Q2 2022 report

Conference call for investors and analysts

rare **strength**

19 July 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 R&D, Chief Medical Officer
Summary and Q&A		All

Overview: continued solid performance

- **Revenue up 10%**, and 21% at actual exchange rates, with continued phasing of Doptelet® sales to China
- **Launch medicines[1] up 96%**
- **Strong commercial execution**

- Continued investment for growth; Selling and R&D/Medical
- Efficiency programmes concluded; limited quarterly impact
- **EBITA margin adjusted 25%**

- **Pipeline progressed** with first efanesoctocog alfa phase 3 presentation
- Significant pipeline **news flow to continue** in 2022 and 2023

- Agreement to license loncastuximab tesirine in haematology

- **2022 outlook solid**

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

1. Launch medicines include Doptelet, Aspaveli®/Empaveli™ and Gamifant®. Change at constant exchange rates.

Business: double-digit growth driven by Doptelet in Haematology plus North America and Rest of world

	Q2 '22	change	ratio	H1 '22	change	ratio
	SEK M	%	%	SEK M	%	%
Haematology	2,688	16	69	5,187	20	59
– Haemophilia	*2,033*	*1*	*52*	*3,934*	*3*	*45*
Immunology	847	0	22	2,967	15	34
Specialty Care	341	-6	9	647	6	7
Total	**3,876**	**10**	**100**	**8,801**	**17**	**100**

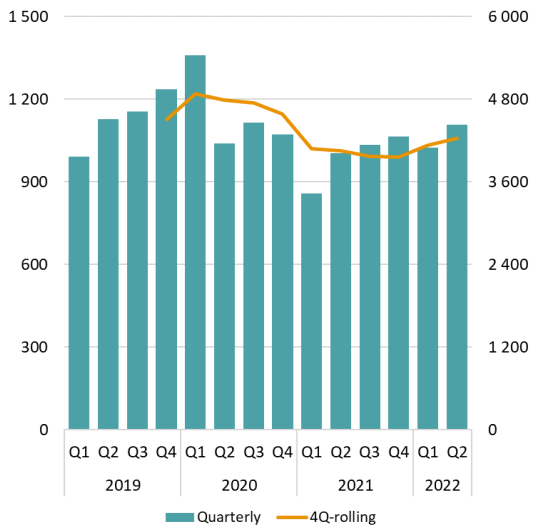
	Q2 '22	change	ratio	H1 '22	change	ratio
	SEK M	%	%	SEK M	%	%
Europe	1,893	2	49	3,696	4	42
North America	1,071	19	27	3,189	24	36
Rest of world	536	42	14	1,207	89	14
Other[1]	376	-1	10	709	-1	8
Total	**3,876**	**10**	**100**	**8,801**	**17**	**100**

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

1. Royalty revenue.

Haematology: haemophilia sales grew 5%; revenue 1%[1]

Elocta®
+6% Q2 | +10% H1



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

Haemophilia expected to continue stability in 2022

Elocta

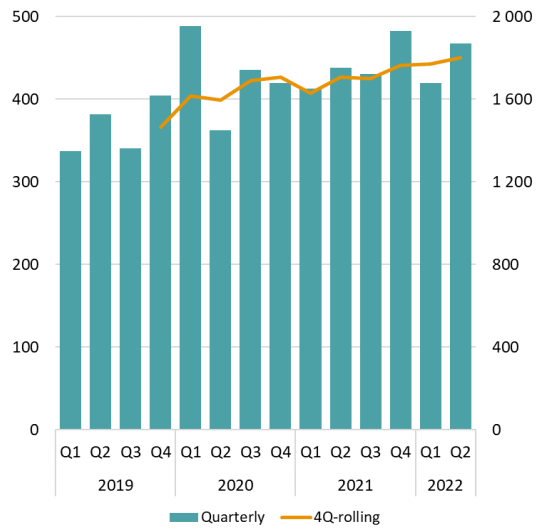
- Growth in patients and factor consumption slightly offset by price

Alprolix

- Growth in patients slightly offset by price and stocking. Stable factor consumption

