Q1 2023 report

Continued solid progress

First quarter 2023

- Total revenue SEK 5,239 M (4,925), +6 per cent, -2 per cent at constant exchange rates (CER).[i]
- Haematology revenue SEK 2,815 M (2,499), +5 per cent at CER of which Elocta® SEK 1,196 M (1,024), +9 per cent at CER; Alprolix® SEK 514 M (419), +16 per cent at CER; Doptelet® SEK 475 M (593), -28 per cent at CER and Aspaveli®/Empaveli® SEK 95 M (4)
- Immunology revenue SEK 2,151 M (2,119), -9 per cent at CER of which Kineret® SEK 533 M (645), -24 per cent at CER; Synagis® SEK 1,398 M (1,286), -3 per cent at CER and Gamifant® SEK 219 M (189), +5 per cent at CER
- EBITA[i] SEK 2,121 M (1,290); EBITA margin[i] 40 per cent (26). EBIT SEK 1,495 M (776)
- Earnings per share (EPS) before dilution SEK 3.60 (1.84), EPS adjusted before dilution[i] SEK 3.60 (3.67). Cash flow from operating activities SEK 1,983 M (1,644)
- SEL-212 CRG positive phase 3 studies topline data readout
- Efanesoctocog alfa regulatory approval in the US (by Sanofi) and positive XTEND-Kids phase 3 study topline data readout

Significant event after the first quarter

- Nirsevimab economics simplified through a new royalty agreement with Sanofi and the termination of the participation agreement with AstraZeneca

Outlook 2023 - unchanged[1]

- Revenue is anticipated to grow by a low-to-mid single-digit percentage at CER
- EBITA margin adjusted[2] is anticipated to be at a low 30s percentage of revenue

Financial summary

SEK M	Q1 2023	Q1 2022	Change	FY 2022
Total revenue	5,239	4,925	6%	18,790
Gross profit	4,172	3,409	22%	14,014
Gross margin[i]	80%	69%		75%
EBITA[i]	2,121	1,290	64%	5,930
EBITA adjusted[i, ii]	2,121	1,951	9%	6,605
EBITA margin[i]	40%	26%		32%
EBITA margin adjusted[i, ii]	40%	40%		35%
Profit for the period	1,067	543	96%	2,638
EPS, before dilution, SEK	3.60	1.84	96%	8.92
EPS, before dilution, SEK adjusted[i, ii]	3.60	3.67	-2%	10.77

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

ii. Items affecting comparability (IAC) in 2022, see page 4 for further information.

[1] The outlook excludes Sobi´s right to royalty on net sales of nirsevimab in the US.
[2] Excluding IAC.

CEO statement

We are pleased to conclude our first quarter with strong earnings, strength in major product areas and progress of our pipeline.

Revenue increased by 6 per cent and decreased by 2 per cent at CER, reflecting phasing of sales to the partner in China and a high comparison base for Kineret due to previous COVID-19 related sales. Excluding these two factors, revenue increased by 8 per cent at CER, driven by continued strong performance for Doptelet in markets outside China, as well as the Haemophilia medicines. EBITA reached SEK 2,121 M with a margin of 40 per cent.

In Haematology, Doptelet grew by 78 per cent at CER in markets outside China, driven by increased uptake of new patients in the US and on-going launches in Europe and international markets. The quarter was adversely impacted by no sales of Doptelet to the partner in China, explained by the customary irregular order pattern. In 2023, the Chinese market will open up for avatrombopag generic entry creating uncertainty for the future development and we are currently not foreseeing any further sales to the partner in China in 2023 beyond the second quarter.

In March Doptelet was granted regulatory approval by PMDA in Japan for the treatment of thrombocytopenia in patients with CLD who are scheduled to undergo a procedure.

Elocta and Alprolix grew by 9 and 16 per cent at CER respectively, with both products seeing a steady net patient growth and increased consumption per patient. The FDA granted approval for efanesoctocog alfa which is a key achievement in reinforcing a transformative treatment started with Elocta/Eloctate.

Furthermore, positive topline results from the XTEND-Kids phase 3 study of efanesoctocog alfa was announced which confirms our perspective for the medicine. The completion of XTEND-Kids represents the final milestone needed for regulatory submission in the EU.

The launch of Aspaveli/Empaveli progressed well with strong growth in number of patients on treatment, however quarter-on-quarter sales was adversely impacted by launch related order phasing. In March Empaveli received regulatory approval by PMDA in Japan for the treatment of patients with PNH.

The performance in Immunology reflected a softer first quarter with a high comparison base for Kineret as already mentioned.

Synagis sales was slightly down reflecting the seasonal variation of RS virus virology levels and strong demand earlier in the season.

In April we announced the new royalty agreement with Sanofi for nirsevimab and the termination of the participation agreement with AstraZeneca. This new structure provides simplification and gives Sobi increased strategic flexibility. Nirsevimab is under regulatory review in the US and was recently approved in the EU.

Gamifant, increased by 5 per cent at CER and the trend of increased number of patients continued. Phase 2 results in secondary HLH (MAS, secondary to Still's disease) were published. The study demonstrated a favourable efficacy and safety profile. In the EMERALD phase 3 study patient recruitments for the first cohort were completed and data readout is anticipated in the second half of 2023.

To conclude the news on pipeline development in the quarter, SEL-212 is nearing completion of phase 3 clinical development in collaboration with Selecta. In March positive topline results were announced from the Phase 3 DISSOLVE program where the DISSOLVE I & II studies both met primary end points. A recent survey among immunologists suggests that SEL-212's profile will likely make an important addition in Chronic Refractory Gout treatment.

With all considered, we confirm the outlook for full year 2023 with revenue anticipated to grow by a low-to-mid-single-digit percentage at CER, and for adjusted EBITA margin to be at a low 30s percentage of revenue. The outlook excludes Sobi's right to royalty on net sales of nirsevimab in the US.

