

# Q1 2022 report

Conference call for  
investors and analysts

rare **strength**



28 April 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: a good start in 2022

- **Revenue up 24%**, incl. phasing of Doptelet® sales to China
- **Launch medicines<sup>1</sup> up 126%**
- EBITA margin 26%, incl. provision for expected credit losses in Russia and restructuring (contract manufacturing closure, site simplification, efficiency programmes)
- **EBITA margin adjusted 40%**
- Efficiency programmes will focus resources into core areas, simplify the organisation and adjust the cost base to enable Sobi to continue sustainable growth and margin improvement over time
- Pipeline progressed with first **efanesoctocog alfa phase 3 data**
- Significant pipeline news flow over 2022 and 2023 timeframe
- **2022 outlook underpinned**

**Strategy on track:**

**Good start in 2022 with delivery on strategic agenda and the 2022 outlook is underpinned**

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



## Business: strong growth amongst all disease areas and increased diversification across global regions

	Q1 '22	change	ratio
	SEK M	%	%
<b>Haematology</b>	2,499	25	52
– <i>haemophilia</i>	1,777	7	37
<b>Immunology</b>	2,119	24	42
<b>Speciality Care</b>	307	24	6

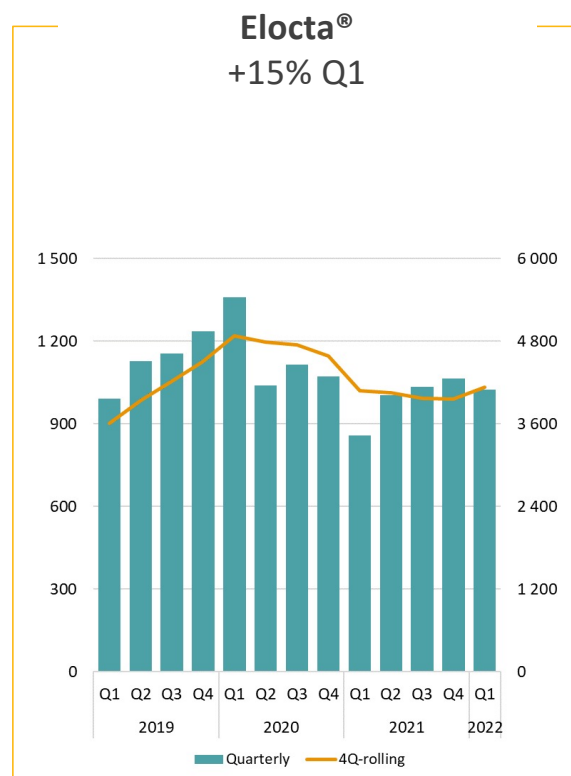
<b>Total</b>	<b>4,925</b>	<b>24</b>	<b>100</b>
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	Q1 '22	change	ratio
	SEK M	%	%
<b>Europe</b>	1,803	6	38
<b>North America</b>	2,117	29	42
<b>Rest of world</b>	672	149	14
<b>Other<sup>1</sup></b>	333	1	7

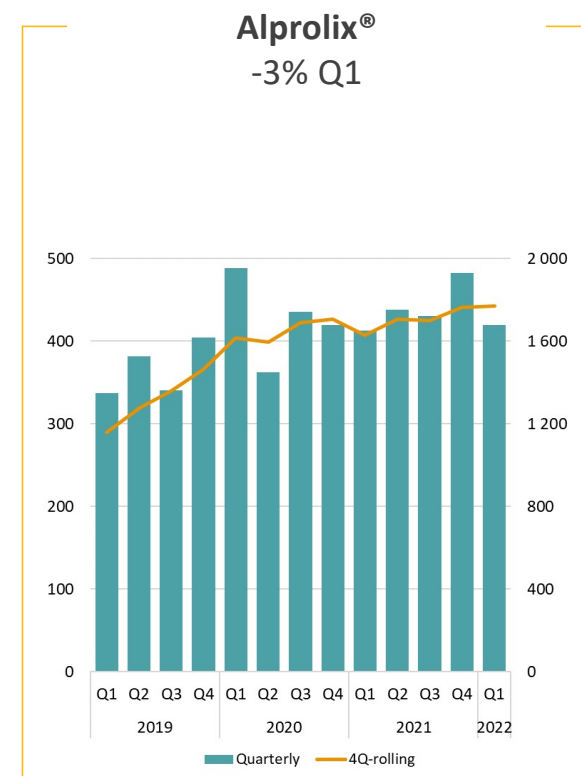
<b>Total</b>	<b>4,925</b>	<b>24</b>	<b>100</b>
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1. Royalty revenue.  
Revenue at actual exchange rates; change at constant exchange rates (by segment and geographic area).