1. Revenue includes royalty and manufacturing.

Alprolix®
+2% Q2 | +0% H1

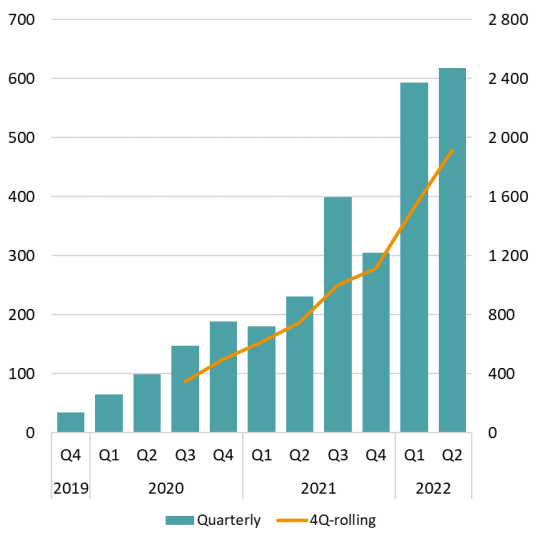


Sales in SEK million at actual exchange rates; change at constant exchange rates.

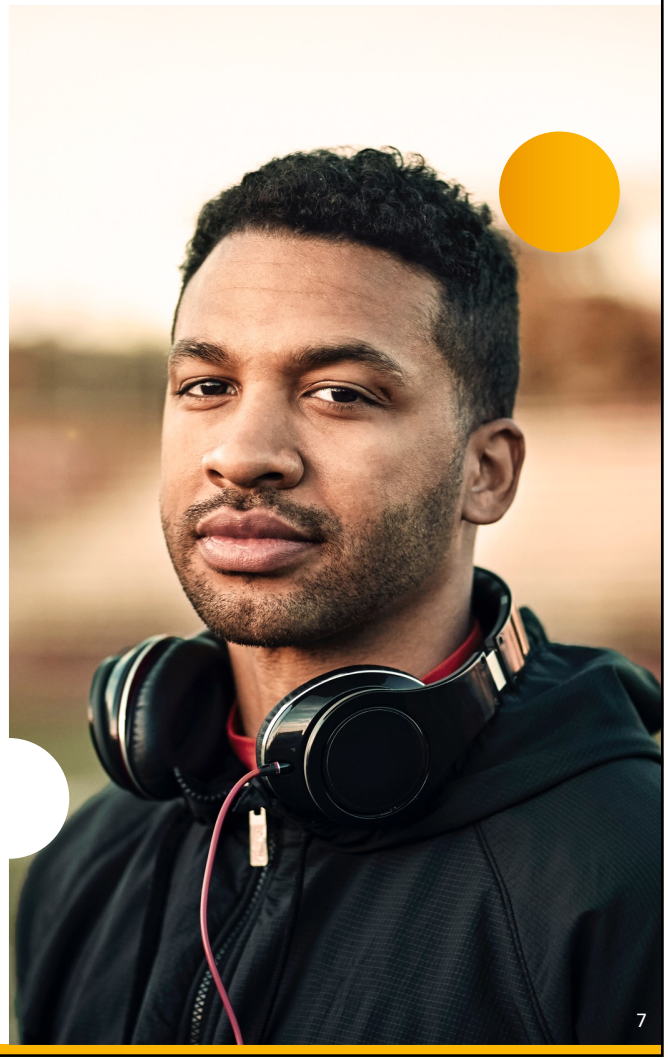
Haematology: Doptelet up 66% in Q2 excluding sales to the partner in China

Doptelet

+126% Q2 | +155% H1



- US launch progressed with increasing market share
- Europe launch continued with Germany leading in sales
- China sales strong (SEK 281 M in Q2) with continued phasing. In China, Doptelet has NRDL[1] inclusion



