

Gamifant

Gamifant recently initiated dosing in a new phase 3 study, EMERALD. EMERALD evaluates the treatment of macrophage activation syndrome (MAS) in paediatric and adult patients with underlying rheumatological diseases, specifically Still´s disease and systemic lupus erythematosus. If the results are positive at the conclusion of the study, the first regulatory submission for a new indication is planned for the US with other countries to follow.

At the ASH medical meeting, new data were presented on the use of Gamifant in primary haemophagocytic lymphohistiocytosis (pHLH) (a severe systemic inflammatory syndrome which can be fatal and an approved indication in some countries) as well as clinical experience from use in other diseases, including MAS in systemic juvenile idiopathic arthritis.

SEL-212

SEL-212, a potential new medicine for the treatment of chronic refractory gout (CRG), is advancing in phase 3 clinical development.

In December 2021, Sobi and Selecta Biosciences, Inc., the collaboration development partner and originator of SEL-212, announced the completion of enrolment in the DISSOLVE I clinical study. The other study in the phase 3 DISSOLVE clinical study programme, DISSOLVE II, is anticipated to achieve the same milestone in the first half of 2022. Phase 3 data readout is anticipated during the second half of 2022.

Nirsevimab

Nirsevimab, a potential new immunisation for the prevention of RSV infections in infants, is nearing the completion of phase 3 clinical development by the collaborators AstraZeneca PLC and Sanofi.

Results from the MEDLEY phase 2/3 safety study were presented in November 2021 at the RSVVW'21 conference, a global medical meeting on novel RSV preventive and therapeutic interventions. The data showed that nirsevimab had a similar safety and tolerability profile to Synagis in infants with coronary heart disease, chronic lung disease and those born pre-term. This followed prior data presentations from the MELODY phase 3 efficacy study.

AstraZeneca and Sanofi intend to make a regulatory submission for nirsevimab in the US in the second half of 2022 based on the earlier phase 2b study and the MELODY and MEDLEY studies. Sobi has the right to AstraZeneca's full share of US losses and profits for nirsevimab.

News flow

Anticipated major upcoming pipeline news flow

H1 2022	Efanesoctocog alfa – haemophilia A: XTEND-1 phase 3 study data readout Efanesoctocog alfa – haemophilia A (paediatric): XTEND-Kids phase 3 study enrolment completion Aspaveli/Empaveli – CAD: phase 3 study first patient dosed Aspaveli/Empaveli – IC-MPGN and C3G: phase 3 study first patient dosed (by Apellis) Aspaveli/Empaveli – ALS: MERIDIAN phase 2 study enrolment completion (by Apellis) Kineret – COVID-19: regulatory submission, emergency use (US) Gamifant – pHLH: regulatory decision (CN) SEL-212 – CRG: DISSOLVE II phase 3 study enrolment completion
H2 2022	Efanesoctocog alfa – haemophilia A: regulatory submission (US) (by Sanofi in mid 2022) Nirsevimab – RSV prevention: regulatory submission (US) (by AstraZeneca/Sanofi) (financial participation by Sobi) Gamifant – MAS in rheumatological diseases: EMERALD phase 3 study data readout SEL-212 – CRG: phase 3 data readout
2023	Efanesoctocog alfa – haemophilia A (paediatric): XTEND-Kids phase 3 study data readout Efanesoctocog alfa – haemophilia A: regulatory submission (EU) Gamifant – MAS in rheumatological diseases: regulatory submission (US) SEL-212 – CRG: regulatory submission

Research and development expenses

SEK M	Q4 2021	Q4 2020	Full-year 2021	Full-year 2020
Research and development expenses	-554	-486	-1,994	-1,594
Total revenue	4,896	4,581	15,529	15,261
Research and development expenses in relation to total revenues	**11%**	**11%**	**13%**	**10%**

Other information

Business development

In October 2021, Sobi signed an agreement with Galapagos NV regarding the distribution of Jyseleca® (filgotinib), a medicine in immunology and approved to treat rheumatoid arthritis and ulcerative colitis. Sobi will distribute the medicine in central and eastern Europe, Greece, Portugal and the Baltic countries.

