Q4 and FY 2022 report

A good year and a solid future

Fourth quarter 2022

- Total revenue SEK 5,991 M (4,896), +22 per cent, +5 per cent at constant exchange rates (CER)[i]
- Haematology revenue SEK 3,025 M (2,242), +19 per cent at CER of which Elocta® SEK 1,230 M (1,063), +6 per cent at CER; Alprolix® SEK 534 M (482), +1 per cent at CER; Doptelet® SEK 771 M (306), +107 per cent at CER and Aspaveli®/Empaveli® SEK 87 M (1)
- Immunology revenue SEK 2,643 M (2,330), -6 per cent at CER of which Kineret® SEK 553 M (682), -30 per cent at CER; Synagis® SEK 1,849 M (1,364), +12 per cent at CER and Gamifant® SEK 241 M (284), -31 per cent at CER
- EBITA[i] SEK 2,455 M (2,002); EBITA margin[i] 41 per cent (41). EBIT SEK 1,916 M (1,525)
- Earnings per share (EPS) before dilution SEK 4.68 (4.21). Cash flow from operating activities SEK 1,898 M (2,121)

Full year 2022

- Total revenue SEK 18,790 M (15,529), +21 per cent, +8 per cent at CER
- Haematology revenue SEK 10,831 M (8,536), +15 per cent at CER of which Elocta SEK 4,402 M (3,960), +5 per cent at CER; Alprolix SEK 1,885 M (1,764), +1 per cent at CER; Doptelet SEK 2,526 M (1,116), +91 per cent at CER and Aspaveli/Empaveli SEK 178 M (1)
- Immunology revenue SEK 6,679 M (5,780), -1 per cent at CER of which Kineret SEK 2,284 M (2,290), -11 per cent at CER; Synagis SEK 3,501 M (2,650), +12 per cent at CER and Gamifant SEK 895 M (840), -10 per cent at CER
- EBITA SEK 5,930 M (5,575); EBITA margin 32 per cent (36) including items affecting comparability (IAC)[ii] of SEK -675 M. Excluding IAC, EBITA adjusted[i] SEK 6,605 M corresponding to an EBITA margin adjusted[i] of 35 per cent (36). EBIT SEK 3,813 M (3,733); EBIT adjusted[i] SEK 4,488 M (3,733)
- EPS before dilution SEK 8.92 (9.08), EPS adjusted[i] before dilution SEK 10.77 (9.08). Cash flow from operating activities SEK 4,665 M (5,470)

Outlook 2023

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

Financial summary

SEK M	Q4 2022	Q4 2021	Change	FY 2022	FY 2021	Change
Total revenue	5,991	4,896	22 %	18,790	15,529	21 %
Gross profit	4,683	3,880	21 %	14,014	12,045	16 %
Gross margin[i]	78 %	79 %		75 %	78 %	
EBITA[i]	2,455	2,002	23 %	5,930	5,575	6 %
EBITA adjusted[i,ii]	2,455	2,002	23 %	6,605	5,575	18 %
EBITA margin[i]	41 %	41 %		32 %	36 %	
EBITA margin adjusted[i,ii]	41 %	41 %		35 %	36 %	
Profit for the period	1,386	1,241	12 %	2,638	2,679	-2 %
EPS, before dilution, SEK	4.68	4.21	11 %	8.92	9.08	-2 %
EPS, before dilution, SEK adjusted[i,ii]	4.68	4.21	11 %	10.77	9.08	19 %

i. Alternative Performance Measures (APMs), see section APM for further information.

ii. Items affecting comparability (IAC) in 2022, see page 3 for further information.

CEO statement

2022 was a good year for Sobi and we met the objectives provided as part of the 2022 outlook. The fourth quarter continued the trend of solid performance bringing more medicines to people who need them and advancing our pipeline. I look back on these achievements with thanks to all Sobi colleagues in an ever-changing world with geopolitical and economic uncertainties.

Revenue increased by 22 per cent in the fourth quarter and by 5 per cent at constant exchange rates (CER), reflecting a strong performance in Haematology with Doptelet. In the full-year period, revenue grew by 8 per cent at CER, in the higher end of the range provided as part of 2022 outlook.

As indicated, Doptelet led the performance in Haematology with revenue advancing by 107 per cent at CER in the quarter, including by 199 per cent in China and by 72 per cent outside China. Haemophilia had a good fourth quarter with growth of 6 per cent at CER for Elocta and 1 per cent at CER for Alprolix leading to overall slight growth in 2022. As we look ahead for Haemophilia, we will strive to keep stabilising the business ahead of launching efanesoctocog alfa for people with haemophilia A. The launch medicine Aspaveli/Empaveli reached revenue of SEK 87 M in the fourth quarter, continuing its solid launch.

Immunology revenue decreased by 6 per cent at CER in the fourth quarter which reflected a much higher base for Kineret in 2021 due to COVID-19 sales and Gamifant declined mainly due to lower use in adults. On the other hand, Synagis revenue increased by 12 per cent at CER in the fourth quarter reflecting increased use as well as favourable price developments.

The Sobi launch medicines which include Doptelet outside China, Aspaveli/Empaveli and Gamifant combined grew by 29 per cent at CER in the fourth quarter, underpinning our commitment to bringing as swiftly as possible new medicines to people who need them.

EBITA was SEK 2,455 M in the quarter with a margin of 41 per cent. EBITA was SEK 5,930 M in the year with a margin of 32 per cent. Adjusted for items affecting comparability, the margin reached 35 per cent, supported by exchange rates.

The pipeline continued to experience steady progress since the update in October: in Haematology, Doptelet was submitted for registration in immune thrombocytopenia in China and Zynlonta obtained EU approval in advanced forms of diffuse large B-cell lymphoma. In Immunology, Kineret was authorised for emergency use in the US for COVID-19. Finally, nirsevimab was accepted for regulatory review in the US. Sobi has the right to AstraZeneca's full share of US profits and losses for nirsevimab.

With this progress, Sobi continues to find and make available medicines that transform the lives of people with rare and debilitating diseases, and I am pleased to share that the progress is set to continue with the outlook provided for 2023.

Solna, Sweden, 8 February 2023
Guido Oelkers, President & CEO

Financial performance

Total revenue

Total revenue for October to December ('the fourth quarter' or 'the quarter') was SEK 5,991 M (4,896) and increased by 22 per cent compared with the same period a year ago and by 5 per cent at CER. The main contributors to growth were Doptelet and Synagis. Haemophilia remained relatively stable with Elocta benefiting from the timing of orders in the Middle East and Eastern Europe. Launch medicine Aspaveli/Empaveli also contributed to the revenue growth. Kineret performance was reduced by a higher comparison base in 2021 due to COVID-19 sales while Gamifant experienced a softer quarter.

Total revenue for January to December ('the full year' or 'the year') was SEK 18,790 M (15,529) and increased by 21 per cent compared with the same period a year ago and by 8 per cent at CER.

SEK M	Q4 2022	Q4 2021	Change	Change at CER	FY 2022	FY 2021	Change	Change at CER
Haematology	3,025	2,242	35%	19%	10,831	8,536	27%	15%
Immunology	2,643	2,330	13%	-6%	6,679	5,780	16%	-1%
Specialty Care	323	324	0%	-12%	1,280	1,213	6%	-5%
Total	**5,991**	**4,896**	**22%**	**5%**	**18,790**	**15,529**	**21%**	**8%**

Items affecting comparability

In the first half of 2022, Sobi took steps to restructure its business through certain efficiency programmes for which costs were taken over the same period. The programmes refer to the discontinuation of contract manufacturing for Pfizer, the consolidation of a legacy site in Geneva into Basel and restructuring of selling and administrative and research & development (R&D) functions to appropriately support the business. Items affecting comparability (IAC) are outlined in the table below.