# Haematology: haemophilia grew 7% from a low Q1'21 base

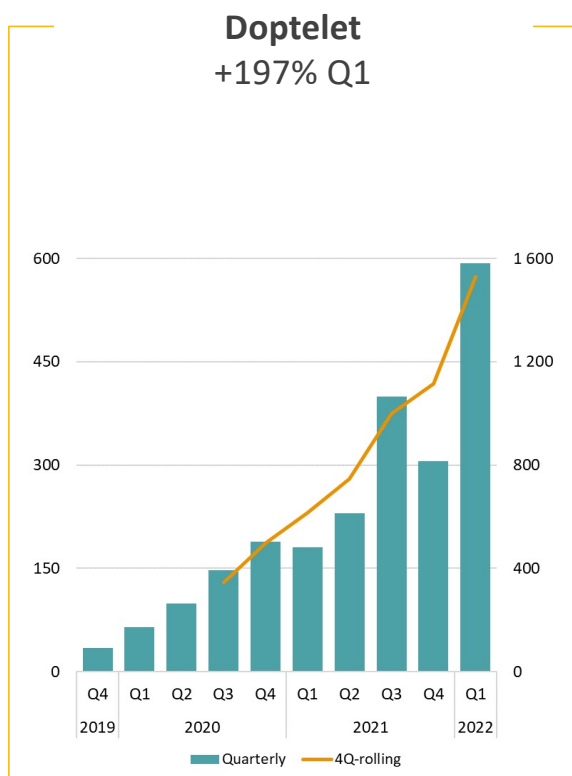


- Haemophilia expected to continue stability in 2022**
- Elocta**
- Growth in patients and factor consumption coupled with a lower base in Q1'21
- Alprolix**
- Growth in patients offset by slightly lower consumption and price adjustments





# Haematology: Doptelet benefitted from phasing of sales to the partner in China



- Continued US launch progress
- Early launches in Europe accelerated with Germany as the largest contributor
- Phasing of sales to partner in China. In China, Doptelet has NRD<sup>1</sup> inclusion



1. National Reimbursement Drug List.  
Revenue in SEK million at actual exchange rates; change at constant exchange rates.