In December 2021, Sobi signed an agreement with Pint Pharma, a company focused on cancers, rare diseases and other specialty conditions, regarding the commercialisation of Sobi medicines in seven Latin American countries, including Brazil. The initial focus is anticipated to be Empaveli for the treatment of PNH.

Sustainability

Sobi's sustainability efforts supports the overall mission to improve lives for people living with rare diseases and are based on two priorities:

- Commitment to patients
- Responsible behaviour

During the fourth quarter, several approvals of Sobi medicines in different markets opened possibilities for more patients to access treatment. Sobi continued its participation in congresses, most notably the ASH medical meeting, to share knowledge. Sobi also provided support to awareness-raising activities such as the world's first-ever World Amyloidosis Day.

Work continued to improve internal processes designed to ascertain responsible behaviour and raise internal awareness of ethics, integrity and data safety with activities such as Ethics & Integrity Week and Cyber Security Month. A data platform to monitor and track progress on sustainability indicators was launched, involving all Sobi functions and geographies.

Sobi's progress was recognised by a nine-point increase in the absolute score in the 2021 S&P Corporate Sustainability Assessment, published in November 2021.

2022 outlook

In 2022, Sobi will continue to expand its presence in haematology and immunology and expand into new geographic markets. As a result of this growth strategy, Sobi expects solid revenue growth:

- Revenue is anticipated to grow by a mid to high single-digit percentage at CER

Sobi will continue to invest in the pipeline and launches of new medicines to unlock the long-term value of the business. With these investments in the future, Sobi maintains a favourable margin:

- EBITA margin is anticipated to be at a low 30s percentage of revenue

Dividend

The Board of Directors proposes that no dividend will be paid for the 2021 financial year.

Annual General Meeting 2022

The Annual General Meeting (AGM) of Swedish Orphan Biovitrum AB (publ) will be held on Tuesday 10 May 2022. Further information regarding the AGM will be available on Sobi's website. The annual report for 2021 will be published on sobi.com three weeks before the AGM. It will also be available at Sobi's head office in Solna, Sweden.

Financial calendar

Q1 2022	28 April 2022
AGM	10 May 2022
Q2 2022	19 July 2022
Q3 2022	27 October 2022

For a full financial calendar, please visit sobi.com.

Forward-looking statements

This report includes forward-looking statements. Actual results may differ from those stated. Internal factors such as the successful management of R&D programmes and intellectual property rights may affect future results. There are also external conditions such as the economic climate, political changes and competing R&D 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. The information was submitted for publication at 08:00 CET on 10 February 2022.

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

Solna, Sweden, 10 February 2022

Guido Oelkers, President & CEO

Financial statements – Group

Consolidated statements of comprehensive income

SEK M	Q4 2021	Q4 2020	Full-year 2021	Full-year 2020
Total revenue	4,896	4,581	15,529	15,261
Cost of goods sold	-1,016	-863	-3,484	-3,225
Gross profit	**3,880**	**3,718**	**12,045**	**12,036**
Selling and administrative expenses[1]	-1,824	-1,552	-6,294	-5,981
Research and development expenses	-554	-486	-1,994	-1,594
Other operating income/expenses	23	435	-24	357
Operating profit	**1,525**	**2,116**	**3,733**	**4,818**
Net financial items[2]	-102	-180	-438	-601
Profit before tax	**1,423**	**1,936**	**3,295**	**4,217**
Income tax	-182	-434	-616	-972
Profit for the period	**1,241**	**1,502**	**2,679**	**3,245**
All earnings are attributable to Parent Company shareholders				
Other comprehensive income				
Items that cannot be reclassified into profit or loss				
Remeasurements on defined-benefit plans (net of tax)	11	-4	17	-3
Fair value of equity instruments (net of tax)	3	9	11	9
Total	**15**	**5**	**28**	**6**
Items that can be reclassified into profit or loss				
Translation differences	253	-450	464	-434
Net investment hedges (net of tax)	-76	198	-242	246
Cash flow hedges (net of tax)	-7	143	-63	130
Total	**170**	**-109**	**159**	**-58**
Other comprehensive income	**185**	**-104**	**187**	**-52**
Comprehensive income for the period	**1,426**	**1,398**	**2,866**	**3,193**
All comprehensive income are attributable to Parent Company shareholders				
Earnings per share, SEK	4.21	5.09	9.08	11.01
Earnings per share, SEK, adjusted[3]	4.21	3.74	9.08	9.66
Earnings per share after dilution, SEK	4.18	5.04	9.03	10.90
Earnings per share after dilution, SEK, adjusted[3]	4.18	3.69	9.03	9.56
[1]Amortisation and impairment of intangible assets included in Selling and administrative expenses.	-477	-460	-1,841	-1,882
[2]Including financing costs.	-8	-10	-35	-32

[3]APMs, see page 21 for further information.

