Q1 2022 report

A good start in 2022

January – March 2022

- **Total revenue** SEK 4,925 M (3,661), +35 per cent, +24 per cent at constant exchange rates (CER)
- **Haematology** revenue SEK 2,499 M (1,877), +25 per cent at CER of which Elocta® SEK 1,024 M (857), +15 per cent at CER; Alprolix® SEK 419 M (413), -3 per cent at CER; Doptelet® SEK 593 M (180), +197 per cent at CER and Aspaveli®/Empaveli™ SEK 4 M (-)
- **Immunology** revenue SEK 2,119 M (1,554), +24 per cent at CER of which Kineret® SEK 645 M (542), +11 per cent at CER; Synagis® SEK 1,286 M (879), +31 per cent at CER and Gamifant® SEK 189 M (133), +27 per cent at CER
- **EBITA**[1] SEK 1,290 M (1,484), **EBITA margin**[1] 26 per cent (41)
- **Items affecting comparability**[2] of SEK -661 M included a provision for expected credit losses in Russia of SEK -157 M. Restructuring comprised contract manufacturing closure of SEK -360 M, site simplification of SEK -72 M and efficiency programmes of SEK -72 M. Excluding these costs, the **EBITA adjusted** amounted to SEK 1,951 M corresponding to an **EBITA margin adjusted**[1] of 40 per cent (41)
- **Efficiency programmes** will focus resources into core areas, simplify the organisation and adjust the cost base to enable Sobi to continue sustainable growth and margin improvement over time
- **EBIT** SEK 776 M (1,034), **EBIT adjusted**[1] SEK 1,437 M (1,034)
- **Earnings per share** (EPS) before dilution SEK 1.84 (2.36), EPS before dilution adjusted SEK 3.67 (2.36)
- **Cash flow** from operating activities SEK 1,644 M (1,699)
- **Efanesoctocog alfa** positive XTEND-1 phase 3 study readout, **Gamifant** approval in China and other encouraging pipeline milestones

2022 outlook

- Revenue is anticipated to grow by a mid to high single-digit percentage at CER (unchanged)
- EBITA margin is anticipated to be at a low 30s percentage of revenue (now based on EBITA margin adjusted)

Total revenue Q1, SEK M

4,925

Total revenue growth Q1, CER

24%

Launch medicines[a] growth Q1, CER

126%

EBITA margin adjusted[1] Q1

40%

Financial summary

SEK M	Q1 2022	Q1 2021	Change	Full-year 2021
Total revenue	4,925	3,661	35%	15,529
Gross profit	3,409	2,935	16%	12,045
Gross margin[1]	69%	80%		78%
EBITA[1]	1,290	1,484	-13%	5,575
EBITA adjusted[1,2]	1,951	1,484	31%	5,575
EBITA margin[1]	26%	41%		36%
EBITA margin adjusted[1,2]	40%	41%		36%
Profit for the period	543	696	-22%	2,679
EPS, before dilution, SEK[1]	1.84	2.36	-22%	9.08
EPS, before dilution, SEK adjusted[1,2]	3.67	2.36	55%	9.08

[1]Alternative Performance Measures (APMs), see page 22 for further information.
[2]Items affecting comparability in Q1 2022, see page 3 for further information.

[a] Launch medicines include Doptelet, Aspaveli/Empaveli and Gamifant.

CEO statement

2022 has started well for Sobi and it is a pleasure to report on our achievements during the first quarter. We have seen continued progress despite increased geopolitical uncertainty in the world and we delivered on our commitment to sustainable revenue growth with revenue of SEK 4,925 M and growth of 24 per cent at CER.

Our launch medicines, Doptelet, Gamifant and now Aspaveli/Empaveli, combined grew by 126 per cent at CER with Doptelet benefitting from an element of phasing of sales to China. Other notable performances included Synagis which finished the RSV season well despite an early start last year.

EBITA was SEK 1,290 M, with a margin of 26 per cent. EBITA included a provision for expected credit losses in Russia and costs related to restructuring and efficiency programmes; without these, the EBITA margin adjusted was 40%.

A majority of items affecting comparability related to the previously announced discontinuation of contract manufacturing for Pfizer. After several extensions, the plan is now to end by the first quarter of 2024. Sincere thanks to all colleagues who helped supply factor VIII medicines since 1998.

We also made a strategic decision to consolidate our Geneva site into Basel as well as look at other efficiency programmes in our business. The efficiency programmes will focus resources into core areas, simplify the organisation and adjust the cost base to enable Sobi to continue sustainable growth and margin improvement over time.

With all considered, we confirm our 2022 outlook for revenue and updated the EBITA margin to now being based on EBITA margin adjusted.

On the pipeline, we received the first positive data from the phase 3 programme for efanesoctocog alfa, a new treatment for haemophilia A, reinforcing our belief in a transformative treatment.

Other pipeline highlights included the UK approval of Aspaveli for PNH, a rare blood disease and the China approval of Gamifant for pHLH, a rare immune disorder. This approval is the first for Sobi in China. In Japan, we made regulatory submission for Doptelet in CLD, also a first for Sobi in Japan.

In addition to finetuning our current activities, we are continuously looking for opportunities to augment our business and pipeline. As we seek new medicines to either license or acquire, we apply a solid set of capital-allocation priorities. They include a focus on rare diseases, preferably in haematology or immunology, medicines in late-stage development or already marketed with peak sales potential between USD 150-500 M and with a preference for not diluting the EBITA margin.

Sobi is devastated by the war unfolding in Ukraine. With the credit exposure covered above, Sobi has 46 colleagues in Russia and supply only a few medicines, including Kineret and Elocta, as part of our commitment to patients. Sobi does not have any colleagues or business in Ukraine and only a few patients are involved in clinical trials, most of them indirectly through our collaborators. To help address the immediate humanitarian needs in Ukraine, Sobi donated SEK 1 M to Red Cross in Sweden to support relief efforts in Ukraine. Our sincere and heartfelt thoughts go to anyone impacted by the war and we will continue to assess the situation as it unfolds.