**ASPARELI®**  
(pegcetacoplan)

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

**UK sales**

commenced in  
late March

**SEK 4 M**

in Q1 2022  
revenue from  
MEA<sup>2</sup> and the UK

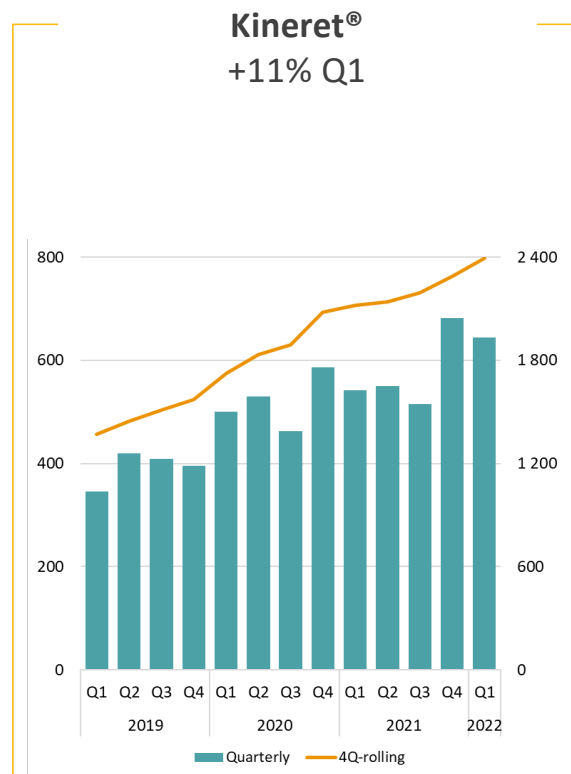
**Launch**

anticipated in  
Germany and  
France in Q2  
2022

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. 2. Middle East and Africa. Revenue in SEK million at actual exchange rates.



# Immunology: Kineret and Gamifant saw continued growth

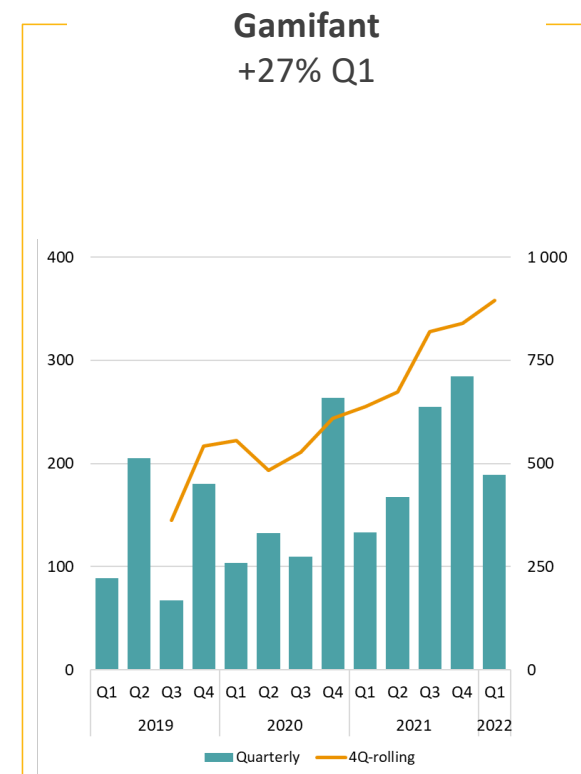


## Kineret

- COVID-19 supplies in emerging markets partly offset by the US. Underlying growth remained single-digit

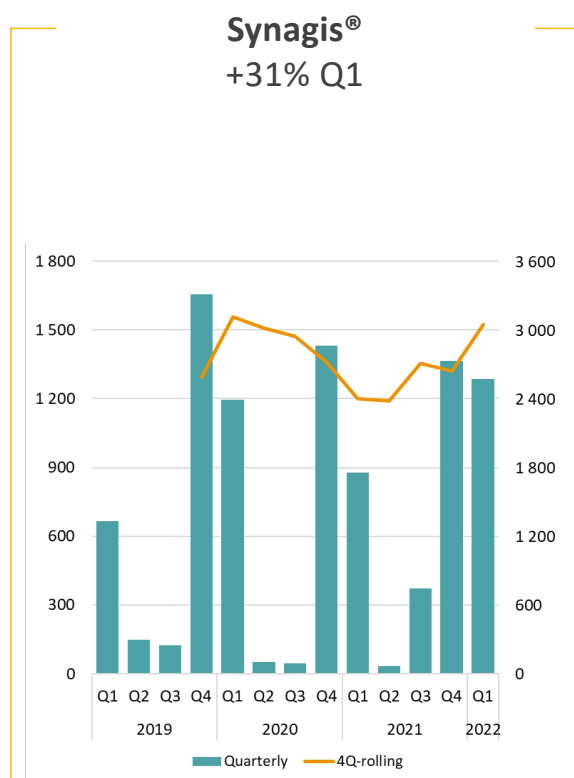
## Gamifant

- Some growth in new patients offset by patients concluding their treatment



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

## Immunology: early Synagis use held up



- Growth driven by patients that remained on treatment despite the early start to the US RSV<sup>1</sup> season as well as the lower base in 2021 caused by reduced infection levels
- With RSV infections remaining low, there is uncertainty as to the timing and size of the new 2022-2023 season

