Q2 2023 report

Growth and pipeline expansion

"Sobi's second quarter demonstrated consistent delivery on our strategy. We saw strong top-line growth and an expansion of our adjusted EBITA margin driven by our on-market medicines as well as successful launches. We successfully added Vonjo to our haematology portfolio and advanced our late-stage pipeline assets towards registration. We look forward with great anticipation and have raised our revenue outlook for the full year."

- Guido Oelkers, President & CEO

Second quarter 2023

- Total revenue increased 26 per cent, +16 per cent at constant exchange rates, (CER)[i], to SEK 4,872 M (3,876)
- Haematology revenue increased 18 per cent at CER to SEK 3,430 M (2,688). Driven by Doptelet® +74 per cent at CER and the launch of Aspaveli®/Empaveli® SEK 144 M
- Immunology revenue increased 29 per cent at CER to SEK 1,179 M (847). Driven by Gamifant® +73 per cent at CER and Kineret® +12 per cent at CER
- Adjusted EBITA[i] margin expanded by 1 percentage point to 26 per cent, excluding transaction costs and other items affecting comparability (IAC)[ii]. EBITA at SEK 1,009 M (944), a margin[i] of 21 per cent (24). EBIT SEK 413 M (423), EBIT adjusted[i] SEK 649 M (437)
- Earnings per share (EPS) before dilution SEK 0.75 (0.87), EPS adjusted before dilution[i] SEK 1.48 (0.91). Cash flow from operating activities SEK 357 M (295)
- The acquisition of CTI BioPharma Corp. (CTI) was completed
- After the end of the quarter, the FDA approved Sanofi and AstraZeneca's Beyfortus™ (nirsevimab-alip) for the prevention of RSV in babies and toddlers
- The Board has today summoned an extraordinary general meeting, to be held on 15 August 2023, to resolve on, among other things, an authorisation for the Board of Directors to resolve on a rights issue of approximately SEK 6 billion, to refinance part of the debt incurred in connection with the acquisition of CTI

Outlook 2023 - updated

- Revenue is anticipated to grow by a high single-digit percentage at CER (previous guidance low-to-mid single digit)
- EBITA margin adjusted[i] is anticipated to be at a low 30s percentage of revenue (unchanged)

The outlook includes the newly acquired company CTI and Sobi's right to royalty on net sales of nirsevimab in the US.

Financial summary

SEK M	Q2 2023	Q2 2022	Change	H1 2023	H1 2022	Change	FY 2022
Total revenue	4,872	3,876	26%	10,111	8,801	15%	18,790
Gross profit	3,500	2,856	23%	7,672	6,265	22%	14,014
Gross margin[ii]	72%	74%		76%	71%		75%
EBITA[ii]	1,009	944	7%	3,131	2,234	40%	5,930
EBITA adjusted[ii,iii]	1,245	958	30%	3,366	2,909	16%	6,605
EBITA margin[ii]	21%	24%		31%	25%		32%
EBITA margin adjusted[ii,iii]	26%	25%		33%	33%		35%
Profit for the period	222	258	-14%	1,288	801	61%	2,638
EPS, before dilution, SEK	0.75	0.87	-14%	4.35	2.71	60%	8.92
EPS, before dilution, SEK adjusted[ii,iii]	1.48	0.91	63%	5.08	4.56	11%	10.77

i. Excluding IAC.

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

iii. Items affecting comparability (IAC), see page 3 for further information.

CEO statement

We are very pleased with Sobi's performance in 2023 so far. Top-line and the adjusted EBITA margin grew in the second quarter due to rising revenue from Haematology and Immunology with an increasing contribution of our launch products from all regions.

We significantly advanced our portfolio and pipeline by acquiring CTI BioPharma (CTI) with the orphan drug Vonjo® (pacritinib) and submitting efanesoctocog alfa to the European Medicines Agency (EMA). All in all, the development during the second quarter shows that our strategy is delivering on all elements; leading in rare haematology, growing in immunology, expanding globally, and capturing the value of our pipeline.

In June, we completed the acquisition of CTI, adding Vonjo to our portfolio. The acquisition offers considerable strategic opportunities by capitalising on our haematology expertise and Vonjo's potential for patients worldwide in the blood cancer myelofibrosis and possible future indications in other rare diseases.

We are excited to welcome the talented team from CTI. They have developed a formidable expertise in haemato-oncology which will expand our collective capabilities and creates new opportunities for the future.

Efanesoctocog alfa has the potential to become a new standard of care for haemophilia A patients. The validation of our marketing authorisation application by EMA in May was an important milestone as was the recent FDA approval of nirsevimab in babies and toddlers.

Revenue increased by 26 per cent in the second quarter and by 16 per cent at constant exchange rates (CER), reflecting a strong performance in both Haematology and Immunology, especially for our launch medicines.

Haematology revenues were driven by continued strong growth of Doptelet supported by stable sales of Elocta® and Alprolix®. This provides us with a stable basis in haemophilia which, together with the progress on efanesoctocog alfa, confirms our strength in rare haematology.

Immunology revenue increased by 29 per cent at CER in the second quarter, which reflected strong Kineret and Gamifant sales.

Sobi's launch medicines, Doptelet outside China, Aspaveli/Empaveli, Gamifant, Zynlonta® and Vonjo, grew by 83 per cent at CER, underpinning our commitment to effectively deliver new innovative medicines to people with rare diseases.

Adjusted EBITA was SEK 1,245 M, with a margin of 26 per cent, up 1 percentage point year on year. Adjusted EBITA for the first half year was SEK 3,366 M with a margin of 33 per cent, the same level as in the same period last year.

Sobi continues to encourage innovation, ambition and collaborations both internally and externally, key to reaching more patients globally. Today our medicines are helping some 45,000 patients and we continue to push boundaries to lead in rare haematology and grow in immunology and specialty care.

With all considered, we have raised our revenue outlook for the full year 2023 and look forward with great anticipation.

Solna, Sweden, 18 July 2023
Guido Oelkers, President & CEO

Financial performance

Total revenue

Total revenue for April to June ('the quarter') was SEK 4,872 M (3,876) and increased by 26 per cent compared with the same period a year ago and by 16 per cent at CER. The increase was driven by strong performance across most product areas, with Doptelet and Gamifant as main contributors, further supported by Kineret and launch product Aspaveli/Empaveli. The first sales of our newly acquired medicine Vonjo were recorded in the quarter. The demand for haemophilia medicines (Elocta and Alprolix) remained stable.

Total revenue for January to June ('the half year') was SEK 10,111 M (8,801) and increased by 15 per cent compared with the same period a year ago and by 6 per cent at CER.

SEK M	Q2 2023	Q2 2022	Change	Change at CER	H1 2023	H1 2022	Change	Change at CER	FY 2022
Haematology	3,430	2,688	28%	18%	6,245	5,187	20%	12%	10,831
Immunology	1,179	847	39%	29%	3,330	2,967	12%	2%	6,679
Specialty Care	263	341	-23%	-29%	536	647	-17%	-23%	1,280
Total	**4,872**	**3,876**	**26%**	**16%**	**10,111**	**8,801**	**15%**	**6%**	**18,790**

Items affecting comparability (IAC)

On 26 June the acquisition of CTI was completed. Items affecting comparability (IAC) related to the acquisition have been expensed during the quarter and refers to transaction costs, integration costs and restructuring costs. Further, IACs relating to the discontinuation of contract manufacturing for Pfizer in 2022, were released during the quarter. IACs are outlined in the table below.

