

# Sustained progress

Q3 2022  
report

## July – September 2022

- **Total revenue** SEK 3,999 M (3,761), +6 per cent, -6 per cent at constant exchange rates (CER)<sup>1</sup>
- **Haematology** revenue SEK 2,619 M (2,291), +3 per cent at CER of which Elocta® SEK 1,041 M (1,035), -5 per cent at CER; Alprolix® SEK 464 M (430), +2 per cent at CER; Doptelet® SEK 543 M (400), +12 per cent at CER and Aspaveli®/Empaveli™ SEK 49 M (-)
- **Immunology** revenue SEK 1,070 M (1,144), -22 per cent at CER of which Kineret® SEK 542 M (516), -10 per cent at CER; Synagis® SEK 327 M (374), -30 per cent at CER and Gamifant® SEK 202 M (255), -36 per cent at CER
- **EBITA**<sup>1</sup> SEK 1,241 M (1,166); **EBITA margin**<sup>1</sup> 31 per cent (31). **EBIT** SEK 699 M (708)
- **Earnings per share** (EPS) before dilution SEK 1.52 (1.60). **Cash flow** from operating activities SEK 780 M (257)

## January – September 2022

- **Total revenue** SEK 12,800 M (10,633), +20 per cent, +9 per cent at CER
- **Haematology** revenue SEK 7,806 M (6,294), +14 per cent at CER of which Elocta SEK 3,173 M (2,896), +5 per cent at CER; Alprolix SEK 1,351 M (1,281), stable at CER; Doptelet SEK 1,754 M (810), +85 per cent at CER and Aspaveli/Empaveli SEK 91 M (-)
- **Immunology** revenue SEK 4,036 M (3,450), +3 per cent at CER of which Kineret SEK 1,731 M (1,608), -4 per cent at CER; Synagis SEK 1,652 M (1,286), +12 per cent at CER and Gamifant SEK 653 M (556), stable at CER
- **EBITA** SEK 3,475 M (3,572); **EBITA margin** 27 per cent (34) including **items affecting comparability (IAC)**<sup>2</sup> of SEK -675 M. Excluding IAC **EBITA adjusted**<sup>1</sup> was SEK 4,150 M corresponding to an **EBITA margin adjusted**<sup>1</sup> of 32 per cent (34). **EBIT** SEK 1,897 M (2,208); **EBIT adjusted**<sup>1</sup> SEK 2,572 M (2,208)
- **EPS** before dilution SEK 4.24 (4.87), **EPS adjusted**<sup>1</sup> before dilution SEK 6.08 (4.87). **Cash flow** from operating activities SEK 2,767 M (3,349)

## 2022 outlook unchanged

## Financial summary

Total revenue Q3, SEK M

3,999

Total revenue  
change Q3, CER

-6%

Total revenue  
change YTD, CER

9%

EBITA margin Q3

31%

EBITA margin  
adjusted YTD

32%

SEK M	Q3 2022	Q3 2021	Change	Jan-Sep 2022	Jan-Sep 2021	Change	Full-year 2021
Total revenue	3,999	3,761	6%	12,800	10,633	20%	15,529
Gross profit	3,067	2,802	9%	9,332	8,165	14%	12,045
Gross margin <sup>1</sup>	77%	75%		73%	77%		78%
EBITA <sup>1</sup>	1,241	1,166	6%	3,475	3,572	-3%	5,575
EBITA adjusted <sup>1,2</sup>	1,241	1,166	6%	4,150	3,572	16%	5,575
EBITA margin <sup>1</sup>	31%	31%		27%	34%		36%
EBITA margin adjusted <sup>1,2</sup>	31%	31%		32%	34%		36%
Profit for the period	451	473	-5%	1,252	1,438	-13%	2,679
EPS, before dilution, SEK	1.52	1.60	-5%	4.24	4.87	-13%	9.08
EPS, before dilution, SEK adjusted <sup>1,2</sup>	1.52	1.60	-5%	6.08	4.87	25%	9.08

<sup>1</sup>Alternative Performance Measures (APMs), see page 23 for further information.

<sup>2</sup>Items affecting comparability (IAC) in 2022, see page 3 for further information.

# CEO statement

Sobi continued to perform well with sustained progress in support of the outlook for 2022.

Revenue increased by 6 per cent in the third quarter and decreased by 6 per cent at constant exchange rates (CER), reflecting the higher base in the third quarter of 2021 which was elevated by the COVID-19 pandemic. In the year-to-date September 2022 period, revenue grew by 9 per cent at CER. This performance was achieved despite many geopolitical uncertainties in the world today.

Sobi's medicines continued to make sustained progress and benefit more patients with rare disease in more countries.

In Haematology, Doptelet increased by 12 per cent at CER in the quarter, but by 77 per cent at CER outside China. Haemophilia continued to exhibit overall stability, as expected, and a milestone was reached with efanesoctocog alfa and the US regulatory submission acceptance and granting of priority review.

The performance in Immunology reflected a higher base for Kineret due to COVID-19 sales in 2021 and while Synagis had a good start to the RSV season seen through a historic lens, sales were lower in the third quarter due to the pandemic-driven early start of the RSV season last year. Gamifant had a softer quarter following a strong second quarter and Sobi is underway with the generation of new data to expand the number of patients that can benefit from the medicine.

Launch medicines Doptelet (outside China), Aspaveli and Gamifant combined grew by 22 per cent at CER in the third quarter and by 40 per cent at CER in the year-to-date period, underpinning the sustainability of the Sobi revenue base, the focus on Haematology and Immunology and prospects for the current portfolio.

EBITA for the quarter was SEK 1,241 M with a margin of 31 per cent. Based on the revenue and earnings performance today, Sobi is fully on track and the full-year 2022 outlook is confirmed.

The pipeline continued to experience solid progress since the update in July with several new milestones achieved. In addition to the efanesoctocog alfa progress mentioned, Orfadin® was approved in Brazil, loncastuximab tesirine achieved a positive EU regulatory opinion for marketing authorisation and Kineret was submitted for regulatory review in China for a second indication. With this progress, Sobi continues to find and make available medicines that transform the lives of people with rare and debilitating diseases.

Sobi's performance is a result of the hard work by 1,600 dedicated colleagues around the world. All colleagues are inspired by caring and powered by science and my sincere thanks go to all of them for their dedication to patients, Sobi and our future together.

Solna, Sweden, 27 October 2022

**Guido Oelkers, President & CEO**



# Financial performance

## Total revenue

Total revenue for July to September ('the quarter') was SEK 3,999 M (3,761) and increased by 6 per cent compared with the same period a year ago and decreased by 6 per cent at CER. A higher comparison base in 2021, partly due to the COVID-19 pandemic, reduced the performance of Kineret and Synagis. Gamifant experienced a softer quarter and Doptelet saw a negative impact from the phasing of sales to the partner in China. Outside China, growth was strong for Doptelet across all Sobi countries, especially driven by increased market share in the US. The ongoing launch of Aspavali continued to contribute to revenue growth.

Total revenue for January to September ('the year-to-date period') was SEK 12,800 M (10,633) and increased by 20 per cent compared with the same period a year ago and by 9 per cent at CER.