As we strive to bring life-saving medicines to patients faster and ensure an inspiring workplace, I wanted to thank everyone in Sobi for their support and contributions to the first-quarter results.

Solna, Sweden, 28 April 2022

Guido Oelkers, President & CEO

Financial performance

Total revenue

Total revenue for January to March ('the quarter') was SEK 4,925 M (3,661) and increased by 35 per cent compared with the same period a year ago and by 24 per cent at CER. Growth was strong across all disease areas, with particular strong performance for Doptelet, which benefitted from phasing of sales to the partner in China and increased uptake in the US, and strong Synagis sales.

SEK M	Q1 2022	Q1 2021	Change	Change at CER	Full-year 2021
Haematology	2,499	1,877	33%	25%	8,536
Immunology	2,119	1,554	36%	24%	5,780
Specialty Care	307	230	34%	24%	1,213
Total	**4,925**	**3,661**	**35%**	**24%**	**15,529**

Items affecting comparability

During the quarter Sobi took steps to restructure the business through certain efficiency programmes. These steps refer to the discontinuation of contract manufacturing for Pfizer, the decision to consolidate the Geneva site into Basel and to restructure selling and administration and research and development functions to appropriately support the business. These steps have resulted in costs in the quarter of SEK 504 M. In addition, a provision for expected credit losses in Russia of SEK 157 M was taken. These costs affected the comparability as outlined in the table below.

SEK M	Q1 2022	Items affecting comparability	Q1 2022 excluding items affecting comparability
Total revenue	4,925	–	4,925
Cost of goods sold[1]	-1,516	-360	-1,156
Gross profit	**3,409**	**-360**	**3,769**
Gross margin	*69%*		*77%*
Selling and administrative expenses[2,3,4]	-2,053	-249	-1,804
Research and development expenses[2,3]	-578	-52	-526
Other operating income/expenses	-2	–	-2
Operating profit (EBIT)	**776**	**-661**	**1,437**
Net financial items	-102	–	-102
Profit before tax	**674**	**-661**	**1,335**
Income tax	-131	121	-252
Profit for the period	**543**	**-540**	**1,083**
EBITA	1,290	-661	1,951
EBITDA	1,461	-529	1,990
Amortisation and impairment of intangible assets related to Selling and administrative expenses	-514	–	-514
Depreciation and impairment of tangible assets[1,2]	-171	-132	-39
Operating profit (EBIT)	**776**	**-661**	**1,437**

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

1) Refers to restructuring costs of SEK 360 M including impairment of tangible assets of SEK 121 M followed by the discontinuation of contract manufacturing for Pfizer. The process of downsizing the manufacturing facility will start in the second half of 2022, with the last volumes anticipated to be delivered to Pfizer in the beginning of 2024. An estimated 80 positions are expected to be affected over the next 24 months.
2) Refers to restructuring costs of SEK 72 M including impairment of tangible assets of SEK 11 M followed by the decision to consolidate the Geneva site into Basel. SEK 25 M were allocated to selling and administrative expenses and SEK 47 M were allocated to research and development expenses.
3) Refers to external expenses of SEK 72 M related to structural efficiency programmes to enable restructuring of selling and administration and research and development functions to appropriately support the business in the future. SEK 67 M were allocated to selling and administrative expenses and SEK 5 M were allocated to research and development expenses.
4) Refers to provision for expected credit losses in Russia of SEK 157 M.

Gross profit

Gross profit was SEK 3,409 M (2,935) and included costs of SEK 360 M affecting comparability. The gross margin excluding these costs was 77 per cent (80). The margin decrease was driven by unfavourable mix of business, mainly due to industrial sales of Doptelet to the partner in China.

Operating expenses

Selling and administrative expenses before amortisation and impairment amounted to SEK 1,538 M (981) and included costs of SEK 249 M affecting comparability. Excluding these costs, the increase was 23 per cent at CER and reflected launch preparations and activities for Aspaveli/Empaveli and Doptelet in Europe and Tegsedi® in the US.

Research and development expenses amounted to SEK 578 M (471) and included costs of SEK 52 M affecting comparability. Excluding these costs, the increase was 4 per cent at CER mainly due to Aspaveli/Empaveli-related activities.

Operating profit

EBITA was SEK 1,290 M (1,484), corresponding to a margin of 26 per cent (41). EBITA adjusted was SEK 1,951 M, corresponding to a margin of 40 per cent. Amortisation of intangible assets was SEK 514 M (450), resulting in an EBIT of SEK 776 M (1,034).

SEK M	Q1 2022	Q1 2021	Full-year 2021
Total revenue	4,925	3,661	15,529
Cost of goods sold	-1,516	-726	-3,484
Gross profit	**3,409**	**2,935**	**12,045**
Gross margin	*69%*	*80%*	*78%*
Selling and administrative expenses before amortisation and impairment of intangible assets	-1,538	-981	-4,453
Research and development expenses	-578	-471	-1,994
Operating expenses less amortisation and impairment of intangible asset	**-2,116**	**-1,452**	**-6,446**
Other operating income/expenses	-2	0	-24
EBITA	**1,290**	**1,484**	**5,575**
Amortisation and impairment of intangible assets related to Selling and administrative expenses	-514	-450	-1,841
Operating profit (EBIT)	**776**	**1,034**	**3,733**

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

Net financial items

Net financial items were SEK -102 M (-115), reflecting lower borrowings.

Tax

Income tax was SEK -131 M (-223), corresponding to an effective tax rate of 19.4 per cent (24.2).

Profit

Profit for the period totalled SEK 543 M (696).