SEK M	Q4 2022	IAC	Q4 2022 adjusted	Q4 2021	FY 2022	IAC	FY 2022 adjusted	FY 2021
Total revenue	5,991		5,991	4,896	18,790		18,790	15,529
Cost of goods sold[i]	-1,308	—	-1,308	-1,016	-4,776	-363	-4,413	-3,484
Gross profit	**4,683**	**—**	**4,683**	**3,880**	**14,014**	**-363**	**14,377**	**12,045**
Gross margin	78 %		78 %	79 %	75 %		77 %	78 %
Selling and administrative expenses[ii,iii,iv]	-2,120	—	-2,120	-1,824	-7,847	-210	-7,636	-6,294
Research and development expenses[ii,iv]	-643		-643	-554	-2,354	-102	-2,252	-1,994
Operating expenses	**-2,763**	**—**	**-2,763**	**-2,378**	**-10,201**	**-312**	**-9,889**	**-8,288**
Other operating income/ expenses	-4		-4	23	-1		-1	-24
Operating profit (EBIT)	**1,916**	**—**	**1,916**	**1,525**	**3,813**	**-675**	**4,488**	**3,733**
Plus amortisation and impairment of intangible assets	539		539	477	2,117		2,117	1,841
EBITA	**2,455**	**—**	**2,455**	**2,002**	**5,930**	**-675**	**6,605**	**5,575**
EBITA margin	41 %		41 %	41 %	32 %		35 %	36 %

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

i) Full-year restructuring costs were SEK 363 M including impairment and accelerated depreciation of tangible assets of SEK 136 M following the decision to discontinue contract manufacturing for Pfizer. The process of downsizing the manufacturing facility started in the second half of 2022 with the last volumes anticipated to be delivered to Pfizer in the beginning of 2024.

ii) Full year refers to external expenses and restructuring costs of SEK 134 M related to structural efficiency programmes, whereof SEK 77 M were allocated to selling and administrative expenses and SEK 57 M were allocated to R&D expenses.

iii) Refers to provision for expected credit losses in Russia of SEK 106 M.

iv) Full-year restructuring costs were SEK 72 M including impairment of tangible assets of SEK 12 M followed by the decision in the first quarter to consolidate the Geneva site into Basel. SEK 27 M were allocated to selling and administrative expenses and SEK 45 M were allocated to R&D expenses.

Gross profit

Gross profit was SEK 4,683 M (3,880) in the quarter and the gross margin was 78 per cent (79). The margin benefited from strong Synagis sales and currency effects offset by an increased share of lower-margin Doptelet sales to the partner in China.

Gross profit was SEK 14,014 M (12,045) in the year and included IAC of SEK 363 M. The gross margin excluding IAC was 77 per cent (78).

Operating expenses

Selling and administrative expenses were SEK 2,120 M (1,824) in the quarter and included amortisation of SEK 539 M (477). Excluding amortisation, the increase was 4 per cent at CER and reflected launch preparations and activities for Aspaveli/Empaveli and Zynlonta. Selling and administrative expenses were SEK 7,847 M (6,294) in the year and included IAC of SEK 210 M and amortisation of SEK 2,117 M (1,841). Excluding IAC and amortisation, the increase was 11 per cent at CER.

R&D expenses were SEK 643 M (554) in the quarter and increased by 6 per cent at CER, mainly due to phasing of development programmes for Aspaveli/Empaveli and efanesoctocog alfa. The quarter also included development costs for Zynlonta. R&D expenses were SEK 2,354 M (1,994) in the year and included IAC of SEK 102 M. Excluding IAC, the increase was 4 per cent at CER.

Operating profit

EBITA was SEK 2,455 M (2,002) in the quarter and SEK 5,930 M (5,575) in the year, corresponding to a margin of 41 per cent (41) and 32 per cent (36), respectively. EBITA adjusted was SEK 6,605 M in the year, corresponding to a margin of 35 per cent.

EBIT was SEK 1,916 M (1,525) in the quarter and SEK 3,813 M (3,733) in the year.

Net financial items

Net financial items were SEK -150 M (-102) in the quarter. The increase mainly reflected higher interest rates on loans. Net financial items were SEK -492 M (-438) in the year.

Income tax

Income tax was SEK -380 M (-182) in the quarter, corresponding to an effective tax rate (ETR) of 21.5 per cent (12.8). Income tax was SEK -683 M (-616) in the year, corresponding to an ETR of 20.6 per cent (18.7). The lower comparative ETR in 2021 mainly related to capitalisation of losses from prior years.

Profit

Profit totalled SEK 1,386 M (1,241) in the quarter and SEK 2,638 M (2,679) in the year.

Cash flow

Cash flow from operating activities was SEK 1,898 M (2,121) in the quarter and SEK 4,665 M (5,470) in the year. The decrease was driven by Synagis following a later start of the RSV season in the US compared to 2021 and timing in collection of receivables, both negatively impacting the cash flow from working capital. This was partly offset by the timing of payments for inventory purchases. Cash flow from operating activities in the year was also negatively impacted by retroactive rebate payments and phasing. The full-year period included IAC payments of SEK 137 M whereof SEK 20 M were in the quarter.

Cash flow from investing activities was SEK -62 M (-245) in the quarter. Investing activities were SEK -1,477 M (-367) in the year and included an upfront payment of SEK -588 M to ADC Therapeutics for Zynlonta, a milestone payment of SEK -479 M to Apellis for Aspaveli/Empaveli, a milestone payment of SEK -115 M to Eisai for Doptelet and a milestone payment of SEK -106 M to Selecta for SEL-212.

The regulatory submission acceptance of nirsevimab in the US in January 2023 will trigger a milestone payment to AstraZeneca in the first quarter of 2023 of USD 175 M and additional contractual payments for R&D costs.

Cash and net debt

On 31 December 2022, cash and cash equivalents were SEK 1,361 M (1,045). Sobi ended the year with available undrawn committed credit facilities totalling SEK 5,440 M (4,336). In the first quarter, Sobi established a commercial paper programme of up to SEK 4,000 M and a back-up facility of SEK 2,000 M. During the fourth quarter a revolving credit facility of EUR 335 M matured. Drawn credit facilities and issued commercial papers totalled SEK 8,796 M at the end of the year (10,597). Net debt at the end of the year was SEK 7,406 M (9,500). Net debt was mainly reduced by strong cash flow during the year.

Equity

On 31 December 2022, consolidated shareholders' equity was SEK 26,525 M (23,203).

Personnel

On 31 December 2022, the number of full-time equivalent employees was 1,556 (1,559).

Parent Company

Total revenue for the Parent Company, Swedish Orphan Biovitrum AB (publ), was SEK 4,560 M (5,031) in the quarter, of which Group companies accounted for SEK 2,347 M (3,806). Revenue was SEK 13,381 M (12,401) in the year of which SEK 7,841 (7,967) referred to Group companies' sales.

Profit was SEK 1,267 M (-96) in the quarter and SEK 2,451 M (1,790) in the year, including a reversal of a write-down of SEK 1,000 M for the value of the shares in the subsidiary Swedish Orphan Biovitrum International AB. Investing activities affecting cash flow were SEK -17 M (-233) in the quarter and SEK -1,289 M (-288) in the year.