SEK M	Q3 2022	Q3 2021	Change	Change at CER	Jan-Sep 2022	Jan-Sep 2021	Change	Change at CER	Full-year 2021
Haematology	2,619	2,291	14%	3%	7,806	6,294	24%	14%	8,536
Immunology	1,070	1,144	-7%	-22%	4,036	3,450	17%	3%	5,780
Specialty Care	310	326	-5%	-16%	957	890	8%	-2%	1,213
<b>Total</b>	<b>3,999</b>	<b>3,761</b>	<b>6%</b>	<b>-6%</b>	<b>12,800</b>	<b>10,633</b>	<b>20%</b>	<b>9%</b>	<b>15,529</b>

## Items affecting comparability

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

SEK M	Q3 2022	IAC	Q3 2022 adjusted	Q3 2021	Jan-Sep 2022	IAC	Jan-Sep 2022 adjusted	Jan-Sep 2021	Full-year 2021
Total revenue	3,999	–	3,999	3,761	12,800	–	12,800	10,633	15,529
Cost of goods sold <sup>1</sup>	-932	–	-932	-959	-3,468	-363	-3,105	-2,468	-3,484
<b>Gross profit</b>	<b>3,067</b>	–	<b>3,067</b>	<b>2,802</b>	<b>9,332</b>	<b>-363</b>	<b>9,695</b>	<b>8,165</b>	<b>12,045</b>
Gross margin	77%		77%	75%	73%		76%	77%	78%
Selling and administrative expenses <sup>2,3,4</sup>	-1,834	–	-1,834	-1,571	-5,726	-210	-5,516	-4,470	-6,294
Research and development expenses <sup>2,4</sup>	-526	–	-526	-485	-1,711	-102	-1,609	-1,440	-1,994
<b>Operating expenses</b>	<b>-2,360</b>	–	<b>-2,360</b>	<b>-2,056</b>	<b>-7,437</b>	<b>-312</b>	<b>-7,125</b>	<b>-5,910</b>	<b>-8,288</b>
Other operating income/expenses	-8	–	-8	-38	3	–	3	-47	-24
<b>Operating profit (EBIT)</b>	<b>699</b>	–	<b>699</b>	<b>708</b>	<b>1,897</b>	<b>-675</b>	<b>2,572</b>	<b>2,208</b>	<b>3,733</b>
Plus amortisation and impairment of intangible assets	542	–	542	459	1,578	–	1,578	1,364	1,841
<b>EBITA</b>	<b>1,241</b>	–	<b>1,241</b>	<b>1,166</b>	<b>3,475</b>	<b>-675</b>	<b>4,150</b>	<b>3,572</b>	<b>5,575</b>
EBITA margin	31%		31%	31%	27%		32%	34%	36%

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

- 1) Year to date, restructuring costs were SEK 363 M including impairment and accelerated depreciation of tangible assets of SEK 124 M following the decision to discontinue contract manufacturing for Pfizer. The process of downsizing the manufacturing facility started in the second half of 2022 with the last volumes anticipated to be delivered to Pfizer in the beginning of 2024.
- 2) Year to date refers to external expenses and restructuring costs of SEK 134 M related to structural efficiency programmes, whereof SEK 77 M were allocated to selling and administrative expenses and SEK 57 M were allocated to research and development expenses.
- 3) Refers to provision for expected credit losses in Russia of SEK 106 M.
- 4) Year to date, 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 3,067 M (2,802) in the quarter and the gross margin was 77 per cent (75). The margin increase benefitted from a favourable mix of business, including growth of Doptelet sales outside China as well as lower sales of Doptelet, with low margin, to the partner in China. The gross margin was also positively impacted by currency effects.

In the year-to-date period, gross profit was SEK 9,332 M (8,165) and included IAC of SEK 363 M. The gross margin excluding IAC was 76 per cent (77).

### Operating expenses

Selling and administrative expenses were SEK 1,834 M (1,571) in the quarter and included amortisation of SEK 542 M (459). Excluding amortisation, the increase was 1 per cent at CER and reflected launch preparations and activities for Aspaveli/Empaveli. In the year-to-date period, expenses were SEK 5,726 M (4,470) and included IAC of SEK 210 M and amortisation of SEK 1,578 M (1,364). Excluding IAC and amortisation, the increase was 12 per cent at CER.

Research and development expenses were SEK 526 M (485) in the quarter, a decrease of 3 per cent at CER, mainly due to phasing of development programmes in haemophilia and for Gamifant and SEL-212. The quarter also included a small element of development costs for loncastuximab tesirine. In the year-to-date period, expenses were SEK 1,711 M (1,440) and included IAC of SEK 102 M. Excluding IAC, the increase was 2 per cent at CER.

### Operating profit

EBITA was SEK 1,241 M (1,166) in the quarter, corresponding to a margin of 31 per cent (31). In the year-to-date period, EBITA was SEK 3,475 M (3,572), corresponding to a margin of 27 per cent (34). Year-to-date EBITA adjusted was SEK 4,150 M, corresponding to a margin of 32 per cent. Amortisation of intangible assets was SEK 542 M (459) in the quarter and SEK 1,578 M (1,364) in the year-to-date period. EBIT was SEK 699 M (708) in the quarter and SEK 1,897 M (2,208) in the year-to-date period.

### Net financial items

Net financial items were SEK -135 M (-109) in the quarter, mainly reflecting increased interest rates on loans. In the year-to-date period, net financial items were SEK -342 M (-336).

### Income tax

Income tax was SEK -113 M (-125) in the quarter, corresponding to an effective tax rate of 20.0 per cent (20.9). In the year-to-date period, income tax was SEK -303 M (-434), corresponding to an effective tax rate of 19.5 per cent (23.2).

### Profit

Profit totalled SEK 451 M (473) in the quarter and SEK 1,252 M (1,438) in the year-to-date period.

### Cash flow

Cash flow from operating activities was SEK 780 M (257) in the quarter, mainly reflecting reduced inventory levels due to timing of inventory purchases and collection of receivables. In the year-to-date period cash flow from operating activities was SEK 2,767 M (3,349) mainly reflecting timing of rebate payments and higher seasonal sales of Synagis compared to the previous RSV season. The year-to-date period also included IAC payments of SEK 117 M whereof SEK 26 M in the quarter.

Cash flow from investing activities was SEK -724 M (-17) in the quarter and included an upfront payment of SEK -588 M to ADC Therapeutics for loncastuximab tesirine and a milestone payment of SEK -106 M to Selecta for SEL-212. In the year-to-date period investing activities were SEK -1,414 M (-122), including a milestone payment of SEK -479 M to Apellis for Aspaveli/Empaveli in the second quarter and a milestone payment of SEK -115 M to Eisai for Doptelet in the first quarter.

The regulatory submission acceptance for nirsevimab in the US anticipated in the fourth quarter of 2022 will trigger a milestone payment of USD 175 M to AstraZeneca and additional contractual payments for R&D costs.

### Cash and net debt

On 30 September 2022, cash and cash equivalents were SEK 288 M (1,045 on 31 December 2021). Sobi ended the quarter with undrawn committed credit facilities totalling SEK 8,628 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 the first quarter Sobi established a commercial paper programme of up to SEK 4,000 M. Drawn credit facilities and issued commercial papers totalled SEK 9,856 M at the end of quarter (SEK 10,597 M on 31 December 2021). Net debt at the end of the quarter was SEK 9,533 M (SEK 9,500 M on 31 December 2021).

### **Equity**

On 30 September 2022, consolidated shareholders' equity was SEK 25,065 M (SEK 23,203 M on 31 December 2021).

### **Personnel**

On 30 September 2022, the number of full-time equivalent employees was 1,555 (1,559 on 31 December 2021).

### **Parent Company**

Total revenue for the Parent Company, Swedish Orphan Biovitrum AB (publ), was SEK 3,083 M (2,627) in the quarter, of which Group companies accounted for SEK 1,992 M (1,654). In the year-to-date period, revenue was SEK 8,821 M (7,370) of which SEK 5,494 (4,161) referred to Group companies' sales.

Profit was SEK 878 M (761) in the quarter and SEK 1,184 M (1,886) in the year-to-date period. Investing activities affecting cash flow were SEK -709 M (-16) in the quarter and SEK -1,272 M (-55) in the year-to-date period.

# 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	Q3 2022	Q3 2021	Change	Change at CER	Jan-Sep 2022	Jan-Sep 2021	Change	Change at CER	Full-year 2021
Elocta	1,041	1,035	1%	-5%	3,173	2,896	10%	5%	3,960
Alprolix	464	430	8%	2%	1,351	1,281	5%	0%	1,764
Royalty	377	315	20%	-4%	1,086	934	16%	-2%	1,251
Doptelet	543	400	36%	12%	1,754	810	117%	85%	1,116
Aspaveli/Empaveli	49	–	n/a	n/a	91	–	n/a	n/a	1
Manufacturing	145	110	31%	31%	351	373	-6%	-6%	445
<b>Total</b>	<b>2,619</b>	<b>2,291</b>	<b>14%</b>	<b>3%</b>	<b>7,806</b>	<b>6,294</b>	<b>24%</b>	<b>14%</b>	<b>8,536</b>

Haematology revenue was SEK 2,619 M (2,291) in the quarter and increased by 14 per cent, 3 per cent at CER. In the year-to-date period, revenue was SEK 7,806 M (6,294) and increased by 24 per cent, 14 per cent at CER.