Finally, I want to thank all our engaged employees for their contribution in our everyday strive to bring medicines to patients faster.

Solna, Sweden, 27 April 2023
Guido Oelkers, President & CEO

Financial performance

Total revenue

Total revenue for January to March ('the first quarter' or 'the quarter') was SEK 5,239 M (4,925) and increased by 6 per cent compared with the same period a year ago and decreased by 2 per cent at CER. The decline was mainly driven by the volatile sales pattern of Doptelet to the partner in China, with no deliveries in the quarter, and a high comparison base for Kineret due to COVID-19 related sales. Excluding these two factors revenue increased by 8 per cent at CER driven by Doptelet, with strong performance in all markets outside China, and the Haemophilia medicines which benefited from the timing of orders in the Middle East and Eastern Europe. The launch medicines, Aspaveli/Empaveli and Gamifant also contributed. Synagis sales were slightly down, mainly explained by the RS virus seasonal pattern and a strong demand earlier in the season.

SEK M	Q1 2023	Q1 2022	Change	Change at CER	FY 2022
Haematology	2,815	2,499	13%	5%	10,831
Immunology	2,151	2,119	1%	-9%	6,679
Specialty Care	273	307	-11%	-17%	1,280
Total	**5,239**	**4,925**	**6%**	**-2%**	**18,790**

Gross profit

Gross profit was SEK 4,172 M (3,409) and gross margin was 80 per cent (69). Gross profit for the first quarter 2022 included costs of SEK 360 M affecting comparability, excluding these costs gross margin for the first quarter 2022 was 77 per cent. The margin improvement was mainly driven by no low-margin Doptelet sales to the partner in China, but also favourable currency effects contributed.

Operating expenses

Selling and administrative expenses were SEK 2,026 M (2,053) and included amortisation and impairment of SEK 626 M (514). First quarter 2022 included costs of SEK 249 M affecting comparability (IAC). Excluding these costs in prior year and excluding amortisation and impairment, the selling and administrative expenses were flat at CER. Launch preparations and activities for Aspaveli/Empaveli and Zynlonta as well as increased activities for Doptelet were offset by lower costs in other areas.

R&D expenses were SEK 645 M (525) and increased by 15 per cent at CER, excluding IAC of SEK 52 M in the first quarter 2022, mainly due to phasing of development programmes for Aspaveli/Empaveli, efanesoctocog alfa, SEL-212 and development costs for Zynlonta.

Operating profit

EBITA was SEK 2,121 M (1,290), corresponding to a margin of 40 per cent (26). EBITA adjusted first quarter 2022 was SEK 1,951 M, corresponding to a margin of 40 per cent. Operating profit was SEK 1,495 M (776) in the first quarter 2023.

SEK M	Q1 2023	Q1 2022	IAC	Q1 adjusted 2022	FY 2022	IAC	FY adjusted 2022
Total revenue	5,239	4,925		4,925	18,790		18,790
Cost of goods sold[i]	-1,067	-1,516	-360	-1,156	-4,776	-363	-4,413
Gross profit	**4,172**	**3,409**	**-360**	**3,769**	**14,014**	**-363**	**14,377**
Gross margin	80%	69%		77%	75%		77%
Selling and administrative expenses[ii, iii, iv]	-2,026	-2,053	-249	-1,804	-7,847	-210	-7,636
Research and development expenses[ii, iv]	-645	-578	-52	-526	-2,354	-102	-2,252
Operating expenses	**-2,670**	**-2,631**	**-301**	**-2,330**	**-10,201**	**-312**	**-9,889**
Other operating income/ expenses	-7	-2		-2	-1		-1
Operating profit (EBIT)	**1,495**	**776**	**-661**	**1,437**	**3,813**	**-675**	**4,488**
Plus amortisation and impairment of intangible assets	626	514		514	2,117		2,117
EBITA	**2,121**	**1,290**	**-661**	**1,951**	**5,930**	**-675**	**6,605**
EBITA margin	40%	26%		40%	32%		35%

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

i. Q1 2022 restructuring costs were SEK 360 M including impairment and accelerated depreciation of tangible assets of SEK 121 M following the decision to discontinue contract manufacturing for Pfizer. Full-year 2022 restructuring costs were SEK 363 M including impairment and accelerated depreciation of tangible assets of SEK 136 M.

ii. Q1 2022 refers to external expenses and restructuring costs of SEK 72 M related to structural efficiency programmes, whereof SEK 67 M were allocated to selling and administrative expenses and SEK 5 M were allocated to R&D expenses. Full-year 2022 amounted to SEK 134 M 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 157 M in Q1 2022 and SEK 106 M for the full-year 2022.

iv. Q1 2022 restructuring costs were 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 R&D expenses. Full-year 2022 restructuring costs were SEK 72 M including impairment of tangible assets of SEK 12 M, whereof SEK 27 M were allocated to selling and administrative expenses and SEK 45 M were allocated to R&D expenses.

Net financial items

Net financial items were SEK -170 M (-102), reflecting higher interest rates on loans.

Income tax

Income tax was SEK -258 M (-131), corresponding to an effective tax rate (ETR) of 19.5 per cent (19.4).

Profit

Profit for the period totalled SEK 1,067 M (543).

Cash flow

Cash flow from operating activities increased to SEK 1,983 M (1,644), mainly reflecting an increased operating profit. Cash flow from investing activities was SEK -3,258 M (-157) and included milestone payments of SEK 3,009 M, whereof SEK 1,811 M to AstraZeneca for nirsevimab, SEK 678 M to Eisai for Doptelet and SEK 520 M to ADC Therapeutics for Zynlonta, and a payment of SEK 163 M to Sanofi, related to the agreement to reconstruct and validate Sanofi's production facility ahead of the production of the active substance for efanesoctocog alfa. The quarter included IAC payments of SEK 13 M (3) for efficiency programmes initiated in the first quarter 2022.

