

# Q3 2022 report

Conference call for  
investors and analysts

rare **strength**



27 October 2022



## Forward-looking statements

In order to utilise the 'Safe Harbor' provisions of the United States Private Securities Litigation Reform Act of 1995, Swedish Orphan Biovitrum AB (publ) (Sobi®) is providing the following cautionary statement: This presentation contains forward-looking statements with respect to the financial condition, results of operations and businesses of Sobi. By their nature, forward-looking statements and forecasts involve risk and uncertainty because they relate to events and depend on circumstances that will occur in the future. There are a number of factors that could cause actual results and developments to differ materially from that expressed or implied by these forward-looking statements. These factors include, among other things, the loss or expiration of patents, marketing exclusivity or trade marks; exchange rate fluctuations; the risk that R&D will not yield new products that achieve commercial success; the impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any failure by third parties to supply materials or services; the risk of delay to new product launches; the difficulties of obtaining and maintaining governmental approvals for products; the risk of failure to observe ongoing regulatory oversight; the risk that new products do not perform as we expect; and the risk of environmental liabilities.

# Agenda and presenters

Overview and business



Guido Oelkers, Chief Executive Officer

Financials



Henrik Stenqvist, Chief Financial Officer

Pipeline



Anders Ullman, Head of RDMA<sup>1</sup>, Chief Medical Officer

Summary and Q&A

All

# Overview: sustained progress

- **Revenue** -6% in Q3 due to high base; **+9% YTD**, fully underpinning 2022 outlook
- **Commercial execution** with launch medicines<sup>1</sup> +22% in Q3  
Haemophilia continued relative stability, strong Doptelet®, Aspaveli® launch progressed; Immunology had a large element of COVID-19 y-o-y comparison

- Investment for growth: Selling expenses slightly up; R&D/Medical slightly down
- **EBITA margin 31%**

- **Pipeline progressed** with the first efanesoctocog alfa regulatory submission and US priority review. Further progress with loncastuximab tesirine and Kineret® in China
- **Increased pipeline news flow in 2023**

- **2022 outlook unchanged**

**Strategy on track:**

**Continued solid performance in 2022  
with delivery on the strategic agenda**

Change at constant exchange rates.

1. Launch medicines include Doptelet (outside China), Aspaveli and Gamifant®.



# Business: growth driven by Doptelet in Haematology and by Europe

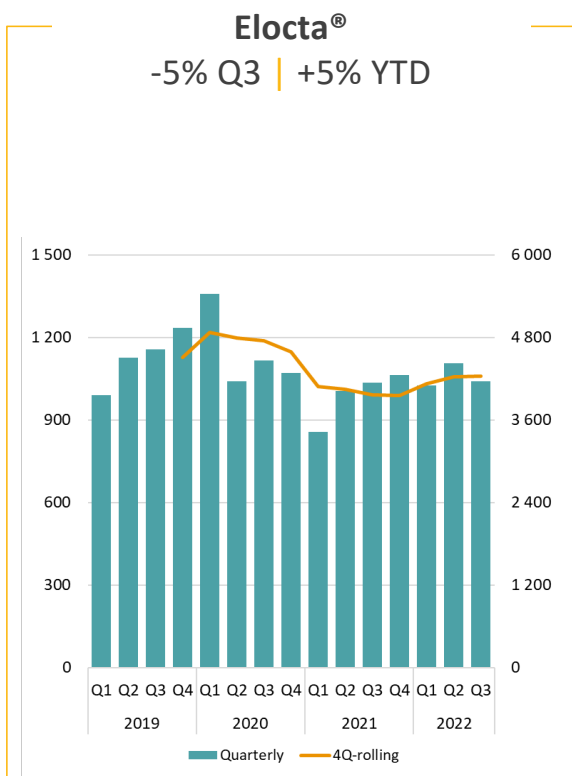
|                       | Q3 '22       | change    | ratio      | YTD'22        | change   | ratio      |
|-----------------------|--------------|-----------|------------|---------------|----------|------------|
|                       | SEK M        | %         | %          | SEK M         | %        | %          |
| <b>Haematology</b>    | 2,619        | 3         | 65         | 7,806         | 14       | 61         |
| <b>– Haemophilia</b>  | 1,882        | -3        | 47         | 5,610         | 2        | 44         |
| <b>Immunology</b>     | 1,070        | -22       | 27         | 4,036         | 3        | 32         |
| <b>Specialty Care</b> | 310          | -16       | 8          | 957           | -2       | 7          |
| <b>Total</b>          | <b>3,999</b> | <b>-6</b> | <b>100</b> | <b>12,800</b> | <b>9</b> | <b>100</b> |