1. Respiratory syncytial virus.  
Revenue in SEK million at actual exchange rates; change at constant exchange rates.



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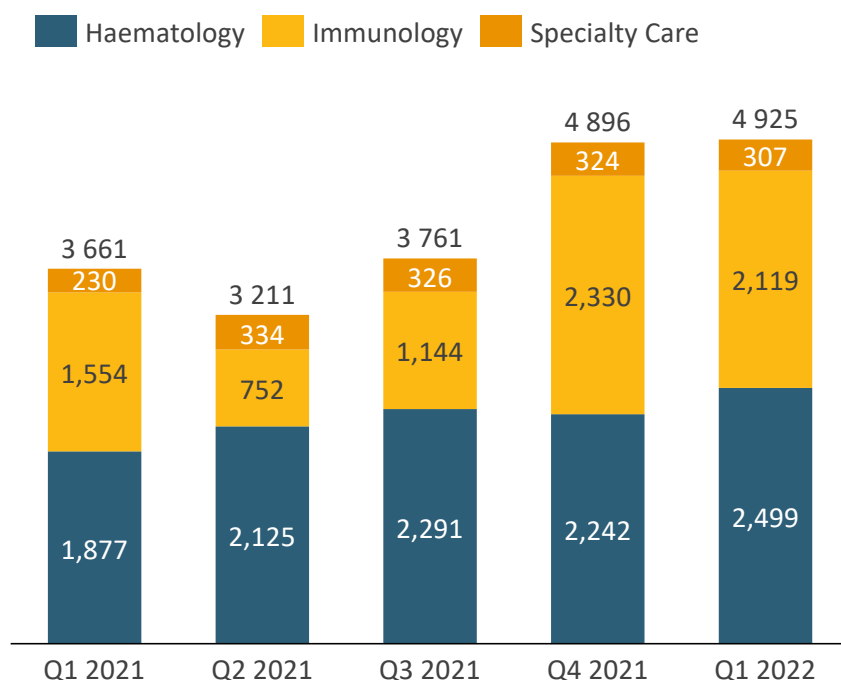
Anders Ullman, Head of R&D, Chief Medical Officer