Elocta sales were SEK 1,041 M (1,035) in the quarter and increased by 1 per cent, -5 per cent at CER. Continued growth in patient numbers and a higher factor consumption per patient was more than offset in the quarter by retrospective price-clawback adjustments in Greece and Italy and unfavourable price developments. Phasing of sales in the Middle East also contributed negatively. In the year-to-date period, sales were 3,173 M (2,896) and increased by 10 per cent, 5 per cent at CER.

Alprolix sales were SEK 464 M (430) in the quarter and increased by 8 per cent, 2 per cent at CER. Growth in patient numbers was slightly offset by an unfavourable country mix. In the year-to-date period, sales were SEK 1,351 M (1,281) and increased by 5 per cent, stable at CER.

Doptelet sales were SEK 543 M (400) in the quarter and increased by 36 per cent, 12 per cent at CER. Growth was driven by increased uptake in the US and ongoing launches in Europe, however somewhat offset by phasing of sales to the partner in China. In the year-to-date period, sales were SEK 1,754 M (810) and increased by 117 per cent, 85 per cent at CER.

Doptelet sales to the partner in China were SEK 145 M (214) in the quarter and decreased by 32 per cent, -44 per cent at CER. In the year-to-date period, sales were SEK 351 M (319) and increased by 146 per cent, 109 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 49 M (-) driven by ongoing launches in the UK, Germany, France and the Middle East. In the quarter the first sales were registered in Poland and Luxembourg. In the year-to-date period, sales were SEK 91 M (-).

ReFacto AF/Xyntha manufacturing revenue was SEK 145 M (110) driven by earlier deliveries to Pfizer. In the year-to-date period, sales were SEK 351 M (373).

# Immunology

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

## Revenue Immunology

SEK M	Q3 2022	Q3 2021	Change	Change at CER	Jan-Sep 2022	Jan-Sep 2021	Change	Change at CER	Full-year 2021
Kineret	542	516	5%	-10%	1,731	1,608	8%	-4%	2,290
Synagis	327	374	-13%	-30%	1,652	1,286	28%	12%	2,650
Gamifant	202	255	-21%	-36%	653	556	18%	0%	840
<b>Total</b>	<b>1,070</b>	<b>1,144</b>	<b>-7%</b>	<b>-22%</b>	<b>4,036</b>	<b>3,450</b>	<b>17%</b>	<b>3%</b>	<b>5,780</b>

Immunology revenue was SEK 1,070 M (1,144) in the quarter and decreased by 7 per cent, -22 per cent at CER. In the year-to-date period, revenue was SEK 4,036 M (3,450) and increased by 17 per cent, 3 per cent at CER.

Kineret sales were SEK 542 M (516) in the quarter and increased by 5 per cent, -10 per cent at CER. The decrease reflected no COVID-19 related sales, slightly offset by increased demand in other indications. In the year-to-date period, sales were SEK 1,731 M (1,608) and increased by 8 per cent, -4 per cent at CER.

Synagis sales were SEK 327 M (374) in the quarter and decreased by 13 per cent, -30 per cent at CER, reflecting a later start to the RSV season in the US compared to the earlier start in 2021, an effect of the COVID-19 pandemic. In the year-to-date period, sales were SEK 1,652 M (1,286) and increased by 28 per cent, 12 per cent at CER.

Gamifant sales were SEK 202 M (255) in the quarter and decreased by 21 per cent, -36 per cent at CER. The decrease was driven by patient mix, i.e. a lower share of heavier patients, and fewer new patients. In the year-to-date period, sales were SEK 653 M (556) and increased by 18 per cent, stable 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	Q3 2022	Q3 2021	Change	Change at CER	Jan-Sep 2022	Jan-Sep 2021	Change	Change at CER	Full-year 2021
Orfadin	117	116	1%	-11%	337	338	0%	-9%	459
Tegsedi	107	112	-5%	-17%	339	304	12%	0%	427
Waylivra	31	33	-6%	-11%	105	91	15%	10%	121
Other Specialty Care	55	65	-15%	-25%	176	157	13%	2%	207
<b>Total</b>	<b>310</b>	<b>326</b>	<b>-5%</b>	<b>-16%</b>	<b>957</b>	<b>890</b>	<b>8%</b>	<b>-2%</b>	<b>1,213</b>

Specialty Care revenue was SEK 310 M (326) in the quarter and decreased by 5 per cent, -16 per cent at CER, reflecting continued generic price competition to Orfadin and fewer patients treated with Tegsedi. In the year-to-date period, sales were SEK 957 M (890) and increased by 8 per cent, -2 per cent at CER.

# Pipeline

For the full Sobi pipeline, please visit [sobi.com](https://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: regulatory submission acceptance and granting of priority review in the US (by Sanofi)</p> <p>Aspaveli/Empaveli – CAD: CASCADE phase 3 study first patient dosed</p> <p>loncastuximab tesirine – DLBCL: positive regulatory opinion in the EU</p> <p>Kineret – Still's disease: regulatory submission in China</p> <p>Orfadin – HT-1: regulatory approval in Brazil</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 and now also under regulatory review in the US.

In August, Sanofi and Sobi announced that the US Food and Drug Administration (FDA) had accepted for priority review the Biologics License Application (BLA) for efanesoctocog alfa. With the shorter timeline under a priority review, the target action date for the FDA decision is 28 February 2023.

The BLA was supported by data from the pivotal XTEND-1 phase 3 study. Results were presented in July at the International Society of Thrombosis and Haemostasis 2022 Congress. The data demonstrated a clinically meaningful prevention of bleeds and superiority to prior factor prophylaxis based on an intra-patient comparison. Efanesoctocog alfa was well-tolerated and inhibitor development to factor VIII was not detected.

Regulatory submission in the EU, anticipated in the second half of 2023, will follow availability of data from the ongoing, fully recruited XTEND-Kids paediatric study, expected in the first half of 2023.

### Aspaveli/Empaveli

Aspaveli/Empaveli, a medicine for the treatment of paroxysmal nocturnal haemoglobinuria (PNH), is in clinical development for use in new indications with the collaborator Apellis Pharmaceuticals, Inc.

#### New indications

During the quarter, Sobi achieved the first patient dosed in the CASCADE phase 3 study evaluating Aspaveli/Empaveli in cold agglutinin disease (CAD). CAD is a serious and chronic type of autoimmune haemolytic anaemia characterised by chronic anaemia, profound fatigue, acute haemolytic crises and other potential complications, including an increased risk of life-threatening thromboembolic events such as stroke. Only recently, new treatment options for CAD became available.

This follows a recent announcement that the first patient had been dosed in the VALIANT phase 3 study evaluating Aspaveli/Empaveli in primary immune-complex membranoproliferative glomerulonephritis and C3 glomerulopathy, two rare and debilitating kidney diseases. Data readout from the new phase 3 studies is anticipated after 2023.

### Loncastuximab tesirine

Loncastuximab tesirine, a medicine for certain debilitating diseases in haematology, is in clinical development with the collaborator ADC Therapeutics SA and under EU regulatory review<sup>a</sup>.

<sup>a</sup> In September 2021, ADC Therapeutics announced that the European Commission had granted orphan designation to loncastuximab tesirine which is subject to review at time of marketing authorisation.



In September, Sobi and ADC Therapeutics announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency had adopted a positive opinion recommending the marketing authorisation of loncastuximab tesirine for the treatment of relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL), a debilitating disease in haematology. The positive opinion from the CHMP was referred to the European Commission for a decision.

In September, at the Annual Meeting of the Society of Hematologic Oncology 2022, initial data were presented on loncastuximab tesirine from the safety run-in of the ongoing LOTIS-5 phase 3 study. LOTIS-5 is intended as the confirmatory study in R/R DLBCL. The combination of rituximab, an established treatment in lymphoma, and loncastuximab tesirine demonstrated no new safety signals and showed encouraging antitumor activity, including an overall response rate by central review of 75 per cent with 40 per cent of patients attaining a complete response. 20 patients were enrolled in this nonrandomised safety run-in while approximately 330 patients will be receiving either rituximab and loncastuximab tesirine or rituximab, gemcitabine and oxaliplatin in the randomised part of the study which is ongoing. Data readout is anticipated after 2023.