|                          | Q3 '22       | change    | ratio      | YTD'22        | change   | ratio      |
|--------------------------|--------------|-----------|------------|---------------|----------|------------|
|                          | SEK M        | %         | %          | SEK M         | %        | %          |
| <b>Europe</b>            | 1,912        | 3         | 48         | 5,608         | 4        | 44         |
| <b>North America</b>     | 1,373        | -8        | 35         | 4,562         | 13       | 36         |
| <b>Rest of world</b>     | 337          | -37       | 8          | 1,544         | 32       | 12         |
| <b>Other<sup>1</sup></b> | 377          | -4        | 9          | 1,086         | -2       | 8          |
| <b>Total</b>             | <b>3,999</b> | <b>-6</b> | <b>100</b> | <b>12,800</b> | <b>9</b> | <b>100</b> |

Revenue at actual exchange rates; change at constant exchange rates (by segment and geographic area).

1. Royalty revenue.

# Haematology: haemophilia continued relative stability



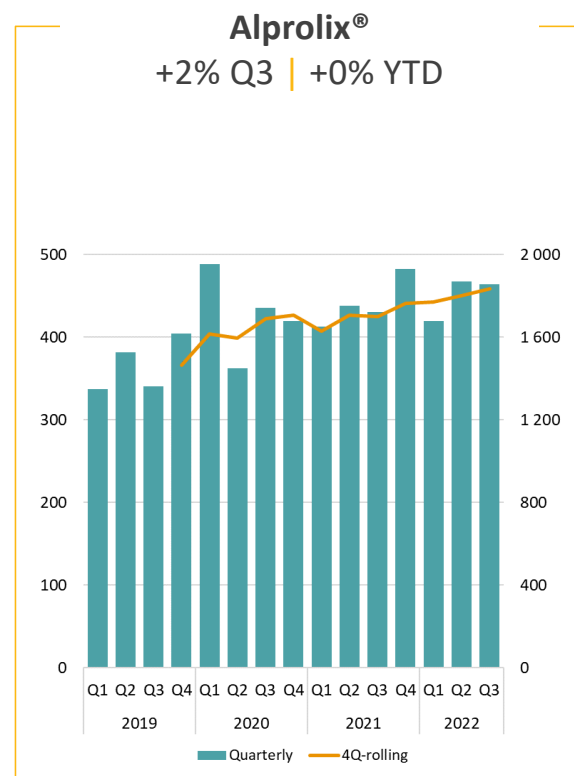
**Haemophilia expected to continue stability in 2022**

**Elocta**

- Growth in patients and factor consumption offset by price and retrospective clawbacks