Cash flow

Cash flow from operating activities was SEK 1,644 M (1,699). Cash flow from investing activities was SEK -157 M (-91), including a milestone payment for Doptelet to Eisai of SEK 115 M.

Cash and net debt

On 31 March 2022, cash and cash equivalents amounted to SEK 1,063 M (1,045 on 31 December 2021). Sobi ended the quarter with undrawn committed credit facilities totalling SEK 7,626 M (SEK 4,336 M on 31 December 2021). The increase was driven by a raised facility of SEK 2,000 M and repayment of revolving credit facilities. In addition, Sobi established a commercial paper programme of up to SEK 4,000 M. Drawn credit facilities and issued commercial papers totalled SEK 9,432 M at the end of quarter (SEK 10,597 M on 31 December 2021). Net debt at the end of the quarter amounted to SEK 8,321 M (SEK 9,500 M on 31 December 2021).

Equity

On 31 March 2022, consolidated shareholders' equity was SEK 23,757 M (SEK 23,203 M on 31 December 2021).

Personnel

On 31 March 2022, the number of full-time equivalent employees was 1,569 (1,559 on 31 December 2021).

Parent Company

Total revenue for the Parent Company, Swedish Orphan Biovitrum AB (publ), was SEK 3,360 M (2,463), of which Group companies accounted for SEK 2,224 M (1,397), mainly reflecting increased sales of Kineret, Elocta, Alprolix and Gamifant to subsidiaries. Profit/loss for the period was SEK -99 M (264) and investing activities affecting cash flow amounted to SEK 38 M (25).

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	Q1 2022	Q1 2021	Change	Change at CER	Full-year 2021
Elocta	1,024	857	20%	15%	3,960
Alprolix	419	413	2%	-3%	1,764
Royalty	333	298	12%	1%	1,251
Doptelet	593	180	229%	197%	1,116
Aspaveli/Empaveli	4	–	n/a	n/a	1
Manufacturing	124	130	-4%	-4%	445
Total	**2,499**	**1,877**	**33%**	**25%**	**8,536**

Haematology revenue was SEK 2,499 M (1,877) and increased by 33 per cent, 25 per cent at CER.

Elocta sales were SEK 1,024 M (857) and increased by 20 per cent, 15 per cent at CER, driven mainly by growth in patient numbers and a higher factor consumption per patient. In addition, the first quarter of 2021 was negatively affected by a retrospective mandatory price adjustment in Germany of SEK 92 M.

Alprolix sales were SEK 419 M (413) and increased by 2 per cent, a decrease of 3 per cent at CER. Growth in patient numbers was offset by slightly lower factor consumption per patient and unfavourable price adjustments.

Doptelet sales were SEK 593 M (180) and increased by 229 per cent, 197 per cent at CER. Growth was driven by phasing of sales to the partner in China and the continued launch progress in the US.

Aspaveli/Empaveli sales in the quarter were SEK 4 M from the first patients in Saudi Arabia and initial supply in the UK.

Immunology

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

Revenue Immunology

SEK M	Q1 2022	Q1 2021	Change	Change at CER	Full-year 2021
Kineret	645	542	19%	11%	2,290
Synagis	1,286	879	46%	31%	2,650
Gamifant	189	133	42%	27%	840
Total	**2,119**	**1,554**	**36%**	**24%**	**5,780**

Immunology revenue was SEK 2,119 M (1,554) and increased by 36 per cent, 24 per cent at CER.

Kineret sales were SEK 645 M (542) and increased by 19 per cent, 11 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 emerging markets related to COVID-19. This was partly offset by lower spontaneous use for COVID-19 in the US.

Synagis sales were SEK 1,286 M (879) and increased by 46 per cent, 31 per cent at CER. Growth was driven by continued demand from patients that remained longer on treatment as well as benefitted from a lower base in 2021 caused by reduced levels of RSV infections.

Gamifant sales were SEK 189 M (133) and increased by 42 per cent, 27 per cent at CER and reflected some growth in new patients, increased volume per patient and longer duration of therapy offset by a number of patients who concluded their treatment.

Specialty Care

Revenue is generated from sales of the medicines Orfadin®, Tegsedi, Waylivra® and other medicines in Specialty Care.

Revenue Specialty Care

SEK M	Q1 2022	Q1 2021	Change	Change at CER	Full-year 2021
Orfadin	106	97	9%	2%	459
Tegsedi	110	60	84%	69%	427
Waylivra	38	31	24%	19%	121
Other Specialty Care	53	42	25%	16%	207
Total	**307**	**230**	**34%**	**24%**	**1,213**

Specialty Care revenue was SEK 307 M (230) and increased by 34 per cent, 24 per cent at CER. The increase was mainly driven by recently in-licensed Tegsedi in the US.

Pipeline

For the full Sobi pipeline, please visit sobi.com.

Major pipeline milestones since the previous quarterly report

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

Regulatory approval	Aspaveli – PNH: approval in the UK Gamifant – pHLH: approval in China
Other significant milestones	Efanesoctocog alfa – haemophilia A: positive XTEND-1 phase 3 study Efanesoctocog alfa – haemophilia A: XTEND-Kids phase 3 study enrolment completion Doptelet – CLD: regulatory submission acceptance in Japan Aspaveli/Empaveli – ALS: MERIDIAN phase 2 study enrolment completion (by Apellis) Kineret – COVID-19: regulatory submission for emergency use in the US

Haematology

Efanesoctocog alfa

Efanesoctocog alfa (formerly BIVV001), a potential new treatment for haemophilia A, is in phase 3 clinical development with the collaborator Sanofi.

In March, Sobi and Sanofi announced the first phase 3 study results for efanesoctocog alfa. The XTEND-1 phase 3 study in previously treated patients aged 12 years or older met the primary endpoint, showing a clinically meaningful prevention of bleeds in people with severe haemophilia A receiving weekly prophylaxis with efanesoctocog alfa over a period of 52 weeks. The median annualised bleeding rate (ABR) was 0 with a mean ABR of 0.71. The key secondary endpoint was also met, demonstrating once weekly efanesoctocog alfa was superior to prior prophylactic factor VIII replacement therapy, showing a statistically significant reduction in ABR based on intra-patient comparison.