## Immunology

### Kineret

During the quarter, the second regulatory submission was made for Kineret in China, this time for the potential use in the treatment of Still's disease. Still's is a rare type of inflammatory arthritis that features fevers, rash and joint pain.

### Gamifant

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

In September, at the Paediatric Rheumatology European Society Congress 2022, data were presented from a long-term follow-up study assessing efficacy, safety and pharmacology of Gamifant in patients with macrophage activation syndrome (MAS) associated with systemic juvenile idiopathic arthritis (sJIA), a rare rheumatological disease. All patients had initially been part of a parent phase 2 study assessing Gamifant as a treatment for MAS associated with sJIA and all 14 participating patients were enrolled into the long-term follow-up study where no Gamifant was administered. During long-term follow-up for up to 12 months, 13 of the 14 patients did not have MAS episodes. No new safety signals were observed which confirmed the favourable safety profile of Gamifant.

Earlier in the year, dosing was initiated in a new phase 3 study, EMERALD. EMERALD evaluates Gamifant in the treatment of MAS in paediatric and adult patients with underlying rheumatological diseases, including Still's disease, the first data cohort.

### SEL-212

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

### Nirsevimab

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

In September, the companies announced that nirsevimab had been recommended for marketing authorisation in the EU for the prevention of RSV lower respiratory tract disease in new-borns and infants during their first RSV season. This recommendation precedes an anticipated regulatory submission acceptance for nirsevimab in the US in the fourth quarter of 2022. Sobi has the right to AstraZeneca's full share of US losses and profits for nirsevimab.

## Specialty Care

### Orfadin

During the quarter, Orfadin capsules and oral suspension were approved in Brazil by ANVISA, the Brazilian health authority. Orfadin was approved for the treatment of adult and paediatric patients with confirmed diagnosis of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

## Pipeline news flow

### Anticipated major upcoming pipeline news flow

<b>Fourth quarter 2022</b>	<p>loncastuximab tesirine – DLBCL: regulatory decision (EU)</p> <p>Kineret – COVID-19: regulatory decision, emergency use (US)</p> <p>nirsevimab – RSV prevention: regulatory submission acceptance (US) (by AstraZeneca/Sanofi)</p>
<b>First half 2023</b>	<p>efanesoctocog alfa – haemophilia A: regulatory decision (US)</p> <p>efanesoctocog alfa – haemophilia A (paediatric): XTEND-Kids phase 3 study data readout</p> <p>Doptelet – CLD<sup>b</sup>: regulatory decision (JP)</p> <p>Empaveli – PNH: regulatory decision (JP)</p> <p>Gamifant – MAS in rheumatological diseases: EMERALD phase 3 study data readout (Still's disease cohort)</p> <p>SEL-212 – CRG: phase 3 studies data readout</p>
<b>Second half 2023</b>	<p>efanesoctocog alfa – haemophilia A: regulatory submission (EU)</p> <p>Aspaveli/Empaveli – ALS<sup>c</sup>: MERIDIAN phase 2 study data readout (by Apellis in mid-2023)</p> <p>Kineret – FMF<sup>d</sup>: regulatory decision (CN)</p> <p>Kineret – Still's disease: regulatory decision (CN)</p> <p>Gamifant – MAS in rheumatological diseases: regulatory submission (Still's disease cohort) (US)</p> <p>SEL-212 – CRG: regulatory submission (US)</p>

<sup>b</sup> Chronic liver disease.

<sup>c</sup> Amyotrophic lateral sclerosis.

<sup>d</sup> Familial Mediterranean fever.

# Other information

## Business development

In September, Sobi and Asahi Kasei Pharma Co., Ltd. entered into an exclusive distribution agreement in Japan for Empaveli and Doptelet. Both medicines are currently under regulatory review for their first indication in the country. Sobi will continue development, medical, quality-control and safety-control activities while Asahi Kasei obtains exclusive distribution rights. During the period, Sobi Japan also obtained a wholesaler license from the Tokyo Metropolitan Government which will allow for the support of the future arrangements.

## 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 quarter, Sobi reached several milestones in the strive to expand access to medicine. In addition to the exclusive licensing agreement on loncastuximab tesirine, a first step towards providing further options for patients with certain debilitating diseases in haematology in the EU, UK and other Sobi countries, Orfadin Capsules and Orfadin Oral Suspension were approved in Brazil by ANVISA, the Brazilian health authority, making it easier for Orfadin to be reimbursed and enter tenders, thereby enabling greater access for patients with HT-1 in Brazil.

In conjunction with Still's Awareness Day, and for the third year in a row, Sobi supported patient organisation AiArthritis and their international effort to raise awareness of Still's disease. The support enabled the co-creation of patient videos, brochures and posters together with the patient community.

Responding to hurricane Ian, Sobi North America reached out to provide hurricane relief information to patients and caregivers, striving to bridge potential disruptions in prescribed medicines to patients. Sobi North America also proactively reached out to all employees to advise on precautions and available assistance.

Sobi continued to share knowledge within the scientific community at the International Society on Thrombosis and Haemostasis 2022 Congress, a key congress for haemophilia and idiopathic thrombocytopenic purpura (immune thrombocytopenia, ITP) this year.

Three annual investor scorecards were updated during the quarter. In the 2022 Standard & Poor Corporate Sustainability Assessment scorecard, Sobi gained four points in the overall score and improved its already strong performance in the Governance and Economic dimension by the same number of points. Furthermore, Sobi retained its good MSCI evaluation (A) and improved its score in Sustainability slightly to 20.4.

## The war in Ukraine

There are still uncertainties on how and to what extent Sobi's operations will be affected by the war in Ukraine. Sales in Russia were not material in the quarter. At the end of the quarter the provision for expected credit losses was SEK 106 M, unchanged since the previous quarter. Sobi maintains an office in Moscow with c. 45 colleagues and 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, 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, including the cost effects of the agreement to license the new medicine loncastuximab tesirine in haematology

This outlook currently excludes any potential elements of Sobi's right to AstraZeneca's full share of US losses and profits for nirsevimab.

## Financial calendar

Q4 2022 report	8 February 2023
Q1 2023 report	27 April 2023
Annual General Meeting	9 May 2023
Q2 2023 report	18 July 2023
Q3 2023 report	26 October 2023

## Forward-looking statements

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

This information is information that Sobi is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out in the press release concerning this report, at 08:00 CEST on 27 October 2022.

# Auditor's review report

## Introduction

We have reviewed the condensed interim report for Swedish Orphan Biovitrum AB (publ) as of 30 September 2022 and for the nine-month period then ended. The Board of Directors and the Chief Executive Officer 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, 27 October 2022