Haematology

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

Revenue Haematology

SEK M	Q4 2022	Q4 2021	Change	Change at CER	FY 2022	FY 2021	Change	Change at CER
Elocta	1,230	1,063	16%	6%	4,402	3,960	11%	5%
Alprolix	534	482	11%	1%	1,885	1,764	7%	1%
Royalty	342	317	8%	-11%	1,427	1,251	14%	-4%
Doptelet	771	306	152%	107%	2,526	1,116	126%	91%
Aspaveli/Empaveli	87	1	>200%	>200%	178	1	>200%	>200%
Manufacturing	61	72	-15%	-15%	413	445	-7%	-7%
Total	**3,025**	**2,242**	**35%**	**19%**	**10,831**	**8,536**	**27%**	**15%**

Haematology revenue was SEK 3,025 M (2,242) in the quarter and increased by 35 per cent, 19 per cent at CER. Revenue was SEK 10,831 M (8,536) in the year and increased by 27 per cent, 15 per cent at CER.

Elocta sales were SEK 1,230 M (1,063) in the quarter and increased by 16 per cent, 6 per cent at CER. The performance benefited from the timing of orders in the Middle East and Eastern Europe and continued growth in patients and consumption per patient. This was somewhat offset by unfavourable price developments and retroactive adjustments. Sales were SEK 4,402 M (3,960) in the year and increased by 11 per cent, 5 per cent at CER.

Alprolix sales were SEK 534 M (482) in the quarter and increased by 11 per cent, 1 per cent at CER. Growth in patients and consumption per patient was slightly offset by unfavourable price developments and retroactive adjustments. Sales were SEK 1,885 M (1,764) in the year and increased by 7 per cent, 1 per cent at CER.

Doptelet sales were SEK 771 M (306) in the quarter and increased by 152 per cent, 107 per cent at CER, including sales to the partner in China of SEK 317 M (85), up 274 per cent, 199 per cent at CER. In addition to China, growth was driven by increased uptake in the US and ongoing launches in Europe. Sales were SEK 2,526 M (1,116) in the year and increased by 126 per cent, 91 per cent at CER, including sales to the partner in China of SEK 1,102 M (404), up 173 per cent, 128 per cent at CER.

Doptelet entered the China National Reimbursement Drug List (NRDL) in 2020 with renewal confirmed from 1 March 2023. Doptelet, and any approved avatrombopag generic from 2023, are anticipated to remain on the NRDL until three avatrombopag generics have been approved for sale in China. At this point, a transfer to competitive volume-based procurement is anticipated.

Aspaveli/Empaveli sales were SEK 87 M (1) in the quarter, driven by ongoing launches in Germany, the UK, France and the Middle East. First sales were achieved in Denmark, Hungary, Italy, Kuwait and Australia and the number of patients reached ~100 at year-end. Sales were SEK 178 M (1) in the year.

ReFacto AF/Xyntha manufacturing revenue was SEK 61 M (72) in the quarter and SEK 413 M (445) in the year.

Immunology

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

Revenue Immunology

SEK M	Q4 2022	Q4 2021	Change	Change at CER	FY 2022	FY 2021	Change	Change at CER
Kineret	553	682	-19 %	-30 %	2,284	2,290	0 %	-11 %
Synagis	1,849	1,364	36 %	12 %	3,501	2,650	32 %	12 %
Gamifant	241	284	-15 %	-31 %	895	840	6 %	-10 %
Total	**2,643**	**2,330**	**13 %**	**-6 %**	**6,679**	**5,780**	**16 %**	**-1 %**

Immunology revenue was SEK 2,643 M (2,330) in the quarter and increased by 13 per cent, decreased by 6 per cent at CER. Revenue was SEK 6,679 M (5,780) in the year and increased by 16 per cent, decreased by 1 per cent at CER.

Kineret sales were SEK 553 M (682) in the quarter and decreased by 19 per cent, 30 per cent at CER. The decrease reflected no sales in COVID-19. Sales were SEK 2,284 M (2,290) in the year and unchanged, decreased by 11 per cent at CER.

Synagis sales were SEK 1,849 M (1,364) in the quarter and increased by 36 per cent, 12 per cent at CER, reflecting increased use as well as favourable price developments. Sales were SEK 3,501 M (2,650) in the year and increased by 32 per cent, 12 per cent at CER.

Gamifant sales were SEK 241 M (284) in the quarter and decreased by 15 per cent, 31 per cent at CER. Gamifant has reached high adoption in the US and declined mainly due to lower use in adults. Sales were SEK 895 M (840) in the year and increased by 6 per cent, decreased by 10 per cent at CER.

Specialty Care

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

Revenue Specialty Care

SEK M	Q4 2022	Q4 2021	Change	Change at CER	FY 2022	FY 2021	Change	Change at CER
Orfadin	124	121	2 %	-11 %	462	459	1 %	-10 %
Tegsedi	90	123	-27 %	-36 %	429	427	0 %	-10 %
Waylivra	47	30	57 %	46 %	152	121	26 %	19 %
Other Specialty Care	61	50	22 %	9 %	237	207	15 %	4 %
Total	**323**	**324**	**0 %**	**-12 %**	**1,280**	**1,213**	**6 %**	**-5 %**

Specialty Care revenue was SEK 323 M (324) in the quarter and unchanged, decreased by 12 per cent at CER, reflecting continued generic competition to Orfadin and fewer people treated with Tegsedi. Sales were SEK 1,280 M (1,213) in the year and increased by 6 per cent, decreased by 5 per cent at CER.

Pipeline

For more information, please visit https://www.sobi.com/en/pipeline.

Major pipeline milestones since the previous report
(Abbreviations used in the table are explained in the text below)

Significant milestones	Doptelet – ITP: regulatory submission in China Zynlonta (loncastuximab tesirine) – DLBCL: approval in the EU Kineret – COVID-19: authorised for emergency use in the US nirsevimab – RSV prevention: regulatory submission acceptance in the US (by AstraZeneca/ Sanofi)

Haematology

Efanesoctocog alfa

Efanesoctocog alfa (formerly BIVV001), a potential new medicine for haemophilia A, is in phase 3 clinical development in collaboration with Sanofi and under regulatory priority review in the US.

At the 64th American Society of Hematology (ASH) Annual Meeting and Exposition in December 2022, new data on efanesoctocog alfa was presented. This included the efficacy of efanesoctocog alfa on physical functioning, efficacy on pain in people with haemophilia A and a population pharmacokinetic model to characterise efanesoctocog alfa factor VIII activity levels in people with severe haemophilia A.

Efanesoctocog alfa is under US regulatory priority review with a target action date for the Food and Drug Administration (FDA) decision of 28 February 2023. Regulatory submission in the EU, anticipated in the second half of 2023, will follow availability of data from the ongoing, fully recruited XTEND-Kids paediatric study, expected in the first half of 2023.

Doptelet

During the quarter, a second regulatory submission was made for Doptelet in China, for the potential use in immune thrombocytopenia (ITP). ITP is a blood disorder characterised by an abnormal decrease in the number of platelets in the blood, usually caused when the immune system mistakenly attacks and destroys platelets. Doptelet is already approved in China for the treatment of thrombocytopenia in adults with chronic liver disease (CLD) who are scheduled to undergo a procedure.

Aspaveli/Empaveli

Aspaveli/Empaveli, a medicine to treat paroxysmal nocturnal haemoglobinuria (PNH), is in clinical development for use in new indications in collaboration with Apellis Pharmaceuticals, Inc.

At the ASH Annual Meeting and Exposition in December 2022, results from the long-term extension study of Aspaveli/Empaveli in adults with PNH were presented, demonstrating robust and sustained improvements for up to two years in key markers of disease across a broad population. Data from a more intensive dosing regimen to manage acute haemolysis was also presented.

Zynlonta

Zynlonta (loncastuximab tesirine), a medicine for certain debilitating diseases in haematology, is in clinical development in collaboration with ADC Therapeutics SA.