Efanesoctocog alfa was well-tolerated, and inhibitor development to factor VIII was not detected. The most common treatment-emergent adverse events (in more than five per cent of participants overall) were headache, arthralgia, fall, and back pain. Sobi and Sanofi intend to present the detailed data at a forthcoming medical meeting.

The data will be the basis for submission to regulatory authorities around the globe beginning this year, including a biologics license application by Sanofi to the US FDA anticipated in the second half of 2022. Regulatory submission in the EU will follow availability of data from the ongoing XTEND-Kids paediatric study, expected in 2023. As planned, enrolment into this study was completed during the first quarter of 2022.

Doptelet

In March, Sobi made a regulatory submission in Japan for Doptelet as a potential treatment of induced thrombocytopaenia in chronic liver disease (CLD). This achievement marked a milestone as the first regulatory submission acceptance for Sobi in Japan. In Japan transfusion remains the traditional therapy for CLD.

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 February, Aspaveli, the trade name in the EU, was approved in the UK by the Medicines and Healthcare products Regulatory Agency for the treatment of adult patients with PNH who are anaemic after treatment with a C5 inhibitor for at least three months. With the approval, Aspaveli became the first new medicine in the UK since 2007 for the treatment of PNH with a novel mechanism of action, providing expanded choice to treating physicians and patients. The UK launch initiated formally in the beginning of April.

Earlier in April, Apellis concluded the enrolment into the MERIDIAN phase 2 study for the treatment of amyotrophic lateral sclerosis (ALS). Apellis anticipates data from this study which has potential registrational intent to be available by mid-2023.

Immunology

Kineret

During the period, Sobi made a US regulatory submission for emergency use of Kineret in the treatment of coronavirus disease 2019 (COVID-19). This followed the EU approval in December 2021.

Gamifant

In mid-March, Sobi announced that the National Medical Products Administration of China had approved Gamifant for use in China. The indication is for treatment of adult and paediatric (new-born and older) patients with primary haemophagocytic lymphohistiocytosis (pHLH) with refractory, recurrent or progressive disease or intolerance to conventional HLH therapy. The approval followed the recommendation announced in February 2022 and this achievement marked the first-ever approval for Sobi in China.

SEL-212

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

In mid-March, Sobi's collaborator Selecta Biosciences, Inc. announced an update to the currently enrolling DISSOLVE II study. This study has sites in the US and four Eastern European countries, including Russia and Ukraine. Selecta has temporarily closed screening and randomisation in both Russia and Ukraine to preserve in-country study supplies and proactively activated additional enrolment sites in the US.

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.

In early March, AstraZeneca announced the publication in The New England Journal of Medicine of detailed results from the MELODY phase III study which showed that a single dose of nirsevimab met the primary efficacy endpoint of reducing the incidence of medically attended lower respiratory tract infections caused by respiratory syncytial virus (RSV) by 74.5% (95% confidence interval (CI): 49.6-87.1; p<0.001), compared to placebo. The study involved healthy term and late preterm (gestational age at least 35 weeks) infants entering their first RSV season.

There was numerical reduction, although not statistically significant, of the risk of RSV associated hospitalisations observed in the MELODY study alone (62.1%, 95% CI: -8.6-86.8; p=0.07). However, a prespecified pooled analysis of the MELODY and Phase IIb studies for term and preterm infants (greater than 28 weeks gestational age) achieved an estimate of efficacy of 77.3% (95% CI: 50.3-89.7; p<0.001) through 150 days post dose.

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.

Pipeline news flow

Anticipated major upcoming pipeline news flow

H1 2022	Aspaveli/Empaveli – IC-MPGN and C3G[b]: phase 3 study first patient dosed (by Apellis) Aspaveli/Empaveli – CAD[c]: phase 3 study first patient dosed 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) Kineret – COVID-19: regulatory decision, emergency use (US) Gamifant – MAS[d] in rheumatological diseases: EMERALD phase 3 study data readout SEL-212 – CRG: phase 3 studies data readout
2023	Efanesoctocog alfa – haemophilia A (paediatric): XTEND-Kids phase 3 study data readout Efanesoctocog alfa – haemophilia A: regulatory submission (EU) Doptelet – CLD: regulatory decision (JP) Aspaveli/Empaveli – ALS: MERIDIAN phase 2 study data readout (by Apellis in mid-2023) Gamifant – MAS in rheumatological diseases: regulatory submission (US) SEL-212 – CRG: regulatory submission (US)

[b] Immune complex-mediated membranoproliferative glomerulonephritis and C3 glomerulopathy.
[c] Cold agglutinin disease.
[d] Macrophage activation syndrome.

Other information

Sustainability

Sobi's sustainability efforts support the overall mission of improving life for people living with rare diseases and are based on two priorities:

- Commitment to patients
- Responsible behaviour

During the first quarter, several approvals of Sobi medicines in different countries expanded possibilities for patients to access treatment, notably Aspaveli/Empaveli for PNH in the UK and Australia.

Sobi continued to share knowledge at events such as EAHAD (European Association for Haemophilia and Allied Disorders) 2022 and took part in discussions about the future of life science as part of the Swedish delegation at Expo 2020 Dubai during the Health & Wellness Week.

To help Ukraine and Ukrainian refugees, Sobi donated SEK 1 M to the Red Cross to support relief efforts and is working continuously to find ways of ensuring access to Sobi medicines in Ukraine.