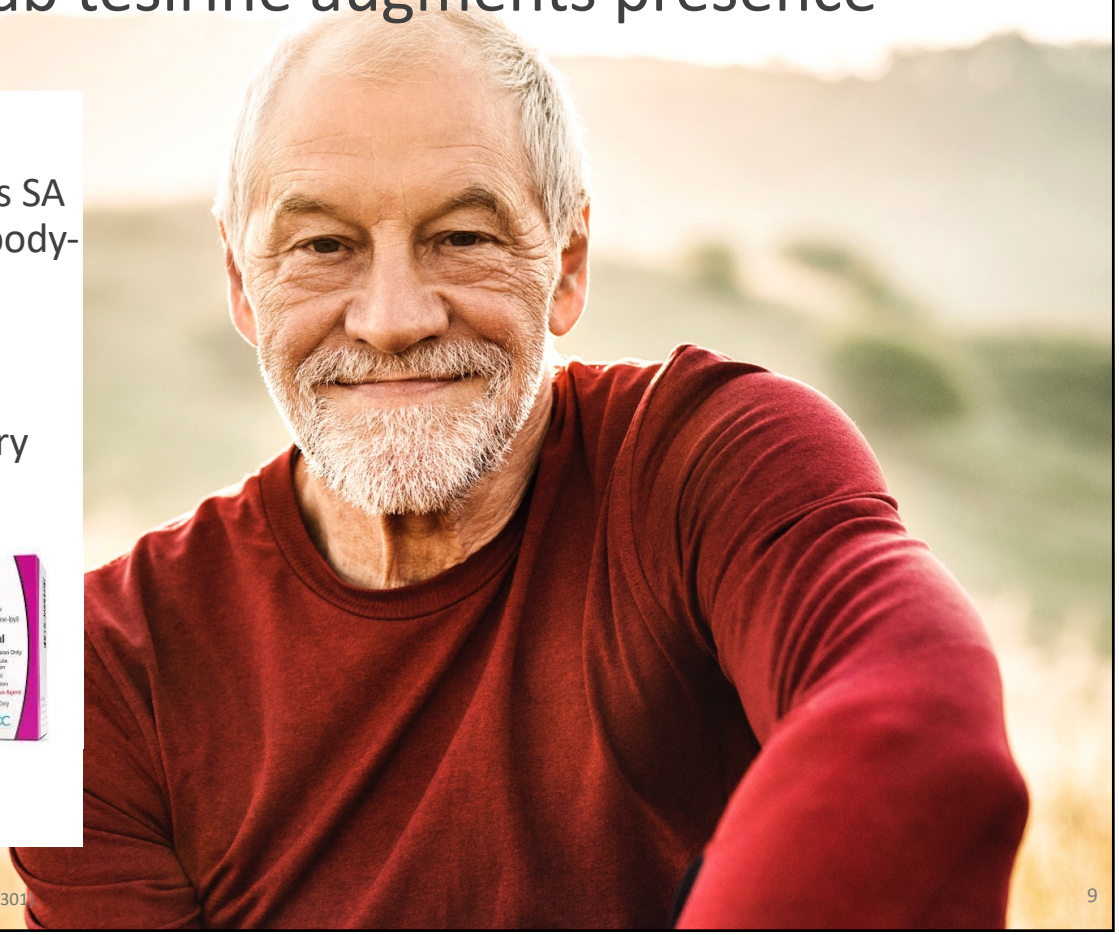
Sales in SEK million at actual exchange rates; change at constant exchange rates.

1. National Reimbursement Drug List.

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.

Haematology: loncastuximab tesirine augments presence

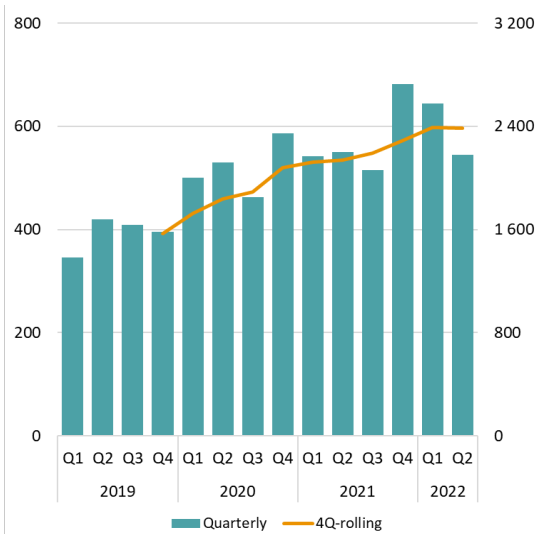
- License agreement with ADC Therapeutics SA to develop and commercialise novel antibody-drug conjugate in haematology
- Europe and most international markets
- EU orphan drug designation and regulatory review (3rd-line DLBCL[1]) with anticipated decision in Q1 2023
- Attractive financial terms
  - USD 55 M upfront
  - USD 50 M at approval
  - Royalty, regulatory and sales milestones[2]