In December 2022, the European Commission granted conditional marketing authorisation in the EU for the use of Zynlonta as monotherapy for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma after two or more lines of systemic therapy.

The approval was based on data from LOTIS-2, a large (n=145) phase 2 multinational, single-arm clinical study of Zynlonta for the treatment of adults with relapsed or refractory DLBCL following two or more prior lines of systemic therapy.

In July 2022, Sobi announced an exclusive license agreement with ADC Therapeutics to develop and commercialise Zynlonta for use in haematology and other indications of large unmet medical need in Europe and most international markets. The license agreement aimed at augmenting Sobi's presence in haematology, one of Sobi's two main disease areas. Zynlonta will be made commercially available alongside other Sobi haematology medicines.

Immunology

Kineret

In November 2022, the US FDA granted Emergency Use Authorisation for the use of Kineret for the treatment of coronavirus disease 2019 (COVID-19) in hospitalised adults with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure. The authorisation was based on results from the SAVE-MORE phase 3 study and followed approval in the EU in December 2021.

Gamifant

Gamifant, a medicine for primary haemophagocytic lymphohistiocytosis, is in clinical development to treat other types of immune disorders of large unmet medical need.

At the ASH Annual Meeting and Exposition in December 2022, new data was presented from the REAL-HLH study, the first study describing the clinical characteristics, treatment patterns and treatment outcomes of a larger cohort of people who received Gamifant in a real-world setting.

The EMERALD phase 3 study evaluates Gamifant in the treatment of macrophage activation syndrome (MAS) in paediatrics and adults with underlying rheumatological diseases, including Still's disease, the first data cohort. Data readout is anticipated in the first half of 2023.

SEL-212

SEL-212, a potential new medicine to treat chronic refractory gout (CRG), is nearing completion of phase 3 clinical development in collaboration with Selecta Biosciences, Inc. Data readout continues to be anticipated in the first half of 2023.

Nirsevimab

Nirsevimab, a potential new immunisation for the prevention of respiratory syncytial virus (RSV) infections in infants, is nearing the completion of development by AstraZeneca PLC and Sanofi.

In November, the companies announced that nirsevimab had been approved in the EU for the prevention of RSV lower respiratory tract disease in new-borns and infants during their first RSV season. In January 2023, the companies announced the US regulatory submission acceptance. Sobi has the right to AstraZeneca's full share of US profits and losses for nirsevimab.

Pipeline news flow

Anticipated major upcoming pipeline news flow

First half of 2023	efanesoctocog alfa – haemophilia A: regulatory decision (US)
	efanesoctocog alfa – haemophilia A (paediatric): XTEND-Kids phase 3 study data readout
	Doptelet – CLD: regulatory decision (JP)
	Empaveli – PNH: regulatory decision (JP)
	Gamifant – MAS in rheumatological diseases: EMERALD phase 3 study data readout (Still's disease cohort)
	SEL-212 – CRG: phase 3 studies data readout
Second half of 2023	efanesoctocog alfa – haemophilia A: regulatory submission (EU)
	Doptelet – ITP: regulatory decision (CN)
	Aspaveli/Empaveli – ALS: MERIDIAN phase 2 study data readout (by Apellis in mid-2023)[1]
	Aspaveli/Empaveli – TA-TMA: phase 2 study data readout[2]
	Kineret – FMF: regulatory decision (CN)[3]
	Gamifant – MAS in rheumatological diseases: regulatory submission (Still's disease cohort) (US)
	SEL-212 – CRG: regulatory submission (US)
	nirsevimab – RSV prevention: regulatory decision (US) (by AstraZeneca/Sanofi)
2024	Doptelet – ITP: regulatory submission (JP)
	Aspaveli/Empaveli – IC-MPGN and C3G: VALIANT phase 3 study data readout[4]
	Kineret – Still's disease: regulatory decision (CN)

[1] ALS; amyotrophic lateral sclerosis.
[2] TA-TMA; transplant-associated thrombotic microangiopathy after allogenic haematopoietic stem cell transplantation.
[3] FMF; familial Mediterranean fever.
[4] IC-MPGN and C3G; immune-complex membranoproliferative glomerulonephritis and C3 glomerulopathy.

Other information

Chairman succession

In October 2022, Sobi announced that chairman Håkan Björklund will not be available for re-election at the next annual general meeting. The Nomination committee then began the process of proposing a successor. In November 2022, Sobi announced that the Nomination committee proposed that the current board member and deputy chairman Bo Jesper Hansen is elected as chairman of the board at the annual general meeting on 9 May 2023.

Management change

From April 2023, Anton (Tony) Hoos, MD, PhD, MBA will become Head of R&D and Medical Affairs and Chief Medical Officer and replace Anders Ullman, MD, PhD who will retire. Dr Hoos brings more than three decades of experience from the global pharmaceutical industry, including positions at Amgen, GSK and Aventis and most recently as a member of the board of Patient Focused Medicine Development.

Sustainability

Sobi's sustainability efforts support the overall mission of working together to find and make available medicines that transform the lives of people with rare and debilitating diseases and are based on two priorities:

- Maintain commitment to patients
- Always act responsibly

During the last quarter of 2022, Sobi reached several milestones in the strive to expand access to medicine. The European Commission's approval of Zynlonta gives people in the EU a new treatment option for relapsed or refractory diffuse large B-cell lymphoma. The UK National Institute for Health and Care Excellence issued a final guidance on Doptelet. Furthermore, the US FDA granted Emergency Use Authorisation for the use of Kineret for the treatment of COVID-19 related pneumonia.

With the aim of supporting people with rare blood disorders, Sobi launched a new digital platform, my-PNH.com, offering caretakers and caregivers information and tools to increase understanding of PNH and its symptoms.

Sobi continued to share knowledge and study data within the scientific community at the 64th Annual Meeting of the American Society of Hematology and contributed at the 2022 European Haemophilia Consortium as well as the German Society of Hematology and Oncology.

A company-wide diversity, equity and inclusion initiative was launched, led by a work group with a wide representation from different functions, geographies and cultural backgrounds.

For the first time, Sobi has qualified as a constituent of the Dow Jones Sustainability Indices (DJSI). Sobi joins the DJSI Europe as one of eight companies within the industry grouping Pharmaceuticals, Biotechnology & Life Sciences. In total, 153 companies were included in the DJSI Europe in 2022.

The war in Ukraine

There are still uncertainties on how and to what extent Sobi's operations will be affected by the war in Ukraine. Sales in Russia corresponded to 2 per cent of total revenue in the quarter and 1 per cent in the year and Sobi maintains an office in Moscow with ~45 colleagues. At the end of the year, the net exposure in accounts receivables towards customers in Russia amounted to SEK 128 M, including a provision for expected credit losses of SEK 106 M. Sobi continues to follow the situation closely in order

to comply with any rules and regulations implemented by the governmental bodies at international level and to assess the potential and actual risks stemming from the situation.

Capital-allocation priorities

As covered initially in the Q1 2022 report and as an integral part of its business model, Sobi is continuously looking for opportunities to augment its business and pipeline. As Sobi seeks new medicines to either license or acquire, the company applies 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.

Outlook 2023

Sobi will continue to expand its presence in haematology, immunology and specialty care through ongoing launches, new medicines and geographic markets and anticipates sustained sales growth:

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

As Sobi continues to invest in launches and advance the pipeline of new medicines and emphasise the long-term value of the business, Sobi anticipates keeping a favourable EBITA margin adjusted:

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

The outlook continues to exclude any elements of Sobi's right to the full share of US profits and losses for nirsevimab.

Dividend

The board of directors proposes that no dividend will be paid for the 2022 financial year.