The war in Ukraine

It is still unclear how and to what extent Sobi´s operations will be affected by the war in Ukraine. Sales in Russia amounted to SEK 59 M in the quarter which took place in January, corresponding to 1 per cent of Sobi´s total revenue in the quarter. At the end of the quarter Sobi reported outstanding accounts receivables related to Russia of net, approximately SEK 60 M, including a provision for expected credit losses of SEK 157 M that impacted the profit followed by the current sanctions against Russia. Sobi continues to follow the events closely to assess the potential and actual risks stemming from the situation.

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 (unchanged)

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 (now based on EBITA margin adjusted)

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 is available on sobi.com.

The Annual Report for 2021 was published on sobi.com and is available at Sobi's head office in Solna.

Financial calendar

AGM	10 May 2022
Q2 2022 report	19 July 2022
Q3 2022 report	27 October 2022
Q4 2022 report	8 February 2023

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 Sobi is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out in the press release concerning this report, at 08:00 CEST on 28 April 2022.

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

Solna, Sweden, 28 April 2022

Guido Oelkers, President & CEO

Financial statements – Group

Consolidated statements of comprehensive income

SEK M	Q1 2022	Q1 2021	Full-year 2021
Total revenue	4,925	3,661	15,529
Cost of goods sold	-1,516	-726	-3,484
Gross profit	**3,409**	**2,935**	**12,045**
Selling and administrative expenses[1]	-2,053	-1,431	-6,294
Research and development expenses	-578	-471	-1,994
Other operating income/expenses	-2	0	-24
Operating profit	**776**	**1,034**	**3,733**
Net financial items[2]	-102	-115	-438
Profit before tax	**674**	**919**	**3,295**
Income tax	-131	-223	-616
Profit for the period	**543**	**696**	**2,679**
All profit are attributable to Parent Company shareholders			
Other comprehensive income			
Items that will not be reclassified into profit or loss			
Remeasurements on defined-benefit pension plans and similar plans (net of tax)	–	8	17
Remeasurement of equity instruments (net of tax)	-66	7	11
Total	**-66**	**15**	**28**
Items that may be reclassified into profit or loss			
Translation differences	110	138	464
Net investment hedges (net of tax)	-66	-147	-242
Cash flow hedges (net of tax)	-18	-62	-63
Total	**26**	**-71**	**159**
Other comprehensive income	**-40**	**-56**	**187**
Total comprehensive income for the period	**503**	**640**	**2,866**
All comprehensive income are attributable to Parent Company shareholders			
Earnings per share, SEK			
EPS	1.84	2.36	9.08
EPS adjusted[3]	3.67	2.36	9.08
EPS after dilution	1.83	2.33	9.03
EPS after dilution adjusted[3]	3.64	2.33	9.03
[1]Amortisation and impairment of intangible assets included in Selling and administrative expenses.	-514	-450	-1,841
[2]Including financing costs.	-9	-9	-35

[3]APMs, see page 22 for further information.

Consolidated balance sheet

SEK M	Mar 2022	Dec 2021	Mar 2021
ASSETS			
Non-current assets			
Intangible assets[1]	38,264	38,424	38,978
Tangible assets	380	493	516
Financial assets	121	199	188
Deferred tax assets	682	767	541
Total non-current assets	**39,446**	**39,883**	**40,223**
Current assets			
Inventories	3,365	3,424	3,076
Accounts receivable	3,748	3,439	3,336
Other receivables, non-interest bearing	1,187	870	923
Cash and cash equivalents	1,063	1,045	633
Total current assets	**9,363**	**8,778**	**7,969**
Total assets	**48,809**	**48,661**	**48,192**
EQUITY AND LIABILITIES			
Shareholders´ equity	**23,757**	**23,203**	**20,864**
Non-current liabilities			
Borrowings	8,360	8,777	9,212
Deferred tax liabilities	3,461	3,605	3,517
Lease liabilities	264	247	289
Other liabilities, non-interest bearing	3,912	4,068	3,979
Total non-current liabilities	**15,996**	**16,697**	**16,997**
Current liabilities			
Borrowings	1,024	1,768	4,095
Accounts payable	545	558	392
Lease liabilities	125	114	113
Other liabilities, non-interest bearing	7,363	6,321	5,730
Total current liabilities	**9,056**	**8,761**	**10,330**
Total equity and liabilities	**48,809**	**48,661**	**48,192**

[1]Including goodwill of SEK 6,398 M (SEK 6,288 M on 31 December 2021).

Changes in equity

SEK M	Jan-Mar 2022	Full-year 2021	Jan-Mar 2021
Opening balance	**23,203**	**20,206**	**20,206**
Share-based compensation to employees	41	134	26
Tax deductions for share programmes[1]	9	-3	-9
Total comprehensive income for the period[2]	503	2,866	640
Closing balance	**23,757**	**23,203**	**20,864**

[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 -18 M (SEK -63 M on 31 December 2021) and net investment hedges (net of tax) amounted to SEK -66 M (SEK -242 M on 31 December 2021).

Consolidated cash flow statement

SEK M	Q1 2022	Q1 2021	Full-year 2021
Profit before tax	674	919	3,295
Amortisation, depreciation and impairment	685	485	2,006
Other, including non-cash items[1]	395	-14	179
Income tax paid	-208	-634	-1,124
Cash flow from operating activities before change in working capital	**1,546**	**756**	**4,356**
Changes in working capital	98	943	1,114
Cash flow from operating activities	**1,644**	**1,699**	**5,470**
Investment in intangible assets[2]	-155	-85	-323
Investment in tangible assets	-2	-6	-47
Disposal of tangible assets	–	–	3
Cash flow from investing activities	**-157**	**-91**	**-367**
Borrowings/repayments of borrowings	-1,311	-1,163	-3,998
Hedging arrangement for financing	-146	-191	-351
Repayment of leasing	-34	-30	-125
Cash flow from financing activities	**-1,491**	**-1,384**	**-4,474**
Change in cash and cash equivalents	**-4**	**224**	**629**
Cash and cash equivalents at the beginning of the period	1,045	404	404
Translation difference in cash flow and cash and cash equivalents	22	5	12
Cash and cash equivalents at the end of the period	**1,063**	**633**	**1,045**

[1]Refers mainly to restructuring costs and provision for expected credit losses in Russia.

