


The Sobi logo, consisting of a yellow circle with three vertical dots inside, followed by the word "sobi" in a lowercase, sans-serif font.

Sobi

J.P. Morgan
2023 Healthcare
Conference

rare **strength**

A solid yellow circle.

11 January 2023



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

Overview



Guido Oelkers, Chief Executive Officer

Current performance

Pipeline

Q&A

Sobi at a glance



Specialised international biopharmaceutical company



Providing reliable access to innovative medicines



In the areas of haematology, immunology and specialty care



Own presence in around 30 countries, delivering treatments to patients in many more



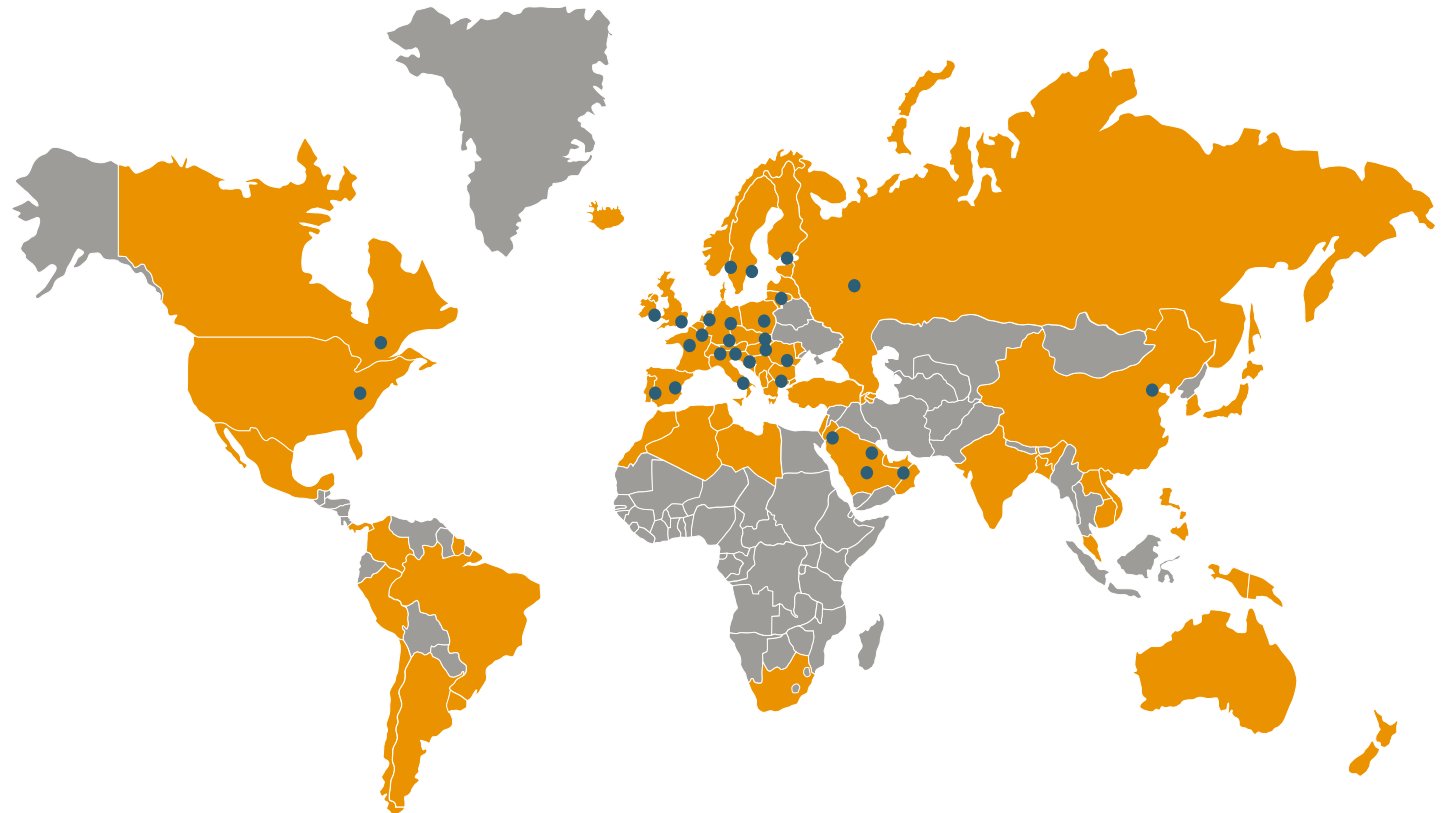
Around 1,600 employees



Global head office in Stockholm, Sweden



Revenue of SEK 15.5 billion (2021)