2023 SEK M	Q2 2023	IAC	Q2 2023 adjusted	H1 2023	IAC	H1 2023 adjusted
Total revenue	4,872	—	4,872	10,111	—	10,111
Cost of goods sold[i]	-1,372	22	-1,394	-2,439	22	-2,461
Gross profit	**3,500**	**22**	**3,478**	**7,672**	**22**	**7,650**
Gross margin	72%		71%	76%		76%
Selling and administrative expenses[ii]	-2,477	-255	-2,223	-4,503	-255	-4,248
Research and development expenses[iii]	-548	-3	-545	-1,192	-3	-1,190
Operating expenses	**-3,025**	**-257**	**-2,768**	**-5,695**	**-257**	**-5,438**
Other operating income/expenses	-61	—	-61	-68	—	-68
Operating profit (EBIT)	**413**	**-236**	**649**	**1,909**	**-236**	**2,144**
Plus amortisation and impairment of intangible assets	596	—	596	1,222	—	1,222
EBITA	**1,009**	**-236**	**1,245**	**3,131**	**-236**	**3,366**
EBITA margin	21%		26%	31%		33%

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

i. Refers to release of provisions of SEK 32 M related to the discontinuation of contract manufacturing for Pfizer expensed as IAC in the first quarter 2022. This was offset by restructuring costs of SEK 7 M and a dissolvement of the fair value of SEK 3 M from the PPA related to the acquired inventory from CTI.

ii. Refers to transaction costs of SEK 158 M, restructuring costs of SEK 70 M and integration costs of SEK 27 M related to the acquisition of CTI. Integration costs refers to external expenses related to structural efficiency programmes to enable synergies and structure the combined business to appropriately support the business in the future.

iii. Refers to restructuring costs related to the acquisition of CTI.

2022 SEK M	Q2 2022	IAC	Q2 2022 adjusted	H1 2022	IAC	H1 2022 adjusted	FY 2022	IAC	FY 2022 adjusted
Total revenue	3,876	—	3,876	8,801	—	8,801	18,790	—	18,790
Cost of goods sold[i]	-1,020	-3	-1,017	-2,536	-363	-2,173	-4,776	-363	-4,413
Gross profit	**2,856**	**-3**	**2,859**	**6,265**	**-363**	**6,628**	**14,014**	**-363**	**14,377**
Gross margin	74%		74%	71%		75%	75%		77%
Selling and administrative expenses[ii, iii, iv]	-1,840	39	-1,879	-3,893	-210	-3,683	-7,847	-210	-7,636
Research and development expenses[ii, iv]	-607	-50	-557	-1,185	-102	-1,083	-2,354	-102	-2,252
Operating expenses	**-2,447**	**-11**	**-2,436**	**-5,077**	**-312**	**-4,765**	**-10,201**	**-312**	**-9,889**
Other operating income/ expenses	14	—	14	11	—	11	-1	—	-1
Operating profit (EBIT)	**423**	**-14**	**437**	**1,198**	**-675**	**1,873**	**3,813**	**-675**	**4,488**
Plus amortisation and impairment of intangible assets	521	—	521	1,035	—	1,035	2,117	—	2,117
EBITA	**944**	**-14**	**958**	**2,234**	**-675**	**2,909**	**5,930**	**-675**	**6,605**
EBITA margin	24%		25%	25%		33%	32%		35%

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

i. Q2 2022 restructuring costs were SEK 3 M and referred to accelerated depreciation, following the decision to discontinue contract manufacturing for Pfizer. FY 2022 restructuring costs were SEK 363 M including impairment and accelerated depreciation of tangible assets of SEK 136 M.

ii. Q2 2022 refers to external expenses and restructuring costs of SEK 62 M related to structural efficiency programmes, whereof SEK 12 M were allocated to selling and administrative expenses and SEK 50 M were allocated to R&D expenses. FY 2022 these expenses 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 whereof SEK 51 M was paid in Q2 2022 and positively impacted selling and administrative expenses. At year-end 2022 the provision was SEK 106 M.

iv. FY 2022 restructuring costs were SEK 72 M including impairment of tangible assets of SEK 12 M, followed by the decision 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 3,500 M (2,856) in the quarter and gross margin was 72 per cent (74). Gross profit for the quarter included positive IAC of SEK 22 M (-3), excluding these the gross margin was 71 per cent (74). The margin decline was mainly driven by higher low-margin Doptelet sales to the partner in China.

In the half year, gross profit was SEK 7,672 M (6,265) and included IAC of SEK 22 M (-363). The gross margin excluding IAC was 76 per cent (75).

Operating expenses

Selling and administrative expenses were SEK 2,477 M (1,840) in the quarter and included amortisation and impairment of SEK 596 M (521). IAC amounted to SEK -255 M (39). Excluding these costs and amortisation and impairment the selling and administrative expenses increased by 12 per cent at CER, driven by launch and pre-launch activities for Aspaveli/Empaveli, Zynlonta and efanesoctocog alfa as well as increased activities for Doptelet. In the half year, expenses were SEK 4,503 M (3,893) and included IAC of SEK -255 M (-210) and amortisation and impairment of SEK 1,222 M (1,035). Excluding IAC and amortisation and impairment, the increase was 6 per cent at CER.

R&D expenses were SEK 548 M (607) in the quarter and decreased by 10 per cent at CER. The decrease was mainly due to lower spend in development programmes for SEL-212 following read-outs of Dissolve I and Dissolve II. IAC amounted to SEK -3 M (-50). In the half year, expenses were SEK 1,192 M (1,185) and included IAC of SEK -3 M (-102). Excluding IAC, the increase was 2 per cent at CER.

Operating profit

EBITA was SEK 1,009 M (944) in the quarter, corresponding to a margin of 21 per cent (24). EBITA adjusted was SEK 1,245 M (958), corresponding to an adjusted margin of 26 per cent (25). In the half year, EBITA was SEK 3,131 M (2,234), corresponding to a margin of 31 per cent (25). EBITA adjusted was SEK 3,366 M (2,909) corresponding to an adjusted margin of 33 per cent (33). Operating profit was SEK 413 M (423) in the quarter and SEK 1,909 M (1,198) in the half year.

Net financial items

Net financial items were SEK -138 M (-105) in the quarter and SEK -308 M (-207) in the half year, reflecting higher interest rates on loans.

Income tax

Income tax was SEK -54 M (-60) in the quarter, corresponding to an effective tax rate (ETR) of 19.5 per cent (18.8). In the half year, income tax was SEK -312 M (-190), corresponding to an effective tax rate of 19.5 per cent (19.2).

Profit

Profit for the quarter totalled SEK 222 M (258) and SEK 1,288 M (801) for the half year.

Cash flow

Cash flow from operating activities increased to SEK 357 M (295) in the quarter and SEK 2,340 M (1,939) in the half year. Cash flow from investing activities was SEK -17,774 M (-533) in the quarter and SEK -21,033 M (-691) in the half year, including the acquisition of CTI of SEK 16,961 M and a payment of SEK 681 M to Sanofi following the new royalty agreement for nirsevimab. The half year also included milestone payments of SEK 3,009 M. The quarter included IAC payments of SEK 37 M (88) and SEK 50 M (91) for the half year.

Cash and net debt

On 30 June 2023, cash and cash equivalents were SEK 790 M (1,361 on 31 December 2022). Sobi ended the quarter with net available committed credit facilities totalling SEK 5,702 M (5,440 on 31 December 2022). Utilized credit facilities (excluding amounts reserved for checks) and issued commercial papers totalled SEK 27,766 M at the end of the quarter (8,796 on 31 December 2022). Net debt at the end of the quarter was SEK 27,033 M (7,406 on 31 December 2022). The increase in loans and net debt was mainly related to the financing of the CTI acquisition.