[2]2022 investments mainly refers to milestone payment linked to Doptelet.

Key ratios and other information

SEK M	Q1 2022	Q1 2021	Full-year 2021
Profit measures			
Gross profit	3,409	2,935	12,045
Gross profit adjusted[1,2]	3,769	2,935	12,045
EBITDA[1]	1,461	1,519	5,740
EBITDA adjusted[1,2]	1,990	1,519	5,740
EBITA[1]	1,290	1,484	5,575
EBITA adjusted[1,2]	1,951	1,484	5,575
EBIT	776	1,034	3,733
EBIT adjusted[1,2]	1,990	1,519	5,740
Profit for the period	543	696	2,679
Profit for the period adjusted[1,2]	1,083	696	2,679
Per share data (SEK)			
EPS	1.84	2.36	9.08
EPS adjusted[1,2]	3.67	2.36	9.08
EPS after dilution	1.83	2.33	9.03
EPS after dilution adjusted[1,2]	3.64	2.33	9.03
Shareholders' equity per share[1]	77.4	68.7	75.6
Shareholders' equity per share after dilution[1]	76.8	67.8	75.1
Other information			
Gross margin[1]	69%	80%	78%
Gross margin adjusted[1,2]	77%	80%	78%
EBITA margin[1]	26%	41%	36%
EBITA margin adjusted[1,2]	40%	41%	36%
Equity ratio[1]	49%	43%	48%
Net debt[1]	8,321	12,674	9,500
Number of ordinary shares[3]	307,114,495	303,815,511	307,114,495
Number of ordinary shares (in treasury)	11,959,198	8,916,033	11,959,198
Number of ordinary shares (ex shares in treasury)	295,155,297	294,899,478	295,155,297
Number of ordinary shares after dilution	309,436,738	307,650,103	308,862,835
Average number of ordinary shares (ex shares in treasury)	295,155,297	294,899,097	295,051,119
Average number of ordinary shares after dilution (ex shares in treasury)	297,477,540	298,733,689	296,799,459

[1]APMs, see page 22 for further information.

[2]Items affecting comparability in Q1 2022, see page 3 for further information.

[3]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	Q1 2022	Q1 2021	Full-year 2021
Total revenue	3,360	2,463	12,401
Cost of goods sold	-1,184	-617	-2,933
Gross profit	**2,176**	**1,846**	**9,468**
Selling and administrative expenses[1]	-1,890	-1,058	-4,179
Research and development expenses	-358	-311	-1,256
Other operating income/expenses	101	58	350
Operating profit	**29**	**535**	**4,383**
Net financial items	-92	-190	-392
Profit/loss after financial items	**-63**	**345**	**3,991**
Appropriations	–	–	-1,713
Profit/loss before tax	**-63**	**345**	**2,278**
Income tax	-36	-81	-488
Profit/loss for the period	**-99**	**264**	**1,790**
[1]Amortisation and impairment of intangible assets included in Selling and administrative expenses.	-130	-83	-359

Statement of comprehensive income

SEK M	Q1 2022	Q1 2021	Full-year 2021
Profit/loss for the period	-99	264	1,790
Items that will not be reclassified into profit or loss			
Remeasurement of equity instruments (net of tax)	-66	7	11
Items that may be reclassified into profit or loss			
Cash flow hedges (net of tax)	-18	-62	-63
Other comprehensive income	**-84**	**-55**	**-52**
Total comprehensive income for the period	**-183**	**209**	**1,738**

Balance sheet

SEK M	Mar 2022	Dec 2021	Mar 2021
ASSETS			
Non-current assets			
Intangible assets	10,001	10,107	10,127
Tangible assets	75	89	61
Financial assets	21,221	22,164	22,234
Deferred tax assets	165	27	17
Total non-current assets	**31,462**	**32,387**	**32,439**
Current assets			
Inventories	2,466	2,536	2,487
Accounts receivable	1,047	1,126	979
Receivables Group companies	3,689	4,308	2,872
Other receivables, non-interest bearing	990	747	798
Cash and cash equivalents	808	878	472
Total current assets	**8,999**	**9,595**	**7,608**
Total assets	**40,461**	**41,982**	**40,047**
EQUITY AND LIABILITIES			
Shareholders´ equity	**18,937**	**19,069**	**17,427**
Untaxed reserves	3,691	3,691	3,091
Non-current liabilities			
Borrowings	8,360	8,777	9,212
Other liabilities, non-interest bearing	3,275	2,897	2,739
Total non-current liabilities	**11,635**	**11,674**	**11,951**
Current liabilities			
Borrowings	1,024	1,768	4,095
Accounts payable	399	359	271
Liabilities Group companies	2,520	3,229	1,376
Other liabilities, non-interest bearing	2,256	2,192	1,836
Total current liabilities	**6,198**	**7,548**	**7,578**
Total equity and liabilities	**40,461**	**41,982**	**40,047**

Change in shareholders' equity

SEK M	Jan-Mar 2022	Full-year 2021	Jan-Mar 2021
Opening balance	**19,069**	**17,200**	**17,200**
Share-based compensation to employees	41	134	26
Tax deductions for share programmes[1]	9	-3	-8
Total comprehensive income for the period[2]	-183	1,738	209
Closing balance	**18,937**	**19,069**	**17,427**

[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 -18 M (SEK -63 M on 31 December 2021).

Notes

Note 1 Accounting policies and measurement bases and other information

Accounting policies

This report has been prepared in accordance with IAS 34 and the Swedish Annual Accounts Act. The consolidated financial statements 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 2021 Annual and Sustainability Report. IASB has published amendments of standards that were effective as of 1 January 2022 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 2021 Annual and Sustainability Report, available at sobi.com.