Annual general meeting

The annual general meeting (AGM) of Swedish Orphan Biovitrum AB (publ) will be held on Tuesday 9 May 2023. Further information regarding the AGM will be available on sobi.com. The Annual and sustainability report 2022 will be published on sobi.com latest three weeks before the AGM and it will also be available at Sobi's head office in Solna, Sweden.

Financial calendar

Q1 2023 report	27 April 2023
Annual general meeting	9 May 2023
Q2 2023 report	18 July 2023
Q3 2023 report	26 October 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, on 8 February 2023 at 08:00 CET.

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

Solna, Sweden, 8 February 2023

Guido Oelkers, President & CEO

Financial statements - condensed

Consolidated statement of comprehensive income

SEK M	Q4 2022	Q4 2021	FY 2022	FY 2021
Total revenue	5,991	4,896	18,790	15,529
Cost of goods sold	-1,308	-1,016	-4,776	-3,484
Gross profit	**4,683**	**3,880**	**14,014**	**12,045**
Selling and administrative expenses[i]	-2,120	-1,824	-7,847	-6,294
Research and development expenses	-643	-554	-2,354	-1,994
Other operating income/expenses	-4	23	-1	-24
Operating profit	**1,916**	**1,525**	**3,813**	**3,733**
Net financial items[ii]	-150	-102	-492	-438
Profit before tax	**1,766**	**1,423**	**3,321**	**3,295**
Income tax	-380	-182	-683	-616
Profit for the period	**1,386**	**1,241**	**2,638**	**2,679**
All profit is 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)	-7	11	60	17
Remeasurement of equity instruments (net of tax)	-35	3	-76	11
Total	**-42**	**15**	**-16**	**28**
Items that may be reclassified into profit or loss				
Translation differences	-150	253	880	464
Net investment hedges (net of tax)	222	-76	-363	-242
Cash flow hedges (net of tax)	-5	-7	-85	-63
Total	**67**	**170**	**432**	**159**
Other comprehensive income	**25**	**185**	**416**	**187**
Total comprehensive income for the period	**1,410**	**1,426**	**3,054**	**2,866**
All comprehensive income is attributable to Parent Company shareholders				
Earnings per share, SEK				
EPS before dilution	4.68	4.21	8.92	9.08
EPS before dilution adjusted[iii]	4.68	4.21	10.77	9.08
EPS after dilution	4.64	4.18	8.84	9.03
EPS after dilution adjusted[iii]	4.64	4.18	10.66	9.03
i. Amortisation and impairment of intangible assets included in Selling and administrative expenses.	-539	-477	-2,117	-1,841
ii. Including financing costs.	-6	-8	-27	-35

iii. See section APM for further information.

Consolidated balance sheet

SEK M	Dec 2022	Dec 2021
ASSETS		
Non-current assets		
Intangible assets[i]	40,013	38,424
Tangible assets	274	493
Financial assets	121	199
Deferred tax assets	877	767
Total non-current assets	**41,285**	**39,883**
Current assets		
Inventories	3,332	3,424
Accounts receivable	5,249	3,439
Other receivables, non-interest bearing	1,269	870
Cash and cash equivalents	1,361	1,045
Total current assets	**11,210**	**8,778**
Total assets	**52,496**	**48,661**
EQUITY AND LIABILITIES		
Shareholders´ equity	**26,525**	**23,203**
Non-current liabilities		
Borrowings	2,971	8,777
Deferred tax liabilities	3,797	3,605
Lease liabilities	200	247
Other liabilities, non-interest bearing	4,146	4,068
Total non-current liabilities	**11,114**	**16,697**
Current liabilities		
Borrowings	5,796	1,768
Accounts payable	1,252	558
Lease liabilities	134	114
Other liabilities, non-interest bearing	7,674	6,321
Total current liabilities	**14,857**	**8,761**
Total equity and liabilities	**52,496**	**48,661**

i. Including goodwill of SEK 7,007 M (6,288).

Consolidated statement of changes in equity

SEK M	FY 2022	FY 2021
Opening balance	**23,203**	**20,206**
Share-based compensation to employees	261	134
Tax deductions for share programmes[i]	6	-3
Total comprehensive income for the period[ii]	3,054	2,866
Closing balance	**26,525**	**23,203**

i. The change relates to difference between the market value and recognised IFRS 2 cost.

ii. Whereof changes in cash flow hedges (net of tax) amounted to SEK -85 M (-63) and net investment hedges (net of tax) amounted to SEK -363 M (-242).

Consolidated cash flow statement

SEK M	Q4 2022	Q4 2021	FY 2022	FY 2021
Profit before tax	1,766	1,423	3,321	3,295
Amortisation, depreciation and impairment	590	536	2,419	2,006
Other, including non-cash items[i]	-28	76	405	179
Income tax paid	-127	-179	-673	-1,124
Cash flow from operating activities before change in working capital	**2,200**	**1,856**	**5,472**	**4,356**
Changes in working capital	-303	265	-807	1,114
Cash flow from operating activities	**1,898**	**2,121**	**4,665**	**5,470**
Investment in intangible assets[ii]	-16	-213	-1,405	-323
Investment in tangible assets	-46	-32	-72	-47
Disposal of tangible assets	—	—	—	3
Cash flow from investing activities	**-62**	**-245**	**-1,477**	**-367**
Borrowings/repayments of borrowings	-1,043	-893	-2,420	-3,998
Hedging arrangement for financing	304	-122	-438	-351
Repayment of leasing	-37	-32	-133	-125
Cash flow from financing activities	**-776**	**-1,047**	**-2,991**	**-4,474**
Change in cash and cash equivalents	**1,059**	**829**	**197**	**629**
Cash and cash equivalents at the beginning of the period	288	212	1,045	404
Translation difference in cash flow and cash and cash equivalents	14	4	119	12
Cash and cash equivalents at the end of the period	**1,361**	**1,045**	**1,361**	**1,045**

i. 2022 refers mainly to restructuring costs, provision for expected credit losses in Russia and IFRS 2 costs on share-based compensation to employees.

ii. 2022 investments refers mainly to milestone payments linked to Aspaveli/Empaveli, Doptelet and SEL-212 and an upfront payment to ADC Therapeutics for Zynlonta.

Key ratios and other information

SEK M	Q4 2022	Q4 2021	FY 2022	FY 2021
Profit measures				
Gross profit	4,683	3,880	14,014	12,045
Gross profit adjusted[i,ii]	4,683	3,880	14,377	12,045
EBITDA[i]	2,505	2,061	6,231	5,740
EBITDA adjusted[i,ii]	2,493	2,061	6,758	5,740
EBITA[i]	2,455	2,002	5,930	5,575
EBITA adjusted[i,ii]	2,455	2,002	6,605	5,575
EBIT	1,916	1,525	3,813	3,733
EBIT adjusted[i,ii]	1,916	1,525	4,488	3,733
Profit for the period	1,386	1,241	2,638	2,679
Profit for the period adjusted[i,ii]	1,386	1,241	3,183	2,679
Per share data (SEK)				
EPS before dilution	4.68	4.21	8.92	9.08
EPS before dilution adjusted[i,ii]	4.68	4.21	10.77	9.08
EPS after dilution	4.64	4.18	8.84	9.03
EPS after dilution adjusted[i,ii]	4.64	4.18	10.66	9.03
Shareholders' equity per share[i]	85.6	75.6	85.6	75.6
Shareholders' equity per share after dilution[i]	84.8	75.1	84.8	75.1
Other information				
Gross margin[i]	78 %	79 %	75 %	78 %
Gross margin adjusted[i,ii]	78 %	79 %	77 %	78 %
EBITA margin[i]	41 %	41 %	32 %	36 %
EBITA margin adjusted[i,ii]	41 %	41 %	35 %	36 %
Equity ratio[i]	51 %	48 %	51 %	48 %
Net debt[i]	7,406	9,500	7,406	9,500
Number of ordinary shares[iii]	309,804,782	307,114,495	309,804,782	307,114,495
Number of ordinary shares (in treasury)	13,789,723	11,959,198	13,789,723	11,959,198
Number of ordinary shares (ex shares in treasury)	296,015,059	295,155,297	296,015,059	295,155,297
Number of ordinary shares after dilution	312,648,912	308,862,835	312,648,912	308,862,835
Average number of ordinary shares (ex shares in treasury)	295,996,975	295,149,731	295,604,246	295,051,119
Average number of ordinary shares after dilution (ex shares in treasury)	298,841,105	296,898,071	298,448,376	296,799,459

i. See section APM for further information.

ii. Items affecting comparability in 2022, see page 3 for further information.

iii. The increase in the number of shares results from an issue of 2,690,287 shares for the purpose of ensuring fulfilment of commitments under incentive programmes, offset by allotment of shares for the programmes expired.