Consolidated balance sheet

SEK M	Dec 2021	Dec 2020
ASSETS		
Non-current assets		
Intangible assets[1]	38,424	38,791
Tangible assets	493	534
Financial assets	199	179
Deferred tax assets	767	611
Total non-current assets	**39,883**	**40,115**
Current assets		
Inventories	3,424	3,053
Accounts receivable	3,439	3,756
Other receivables, non-interest bearing	870	955
Cash and cash equivalents	1,045	404
Total current assets	**8,778**	**8,168**
Total assets	**48,661**	**48,283**
EQUITY AND LIABILITIES		
Shareholders´ equity	**23,203**	**20,206**
Non-current liabilities		
Borrowings	8,777	10,137
Deferred tax liabilities	3,605	3,464
Lease liabilities	247	308
Other liabilities, non-interest bearing	4,068	3,725
Total non-current liabilities	**16,697**	**17,634**
Current liabilities		
Borrowings	1,768	4,015
Accounts payable	558	569
Lease liabilities	114	111
Other liabilities, non-interest bearing	6,321	5,748
Total current liabilities	**8,761**	**10,443**
Total equity and liabilities	**48,661**	**48,283**

[1]Including goodwill of SEK 6,288 M (5,873).

Changes in equity

SEK M	Full-year 2021	Full-year 2020
Opening balance	**20,206**	**16,930**
Adjusted opening balance for post employment-benefits from prior years[1]	–	-38
Share-based compensation to employees	134	114
Share-based compensation to employees tax effect[2]	-3	7
Comprehensive income for the period[3]	2,866	3,193
Equity at end of period	**23,203**	**20,206**

[1]Refers to post employment-benefits, mainly in Switzerland not previously included on December 2019 (net of tax).

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

[3]Whereof changes in cash flow hedges (net of tax) amounted to SEK -63 M (130) and net investment hedges (net of tax) amounted to SEK -242 M (246).

Consolidated cash flow statement

SEK M	Q4 2021	Q4 2020	Full-year 2021	Full-year 2020
Profit before tax[1]	1,423	1,936	3,295	4,217
Amortisation, depreciation and impairment	536	497	2,006	2,023
Other, including non-cash items	76	-226	179	45
Income tax paid	-179	-160	-1,124	-918
Cash flow from operating activities before change in working capital	**1,856**	**2,047**	**4,356**	**5,367**
Changes in working capital	265	-1,331	1,114	-441
Cash flow from operating activities	**2,121**	**716**	**5,470**	**4,926**
Investment in intangible assets[2]	-213	-2,523	-323	-3,811
Investment in tangible assets	-32	-13	-47	-41
Investment in financial assets[2]	–	–	–	-120
Disposal of tangible assets	–	8	3	8
Cash flow from investing activities	**-245**	**-2,528**	**-367**	**-3,964**
Borrowings/repayments of borrowings	-893	1,955	-3,998	-1,452
Hedging arrangement for financing	-122	141	-351	288
Repayment of leasing	-32	-30	-125	-118
Cash flow from financing activities	**-1,047**	**2,066**	**-4,474**	**-1,282**
Change in cash and cash equivalents	**829**	**254**	**629**	**-320**
Cash and cash equivalents at the beginning of the period	212	164	404	737
Translation difference in cash flow and cash and cash equivalents	4	-14	12	-13
Cash and cash equivalents at the end of the period	**1,045**	**404**	**1,045**	**404**

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

[2] 2020 investments mainly refers to SEL-212 and Aspaveli.

