

Continued solid performance

April – June 2022

- **Total revenue** SEK 3,876 M (3,211), +21 per cent, +10 per cent at constant exchange rates (CER)¹
- **Haematology** revenue SEK 2,688 M (2,125), +16 per cent at CER of which Elocta® SEK 1,107 M (1,005), +6 per cent at CER; Alprolix® SEK 468 M (438), +2 per cent at CER; Doptelet® SEK 618 M (230), +126 per cent at CER and Aspaveli®/Empaveli™ SEK 38 M (-)
- **Immunology** revenue SEK 847 M (752), stable at CER of which Kineret® SEK 545 M (550), -11 per cent at CER; Synagis® SEK 39 M (33), +10 per cent at CER and Gamifant® SEK 263 M (168), +34 per cent at CER
- **EBITA**¹ SEK 944 M (922); **EBITA margin**¹ 24 per cent (29). **Items affecting comparability**² (IAC) of SEK -14 M included a reversal of a provision for Russian receivables of SEK 51 M. Excluding IAC, **EBITA adjusted**¹ was SEK 958 M corresponding to an **EBITA margin adjusted**¹ of 25 per cent (29). **EBIT** SEK 423 M (467); **EBIT adjusted**¹ SEK 437 M (467)
- **Earnings per share** (EPS) before dilution SEK 0.87 (0.91); EPS before dilution adjusted SEK 0.91 (0.91). **Cash flow** from operating activities SEK 343 M (1,393)
- **Significant events after the reporting period:** efanesoctocog alfa phase 3 data presentation; agreement to license the new orphan medicine loncastuximab tesirine in haematology

January – June 2022

- **Total revenue** SEK 8,801 M (6,872), +28 per cent, +17 per cent at CER¹
- **Haematology** revenue SEK 5,187 M (4,003), +20 per cent at CER of which Elocta SEK 2,132 M (1,861), +10 per cent at CER; Alprolix SEK 887 M (851), stable at CER; Doptelet SEK 1,211 M (411), +155 per cent at CER and Aspaveli/Empaveli SEK 42 M (-)
- **Immunology** revenue SEK 2,967 M (2,305), +15 per cent at CER of which Kineret SEK 1,190 M (1,092), stable at CER; Synagis SEK 1,325 M (912), +29 per cent at CER and Gamifant SEK 452 M (301), +30 per cent at CER
- **EBITA**¹ SEK 2,234 M (2,406); **EBITA margin**¹ 25 per cent (35). **IAC**² of SEK -675 M, excluding IAC, **EBITA adjusted**¹ was SEK 2,909 M corresponding to an **EBITA margin adjusted**¹ of 33 per cent (35). **EBIT** SEK 1,198 M (1,500); **EBIT adjusted**¹ SEK 1,873 M (1,500)
- **EPS** before dilution SEK 2.71 (3.27), EPS before dilution adjusted SEK 4.56 (3.27). **Cash flow** from operating activities SEK 1,987 M (3,092)

2022 outlook

- Revenue is anticipated to grow by a mid to high single-digit percentage at CER, now potentially towards the higher end of the range
- EBITA margin adjusted is anticipated to be at a low 30s percentage of revenue, now including the cost effects of the agreement to license the new orphan medicine loncastuximab tesirine in haematology

Financial summary

SEK M	Q2 2022	Q2 2021	Change	H1 2022	H1 2021	Change	Full-year 2021
Total revenue	3,876	3,211	21%	8,801	6,872	28%	15,529
Gross profit	2,856	2,428	18%	6,265	5,363	17%	12,045
Gross margin ¹	74%	76%		71%	78%		78%
EBITA ¹	944	922	2%	2,234	2,406	-7%	5,575
EBITA adjusted ^{1,2}	958	922	4%	2,909	2,406	21%	5,575
EBITA margin ¹	24%	29%		25%	35%		36%
EBITA margin adjusted ^{1,2}	25%	29%		33%	35%		36%
Profit for the period	258	268	-4%	801	964	-17%	2,679
EPS, before dilution, SEK	0.87	0.91	-4%	2.71	3.27	-17%	9.08
EPS, before dilution, SEK adjusted ^{1,2}	0.91	0.91	0%	4.56	3.27	39%	9.08

¹Alternative Performance Measures (APMs), see page 23 for further information.

²Items affecting comparability (IAC) in Q2 and H1 2022, see page 3 for further information.

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

Q2 2022
report

Total revenue Q2, SEK M

3,876

Total revenue
growth Q2, CER¹

10%

Launch medicines^a
growth Q2, CER¹

96%

EBITA margin
adjusted¹ Q2

25%

CEO statement

2022 has progressed well for Sobi and we saw solid business performance sustained into the second quarter. Despite the prevailing geopolitical uncertainty in the world around us, Sobi advanced positively on many fronts; revenue, geographic expansion, efficiency programmes and pipeline.

Revenue was SEK 3,876 M in the quarter and increased by 21 per cent, 10 per cent at constant exchange rates (CER). Launch medicines Doptelet, Gamifant and Aspaveli combined grew by 96 per cent at CER.

Doptelet continued to benefit from phased sales to China underpinned by strong US performance and early uptake in Europe where more countries granted reimbursement. Aspaveli/Empaveli is starting to gain launch momentum and we are pleased to have the first patients being treated with this novel medicine approved for the treatment of a rare haematological disease, PNH.

The efficiency programmes discussed last quarter were further implemented in the second quarter with the merger of Research & Development and Medical & Scientific Affairs into one, joint science organisation, R&D and Medical Affairs, or RDMA. During the second quarter, we also concluded the restructurings announced in the general and administrative functions.

The efficiency programmes have focused resources into core areas, simplified the organisation and adjusted the cost base to enable Sobi to continue sustainable growth and margin improvement over time.

The EBITA adjusted was SEK 958 M with a margin of 25 per cent. Based on the revenue and earnings performance, we continue to be pleased about 2022 and the full-year outlook.

The pipeline has seen continued progress since the update in April with several key milestones achieved. They included the first phase 3 study data presentation for efanesoctocog alfa, formerly BIVV001, at the International Society on Thrombosis and Haemostasis 2022 Congress and earlier on the medicine had been rewarded US Breakthrough Therapy designation. With this new medicine, we aim at transforming the treatment of haemophilia A from treating bleeds to normalising lives.

Aspaveli/Empaveli also achieved multiple milestones, with regulatory submission acceptance in Japan for the potential treatment of PNH and the start of a new phase 3 study in two rare haematologic kidney disorders. Kineret saw its first regulatory submission in China and SEL-212 had the last patient dosed in the phase 3 programme.

Earlier in July, we announced an exclusive license agreement with ADC Therapeutics SA to develop and commercialise loncastuximab tesirine for use in haematology and other indications of large unmet medical need in Europe and most international markets. The license agreement for loncastuximab tesirine aims at augmenting Sobi's presence in orphan diseases within haematology, one of Sobi's two main disease areas. The medicine will expand Sobi's offering to patients with debilitating diseases and is anticipated to be made commercially available alongside other Sobi haematology medicines, including Doptelet.

As we now close the first half of 2022, I would like to extend my sincere thanks to all Sobi colleagues worldwide for their dedication and hard work. The past six months have seen large changes in the world around us and internally at Sobi. Inspired by caring and powered by science, I trust that the second half of the year will bring continued opportunities to further our focus on providing innovative medicines that transform the lives of people with rare and debilitating diseases.

Solna, Sweden, 19 July 2022

Guido Oelkers, President & CEO



Financial performance

Total revenue

Total revenue for April to June ('the quarter') was SEK 3,876 M (3,211) and increased by 21 per cent compared with the same period a year ago and by 10 per cent at CER. Growth was strong for Doptelet, which benefitted from phasing of sales to the partner in China as well as increased uptake in the US. Gamifant and the launch of Aspaveli also contributed.