1. Diffuse large B-cell lymphoma 2. For full financial terms, please refer to 8 July 2022 press release (https://www.sobi.com/en/press-releases/sobi-license-loncastuximab-tesirine-adc-therapeutics-2035301)

Immunology: Kineret COVID-19 impact; Gamifant back up

Kineret®
-11% Q2 | +0% H1



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

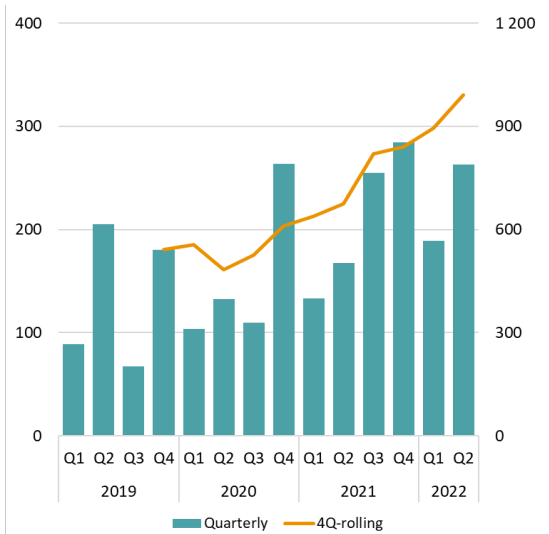
Kineret

- Lower COVID-19 sales in emerging markets slightly offset by other indications

Gamifant

- Growth in new patients supported performance

Gamifant
+34% Q2 | +30% H1

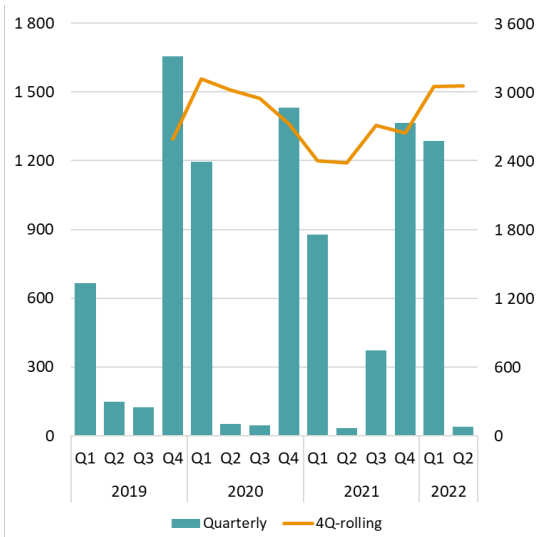


Sales in SEK million at actual exchange rates; change at constant exchange rates.

Immunology: very limited Synagis revenue

Synagis®

+10% Q2 | +29% H1



- Very limited Synagis revenue from positive gross-to-net (rebate) adjustments
- No sales benefit from an early increase in US RSV[1] infections
- Sobi continues to anticipate a 2022-2023 season that will follow a normal pattern