Key ratios and other information

SEK M	Q4 2021	Q4 2020	Full-year 2021	Full-year 2020
Profit measures				
Gross profit	3,880	3,718	12,045	12,036
EBITDA[1]	2,061	2,613	5,740	6,841
EBITA[1]	2,002	2,576	5,575	6,700
EBITA adjusted[1,2]	2,002	2,177	5,575	6,301
EBIT (operating profit)	1,525	2,116	3,733	4,818
Profit for the period	1,241	1,502	2,679	3,245
Per share data (SEK)				
Earnings per share	4.21	5.09	9.08	11.01
Earnings per share, adjusted[2,3]	4.21	3.74	9.08	9.66
Earnings per share after dilution	4.18	5.04	9.03	10.90
Earnings per share after dilution, adjusted[2,3]	4.18	3.69	9.03	9.56
Shareholders' equity per share[1]	75.6	66.5	75.6	66.5
Shareholders' equity per share after dilution[1]	75.1	65.9	75.1	65.9
Other information				
Gross margin[1]	79%	81%	78%	79%
EBITA margin[1]	41%	56%	36%	44%
EBITA margin adjusted[1,2]	41%	48%	36%	41%
Equity ratio[1]	48%	42%	48%	42%
Net debt	9,500	13,748	9,500	13,748
Number of ordinary shares[4]	307,114,495	303,815,511	307,114,495	303,815,511
Number of ordinary shares (in treasury)	11,959,198	8,918,672	11,959,198	8,918,672
Number of ordinary shares (ex shares in treasury)	295,155,297	294,896,839	295,155,297	294,896,839
Number of ordinary shares after dilution	308,862,835	306,797,549	308,862,835	306,797,549
Average number of ordinary shares (ex shares in treasury)	295,149,731	294,896,839	295,051,119	294,658,136
Average number of ordinary shares after dilution (ex shares in treasury	296,898,071	297,878,877	296,799,459	297,640,174

[1]APMs, see page 21 for further information.

[2]EBITA in full-year 2020 excluding non-recurring items; other operating income related to the reversal of the CVR liability of SEK 399 M, see page 22 for further information.

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

[4]The increase in the number of shares results from an issue of 3,298,984 shares for the purpose of ensuring fulfilment of commitments under incentive programmes, offset by allotment of shares for the programmes expired.

Financial statements – Parent Company

Income statement

SEK M	Q4 2021	Q4 2020	Full-year 2021	Full-year 2020
Total revenue	5,031	3,565	12,401	13,968
Cost of goods sold	-964	-763	-2,933	-3,134
Gross profit	**4,067**	**2,802**	**9,468**	**10,834**
Selling and administrative expenses[1]	-1,829	-1,543	-4,179	-4,174
Research and development expenses	-348	-317	-1,256	-923
Other operating income/expenses	104	76	350	96
Operating profit	**1,994**	**1,018**	**4,383**	**5,833**
Net financial items	-101	185	-392	194
Profit after financial items	**1,893**	**1,203**	**3,991**	**6,027**
Appropriations	-1,713	-1,690	-1,713	-1,690
Profit/loss before tax	**180**	**-487**	**2,278**	**4,337**
Income tax	-276	-285	-488	-931
Profit/loss for the period	**-96**	**-772**	**1,790**	**3,406**
[1]Amortisation and impairment of intangible assets included in Selling and administrative expenses.	-102	-82	-359	-328

Statement of comprehensive income

SEK M	Q4 2021	Q4 2020	Full-year 2021	Full-year 2020
Profit/loss for the period	-96	-772	1,790	3,406
Items that cannot be reclassified into profit or loss				
Fair value of equity instruments (net of tax)	3	9	11	9
Items that can be reclassified into profit or loss				
Cash flow hedges (net of tax)	-7	144	-63	130
Comprehensive income for the period	**-100**	**-619**	**1,738**	**3,545**

Balance sheet

SEK M	Dec 2021	Dec 2020
ASSETS		
Non-current assets		
Intangible assets	10,107	10,205
Tangible assets	89	64
Financial assets	22,164	23,164
Deferred tax assets	27	24
Total non-current assets	**32,387**	**33,457**
Current assets		
Inventories	2,536	2,527
Accounts receivable	1,126	731
Receivables Group companies	4,308	3,947
Other receivables, non-interest bearing	747	835
Cash and cash equivalents	878	240
Total current assets	**9,595**	**8,280**
Total assets	**41,982**	**41,737**
EQUITY AND LIABILITIES		
Shareholders´ equity	**19,069**	**17,200**
Untaxed reserves	3,691	3,091
Non-current liabilities		
Borrowings	8,777	10,137
Liabilities Group companies	–	157
Other liabilities, non-interest bearing	2,897	2,557
Total non-current liabilities	**11,674**	**12,851**
Current liabilities		
Borrowings	1,768	4,015
Accounts payable	359	398
Liabilities Group companies	3,229	1,674
Other liabilities, non-interest bearing	2,192	2,508
Total current liabilities	**7,548**	**8,595**
Total equity and liabilities	**41,982**	**41,737**