Ernst & Young AB

Jonatan Hansson

Authorised Public Accountant

# Financial statements – Group

## Consolidated statements of comprehensive income

SEK M	Q3 2022	Q3 2021	Jan-Sep 2022	Jan-Sep 2021	Full-Year 2021
Total revenue	3,999	3,761	12,800	10,633	15,529
Cost of goods sold	-932	-959	-3,468	-2,468	-3,484
<b>Gross profit</b>	<b>3,067</b>	<b>2,802</b>	<b>9,332</b>	<b>8,165</b>	<b>12,045</b>
Selling and administrative expenses <sup>1</sup>	-1,834	-1,571	-5,726	-4,470	-6,294
Research and development expenses	-526	-485	-1,711	-1,440	-1,994
Other operating income/expenses	-8	-38	3	-47	-24
<b>Operating profit</b>	<b>699</b>	<b>708</b>	<b>1,897</b>	<b>2,208</b>	<b>3,733</b>
Net financial items <sup>2</sup>	-135	-109	-342	-336	-438
<b>Profit before tax</b>	<b>564</b>	<b>598</b>	<b>1,555</b>	<b>1,872</b>	<b>3,295</b>
Income tax	-113	-125	-303	-434	-616
<b>Profit for the period</b>	<b>451</b>	<b>473</b>	<b>1,252</b>	<b>1,438</b>	<b>2,679</b>
<i>All profit are attributable to Parent Company shareholders</i>					
<b>Other comprehensive income</b>					
<i>Items that will not be reclassified into profit or loss</i>					
Remeasurements on defined-benefit pension plans and similar plans (net of tax)	-1	-2	67	6	17
Remeasurement of equity instruments (net of tax)	17	4	-41	8	11
<b>Total</b>	<b>16</b>	<b>1</b>	<b>26</b>	<b>14</b>	<b>28</b>
<i>Items that may be reclassified into profit or loss</i>					
Translation differences	459	145	1,030	211	464
Net investment hedges (net of tax)	-264	-78	-585	-167	-242
Cash flow hedges (net of tax)	-18	-22	-80	-56	-63
<b>Total</b>	<b>177</b>	<b>45</b>	<b>365</b>	<b>-11</b>	<b>159</b>
<b>Other comprehensive income</b>	<b>193</b>	<b>46</b>	<b>392</b>	<b>2</b>	<b>187</b>
<b>Total comprehensive income for the period</b>	<b>645</b>	<b>519</b>	<b>1,644</b>	<b>1,440</b>	<b>2,866</b>
<i>All comprehensive income is attributable to Parent Company shareholders</i>					
<b>Earnings per share, SEK</b>					
EPS before dilution	1.52	1.60	4.24	4.87	9.08
EPS before dilution adjusted <sup>3</sup>	1.52	1.60	6.08	4.87	9.08
EPS after dilution	1.51	1.59	4.20	4.85	9.03
EPS after dilution adjusted <sup>3</sup>	1.51	1.59	6.02	4.85	9.03
<sup>1</sup> Amortisation and impairment of intangible assets included in Selling and administrative expenses.	-542	-459	-1,578	-1,364	-1,841
<sup>2</sup> Including financing costs.	-6	-9	-21	-27	-35
<sup>3</sup> APMs, see page 23 for further information.					

## Consolidated balance sheet

SEK M	Sep 2022	Dec 2021	Sep 2021
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets <sup>1</sup>	41,493	38,424	38,181
Tangible assets	309	493	481
Financial assets	158	199	189
Deferred tax assets	874	767	489
<b>Total non-current assets</b>	<b>42,834</b>	<b>39,883</b>	<b>39,340</b>
<b>Current assets</b>			
Inventories	3,308	3,424	3,215
Accounts receivable	3,248	3,439	3,085
Other receivables, non-interest bearing	1,255	870	881
Cash and cash equivalents	288	1,045	212
<b>Total current assets</b>	<b>8,099</b>	<b>8,778</b>	<b>7,392</b>
<b>Total assets</b>	<b>50,933</b>	<b>48,661</b>	<b>46,733</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>	<b>25,065</b>	<b>23,203</b>	<b>21,743</b>
<b>Non-current liabilities</b>			
Borrowings	8,133	8,777	9,303
Deferred tax liabilities	3,775	3,605	3,448
Lease liabilities	225	247	260
Other liabilities, non-interest bearing	4,563	4,068	4,069
<b>Total non-current liabilities</b>	<b>16,695</b>	<b>16,697</b>	<b>17,080</b>
<b>Current liabilities</b>			
Borrowings	1,689	1,768	2,040
Accounts payable	361	558	795
Lease liabilities	136	114	114
Other liabilities, non-interest bearing	6,987	6,321	4,962
<b>Total current liabilities</b>	<b>9,173</b>	<b>8,761</b>	<b>7,910</b>
<b>Total equity and liabilities</b>	<b>50,933</b>	<b>48,661</b>	<b>46,733</b>

<sup>1</sup>Including goodwill of SEK 7,304 M (SEK 6,288 M on 31 December 2021).

## Changes in equity

SEK M	Jan-Sep 2022	Full-year 2021	Jan-Sep 2021
<b>Opening balance</b>	<b>23,203</b>	<b>20,206</b>	<b>20,206</b>
Share-based compensation to employees	215	134	93
Tax deductions for share programmes <sup>1</sup>	4	-3	4
Total comprehensive income for the period <sup>2</sup>	1,644	2,866	1,440
<b>Closing balance</b>	<b>25,065</b>	<b>23,203</b>	<b>21,743</b>

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

<sup>2</sup>Whereof changes in cash flow hedges (net of tax) amounted to SEK -80 M (SEK -63 M on 31 December 2021) and net investment hedges (net of tax) amounted to SEK -585 M (SEK -242 M on 31 December 2021).

## Consolidated cash flow statement

SEK M	Q3 2022	Q3 2021	Jan-Sep 2022	Jan-Sep 2021	Full-year 2021
Profit before tax	564	598	1,555	1,872	3,295
Amortisation, depreciation and impairment	579	494	1,829	1,470	2,006
Other, including non-cash items <sup>1</sup>	90	35	434	104	179
Income tax paid	-157	-149	-546	-945	-1,124
<b>Cash flow from operating activities before change in working capital</b>	<b>1,076</b>	<b>978</b>	<b>3,271</b>	<b>2,500</b>	<b>4,356</b>
Changes in working capital	-296	-721	-505	849	1,114
<b>Cash flow from operating activities</b>	<b>780</b>	<b>257</b>	<b>2,767</b>	<b>3,349</b>	<b>5,470</b>
Investment in intangible assets <sup>2</sup>	-711	-15	-1,388	-110	-323
Investment in tangible assets	-13	-3	-26	-15	-47
Disposal of tangible assets	-	1	-	3	3
<b>Cash flow from investing activities</b>	<b>-724</b>	<b>-17</b>	<b>-1,414</b>	<b>-122</b>	<b>-367</b>
Borrowings/repayments of borrowings	160	-226	-1,376	-3,105	-3,998
Hedging arrangement for financing	-304	-7	-742	-230	-351
Repayment of leasing	-30	-32	-97	-93	-125
<b>Cash flow from financing activities</b>	<b>-174</b>	<b>-264</b>	<b>-2,215</b>	<b>-3,427</b>	<b>-4,474</b>
<b>Change in cash and cash equivalents</b>	<b>-118</b>	<b>-24</b>	<b>-862</b>	<b>-200</b>	<b>629</b>
Cash and cash equivalents at the beginning of the period	360	233	1,045	404	404
Translation difference in cash flow and cash and cash equivalents	46	3	106	7	12
<b>Cash and cash equivalents at the end of the period</b>	<b>288</b>	<b>212</b>	<b>288</b>	<b>212</b>	<b>1,045</b>

<sup>1</sup>2022 refers mainly to restructuring costs and provision for expected credit losses in Russia.

<sup>2</sup>2022 investments mainly refer to milestone payments linked to Aspaveli/Empaveli, Doptelet and SEL-212 and an upfront payment to ADC Therapeutics for loncastuximab tesirine.