Financial statements - condensed

Parent Company income statement

SEK M	Q4 2022	Q4 2021	FY 2022	FY 2021
Total revenue	4,560	5,031	13,381	12,401
Cost of goods sold	-1,042	-964	-3,609	-2,933
Gross profit	**3,518**	**4,067**	**9,772**	**9,468**
Selling and administrative expenses[i]	-2,375	-1,829	-5,775	-4,179
Research and development expenses	-458	-348	-1,601	-1,256
Other operating income/expenses	116	104	365	350
Operating profit	**801**	**1,994**	**2,761**	**4,383**
Result from participation in Group companies[ii]	1,000	—	1,000	—
Net financial items	294	-101	-442	-392
Profit after financial items	**2,095**	**1,893**	**3,318**	**3,991**
Appropriations	-478	-1,713	-478	-1,713
Profit before tax	**1,617**	**180**	**2,840**	**2,278**
Income tax	-350	-276	-389	-488
Profit for the period	**1,267**	**-96**	**2,451**	**1,790**
[i]Amortisation and impairment of intangible assets included in Selling and administrative expenses.	-131	-102	-527	-359

[ii] Refers to a reversal of a write-down for the value of the shares in the subsidiary Swedish Orphan Biovitrum International AB.

Parent Company statement of comprehensive income

SEK M	Q4 2022	Q4 2021	FY 2022	FY 2021
Profit for the period	1,267	-96	2,451	1,790
Items that will not be reclassified to profit/loss				
Remeasurement of equity instruments (net of tax)	-35	3	-76	11
Items that may be reclassified into profit or loss				
Cash flow hedges (net of tax)	-5	-7	-85	-63
Other comprehensive income	**-40**	**-4**	**-161**	**-52**
Total comprehensive income for the period	**1,227**	**-100**	**2,290**	**1,738**

Parent Company balance sheet

SEK M	Dec 2022	Dec 2021
ASSETS		
Non-current assets		
Intangible assets	11,094	10,107
Tangible assets	44	89
Financial assets	22,106	22,164
Deferred tax assets	125	27
Total non-current assets	**33,369**	**32,387**
Current assets		
Inventories	2,703	2,536
Accounts receivable	995	1,126
Receivables Group companies	5,508	4,308
Other receivables, non-interest bearing	1,073	747
Cash and cash equivalents	1,146	878
Total current assets	**11,426**	**9,595**
Total assets	**44,794**	**41,982**
EQUITY AND LIABILITIES		
Shareholders´ equity	**21,627**	**19,069**
Untaxed reserves	3,909	3,691
Non-current liabilities		
Borrowings	2,971	8,777
Other liabilities, non-interest bearing	3,620	2,897
Total non-current liabilities	**6,591**	**11,674**
Current liabilities		
Borrowings	5,796	1,768
Accounts payable	958	359
Liabilities Group companies	3,292	3,229
Other liabilities, non-interest bearing	2,621	2,192
Total current liabilities	**12,667**	**7,548**
Total equity and liabilities	**44,794**	**41,982**

Parent Company statement of change in equity

SEK M	FY 2022	FY 2021
Opening balance	**19,069**	**17,200**
Share-based compensation to employees	261	134
Tax deductions for share programmes[i]	6	-3
Total comprehensive income for the period[ii]	2,290	1,738
Closing balance	**21,627**	**19,069**

i. The change relates to difference between the market value and recognised IFRS 2 cost.

ii. Whereof changes in cash flow hedges (net of tax) amounted to SEK -85 M (-63).

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.

All amounts reported in this report are presented in SEK M (millions of Swedish kronor), unless otherwise stated. All amounts are rounded to the nearest million kronor.

The accounting policies apply with those described in the Annual and sustainability report 2021. 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 Annual and sustainability report 2021, 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
- Pipeline and intellectual property
- Commercialisation
- Business execution
- Finance and taxation
- Legal, regulatory and compliance

With the current global macroeconomic situation there have been a significant increase in inflation and interest rates. Sobi does not see any immediate material impact of higher costs due to long-term contracts with many suppliers. During the fourth quarter the increased interest rates have impacted Sobi's financial expenses slightly negatively. More details about risk exposure and risk management are included in the Annual and sustainability report 2021.

Note 2 | Segment reporting

Q4 2022	Haematology	Immunology	Specialty Care	Group - other[iv]	Total
Total revenue	3,025	2,643	323	—	5,991
EBITA[i]	1,112	1,515	51	-223	2,455
EBITA adjusted[i]	1,112	1,515	51	-223	2,455
Amortisation	-223	-263	-41	-12	-539
EBIT	889	1,252	10	-235	1,916

Q4 2021	Haematology	Immunology	Specialty Care	Group - other[iv]	Total
Total revenue	2,242	2,330	324	—	4,896
EBITA[i]	888	1,148	95	-128	2,002
EBITA adjusted[i]	888	1,148	95	-128	2,002
Amortisation	-170	-253	-40	-13	-477
EBIT	718	895	55	-141	1,525

FY 2022	Haematology	Immunology	Specialty Care	Group - other[iv]	Total
Total revenue	10,831	6,679	1,280	—	18,790
EBITA[i]	4,111	2,304	287	-774	5,930
EBITA adjusted[i,ii,iii]	4,475	2,410	287	-568	6,605
Amortisation	-857	-1,041	-162	-57	-2,117
EBIT	3,255	1,264	124	-830	3,814

FY 2021	Haematology	Immunology	Specialty Care	Group - other[iv]	Total
Total revenue	8,536	5,780	1,213	—	15,529
EBITA[i]	3,698	2,054	388	-566	5,575
EBITA adjusted[i]	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.

i. See section APM for further information.

ii. Items affecting comparability in 2022, see page 3 for further information.

iii. EBITA adjusted; Haematology refers to discontinuation of contract manufacturing of SEK 363 M, Immunology refers to provision for expected credit losses in Russia of SEK 106 M, Group - other refers to consolidation of sites of SEK 72 M and efficiency programmes of SEK 134 M.

iv. The category Group-other mainly refers to costs for central functions such as finance, legal, communication, human resources and other items that cannot 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.

Liabilities related to contingent considerations were SEK 5,152 M at the end of the year. These are measured at amortised cost using the effective interest method. Fair value for these liabilities was SEK 4,612 M at the end of the year. All other financial instruments on the balance sheet had reported values that are in all material aspects equivalent to fair value on 31 December 2022.

Dec 2022	Level 1	Level 2	Level 3	Total
Financial assets and liabilities measured at fair value through profit or loss				
Derivatives held for trading	—	-13	—	-13
Endowment policies	—	—	48	48
Financial assets measured at fair value through other comprehensive income				
Equity instruments	64	—	—	64
Total	**64**	**-13**	**48**	**99**

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**

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. Numbers are presented in SEK M unless otherwise stated.