**Alprolix**

- Growth in patients reduced by unfavourable country mix

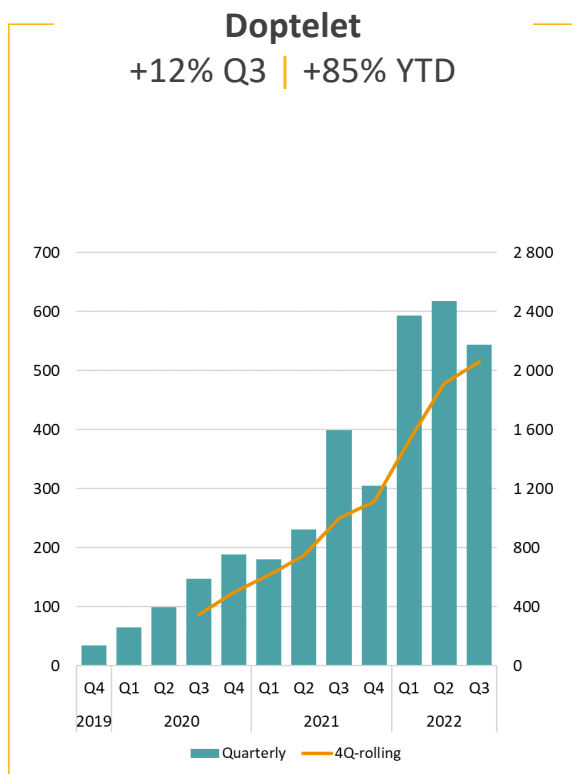


Sales in SEK million at actual exchange rates; change at constant exchange rates.

Sales in SEK million at actual exchange rates; change at constant exchange rates.



# Haematology: Doptelet up 77% in Q3 excluding sales to the partner in China



- US performance from new patients, new prescribers, higher market share and longer duration of treatment
- Europe saw strong growth from Germany and recent country reimbursements
- China sales SEK 145 M (214), lower than in 2021 due to phasing. Doptelet has NRDL<sup>1</sup>



Sales in SEK million at actual exchange rates; change at constant exchange rates.

1. (China) National Reimbursement Drug List.



**ASPARELI<sup>®</sup>**  
(pegcetacoplan)

**now launching in  
Europe for PNH<sup>1</sup>**

**SEK  
49 M**  
in Q3 2022 sales

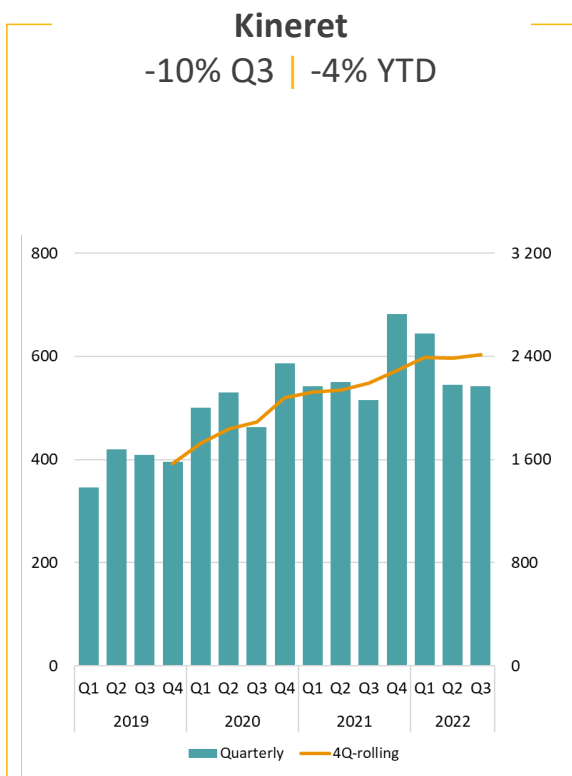
**Launching**  
in the UK,  
Germany, France  
and the Middle  
East

**c. 65**  
patients on  
commercial  
supply

1. In the EU and the UK, Aspareli is indicated for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who are anaemic after treatment with a C5 inhibitor for at least three months. Sales in SEK million at actual exchange rates.