## Key ratios and other information

SEK M	Q3 2022	Q3 2021	Jan-Sep 2022	Jan-Sep 2021	Full-year 2021
<b>Profit measures</b>					
Gross profit	3,067	2,802	9,332	8,165	12,045
Gross profit adjusted <sup>1,2</sup>	3,067	2,802	9,695	8,165	12,045
EBITDA <sup>1</sup>	1,278	1,202	3,726	3,678	5,740
EBITDA adjusted <sup>1,2</sup>	1,278	1,202	4,265	3,678	5,740
EBITA <sup>1</sup>	1,241	1,166	3,475	3,572	5,575
EBITA adjusted <sup>1,2</sup>	1,241	1,166	4,150	3,572	5,575
EBIT	699	708	1,897	2,208	3,733
EBIT adjusted <sup>1,2</sup>	699	708	2,572	2,208	3,733
Profit for the period	451	473	1,252	1,438	2,679
Profit for the period adjusted <sup>1,2</sup>	451	473	1,797	1,438	2,679
<b>Per share data (SEK)</b>					
EPS before dilution	1.52	1.60	4.24	4.87	9.08
EPS before dilution adjusted <sup>1,2</sup>	1.52	1.60	6.08	4.87	9.08
EPS after dilution	1.51	1.59	4.20	4.85	9.03
EPS after dilution adjusted <sup>1,2</sup>	1.51	1.59	6.02	4.85	9.03
Shareholders' equity per share <sup>1</sup>	80.9	70.8	80.9	70.8	75.6
Shareholders' equity per share after dilution <sup>1</sup>	80.2	70.5	80.2	70.5	75.1
<b>Other information</b>					
Gross margin <sup>1</sup>	77%	75%	73%	77%	78%
Gross margin adjusted <sup>1,2</sup>	77%	75%	76%	77%	78%
EBITA margin <sup>1</sup>	31%	31%	27%	34%	36%
EBITA margin adjusted <sup>1,2</sup>	31%	31%	32%	34%	36%
Equity ratio <sup>1</sup>	49%	47%	49%	47%	48%
Net debt <sup>1</sup>	9,533	11,131	9,533	11,131	9,500
Number of ordinary shares <sup>3</sup>	309,804,782	307,114,495	309,804,782	307,114,495	307,114,495
Number of ordinary shares (in treasury)	13,813,835	11,969,866	13,813,835	11,969,866	11,959,198
Number of ordinary shares (ex shares in treasury)	295,990,947	295,144,629	295,990,947	295,144,629	295,155,297
Number of ordinary shares after dilution	312,593,949	308,624,353	312,593,949	308,624,353	308,862,835
Average number of ordinary shares (ex shares in treasury)	295,932,119	295,144,629	295,471,898	295,017,887	295,051,119
Average number of ordinary shares after dilution (ex shares in treasury)	298,721,286	296,654,487	298,261,065	296,527,745	296,799,459

<sup>1</sup>APMs, see page 23 for further information.

<sup>2</sup>Items affecting comparability in 2022, see page 3 for further information.

<sup>3</sup>The increase in the number of shares results from an issue of 2,690,287 shares for the purpose of ensuring fulfilment of commitments under incentive programmes, offset by allotment of shares for the programmes expired.

# Financial statements – Parent Company

## Income statement

SEK M	Q3 2022	Q3 2021	Jan-Sep 2022	Jan-Sep 2021	Full-year 2021
Total revenue	3,083	2,627	8,821	7,370	12,401
Cost of goods sold	-738	-720	-2,568	-1,969	-2,933
<b>Gross profit</b>	<b>2,345</b>	<b>1,907</b>	<b>6,254</b>	<b>5,401</b>	<b>9,468</b>
Selling and administrative expenses <sup>1</sup>	-775	-736	-3,400	-2,350	-4,179
Research and development expenses	-385	-319	-1,143	-908	-1,256
Other operating income/expenses	69	118	250	246	350
<b>Operating profit</b>	<b>1,254</b>	<b>970</b>	<b>1,960</b>	<b>2,389</b>	<b>4,383</b>
Net financial items	-318	-173	-737	-291	-392
<b>Profit after financial items</b>	<b>936</b>	<b>797</b>	<b>1,223</b>	<b>2,098</b>	<b>3,991</b>
Appropriations	–	–	–	–	-1,713
<b>Profit before tax</b>	<b>936</b>	<b>797</b>	<b>1,223</b>	<b>2,098</b>	<b>2,278</b>
Income tax	-58	-36	-39	-212	-488
<b>Profit for the period</b>	<b>878</b>	<b>761</b>	<b>1,184</b>	<b>1,886</b>	<b>1,790</b>
<sup>1</sup> Amortisation and impairment of intangible assets included in Selling and administrative expenses.	-138	-87	-397	-257	-359

## Statement of comprehensive income

SEK M	Q3 2022	Q3 2021	Jan-Sep 2022	Jan-Sep 2021	Full-year 2021
Profit for the period	878	761	1,184	1,886	1,790
<i>Items that will not be reclassified into profit or loss</i>					
Remeasurement of equity instruments (net of tax)	17	4	-41	8	11
<i>Items that may be reclassified into profit or loss</i>					
Cash flow hedges (net of tax)	-18	-22	-80	-56	-63
<b>Other comprehensive income</b>	<b>-1</b>	<b>-17</b>	<b>-121</b>	<b>-48</b>	<b>-52</b>
<b>Total comprehensive income for the period</b>	<b>877</b>	<b>744</b>	<b>1,063</b>	<b>1,838</b>	<b>1,738</b>

## Balance sheet

SEK M	Sep 2022	Dec 2021	Sep 2021
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	11,407	10,107	9,981
Tangible assets	43	89	55
Financial assets	21,822	22,164	23,248
Deferred tax assets	134	27	36
<b>Total non-current assets</b>	<b>33,406</b>	<b>32,387</b>	<b>33,320</b>
<b>Current assets</b>			
Inventories	2,434	2,536	2,576
Accounts receivable	782	1,126	821
Receivables Group companies	5,090	4,308	3,330
Other receivables, non-interest bearing	1,041	747	757
Cash and cash equivalents	125	878	61
<b>Total current assets</b>	<b>9,473</b>	<b>9,595</b>	<b>7,545</b>
<b>Total assets</b>	<b>42,879</b>	<b>41,982</b>	<b>40,865</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>	<b>20,351</b>	<b>19,069</b>	<b>19,134</b>
Untaxed reserves	3,691	3,691	3,091
<b>Non-current liabilities</b>			
Borrowings	8,133	8,777	9,303
Other liabilities, non-interest bearing	3,991	2,897	2,800
<b>Total non-current liabilities</b>	<b>12,123</b>	<b>11,674</b>	<b>12,103</b>
<b>Current liabilities</b>			
Borrowings	1,689	1,768	2,040
Accounts payable	224	359	335
Liabilities Group companies	1,844	3,229	2,408
Other liabilities, non-interest bearing	2,957	2,192	1,754
<b>Total current liabilities</b>	<b>6,714</b>	<b>7,548</b>	<b>6,537</b>
<b>Total equity and liabilities</b>	<b>42,879</b>	<b>41,982</b>	<b>40,865</b>

## Change in shareholders' equity

SEK M	Jan-Sep 2022	Full-year 2021	Jan-Sep 2021
<b>Opening balance</b>	<b>19,069</b>	<b>17,200</b>	<b>17,200</b>
Share-based compensation to employees	215	134	93
Tax deductions for share programmes <sup>1</sup>	4	-3	4
Total comprehensive income for the period <sup>2</sup>	1,063	1,738	1,838
<b>Closing balance</b>	<b>20,351</b>	<b>19,069</b>	<b>19,134</b>

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

<sup>2</sup>Whereof changes in cash flow hedges (net of tax) amounted to SEK -80 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 Annual and Sustainability Report 2021. IASB has published amendments of standards that were effective as of 1 January 2022 or later. These have not had any material impact on the consolidated financial statements.

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

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

## Note 2 | Segment reporting

### SEK M

Q3 2022	Haematology	Immunology	Specialty Care	Group - other <sup>4</sup>	Total
Total revenue	2,619	1,070	310	–	3,999
EBITA <sup>1</sup>	1,194	106	90	-150	1,241
EBITA adjusted <sup>1</sup>	1,194	106	90	-150	1,241
Amortisation	-220	-262	-41	-19	-542
EBIT	974	-156	49	-169	699

Q3 2021	Haematology	Immunology	Specialty Care	Group - other <sup>4</sup>	Total
Total revenue	2,291	1,144	326	–	3,761
EBITA <sup>1</sup>	998	244	118	-194	1,166
EBITA adjusted <sup>1</sup>	998	244	118	-194	1,166
Amortisation	-155	-252	-40	-12	-459
EBIT	843	-8	78	-206	708

Jan-Sep 2022	Haematology	Immunology	Specialty Care	Group - other <sup>4</sup>	Total
Total revenue	7,806	4,036	957	–	12,800
EBITA <sup>1</sup>	3,001	789	235	-551	3,475
EBITA adjusted <sup>1,2,3</sup>	3,363	896	235	-344	4,150
Amortisation	-634	-777	-121	-45	-1,578
EBIT	2,367	12	114	-596	1,897

Jan-Sep 2021	Haematology	Immunology	Specialty Care	Group - other <sup>4</sup>	Total
Total revenue	6,294	3,450	890	–	10,633
EBITA <sup>1</sup>	2,810	908	293	-438	3,572
EBITA adjusted <sup>1</sup>	2,810	908	293	-438	3,572
Amortisation	-457	-754	-118	-35	-1,364
EBIT	2,353	153	175	-473	2,208

Full-year 2021	Haematology	Immunology	Specialty Care	Group - other <sup>4</sup>	Total
Total revenue	8,536	5,780	1,213	–	15,529
EBITA <sup>1</sup>	3,698	2,054	388	-566	5,575
EBITA adjusted <sup>1</sup>	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.