Cash and net debt

On 31 March 2023, cash and cash equivalents were SEK 198 M (1,361 on 31 December 2022). Sobi ended the quarter with net available committed credit facilities totalling SEK 5,049 M (5,440 on 31 December 2022). Utilized credit facilities (excluding amounts reserved for checks) and issued commercial papers totalled SEK 8,596 M at the end of the quarter (8,796 on 31 December 2022). Net debt at the quarter was SEK 8,708 M (7,406 on 31 December 2022).

Equity

On 31 March 2023, consolidated shareholders' equity was SEK 27,828 M (26,525 on 31 December 2022).

Personnel

On 31 March 2023, the number of full-time equivalent employees was 1,612 (1,556 on 31 December 2022).

Parent Company

Total revenue for the Parent Company, Swedish Orphan Biovitrum AB (publ), was SEK 3,852 M (3,360), of which Group companies accounted for SEK 2,609 M (2,224).

Profit/loss for the period was SEK 493 M (-99). Investing activities affecting cash flow were SEK 706 M (38) and included a milestone payment of SEK 520 M for Zynlonta and a payment of SEK 163 M to Sanofi for efanesoctocog alfa.

Haematology

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

Revenue Haematology

SEK M	Q1 2023	Q1 2022	Change	Change at CER	FY 2022
Elocta	1,196	1,024	17%	9%	4,402
Alprolix	514	419	23%	16%	1,885
Royalty	343	333	3%	-7%	1,427
Doptelet	475	593	-20%	-28%	2,526
Aspaveli/Empaveli	95	4	>200%	>200%	178
Zynlonta	3	—	n/a	n/a	—
Manufacturing	189	124	52%	52%	413
Total	**2,815**	**2,499**	**13%**	**5%**	**10,831**

Haematology revenue was SEK 2,815 M (2,499) and increased by 13 per cent, 5 per cent at CER.

Elocta sales were SEK 1,196 M (1,024) and increased by 17 per cent, 9 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 in some European markets.

Alprolix sales were SEK 514 M (419) and increased by 23 per cent, 16 per cent at CER. Growth was driven by increased patient numbers and consumption per patient and awarded tenders in the Middle East, slightly offset by unfavourable price developments.

Doptelet sales were SEK 475 M (593) and decreased by 20 per cent, 28 per cent at CER. The quarter included no sales to the partner in China (SEK 352 M). Sales growth in other markets was strong, driven by increased uptake in the US and ongoing launches in Europe.

Doptelet inclusion on the China National Reimbursement Drug List (NRDL) was renewed in the first quarter 2023 and will together with any approved avatrombopag generic remain on the NRDL at least throughout 2024. Following the approval of three avatrombopag generics for sale in China, the initiation of a competitive volume-based procurement (VBP) model is anticipated to take place from mid-2024. Due to the uncertainty regarding entry of avatrombopag generics and the outcome of the anticipated VBP process, we are currently not foreseeing any further sales to the partner in China in 2023 beyond the second quarter.

Aspaveli/Empaveli sales were SEK 95 M (4) reflecting strong growth in number of patients in the quarter.

First sales of Zynlonta of SEK 3 M were recorded in Saudi Arabia.

ReFacto AF/Xyntha manufacturing revenue was SEK 189 M (124).

Immunology

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

Revenue Immunology

SEK M	Q1 2023	Q1 2022	Change	Change at CER	FY 2022
Kineret	533	645	-17%	-24%	2,284
Synagis	1,398	1,286	9%	-3%	3,501
Gamifant	219	189	16%	5%	895
Total	**2,151**	**2,119**	**1%**	**-9%**	**6,679**

Immunology revenue was SEK 2,151 M (2,119) and increased by 1 per cent, decreased by 9 per cent at CER.

Kineret sales were SEK 533 M (645) and decreased by 17 per cent, 24 per cent at CER, impacted by high sales related to COVID-19 in the first quarter of 2022.

Synagis sales were SEK 1,398 M (1,286) and increased by 9 per cent and decreased by 3 per cent at CER, reflecting expected seasonal variability following strong demand earlier in the season, somewhat offset by favourable price developments.

Gamifant sales were SEK 219 M (189) and increased by 16 per cent, 5 per cent at CER. A continued growth in number of patients in the US market is offset by lower weight of patients and shorter treatment duration.

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 2023	Q1 2022	Change	Change at CER	FY 2022
Orfadin	111	106	5%	-3%	462
Tegsedi	81	110	-26%	-31%	429
Waylivra	55	38	43%	34%	152
Other Specialty Care	26	53	-51%	-52%	237
Total	**273**	**307**	**-11%**	**-17%**	**1,280**

Specialty Care revenue was SEK 273 M (307) and decreased by 11 per cent, 17 per cent at CER, reflecting fewer people treated with Tegsedi and no sales in the quarter for Kepivance due to supply shortages.

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	efanesoctocog alfa – haemophilia A: regulatory approval in the US (by Sanofi)
	efanesoctocog alfa – haemophilia A (paediatric): positive XTEND-Kids phase 3 study topline data readout
	Doptelet – CLD: regulatory approval in Japan
	Empaveli – PNH: regulatory approval in Japan
	Kineret – CAPS: regulatory submission in China
	SEL-212 – CRG: positive phase 3 studies topline data readout

Haematology

Efanesoctocog alfa

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

In February, the US Food and Drug Administration (FDA) approved efanesoctocog alfa for routine prophylaxis, on-demand treatment and control of bleeding episodes and perioperative management of bleeding. The recommended weekly dose of 50 IU/kg is intended for prophylaxis in patients of all ages and the same dose or 30 IU/kg can be administered according to needs in different clinical settings.