# Immunology: Kineret COVID-19 reset; Gamifant soft quarter

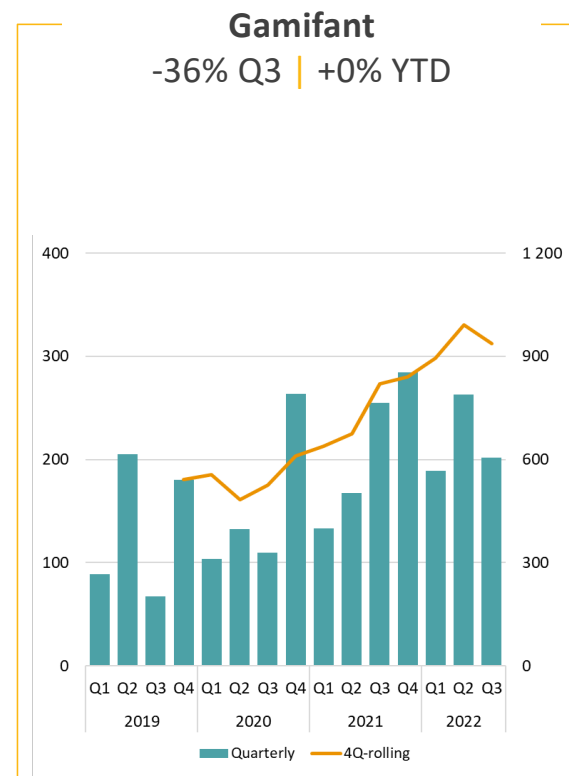


### Kineret

- No COVID-19 sales reduced growth coming from other indications

### Gamifant

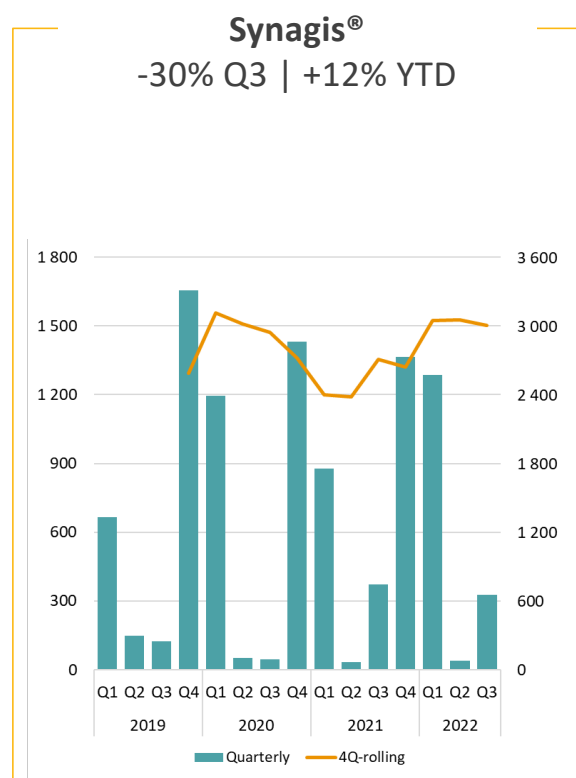
- Unfavourable patient mix, i.e. lower share of heavier patients, and fewer new patients



Sales in SEK million at actual exchange rates; change at constant exchange rates.

Sales in SEK million at actual exchange rates; change at constant exchange rates.

# Immunology: later Synagis start than in 2021



- Later start to the 2022-2023 RSV<sup>1</sup> season compared to 2021
- US RSV infections have continued to increase
- Sobi continues to anticipate a 2022-2023 season that will follow a pattern closer to a normal season than in 2021



Sales in SEK million at actual exchange rates; change at constant exchange rates.