<sup>1</sup>APMs, see page 23 for further information.

<sup>2</sup>Items affecting comparability in 2022, see page 3 for further information.

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

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

## Note 3 | Fair value of financial instruments

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

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

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

<b>Q3 2022</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<i>Financial assets and liabilities measured at fair value through profit or loss</i>				
Derivatives held for trading	–	-240	–	<b>-240</b>
Endowment policies	–	–	50	<b>50</b>
<i>Financial assets measured at fair value through other comprehensive income</i>				
Equity instruments	99	–	–	<b>99</b>
<b>Total</b>	<b>99</b>	<b>-240</b>	<b>50</b>	<b>-91</b>
<b>Q3 2021</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<i>Financial assets and liabilities measured at fair value through profit or loss</i>				
Derivatives held for trading	–	-14	–	<b>-14</b>
Endowment policies	–	–	44	<b>44</b>
<i>Financial assets measured at fair value through other comprehensive income</i>				
Equity instruments	141	–	–	<b>141</b>
<b>Total</b>	<b>141</b>	<b>-14</b>	<b>44</b>	<b>171</b>
<b>Full-year 2021</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<i>Financial assets and liabilities measured at fair value through profit or loss</i>				
Derivatives held for trading	–	1	–	<b>1</b>
Endowment policies	–	–	45	<b>45</b>
<i>Financial assets measured at fair value through other comprehensive income</i>				
Equity instruments	145	–	–	<b>145</b>
<b>Total</b>	<b>145</b>	<b>1</b>	<b>45</b>	<b>191</b>

## 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.

Q3 2022	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
<b>Haematology</b>					
Elocta	1,041	-53	988	1,035	-5%
Alprolix	464	-24	441	430	2%
Royalty	377	-74	303	315	-4%
Doptelet	543	-95	449	400	12%
Aspaveli/Empaveli	49	-3	46	–	n/a
Manufacturing	145	–	145	110	31%
<b>Total</b>	<b>2,619</b>	<b>-248</b>	<b>2,371</b>	<b>2,291</b>	<b>3%</b>
<b>Immunology</b>					
Kineret	542	-79	463	516	-10%
Synagis	327	-66	260	374	-30%
Gamifant	202	-38	164	255	-36%
<b>Total</b>	<b>1,070</b>	<b>-183</b>	<b>887</b>	<b>1,144</b>	<b>-22%</b>
<b>Specialty Care</b>	<b>310</b>	<b>-36</b>	<b>273</b>	<b>326</b>	<b>-16%</b>
<b>Total</b>	<b>3,999</b>	<b>-467</b>	<b>3,532</b>	<b>3,761</b>	<b>-6%</b>

Q3 2021	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
<b>Haematology</b>					
Elocta	1,035	14	1,049	1,115	-6%
Alprolix	430	3	433	435	0%
Royalty	315	10	325	314	3%
Doptelet	400	15	415	145	187%
Manufacturing	110	–	110	138	-20%
<b>Total</b>	<b>2,291</b>	<b>42</b>	<b>2,333</b>	<b>2,147</b>	<b>9%</b>
<b>Immunology</b>					
Kineret	516	7	523	463	13%
Synagis	374	13	386	46	739%
Gamifant	255	9	263	110	139%
<b>Total</b>	<b>1,144</b>	<b>29</b>	<b>1,173</b>	<b>619</b>	<b>89%</b>
<b>Specialty Care</b>	<b>326</b>	<b>7</b>	<b>333</b>	<b>204</b>	<b>63%</b>
<b>Total</b>	<b>3,761</b>	<b>78</b>	<b>3,839</b>	<b>2,970</b>	<b>29%</b>

Jan-Sep 2022	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
<b>Haematology</b>					
Elocta	3,173	-141	3,032	2,896	5%
Alprolix	1,351	-64	1,287	1,281	0%
Royalty	1,086	-171	915	934	-2%
Doptelet	1,754	-256	1,498	810	85%
Aspaveli/Empaveli	91	-7	84	–	n/a
Manufacturing	351	–	351	373	-6%
<b>Total</b>	<b>7,806</b>	<b>-639</b>	<b>7,167</b>	<b>6,294</b>	<b>14%</b>
<b>Immunology</b>					
Kineret	1,731	-181	1,551	1,608	-4%
Synagis	1,652	-215	1,436	1,286	12%
Gamifant	653	-98	556	556	0%
<b>Total</b>	<b>4,036</b>	<b>-493</b>	<b>3,543</b>	<b>3,450</b>	<b>3%</b>
<b>Specialty Care</b>	<b>957</b>	<b>-86</b>	<b>871</b>	<b>890</b>	<b>-2%</b>
<b>Total</b>	<b>12,800</b>	<b>-1,219</b>	<b>11,581</b>	<b>10,633</b>	<b>9%</b>

Jan-Sep 2021	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
<b>Haematology</b>					
Elocta	2,896	119	3,015	3,514	-14%
Alprolix	1,281	50	1,331	1,286	4%
Royalty	934	98	1,032	985	5%
Doptelet	810	82	892	396	126%
Manufacturing	373	–	373	398	-6%
<b>Total</b>	<b>6,294</b>	<b>350</b>	<b>6,644</b>	<b>6,578</b>	<b>1%</b>
<b>Immunology</b>					
Kineret	1,608	118	1,726	1,493	16%
Synagis	1,286	171	1,457	1,294	13%
Gamifant	556	60	615	346	78%
<b>Total</b>	<b>3,450</b>	<b>349</b>	<b>3,798</b>	<b>3,133</b>	<b>21%</b>
<b>Specialty Care</b>	<b>890</b>	<b>65</b>	<b>954</b>	<b>968</b>	<b>-1%</b>
<b>Total</b>	<b>10,633</b>	<b>763</b>	<b>11,396</b>	<b>10,680</b>	<b>7%</b>

Full-year 2021	Total revenue	FX impact	Total revenue, adjusted for FX impact	Total revenue, comparable period	Change at CER
<b>Haematology</b>					
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%
<b>Total</b>	<b>8,536</b>	<b>361</b>	<b>8,898</b>	<b>8,660</b>	<b>3%</b>
<b>Immunology</b>					
Kineret	2,290	116	2,406	2,079	16%
Synagis	2,650	249	2,899	2,726	6%
Gamifant	840	61	901	609	48%
<b>Total</b>	<b>5,780</b>	<b>427</b>	<b>6,207</b>	<b>5,415</b>	<b>15%</b>
<b>Specialty Care</b>	<b>1,213</b>	<b>66</b>	<b>1,279</b>	<b>1,186</b>	<b>8%</b>
<b>Total</b>	<b>15,529</b>	<b>854</b>	<b>16,384</b>	<b>15,261</b>	<b>7%</b>