Total revenue for January to June ('the half year') was SEK 8,801 M (6,872) and increased by 28 per cent compared with the same period a year ago and by 17 per cent at CER.

SEK M	Q2 2022	Q2 2021	Change	Change at CER	H1 2022	H1 2021	Change	Change at CER	Full-year 2021
Haematology	2,688	2,125	26%	16%	5,187	4,003	30%	20%	8,536
Immunology	847	752	13%	0%	2,967	2,305	29%	15%	5,780
Specialty Care	341	334	2%	-6%	647	564	15%	6%	1,213
Total	3,876	3,211	21%	10%	8,801	6,872	28%	17%	15,529

Items affecting comparability (IAC)

In the first quarter, Sobi took steps to restructure its business through certain efficiency programmes which continued into the second quarter. The programmes refer to the discontinuation of contract manufacturing for Pfizer, the consolidation of a legacy site in Geneva into Basel and restructuring of selling and administrative and research and development functions to appropriately support the business. In addition, a provision for expected credit losses in Russia was taken. During the quarter these steps resulted in costs of SEK 65 M and a release of a provision of SEK 51 M for expected credit losses in Russia. These IACs are outlined in the table below.

SEK M	Q2 2022	IAC	Q2 2022 adjusted	Q2 2021	H1 2022	IAC	H1 2022 adjusted	H1 2021	Full-year 2021
Total revenue	3,876	–	3,876	3,211	8,801	–	8,801	6,872	15,529
Cost of goods sold ¹	-1,020	-3	-1,017	-783	-2,536	-363	-2,173	-1,509	-3,484
Gross profit	2,856	-3	2,859	2,428	6,265	-363	6,628	5,363	12,045
<i>Gross margin</i>	74%		74%	76%	71%		75%	78%	78%
Selling and administrative expenses ^{2,3,4}	-1,840	39	-1,879	-1,468	-3,893	-210	-3,683	-2,900	-6,294
Research and development expenses ^{2,4}	-607	-50	-557	-484	-1,185	-102	-1,083	-954	-1,994
Operating expenses	-2,447	-11	-2,436	-1,952	-5,077	-312	-4,765	-3,854	-8,288
Other operating income/expenses	14	–	14	-9	11	–	11	-9	-24
Operating profit (EBIT)	423	-14	437	467	1,198	-675	1,873	1,500	3,733
Plus amortisation and impairment of intangible assets	521	–	521	455	1,035	–	1,035	905	1,841
EBITA	944	-14	958	922	2,234	-675	2,909	2,406	5,575
<i>EBITA margin</i>	24%		25%	29%	25%		33%	35%	36%

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

- 1) Refers to accelerated depreciation of SEK 3 M in the quarter. In the half year, restructuring costs were SEK 363 M including impairment and accelerated depreciation of tangible assets of SEK 124 M followed by the discontinuation of contract manufacturing for Pfizer. The process of downsizing the manufacturing facility will start in the second half of 2022 with the last volumes anticipated to be delivered to Pfizer in the beginning of 2024.
- 2) Refers to external expenses and restructuring costs of SEK 62 M in the quarter related to structural efficiency programmes, whereof SEK 12 M were allocated to selling and administrative expenses and SEK 50 M were allocated to research and development expenses. In the half year, this was SEK 134 M whereof SEK 77 M were allocated to selling and administrative expenses and SEK 57 M were allocated to research and development expenses.
- 3) During the quarter payments of SEK 51 M for impaired receivables in Russia were collected, whereby the corresponding provision on the balance sheet was reversed, positively impacting selling and administrative expenses. The remaining provision for expected credit losses in Russia is SEK 106 M.

- 4) In the half year, restructuring costs were SEK 72 M including impairment of tangible assets of SEK 12 M followed by the decision in the first quarter to consolidate the Geneva site into Basel. SEK 27 M were allocated to selling and administrative expenses and SEK 45 M were allocated to research and development expenses.

Gross profit

Gross profit was SEK 2,856 M (2,428) in the quarter and included IAC of SEK 3 M. The gross margin excluding IAC was 74 per cent (76). The margin decrease was driven by unfavourable mix of business due to significant sales of Doptelet to the partner in China.

In the half year, gross profit was SEK 6,265 M (5,363) and included IAC of SEK 363 M. The gross margin excluding IAC was 75 per cent (78).

Operating expenses

Selling and administrative expenses were SEK 1,840 M (1,468) in the quarter and included a positive IAC of SEK 39 M, containing a reversal of collected impaired receivables in Russia of SEK 51 M. Excluding IAC and amortisation, the increase was 22 per cent at CER and reflected launch preparations and activities for Aspaveli/Empaveli and Doptelet. In the half year, expenses were SEK 3,893 M (2,900) and included IAC of SEK 210 M and amortisation of SEK 1,035 M (905). Excluding IAC and amortisation, the increase was 23 per cent at CER.

Research and development expenses were SEK 607 M (484) in the quarter and included IAC of SEK 50 M. Excluding IAC, the increase was 7 per cent at CER mainly due to development programmes for Aspaveli and SEL-212 offset by less spending on Gamifant. In the half year, expenses were SEK 1,185 M (954) and included IAC of SEK 102 M. Excluding IAC, the increase was 6 per cent at CER.

Operating profit

EBITA was SEK 944 M (922) in the quarter, corresponding to a margin of 24 per cent (29). EBITA adjusted was SEK 958 M, corresponding to a margin of 25 per cent. In the half year, EBITA was SEK 2,234 M (2,406), corresponding to a margin of 25 per cent (35). EBITA adjusted was SEK 2,909 M, corresponding to a margin of 33 per cent. Amortisation of intangible assets was SEK 521 M (455) in the quarter and SEK 1,035 M (905) in the half year. EBIT was SEK 423 M (467) in the quarter and SEK 1,198 M (1,500) in the half year.

Net financial items

Net financial items were SEK -105 M (-112) in the quarter and SEK -207 M (-227) in the half year, reflecting lower borrowings.

Income tax

Income tax was SEK -60 M (-87) in the quarter, corresponding to an effective tax rate of 18.8 per cent (24.5). In the half year, income tax was SEK -190 M (-309), corresponding to an effective tax rate of 19.2 per cent (24.3).

Profit

Profit totalled SEK 258 M (268) in the quarter and SEK 801 M (964) in the half year.

Cash flow

Cash flow from operating activities was SEK 343 M (1,393) in the quarter and SEK 1,987 M (3,092) in the half year mainly reflecting the timing of rebate payments in the US and higher seasonal sales of Synagis compared to the previous season. Cash flow from investing activities was SEK -533 M (-14) in the quarter and SEK -691 M (-105) in the half year, including a milestone payment for Aspaveli/Empaveli of SEK 479 M in the second quarter and a milestone payment for Doptelet to Eisai of SEK 115 M in the first quarter.

AstraZeneca and Sanofi intend to make a regulatory submission for nirsevimab in the US in the second half of 2022 which would trigger a milestone payment of USD 175 M to AstraZeneca.

Cash and net debt

On 30 June 2022, cash and cash equivalents were SEK 360 M (1,045 on 31 December 2021). Sobi ended the quarter with undrawn committed credit facilities totalling SEK 8,482 M (SEK 4,336 M on 31 December 2021). The increase was driven by a raised facility of SEK 2,000 M and repayment of revolving credit facilities. In addition, Sobi established a commercial paper programme of up to SEK 4,000 M. Drawn credit facilities and issued commercial papers totalled SEK 9,483 M at the end of

quarter (SEK 10,597 M on 31 December 2021). Net debt at the end of the quarter was SEK 9,082 M (SEK 9,500 M on 31 December 2021).