● Patient access
● Sobi operations

Strategic business priorities

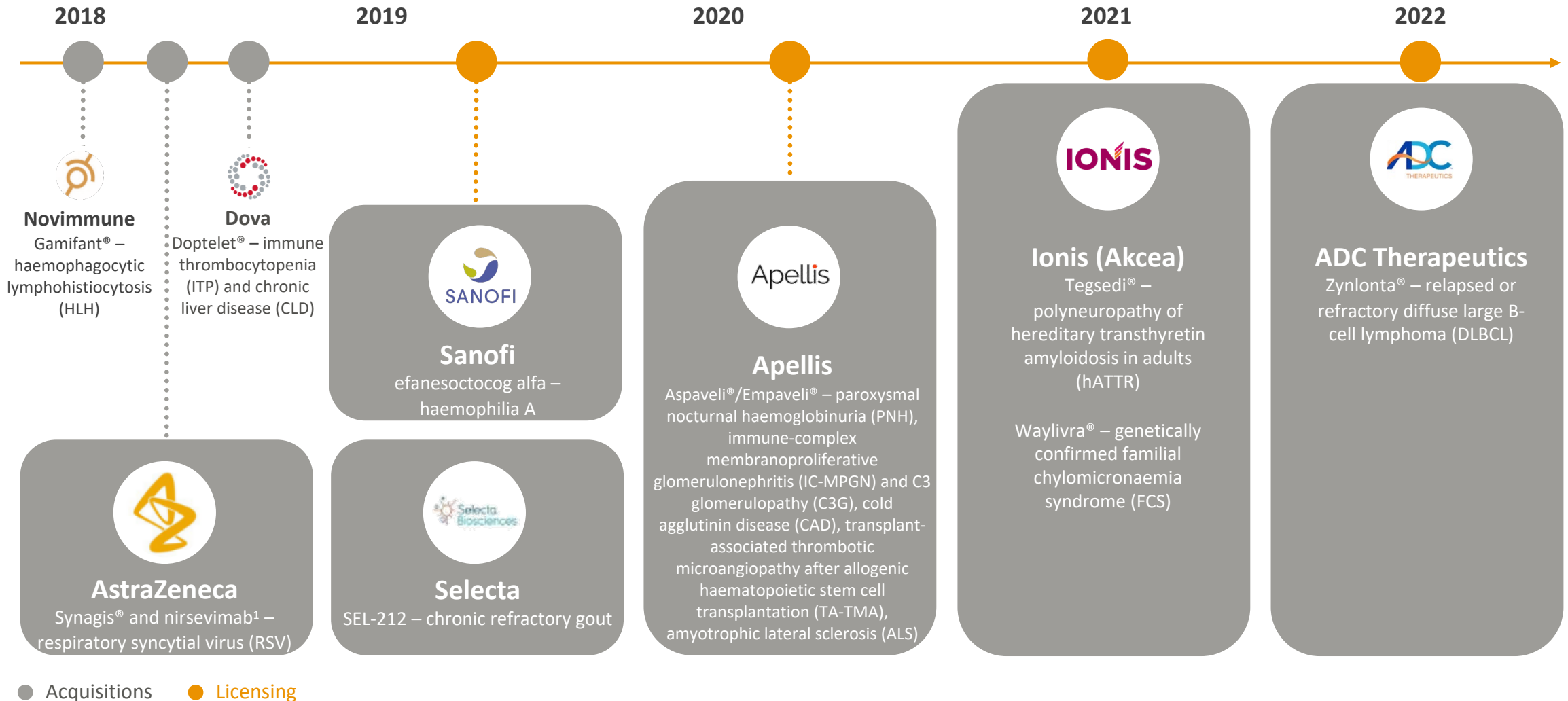
**Lead in
Haematology**

**Capture the
value of the
pipeline**

**Grow
Immunology
and
Speciality
Care**

Go global

Building for the future through licensing and acquisitions



1. Sobi has the right to AstraZeneca PLC's full share of US losses and profits for nirsevimab.

Agenda

Overview

Current performance



Guido Oelkers, Chief Executive Officer

Pipeline

Q&A

Q3 2022: sustained progress

- **Revenue** -6% in Q3 due to high base; **+9% YTD**, fully underpinning 2022 outlook
- **Commercial execution** with launch medicines¹ +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.

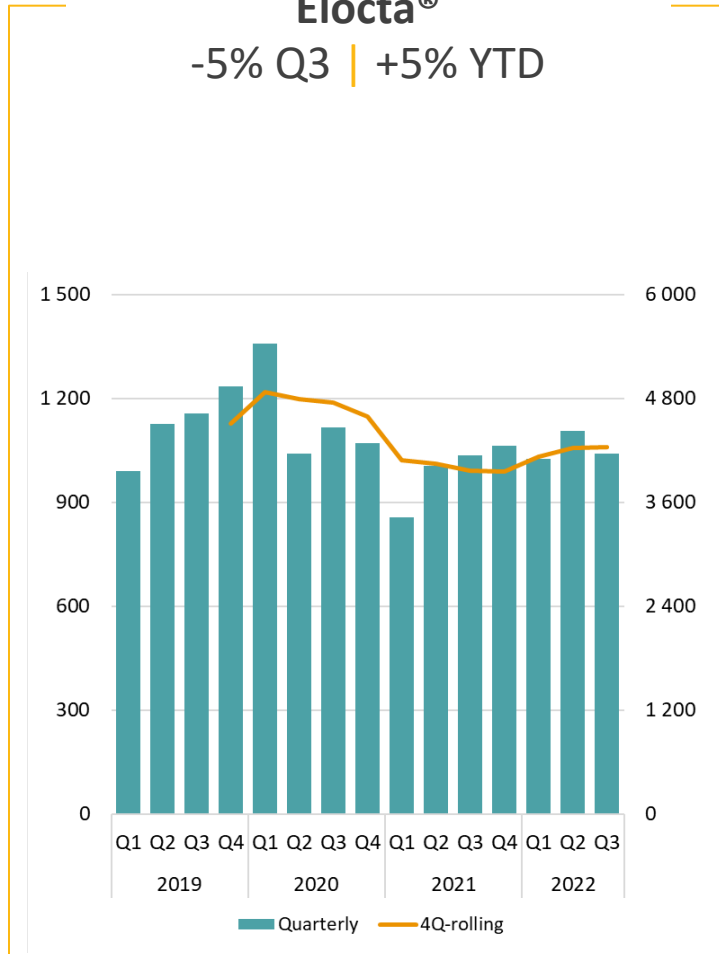
Business: growth driven by Doptelet in Haematology and by Europe