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# Revenue and profit & loss

## Total revenue (SEK M)



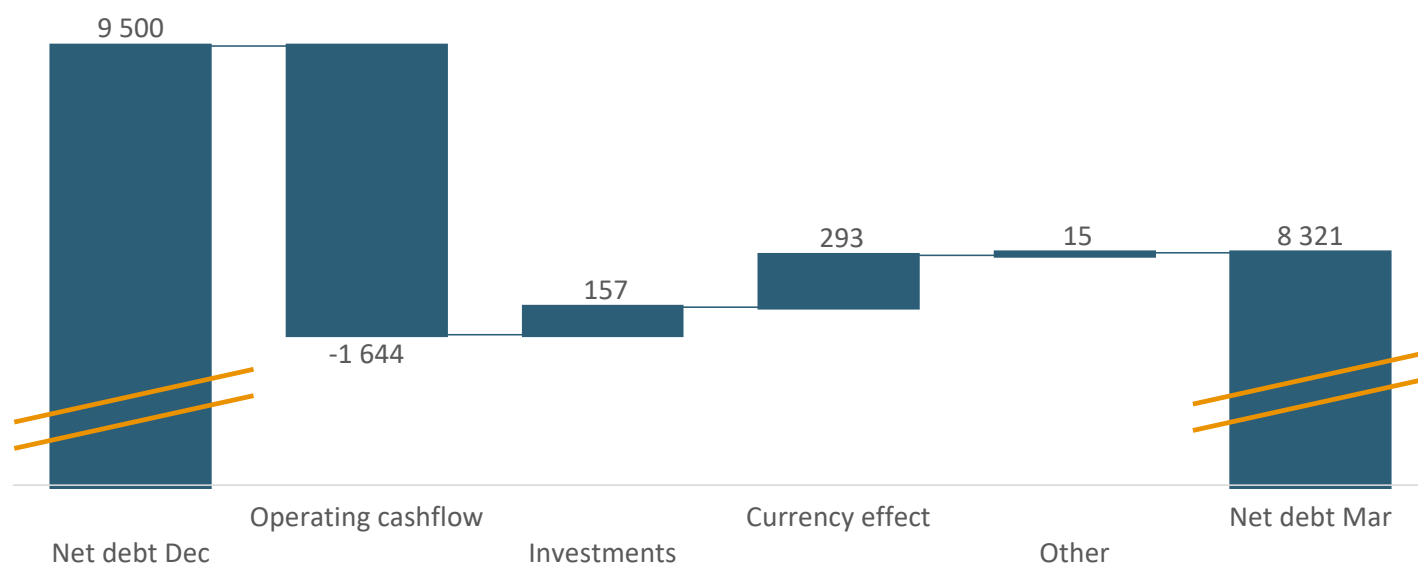
	Q1 2022	Q1 2021	Change	Full-year 2021
Total revenue	4,925	3,661	35%	15,529
Gross profit	3,409	2,935	16%	12,045
Gross margin <sup>1</sup>	69%	80%		78%
EBITA <sup>1</sup>	1,290	1,484	-13%	5,575
EBITA adjusted <sup>1,2</sup>	1,951	1,484	31%	5,575
EBITA margin <sup>1</sup>	26%	41%		36%
EBITA margin adjusted <sup>1,2</sup>	40%	41%		36%
Profit	543	696	-22%	2,679
Earnings per share (EPS), before dilution, SEK <sup>1</sup>	1.84	2.36	-22%	9.08
EPS, before dilution, SEK adjusted	3.67	2.36	55%	9.08
Operating cashflow	1,644	1,699	-3%	
Net debt (+)/net cash (-)	8,321	12,674		9,500

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

2. Items affecting comparability in Q1 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).

## Net debt: continued strong cash generation in Q1 2022



Absolute amounts in SEK million and at actual exchange rates.