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

1. Respiratory syncytial virus.

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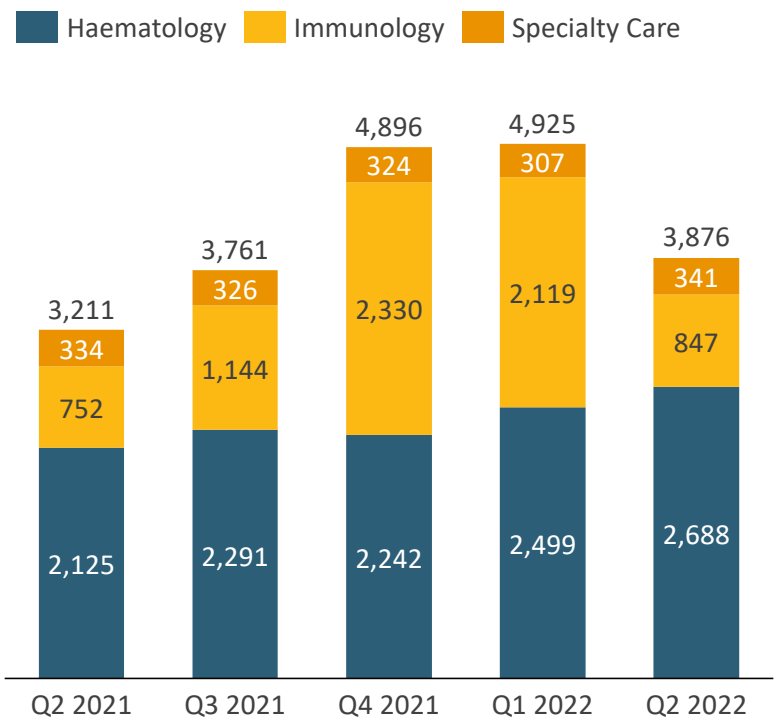
Revenue, profit & loss

Total revenue (SEK M)



	Q2 2022	Q2 2021	Change	Full-year 2021
Total revenue	**3,876**	3,211	21%	15,529
Gross profit	**2,856**	2,428	18%	12,045
Gross margin[1]	**74%**	76%		78%
EBITA[1]	**944**	922	2%	5,575
EBITA adjusted[1,2]	**958**	922	4%	5,575
EBITA margin[1]	**24%**	29%		36%
EBITA margin adjusted[1,2]	**25%**	29%		36%
Profit	**258**	268	-4%	2,679
Earnings per share (EPS), before dilution, SEK[1]	**0.87**	0.91	-4%	9.08
EPS, before dilution, SEK adjusted[1,2]	**0.91**	0.91	0%	9.08
Operating cashflow	**343**	1,393	-75%	5,470
Net debt (+)/net cash (-)	**9,082**	11,206		9,500

1. Alternative Performance Measures (APMs); see the quarterly report for further information.
2. Items affecting comparability in Q2 2022, see page 3 in report for further information.

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

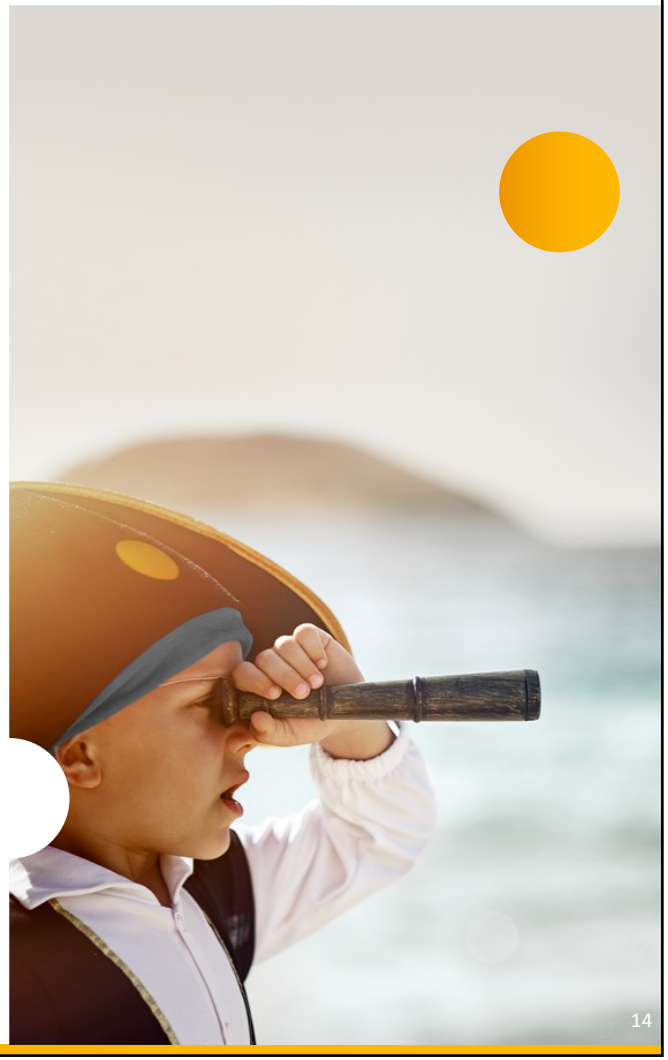
2022 outlook

Revenue

Anticipated to grow by a mid to high single-digit percentage at CER[1],
now potentially towards the higher end of the range