Change at CER

Definition: Change at CER (constant exchanges rates) on total revenue excludes the effect of exchange rates by recalculating total revenue for the relevant period using the exchanges rates that were used for the comparable period.

Reason to use: The measure is important in order to understand the underlying performance of the operations and increases the comparability between periods.

Q4 2022	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
Haematology					
Elocta	1,230	-104	1,126	1,063	6%
Alprolix	534	-46	488	482	1%
Royalty	342	-61	281	317	-11%
Doptelet	771	-139	633	306	107%
Aspaveli/Empaveli	87	-8	79	1	>200%
Manufacturing	61	—	61	72	-15%
Total	**3,025**	**-358**	**2,667**	**2,242**	**19%**
Immunology					
Kineret	553	-73	480	682	-30%
Synagis	1,849	-328	1,521	1,364	12%
Gamifant	241	-45	196	284	-31%
Total	**2,643**	**-446**	**2,197**	**2,330**	**-6%**
Specialty Care	**323**	**-38**	**285**	**324**	**-12%**
Total	**5,991**	**-841**	**5,149**	**4,896**	**5%**

Q4 2021	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
Haematology					
Elocta	1,063	3	1,066	1,071	0%
Alprolix	482	3	485	419	16%
Royalty	317	-3	314	316	-1%
Doptelet	306	—	306	191	60%
Aspaveli/Empaveli	1	—	1	—	n/a
Manufacturing	72	—	73	84	-13%
Total	**2,242**	**3**	**2,245**	**2,081**	**8%**
Immunology					
Kineret	682	—	682	586	16%
Synagis	1,364	76	1,440	1,432	1%
Gamifant	284	4	288	263	10%
Total	**2,330**	**80**	**2,410**	**2,281**	**6%**
Specialty Care	**324**	**-6**	**318**	**218**	**46%**
Total	**4,896**	**77**	**4,973**	**4,581**	**9%**

FY 2022	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
Haematology					
Elocta	4,402	-245	4,157	3,960	5%
Alprolix	1,885	-110	1,775	1,764	1%
Royalty	1,427	-232	1,195	1,251	-4%
Doptelet	2,526	-395	2,130	1,116	91%
Aspaveli/Empaveli	178	-15	163	1	>200%
Manufacturing	413	—	413	445	-7%
Total	**10,831**	**-997**	**9,834**	**8,536**	**15%**
Immunology					
Kineret	2,284	-254	2,031	2,290	-11%
Synagis	3,501	-544	2,957	2,650	12%
Gamifant	895	-142	752	840	-10%
Total	**6,679**	**-939**	**5,740**	**5,780**	**-1%**
Specialty Care	**1,280**	**-124**	**1,156**	**1,213**	**-5%**
Total	**18,790**	**-2,060**	**16,730**	**15,529**	**8%**

FY 2021	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
Haematology					
Elocta	3,960	133	4,093	4,585	-11%
Alprolix	1,764	53	1,817	1,705	7%
Royalty	1,251	93	1,344	1,301	3%
Doptelet	1,116	82	1,198	587	104%
Aspaveli/Empaveli	1	—	1	—	n/a
Manufacturing	445	—	445	481	-8%
Total	**8,536**	**361**	**8,898**	**8,660**	**3%**
Immunology					
Kineret	2,290	116	2,406	2,079	16%
Synagis	2,650	249	2,899	2,726	6%
Gamifant	840	61	901	609	48%
Total	**5,780**	**427**	**6,207**	**5,415**	**15%**
Specialty Care	**1,213**	**66**	**1,279**	**1,186**	**8%**
Total	**15,529**	**854**	**16,384**	**15,261**	**7%**

Gross margin

Definition: Gross profit as a percentage of total revenue.

Reason to use: Gross margin is an important measure which provides a better understanding of the business development. Gross margin is impacted by several factors such as business, product and region mix and price developments.

Items affecting comparability

Definition: 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.

Reason to use: Provides a better understanding of the company's underlying operating activities.

SEK M	Q4 2022	Q4 2021	FY 2022	FY 2021
Total revenue	5,991	4,896	18,790	15,529
Total cost of goods sold	-1,308	-1,016	-4,776	-3,484
Gross profit	**4,683**	**3,880**	**14,014**	**12,045**
Gross margin	**78 %**	**79 %**	**75 %**	**78 %**
Items affecting comparability				
-Restructuring costs:				
-Discontinuation of contract manufacturing	—	—	*-363*	—
Items affecting comparability[i]	—	—	**-363**	—
Gross profit adjusted	**4,683**	**3,880**	**14,377**	**12,045**
Gross margin adjusted	**78 %**	**79 %**	**77 %**	**78 %**
EBIT[ii]	**1,916**	**1,525**	**3,813**	**3,733**
Items affecting comparability				
-Restructuring costs:				
-Discontinuation of contract manufacturing	—	—	*-363*	—
-Consolidation of sites	—	—	*-72*	—
-Efficiency programmes	—	—	*-134*	
-Other:				
-Provision for expected credit losses in Russia	—	—	*-106*	—
Items affecting comparability	**—**	**—**	**-675**	**—**
EBIT adjusted	**1,916**	**1,525**	**4,488**	**3,733**

i. Items affecting comparability in 2022, see page 3 for further information.

ii. For EBIT and EBITA per segment see Note 2.

EBITA and EBITA margin

Definition: Earnings before interest, tax, amortisation and impairment of intangible assets. EBITA margin; EBITA as a percentage of total revenue.

Reason to use: EBITA is a key performance measure and gives a fair view of the profitability of the ongoing business.

SEK M	Q4 2022	Q4 2021	FY 2022	FY 2021
EBIT[i]	1,916	1,525	3,813	3,733
Plus amortisation and impairment of intangible assets	539	477	2,117	1,841
EBITA[i]	**2,455**	**2,002**	**5,930**	**5,575**
EBITA margin	**41 %**	**41 %**	**32 %**	**36 %**

i. For EBIT and EBITA per segment see Note 2.

Items affecting comparability				
-Restructuring costs:				
-Discontinuation of contract manufacturing	—	—	*-363*	—
-Consolidation of sites	—	—	*-72*	—
-Efficiency programmes	—	—	*-134*	—
-Other:	—	—	—	—
-Provision for expected credit losses in Russia	—	—	*-106*	—
Items affecting comparability	**—**	**—**	**-675**	**—**
EBITA adjusted	**2,455**	**2,002**	**6,605**	**5,575**
EBITA margin adjusted	**41 %**	**41 %**	**35 %**	**36 %**

EBITDA

Definition: Earnings before interest, taxes, depreciation, amortisation and impairment of intangible and tangible assets.

Reason to use: It is a relevant measure to present profitability aligned with industry standard.

EBITA	2,455	2,002	5,930	5,575
Plus depreciation and impairment of tangible assets	50	59	301	165
EBITDA	**2,505**	**2,061**	**6,231**	**5,740**
Items affecting comparability				
-Restructuring costs:				
-Discontinuation of contract manufacturing	*12*	—	*-227*	—
-Consolidation of sites	—	—	*-60*	—
-Efficiency programmes	—	—	*-134*	—
-Other:				
-Provision for expected credit losses in Russia	—	—	*-106*	—
Items affecting comparability[i]	**12**	**—**	**-527**	**—**
EBITDA adjusted	**2,493**	**2,061**	**6,758**	**5,740**

i. Items affecting comparability excluding impairment of tangible assets of SEK 148 M, see page 3 for more information.

Earnings per share, adjusted

Definition: Profit for the period adjusted divided by the average number of ordinary shares.