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

| | Q3 '22 | change | ratio | YTD'22 | change | ratio |
|--------------------------|--------------|-----------|------------|---------------|----------|------------|
| | SEK M | % | % | SEK M | % | % |
| Europe | 1,912 | 3 | 48 | 5,608 | 4 | 44 |
| North America | 1,373 | -8 | 35 | 4,562 | 13 | 36 |
| Rest of world | 337 | -37 | 8 | 1,544 | 32 | 12 |
| Other¹ | 377 | -4 | 9 | 1,086 | -2 | 8 |
| Total | 3,999 | -6 | 100 | 12,800 | 9 | 100 |

Haematology: haemophilia continued relative stability

Elocta®
-5% Q3 | +5% YTD



Haemophilia expected to continue stability in 2022

Elocta

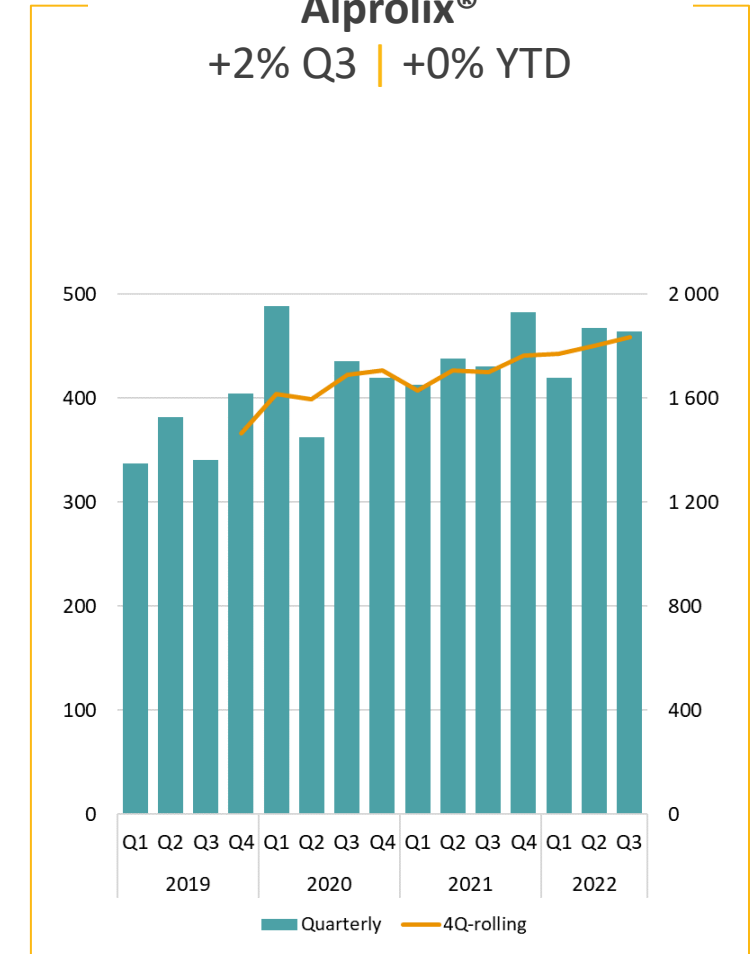
- Growth in patients and factor consumption offset by price and retrospective clawbacks