Equity

On 30 June 2023, consolidated shareholders' equity was SEK 28,375 M (26,525 on 31 December 2022).

Personnel

On 30 June 2023, the number of full-time equivalent employees was 1,793 now including CTI employees (1,556 on 31 December 2022).

Parent Company

Total revenue for the Parent Company, Swedish Orphan Biovitrum AB (publ), was SEK 2,586 M (2,379) in the quarter, of which Group companies accounted for SEK 1,295 M (1,277). In the half year, revenue was SEK 6,438 M (5,739) of which SEK 3,904 (3,502) referred to Group companies´ sales.

Profit for the quarter was SEK 798 M (405) and SEK 1,292 M (306) in the half year. Investing activities affecting cash flow were SEK -126 M (-525) in the quarter and SEK -832 M (-563) in the half year, including 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, Zynlonta and Vonjo. 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	Q2 2023	Q2 2022	Change	Change at CER	H1 2023	H1 2022	Change	Change at CER	FY 2022
Elocta	1,151	1,107	4%	-5%	2,347	2,132	10%	2%	4,402
Alprolix	511	468	9%	0%	1,025	887	16%	8%	1,885
Royalty	389	376	4%	-5%	733	709	3%	-6%	1,427
Doptelet	1,144	618	85%	74%	1,620	1,211	34%	24%	2,526
Aspaveli/Empaveli	144	38	>200%	>200%	239	42	>200%	>200%	178
Zynlonta	6	—	n/a	n/a	8	—	n/a	n/a	—
Vonjo[i]	36	—	n/a	n/a	36	—	n/a	n/a	—
Manufacturing	48	82	-41%	-41%	237	206	15%	15%	413
Total	**3,430**	**2,688**	**28%**	**18%**	**6,245**	**5,187**	**20%**	**12%**	**10,831**

i. Revenue for period 26-30 June.

Haematology revenue was SEK 3,430 M (2,688) in the quarter and increased by 28 per cent, 18 per cent at CER. In the half year, revenue was SEK 6,245 M (5,187) and increased by 20 per cent, 12 per cent at CER.

Elocta sales were SEK 1,151 M (1,107) in the quarter and increased by 4 per cent and decreased by 5 per cent at CER. The performance benefited from continued growth in patients and geographic expansion however offset by unfavourable price developments in some European markets. In the half year, revenue was SEK 2,347 M (2,132) and increased by 10 per cent, 2 per cent at CER.

Alprolix sales were SEK 511 M (468) in the quarter and increased by 9 per cent, flat at CER. Growth from increased patient numbers and consumption per patient was offset by phasing in the Middle East and unfavourable price developments. In the half year, revenue was SEK 1,025 M (887) and increased by 16 per cent, 8 per cent at CER.

Doptelet sales were SEK 1,144 M (618) in the quarter and increased by 85 per cent, 74 per cent at CER. Sales growth was strong, driven by increased uptake in the US and ongoing launches in the regions Europe and International. In the half year, revenue was SEK 1,620 M (1,211) and increased by 34 per cent, 24 per cent at CER. The quarter also benefited from phasing of sales to the partner in China, SEK 577 M (281) and SEK 577 M (639) in the half year. 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.

Aspaveli/Empaveli sales were SEK 144 M (38) in the quarter, reflecting continued strong growth in number of patients. In the half year, revenue was SEK 239 M (42).

Zynlonta sales was SEK 6 M reflecting first sales in Germany.

First Sobi sales of the newly acquired product Vonjo of SEK 36 M was recorded in the quarter representing sales for the period 26-30 June.

Immunology

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

Revenue Immunology

SEK M	Q2 2023	Q2 2022	Change	Change at CER	H1 2023	H1 2022	Change	Change at CER	FY 2022
Kineret	661	545	21%	12%	1,194	1,190	0%	-7%	2,284
Synagis	28	39	-29%	-34%	1,426	1,325	8%	-4%	3,501
Gamifant	491	263	87%	73%	710	452	57%	45%	895
Total	**1,179**	**847**	**39%**	**29%**	**3,330**	**2,967**	**12%**	**2%**	**6,679**

Immunology revenue was SEK 1,179 M (847) in the quarter and increased by 39 per cent and by 29 per cent at CER. In the half year, revenue was SEK 3,330 M (2,967), and increased by 12 per cent and by 2 per cent at CER.

Kineret sales were SEK 661 M (545) in the quarter and increased by 21 per cent, 12 per cent at CER, driven by increased demand in the US and International markets. In the half year, sales were flat at SEK 1,194 M (1,190) and decreased by 7 per cent at CER.

Synagis sales, consisting mainly of gross to net adjustments, were SEK 28 M (39) in the quarter. In the half year, sales were SEK 1,426 M (1,325), increased by 8 per cent and decreased by 4 per cent at CER.

Gamifant sales were SEK 491 M (263) in the quarter and increased by 87 per cent, 73 per cent at CER. The strong growth reflected growth in number of patients in the US market as well as higher average weight of patients. The quarter also benefited from sales to distributors for inventory build up due to increased demand. In the half year, sales were SEK 710 M (452) and increased by 57 per cent, by 45 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	Q2 2023	Q2 2022	Change	Change at CER	H1 2023	H1 2022	Change	Change at CER	FY 2022
Orfadin	113	114	-1%	-8%	224	220	2%	-6%	462
Tegsedi	82	123	-33%	-38%	163	232	-30%	-35%	429
Waylivra	45	36	26%	16%	100	74	35%	25%	152
Other Specialty Care	23	68	-67%	-68%	49	121	-59%	-61%	237
Total	**263**	**341**	**-23%**	**-29%**	**536**	**647**	**-17%**	**-23%**	**1,280**

Specialty Care revenue was SEK 263 M (341) in the quarter and decreased by 23 per cent, 29 per cent at CER, reflecting fewer people treated with Tegsedi and no sales in the quarter for Kepivance due to supply shortages. In the half year, sales were SEK 536 M (647) and decreased by 17 per cent, 23 per cent at CER.

Pipeline

For more information, please visit 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: EMA validates marketing authorisation application
	Efanesoctocog alfa – haemophilia A (paediatric): XTEND-Kids data presented at ISTH congress
	Nirsevimab — FDA approved nirsevimab on July 17, 2023

Haematology

Efanesoctocog alfa

In May,the European Medicines Agency (EMA) accepted and validated a marketing authorisation application for efanesoctocog alfa, a new class of high-sustained FVIII developed for the treatment of people with haemophilia A of all age groups. The application is based on data from the pivotal XTEND-1 phase 3 study in adults and adolescents and the XTEND-Kids paediatric study in patients <12 years of age. Efanesoctocog alfa was approved by the US Food and Drug Administration (FDA) as ALTUVIIIO™ earlier this year. Efanesoctocog alfa was granted orphan designation by the European Commission in June 2019.

In June, data from the XTEND-Kids pediatric study was presented in a late-breaker session at ISTH 2023, the 31st Congress of the International Society on Thrombosis and Haemostasis. It demonstrates highly effective bleed protection in children with severe haemophilia A with once-weekly dosing and confirms the efficacy and safety profile of efanesoctocog alfa with 50 IU/kg dosing in previously treated children as already shown in adults and adolescents. Factor VIII inhibitor development was not detected during the study. Once-weekly efanesoctocog alfa was shown to sustain FVIII levels in the normal near-normal range (above 40%) for approximately 3 days in patients under 12 years of age, providing effective bleed protection throughout the weekly dosing interval.

Zynlonta

In June, Sobi presented data on Zynlonta in relapsed or refractory diffuse large b-cell lymphoma (DLBCL) at the EHA (European Haematology Association) congress. In May, the first patients started receiving Zynlonta in Germany. Sobi is planning for further launches in Europe and region International during 2023 and 2024.