EBITA margin adjusted[2]

Anticipated to be at a low 30s percentage of revenue,
now including the cost effects of the agreement to license the
new orphan medicine loncastuximab tesirine in haematology



1. Constant exchange rates 2. Excluding items affecting comparability.

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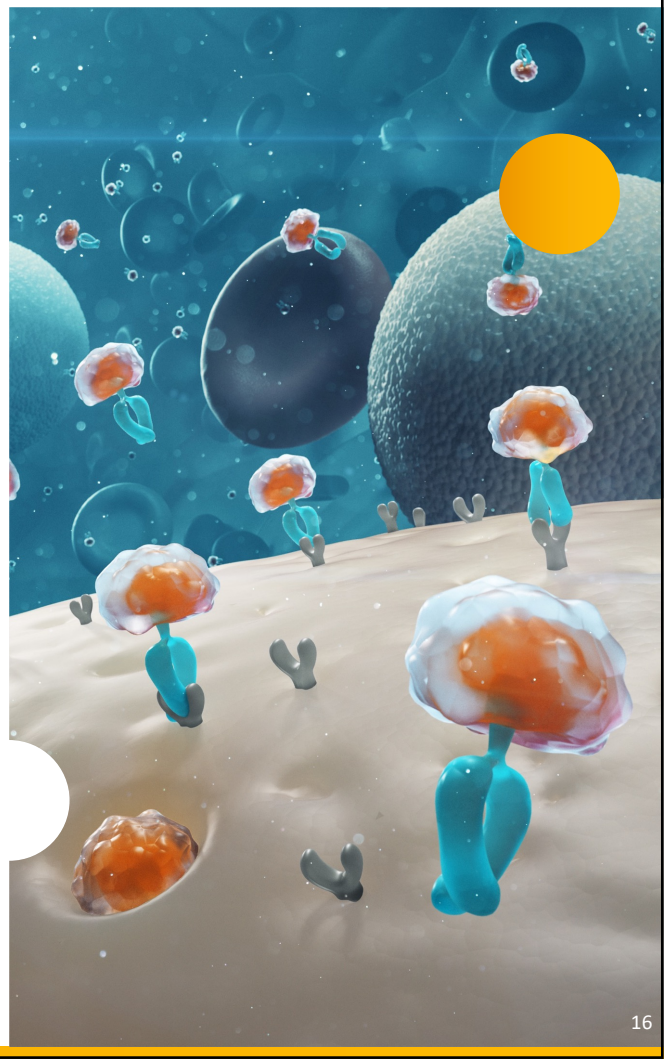
Pipeline: significant progress on key milestones

Major pipeline milestones since the previous quarterly report

Significant milestones	efanesoctocog alfa	haemophilia A	Breakthrough Therapy designation in the US (by Sanofi)
			first phase 3 study data presentation
	Empaveli	PNH[1]	regulatory submission acceptance in Japan
	Aspaveli/ Empaveli	IC-MPGN[2] and C3G[3]	VALIANT phase 3 study first patient dosed (by Apellis)
	Kineret	FMF[4]	regulatory submission in China
	SEL-212	CRG[5]	DISSOLVE II phase 3 study enrolment completion



1. Paroxysmal nocturnal haemoglobinuria 2. Immune-complex membranoproliferative glomerulonephritis 3. C3 glomerulopathy 4. Familial Mediterranean fever 5. Chronic refractory gout. Status as of 18 July 2022.