Change in shareholders' equity

SEK M	Dec 2021	Dec 2020
Opening balance	**17,200**	**13,534**
Share-based compensation to employees	134	114
Share-based compensation to employees tax effect[1]	-3	7
Comprehensive income for the period[2]	1,738	3,545
Equity at end of period	**19,069**	**17,200**

[1]The change relates to difference between the market value of vested shares and recognised IFRS 2 cost.
[2]Whereof changes in cash flow hedges (net of tax) amounted to SEK -63 M (130).

Notes

Note 1 Accounting policies and measurement bases and other information

Accounting policies

This year-end report has been prepared in accordance with IAS 34 and the Swedish Annual Accounts Act. The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) and the International Financial Reporting Interpretations Committee (IFRIC) as adopted by the EU. The Parent Company applies the Annual Accounts Act and the Swedish Financial Reporting Board's Recommendation RFR 2 Accounting for Legal Entities.

The accounting policies apply with those described in the 2020 Annual and Sustainability Report. IFRIC published an agenda decision in April 2021 on cloud computing arrangement costs, i.e., costs for configuring or adapting software in a cloud-based solution. The consequences of the IFRIC decision were that some previously reported intangible assets have been reclassified in the balance sheet or expensed retroactively during the period. Another consequence is that it will not be possible to capitalise future configuration or customisation costs in cloud computing arrangements to the same extent in future financial reports as in previous periods. IASB has published other amendments of standards that were effective as of 1 January 2021 or later. These have not had any material impact on the consolidated financial statements.

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

Cash flow statement

As of 2021, Sobi has changed the form of presentation for the cash flow statement and reclassified hedging arrangements for financing from cash flow from operating activities to cash flow from financing activities. Comparative figures for 2020 have been recalculated, whereby the cash flow from operating activities for the quarter October-December 2020 has been adjusted from SEK 858 M to SEK 716 M and the full year 2020 from SEK 5,214 M to SEK 4,926 M. Cash flow from financing activities has been adjusted for the corresponding periods from SEK 1,925 M to SEK 2,066 M and from SEK -1,570 M to SEK -1,282 M, respectively.

Risks and uncertainties

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

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

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

Note 2 Segment reporting

SEK M

Q4 2021	Haematology	Immunology	Specialty Care	Group - other[3]	Total
Total revenue	2,242	2,330	324	–	4,896
EBITA[1]	888	1,148	95	-128	2,002
Adjusted EBITA[1,2]	888	1,148	95	-128	2,002
Amortisation	-170	-253	-40	-13	-477
EBIT (Operating profit)	718	895	55	-141	1,525

Q4 2020	Haematology	Immunology	Specialty Care	Group - other[3]	Total
Total revenue	2,081	2,281	218	–	4,581
EBITA[1]	1,378	1,265	59	-126	2,576
Adjusted EBITA[1,2]	980	1,265	59	-126	2,178
Amortisation	160	-250	-42	-9	-141
EBIT (Operating profit)	1,538	1,015	17	-135	2,436

Full-year 2021	Haematology	Immunology	Specialty Care	Group - other[3]	Total
Total revenue	8,536	5,780	1,213	–	15,529
EBITA[1]	3,698	2,054	388	-566	5,575
Adjusted EBITA[1,2]	3,698	2,054	388	-566	5,575
Amortisation	-627	-1,008	-158	-48	-1,841
EBIT (Operating profit)	3,071	1,047	230	-614	3,733

Full-year 2020	Haematology	Immunology	Specialty Care	Group - other[3]	Total
Total revenue	8,660	5,415	1,186	–	15,261
EBITA[1]	4,775	1,902	564	-541	6,700
Adjusted EBITA[1,2]	4,376	1,902	564	-540	6,301
Amortisation	-652	-1,009	-179	-42	-1,882
EBIT (Operating profit)	4,123	893	385	-583	4,818

There are no intersegment transactions.