Immunology

Nirsevimab

After the end of the quarter, the FDA approved Sanofi and AstraZeneca's Beyfortus™ (nirsevimab-alip) for the prevention of RSV in babies and toddlers.

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.

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Pipeline news flow

Anticipated major upcoming pipeline news flow

Second half of 2023	Doptelet – ITP: regulatory decision in China[1]
	Gamifant – MAS in rheumatological diseases: EMERALD phase 3 study interim data readout (Still's disease cohort)
	Gamifant – MAS in rheumatological diseases: regulatory submission in the US (Still's disease cohort)
2024	Aspaveli/Empaveli – C3G and IC-MPGN: VALIANT phase 3 study data readout[2]
	Aspaveli/Empaveli – TA-TMA: phase 2 study data readout[3]
	Doptelet - ITP: regulatory submission in Japan
	Kineret – FMF: regulatory decision in China[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] IC-MPGN and C3G; immune-complex membranoprliferative glomerulonephritis and C3 glomerulopathy
[3] TA.TMA; transplant-associated thrombotic microangiopathy after allogenic haematopoietic stem cell transplantation
[4] FMF; familial Mediterranean fever

Other information

Significant events

In the quarter

CTI acquisition

Sobi announced on 10 May 2023 that it had agreed to acquire CTI BioPharma Corp. by means of a tender offer and that Sobi anticipated to refinance part of the debt incurred in connection with the acquisition through a rights issue to be carried out after completion of the acquisition. On 26 June 2023 Sobi announced the completion of the acquisition, whereby Sobi acquired all outstanding shares of common stock of CTI for USD 9.10 per share in cash corresponding to a total consideration of USD 1.7 billion.

The Board has today summoned an extraordinary general meeting, to be held on 15 August 2023, to resolve on, among other things, an authorisation for the Board of Directors to resolve on a rights issue of approximately SEK 6 billion. Additional details will be stated in the notice convening the extraordinary general meeting.

The acquisition added Vonjo to Sobis product portfolio within Haematology, a medicine for the treatment of adults with certain types of myelofibrosis, specifically with severe thrombocytopenia, an unmet medical need. See Note 4 for more information.

Nirsevimab

In April Sobi announced the new royalty agreement with Sanofi and the termination of the participation agreement with AstraZeneca. Through the termination agreement, the obligation to pay and receive future milestones of net approximately USD 110 M to AstraZeneca was removed. These were recognised as part of the Synagis asset with a corresponding liability in the first quarter according to the principles described in the Annual and sustainability report 2022, Note 2 and 4. At termination, the asset and the corresponding liability was removed from the financial statements.

After the quarter

Nirsevimab

The FDA approved Sanofi and AstraZeneca's Beyfortus™ (nirsevimab-alip) for the prevention of RSV in babies and toddlers.

Zynlonta

On 11 July 2023, Sobi's partner ADC Therapeutics announced a voluntary pause in the enrolment of new patients in the Phase 2 LOTIS-9 clinical trial. The study investigates loncastuximab tesirine and rituximab in unfit or frail patients with previously untreated diffuse large B-cell lymphoma (DLBCL). This patient groups currently has very limited treatment options and is not the target group for Zynlonta as single agent today.

As a result of the pause, no new patients will be included in the study. Patients who are currently being treated in the study may continue. The pause is due to seven fatal and five severe adverse events involving the respiratory system. As per investigator assessment, eleven of the twelve events (including six of the seven fatal events) were individually assessed as unlikely or unrelated to the study drugs. It is important to note that all twelve affected patients in the LOTIS-9 study would have been excluded from the LOTIS-5 trial, i.e., the confirmatory Phase 3 study for the current indication. The cause of these events remain under investigation, and the decision to pause enrolment enables time to collect and analyse more data.

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 quarter, Sobi reached several milestones in the strive to expand access to medicine. Zynlonta (loncastuximab teserine) was launched in the EU as a treatment for severely ill patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL). Empaveli (pegcetacoplan) was formally approved in Argentina for treatment of nocturnal paroxysmal haemoglobinuria (PNH) and Doptelet (avatrombopag) became the first ever commercially shipped Sobi product in Japan.

Sobi shared knowledge within the scientific community by presenting data at the European Haematology Association (EHA) congress in Frankfurt and at the 31st Congress of the International Society on Thrombosis and Haemostasis (ISTH), and together with Sanofi hosted a medical educational symposium at the World Federation of Hemophilia (WFH) Comprehensive Care summit in Buenos Aires.

World Haemophilia Day was commemorated throughout April by many local activities and a global townhall with representatives from the World Federation of Hemophilia and the patient community.

Sobi also focused on raising awareness about gout and supported the launch of the first global Gout Awareness Day under leadership of the Global Alliance for Patient Access (GAFPA), bringing together patient organisations from Europe, North America and South America.

Sobi continued to focus on leadership and personal development. Sobi's leadership competency model was further detailed to senior management globally and a new support tool was launched for manager-employee dialogues.

In April, Sobi released its 2022 sustainability report. It was in June short-listed as finalist by IR Magazine for Best ESG materiality reporting (mid-cap).

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. Sobi maintains an office in Moscow with ~45 colleagues. There were no sales in Russia in the quarter and no net exposure in accounts receivables towards customers in Russia. At the end of the quarter the accounts receivables included a provision for expected credit losses in Russia of SEK 106 M, expensed in 2022. 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 - updated

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 high-single-digit percentage at CER (previous guidance low-to-mid single digit)

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 (unchanged)

The outlook includes the newly acquired company CTI BioPharma Corp. and Sobi's right to royalty on net sales of nirsevimab in the US.

Financial calendar

Extraordinary general meeting	15 August 2023
Q3 2023 report	30 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 and the Swedish Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out in the press release concerning this report, on 18 July 2023 at 08:00 CEST.

[1] Excluding IAC.

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

Solna, 18 July 2023

Bo Jesper Hansen
Chairman

Christophe Bourdon
Board Member

Annette Clancy
Board Member

Helena Saxon
Board Member

Staffan Schüberg
Board Member

Filippa Stenberg
Board Member

Anders Ullman
Board Member

Erika Husing
Employee Representative

Katy Mazibuko
Employee Representative

Guido Oelkers
CEO and President

Auditor´s review report

Introduction

We have reviewed the condensed interim report for Swedish Orphan Biovitrum AB (publ) as of June 30, 2023, and for the six months period then ended. The Board of Directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 Review of Interim Financial Statements Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden.

The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act regarding the Group, and in accordance with the Swedish Annual Accounts Act regarding the Parent Company.