# 2022 outlook

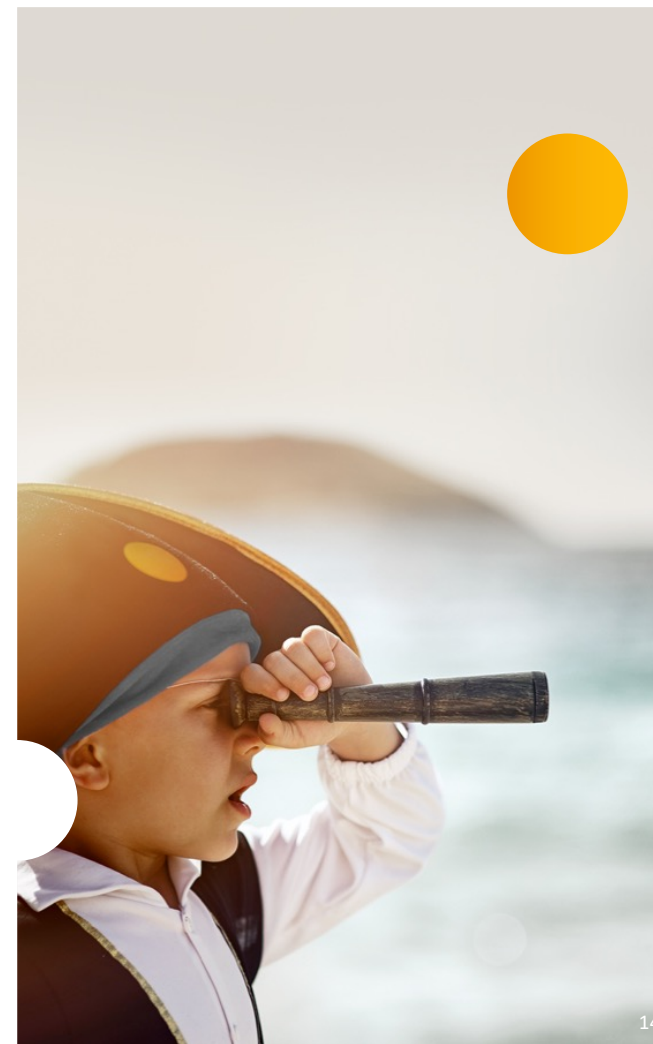
## Revenue

Anticipated to grow by a mid to high single-digit percentage at CER<sup>1</sup>

## EBITA margin

Anticipated to be at a low 30s percentage of revenue  
(now based on EBITA margin adjusted<sup>2</sup>)

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



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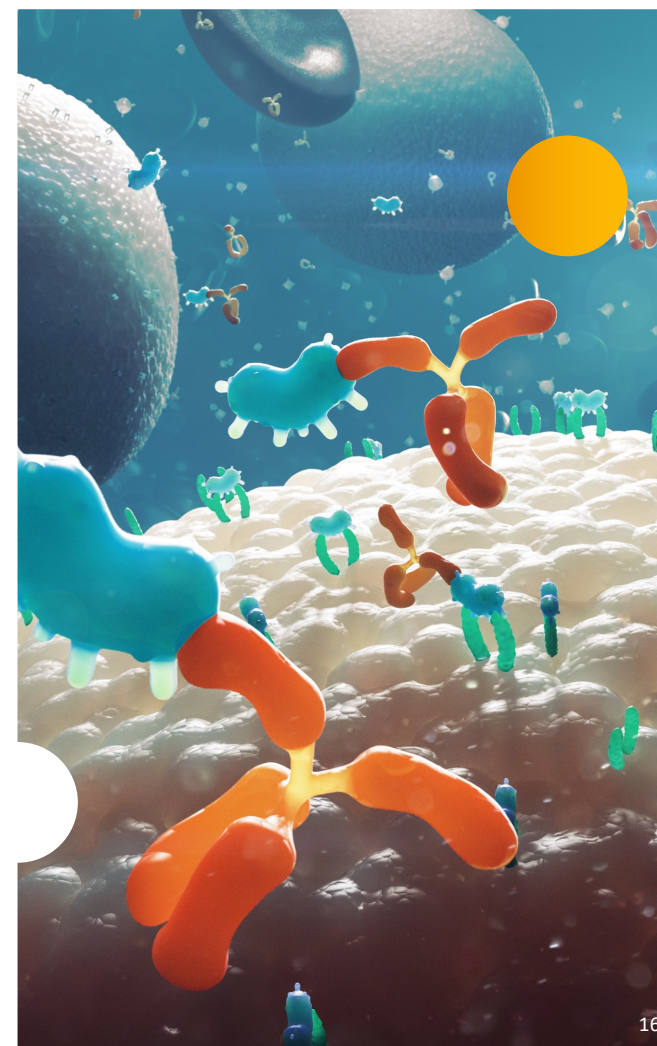
All

# Pipeline: significant progress on approvals and other milestones

Major pipeline milestones since the previous quarterly report

<b>Regulatory approval</b>	Aspaveli	PNH	UK
	Gamifant	pHLH <sup>1</sup>	China
<b>Other significant milestones</b>	Efanesoctocog alfa	haemophilia A	positive XTEND-1 phase 3 study
			XTEND-Kids phase 3 study enrolment completion
	Doptelet	CLD <sup>2</sup>	regulatory submission acceptance in Japan
	Aspaveli/ Empaveli	ALS <sup>3</sup>	MERIDIAN phase 2 study enrolment completion (by Apellis)
	Kineret	COVID-19	regulatory submission for emergency use in the US

1. Primary haemophagocytic lymphohistiocytosis 2. Chronic liver disease 3. Amyotrophic lateral sclerosis. Status as of 27 April 2022.