1. Respiratory syncytial virus.

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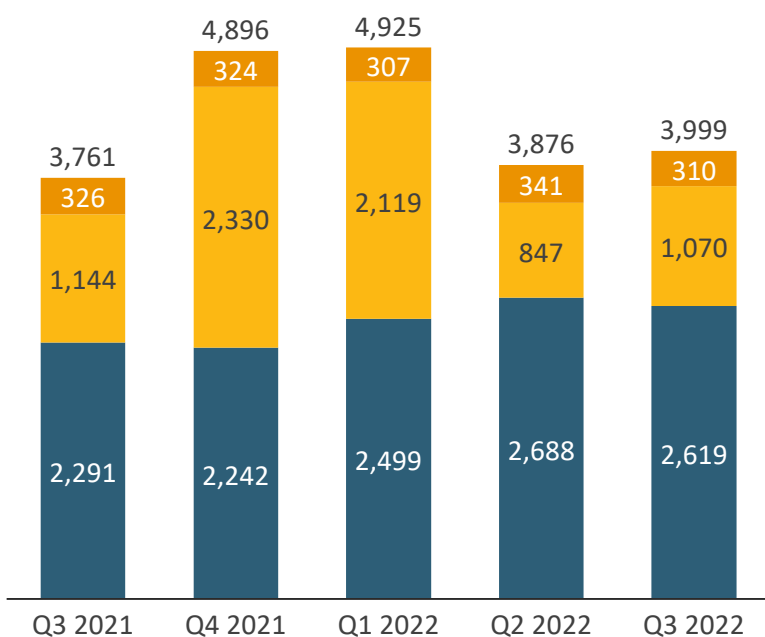
Anders Ullman, Head of RDMA, Chief Medical Officer

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# Revenue, profit & loss

■ Haematology ■ Immunology ■ Specialty Care



|   | Q3<br>2022 | Q3<br>2021 | Change | Full-year<br>2021 |
|---|------------|------------|--------|-------------------|
| Total revenue   | 3,999      | 3,761      | 6%     | 15,529            |
| Gross profit  | 3,067      | 2,802      | 9%     | 12,045            |
| Gross margin <sup>1</sup>                                   | 77%        | 75%        |        | 78%               |
| EBITA <sup>1</sup>  | 1,241      | 1,166      | 6%     | 5,575             |
| EBITA margin <sup>1</sup>                                   | 31%        | 31%        |        | 36%               |
| Profit  | 451        | 473        | -5%    | 2,679             |
| Earnings per share (EPS), before dilution, SEK <sup>1</sup> | 1.52       | 1.60       | -5%    | 9.08              |
| Operating cashflow  | 780        | 257        | 204%   | 5,470             |
| Net debt (+)/net cash (-)                                   | 9,533      | 11,131     |        | 9,500             |

1. Alternative Performance Measures (APMs); see the quarterly report for further information.

Absolute amounts in SEK million (except EPS) and at actual exchange rates; change at actual exchange rates (statutory view).

## 2022 outlook

### Revenue

Anticipated to grow by a mid to high single-digit percentage at CER<sup>1</sup>, potentially towards the higher end of the range

### EBITA margin adjusted<sup>2</sup>

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

1. Constant exchange rates 2. Excluding items affecting comparability. This outlook currently excludes any potential elements of Sobi's right to AstraZeneca's full share of US losses and profits for nirsevimab.





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# Pipeline: significant progress on key milestones

Major pipeline milestones since the previous quarterly report

**Significant milestones**

|                                |                    |  |
|--------------------------------|--------------------|--|
| <b>efanesoctocog alfa</b>      | haemophilia A      | regulatory submission acceptance and granting of priority review in the US (by Sanofi) |
| <b>Aspaveli/<br/>Empaveli™</b> | CAD <sup>1</sup>   | CASCADE phase 3 study first patient dosed  |
| <b>loncastuximab tesirine</b>  | DLBCL <sup>2</sup> | positive regulatory opinion in the EU  |
| <b>Kineret</b>                 | Still's disease    | regulatory submission in China   |
| <b>Orfadin</b>                 | HT-1 <sup>3</sup>  | regulatory approval in Brazil  |



1. Cold agglutinin disease 2. Diffuse large B-cell lymphoma 3. Hereditary tyrosinemia type-1. Status as of 26 October 2022.