### 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	Q3 2022	Q3 2021	Jan-Sep 2022	Jan-sep 2021	Full-year 2021
Total revenue	3,999	3,761	12,800	10,633	15,529
Total cost of goods sold	-932	-959	-3,468	-2,468	-3,484
<b>Gross profit</b>	<b>3,067</b>	<b>2,802</b>	<b>9,332</b>	<b>8,165</b>	<b>12,045</b>
<b>Gross margin</b>	<b>77%</b>	<b>75%</b>	<b>73%</b>	<b>77%</b>	<b>78%</b>
Items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	-	-	-363	-	-
<b>Items affecting comparability<sup>1</sup></b>	<b>-</b>	<b>-</b>	<b>-363</b>	<b>-</b>	<b>-</b>
<b>Gross profit adjusted</b>	<b>3,067</b>	<b>2,802</b>	<b>9,695</b>	<b>8,165</b>	<b>12,045</b>
<b>Gross margin adjusted</b>	<b>77%</b>	<b>75%</b>	<b>76%</b>	<b>77%</b>	<b>78%</b>
<b>EBIT<sup>2</sup></b>	<b>699</b>	<b>708</b>	<b>1,897</b>	<b>2,208</b>	<b>3,733</b>
Items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	-	-	-363	-	-
-Consolidation of sites	-	-	-72	-	-
-Efficiency programmes	-	-	-134	-	-
-Other:					
-Provision for expected credit losses in Russia	-	-	-106	-	-
<b>Items affecting comparability</b>	<b>-</b>	<b>-</b>	<b>-675</b>	<b>-</b>	<b>-</b>
<b>EBIT adjusted</b>	<b>699</b>	<b>708</b>	<b>2,572</b>	<b>2,208</b>	<b>3,733</b>

### 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 <sup>2</sup>	699	708	1,897	2,208	3,733
Plus amortisation and impairment of intangible assets	542	459	1,578	1,364	1,841
<b>EBITA<sup>2</sup></b>	<b>1,241</b>	<b>1,166</b>	<b>3,475</b>	<b>3,572</b>	<b>5,575</b>
<b>EBITA margin</b>	<b>31%</b>	<b>31%</b>	<b>27%</b>	<b>34%</b>	<b>36%</b>

<sup>1</sup>Items affecting comparability in 2022, see page 3 for further information.

<sup>2</sup>For EBIT and EBITA per segment see Note 2.

SEK M	Q3 2022	Q3 2021	Jan-Sep 2022	Jan-Sep 2021	Full-year 2021
Items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	–	–	-363	–	–
-Consolidation of sites	–	–	-72	–	–
-Efficiency programmes	–	–	-134	–	–
-Other:					
-Provision for expected credit losses in Russia	–	–	-106	–	–
<b>Items affecting comparability</b>	<b>–</b>	<b>–</b>	<b>-675</b>	<b>–</b>	<b>–</b>
<b>EBITA adjusted</b>	<b>1,241</b>	<b>1,166</b>	<b>4,150</b>	<b>3,572</b>	<b>5,575</b>
<b>EBITA margin adjusted</b>	<b>31%</b>	<b>31%</b>	<b>32%</b>	<b>34%</b>	<b>36%</b>

#### 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	1,241	1,166	3,475	3,572	5,575
Plus depreciation and impairment of tangible assets	36	35	251	106	165
<b>EBITDA</b>	<b>1,278</b>	<b>1,202</b>	<b>3,726</b>	<b>3,678</b>	<b>5,740</b>
Items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	–	–	-239	–	–
-Consolidation of sites	–	–	-60	–	–
-Efficiency programmes	–	–	-134	–	–
-Other:					
-Provision for expected credit losses in Russia	–	–	-106	–	–
<b>Items affecting comparability<sup>1</sup></b>	<b>–</b>	<b>–</b>	<b>-539</b>	<b>–</b>	<b>–</b>
<b>EBITDA adjusted</b>	<b>1,278</b>	<b>1,202</b>	<b>4,265</b>	<b>3,678</b>	<b>5,740</b>

#### 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	451	473	1,252	1,438	2,679
Items affecting comparability	–	–	-675	–	–
Tax on items affecting comparability					
-Restructuring costs:					
-Discontinuation of contract manufacturing	–	–	75	–	–
-Consolidation of sites	–	–	6	–	–
-Efficiency programmes	–	–	28	–	–
-Other:					
-Provision for expected credit losses in Russia	–	–	22	–	–
Tax on items affecting comparability	–	–	130	–	–
Items affecting comparability (net of tax)	–	–	-545	–	–
<b>Profit for the period adjusted</b>	<b>451</b>	<b>473</b>	<b>1,797</b>	<b>1,438</b>	<b>2,679</b>
Average number of ordinary shares (excluding shares in treasury)	295,932,119	295,144,629	295,471,898	295,017,887	295,051,119
Average number of ordinary shares after dilution (excluding shares in treasury)	298,721,286	296,654,487	298,261,065	296,527,745	296,799,459
<b>EPS before dilution, SEK adjusted</b>	<b>1.52</b>	<b>1.60</b>	<b>6.08</b>	<b>4.87</b>	<b>9.08</b>
<b>EPS after dilution, SEK adjusted</b>	<b>1.51</b>	<b>1.59</b>	<b>6.02</b>	<b>4.85</b>	<b>9.03</b>

<sup>1</sup>Items 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	Q3 2022	Q3 2021	Jan-Sep 2022	Jan-Sep 2021	Full-year 2021
Borrowings	9,821	11,343	9,821	11,343	10,545
Cash and cash equivalents	288	212	288	212	1,045
<b>Net debt</b>	<b>9,533</b>	<b>11,131</b>	<b>9,533</b>	<b>11,131</b>	<b>9,500</b>

**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	25,065	21,743	25,065	21,743	23,203
Total assets	50,933	46,733	50,933	46,733	48,661
<b>Equity ratio</b>	<b>49%</b>	<b>47%</b>	<b>49%</b>	<b>47%</b>	<b>48%</b>
Number of ordinary shares	309,804,782	307,114,495	309,804,782	307,114,495	307,114,495
Number of ordinary shares after dilution	312,593,949	308,624,353	312,593,949	308,624,353	308,862,835
<b>Equity per share, SEK</b>	<b>80.9</b>	<b>70.8</b>	<b>80.9</b>	<b>70.8</b>	<b>75.6</b>
<b>Equity per share after dilution, SEK</b>	<b>80.2</b>	<b>70.5</b>	<b>80.2</b>	<b>70.5</b>	<b>75.1</b>

# 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.

## Cold agglutinin disease, CAD

A serious and chronic type of autoimmune haemolytic anaemia characterised by chronic anaemia, profound fatigue, acute haemolytic crises, and other potential complications, including an increased risk of life-threatening thromboembolic events such as stroke.

## Diffuse large B-cell lymphoma, DLBCL

An aggressive, malignant disease in haematology with an incidence in Europe of approximately 4 cases per 100,000 adults per year. As many as 40 per cent of all patients with DLBCL will need at least a 2nd-line treatment as their disease is relapsing or refractory. For those patients, effective treatment options are limited, representing a critical unmet need.

## 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

	<p>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.</p>
<b>Kineret (anakinra)</b>	<p>A recombinant protein medicine that blocks the biological activity of interleukin-1<math>\alpha</math> and <math>\beta</math> (IL-1<math>\alpha</math> and IL-1<math>\beta</math>) 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.</p>
<b>Launch medicines</b>	<p>Include Doptelet (outside China), Aspaveli/Empaveli and Gamifant.</p>
<b>Loncastuximab tesirine</b>	<p>A CD19-directed antibody drug conjugate. Once bound to a CD19-expressing cell, loncastuximab tesirine is internalised by the cell, where enzymes release a pyrrolobenzodiazepine payload. The potent payload binds to DNA minor groove with little distortion, remaining less visible to DNA repair mechanisms. This ultimately results in cell cycle arrest and tumour cell death.</p>
<b>Nirsevimab</b>	<p>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.</p>
<b>Orfadin (nitisinone)</b>	<p>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.</p>
<b>Paroxysmal nocturnal haemoglobinuria, PNH</b>	<p>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.</p>
<b>Primary haemophagocytic lymphohistiocytosis, pHLH</b>	<p>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.</p>
<b>Respiratory syncytial virus, RSV</b>	<p>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.</p>
<b>SEL-212</b>	<p>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.</p>
<b>Synagis (palivizumab)</b>	<p>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.</p>
<b>Tegsedi (inotersen)</b>	<p>A medicine for the treatment of polyneuropathy of hereditary transthyretin amyloidosis in adults.</p>

**Waylivra (volanesorsen)**

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

Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Providing sustainable access to innovative medicines in the areas of haematology, immunology and specialty care, Sobi has approximately 1,600 employees across Europe, North America, the Middle East and Asia. In 2021, revenue amounted to SEK 15.5 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at [sobi.com](https://sobi.com), [LinkedIn](#) and [YouTube](#).



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