The FDA approval was primarily based on data from the pivotal XTEND-1 phase 3 study where once-weekly efanesoctocog alfa met the primary endpoint, providing significant improvements in bleed protection for people with severe haemophilia A with median and mean annualised bleeding rates (ABR) of 0.00 (interquartile range: 0.00-1.04) and 0.71 (95 per cent confidence interval: 0.52-0.97), respectively.

In March, Sobi and Sanofi announced that the XTEND-Kids phase 3 paediatric study evaluating the safety, efficacy and pharmacokinetics of efanesoctocog alfa as once-weekly prophylaxis in previously treated patients under 12 years of age with severe haemophilia A met its primary endpoint. No factor VIII inhibitors were observed in the 74 children enrolled in the study, of which 65 experienced at least 50 exposure days. Efanesoctocog alfa provided high sustained factor VIII levels throughout the weekly dosing interval with a median ABR of 0.00 (interquartile range: 0.00-1.02) and an estimated mean ABR (95 per cent confidence interval) of 0.89 (0.56-1.42).

Combined with the XTEND-1 phase 3 trial, these results will provide the basis for regulatory submission in the EU. Efanesoctocog alfa was granted orphan designation by the European Commission in June 2019.

Doptelet

Doptelet received regulatory approval by PMDA in Japan on March 27, 2023 for the treatment of thrombocytopenia in patients with chronic liver disease (CLD) who are scheduled to undergo a procedure. Doptelet provides an alternative to platelet transfusions, which represent the traditional therapy and standard of care.

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.

Empaveli received regulatory approval by PMDA on March 27th, 2023 for the treatment of patients with paroxysmal nocturnal hemoglobinuria in Japan.

Immunology

Kineret

During the quarter, the third regulatory submission was made for Kineret in China, this time for the potential use in the treatment of cryopyrin-associated periodic syndromes (CAPS). CAPS is a group of rare illnesses related to defects in the protein cryopyrin. A regulatory decision is anticipated in 2024.

Gamifant

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

In March, the so-called 'Study 06' (NI-0501-06) phase 2 study in patients with macrophage activation syndrome (MAS) secondary to Still's disease was published in Annals of the Rheumatic Diseases. Study 06 was the first prospective study assessing a treatment for patients with this condition who had an inadequate response to high-dose glucocorticoids. Key results published show the adequacy of the chosen Gamifant dosing regimen in this setting. Further, it shows that neutralisation of interferon gamma (IFNγ) with Gamifant led to MAS remission in 13 of 14 patients by week 8 and that Gamifant treatment enabled glucocorticoid tapering in all patients. Gamifant treatment was well tolerated and safety data were consistent with its established safety profile. Observations over the 12-month, post-treatment, follow-up period suggest no increased risk of adverse events, even when Gamifant levels remained detectable in some patients. The findings at 12 months were previously presented at PReS 2022, the Paediatric Rheumatology European Society. In summary, the results of this study show that neutralisation of IFNγ with Gamifant is a therapeutic option for patients with severe MAS who have failed standard of care with high-dose glucocorticoids.

The EMERALD phase 3 study first data cohort evaluates Gamifant in the treatment of MAS in paediatric and adult patients with underlying rheumatological diseases, including Still's disease.

Following the recent completion of recruitment into that cohort of a required number of patients, data readout is now anticipated in the second 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.

In March, Sobi and Selecta announced positive topline results from the Phase 3 DISSOLVE I & II placebo-controlled randomised clinical studies to determine safety and efficacy of two different dose levels of SEL-212 in adult patients with CRG. The DISSOLVE I study met its primary endpoint, with 56 per cent of patients receiving monthly doses of SEL-212 at 0.15 mg/kg achieving a response (defined as achievement and maintenance of reduction in serum urate (SU) <6mg/dL for at least 80 per cent of the time during month six). The DISSOLVE II study also met its primary endpoint, with 47 per cent receiving monthly doses of SEL-212 at 0.15 mg/kg achieving a response.

In the 69 per cent of patients above the age of 50, 65 per cent and 47 per cent of DISSOLVE I patients randomised to receive SEL-212 at the high dose ($p<0.0001$) and the low dose ($p<0.0001$) of ImmTOR (an immunosuppressant), respectively, versus 5 per cent of patients randomised to receive the placebo reached the primary endpoint; 48 per cent and 45 per cent of DISSOLVE II patients randomised to receive SEL-212 at the high dose ($p=0.0017$) and the low dose ($p=0.0044$) of ImmTOR, respectively, versus 14 per cent of patients randomised to receive the placebo reached the primary endpoint. SEL-212 was observed to have a favourable safety profile and was well-tolerated across both doses of ImmTOR.

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 the US, nirsevimab is progressing with regulatory review with a decision anticipated at the end of the third quarter. Sobi has the right to royalties on Sanofi's future net sales of nirsevimab in the US.

Pipeline news flow

Anticipated major upcoming pipeline news flow

Second half of 2023	efanesoctocog alfa – haemophilia A: regulatory submission in the EU
	Doptelet – ITP: regulatory decision in China[1]
	Kineret – FMF: regulatory decision in China[2]
	Gamifant – MAS in rheumatological diseases: EMERALD phase 3 study data readout (Still's disease cohort)
	Gamifant – MAS in rheumatological diseases: regulatory submission in the US (Still's disease cohort)
	nirsevimab – RSV prevention: regulatory decision in the US (by AstraZeneca/Sanofi)
2024	Doptelet – ITP: regulatory submission in Japan
	Aspaveli/Empaveli – IC-MPGN and C3G: VALIANT phase 3 study data readout[3]
	Aspaveli/Empaveli – TA-TMA: phase 2 study data readout[4]
	Kineret – Still's disease: regulatory decision in China
	Kineret – CAPS: regulatory decision in China
	SEL-212 – CRG: regulatory submission in the US (in first half 2024)

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

Other information

Significant events after the reporting period

Nirsevimab

In April Sobi announced a streamlining and simplification of the contractual economics for nirsevimab. Through a new royalty agreement with Sanofi, Sobi will receive a quarterly royalty on net sales of nirsevimab in the US. Royalty rates will start at 25 per cent at launch, which is anticipated in 2023, continue in 2024 and increase each year from 2025 to 2028 in a tiered fashion to a range of 30 to 35 per cent of net sales. Beyond 2028, the royalty rates will remain at these levels. As part of the new royalty agreement with Sanofi, Sobi will pay Sanofi USD 66 million as reimbursement of prior costs for research & development of nirsevimab in the US with Sobi owing no further payments.