Alprolix

- Growth in patients reduced by unfavourable country mix

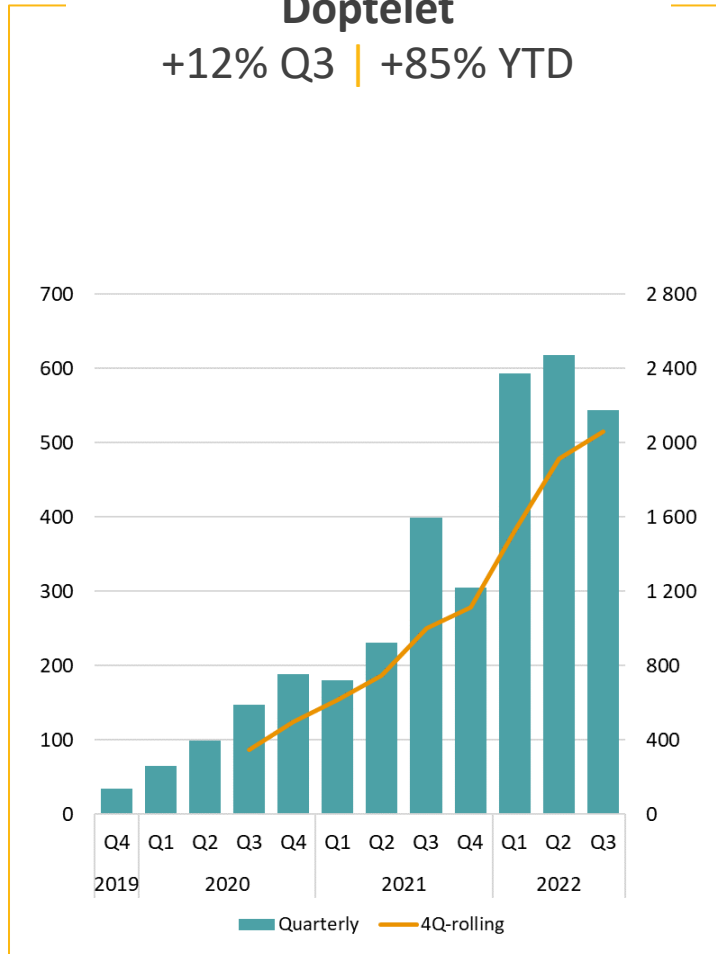


Alprolix®
+2% Q3 | +0% YTD



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

Doptelet
+12% Q3 | +85% YTD



- 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 NRDL¹



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

1. (China) National Reimbursement Drug List.