Equity

On 30 June 2022, consolidated shareholders' equity was SEK 24,326 M (SEK 23,203 M on 31 December 2021).

Personnel

On 30 June 2022, the number of full-time equivalent employees was 1,554 (1,559 on 31 December 2021).

Parent Company

Total revenue for the Parent Company, Swedish Orphan Biovitrum AB (publ), was SEK 2,379 M (2,280) in the quarter, of which Group companies accounted for SEK 1,277 M (1,110). In the half year, revenue was SEK 5,739 M (4,743) of which SEK 3,502 (2,507) referred to Group companies' sales, reflecting increased sales of Elocta, Alprolix, Kineret and Gamifant to subsidiaries.

Profit was SEK 405 M (859) in the quarter and SEK 306 M (1,124) in the half year. Investing activities affecting cash flow were SEK -525 M (-14) in the quarter and SEK -563 M (-39) in the half year.

Haematology

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

Revenue Haematology

SEK M	Q2 2022	Q2 2021	Change	Change at CER	H1 2022	H1 2021	Change	Change at CER	Full-year 2021
Elocta	1,107	1,005	10%	6%	2,132	1,861	15%	10%	3,960
Alprolix	468	438	7%	2%	887	851	4%	0%	1,764
Royalty	376	320	18%	-1%	709	618	15%	-1%	1,251
Doptelet	618	230	168%	126%	1,211	411	195%	155%	1,116
Aspaveli/Empaveli	38	–	n/a	n/a	42	–	n/a	n/a	1
Manufacturing	82	132	-38%	-38%	206	262	-21%	-21%	445
Total	2,688	2,125	26%	16%	5,187	4,003	30%	20%	8,536

Haematology revenue was SEK 2,688 M (2,125) in the quarter and increased by 26 per cent, 16 per cent at CER. In the half year, revenue was SEK 5,187 M (4,003) and increased by 30 per cent, 20 per cent at CER.

Elocta sales were SEK 1,107 M (1,005) in the quarter and increased by 10 per cent, 6 per cent at CER, driven by growth in patient numbers and a higher factor consumption per patient, slightly offset by unfavourable price development. In the half year, sales were 2,132 M (1,861) and increased by 15 per cent, 10 per cent at CER.

Alprolix sales were SEK 468 M (438) in the quarter and increased by 7 per cent, 2 per cent at CER. Growth in patient numbers was slightly offset by unfavourable price development and negative stocking effects. Factor consumption per patient was stable. In the half year, sales were SEK 887 M (851) and increased by 4 per cent, stable at CER.

Doptelet sales were SEK 618 M (230) in the quarter and increased by 168 per cent, 126 per cent at CER. Growth was driven by phasing of sales to the partner in China, the continued launch in the US and early launches in Europe. In the half year, sales were SEK 1,211 M (411) and increased by 195 per cent, 155 per cent at CER.

Doptelet sales to the partner in China were SEK 281 M (58) in the quarter and increased by 387 per cent, 304 per cent at CER. In the half year, sales were SEK 639 M (105) and increased by 509 per cent, 429 per cent at CER. Doptelet entered the China National Reimbursement Drug List (NRDL) in 2020 with renewal anticipated from 2023. NRDL inclusion generally facilitates broad access to the medicine. The partner in China anticipates Doptelet to remain on the NRDL into 2024 when transition to volume-based procurement may happen if three generics have been approved for sale in China.

Aspaveli/Empaveli sales were SEK 38 M (-) driven by ongoing launches in the UK, Germany and France. In the half year, sales were SEK 42 M (-).

Immunology

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

Revenue Immunology

SEK M	Q2 2022	Q2 2021	Change	Change at CER	H1 2022	H1 2021	Change	Change at CER	Full-year 2021
Kineret	545	550	-1%	-11%	1 190	1 092	9%	0%	2 290
Synagis	39	33	17%	10%	1 325	912	45%	29%	2 650
Gamifant	263	168	57%	34%	452	301	50%	30%	840
Total	847	752	13%	0%	2 967	2 305	29%	15%	5 780

Immunology revenue was SEK 847 M (752) in the quarter and increased by 13 per cent, stable at CER. In the half year, revenue was SEK 2,967 M (2,305) and increased by 29 per cent, 15 per cent at CER.

Kineret sales were SEK 545 M (550) in the quarter and decreased by 1 per cent, -11 per cent at CER. The decline was due to lower sales in emerging markets related to COVID-19, slightly offset by increased demand in other indications. In the half year, sales were SEK 1,190 M (1,092) and increased by 9 per cent, stable at CER.

Synagis sales were SEK 39 M (33) in the quarter and increased by 17 per cent, 10 per cent at CER, reflecting positive gross-to-net adjustments. In the half year, sales were SEK 1,325 M (912) and increased by 45 per cent, 29 per cent at CER.

Gamifant sales were SEK 263 M (168) in the quarter and increased by 57 per cent, 34 per cent at CER and reflected growth in new patients. In the half year, sales were SEK 452 M (301) and increased by 50 per cent, 30 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 2022	Q2 2021	Change	Change at CER	H1 2022	H1 2021	Change	Change at CER	Full-year 2021
Orfadin	114	125	-9%	-15%	220	222	-1%	-8%	459
Tegsedi	123	133	-7%	-16%	232	192	21%	10%	427
Waylivra	36	27	31%	27%	74	58	27%	22%	121
Other Specialty Care	68	50	37%	25%	121	92	32%	21%	207
Total	341	334	2%	-6%	647	564	15%	6%	1,213

Specialty Care revenue was SEK 341 M (334) in the quarter and increased by 2 per cent, -6 per cent at CER. The decrease was driven by generic price competition to Orfadin and fewer patients treated with Tegsedi. In the half year, sales were SEK 647 M (564) and increased by 15 per cent, 6 per cent at CER.

Pipeline

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

Major pipeline milestones since the previous quarterly report

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

Significant milestones	<p>efanesoctocog alfa – haemophilia A: Breakthrough Therapy designation in the US (by Sanofi)</p> <p>efanesoctocog alfa – haemophilia A: first phase 3 study data presentation</p> <p>Empaveli – PNH: regulatory submission acceptance in Japan</p> <p>Aspaveli/Empaveli – IC-MPGN and C3G: VALIANT phase 3 study first patient dosed (by Apellis)</p> <p>Kineret – FMF: regulatory submission in China</p> <p>SEL-212 – CRG: DISSOLVE II phase 3 study enrolment completion</p>
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Haematology

Efanesoctocog alfa

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

In June, Sobi and Sanofi announced that the US Food and Drug Administration (FDA) had granted Breakthrough Therapy designation (BTD) to efanesoctocog alfa for the treatment of haemophilia A, based on data from the pivotal XTEND-1 phase 3 study. BTD is designed to expedite the development and regulatory review and is based upon preliminary clinical evidence of a substantial improvement on clinically significant endpoints over available therapies.