Efanesoctocog alfa: key data from XTEND-1 phase 3 study

Primary endpoint met

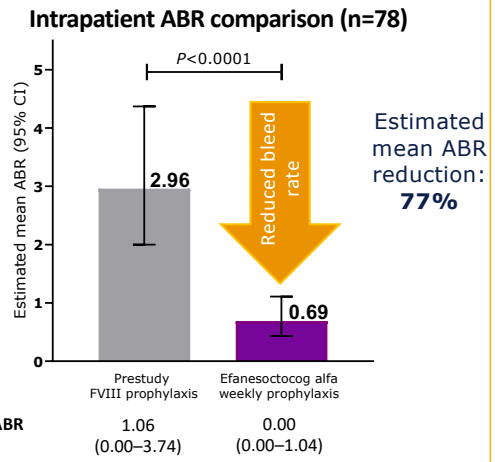
- Annualised bleeding rate (ABR) in the prophylaxis treatment arm (A)

	Arm A (n=133)
ABR, median (IQR[1])	**0.00** (0.00 – 1.04)
ABR, mean model-based (95% CI[2])	**0.71** (0.52 – 0.97)

- **Efanesoctocog alfa provided effective bleed protection**

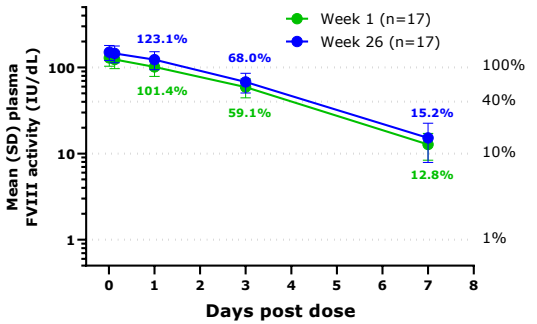
Key secondary endpoint met

- Bleed control vs. prior FVIII[3] SOC[4]



Pharmacokinetics

- Mean FVIII levels remained in the normal to near-normal range (>40 IU/dL) for ~4 days post dose, and at 15 IU/dL at Day 7



Other efficacy endpoints met: clinically meaningful improvements in physical health, pain, and joint health
Treatment-emergent adverse events generally consistent with a population with severe haemophilia A

1. Interquartile range 2. Confidence interval 3. Factor VIII 4. Standard of care (prophylaxis treatment). Source: abstract LB 01.4, The International Society on Thrombosis and Haemostasis 2022 Congress.

Pipeline: integration of R&D and Medical and the creation of core assets teams (CATs) anticipated to improve productivity

Clear roles and governance

Cross-functional operating model

Effective and simple organisation

Combined R&D and Medical Affairs

Efficiency

Simpler processes

Flexibility and agility

Strategic sourcing

Pipeline news flow

Anticipated major upcoming pipeline news flow

H2 2022	H1 2023	H2 2023
efanesoctocog alfa – haemophilia A: regulatory submission acceptance (US)	**efanesoctocog alfa** – haemophilia A (paediatric): XTEND-Kids phase 3 study data readout	**efanesoctocog alfa** – haemophilia A: regulatory submission (EU)
Aspaveli/Empaveli – CAD[1]: phase 3 study first patient dosed	**Doptelet** – CLD[3]: regulatory decision (JP)	**Aspaveli/Empaveli** – ALS[5]: MERIDIAN phase 2 study data readout (by Apellis in mid-2023)
nirsevimab – RSV prevention: regulatory submission (US) (by AstraZeneca/Sanofi)[2]	**Empaveli** – PNH: regulatory decision (JP)	**Kineret** – FMF: regulatory decision (CN)
Kineret – COVID-19: regulatory decision, emergency use (US)	**loncastuximab tesirine** – DLBCL: regulatory decision (EU) (by ADC Therapeutics in the first quarter of 2023)	**Gamifant** – MAS in rheumatological diseases: regulatory submission (US)
	Gamifant – MAS[4] in rheumatological diseases: EMERALD phase 3 study data readout	**SEL-212** – CRG: regulatory submission (US)
	SEL-212 – CRG: phase 3 studies data readout	

1. Cold agglutinin disease 2. Sobi has the right to AstraZeneca's full share of US losses and profits for nirsevimab. 3. Chronic liver disease 4. Macrophage activation syndrome 5. Amyotrophic lateral sclerosis. Status as of 18 July 2022.