Reason to use: Earnings per share adjusted is a good measure of the company's profitability and is used to determine the value of the company's outstanding shares.

SEK M	Q4 2022	Q4 2021	FY 2022	FY 2021
Profit for the period	1,386	1,241	2,638	2,679
Items affecting comparability			-675	—
Tax on items affecting comparability				
-Restructuring costs:				
-Discontinuation of contract manufacturing	—	—	*75*	—
-Consolidation of sites	—	—	*6*	—
-Efficiency programmes	—	—	*28*	—
-Other:				
-Provision for expected credit losses in Russia	—	—	*22*	—
Tax on items affecting comparability	—	—	*130*	—
Items affecting comparability (net of tax)	—	—	-545	—
Profit for the period adjusted	**1,386**	**1,241**	**3,183**	**2,679**
Average number of ordinary shares (excluding shares in treasury)	295,996,975	295,149,731	295,604,246	295,051,119
Average number of ordinary shares after dilution (excluding shares in treasury)	298,841,105	296,898,071	298,448,376	296,799,459
EPS before dilution, SEK adjusted	**4.68**	**4.21**	**10.77**	**9.08**
EPS after dilution, SEK adjusted	**4.64**	**4.18**	**10.66**	**9.03**

Net debt

Definition: Borrowings less cash and cash equivalents.

Reason to use: Net debt is relevant to present as it is useful to illustrate the indebtedness, financial flexibility and capital structure.

Borrowings	8,768	10,545	8,768	10,545
Cash and cash equivalents	1,361	1,045	1,361	1,045
Net debt	**7,406**	**9,500**	**7,406**	**9,500**

Equity ratio

Definition: Shareholders' equity as a proportion of total assets.

Reason to use: A measure for showing financial risk, expressing the percentage of total assets that is financed by the owners.

Equity per share

Definition: Equity divided by the number of ordinary shares.

Reason to use: A measure of the amount of equity that exists per outstanding share and is used for measuring the share against the share price.

Shareholders' equity	26,525	23,203	26,525	23,203
Total assets	52,496	48,661	52,496	48,661
Equity ratio	**51 %**	**48 %**	**51 %**	**48 %**
Number of ordinary shares	309,804,782	307,114,495	309,804,782	307,114,495
Number of ordinary shares after dilution	312,648,912	308,862,835	312,648,912	308,862,835
Equity per share, SEK	**85.6**	**75.6**	**85.6**	**75.6**
Equity per share after dilution, SEK	**84.8**	**75.1**	**84.8**	**75.1**

Definitions

Alprolix (eftrenonacog alfa)	A recombinant, extended half-life (EHL) clotting factor IX medicine for the treatment of haemophilia B.
Amyotrophic lateral sclerosis, ALS	A neurodegenerative disorder characterised by the progressive degeneration and eventual death of nerve cells (neurons) in the brain, brainstem and spinal cord.
Aspaveli/Empaveli (pegcetacoplan)	A medicine targeting complement component 3 (C3) designed to regulate excessive complement activation, which can lead to the onset and progression of many serious rare diseases.
Chronic liver disease, CLD	A liver disease becomes chronic when it has been present for more than 6-12 months without signs of resolution. Chronic liver disease can be inherited (genetic) or caused by a variety of factors such as viruses, auto-immunity, obesity and alcohol use.
Cold agglutinin disease, CAD	A rare autoimmune disorder characterised by the premature destruction of red blood cells (haemolysis). More specifically, CAD is a subtype of autoimmune haemolytic anaemia. The disease is termed "cold" because the disease is active and cause haemolysis at cold temperatures, usually 3 to 4^0C.
Diffuse large B-cell lymphoma, DLBCL	A form of non-Hodgkin lymphoma and the most common blood cancer. Lymphomas occur when cells of the immune system, known as B lymphocytes, grow and multiply uncontrollably. DLBCL occurs mostly in adults and is a fast-growing (aggressive) lymphoma.
Doptelet (avatrombopag)	A second-generation, small-molecule, thrombopoietin-receptor agonist used in the treatment of thrombocytopenia by increasing platelet count.
Efanesoctocog alfa	A new factor VIII medicine designed to extend protection from bleeds with once-weekly prophylactic dosing for the treatment of haemophilia A. It adds a region of von Willebrand factor and XTEN® polypeptides to extend its time in circulation and is the first new factor VIII medicine to break through the von Willebrand factor ceiling.
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.
Full-time equivalents	A unit that indicates the workload of an employee in a way that makes it comparable.
Gamifant (emapalumab)	A monoclonal antibody medicine that binds to and neutralises interferon gamma for the treatment of ultra-rare syndromes of hyperinflammation.
Gout	A disorder of purine metabolism, occurring especially in men, characterised by a raised but variable blood uric acid level and severe recurrent acute arthritis of sudden onset resulting from deposition of crystals of sodium urate in connective tissues and articular cartilage.
Haemophilia	A genetic bleeding disorder caused by insufficient levels of blood proteins, including factor VIII (haemophilia A) and factor IX (haemophilia B). Clotting factors are essential for proper clotting, the process by which blood clumps together to plug the site of a wound to stop bleeding. 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.
Immune-complex membranoproliferative glomerulonephritis, IC-MPGN and C3 glomerulopathy, C3G	Are complement-mediated renal diseases. Although IC-MPGN is considered a distinct disease from C3G, the underlying cause and progression of the two diseases are remarkably similar and include overactivation of the complement cascade, with excessive accumulation of C3 breakdown products in the kidney causing inflammation and damage to the organ.
Kineret (anakinra)	A recombinant protein medicine that blocks interleukin-1α and β by binding to interleukin-1 type 1 receptors. Interleukin-1 is a key mediator of inflammation and a significant contributor to autoinflammatory diseases, including several rare diseases.
Launch medicines	Include Doptelet (outside China), Aspaveli/Empaveli and Gamifant.
Nirsevimab	A single-dose, long-acting antibody, developed and commercialised in partnership by AstraZeneca and Sanofi. It is designed to protect infants entering or during their first RSV season and for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.
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 alkaptonuria.
Paroxysmal nocturnal haemoglobinuria, PNH	A rare disorder in which red blood cells break apart prematurely. It is an acquired hematopoietic stem cell disorder. Some hematopoietic stem cells in individuals with PNH are defective and consequently produce defective blood cells. These defective red blood cells of PNH are extremely susceptible to premature destruction by a particular part of a person's own immune system called the complement system.
Primary haemophagocytic lymphohistiocytosis, pHLH	A rare, life-threatening condition caused by an overactive, abnormal response of the immune system. In hemophagocytic lymphohistiocytosis, the immune system responds to a stimulus or 'trigger', often an infection, but the response is ineffective and abnormal. Some affected individuals may have a genetic predisposition to developing hemophagocytic lymphohistiocytosis. This is known as the primary or familial form.
Respiratory syncytial virus, RSV	A common virus and the most common cause of lower respiratory tract infections in young children. The RSV season usually occurs from early autumn until late spring and peaks during the winter.

SEL-212	A novel combination therapy and potential new medicine designed to sustain control of serum uric acid levels in people 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 RSV F protein inhibitor monoclonal antibody 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.
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.
Zynlonta (loncastuximab tesirine)	A CD19-directed antibody drug conjugate medicine. Once bound to a CD19-expressing cell, Zynlonta is internalised by the cell, where enzymes release a pyrrolobenzodiazepine payload which ultimately results in cell cycle arrest and tumour cell death in DLBCL.

Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare and debilitating diseases. Providing reliable 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, Asia and Australia. In 2022, revenue amounted to SEK 18.8 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com, LinkedIn and YouTube.

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