Earlier in July, positive results from the XTEND-1 phase 3 study of efanesoctocog alfa were presented at the 30th International Society on Thrombosis and Haemostasis (ISTH) 2022 Congress. The study met the primary efficacy endpoint, with once-weekly efanesoctocog alfa prophylaxis providing clinically meaningful bleed protection in previously treated adults and adolescents 12 years or older with severe haemophilia A. The median and mean annualised bleeding rates (ABR) were 0.00 (interquartile range: 0.00 – 1.04) and 0.71 (standard deviation: 1.43) respectively. The study also met the key secondary endpoint, demonstrating superior bleed protection ($p < 0.0001$) over prior factor VIII prophylaxis with an estimated ABR reduction of 77 per cent and a mean ABR of 0.69 compared to 2.96 on prior prophylaxis, based on an intra-patient comparison ($n = 78$). In a subset of participants ($n = 17$) studied at baseline and week 26, mean factor VIII levels remained in the normal to near-normal range (> 40 international units (IU)/dL) for the majority of the week, and at 15 IU/dL at day seven, providing increased factor-activity level protection for patients. Efanesoctocog alfa was well tolerated and inhibitor development to factor VIII was not detected. The most common treatment-emergent adverse events (> 5 per cent of participants overall) were headache, arthralgia, fall, and back pain.

The data form the basis for regulatory submissions globally, including the biologics license application by Sanofi to the US FDA which already occurred in June 2022, now awaiting acceptance. Regulatory submission in the EU, anticipated in the second half of 2023, will follow availability of data from the ongoing and fully recruited XTEND-Kids paediatric study, expected in the first half of 2023.

Aspaveli/Empaveli

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

PNH

In June, Sobi and the collaborator Apellis Pharmaceuticals, Inc. (Apellis) presented new analyses of phase 3 studies that reinforce the robust efficacy and safety profile of Aspaveli/Empaveli in the treatment of PNH. The data were presented at the hybrid European Hematology Association Congress in Vienna, Austria. Treatment with Aspaveli/Empaveli resulted in meaningful improvements in quality of life for treatment-naïve patients and suggested the incidence of thrombosis was comparable to eculizumab, a C5 inhibitor. Additionally, a matching-adjusted indirect comparison showed significant improvements in clinical outcomes in treatment-naïve patients who received Aspaveli/Empaveli compared to C5 inhibitors. During the quarter, Sobi also made a regulatory submission in Japan for a potential indication in PNH.

New indications

In June, Apellis and Sobi announced that the first patient had been dosed in the VALIANT phase 3 study evaluating Aspaveli/Empaveli in primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) and C3 glomerulopathy (C3G), two rare and debilitating kidney diseases where excessive accumulation of C3 breakdown products in the kidney causes inflammation and organ damage. There are currently no approved treatments for these diseases. Data readout from the new phase 3 study is anticipated after 2023.

Loncastuximab tesirine

Earlier in July, Sobi announced an exclusive license agreement with ADC Therapeutics SA to develop and commercialise loncastuximab tesirine for use in haematology and other indications of large unmet medical need in Europe and most international markets. Loncastuximab tesirine is an antibody-drug conjugate against CD19, a protein expressed on the surface of B cells. It is currently approved in the US for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy. The medicine has orphan drug designation in the EU and is under regulatory review with a decision anticipated in the first quarter of 2023.

Immunology

Kineret

During the quarter, the first regulatory submission was made for Kineret in China for the potential use in the treatment of Familial Mediterranean fever (FMF). FMF is a genetic autoimmune disorder that causes recurrent episodes of fever together with abdominal, chest or joint pain.

Gamifant

Earlier in the year, dosing was initiated in a new phase 3 study, EMERALD. EMERALD evaluates Gamifant in the treatment of macrophage activation syndrome (MAS) in paediatric and adult patients with underlying rheumatological diseases, including Still's disease, the first cohort. EMERALD is on course for the last patient to initiate dosing in the Still's cohort before the end of 2022. Based on new recruitment projections, including seasonality in the occurrence of MAS towards the autumn and winter, coupled with the duration of treatment of eight weeks, the data readout for the cohort is now anticipated in the first half of 2023.

SEL-212

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

In June, Selecta Biosciences, Inc., the licensor of SEL-212 to Sobi, announced that the DISSOLVE phase 3 development programme is on track for completion in Q4 2022 with top-line readout expected during the first quarter of 2023. In support of these timelines, the DISSOLVE II phase 3 study achieved enrolment completion at the end of the second quarter of 2022.

Nirsevimab

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

In May, Sanofi announced results from a prespecified pooled analysis of the pivotal MELODY phase 3 study and the phase 2b study for nirsevimab. The data were presented at the European Society for Paediatric Infectious Diseases meeting and demonstrated an efficacy (relative risk reduction versus placebo) of 79.5 per cent (95 per cent confidence interval: 65.9 – 87.7; $p < 0.0001$) against medically attended lower respiratory tract infections, such as bronchiolitis or pneumonia, caused by RSV in

infants born at term or preterm entering their first RSV season. The safety profile across the nirsevimab and placebo groups, as reported in previous studies, remained similar.

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

Pipeline news flow

Anticipated major upcoming pipeline news flow

H2 2022	<p>efanesoctocog alfa – haemophilia A: regulatory submission acceptance (US)</p> <p>Aspaveli/Empaveli – CAD^b: phase 3 study first patient dosed</p> <p>nirsevimab – RSV prevention: regulatory submission (US) (by AstraZeneca/Sanofi)</p> <p>Kineret – COVID-19: regulatory decision, emergency use (US)</p>
H1 2023	<p>efanesoctocog alfa – haemophilia A (paediatric): XTEND-Kids phase 3 study data readout</p> <p>Doptelet – CLD: regulatory decision (JP)</p> <p>Empaveli – PNH: regulatory decision (JP)</p> <p>loncastuximab tesirine – DLBCL: regulatory decision (EU) (by ADC Therapeutics in the first quarter of 2023)</p> <p>Gamifant – MAS in rheumatological diseases: EMERALD phase 3 study data readout</p> <p>SEL-212 – CRG: phase 3 studies data readout</p>
H2 2023	<p>efanesoctocog alfa – haemophilia A: regulatory submission (EU)</p> <p>Aspaveli/Empaveli – ALS^c: MERIDIAN phase 2 study data readout (by Apellis in mid-2023)</p> <p>Kineret – FMF: regulatory decision (CN)</p> <p>Gamifant – MAS in rheumatological diseases: regulatory submission (US)</p> <p>SEL-212 – CRG: regulatory submission (US)</p>

^b Cold agglutinin disease.

^c Amyotrophic lateral sclerosis.

Other information

Significant events after the reporting period

In July, Sobi announced an exclusive license agreement with ADC Therapeutics SA. Sobi has been granted rights to develop and commercialise loncastuximab tesirine for all hematologic and solid tumour indications outside of the United States, greater China, Singapore and Japan. Sobi will pay USD 55 M in an upfront payment, to be financed by Sobi's cash reserves, and USD 50 M at EU regulatory approval in 3rd-line DLBCL. In addition, Sobi will pay royalties from mid-teens to mid-twenties per cent of net sales and up to approximately USD 330 M in potential regulatory and sales milestones. As loncastuximab tesirine is in development for other indications, Sobi will contribute 25 per cent of the direct development costs up to a cap of USD 10 M per year. ADC Therapeutics is responsible for clinical development and product supply to Sobi.

Sustainability

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

- Commitment to patients
- Responsible behaviour

During the second quarter, several Sobi medicines were launched in new countries expanding access to treatment, notably Aspaveli for PNH in the UK and Germany and Doptelet for immune thrombocytopenia (ITP) in Spain.

In conjunction with World Haemophilia Day in April, Sobi launched a new position statement calling out the need to continue developing care approaches to fit patients' needs and in France, Sobi launched a new app, Hemocoach, to support patients with personalised advice on physical activity.

In the Italian 'Excellences in Scientific Information and Patient Centricity Award', Sobi's Liberate Life programme won 3rd place in the Patient Support Program category.

Sobi continued to share knowledge at events such as World Federation of Hemophilia World Congress in May 2022 and presented new data on PNH and ITP at the 2022 European Haematology Association congress in June 2022.