[1]APMs, see page 21 for further information.

[2]EBITA in 2020 excluding non-recurring items; other operating income related to the reversal of the CVR liability of SEK 399 M, see page 22 for further information.

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

Note 3 Fair value of financial instruments

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

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

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

Dec 2021	**Level 1**	**Level 2**	**Level 3**	**Total**
Financial assets and liabilities measured at fair value through profit or loss				
Derivatives held for trading	–	1	–	**1**
Endowment policies	–	–	45	**45**
Financial assets measured at fair value through other comprehensive income				
Equity instruments	145	–	–	**145**
Total	**145**	**1**	**45**	**191**

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

Alternative performance measures – financial measures not defined according to IFRS

Sobi uses certain financial measures (alternative performance measures, APM) in the interim report that are not defined according to IFRS. The company considers these measures to provide valuable supplementary information for investors and company management, as they enable an assessment and benchmarking of the company's reporting. Since not all companies calculate financial measures in the same way, these are not always comparable to measures used by other companies. These financial measures should not, therefore, be regarded as substitutes for measures defined according to IFRS. The following metrics are not defined according to IFRS:

SEK M unless otherwise stated.

	Q4 2021	Q4 2020	Full-year 2021	Full-year 2020
Total revenue	4,896	4,581	15,529	15,261
Total cost of goods sold	-1,016	-863	-3,484	-3,225
Gross profit	**3,880**	**3,718**	**12,045**	**12,036**
Gross margin	**79%**	**81%**	**78%**	**79%**
EBIT (operating profit)[1]	1,525	2,116	3,733	4,818
Plus amortisation and impairment of intangible assets	477	460	1,841	1,882
EBITA[1]	**2,002**	**2,576**	**5,575**	**6,700**
Plus depreciations and impairment of tangible assets	59	36	165	141
EBITDA	**2,061**	**2,613**	**5,740**	**6,841**
EBITA margin	**41%**	**56%**	**36%**	**44%**
Non-recurring items[2]	–	-399	–	-399
EBITA adjusted	**2,002**	**2,177**	**5,575**	**6,301**
EBITA margin adjusted	**41%**	**48%**	**36%**	**41%**
Profit for the period	1,241	1,502	2,679	3,245
Non-recurring items[2]	–	-399	–	-399
Profit for the period, adjusted	1,241	1,103	2,679	2,846
Average number of ordinary shares (excluding shares in treasury)	295,149,731	294,896,839	295,051,119	294,658,136
Average number of ordinary shares after dilution (excluding shares in treasury)	296,898,071	297,878,877	296,799,459	297,640,174
EPS, SEK adjusted	**4.21**	**3.74**	**9.08**	**9.66**
EPS after dilution, SEK adjusted	**4.18**	**3.69**	**9.03**	**9.56**
Borrowings	10,545	14,152	10,545	14,152
Cash and cash equivalents	1,045	404	1,045	404
Net debt	**9,500**	**13,748**	**9,500**	**13,748**
Shareholders' equity	23,203	20,206	23,203	20,206
Total assets	48,661	48,283	48,661	48,283
Equity ratio	**48%**	**42%**	**48%**	**42%**
Number of ordinary shares	307,114,495	303,815,511	307,114,495	303,815,511
Number of ordinary shares after dilution	308,862,835	306,797,549	308,862,835	306,797,549
Equity per share, SEK	**75.6**	**66.5**	**75.6**	**66.5**
Equity per share after dilution, SEK	**75.1**	**65.9**	**75.1**	**65.9**

[1]For EBIT and EBITA per segment see Note 2.

[2]Relates to the reversal of the CVR liability of SEK 399 M in 2020, see page 22 for further information.