Stockholm, 18 July 2023

Ernst & Young AB

Jonatan Hansson
Authorised Public Accountant

Financial statements – condensed

Consolidated statement of comprehensive income

SEK M	Q2 2023	Q2 2022	H1 2023	H1 2022	FY 2022
Total revenue	4,872	3,876	10,111	8,801	18,790
Cost of goods sold	-1,372	-1,020	-2,439	-2,536	-4,776
Gross profit	**3,500**	**2,856**	**7,672**	**6,265**	**14,014**
Selling and administrative expenses[i]	-2,477	-1,840	-4,503	-3,893	-7,847
Research and development expenses	-548	-607	-1,192	-1,185	-2,354
Other operating income/expenses	-61	14	-68	11	-1
Operating profit	**413**	**423**	**1,909**	**1,198**	**3,813**
Net financial items	-138	-105	-308	-207	-492
Profit before tax	**275**	**317**	**1,600**	**991**	**3,321**
Income tax	-54	-60	-312	-190	-683
Profit for the period	**222**	**258**	**1,288**	**801**	**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)	0	68	0	68	60
Remeasurement of equity instruments (net of tax)	-12	8	2	-58	-76
Total	**-12**	**77**	**2**	**10**	**-16**
Items that may be reclassified into profit or loss					
Translation differences	594	462	598	571	880
Net investment hedges (net of tax)	-159	-255	-108	-321	-363
Cash flow hedges (net of tax)	574	-44	589	-62	-85
Total	**1,009**	**162**	**1,079**	**188**	**432**
Other comprehensive income	**997**	**238**	**1,081**	**198**	**416**
Total comprehensive income for the period	**1,219**	**496**	**2,369**	**999**	**3,054**
All comprehensive income is attributable to Parent Company shareholders					
Earnings per share, SEK					
EPS before dilution	0.75	0.87	4.35	2.71	8.92
EPS before dilution adjusted[ii]	1.48	0.91	5.08	4.56	10.77
EPS after dilution	0.74	0.86	4.30	2.69	8.84
EPS after dilution adjusted[ii]	1.47	0.90	5.03	4.52	10.67
i. Amortisation and impairment of intangible assets included in Selling and administrative expenses.	-596	-521	-1,222	-1,035	-2,117

ii. See section APM for further information.

Consolidated balance sheet

SEK M	Jun 2023	Dec 2022	Jun 2022
ASSETS			
Non-current assets			
Intangible assets[i]	63,673	40,013	39,112
Tangible assets	307	274	360
Financial assets	128	121	132
Deferred tax assets	857	877	780
Total non-current assets	**64,966**	**41,285**	**40,385**
Current assets			
Inventories	4,073	3,332	3,424
Accounts receivable	4,417	5,249	3,127
Other receivables, non-interest bearing	1,537	1,269	1,133
Cash and cash equivalents	790	1,361	360
Total current assets	**10,817**	**11,210**	**8,044**
Total assets	**75,783**	**52,496**	**48,429**
EQUITY AND LIABILITIES			
Equity			
Share capital	171	170	169
Other contributed capital	10,089	10,211	10,068
Other reserves	866	351	133
Retained earnings	15,960	13,155	13,155
Profit for the period	1,288	2,638	801
Equity attributable to Parent Company shareholders	**28,375**	**26,525**	**24,326**
Non-current liabilities			
Borrowings	17,281	2,971	8,121
Deferred tax liabilities	7,531	3,797	3,667
Lease liabilities	206	200	279
Other liabilities, non-interest bearing	4,002	4,146	4,154
Total non-current liabilities	**29,020**	**11,114**	**16,220**
Current liabilities			
Borrowings	10,542	5,796	1,321
Accounts payable	933	1,252	519
Lease liabilities	153	134	132
Other liabilities, non-interest bearing	6,759	7,674	5,910
Total current liabilities	**18,387**	**14,857**	**7,882**
Total equity and liabilities	**75,783**	**52,496**	**48,429**

i. Including goodwill of SEK 10,818 M (7,007 on 31 December 2022).

Consolidated statement of changes in equity

SEK M	Jan-Jun 2023	FY 2022	Jan-Jun 2022
Opening balance	**26,525**	**23,203**	**23,203**
Share-based compensation to employees	191	261	121
Tax adjustments for share programmes[i]	1	6	2
Closure of cash flow hedging at business combination	-712	–	–
Total comprehensive income for the period[ii]	2,369	3,054	999
Closing balance	**28,375**	**26,525**	**24,326**

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 589 M (-85 on 31 December 2022) and net investment hedges (net of tax) amounted to SEK -108 M (-363 on 31 December 2022).

Consolidated cash flow statement

SEK M	Q2 2023	Q2 2022	H1 2023	H1 2022	FY 2022
Cash flow from operating activities					
Profit before tax	275	317	1,600	991	3,321
Amortisation, depreciation and impairment	637	565	1,301	1,250	2,419
Other, including non-cash items	126	-99	121	296	316
Income tax paid	-173	-181	-289	-389	-673
Cash flow from operating activities before change in working capital	**866**	**602**	**2,734**	**2,148**	**5,383**
Changes in working capital	-510	-307	-394	-209	-807
Cash flow from operating activities	**357**	**295**	**2,340**	**1,939**	**4,576**
Acquisition of business, net of cash[i]	-16,961	—	-16,961	—	—
Investment in intangible assets[ii]	-806	-522	-4,000	-677	-1,405
Investment in tangible assets	-8	-12	-71	-14	-72
Cash flow from investing activities	**-17,774**	**-533**	**-21,033**	**-691**	**-1,477**
Borrowings/repayments of borrowings	18,059	-225	18,148	-1,536	-2,420
Hedging arrangement for financing	-45	-292	-42	-438	-438
Repayment of leasing	-39	-33	-78	-67	-133
Proceeds from exercise of share options[iii]	8	48	116	48	89
Cash flow from financing activities	**17,982**	**-502**	**18,144**	**-1,993**	**-2,902**
Change in cash and cash equivalents	**565**	**-741**	**-549**	**-745**	**197**
Cash and cash equivalents at the beginning of the period	198	1,063	1,361	1,045	1,045
Translation difference in cash flow and cash and cash equivalents	28	37	-22	59	119
Cash and cash equivalents at the end of the period	**790**	**360**	**790**	**360**	**1,361**

i. Refers to the acquisition of CTI. See Note 4 for more information.

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

iii. Proceeds from exercise of share options for Q2 2022, H1 2022 and FY 2022, amounting to SEK 48 M and 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 343 M to SEK 295 M in Q2 2022, from SEK 1,987 M to SEK 1,939 M in H1 2022 and from SEK 4,665 M to SEK 4,576 M in FY 2022. Cash flow from financing activities have changed from SEK -550 M to SEK -502 M in Q2 2022, from SEK -2,041 M to SEK -1,993 M in H1 2022 and from SEK -2,991 M to SEK -2,902 M in FY 2022.

Key ratios and other information

SEK M	Q2 2023	Q2 2022	H1 2023	H1 2022	FY 2022
Profit measures					
Gross profit	3,500	2,856	7,672	6,265	14,014
Gross profit adjusted[i, ii]	3,478	2,859	7,650	6,628	14,377
EBITDA[i]	1,051	988	3,210	2,449	6,231
EBITDA adjusted[i, ii]	1,286	997	3,445	2,987	6,758
EBITA[i]	1,009	944	3,131	2,234	5,930
EBITA adjusted[i, ii]	1,245	958	3,366	2,909	6,605
EBIT	413	423	1,909	1,198	3,813
EBIT adjusted[i, ii]	649	437	2,144	1,873	4,488
Profit for the period	222	258	1,288	801	2,638
Profit for the period adjusted[i, ii]	439	268	1,506	1,346	3,183
Per share data (SEK)					
EPS before dilution	0.75	0.87	4.35	2.71	8.92
EPS before dilution adjusted[i, ii]	1.48	0.91	5.08	4.56	10.77
EPS after dilution	0.74	0.86	4.30	2.69	8.84
EPS after dilution adjusted[i, ii]	1.47	0.90	5.03	4.52	10.67
Shareholders' equity per share[i]	91.1	79.2	91.1	79.2	85.6
Shareholders' equity per share after dilution[i]	90.2	78.5	90.2	78.5	84.8
Other information					
Gross margin[i]	72%	74%	76%	71%	75%
Gross margin adjusted[i, ii]	71%	74%	76%	75%	77%
EBITA margin[i]	21%	24%	31%	25%	32%
EBITA margin adjusted[i, ii]	26%	25%	33%	33%	35%
Equity ratio[i]	37%	50%	37%	50%	51%
Net debt[i]	27,033	9,082	27,033	9,082	7,406
Number of ordinary shares[iii]	311,336,796	307,114,495	311,336,796	307,114,495	309,804,782
Number of ordinary shares (in treasury)	14,399,118	11,328,849	14,399,118	11,328,849	13,789,723
Number of ordinary shares (ex shares in treasury)	296,937,678	295,785,646	296,937,678	295,785,646	296,015,059
Number of ordinary shares after dilution	314,472,106	309,771,827	314,472,106	309,771,827	312,648,912
Average number of ordinary shares (ex shares in treasury)	296,694,644	295,319,743	296,483,883	295,237,974	295,604,246
Average number of ordinary shares after dilution (ex shares in treasury)	299,829,954	297,977,075	299,619,193	297,895,306	298,448,376

i. See section APM for further information.