Through a separate agreement with AstraZeneca, Sobi terminated the participation agreement related to nirsevimab that was entered into at the end of 2018 and closed in January 2019. This termination removes Sobi's right to AstraZeneca's full share of US profits and losses for nirsevimab, including US development and commercialisation costs and the obligation to pay future milestones and royalties to AstraZeneca. Sobi will pay AstraZeneca USD 15 million as an upfront final consideration with Sobi owing no further payments.

Aspaveli/Empaveli

A decision has been made to discontinue treatment with systemic pegcetacoplan in the open-label portion of the ALS Phase 2 MERIDIAN study led by Apellis. This decision was made following an unblinded review of the available data by an independent data monitoring committee (IDMC). The IDMC concluded that the available data did not support continuation of treatment. The recommendation was not based on any safety concerns. All patients have completed the randomized treatment portion of the Phase 2 study and the data will be reviewed as planned.

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 first quarter of 2023, Sobi reached several milestones in the strive to expand access to medicine. Positive results were announced from phase 3 studies on SEL-212 used to treat patients with chronic refractory gout. Efanesoctocog alfa, a potential new medicine for haemophilia A in clinical development in collaboration with Sanofi was approved by the FDA in the US and the phase 3 paediatric study in children under 12 years of age with haemophilia had positive topline results.

Sobi continued to share knowledge within the scientific community at EAHAD, the 16th Annual Congress of the European Association for Haemophilia and Allied Disorders.

World Rare Disease Day, February 28, was commemorated in many Sobi markets through events together with patient organisations and key opinion leaders on rare diseases, giving visibility to rare diagnoses and raising awareness about the unmet needs of persons living with these diseases.

Sobi's Rare Strength Awards, instituted to recognise company role models embodying Sobi values, were awarded to two Sobi employees.

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 1 per cent of total revenue in the quarter and Sobi maintains an office in Moscow with ~45 colleagues. At the end of the quarter, the net exposure in accounts receivables towards customers in Russia amounted to SEK 53 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 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 - unchanged

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[1] is anticipated to be at a low 30s percentage of revenue

The outlook excludes Sobi´s right to royalty on net sales of nirsevimab in the US.

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 is available on sobi.com. The Annual and sustainability report 2022 was published on sobi.com on 3 April 2023 and is also available at Sobi's head office in Solna, Sweden.

Financial calendar

Annual general meeting	9 May 2023
Q2 2023 report	18 July 2023
Q3 2023 report	26 October 2023
Q4 2023 report	8 February 2024

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 27 April 2023 at 08:00 CEST.

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

Solna, Sweden, 27 April 2023

Guido Oelkers, President & CEO

[1] Excluding IAC.

Financial statements – condensed

Consolidated statement of comprehensive income

SEK M	Q1 2023	Q1 2022	FY 2022
Total revenue	5,239	4,925	18,790
Cost of goods sold	-1,067	-1,516	-4,776
Gross profit	**4,172**	**3,409**	**14,014**
Selling and administrative expenses[i]	-2,026	-2,053	-7,847
Research and development expenses	-645	-578	-2,354
Other operating income/expenses	-7	-2	-1
Operating profit	**1,495**	**776**	**3,813**
Net financial items	-170	-102	-492
Profit before tax	**1,325**	**674**	**3,321**
Income tax	-258	-131	-683
Profit for the period	**1,067**	**543**	**2,638**
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)	—	—	60
Remeasurement of equity instruments (net of tax)	14	-66	-76
Total	**14**	**-66**	**-16**
Items that may be reclassified into profit or loss			
Translation differences	4	110	880
Net investment hedges (net of tax)	51	-66	-363
Cash flow hedges (net of tax)	15	-18	-85
Total	**70**	**26**	**432**
Other comprehensive income	**84**	**-40**	**416**
Total comprehensive income for the period	**1,151**	**503**	**3,054**
All comprehensive income is attributable to Parent Company shareholders			
Earnings per share, SEK			
EPS before dilution	3.60	1.84	8.92
EPS before dilution adjusted[ii]	3.60	3.67	10.77
EPS after dilution	3.56	1.83	8.84
EPS after dilution adjusted[ii]	3.56	3.64	10.67
i. Amortisation and impairment of intangible assets included in Selling and administrative expenses.	-626	-514	-2,117

ii. See section APM for further information.