# Pipeline: Q3 regulatory and scientific highlights

## loncastuximab tesirine CHMP positive opinion

- Positive EU CHMP<sup>1</sup> opinion for the treatment of R/R DLBCL<sup>2</sup>
- Opinion now deferred to the EU Commission for a decision
- Based on LOTIS-2 phase 2 study of monotherapy in 3rd-line R/R DLBCL

**PRESS RELEASE**  
London, 16 September 2022



**loncastuximab tesirine receives positive CHMP opinion for the treatment of relapsed or refractory diffuse large B-cell lymphoma**

Loncastuximab tesirine (LON) is a novel antibody-drug conjugate (ADC) for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL). LON is a combination of an antibody and a cytotoxic drug, which is designed to target and kill cancer cells. LON is being developed by Sobion and AstraZeneca.

"This announcement marks an important step in meeting the critical needs of patients with relapsed or refractory DLBCL. LON is a novel ADC that is designed to target and kill cancer cells. LON is being developed by Sobion and AstraZeneca. LON is a combination of an antibody and a cytotoxic drug, which is designed to target and kill cancer cells. LON is being developed by Sobion and AstraZeneca.

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## Data presentation at SOHO<sup>3</sup>

- Initial data from 20-patients' safety run-in of LOTIS-5 phase 3 study in R/R DLBCL
- rituximab + loncastuximab tesirine showed no new safety signals
- Encouraging efficacy, incl. **75% overall response rate and 40% complete response rate**
- Study to randomise approx. 330 patients



## Gamifant Data presentation at PRoS<sup>4</sup>

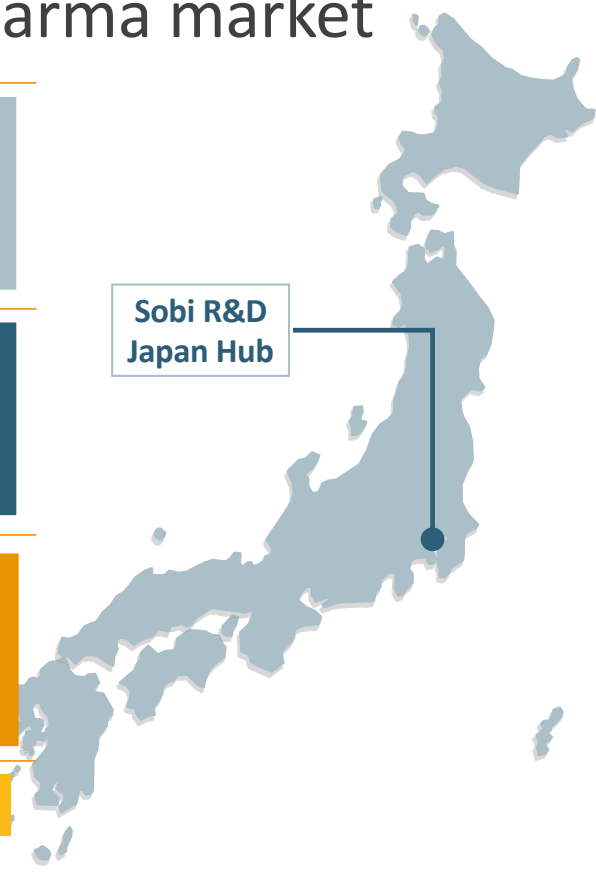
- Long-term follow up study on efficacy, safety and pharmacology in MAS of sJIA<sup>5</sup>
- All patients had rolled over from phase 2 study
- 13 of 14 patients did not experience MAS episodes
- No new safety signals were observed

**Favourable safety profile confirmed**

1. Committee for Medicinal Products for Human Use 2. Relapsed or refractory diffuse large B-cell lymphoma 3. Annual Meeting of the Society of Hematologic Oncology 2022, abstract ABCL-320 4. Paediatric Rheumatology European Society Congress 2022, abstract P502 5. Macrophage activation syndrome of systemic juvenile idiopathic arthritis.