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

iii. The increase in the number of shares results from an issue of 1,532,014 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	Q2 2023	Q2 2022	H1 2023	H1 2022	FY 2022
Total revenue	2,586	2,379	6,438	5,739	13,381
Cost of goods sold	-759	-646	-1,688	-1,830	-3,609
Gross profit	**1,827**	**1,732**	**4,750**	**3,908**	**9,772**
Selling and administrative expenses[i]	-1,361	-736	-3,337	-2,626	-5,775
Research and development expenses	-306	-400	-752	-758	-1,601
Other operating income/expenses	52	80	130	181	365
Operating profit	**212**	**677**	**792**	**706**	**2,761**
Result from participation in Group companies[ii]	—	—	—	—	1,000
Net financial items	572	-327	638	-419	-442
Profit after financial items	**783**	**350**	**1,430**	**287**	**3,318**
Appropriations	—	—	—	—	-478
Profit before tax	**783**	**350**	**1,430**	**287**	**2,840**
Income tax	15	55	-138	19	-389
Profit for the period	**798**	**405**	**1,292**	**306**	**2,451**
i. Amortisation and impairment of intangible assets included in Selling and administrative expenses.	-144	-129	-333	-259	-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	Q2 2023	Q2 2022	H1 2023	H1 2022	FY 2022
Profit for the period	798	405	1,292	306	2,451
Items that will not be reclassified into profit or loss					
Remeasurement of equity instruments (net of tax)	-12	8	2	-58	-76
Items that may be reclassified into profit or loss					
Cash flow hedges (net of tax)	9	-44	24	-62	-85
Other comprehensive income/loss	**-3**	**-36**	**26**	**-120**	**-161**
Total comprehensive income for the period	**796**	**369**	**1,318**	**186**	**2,290**

Parent Company balance sheet

SEK M	Jun 2023	Dec 2022	Jun 2022
ASSETS			
Non-current assets			
Intangible assets	10,974	11,094	9,894
Tangible assets	35	44	69
Financial assets	40,327	22,106	22,780
Deferred tax assets	113	125	145
Total non-current assets	**51,449**	**33,369**	**32,888**
Current assets			
Inventories	2,682	2,703	2,436
Accounts receivable	1,071	995	905
Receivables Group companies	6,165	5,508	4,074
Other receivables, non-interest bearing	1,179	1,073	938
Cash and cash equivalents	399	1,146	205
Total current assets	**11,496**	**11,426**	**8,559**
Total assets	**62,945**	**44,794**	**41,447**
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	171	170	169
Statutory reserve	800	800	800
Total restricted equity	**971**	**970**	**969**
Non-restricted equity			
Retained earnings	20,873	18,206	18,091
Profit for the period	1,292	2,451	319
Total non-restricted equity	**22,165**	**20,657**	**18,410**
Shareholder's equity	**23,136**	**21,627**	**19,379**
Untaxed reserves	3,909	3,909	3,691
Non-current liabilities			
Borrowings	17,281	2,971	8,121
Other liabilities, non-interest bearing	3,705	3,620	3,566
Total non-current liabilities	**20,986**	**6,591**	**11,687**
Current liabilities			
Borrowings	10,542	5,796	1,321
Accounts payable	549	958	373
Liabilities Group companies	1,438	3,292	3,018
Other liabilities, non-interest bearing	2,384	2,621	1,978
Total current liabilities	**14,914**	**12,667**	**6,690**
Total equity and liabilities	**62,945**	**44,794**	**41,447**

Parent Company statement of change in equity

SEK M	Jan-Jun 2023	FY 2022	Jan-Jun 2022
Opening balance	**21,627**	**19,069**	**19,069**
Share-based compensation to employees	191	261	121
Tax adjustments for share programmes[i]	0	6	2
Total comprehensive income/loss for the period[ii]	1,318	2,290	186
Closing balance	**23,136**	**21,627**	**19,379**

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 24 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. The war in Ukraine has affected Sobi's access to markets in Russia and Ukraine, as well as Sobi's ability to reach people. More details about risk exposure and risk management are included in the Annual and sustainability report 2022.

Note 2 | Segment reporting

Q2 2023	Haematology	Immunology	Specialty Care	Group – other[v]	Total
Total revenue	3,430	1,179	263	—	4,872
EBITA[i]	1,092	318	46	-448	1,009
EBITA adjusted[i,ii,iii]	1,143	318	46	-263	1,245
Amortisation and impairment	-251	-297	-39	-10	-596
EBIT	842	21	8	-458	413

Q2 2022	Haematology	Immunology	Specialty Care	Group – other[v]	Total
Total revenue	2,688	847	341	—	3,876
EBITA[i]	1,120	-139	83	-120	944
EBITA adjusted[i,ii,iv]	1,114	-181	83	-58	958
Amortisation and impairment	-210	-258	-41	-12	-521
EBIT	910	-397	42	-132	423

H1 2023	Haematology	Immunology	Specialty Care	Group – other[v]	Total
Total revenue	6,245	3,330	536	—	10,111
EBITA[i]	2,174	1,449	112	-605	3,131
EBITA adjusted[i,ii,iii]	2,225	1,449	112	-419	3,366
Amortisation and impairment	-532	-592	-77	-21	-1,222
EBIT	1,643	857	34	-626	1,909

H1 2022	Haematology	Immunology	Specialty Care	Group – other[v]	Total
Total revenue	5,187	2,967	647	—	8,801
EBITA[i]	1,806	683	146	-401	2,234
EBITA adjusted[i,ii,iii]	2,169	789	146	-195	2,909
Amortisation and impairment	-414	-515	-81	-26	-1,035
EBIT	1,392	167	65	-427	1,198

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 and impairment	-857	-1,041	-162	-57	-2,117
EBIT	3,255	1,264	124	-830	3,813

There are no intersegment transactions.

i. See section APM for further information.

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

iii. EBITA adjusted Q2 and H1 2023; Haematology refers to release of provisions of SEK 32 M related to the discontinuation of contract manufacturing for Pfizer offset by restructuring costs of SEK 80 M and inventory fair value adjustment of SEK 3 M. Group - other refers to transaction costs of SEK 158 M and integration costs of SEK 27 M.

iv. EBITA adjusted 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 4,499 M (5,154 on December 2022). These are measured at amortised cost using the effective interest method. Fair value for these liabilities was SEK 4,003 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 30 June 2023.