Consolidated balance sheet

SEK M	Mar 2023	Dec 2022	Mar 2022
ASSETS			
Non-current assets			
Intangible assets[i]	42,343	40,013	38,264
Tangible assets	270	274	380
Financial assets	135	121	121
Deferred tax assets	865	877	682
Total non-current assets	**43,613**	**41,285**	**39,446**
Current assets			
Inventories	3,662	3,332	3,365
Accounts receivable	4,223	5,249	3,748
Other receivables, non-interest bearing	2,216	1,269	1,187
Cash and cash equivalents	198	1,361	1,063
Total current assets	**10,299**	**11,210**	**9,363**
Total assets	**53,911**	**52,496**	**48,809**
EQUITY AND LIABILITIES			
Equity			
Share capital	170	170	169
Other contributed capital	10,197	10,211	9,995
Other reserves	434	351	-106
Retained earnings	15,960	13,155	13,155
Profit for the period	1,067	2,638	543
Equity attributable to Parent Company shareholders	**27,828**	**26,525**	**23,757**
Non-current liabilities			
Borrowings	2,973	2,971	8,360
Deferred tax liabilities	3,844	3,797	3,461
Lease liabilities	194	200	264
Other liabilities, non-interest bearing	4,359	4,146	3,912
Total non-current liabilities	**11,371**	**11,114**	**15,996**
Current liabilities			
Borrowings	5,933	5,796	1,024
Accounts payable	625	1,252	545
Lease liabilities	134	134	125
Other liabilities, non-interest bearing	8,021	7,674	7,363
Total current liabilities	**14,713**	**14,857**	**9,056**
Total equity and liabilities	**53,911**	**52,496**	**48,809**

i. Including goodwill of SEK 6,975 M (7,007 on 31 December 2022).

Consolidated statement of changes in equity

SEK M	Jan-Mar 2023	FY 2022	Jan-Mar 2022
Opening balance	**26,525**	**23,203**	**23,203**
Share-based compensation to employees	141	261	41
Tax adjustments for share programmes[i]	11	6	9
Total comprehensive income for the period[ii]	1,151	3,054	503
Closing balance	**27,828**	**26,525**	**23,757**

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 15 M (-85 on 31 December 2022) and net investment hedges (net of tax) amounted to SEK 51 M (-363 on 31 December 2022).

Consolidated cash flow statement

SEK M	Q1 2023	Q1 2022	FY 2022
Cash flow from operating activities			
Profit before tax	1,325	674	3,321
Amortisation, depreciation and impairment	664	685	2,419
Other, including non-cash items[i]	-5	395	316
Income tax paid	-116	-208	-673
Cash flow from operating activities before change in working capital	**1,868**	**1,546**	**5,383**
Changes in working capital	115	98	-807
Cash flow from operating activities	**1,983**	**1,644**	**4,576**
Investment in intangible assets[ii]	-3,195	-155	-1,405
Investment in tangible assets	-63	-2	-72
Cash flow from investing activities	**-3,258**	**-157**	**-1,477**
Borrowings/repayments of borrowings	89	-1,311	-2,420
Hedging arrangement for financing	4	-146	-438
Repayment of leasing	-39	-34	-133
Proceeds from exercise of share options[iii]	108	—	89
Cash flow from financing activities	**162**	**-1,491**	**-2,902**
Change in cash and cash equivalents	**-1,113**	**-4**	**197**
Cash and cash equivalents at the beginning of the period	1,361	1,045	1,045
Translation difference in cash flow and cash and cash equivalents	-50	22	119
Cash and cash equivalents at the end of the period	**198**	**1,063**	**1,361**

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

ii. 2023 investments refers mainly to milestone payments linked to nirsevimab, Doptelet, Zynlonta and a payment to Sanofi related to efanesoctocog alfa.

iii. Proceeds from exercise of share options for FY 2022, amounting to SEK 89 M, have been reclassified from other, including non-cash items to cash flow from financing activities. Accordingly, cash flow from operating activities have changed from SEK 4,665 M to SEK 4,576 M and cash flow from financing activities have changed from SEK -2,991 M to SEK -2,902 M.

Key ratios and other information

SEK M	Q1 2023	Q1 2022	FY 2022
Profit measures			
Gross profit	4,172	3,409	14,014
Gross profit adjusted[i, ii]	4,172	3,769	14,377
EBITDA[i]	2,159	1,461	6,231
EBITDA adjusted[i, ii]	2,159	1,990	6,758
EBITA[i]	2,121	1,290	5,930
EBITA adjusted[i, ii]	2,121	1,951	6,605
EBIT	1,495	776	3,813
EBIT adjusted[i, ii]	1,495	1,437	4,488
Profit for the period	1,067	543	2,638
Profit for the period adjusted[i, ii]	1,067	1,083	3,183
Per share data (SEK)			
EPS before dilution	3.60	1.84	8.92
EPS before dilution adjusted[i, ii]	3.60	3.67	10.77
EPS after dilution	3.56	1.83	8.84
EPS after dilution adjusted[i, ii]	3.56	3.64	10.67
Shareholders' equity per share[i]	89.8	77.4	85.6
Shareholders' equity per share after dilution[i]	88.9	76.8	84.8
Other information			
Gross margin[i]	80%	69%	75%
Gross margin adjusted[i, ii]	80%	77%	77%
EBITA margin[i]	40%	26%	32%
EBITA margin adjusted[i, ii]	40%	40%	35%
Equity ratio[i]	52%	49%	51%
Net debt[i]	8,708	8,321	7,406
Number of ordinary shares[iii]	309,804,782	307,114,495	309,804,782
Number of ordinary shares (in treasury)	13,191,257	11,959,198	13,789,723
Number of ordinary shares (ex shares in treasury)	296,613,525	295,155,297	296,015,059
Number of ordinary shares after dilution	312,870,872	309,436,738	312,648,912
Average number of ordinary shares (ex shares in treasury)	296,270,780	295,155,297	295,604,246
Average number of ordinary shares after dilution (ex shares in treasury)	299,336,870	297,477,540	298,448,376

i. See section APM for further information.

ii. Items affecting comparability in 2022, see page 4 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	Q1 2023	Q1 2022	FY 2022
Total revenue	3,852	3,360	13,381
Cost of goods sold	-929	-1,184	-3,609
Gross profit	**2,923**	**2,176**	**9,772**
Selling and administrative expenses[i]	-1,976	-1,890	-5,775
Research and development expenses	-446	-358	-1,601
Other operating income/expenses	79	101	365
Operating profit	**580**	**29**	**2,761**
Result from participation in Group companies[ii]	—	—	1,000
Net financial items	66	-92	-442
Profit/loss after financial items	**647**	**-63**	**3,318**
Appropriations	—	—	-478
Profit/loss before tax	**647**	**-63**	**2,840**
Income tax	-153	-36	-389
Profit/loss for the period	**493**	**-99**	**2,451**
i. Amortisation and impairment of intangible assets included in Selling and administrative expenses.	-190	-130	-527

ii. Refers to a reversal of a write-down for the value of the shares in the subsidiary Swedish Orphan Biovitrum International AB following the progress of the launch of Gamifant.