**efanesoctocog  
alfa (BIVV001)**

**XTEND-1 phase 3  
study positive**

**Zero**

median annualised  
bleeding rate<sup>1</sup>

**0.71**

mean annualised  
bleeding rate<sup>1</sup>

**Potential to  
transform  
haemophilia  
A therapy**

**News flow**

H2 2022  
US BLA<sup>2</sup>

2023  
XTEND-Kids data  
EU filing<sup>3</sup>

1. The study met the primary endpoint, showing a clinically meaningful prevention of bleeds in patients ≥12 years of age with severe haemophilia A receiving weekly prophylaxis with efanesoctocog alfa over a period of 52 weeks. The median annualised bleeding rate (ABR) was 0 with a mean ABR of 0.71 2. Biologics license application by Sanofi in mid-2022 3. Regulatory submission.  
Source: Sobi press release on 9 March 2022 [<https://www.sobi.com/en/press-releases/efanesoctocog-alfa-met-primary-and-key-secondary-endpoints-pivotal-study-haemophilia>].



# Pipeline news flow

Anticipated major upcoming pipeline news flow

H1 2022	H2 2022	2023
<p><b>Aspaveli/Empaveli</b> – IC-MPGN and C3G<sup>1</sup>: phase 3 study first patient dosed (by Apellis)</p> <p><b>Aspaveli/Empaveli</b> – CAD<sup>2</sup>: phase 3 study first patient dosed</p> <p><b>SEL-212</b> – CRG<sup>3</sup>: DISSOLVE II phase 3 study enrolment completion</p>	<p><b>Efanesoctocog alfa</b> – haemophilia A: regulatory submission (US) (by Sanofi in mid-2022)</p> <p><b>Nirsevimab</b> – RSV prevention: regulatory submission (US) (by AstraZeneca/Sanofi) (financial participation by Sobi)</p> <p><b>Kineret</b> – COVID-19: regulatory decision, emergency use (US)</p> <p><b>Gamifant</b> – MAS<sup>4</sup> in rheumatological diseases: EMERALD phase 3 study data readout</p> <p><b>SEL-212</b> – CRG: phase 3 studies data readout</p>	<p><b>Efanesoctocog alfa</b> – haemophilia A (paediatric): XTEND-Kids phase 3 study data readout</p> <p><b>Efanesoctocog alfa</b> – haemophilia A: regulatory submission (EU)</p> <p><b>Doptelet</b> – CLD: regulatory decision (JP)</p> <p><b>Aspaveli/Empaveli</b> – ALS: MERIDIAN phase 2 study data readout (by Apellis in mid-2023)</p> <p><b>Gamifant</b> – MAS in rheumatological diseases: regulatory submission (US)</p> <p><b>SEL-212</b> – CRG: regulatory submission (US)</p>

1. Immune complex-mediated membranoproliferative glomerulonephritis and C3 glomerulopathy 2. Cold agglutinin disease 3. Chronic refractory gout  
4. Macrophage activation syndrome. Status as of 27 April 2022.