June 2023	Level 1	Level 2	Level 3	Total
Financial assets and liabilities measured at fair value through profit or loss				
Derivatives held for trading	—	14	—	14
Endowment policies	—	—	48	48
Financial assets measured at fair value through other comprehensive income				
Equity instruments	66	—	—	66
Total	**66**	**14**	**48**	**128**

June 2022	Level 1	Level 2	Level 3	Total
Financial assets and liabilities measured at fair value through profit or loss				
Derivatives held for trading	—	-59	—	-59
Endowment policies	—	—	50	50
Financial assets measured at fair value through other comprehensive income				
Equity instruments	73	—	—	73
Total	**73**	**-59**	**50**	**64**

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**

Note 4 | Business combinations

On June 26 2023 Sobi completed the acquisition of CTI BioPharma Corp. (CTI), whereby Sobi acquired 100 per cent of the outstanding shares of common stock of CTI, a publicly owned US Company listed on Nasdaq. The total consideration was SEK 18,060 M, which was paid in cash.

Through the acquisition Sobi gained access to CTI´s commercial product Vonjo which is reported within the segment Haematology. Vonjo was approved by the FDA in February 2022 and is a medicine for the treatment of adults with certain types of myelofibrosis, specifically with severe thrombocytopenia, an unmet medical need. The acquisition of CTI strengthen Sobis access on the US market and Vonjo is highly complementary to Doptelet.

In the period 26-30 June CTI contributed to total revenue of SEK 36 M and a net profit of SEK 8 M. If the acquisition had taken place on 1 January 2023 CTI would have contributed to total revenue of SEK 549 M and a net loss of SEK 170 M. The loss have been adjusted for transaction costs, restructuring costs and other costs followed by the acquisition. Group amortisations on the intangible asset (Vonjo) and financing costs have not been considered.

Acquisition-related costs of SEK 158 M have been expensed as IAC and included in administrative expenses in the income statement.

The goodwill represent the opportunity for future growth on the US market and further opportunities in Haematology world wide. Furthermore, it represents the acquired workforce and the expected future synergies and other benefits to be derived from the integration of CTI into Sobi. The goodwill is allocated to Haematology and is not deductible for tax purposes. The purchase price allocation (PPA) is preliminary as the deferred tax asset on acquired operating losses (NOLs) are investigated. The current PPA led to the recognition of SEK 3,513 M of goodwill, determined as follows:

SEK M	Fair value at acquisition date
Agreed purchase price	18,060
Foreign exchange hedge	-712
Total net consideration	**17,349**
Assets	
Intangible assets (Product and marketing rights)[i]	17,421
Inventory[ii]	818
Cash and cash equivalents	388
Other assets[iii]	1,208
Total assets	**19,835**
Liabilities	
Other liabilities and provisions[iv,v]	-1,591
Deferred taxes[iii]	-4,409
Total liabilities	**-6,000**
Total identifiable net assets at fair value	**13,835**
Goodwill	3,513
Purchase consideration transferred	**17,349**
	Cash flow on acquisition
Net cash acquired with the subsidiary	388
Cash paid including hedge impact	17,349
Net cash flow on acquisition	**16,961**

i. The fair value attributable to intangible assets was SEK 17,421 M and represents the intellectual property rights of Vonjo. The fair value was determined using a discounted cash flow analysis (DCF) which uses a number of estimates regarding amount and timing of future cash flows. The key assumptions in cash flows are probability of technical success (PTS) of the PACIFICA trial, peak year sales and competitive pressure in myelofibrosis.

ii. The fair value of the inventory was estimated at SEK 818 M, an uplift of SEK 817 M on the carrying value prior to the acquisition. Costs associated with procurement of APIs, production, labelling and packaging has been expensed by CTI until the FDA approval of Vonjo. Therefore, part of the revaluation to fair value of work in progress and finished goods represents the standard cost value. The fair value was calculated as the estimated selling price less costs to complete and sell the inventory and associated margins on these activities. The release of the fair value adjustment on the inventory, excluding the standard cost value, will be recognised as an IAC.

iii. Other assets includes capitalisation of deferred tax on acquired operating losses (NOLs) of SEK 920 M which are preliminary. Deferred tax liabilities is primarily attributable to the intangible asset Vonjo.

iv. Other liabilities and provisions includes contingent considerations to S*Bio Pte Ltd, a term loan to DRI Healthcare Trust (DRI) and other liabilities and provisions. Contingent considerations are linked to milestone payments for Vonjo of up to USD 108 M. These have been recognised to fair value according to Sobis principles for contingent considerations as described in the Annual and sustainability report for 2022, Note 2 and 4. The term loan was recognised at fair value and repaid by Sobi directly after closing of the acquisition.

v. In 2021 CTI entered into a Royalty Financing Agreement with DRI, pursuant to which CTI sold to DRI the right to recieve certain royalty payments from CTI for a purchase price of up to USD 85 M in cash. Under the agreement DRI is entitled to recieve tiered royalties based on net product sales of Vonjo in the US in an amount equal to 9.6 per cent of annual net sales up to USD 125 M, 4.5 per cent of annual net sales between USD 125 M and USD 175 M, and 0.5 per cent of annual net sales between USD 175 M and USD 400 M. No royalty payments are payable on annual net sales over USD 400 M. In 2022, DRI funded the upfront purchase price of USD 60 M following FDA approval of Vonjo in February 2022. In March 2023 CTI received additional payment in connection with the achievement of certain minimum Vonjo sales thresholds. DRI will be required to provide up to USD 18.5 M of remaining contractual funding if certain minimum Vonjo sales thresholds are met by the end of the third quarter 2023 or sooner. Sobi does not expect this threshold to be met. CTI recorded the agreement as Royalty financing obligation on the balance sheet. The fair value of the obligation has been considered in the value of the intangible asset Vonjo as the agreement does not contain subjective acceleration clauses or provisions that would require repayment of funding. Sobi will expense the royalty as cost of goods sold in the same period as the corresponding sales occurs.

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.

Q2 2023	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
Haematology					
Elocta	1,151	-97	1,054	1,107	-5%
Alprolix	511	-42	469	468	—%
Royalty	389	-33	356	376	-5%
Doptelet	1,144	-70	1,075	618	74%
Aspaveli/Empaveli	144	-12	132	38	>200%
Zynlonta	6	28	34	—	n/a
Vonjo	36	-2	34	—	n/a
Manufacturing	48	—	48	82	-41%
Total	**3,430**	**-228**	**3,203**	**2,688**	**18%**
Immunology					
Kineret	661	-48	612	545	12%
Synagis	28	-2	26	39	-34%
Gamifant	491	-34	456	263	73%
Total	**1,179**	**-85**	**1,094**	**847**	**29%**
Specialty Care	**263**	**-20**	**243**	**341**	**-29%**
Total	**4,872**	**-332**	**4,540**	**3,876**	**16%**

Q2 2022	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
Haematology					
Elocta	1,107	-42	1,065	1,005	6%
Alprolix	468	-20	448	438	2%
Royalty	376	-58	317	320	-1%
Doptelet	618	-98	520	230	126%
Aspaveli/Empaveli	38	-3	35	—	n/a
Zynlonta	—	—	—	—	n/a
Vonjo	—	—	—	—	n/a
Manufacturing	82	—	82	132	-38%
Total	**2,688**	**-221**	**2,467**	**2,125**	**16%**
Immunology					
Kineret	545	-54	491	550	-11%
Synagis	39	-2	37	33	10%
Gamifant	263	-39	224	168	34%
Total	**847**	**-95**	**752**	**752**	**0%**
Specialty Care	**341**	**-27**	**314**	**334**	**-6%**
Total	**3,876**	**-343**	**3,533**	**3,211**	**10%**