Parent Company statement of comprehensive income

SEK M	Q1 2023	Q1 2022	FY 2022
Profit/loss for the period	493	-99	2,451
Items that will not be reclassified into profit or loss			
Remeasurement of equity instruments (net of tax)	14	-66	-76
Items that may be reclassified into profit or loss			
Cash flow hedges (net of tax)	15	-18	-85
Other comprehensive income/loss	**29**	**-84**	**-161**
Total comprehensive income/loss for the period	**522**	**-183**	**2,290**

Parent Company balance sheet

SEK M	Mar 2023	Dec 2022	Mar 2022
ASSETS			
Non-current assets			
Intangible assets	10,989	11,094	10,001
Tangible assets	38	44	75
Financial assets	24,630	22,106	21,221
Deferred tax assets	131	125	165
Total non-current assets	**35,789**	**33,369**	**31,462**
Current assets			
Inventories	2,683	2,703	2,466
Accounts receivable	1,143	995	1,047
Receivables Group companies	5,846	5,508	3,689
Other receivables, non-interest bearing	1,318	1,073	990
Cash and cash equivalents	—	1,146	808
Total current assets	**10,991**	**11,426**	**8,999**
Total assets	**46,780**	**44,794**	**40,461**
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	170	170	169
Statutory reserve	800	800	800
Total restricted equity	**970**	**970**	**969**
Non-restricted equity			
Retained earnings	20,838	18,206	18,067
Profit/loss for the period	493	2,451	-99
Total non-restricted equity	**21,331**	**20,657**	**17,968**
Shareholder's equity	**22,301**	**21,627**	**18,937**
Untaxed reserves	3,909	3,909	3,691
Non-current liabilities			
Borrowings	2,973	2,971	8,360
Other liabilities, non-interest bearing	4,354	3,620	3,275
Total non-current liabilities	**7,327**	**6,591**	**11,635**
Current liabilities			
Borrowings	5,933	5,796	1,024
Accounts payable	405	958	399
Liabilities Group companies	4,727	3,292	2,520
Other liabilities, non-interest bearing	2,178	2,621	2,256
Total current liabilities	**13,243**	**12,667**	**6,198**
Total equity and liabilities	**46,780**	**44,794**	**40,461**

Parent Company statement of change in equity

SEK M	Jan-Mar 2023	FY 2022	Jan-Mar 2022
Opening balance	**21,627**	**19,069**	**19,069**
Share-based compensation to employees	141	261	41
Tax adjustments for share programmes[i]	11	6	9
Total comprehensive income/loss for the period[ii]	522	2,290	-183
Closing balance	**22,301**	**21,627**	**18,937**

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 15 M (SEK -85 M on 31 December 2022).

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 2022. IASB has published amendments of standards that were effective as of 1 January 2023 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 2022, 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. The increased interest rates have impacted Sobi's financial expenses negatively. More details about risk exposure and risk management are included in the Annual and sustainability report 2022.

Note 2 | Segment reporting

Q1 2023	Haematology	Immunology	Specialty Care	Group – other[v]	Total
Total revenue	2,815	2,151	273	—	5,239
EBITA[i]	1,082	1,131	65	-157	2,121
Amortisation and impairment	-281	-295	-39	-11	-626
EBIT	801	836	26	-168	1,495

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

FY 2022	Haematology	Immunology	Specialty Care	Group – other[v]	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, iv]	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

There are no intersegment transactions.

i. See section APM for further information.

ii. Items affecting comparability, see page 4 for further information.

iii. EBITA adjusted Q1 2022; Haematology refers to discontinuation of contract manufacturing of SEK 360 M, Immunology refers to provision for expected credit losses in Russia of SEK 157 M, Group – other refers to consolidation of sites of SEK 72 M and efficiency programmes of SEK 72 M.

iv. EBITA adjusted FY 2022; 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.

v. 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 linked to contingent considerations attributable to intangible assets acquired were SEK 5,555 M (5,154 on December 2022). These are measured at amortised cost using the effective interest method. Fair value for these liabilities was SEK 5,254 M (4,773 on 31 December 2022). All other financial instruments on the balance sheet had reported values that are in all material aspects equivalent to fair value on 31 March 2023.

Q1 2023	Level 1	Level 2	Level 3	Total
Financial assets and liabilities measured at fair value through profit or loss				
Derivatives held for trading	—	129	—	129
Endowment policies	—	—	48	48
Financial assets measured at fair value through other comprehensive income				
Equity instruments	78	—	—	78
Total	**78**	**129**	**48**	**255**

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**

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**

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. 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.