In Italy, Sobi participated in the STEM training and mentoring programme 'Deploy your talents', together with 17 other international companies and nine high schools, reaching 400 16- to 19-year-olds.

The war in Ukraine

It is still unclear how and to what extent Sobi's operations will be affected by the war in Ukraine. Sales in Russia were not material in the quarter. During the second quarter and early July impaired receivables in Russia of SEK 51 M were collected, whereby the corresponding provision on the balance sheet was reversed, positively impacting the profit. At the end of the quarter the remaining provision for expected credit losses was SEK 106 M. Sobi continues to follow the events closely to assess the potential and actual risks stemming from the situation.

Capital-allocation priorities

As covered initially in the Q1 2022 report and as an integral part of its business model, Sobi is continuously looking for opportunities to augment its business and pipeline. As Sobi seeks new medicines to either license or acquire, the company applies a solid set of capital-allocation priorities. They include a focus on rare diseases, preferably in haematology or immunology, medicines in late-stage development or already marketed with peak sales potential between USD 150-500 M and with a preference for not diluting the EBITA margin.

2022 outlook

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

- Revenue is anticipated to grow by a mid to high single-digit percentage at CER, now potentially towards the higher end of the range

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

- EBITA margin adjusted is anticipated to be at a low 30s percentage of revenue, now including the cost effects of the agreement to license the new orphan medicine loncastuximab tesirine in haematology

Financial calendar

Q3 2022 report 27 October 2022

Q4 2022 report 8 February 2023

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

Forward-looking statements

This report includes forward-looking statements. Actual results may differ from those stated. Internal factors such as the successful management of R&D programmes and intellectual property rights may affect future results. There are also external conditions such as the economic climate, political changes and competing R&D programmes that may affect Sobi's results.

This information is information that Sobi is obliged to make public pursuant to the EU Market Abuse Regulation 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, at 08:00 CEST on 19 July 2022.

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

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, Sweden, 19 July 2022

Håkan Björklund
Chairman

Bo Jesper Hansen
Deputy Chairman

Annette Clancy
Board Member

Matthew Gantz
Board Member

Helena Saxon
Board Member

Staffan Schüberg
Board Member

Filippa Stenberg
Board Member

Pia Axelson
Employee Representative

Erika Husing
Employee Representative

Guido Oelkers
CEO and President

Financial statements – Group

Consolidated statements of comprehensive income

SEK M	Q2 2022	Q2 2021	H1 2022	H1 2021	Full-Year 2021
Total revenue	3,876	3,211	8,801	6,872	15,529
Cost of goods sold	-1,020	-783	-2,536	-1,509	-3,484
Gross profit	2,856	2,428	6,265	5,363	12,045
Selling and administrative expenses ¹	-1,840	-1,468	-3,893	-2,900	-6,294
Research and development expenses	-607	-484	-1,185	-954	-1,994
Other operating income/expenses	14	-9	11	-9	-24
Operating profit	423	467	1,198	1,500	3,733
Net financial items ²	-105	-112	-207	-227	-438
Profit before tax	317	354	991	1,273	3,295
Income tax	-60	-87	-190	-309	-616
Profit for the period	258	268	801	964	2,679
<i>All profit are attributable to Parent Company shareholders</i>					
Other comprehensive income					
<i>Items that will not be reclassified into profit or loss</i>					
Remeasurements on defined-benefit pension plans and similar plans (net of tax)	68	0	68	8	17
Remeasurement of equity instruments (net of tax)	8	-3	-58	4	11
Total	77	-3	10	12	28
<i>Items that may be reclassified into profit or loss</i>					
Translation differences	462	-72	571	66	464
Net investment hedges (net of tax)	-255	59	-321	-88	-242
Cash flow hedges (net of tax)	-44	28	-62	-34	-63
Total	162	15	188	-56	159
Other comprehensive income	238	12	198	-44	187
Total comprehensive income for the period	496	280	999	921	2,866
<i>All comprehensive income is attributable to Parent Company shareholders</i>					
Earnings per share, SEK					
EPS	0.87	0.91	2.71	3.27	9.08
EPS adjusted ³	0.91	0.91	4.56	3.27	9.08
EPS after dilution	0.86	0.90	2.69	3.26	9.03
EPS after dilution adjusted ³	0.90	0.90	4.52	3.26	9.03
¹ Amortisation and impairment of intangible assets included in Selling and administrative expenses.	-521	-455	-1,035	-905	-1,841
² Including financing costs.	-6	-9	-15	-18	-35
³ APMs, see page 23 for further information.					

Consolidated balance sheet

SEK M	Jun 2022	Dec 2021	Jun 2021
ASSETS			
Non-current assets			
Intangible assets ¹	39,112	38,424	38,277
Tangible assets	360	493	491
Financial assets	132	199	184
Deferred tax assets	780	767	555
Total non-current assets	40,385	39,883	39,507
Current assets			
Inventories	3,424	3,424	3,302
Accounts receivable	3,127	3,439	2,337
Other receivables, non-interest bearing	1,133	870	817
Cash and cash equivalents	360	1,045	233
Total current assets	8,044	8,778	6,689
Total assets	48,429	48,661	46,197
EQUITY AND LIABILITIES			
Shareholders' equity	24,326	23,203	21,174
Non-current liabilities			
Borrowings	8,121	8,777	9,414
Deferred tax liabilities	3,667	3,605	3,473
Lease liabilities	279	247	268
Other liabilities, non-interest bearing	4,154	4,068	3,915
Total non-current liabilities	16,220	16,697	17,070
Current liabilities			
Borrowings	1,321	1,768	2,025
Accounts payable	519	558	434
Lease liabilities	132	114	112
Other liabilities, non-interest bearing	5,910	6,321	5,381
Total current liabilities	7,882	8,761	7,952
Total equity and liabilities	48,429	48,661	46,197

¹Including goodwill of SEK 6,861 M (SEK 6,288 M on 31 December 2021).

Changes in equity

SEK M	Jan-Jun 2022	Full-year 2021	Jan-Jun 2021
Opening balance	23,203	20,206	20,206
Share-based compensation to employees	121	134	56
Tax deductions for share programmes ¹	2	-3	-8
Total comprehensive income for the period ²	999	2,866	921
Closing balance	24,326	23,203	21,174

¹The change relates to difference between the market value of vested shares and recognised IFRS 2 cost.

²Whereof changes in cash flow hedges (net of tax) amounted to SEK -62 M (SEK -63 M on 31 December 2021) and net investment hedges (net of tax) amounted to SEK -321 M (SEK -242 M on 31 December 2021).

Consolidated cash flow statement

SEK M	Q2 2022	Q2 2021	H1 2022	H1 2021	Full-year 2021
Profit before tax	317	354	991	1,273	3,295
Amortisation, depreciation and impairment	565	490	1,250	976	2,006
Other, including non-cash items ¹	-51	84	344	69	179
Income tax paid	-181	-162	-389	-796	-1,124
Cash flow from operating activities before change in working capital	650	766	2,196	1,522	4,356
Changes in working capital	-307	627	-209	1,570	1,114
Cash flow from operating activities	343	1,393	1,987	3,092	5,470
Investment in intangible assets ²	-522	-10	-677	-95	-323
Investment in tangible assets	-12	-6	-14	-12	-47
Disposal of tangible assets	-	2	-	2	3
Cash flow from investing activities	-533	-14	-691	-105	-367
Borrowings/repayments of borrowings	-225	-1,716	-1,536	-2,879	-3,998
Hedging arrangement for financing	-292	-32	-438	-223	-351
Repayment of leasing	-33	-31	-67	-61	-125
Cash flow from financing activities	-550	-1,778	-2,041	-3,163	-4,474
Change in cash and cash equivalents	-741	-399	-745	-176	629
Cash and cash equivalents at the beginning of the period	1,063	633	1,045	404	404
Translation difference in cash flow and cash and cash equivalents	37	-1	59	4	12
Cash and cash equivalents at the end of the period	360	233	360	233	1,045

¹2022 refers mainly to restructuring costs and provision for expected credit losses in Russia.