**now launching in
Europe for PNH¹**

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

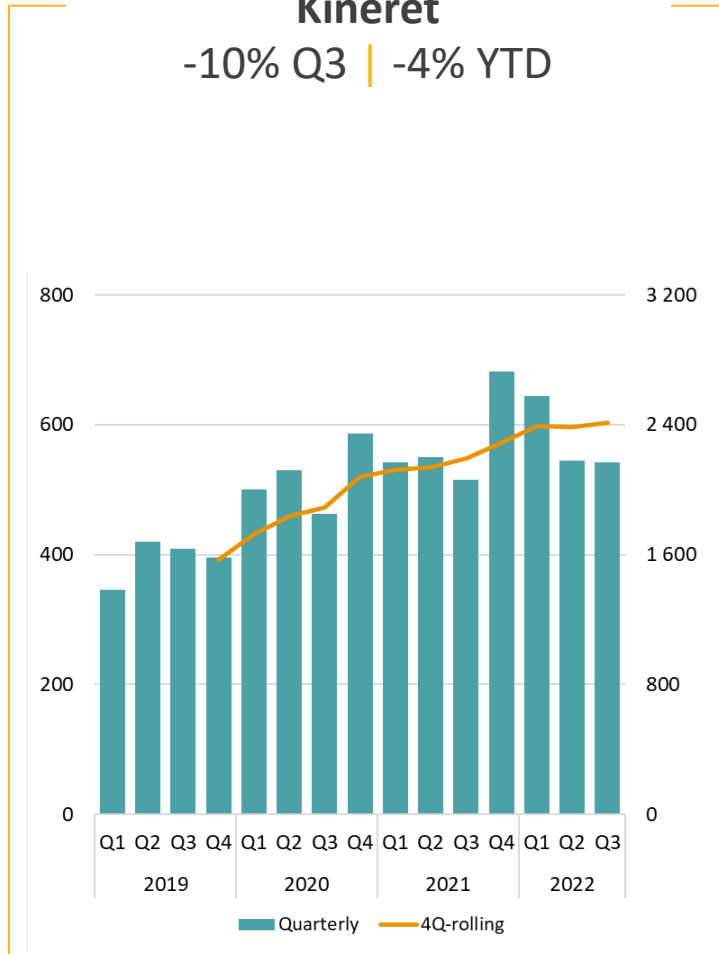
**SEK
49 M**
in Q3 2022 sales

c. 65
patients on
commercial
supply

1. In the EU and the UK, Aspaveli 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 -10% Q3 | -4% YTD



Kineret

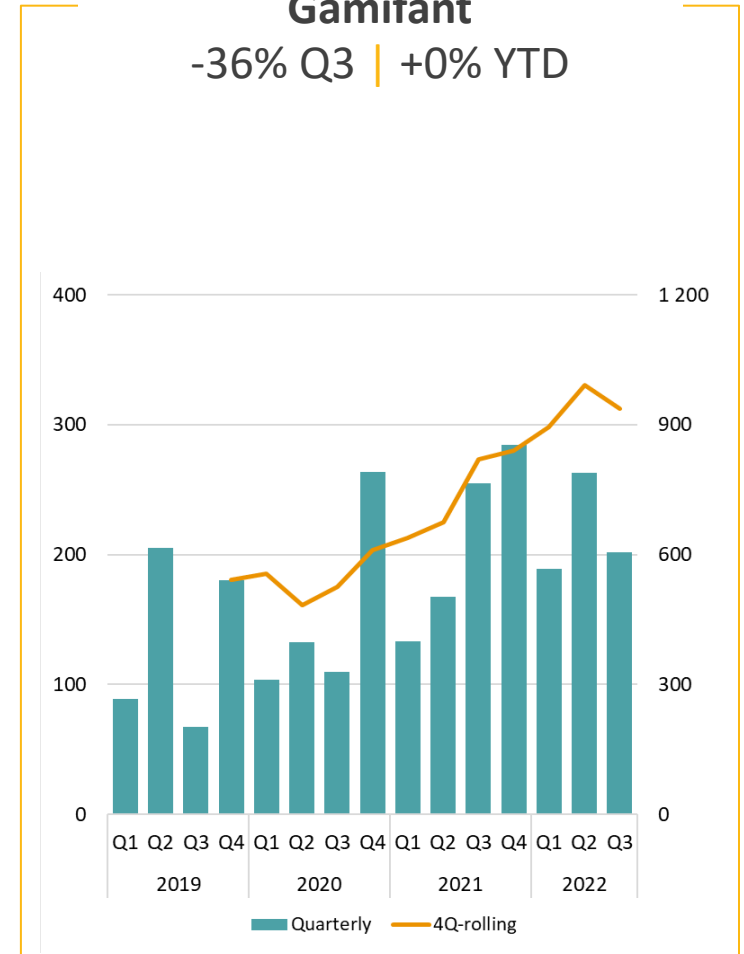
- No COVID-19 sales reduced growth coming from other indications

Gamifant

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



Gamifant -36% Q3 | +0% YTD

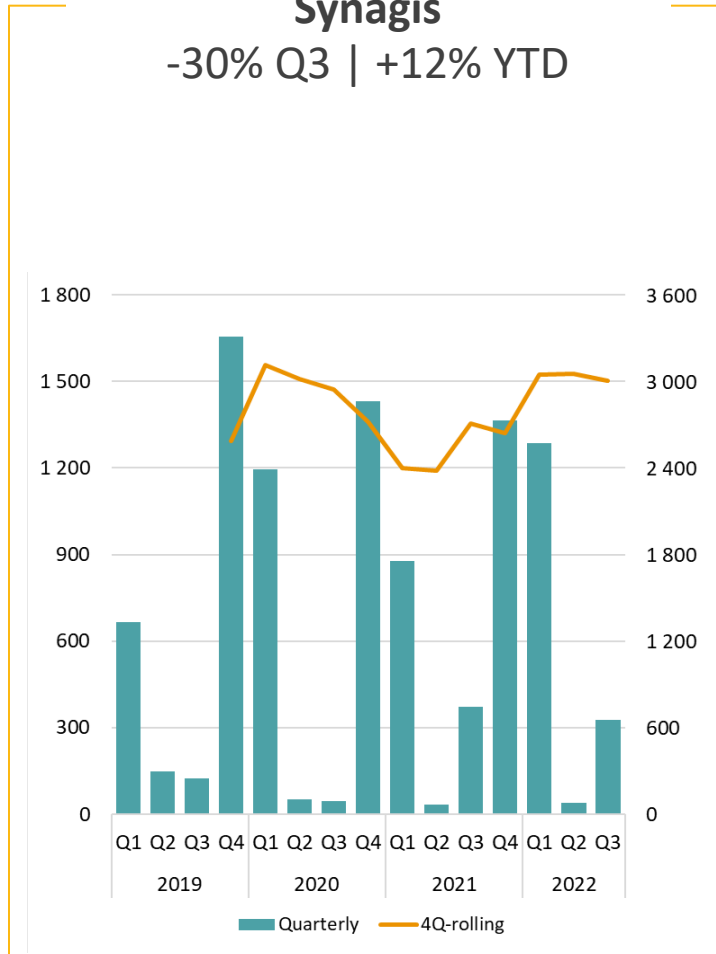


Sales in SEK million at actual exchange rates; change at constant exchange rates.

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

Immunology: later Synagis start than in 2021

Synagis
-30% Q3 | +12% YTD



- Later start to the 2022-2023 RSV¹ 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