Q1 2023	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
Haematology					
Elocta	1,196	-79	1,117	1,024	9%
Alprolix	514	-30	484	419	16%
Royalty	343	-35	309	333	-7%
Doptelet	475	-46	430	593	-28%
Aspaveli/Empaveli	95	-5	90	4	>200%
Zynlonta	3	-1	2	—	n/a
Manufacturing	189	—	189	124	52%
Total	**2,815**	**-196**	**2,621**	**2,499**	**5%**
Immunology					
Kineret	533	-44	489	645	-24%
Synagis	1,398	-155	1,243	1,286	-3%
Gamifant	219	-21	199	189	5%
Total	**2,151**	**-221**	**1,930**	**2,119**	**-9%**
Specialty Care	**273**	**-18**	**255**	**307**	**-17%**
Total	**5,239**	**-435**	**4,806**	**4,925**	**-2%**

Q1 2022	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
Haematology					
Elocta	1,024	-40	984	857	15%
Alprolix	419	-21	398	413	-3%
Royalty	333	-33	300	298	1%
Doptelet	593	-59	535	180	197%
Aspaveli/Empaveli	4	—	4	—	n/a
Zynlonta	—	—	—	—	n/a
Manufacturing	124	—	124	130	-4%
Total	**2,499**	**-153**	**2,346**	**1,877**	**25%**
Immunology					
Kineret	645	-43	602	542	11%
Synagis	1,286	-138	1,148	879	31%
Gamifant	189	-19	170	133	27%
Total	**2,119**	**-200**	**1,919**	**1,554**	**24%**
Specialty Care	**307**	**-22**	**284**	**230**	**24%**
Total	**4,925**	**-376**	**4,549**	**3,661**	**24%**

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%
Zynlonta	—	—	—	—	n/a
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%**

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	Q1 2023	Q1 2022	FY 2022
Total revenue	5,239	4,925	18,790
Total cost of goods sold	-1,067	-1,516	-4,776
Gross profit	**4,172**	**3,409**	**14,014**
Gross margin	**80%**	**69%**	**75%**
Items affecting comparability			
-Restructuring costs:			
-Discontinuation of contract manufacturing	—	*-360*	*-363*
Items affecting comparability	—	**-360**	**-363**
Gross profit adjusted	**4,172**	**3,769**	**14,377**
Gross margin adjusted	**80%**	**77%**	**77%**
EBIT[i]	**1,495**	**776**	**3,813**
Items affecting comparability			
-Restructuring costs:			
-Discontinuation of contract manufacturing	—	*-360*	*-363*
-Consolidation of sites	—	*-72*	*-72*
-Efficiency programmes	—	*-72*	*-134*
-Other:			
-Provision for expected credit losses in Russia	—	*-157*	*-106*
Items affecting comparability[ii]	**—**	**-661**	**-675**
EBIT adjusted	**1,495**	**1,437**	**4,488**

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

ii. Items affecting comparability during 2022, see page 4 for further information.

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	Q1 2023	Q1 2022	FY 2022
EBIT[i]	1,495	776	3,813
Plus amortisation and impairment of intangible assets	626	514	2,117
EBITA[i]	**2,121**	**1,290**	**5,930**
EBITA margin	**40%**	**26%**	**32%**

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

Items affecting comparability			
-Restructuring costs:			
-Discontinuation of contract manufacturing	—	*-360*	*-363*
-Consolidation of sites	—	*-72*	*-72*
-Efficiency programmes	—	*-72*	*-134*
-Other:			
-Provision for expected credit losses in Russia	—	*-157*	*-106*
Items affecting comparability	**—**	**-661**	**-675**
EBITA adjusted	**2,121**	**1,951**	**6,605**
EBITA margin adjusted	**40%**	**40%**	**35%**

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	2,121	1,290	5,930
Plus depreciation and impairment of tangible assets	38	171	301
EBITDA	**2,159**	**1,461**	**6,231**
Items affecting comparability			
-Restructuring costs:			
-Discontinuation of contract manufacturing	—	*-239*	*-227*
-Consolidation of sites	—	*-61*	*-60*
-Efficiency programmes	—	*-72*	*-134*
-Other:			
-Provision for expected credit losses in Russia	—	*-157*	*-106*
Items affecting comparability[i]	**—**	**-529**	**-527**
EBITDA adjusted	**2,159**	**1,990**	**6,758**

i. 2022 Items affecting comparability excluding impairment of tangible assets of SEK 148 M. see page 4 for further 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	Q1 2023	Q1 2022	FY 2022
Profit for the period	1,067	543	2,638
Items affecting comparability	—	-661	-675
Tax on items affecting comparability			
-Restructuring costs:			
-Discontinuation of contract manufacturing	—	*74*	*75*
-Consolidation of sites	—	—	*6*
-Efficiency programmes	—	*15*	*28*
-Other:			
-Provision for expected credit losses in Russia	—	*32*	*22*
Tax on items affecting comparability	—	*121*	*130*
Items affecting comparability (net of tax)	—	-540	-545
Profit for the period adjusted	**1,067**	**1,083**	**3,183**
Average number of ordinary shares (excluding shares in treasury)	296,270,780	295,155,297	295,604,246
Average number of ordinary shares after dilution (excluding shares in treasury)	299,336,870	297,477,540	298,448,376
EPS before dilution, SEK adjusted	**3.60**	**3.67**	**10.77**
EPS after dilution, SEK adjusted	**3.56**	**3.64**	**10.67**

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	8,906	9,384	8,768
Cash and cash equivalents	198	1,063	1,361
Net debt	**8,708**	**8,321**	**7,406**

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	27,828	23,757	26,525
Total assets	53,911	48,809	52,496
Equity ratio	**52%**	**49%**	**51%**
Number of ordinary shares	309,804,782	307,114,495	309,804,782
Number of ordinary shares after dilution	312,870,872	309,436,738	312,648,912
Equity per share, SEK	**89.8**	**77.4**	**85.6**
Equity per share after dilution, SEK	**88.9**	**76.8**	**84.8**

Definitions

Alprolix (eftrenonacog alfa)	A recombinant, extended half-life (EHL) clotting factor IX medicine for the treatment of haemophilia B.
Altuviiio	Sanofi's FDA approved medicine previously referred to as efanesoctocog alfa.
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's 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 haemophagocytic 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 haemophagocytic 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.

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