²2022 investments mainly refer to milestone payments linked to Aspaveli/Empaveli and Doptelet.

Key ratios and other information

SEK M	Q2 2022	Q2 2021	H1 2022	H1 2021	Full-year 2021
Profit measures					
Gross profit	2,856	2,428	6,265	5,363	12,045
Gross profit adjusted ^{1,2}	2,859	2,428	6,628	5,363	12,045
EBITDA ¹	988	957	2,449	2,476	5,740
EBITDA adjusted ^{1,2}	997	957	2,987	2,476	5,740
EBITA ¹	944	922	2,234	2,406	5,575
EBITA adjusted ^{1,2}	958	922	2,909	2,406	5,575
EBIT	423	467	1,198	1,500	3,733
EBIT adjusted ^{1,2}	437	467	1,873	1,500	3,733
Profit for the period	258	268	801	964	2,679
Profit for the period adjusted ^{1,2}	268	268	1,346	964	2,679
Per share data (SEK)					
EPS	0.87	0.91	2.71	3.27	9.08
EPS adjusted ^{1,2}	0.91	0.91	4.56	3.27	9.08
EPS after dilution	0.86	0.90	2.69	3.26	9.03
EPS after dilution adjusted ^{1,2}	0.90	0.90	4.52	3.26	9.03
Shareholders' equity per share ¹	79.2	69.7	79.2	69.7	75.6
Shareholders' equity per share after dilution ¹	78.5	69.5	78.5	69.5	75.1
Other information					
Gross margin ¹	74%	76%	71%	78%	78%
Gross margin adjusted ^{1,2}	74%	76%	75%	78%	78%
EBITA margin ¹	24%	29%	25%	35%	36%
EBITA margin adjusted ^{1,2}	25%	29%	33%	35%	36%
Equity ratio ¹	50%	46%	50%	46%	48%
Net debt ¹	9,082	11,206	9,082	11,206	9,500
Number of ordinary shares ³	307,114,495	303,815,511	307,114,495	303,815,511	307,114,495
Number of ordinary shares (in treasury)	11,328,849	8,670,882	11,328,849	8,670,882	11,959,198
Number of ordinary shares (ex shares in treasury)	295,785,646	295,144,629	295,785,646	295,144,629	295,155,297
Number of ordinary shares after dilution	309,771,827	304,828,251	309,771,827	304,828,251	308,862,835
Average number of ordinary shares (ex shares in treasury)	295,319,743	295,007,237	295,237,974	294,953,465	295,051,119
Average number of ordinary shares after dilution (ex shares in treasury)	297,977,075	296,019,976	297,895,306	295,966,205	296,799,459

¹APMs, see page 23 for further information.

²Items affecting comparability in Q2 and H1 2022, see page 3 for further information.

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

Financial statements – Parent Company

Income statement

SEK M	Q2 2022	Q2 2021	H1 2022	H1 2021	Full-year 2021
Total revenue	2,379	2,280	5,739	4,743	12,401
Cost of goods sold	-646	-632	-1,830	-1,249	-2,933
Gross profit	1,732	1,648	3,908	3,493	9,468
Selling and administrative expenses ¹	-736	-556	-2,626	-1,614	-4,179
Research and development expenses	-400	-278	-758	-589	-1,256
Other operating income/expenses	80	70	181	128	350
Operating profit	677	883	706	1,417	4,383
Net financial items	-327	72	-419	-118	-392
Profit after financial items	350	955	287	1,299	3,991
Appropriations	–	–	–	–	-1,713
Profit before tax	350	955	287	1,299	2,278
Income tax	55	-95	19	-176	-488
Profit for the period	405	859	306	1,124	1,790
¹ Amortisation and impairment of intangible assets included in Selling and administrative expenses.	-129	-87	-259	-170	-359

Statement of comprehensive income

SEK M	Q2 2022	Q2 2021	H1 2022	H1 2021	Full-year 2021
Profit for the period	405	859	306	1,124	1,790
<i>Items that will not be reclassified into profit or loss</i>					
Remeasurement of equity instruments (net of tax)	8	-3	-58	4	11
<i>Items that may be reclassified into profit or loss</i>					
Cash flow hedges (net of tax)	-44	28	-62	-34	-63
Other comprehensive income	-36	25	-120	-30	-52
Total comprehensive income for the period	369	885	186	1,094	1,738

Balance sheet

SEK M	Jun 2022	Dec 2021	Jun 2021
ASSETS			
<i>Non-current assets</i>			
Intangible assets	9,894	10,107	10,055
Tangible assets	69	89	57
Financial assets	22,780	22,164	23,733
Deferred tax assets	145	27	20
Total non-current assets	32,888	32,387	33,865
<i>Current assets</i>			
Inventories	2,436	2,536	2,564
Accounts receivable	905	1,126	857
Receivables Group companies	4,074	4,308	2,406
Other receivables, non-interest bearing	938	747	693
Cash and cash equivalents	205	878	70
Total current assets	8,559	9,595	6,590
Total assets	41,447	41,982	40,455
EQUITY AND LIABILITIES			
<i>Shareholders' equity</i>	19,379	19,069	18,341
Untaxed reserves	3,691	3,691	3,091
<i>Non-current liabilities</i>			
Borrowings	8,121	8,777	9,414
Other liabilities, non-interest bearing	3,566	2,897	2,693
Total non-current liabilities	11,687	11,674	12,107
<i>Current liabilities</i>			
Borrowings	1,321	1,768	2,025
Accounts payable	373	359	235
Liabilities Group companies	3,018	3,229	2,814
Other liabilities, non-interest bearing	1,978	2,192	1,841
Total current liabilities	6,690	7,548	6,915
Total equity and liabilities	41,447	41,982	40,455

Change in shareholders' equity

SEK M	Jan-Jun 2022	Full-year 2021	Jan-Jun 2021
Opening balance	19,069	17,200	17,200
Share-based compensation to employees	121	134	56
Tax deductions for share programmes ¹	2	-3	-8
Total comprehensive income for the period ²	186	1,738	1,094
Closing balance	19,379	19,069	18,341

¹The change relates to difference between the market value and recognised IFRS 2 cost.

²Whereof changes in cash flow hedges (net of tax) amounted to SEK -62 M (SEK -63 M on 31 December 2021).

Notes

Note 1 | Accounting policies and measurement bases and other information

Accounting policies

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

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 2021 Annual and Sustainability Report. IASB has published amendments of standards that were effective as of 1 January 2022 or later. These have not had any material impact on the consolidated financial statements.

More detailed information about the Group's accounting policies and measurement bases can be found in the 2021 Annual and Sustainability Report, available at sobi.com.