# Strong Japan R&D and Medical team supports geographic expansion into world's second-largest Rx pharma market

|  |  |   |   |
|--|--|---|---|
| Key market with high unmet need in rare diseases | Sophisticated healthcare system                                | Universal access/coverage                                 | Market that picks up innovation                         |
| Building the Sobi R&D Japan Hub                  | Local expertise and presence needed for success                | Deliver flow of approvals to support growth               | Medical support of the launches                         |
| Early milestones achieved                        | Regulatory submissions: Doptelet CLD <sup>1</sup> Empaveli PNH | Late-stage priorities: Doptelet Empaveli Kineret Gamifant | Japan represented in six registrational phase 3 studies |



**Q3 2022: distribution agreement announced with Asahi Kasei Pharma Co.<sup>2</sup>**

1. Chronic liver disease 2. <https://sobi-japan.co.jp/press-release>.

# Pipeline news flow

Anticipated major upcoming pipeline news flow

| Q4 2022   | H1 2023   | H2 2023  |
|---|---|--|
| <p><b>loncastuximab tesirine</b> – DLBCL: regulatory decision (EU)</p> <p><b>Kineret</b> – COVID-19: regulatory decision, emergency use (US)</p> <p><b>nirsevimab</b> – RSV prevention: regulatory submission acceptance (US) (by AstraZeneca/Sanofi)<sup>1</sup></p> | <p><b>efanesoctocog alfa</b> – haemophilia A: regulatory decision (US)</p> <p><b>efanesoctocog alfa</b> – haemophilia A (paediatric): XTEND-Kids phase 3 study data readout</p> <p><b>Doptelet</b> – CLD: regulatory decision (JP)</p> <p><b>Empaveli</b> – PNH: regulatory decision (JP)</p> <p><b>Gamifant</b> – MAS<sup>2</sup> in rheumatological diseases: EMERALD phase 3 study data readout (Still's disease cohort)</p> <p><b>SEL-212</b> – CRG<sup>3</sup>: phase 3 studies data readout</p> | <p><b>efanesoctocog alfa</b> – haemophilia A: regulatory submission (EU)</p> <p><b>Aspaveli/Empaveli</b> – ALS<sup>4</sup>: MERIDIAN phase 2 study data readout (by Apellis in mid-2023)</p> <p><b>Kineret</b> – FMF<sup>5</sup>: regulatory decision (CN)</p> <p><b>Kineret</b> – Still's disease: regulatory decision (CN)</p> <p><b>Gamifant</b> – MAS in rheumatological diseases: regulatory submission (Still's disease cohort) (US)</p> <p><b>SEL-212</b> – CRG: regulatory submission (US)</p> |



1. Sobi has the right to AstraZeneca's full share of US losses and profits for nirsevimab 2. Macrophage activation syndrome 3. Chronic refractory gout 4. Amyotrophic lateral sclerosis 5. Familial Mediterranean fever. Status as of 26 October 2022.



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# Q&A

# Appendix: Q3 2022 sustainability performance

## Commitment to patients



Our R&D is ethical and focused on medical need

We expand access to treatment

We are patient centric & engage with our communities

We contribute to knowledge to enhance the practice of medicine

We focus on patient safety

Commitment to the 2030 Agenda, the UN Sustainable Development Goals and the Paris Agreement

## Responsible behaviour



We help our people develop and keep them safe and healthy

We have zero tolerance for corruption

We source responsibly

We reduce our environmental footprint



## Highlights in Q3 2022

- 
- Milestones toward increased access
    - Exclusive licensing agreement on loncastuximab tesirine
    - Approval of Orfadin Capsules and Orfadin Oral Suspension by Brazil Health Authority ANVISA
  - Raising awareness
    - Still's Disease Awareness Day, 3rd year supporting patient organisation to raise awareness internationally
  - Sharing knowledge
    - Presented results at ISTH<sup>1</sup> 2022 Congress
  - Continued good scores in investor indices 2022
    - MSCI (A) and Sustainalytics (20.4)
- 
- Hurricane Ian proactive outreach
    - Relief information to bridge potential medicine delivery disruptions
    - Information on precautions and available assistance to employees
  - Good governance
    - Improved score (+4 points) in Governance and Economic dimension as well as total score (44 to 48) in S&P CSA<sup>2</sup> 2022