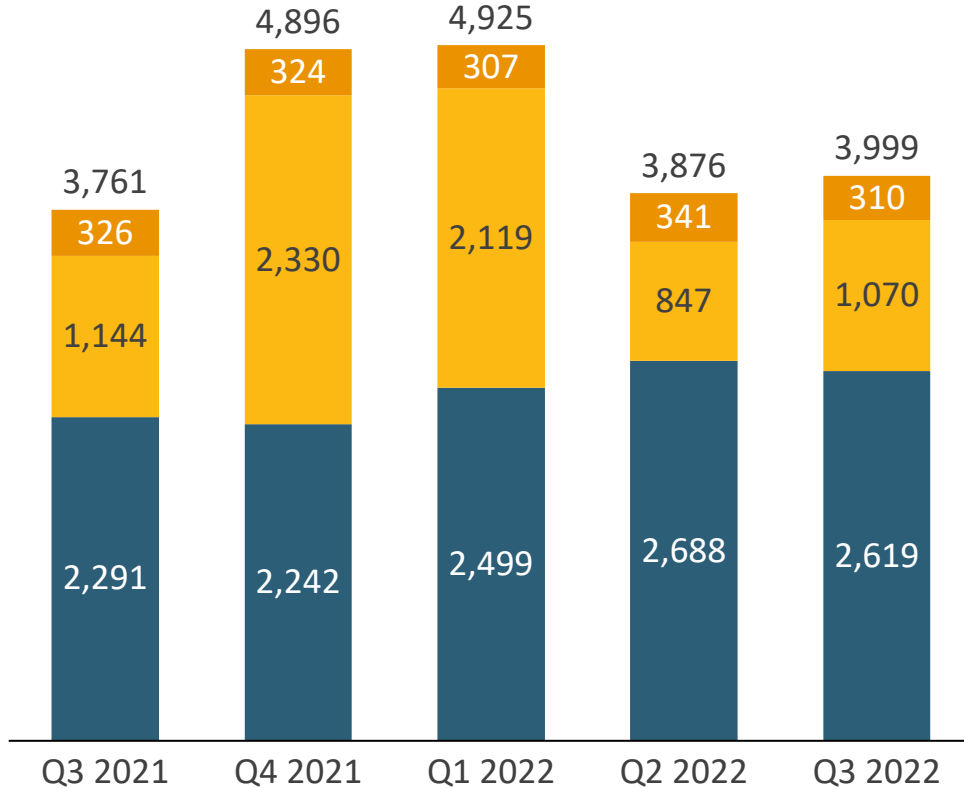
Sales in SEK million at actual exchange rates; change at constant exchange rates.

1. Respiratory syncytial virus.



Revenue, profit & loss

■ Haematology ■ Immunology ■ Specialty Care



| | Q3 2022 | Q3 2021 | Change | Full-year 2021 |
|---|------------|------------|--------|-------------------|
| Total revenue | 3,999 | 3,761 | 6% | 15,529 |
| Gross profit | 3,067 | 2,802 | 9% | 12,045 |
| Gross margin ¹ | 77% | 75% | | 78% |
| EBITA ¹ | 1,241 | 1,166 | 6% | 5,575 |
| EBITA margin ¹ | 31% | 31% | | 36% |
| Profit | 451 | 473 | -5% | 2,679 |
| Earnings per share (EPS), before dilution, SEK ¹ | 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.

2022 outlook

Revenue

Anticipated to grow by a mid to high single-digit percentage at CER¹, potentially towards the higher end of the range

EBITA margin adjusted²

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.