Risks and uncertainties

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

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

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

Note 2 | Segment reporting

SEK M

Q2 2022	Haematology	Immunology	Specialty Care	Group - other ⁴	Total
Total revenue	2,688	847	341	–	3,876
EBITA ¹	1,120	-139	83	-120	944
EBITA adjusted ^{1,2,3}	1,114	-181	83	-58	958
Amortisation	-210	-258	-41	-12	-521
EBIT	910	-397	42	-132	423

Q2 2021	Haematology	Immunology	Specialty Care	Group - other ⁴	Total
Total revenue	2,125	752	334	–	3,211
EBITA ¹	992	-69	102	-102	922
EBITA adjusted ^{1,2}	992	-69	102	-102	922
Amortisation	-151	-251	-40	-12	-455
EBIT	840	-321	62	-115	467

H1 2022	Haematology	Immunology	Specialty Care	Group - other ⁴	Total
Total revenue	5,187	2,967	647	–	8,801
EBITA ¹	1,806	683	146	-401	2,234
EBITA adjusted ^{1,2,3}	2,169	789	146	-195	2,909
Amortisation	-414	-515	-81	-26	-1,035
EBIT	1,392	167	65	-427	1,198

H1 2021	Haematology	Immunology	Specialty Care	Group - other ⁴	Total
Total revenue	4,003	2,305	564	–	6,872
EBITA ¹	1,813	664	174	-245	2,406
EBITA adjusted ^{1,2}	1,813	664	174	-245	2,406
Amortisation	-302	-502	-78	-23	-905
EBIT	1,511	161	96	-268	1,500

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

There are no intersegment transactions.

¹APMs, see page 23 for further information.

²Items affecting comparability in Q2 and H1 2022, see page 3 for further information.

³EBITA adjusted; Haematology refers to discontinuation of contract manufacturing of SEK 363 M, Immunology refers to provision for expected credit losses in Russia of SEK 106 M, Group - other refers to consolidation of sites of SEK 72 M and efficiency programmes of SEK 134 M.

⁴The category Group-other mainly refers to costs for central functions such as finance, legal, communication, human resources and other items that can not be allocated by segment.

Note 3 | Fair value of financial instruments

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

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

On 30 June 2022, all other financial instruments on the balance sheet had reported values that are in all material aspects equivalent to fair value.

Q2 2022	Level 1	Level 2	Level 3	Total
<i>Financial assets and liabilities measured at fair value through profit or loss</i>				
Derivatives held for trading	–	-59	–	-59
Endowment policies	–	–	50	50
<i>Financial assets measured at fair value through other comprehensive income</i>				
Equity instruments	73	–	–	73
Total	73	-59	50	64
Q2 2021	Level 1	Level 2	Level 3	Total
<i>Financial assets and liabilities measured at fair value through profit or loss</i>				
Derivatives held for trading	–	-1	–	-1
Endowment policies	–	–	44	44
<i>Financial assets measured at fair value through other comprehensive income</i>				
Equity instruments	136	–	–	136
Total	136	-1	44	179
Full-year 2021	Level 1	Level 2	Level 3	Total
<i>Financial assets and liabilities measured at fair value through profit or loss</i>				
Derivatives held for trading	–	1	–	1
Endowment policies	–	–	45	45
<i>Financial assets measured at fair value through other comprehensive income</i>				
Equity instruments	145	–	–	145
Total	145	1	45	191

Alternative performance measures – financial measures not defined according to IFRS

Sobi uses certain financial measures (alternative performance measures, APM) in this report that are not defined according to IFRS. Sobi considers these measures to provide valuable supplementary information for stakeholders and company management, as they enable an assessment and benchmarking of the company's reporting. Since not all companies calculate financial measures in the same way, these are not always comparable to measures used by other companies. These financial measures should not, therefore, be regarded as substitutes for measures defined according to IFRS. As of 2022, Sobi has updated its definition of items affecting comparability, formerly called non-recurring items, to provide better guidance for stakeholders and company management on what type of initiatives and costs that can be considered part of restructuring. See below metrics not defined according to IFRS and definitions used, referred to and presented in this report. Numbers are presented in SEK M unless otherwise stated.

Change at CER

Definition: Change at CER (constant exchange rates) on total revenue excludes the effect of exchange rates by recalculating total revenue for the relevant period using the exchange 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 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
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%

Q2 2021	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
Haematology					
Elocta	1,005	53	1,058	1,040	2%
Alprolix	438	23	461	363	27%
Royalty	320	53	373	336	11%
Doptelet	230	34	264	186	42%
Manufacturing	132	–	132	112	18%
Total	2,125	162	2,287	2,037	12%
Immunology					
Kineret	550	56	606	530	14%
Synagis	33	4	37	52	-29%
Gamifant	168	25	193	132	46%
Total	752	85	836	714	17%
Specialty Care	334	31	365	319	14%
Total	3,211	279	3,489	3,070	14%

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
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%

H1 2021	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
Haematology					
Elocta	1,861	109	1,970	2,399	-18%
Alprolix	851	48	899	851	6%
Royalty	618	91	709	671	6%
Doptelet	411	60	471	251	88%
Manufacturing	262	–	262	260	1%
Total	4,003	308	4,311	4,431	-3%
Immunology					
Kineret	1,092	113	1,205	1,030	17%
Synagis	912	133	1,045	1,248	-16%
Gamifant	301	45	346	236	47%
Total	2,305	291	2,596	2,514	3%
Specialty Care	564	48	612	764	-20%
Total	6,872	646	7,518	7,709	-2%

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

Gross margin

Definition: Gross profit as a percentage of total revenue.

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

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 2022	Q2 2021	H1 2022	H1 2021	Full-year 2021
Total revenue	3,876	3,211	8,801	6,872	15,529
Total cost of goods sold	-1,020	-783	-2,536	-1,509	-3,484
Gross profit	2,856	2,428	6,265	5,363	12,045
Gross margin	74%	76%	71%	78%	78%
Items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	-3	-	-363	-	-
Items affecting comparability¹	-3	-	-363	-	-
Gross profit adjusted	2,859	2,428	6,628	5,363	12,045
Gross margin adjusted	74%	76%	75%	78%	78%
EBIT²	423	467	1,198	1,500	3,733
Items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	-3	-	-363	-	-
-Consolidation of sites	-	-	-72	-	-
-Efficiency programmes	-62	-	-134	-	-
-Other:					
-Provision for expected credit losses in Russia	51	-	-106	-	-
Items affecting comparability	-14	-	-675	-	-
EBIT adjusted	437	467	1,873	1,500	3,733

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.

EBIT ²	423	467	1,198	1,500	3,733
Plus amortisation and impairment of intangible assets	521	455	1,035	905	1,841
EBITA²	944	922	2,234	2,406	5,575
EBITA margin	24%	29%	25%	35%	36%

¹Items affecting comparability in Q2 and H1 2022, see page 3 for further information.

²For EBIT and EBITA per segment see Note 2.

SEK M	Q2 2022	Q2 2021	H1 2022	H1 2021	Full-year 2021
Items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	-3	–	-363	–	–
-Consolidation of sites	–	–	-72	–	–
-Efficiency programmes	-62	–	-134	–	–
-Other:					
-Provision for expected credit losses in Russia	51	–	-106	–	–
Items affecting comparability	-14	–	-675	–	–
EBITA adjusted	958	922	2,909	2,406	5,575
EBITA margin adjusted	25%	29%	33%	35%	36%

EBITDA

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

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

EBITA	944	922	2,234	2,406	5,575
Plus depreciation and impairment of tangible assets	44	36	215	70	165
EBITDA	988	957	2,449	2,476	5,740
Items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	–	–	-239	–	–
-Consolidation of sites	–	–	-60	–	–
-Efficiency programmes	-60	–	-134	–	–
-Other:					
-Provision for expected credit losses in Russia	51	–	-106	–	–
Items affecting comparability¹	-9	–	-539	–	–
EBITDA adjusted	997	957	2,987	2,476	5,740

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.