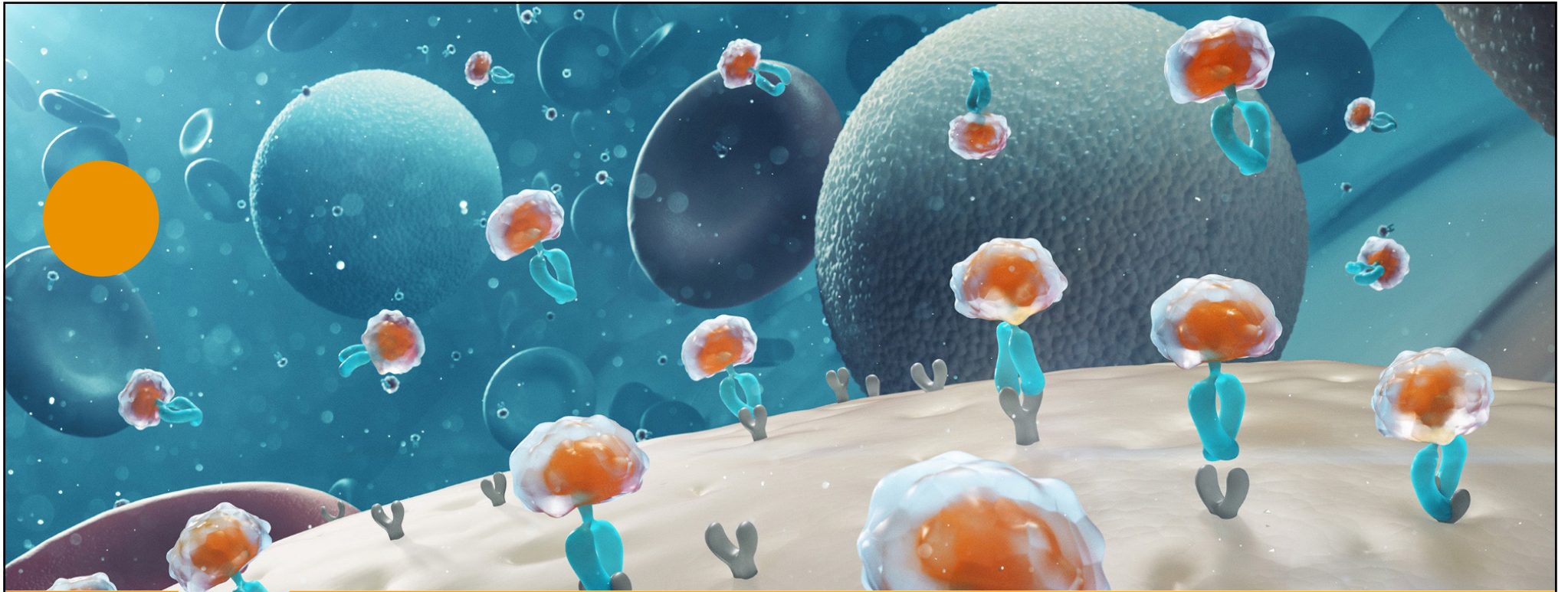
1. International Society on Thrombosis and Haemostasis.  
 2. Standard & Poor Corporate Sustainability Assessment scorecard.

## Appendix: items affecting comparability (IAC)

| SEK M   | Q3<br>2022    | IAC | Q3 2022<br>adjusted | Q3<br>2021    | Jan-Sep<br>2022 | IAC         | Jan-Sep<br>2022<br>adjusted | Jan-Sep<br>2021 | Full-year<br>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>     |
| <i>Gross margin</i>                                   | 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>      |
| <i>EBITA margin</i>                                   | 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.





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