Agenda

Overview

Current performance

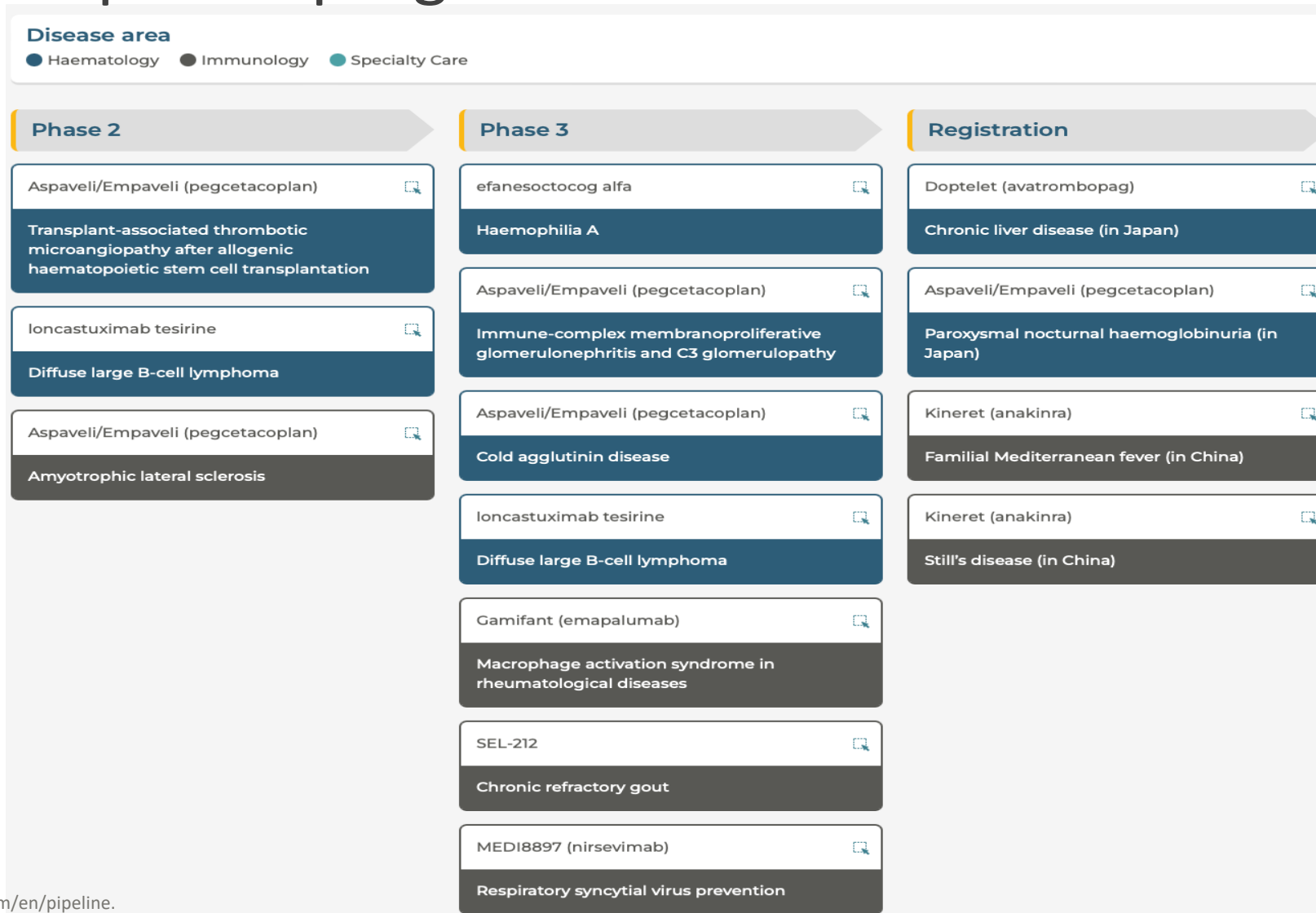
Pipeline



Guido Oelkers, Chief Executive Officer

Q&A

Key Development programmes



Pipeline: significant progress on key milestones in Q3 2022

Major pipeline milestones since the previous quarterly report

Significant milestones

| | | |
|-------------------------------|--------------------|--|
| efanesoctocog alfa | haemophilia A | regulatory submission acceptance and granting of priority review in the US (by Sanofi) |
| Aspaveli/ Empaveli | CAD ¹ | CASCADE phase 3 study first patient dosed |
| loncastuximab tesirine | DLBCL ² | positive regulatory opinion in the EU |
| Kineret | Still's disease | regulatory submission in China |
| Orfadin | HT-1 ³ | 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 CHMP¹ opinion for the treatment of R/R DLBCL²
- Opinion now deferred to the EU Commission for a decision **Approved Dec.** ✓
- Based on LOTIS-2 phase 2 study of monotherapy in 3rd-line R/R DLBCL

PRESS RELEASE
Stockholm, Sweden, 16 September 2022

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

Sobi and ADC Therapeutics SA today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has issued a positive opinion recommending the marketing authorisation of loncastuximab tesirine for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), a debilitating cancer disease in haematology. The positive opinion from the CHMP is now referred to the European Commission for a decision.

"Today's announcement marks an important step in meeting the critical needs of patients with relapsed and refractory large B-cell lymphoma across the EU," said Anders Ullman, Head of Research & Development and Chief Medical Officer at Sobi. "The positive Sobi's heritage and strong presence in haematology will provide a competitive platform for bringing loncastuximab tesirine to more patients."

The opinion is based on data from LOTIS-2, a large (3x3) phase 2 multinational, single-arm clinical study of loncastuximab tesirine as single agent for the treatment of adult patients with relapsed or refractory DLBCL. Following the first two arms of patients therapy in April 2021, the CHMP and Drug Administration granted accelerated approval to loncastuximab tesirine for the first and only CD20-targeted antibody-drug conjugate as single agent treatment for adult patients with relapsed or refractory DLBCL, after two or more lines of systemic therapy. In September 2021, the European Commission granted orphan designation to loncastuximab tesirine for the treatment of DLBCL.

"The positive CHMP opinion demonstrates significant progress toward bringing loncastuximab tesirine to DLBCL patients in Europe," said Annett Skalk, Chief Executive Officer of ADC Therapeutics. "We are committed, along with our partners, to making loncastuximab tesirine available to as many patients as possible worldwide and look forward to the European Commission's final decision."

In July 2022, Sobi announced an exclusive license agreement with ADC Therapeutics SA to develop and commercialize loncastuximab tesirine for use in haematology and other indications of large cancer medical need in Europe and most international markets. The license agreement for loncastuximab tesirine aimed at supporting Sobi's presence in orphan diseases within haematology, one of Sobi's main development areas.



Data presentation at SOHO³

- 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 PReS⁴

- Long-term follow up study on efficacy, safety and pharmacology in MAS of sJIA⁵
- 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

Pipeline news flow

Anticipated major upcoming pipeline news flow

Q4 2022

loncastuximab tesirine – DLBCL: regulatory decision (EU) ✓

Kineret – COVID-19: regulatory decision, emergency use (US) ✓

nirsevimab – RSV prevention: regulatory submission acceptance (US) (by AstraZeneca/Sanofi)¹ ✓

H1 2023

efanesoctocog alfa – haemophilia A: regulatory decision (US)

efanesoctocog alfa – haemophilia A (paediatric): XTEND-Kids phase 3 study data readout

Doptelet – CLD: regulatory decision (JP)

Empaveli – PNH: regulatory decision (JP)

Gamifant – MAS² in rheumatological diseases: EMERALD phase 3 study data readout (Still's disease cohort)

SEL-212 – CRG³: phase 3 studies data readout

H2 2023

efanesoctocog alfa – haemophilia A: regulatory submission (EU)

Aspaveli/Empaveli – ALS⁴: MERIDIAN phase 2 study data readout (by Apellis in mid-2023)

Kineret – FMF⁵: regulatory decision (CN)

Kineret – Still's disease: regulatory decision (CN)

Gamifant – MAS in rheumatological diseases: regulatory submission (Still's disease cohort) (US)

SEL-212 – CRG: regulatory submission (US)



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 with green check marks showing subsequent progress.