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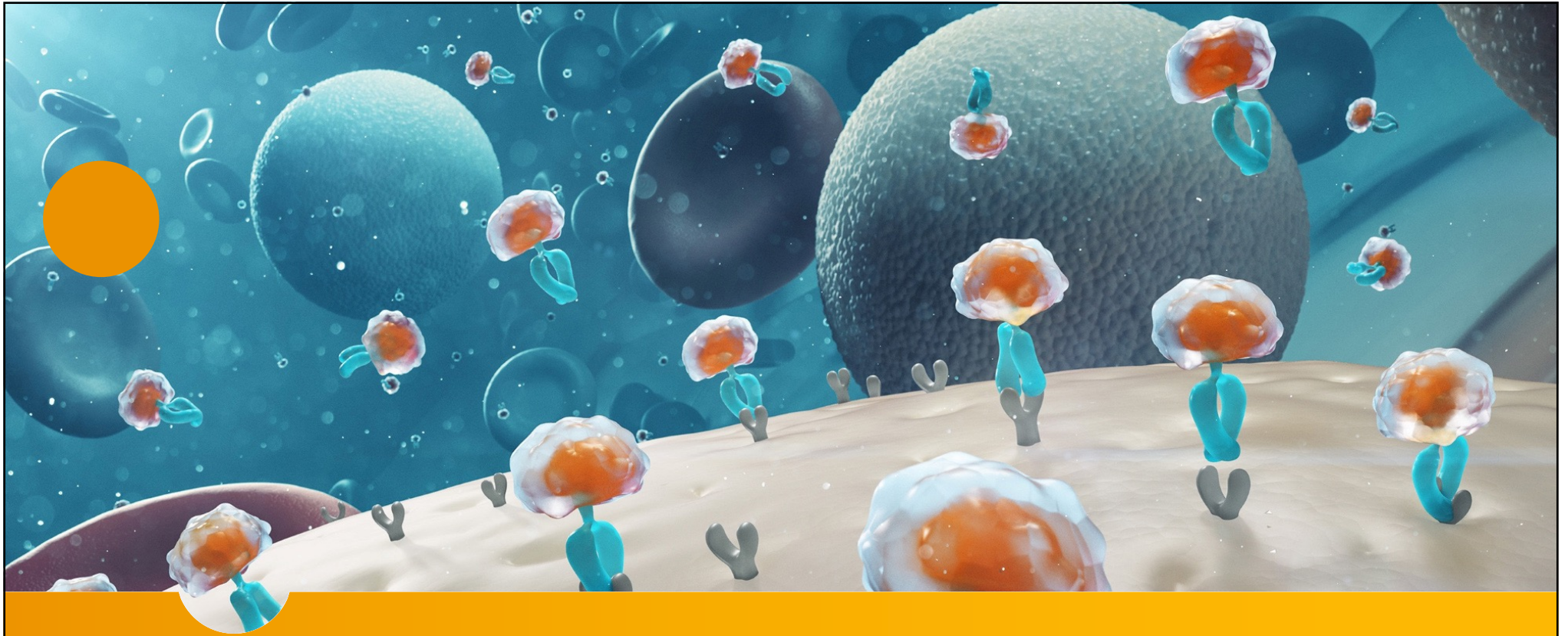




**Q&A**

## Appendix: items affecting comparability

SEK M	Q1 2022	Items affecting comparability	Q1 2022 excluding items affecting comparability
Total revenue	4,925	–	4,925
Cost of goods sold <sup>1</sup>	-1,516	-360	-1,156
<b>Gross profit</b>	<b>3,409</b>	<b>-360</b>	<b>3,769</b>
<i>Gross margin</i>	69%		77%
Selling and administrative expenses <sup>2,3,4</sup>	-2,053	-249	-1,804
Research and development expenses <sup>2,3</sup>	-578	-52	-526
Other operating income/expenses	-2	–	-2
<b>Operating profit (EBIT)</b>	<b>776</b>	<b>-661</b>	<b>1,437</b>
Net financial items	-102	–	-102
<b>Profit before tax</b>	<b>674</b>	<b>-661</b>	<b>1,335</b>
Income tax	-131	121	-252
<b>Profit for the period</b>	<b>543</b>	<b>-540</b>	<b>1,083</b>
EBITA	1,290	-661	1,951
EBITDA	1,461	-529	1,990
Amortisation and impairment of intangible assets related to Selling and administrative expenses	-514	–	-514
Depreciation and impairment of tangible assets <sup>1,2</sup>	-171	-132	-39
<b>Operating profit (EBIT)</b>	<b>776</b>	<b>-661</b>	<b>1,437</b>



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