Profit for the period	258	268	801	964	2,679
Items affecting comparability	-14	–	-675	–	–
Tax on items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	1	–	75	–	–
-Consolidation of sites	–	–	6	–	–
-Efficiency programmes	13	–	28	–	–
-Other:					
-Provision for expected credit losses in Russia	-11	–	22	–	–
Tax on items affecting comparability	3	–	130	–	–
Items affecting comparability (net of tax)	-11	–	-545	–	–
Profit for the period adjusted	268	268	1,346	964	2,679
Average number of ordinary shares (excluding shares in treasury)	295,319,743	295,007,237	295,237,974	294,953,465	295,051,119
Average number of ordinary shares after dilution (excluding shares in treasury)	297,977,075	296,019,976	297,895,306	295,966,205	296,799,459
EPS before dilution, SEK adjusted	0.91	0.91	4.56	3.27	9.08
EPS after dilution, SEK adjusted	0.90	0.90	4.52	3.26	9.03

¹Items affecting comparability excluding impairment of tangible assets of SEK 136 M, see page 3 for more information.

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.

SEK M	Q2 2022	Q2 2021	H1 2022	H1 2021	Full-year 2021
Borrowings	9,442	11,439	9,442	11,439	10,545
Cash and cash equivalents	360	233	360	233	1,045
Net debt	9,082	11,206	9,082	11,206	9,500

Equity ratio

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

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

Equity per share

Definition: Equity divided by the number of ordinary shares.

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

Shareholders' equity	24,326	21,174	24,326	21,174	23,203
Total assets	48,429	46,197	48,429	46,197	48,661
Equity ratio	50%	46%	50%	46%	48%
Number of ordinary shares	307,114,495	303,815,511	307,114,495	303,815,511	307,114,495
Number of ordinary shares after dilution	309,771,827	304,828,251	309,771,827	304,828,251	308,862,835
Equity per share, SEK	79.2	69.7	79.2	69.7	75.6
Equity per share after dilution, SEK	78.5	69.5	78.5	69.5	75.1

Definitions

Alprolix (eftrenonacog alfa)

A recombinant, extended half-life (EHL) clotting factor IX medicine for the treatment of haemophilia B.

Amyotrophic lateral sclerosis, ALS

A devastating neurodegenerative disease that results in progressive muscle weakness and paralysis due to the death of nerve cells, motor neurons, in the brain and spinal cord.

Aspaveli/Empaveli (pegcetacoplan)

A new medicine targeting complement component 3 (C3) designed to regulate excessive complement activation, which can lead to the onset and progression of many serious diseases. Aspaveli/Empaveli is a synthetic cyclic peptide conjugated to a polyethylene glycol polymer that binds specifically to C3 and C3b.

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.

Doptelet (avatrombopag)

A second-generation small molecule thrombopoietin receptor agonist used in the treatment of thrombocytopenia by increasing platelet count.

Efanesoctocog alfa (formerly BIVV001)

A novel and investigational recombinant factor VIII therapy that is designed to extend protection from bleeds with once-weekly prophylactic dosing for people with haemophilia A. It builds on the innovative Fc fusion technology by adding a region of von Willebrand factor and XTEN® polypeptides to extend its time in circulation. It is the first investigational factor VIII therapy that has been shown to break through the von Willebrand factor ceiling, which imposes a half-life limitation on current factor VIII therapies.

Elocta (efmoroctocog alfa)

A recombinant, EHL clotting factor VIII medicine for the treatment of haemophilia A. It is also known as Eloctate in some countries.

Full-time equivalents

Unit that indicates the workload of an employed person in a way that makes workloads comparable.

Gamifant (emapalumab)

A monoclonal antibody that binds to and neutralises interferon gamma. Gamifant is a medicine for pHLH, an ultra-rare syndrome of hyperinflammation that usually occurs within the first year of life and can rapidly become fatal unless diagnosed and treated.

Gout

An autoinflammatory disease that causes intensely painful flares and debilitating inflammatory arthritis due to deposition of pro-inflammatory monosodium urate crystals in synovial fluid and other tissues.

Haemophilia

A rare, genetic disorder in which the ability of a person's blood to clot is impaired. Haemophilia A occurs in about one in 5,000 male births annually, and haemophilia B occurs in about one in 25,000 male births annually. Both occur more rarely in females. People with haemophilia experience bleeding episodes that may cause pain, limited mobility, irreversible joint damage and life-threatening haemorrhages.

Immune-complex membranoproliferative glomerulonephritis, IC-MPGN and C3 glomerulopathy, C3G

Are rare, debilitating kidney diseases that are estimated to affect up to 8,000 people in Europe and 5,000 in the United States. There are no approved therapies for the diseases, and symptoms include blood in the urine, dark foamy urine due to the presence of protein, swelling, and high blood pressure. Approximately 50 per cent of people living with IC-MPGN and C3G ultimately suffer from kidney failure within five to ten years of diagnosis. There are no treatments available that target the underlying complement-mediated mechanism of these diseases and prevent loss of kidney function, before or after renal transplant. 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 the biological activity of interleukin-1 α and β (IL-1 α and IL-1 β) by binding to IL-1 type 1 receptors (IL-R 1), expressed in a variety of tissues and organs, thereby blocking the IL-1 signalling. IL-1 is a key mediator of inflammation and a significant contributor to autoinflammatory diseases.

Launch medicines

Nirsevimab

Launch medicines include Doptelet, Aspaveli/Empaveli and Gamifant.

A long-acting antibody being developed as a passive immunisation for the prevention of lower respiratory tract infections caused by RSV. It is being developed for use with all infants. Due to its extended half-life technology, nirsevimab may only require one dose during a typical five-month RSV season. As a passive immunisation the antibody is given directly to an infant to help prevent RSV, unlike active immunisation, where the infants' own immune system is activated to prevent or fight infection. Passive immunisation could offer immediate protection unlike active immunisation, which can take weeks to develop protection.

Orfadin (nitisinone)

A medicine used to treat hereditary tyrosinaemia type 1. It blocks the breakdown of tyrosine, thereby reducing the amount of toxic tyrosine by-products in the body. Patients must maintain a special diet in combination with Orfadin treatment as tyrosine is not adequately broken down. Orfadin can also be used for the treatment of adult patients with alkaptonuria.

Paroxysmal nocturnal haemoglobinuria, PNH

A rare, chronic, life-threatening blood disorder characterised by the destruction of oxygen-carrying red blood cells through extravascular and intravascular haemolysis. Persistently low haemoglobin can result in debilitating symptoms such as severe fatigue, haemoglobinuria, and difficulty breathing (dyspnoea), and can require frequent transfusions.

Primary haemophagocytic lymphohistiocytosis, pHLH

An ultra-rare, rapidly progressive, often-fatal syndrome of hyperinflammation in which hyperproduction of interferon gamma is thought to drive immune system hyperactivation, ultimately leading to organ failures. Diagnosis is challenging due to the variability in signs and symptoms, which may include fevers, swelling of the liver and spleen, severe low red and white blood cell counts, bleeding disorders, infections, neurological symptoms, organ dysfunction and organ failure. Primary HLH can rapidly become fatal if left untreated, with median survival of less than two months. The immediate goal of treatment is to quickly control the hyperinflammation and to prepare for haematopoietic stem-cell transplantation. The current conventional treatment prior to transplant includes steroids and chemotherapy and are not specifically approved to treat pHLH.

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 patients with chronic refractory gout. SEL-212 consists of pegadricase, co-administered with ImmTOR, designed to mitigate the formation of anti-drug antibodies.

Synagis (palivizumab)

An immunisation indicated for the prevention of serious lower respiratory tract infection caused by RSV in infants and young children at high risk of RSV disease. Synagis is an RSV F protein inhibitor monoclonal antibody that acts as a prophylaxis against serious RSV disease.

Tegsedi (inotersen)

A medicine for the treatment of polyneuropathy of hereditary transthyretin amyloidosis in adults.

Waylivra (volanesorsen)

A medicine for the treatment of genetically confirmed familial chylomicronaemia syndrome.

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