Agenda

Overview

Current performance

Pipeline

Q&A



Guido Oelkers, Chief Executive Officer



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



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



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

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 ISTH¹ 2022 Congress



- 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 CSA² 2022

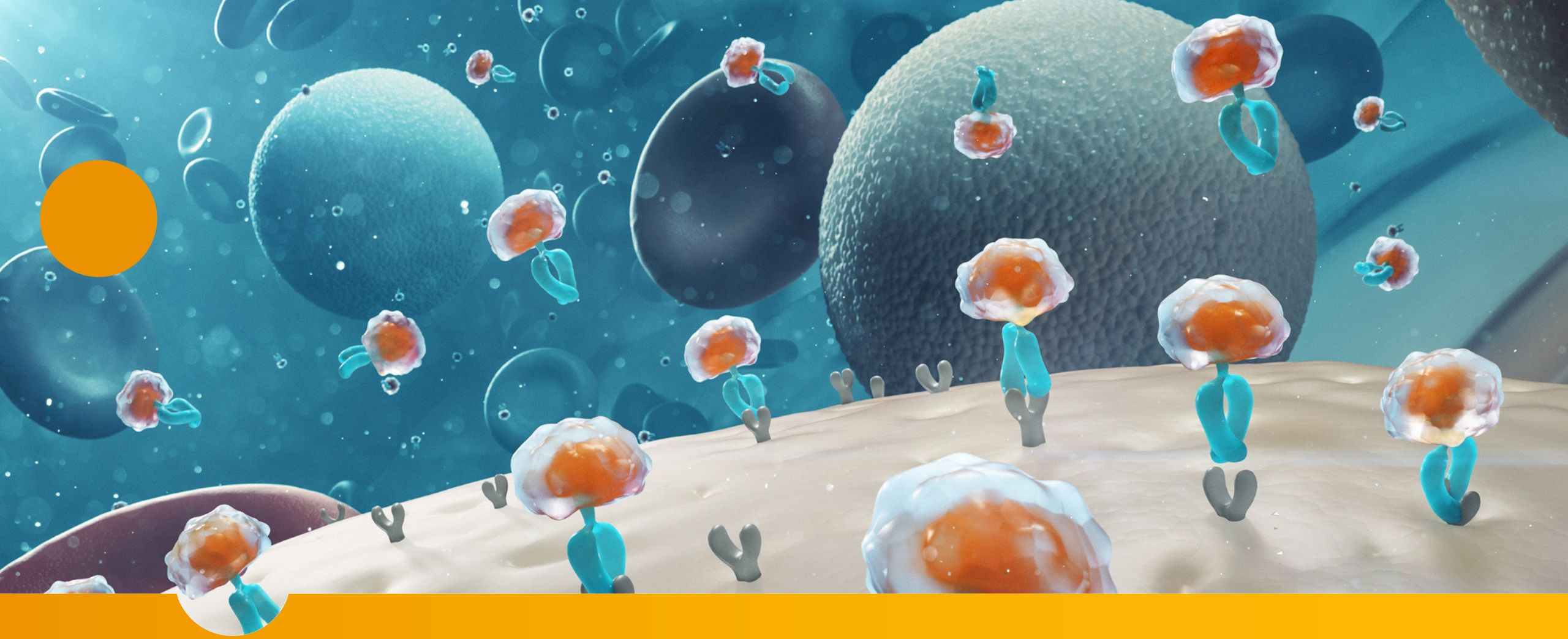
- Continued good scores in investor indices 2022
 - MSCI (A) and Sustainalytics (20.4)

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

Appendix: items affecting comparability (IAC)

| 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 ¹ | -932 | – | -932 | -959 | -3,468 | -363 | -3,105 | -2,468 | -3,484 |
| Gross profit | 3,067 | – | 3,067 | 2,802 | 9,332 | -363 | 9,695 | 8,165 | 12,045 |
| <i>Gross margin</i> | 77% | | 77% | 75% | 73% | | 76% | 77% | 78% |
| Selling and administrative expenses ^{2,3,4} | -1,834 | – | -1,834 | -1,571 | -5,726 | -210 | -5,516 | -4,470 | -6,294 |
| Research and development expenses ^{2,4} | -526 | – | -526 | -485 | -1,711 | -102 | -1,609 | -1,440 | -1,994 |
| Operating expenses | -2,360 | – | -2,360 | -2,056 | -7,437 | -312 | -7,125 | -5,910 | -8,288 |
| Other operating income/expenses | -8 | – | -8 | -38 | 3 | – | 3 | -47 | -24 |
| Operating profit (EBIT) | 699 | – | 699 | 708 | 1,897 | -675 | 2,572 | 2,208 | 3,733 |
| Plus amortisation and impairment of intangible assets | 542 | – | 542 | 459 | 1,578 | – | 1,578 | 1,364 | 1,841 |
| EBITA | 1,241 | – | 1,241 | 1,166 | 3,475 | -675 | 4,150 | 3,572 | 5,575 |
| <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.



 **sobi**
rare **strength**