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Q&A

Appendix: Q2 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 Q2 2022

- Increasing access through **launches** in new markets
  - Aspaveli in UK, Germany (PNH)
  - Doptelet in Spain (ITP[1])
- New app, **Hemocoach**, supporting patients in France with persona-lised advice on physical activity
- **Liberate Life** campaign recognised in the Italian "Excellences in Scientific Information and Patient Centricity Award"
- Shared knowledge at
  - WFH[2] World Congress
  - 2022 EHA[3] congress

- Participated in **STEM[4] training and mentoring programme** "Deploy your talents" in Italy, together with 17 other Italian and international companies and nine high schools, reaching 400 students

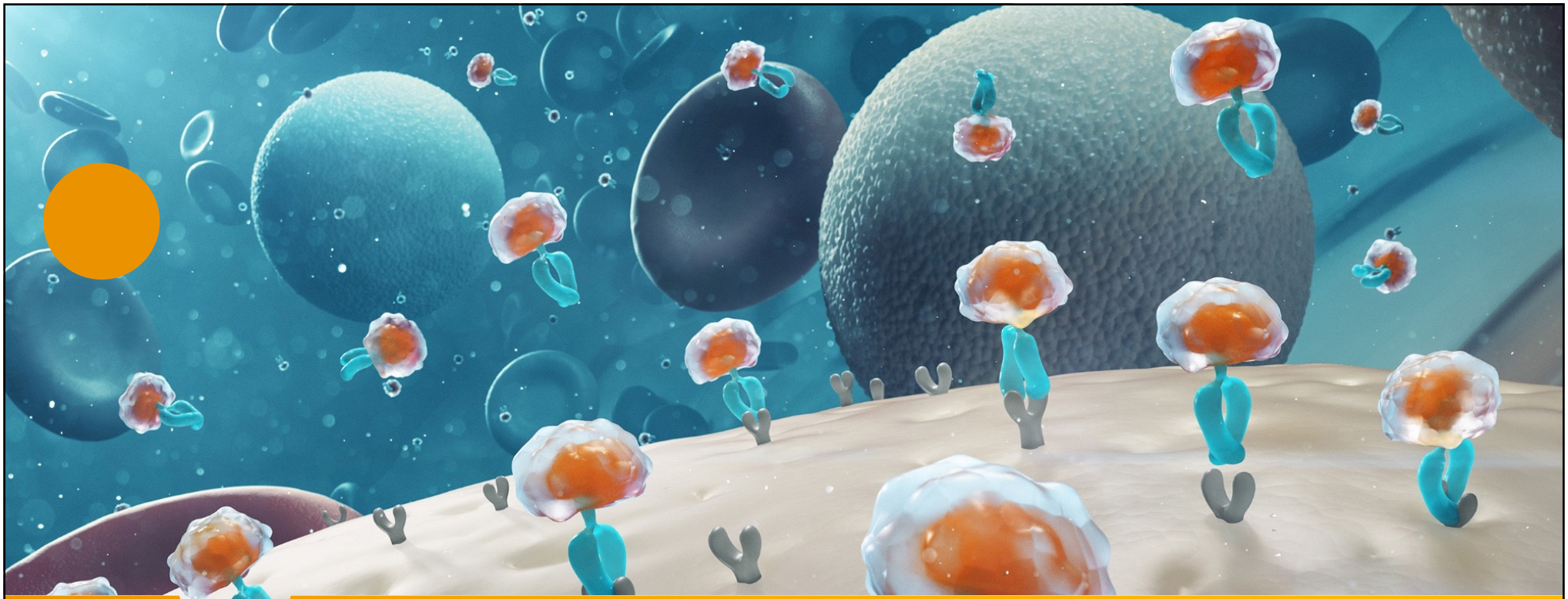
1. Immune thrombocytopenia 2. World Federation of Hemophilia 3. European Hematology Association 4. Science, technology, engineering and math.

Appendix: items affecting comparability (IAC)

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

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

Source: Sobi Q2 2022 report, page 3.



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