Risks and uncertainties

Sobi is exposed to several risks. Effective risk assessment aligns Sobi's business opportunities and value creation with shareholders' and other stakeholders' expectation for sustainable and long-term value growth, and control. Principal risk areas are:

- Business conditions and external events
- Product pipeline and intellectual property
- Commercialisation
- Business execution
- Finance and taxation
- Legal, regulatory and compliance

More details about risk exposure and risk management are included in Sobi´s 2021 Annual and Sustainability Report.

Note 2 Segment reporting

SEK M

Q1 2022	Haematology	Immunology	Specialty Care	Group - other[4]	Total
Total revenue	2,499	2,119	307	–	4,925
EBITA[1]	686	822	63	-281	1,290
EBITA adjusted[1,2,3]	1,055	970	63	-137	1,951
Amortisation	-204	-257	-40	-13	-514
EBIT	482	565	23	-294	776

Q1 2021	Haematology	Immunology	Specialty Care	Group - other[4]	Total
Total revenue	1,877	1,554	230	–	3,661
EBITA[1]	823	732	72	-143	1,484
EBITA adjusted[1,2]	823	732	72	-143	1,484
Amortisation	-151	-251	-38	-10	-450
EBIT	672	481	34	-153	1,034

Full-year 2021	Haematology	Immunology	Specialty Care	Group - other[4]	Total
Total revenue	8,536	5,780	1,213	–	15,529
EBITA[1]	3,698	2,054	388	-566	5,575
EBITA adjusted[1,2]	3,698	2,054	388	-566	5,575
Amortisation	-627	-1,008	-158	-48	-1,841
EBIT	3,071	1,047	230	-614	3,733

There are no intersegment transactions.

[1]APMs, see page 22 for further information.

[2]Items affecting comparability in Q1 2022, see page 3 for further information.

[3]EBITA adjusted; Hematology refers to discontinuation of contract manufacturing of SEK 360 M and provision for expected credit losses in Russia SEK 9 M, Immunology refers to provision for expected credit losses in Russia of SEK 148 M, Group - other refers to consolidation of sites of SEK 72 M and efficiency programmes of SEK 72 M.

[4]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 consisted 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 March 2022, all other financial instruments on the balance sheet had reported values that are in all material aspects equivalent to fair value.

Q1 2022	**Level 1**	**Level 2**	**Level 3**	**Total**
Financial assets and liabilities measured at fair value through profit or loss				
Derivatives held for trading	–	92	–	**92**
Endowment policies	–	–	50	**50**
Financial assets measured at fair value through other comprehensive income				
Equity instruments	62	–	–	**62**
Total	**62**	**92**	**50**	**204**

Q1 2021	**Level 1**	**Level 2**	**Level 3**	**Total**
Financial assets and liabilities measured at fair value through profit or loss				
Derivatives held for trading	–	-42	–	**-42**
Endowment policies	–	–	44	**44**
Financial assets measured at fair value through other comprehensive income				
Equity instruments	140	–	–	**140**
Total	**140**	**-42**	**44**	**142**

Full-year 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**

Alternative performance measures – financial measures not defined according to IFRS

Sobi uses certain financial measures (alternative performance measures, APM) in this report that are not defined according to IFRS. Sobi considers these measures to provide valuable supplementary information for stakeholders 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. As of 2022, Sobi has updated its definition of items affecting comparability, formerly called non-recurring items, to provide better guidance for stakeholders and company management on what type of initiatives and costs that can be considered part of restructuring. See below metrics not defined according to IFRS and definitions used, referred to and presented in this report.

SEK M unless otherwise stated	Q1 2022	Q1 2021	Full-year 2021
Total revenue	4,925	3,661	15,529
FX impact	-376	398	857
Total revenue, adjusted for FX impact	4,549	4,059	16,386
Total revenue, comparable period	3,661	4,639	15,261
Growth at CER	**24%**	**-13%**	**7%**
Total revenue	4,925	3,661	15,529
Total cost of goods sold	-1,516	-726	-3,484
Gross profit	**3,409**	**2,935**	**12,045**
Gross margin	**69%**	**80%**	**78%**
Items affecting comparability			
-Restructuring costs:			
-Discontinuation of contract manufacturing	*-360*	–	–
Items affecting comparability[1]	**-360**	**–**	**–**
Gross profit adjusted	**3,769**	**2,935**	**12,045**
Gross margin adjusted	**77%**	**80%**	**78%**
EBIT[2]	**776**	**1,034**	**3,733**
Items affecting comparability			
-Restructuring costs:			
-Discontinuation of contract manufacturing	*-360*	–	–
-Consolidation of sites	*-72*	–	–
-Efficiency programmes	*-72*	–	–
-Other:			
-Provision for expected credit losses in Russia	*-157*	–	–
Items affecting comparability[1]	**-661**	**–**	**–**
EBIT adjusted	**1,437**	**1,034**	**3,733**
EBIT[2]	776	1,034	3,733
Plus amortisation and impairment of intangible assets	514	450	1,841
EBITA[2]	**1,290**	**1,484**	**5,575**
EBITA margin	**26%**	**41%**	**36%**

[1]Items affecting comparability, see page 3 for further information.