Financial definitions

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

Other definitions

Alprolix (eftrenonacog alfa)	A recombinant, extended half-life (EHL) clotting factor IX medicine approved in the EU, Iceland, Kuwait, Liechtenstein, Norway, Saudi Arabia, and Switzerland, as well as in Australia, Brazil, Canada, Japan, New Zealand, the US and other countries, for the treatment of haemophilia B.
Aspaveli/Empaveli (pegcetacoplan)	A new medicine targeting complement component 3 (C3) designed to regulate excessive complement activation, which can lead to the onset and progression of many serious diseases. Aspaveli/Empaveli is a synthetic cyclic peptide conjugated to a polyethylene glycol polymer that binds specifically to C3 and C3b.
Doptelet (avatrombopag)	A second-generation small molecule thrombopoietin receptor agonist used in the treatmentof thrombocytopenia by increasing platelet count.
Efanesoctocog alfa (formerly BIVV001)	A novel factor VIII potential new medicine designed to extend protection from bleeds with prophylactic dosing of once weekly or longer intervals for people with haemophilia A. Builds on Fc-fusion technology by adding a region of von Willebrand factor and XTEN polypeptides to potentially extend its time in circulation.
Elocta (efmoroctocog alfa)	A recombinant, EHL clotting factor VIII medicine approved in the EU, Algeria, Iceland, Kuwait, Liechtenstein, Norway, Saudi Arabia, and Switzerland for the treatment of haemophilia A. It is also approved in Australia, Brazil, Canada, Japan, New Zealand, the US and other countries, where it is known as Eloctate.
Gamifant (emapalumab)	An anti-interferon-gamma monoclonal antibody, approved in the US and in the United Arab Emirates for the treatment of primary haemophagocytic lymphohistiocytosis, a life-threatening syndrome of immune activation.
Gout	An autoinflammatory disease that causes intensely painful flares and debilitating inflammatory arthritis due to deposition of pro-inflammatory monosodium urate crystals in synovial fluid and other tissues.
Haemophagocytic lymphohistiocytosis, HLH	A rare and life-threatening syndrome of extreme immune activation. The primary form of the disease mainly occurs in infants and young children while the secondary form of the disease is acquired from or associated with infection, autoimmune diseases or malignancy.
Haemophilia	A rare, genetic disorder in which the ability of a person's blood to clot is impaired. Haemophilia A occurs in about one in 5,000 male births annually, and haemophilia B occurs in about one in 25,000 male births annually. Both occur more rarely in females. People with haemophilia can experience bleeding episodes that may cause pain, limited mobility, irreversible joint damage, and life-threatening haemorrhages.
Kineret (anakinra)	A recombinant protein medicine that blocks the biological activity of interleukin-1α 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 medicine used to treat hereditary tyrosinaemia type 1. It blocks the breakdown of tyrosine, thereby reducing the amount of toxic tyrosine by-products in the body. Patients must maintain a special diet in combination with Orfadin treatment as tyrosine is not adequately broken down. Orfadin was approved in the EU in 2020 for the treatment of adult patients with alkaptonuria.
Paroxysmal nocturnal haemoglobinuria, PNH	A rare, chronic, life-threatening blood disorder characterised by the destruction of oxygen-carrying red blood cells through extravascular and intravascular haemolysis. Persistently low haemoglobin can result in debilitating symptoms such as severe fatigue, haemoglobinuria, dyspnoea (difficulty breathing), and the need for frequent transfusions.
Respiratory syncytial virus, RSV	A common virus and the most common cause of lower respiratory tract infections among infants and young children.
SEL-212	A novel combination therapy and potential new medicine designed to sustain control of serum uric acid levels in patients with chronic refractory gout. SEL-212 consists of

	pegadricase, co-administered with ImmTOR, designed to mitigate the formation of anti-drug antibodies.
Synagis (palivizumab)	An immunisation treatment indicated for the prevention of serious lower respiratory tract infection caused by RSV in infants and young children at high risk of RSV disease. Synagis is an RSV F protein inhibitor monoclonal antibody that acts as a prophylaxis against serious RSV disease.
Tegsedi (inotersen)	A medicine for the treatment of polyneuropathy of hereditary transthyretin amyloidosis in adults.
Waylivra (volanesorsen)	A medicine for the treatment of genetically confirmed familial chylomicronaemia syndrome.

Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Providing sustainable access to innovative medicines in the areas of haematology, immunology and specialty care, Sobi has approximately 1,600 employees across Europe, North America, the Middle East and Asia. In 2021, revenue amounted to SEK 15.5 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com, LinkedIn and YouTube.

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