H1 2023	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
Haematology					
Elocta	2,347	-176	2,171	2,132	2%
Alprolix	1,025	-72	953	887	8%
Royalty	733	-68	665	709	-6%
Doptelet	1,620	-115	1,504	1,211	24%
Aspaveli/Empaveli	239	-17	222	42	>200%
Zynlonta	8	27	36	—	n/a
Vonjo	36	-2	34	—	n/a
Manufacturing	237	—	237	206	15%
Total	**6,245**	**-423**	**5,822**	**5,187**	**12%**
Immunology					
Kineret	1,194	-93	1,101	1,190	-7%
Synagis	1,426	-157	1,269	1,325	-4%
Gamifant	710	-55	655	452	45%
Total	**3,330**	**-305**	**3,025**	**2,967**	**2%**
Specialty Care	**536**	**-38**	**498**	**647**	**-23%**
Total	**10,111**	**-766**	**9,345**	**8,801**	**6%**

H1 2022	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
Haematology					
Elocta	2,132	-88	2,044	1,861	10%
Alprolix	887	-40	846	851	0%
Royalty	709	-98	611	618	-1%
Doptelet	1,211	-162	1,049	411	155%
Aspaveli/Empaveli	42	-4	39	—	n/a
Zynlonta	—	—	—	—	n/a
Vonjo	—	—	—	—	n/a
Manufacturing	206	—	206	262	-21%
Total	**5,187**	**-391**	**4,795**	**4,003**	**20%**
Immunology					
Kineret	1,190	-102	1,088	1,092	0%
Synagis	1,325	-149	1,176	912	29%
Gamifant	452	-60	392	301	30%
Total	**2,967**	**-311**	**2,656**	**2,305**	**15%**
Specialty Care	**647**	**-49**	**598**	**564**	**6%**
Total	**8,801**	**-751**	**8,049**	**6,872**	**17%**

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
Vonjo	—	—	—	—	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	Q2 2023	Q2 2022	H1 2023	H1 2022	FY 2022
Total revenue	4,872	3,876	10,111	8,801	18,790
Total cost of goods sold	-1,372	-1,020	-2,439	-2,536	-4,776
Gross profit	**3,500**	**2,856**	**7,672**	**6,265**	**14,014**
Gross margin	**72%**	**74%**	**76%**	**71%**	**75%**
Items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	*32*	*-3*	*32*	*-363*	*-363*
-Acquisition of business	*-10*	*—*	*-10*	*—*	*—*
Items affecting comparability	**22**	**-3**	**22**	**-363**	**-363**
Gross profit adjusted	**3,478**	**2,859**	**7,650**	**6,628**	**14,377**
Gross margin adjusted	**71%**	**74%**	**76%**	**75%**	**77%**
EBIT[i]	**413**	**423**	**1,909**	**1,198**	**3,813**
Items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	*32*	*-3*	*32*	*-363*	*-363*
-Acquisition of business	*-110*	*—*	*-110*	*—*	*—*
-Consolidation of sites	*—*	*—*	*—*	*-72*	*-72*
-Efficiency programmes	*—*	*-62*	*—*	*-134*	*-134*
-Other:					
-Transactions costs	*-158*	*—*	*-158*	*—*	*—*
-Provision for expected credit losses in Russia	*—*	*51*	*—*	*-106*	*-106*
Items affecting comparability[ii]	**-236**	**-14**	**-236**	**-675**	**-675**
EBIT adjusted	**649**	**437**	**2,144**	**1,873**	**4,488**

i. For EBIT and EBITA per segment see Note 2.
ii. Items affecting comparability, see page 3 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	Q2 2023	Q2 2022	H1 2023	H1 2022	FY 2022
EBIT[i]	413	423	1,909	1,198	3,813
Plus amortisation and impairment of intangible assets	596	521	1,222	1,035	2,117
EBITA[i]	**1,009**	**944**	**3,131**	**2,234**	**5,930**
EBITA margin	**21%**	**24%**	**31%**	**25%**	**32%**

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

Items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	*32*	*-3*	*32*	*-363*	*-363*
-Acquisition of business	*-110*	*—*	*-110*	*—*	*—*
-Consolidation of sites	*—*	*—*	*—*	*-72*	*-72*
-Efficiency programmes	*—*	*-62*	*—*	*-134*	*-134*
-Other:					
-Transactions costs	*-158*	*—*	*-158*	*—*	*—*
-Provision for expected credit losses in Russia	*—*	*51*	*—*	*-106*	*-106*
Items affecting comparability	**-236**	**-14**	**-236**	**-675**	**-675**
EBITA adjusted	**1,245**	**958**	**3,366**	**2,909**	**6,605**
EBITA margin adjusted	**26%**	**25%**	**33%**	**33%**	**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	1,009	944	3,131	2,234	5,930
Plus depreciation and impairment of tangible assets	41	44	79	215	301
EBITDA	**1,051**	**988**	**3,210**	**2,449**	**6,231**
Items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	*32*	*—*	*32*	*-239*	*-227*
-Acquisition of business	*-110*	*—*	*-110*	*—*	*—*
-Consolidation of sites	*—*	*—*	*—*	*-60*	*-60*
-Efficiency programmes	*—*	*-60*	*—*	*-134*	*-134*
-Other:					
-Transactions costs	*-158*	*—*	*-158*	*—*	*—*
-Provision for expected credit losses in Russia	*—*	*51*	*—*	*-106*	*-106*
Items affecting comparability	**-236**	**-9**	**-236**	**-539**	**-527**
EBITDA adjusted	**1,286**	**997**	**3,445**	**2,987**	**6,758**

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	Q2 2023	Q2 2022	H1 2023	H1 2022	FY 2022
Profit for the period	222	258	1,288	801	2,638
Items affecting comparability	-236	-14	-236	-675	-675
Tax on items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	*-7*	*1*	*-7*	*75*	*75*
-Acquisition of business	*24*	*—*	*24*	*—*	*—*
-Consolidation of sites		*—*	*—*	*6*	*6*
-Efficiency programmes	*—*	*13*	*—*	*28*	*28*
-Other:					
-Provision for expected credit losses in Russia	*—*	*-11*	*—*	*22*	*22*
Tax on items affecting comparability	18	*3*	*18*	*130*	*130*
Items affecting comparability (net of tax)	-218	-11	-218	-545	-545
Profit for the period adjusted	**439**	**268**	**1,506**	**1,346**	**3,183**
Average number of ordinary shares (excluding shares in treasury)	296,694,644	295,319,743	296,483,883	295,237,974	295,604,246
Average number of ordinary shares after dilution (excluding shares in treasury)	299,829,954	297,977,075	299,619,193	297,895,306	298,448,376
EPS before dilution, SEK adjusted	**1.48**	**0.91**	**5.08**	**4.56**	**10.77**
EPS after dilution, SEK adjusted	**1.47**	**0.90**	**5.03**	**4.52**	**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	27,824	9,442	27,824	9,442	8,768
Cash and cash equivalents	790	360	790	360	1,361
Net debt	**27,033**	**9,082**	**27,033**	**9,082**	**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	28,375	24,326	28,375	24,326	26,525
Total assets	75,783	48,429	75,783	48,429	52,496
Equity ratio	**37%**	**50%**	**37%**	**50%**	**51%**
Number of ordinary shares	311,336,796	307,114,495	311,336,796	307,114,495	309,804,782
Number of ordinary shares after dilution	314,472,106	309,771,827	314,472,106	309,771,827	312,648,912
Equity per share, SEK	**91.1**	**79.2**	**91.1**	**79.2**	**85.6**
Equity per share after dilution, SEK	**90.2**	**78.5**	**90.2**	**78.5**	**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, Gamifant, Zynlonta and Vonjo.
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 haematopoietic stem cell disorder. Some haematopoietic 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.
Vonjo (pacritinib)	A medicine for the treatment of adults with certain types of myelofibrosis, specifically with severe thrombocytopenia, an unmet medical need.
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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