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

SEK M unless otherwise stated	Q1 2022	Q1 2021	Full-year 2021
Items affecting comparability			
-Restructuring costs:			
-Discontinuation of contract manufacturing	*-360*	–	–
-Consolidation of sites	*-72*	–	–
-Efficiency programmes	*-72*	–	–
-Other:			
-Provision for expected credit losses in Russia	*-157*	–	–
Items affecting comparability[1]	**-661**	**–**	**–**
EBITA adjusted	**1,951**	**1,484**	**5,575**
EBITA margin adjusted	**40%**	**41%**	**36%**
EBITA	1,290	1,484	5,575
Plus depreciations and impairment of tangible assets	171	35	165
EBITDA	**1,461**	**1,519**	**5,740**
Items affecting comparability			
-Restructuring costs:			
-Discontinuation of contract manufacturing	*-239*	–	–
-Consolidation of sites	*-61*	–	–
-Efficiency programmes	*-72*	–	–
-Other:			
-Provision for expected credit losses in Russia	*-157*	–	–
Items affecting comparability[2]	**-529**	**–**	**–**
EBITDA adjusted	**1,990**	**1,519**	**5,740**
Profit for the period	**543**	**696**	**2,679**
Items affecting comparability[1]	-661	–	–
Tax on items affecting comparability			
-Restructuring costs:			
-Discontinuation of contract manufacturing	*74*	–	–
-Efficiency programmes	*15*	–	–
-Other:			
-Provision for expected credit losses in Russia	*32*	–	–
Tax on items affecting comparability	121	–	–
Items affecting comparability (net of tax)[1]	-540	–	–
Profit for the period adjusted	**1,083**	**696**	**2,679**
Average number of ordinary shares (excluding shares in treasury)	295,155,297	294,899,097	295,051,119
Average number of ordinary shares after dilution (excluding shares in treasury)	297,477,540	298,733,689	296,799,459
EPS before dilution, SEK adjusted	**3.67**	**2.36**	**9.08**
EPS after dilution, SEK adjusted	**3.64**	**2.33**	**9.03**
Borrowings	9,384	13,307	10,545
Cash and cash equivalents	1,063	633	1,045
Net debt	**8,321**	**12,674**	**9,500**
Shareholders' equity	23,757	20,864	23,203
Total assets	48,809	48,192	48,661
Equity ratio	**49%**	**43%**	**48%**
Number of ordinary shares	307,114,495	303,815,511	307,114,495
Number of ordinary shares after dilution	309,436,738	307,650,103	308,862,835
Equity per share, SEK	**77.4**	**68.7**	**75.6**
Equity per share after dilution, SEK	**76.8**	**67.8**	**75.1**

[1]Items affecting comparability, see page 3 for further information.

[2]Items affecting comparability excluding impairment of tangible assets of SEK 132 M, see page 3 for further information.

Financial definitions

CER	Constant exchange rates
EBIT	Earnings before interest and tax (operating profit)
EBIT adjusted	EBIT less items affecting comparability
EBITA	Earnings before interest, tax, amortisation and impairment
EBITA adjusted	EBITA less items affecting comparability
EBITA margin	EBITA as a percentage of total revenue
EBITA margin adjusted	EBITA less items affecting comparability as a percentage of total revenue
EBITDA	Earnings before interest, tax, depreciation, amortisation and impairment
EBITDA adjusted	EBITDA less items affecting comparability
EPS	Profit for the period divided by the average number of ordinary shares
EPS adjusted	Profit for the period, less items affecting comparability, divided by the average number of ordinary shares
EPS after dilution adjusted	Profit for the period, less items affecting comparability, 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 profit adjusted	Gross profit less items affecting comparability
Gross margin	Gross profit as a percentage of total revenue
Gross margin adjusted	Gross profit less items affecting comparability as a percentage of total revenue
Items affecting comparability	Items that are of significant value, have no clear connection to recurring, ordinary operations and are of such a type that they cannot be expected to occur often. This may, for example, refer to capital gains/losses from divestments, restructuring, impairments and other unusual one-time income and expenses. Restructuring refers to structural efficiency programmes that impact the scope of the business or other changes to business operations. Costs for carrying out restructuring are identified on a project basis and may be incurred over more than one year.
Launch medicines	Launch medicines include Doptelet, Aspaveli/Empaveli and Gamifant
Net debt	Borrowings less cash and cash equivalents
Profit for the period adjusted	Profit for the period less items affecting comparability

Other definitions

Alprolix (eftrenonacog alfa)	A recombinant, extended half-life (EHL) clotting factor IX medicine 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 and investigational recombinant factor VIII therapy that is designed to extend protection from bleeds with once-weekly prophylactic dosing for people with haemophilia A. It builds on the innovative Fc fusion technology by adding a region of von Willebrand factor and XTEN® polypeptides to extend its time in circulation. It is the first investigational factor VIII therapy that has been shown to break through the von Willebrand factor ceiling, which imposes a half-life limitation on current factor VIII therapies.
Elocta (efmoroctocog alfa)	A recombinant, EHL clotting factor VIII medicine for the treatment of haemophilia A. It is also known as Eloctate in some countries.
Gamifant (emapalumab)	A monoclonal antibody that binds to and neutralises interferon gamma. Gamifant is a medicine for pHLH, an ultra-rare syndrome of hyperinflammation that usually occurs within the first year of life and can rapidly become fatal unless diagnosed and treated.
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.
Primary haemophagocytic lymphohistiocytosis, pHLH	An ultra-rare, rapidly progressive, often-fatal syndrome of hyperinflammation in which hyperproduction of interferon gamma is thought to drive immune system hyperactivation, ultimately leading to organ failures. Diagnosis is challenging due to the variability in signs and symptoms, which may include fevers, swelling of the liver and spleen, severe low red and white blood cell counts, bleeding disorders, infections, neurological symptoms, organ dysfunction and organ failure. pHLH can rapidly become fatal if left untreated, with median survival of less than two months. The immediate goal of treatment is to quickly control the hyperinflammation and to prepare for haematopoietic stem-cell transplantation. The current conventional treatment prior to transplant includes steroids and chemotherapy and are not specifically approved to treat pHLH.
Haemophilia	A rare, genetic disorder in which the ability of a person's blood to clot is impaired due to a lack of blood-clotting factors. 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 can cause pain, 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 can also be used 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 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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