



Sobi Q2 results presentation

rare **strength**



17 July 2019

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) is providing the following cautionary statement. This presentation contains forward-looking statements with respect to the financial condition, results of operations and businesses of Swedish Orphan Biovitrum AB (publ), 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.



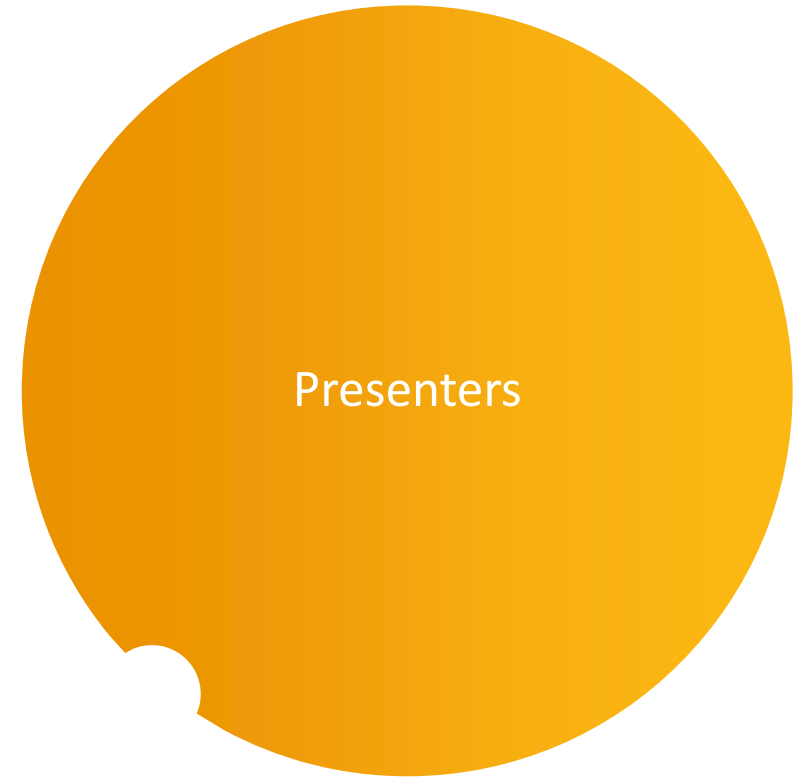
Guido Oelkers, CEO



Henrik Stenqvist, CFO



Milan Zdravkovic, Head of R&D and CMO



Strong performance, sharper focus

- Total revenue of SEK 3,163 M (2,289). 38 per cent revenue growth in the quarter compared with Q2 2018 (32 per cent at CER)
- Organic growth (adjusted for Synagis and measured at CER) amounted to 25 per cent compared with Q2 2018
- Adjusted EBITA^{1,2} was SEK 1,193 M, an increase of 25 per cent
- Sales for Elocta[®] were SEK 1,127 M (794), an increase of 42 per cent (37 per cent at CER)
- Sales for Alprolix[®] were SEK 382 M (263), an increase of 45 per cent (40 per cent at CER)
- Continued strong performance for Gamifant[®] with sales amounting to SEK 205 M
- Purchase agreement of CHF 515 M (SEK 4,897 M) to emapalumab and related assets was signed
- Sharpened strategic focus on core areas of Haematology in Sweden and in Immunology in Switzerland
- Investment into core business and late-stage assets to drive future growth

^{1,2}EBITA excluding non-recurring items; restructuring costs of SEK 157 M in Q2 2019 and gain from divestment of SOBI005 in Q1 2019 of SEK 37 M.

The graphic features a large white circle on the left side of the slide, which has a small semi-circular notch at its bottom edge. To its right is a smaller, solid white circle. The text 'Business Review' is centered within the large white circle.

Business Review

Haemophilia – strong position with substantial potential

Continued exceptional momentum

- Future growth driven by penetration and internationalisation

Individualised therapy only possible with factor replacement

- Ensuring best outcome for patients

Significant promise now and for the future

- Factor replacement will remain standard of care for people with haemophilia

Alprolix – impressive performance continues

Sales revenue (SEK M)

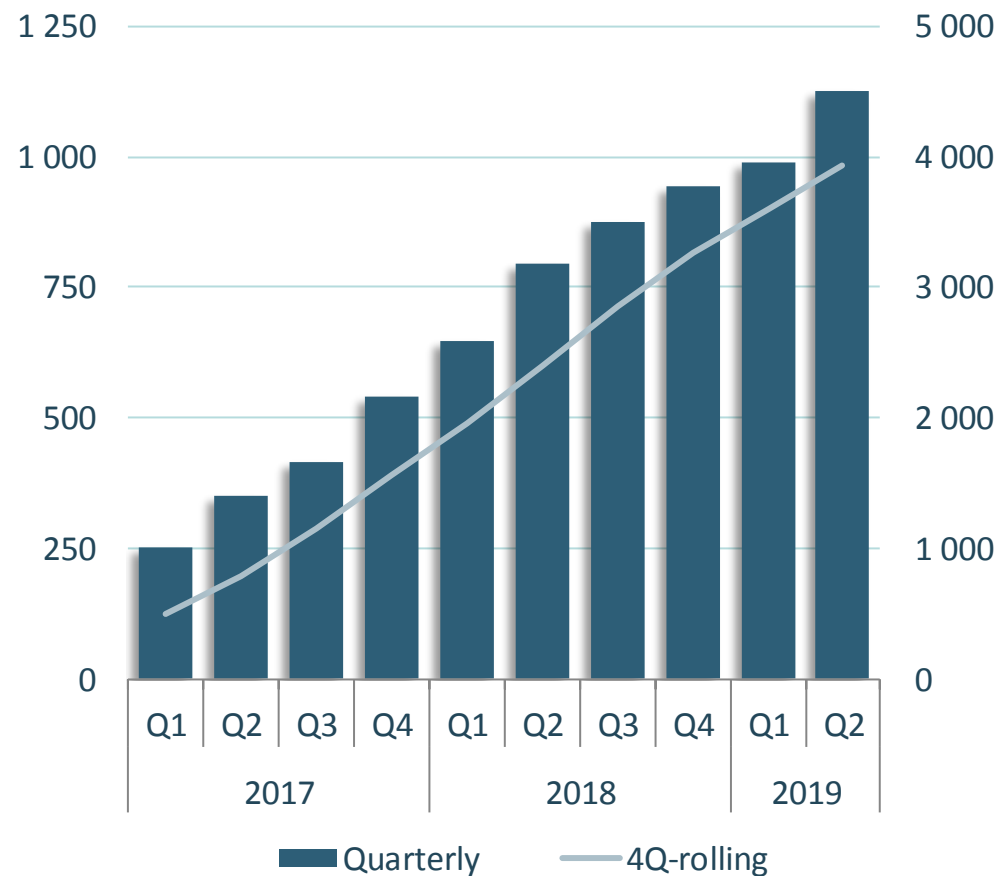


- Q2 product sales of SEK 382 M (263)
 - Sales growth of 45 per cent (40 per cent at CER)
 - Majority of the growth derived from France, Italy and Germany
- Reimbursed in 23 countries
- Debate on clinical benefit of extra vascularisation is intensifying
- Alprolix showed zero bleeds unlike other EHLs in a real-world setting¹

¹ISTH 2019 Malic et al.

Elocta – factor replacement therapies keep up momentum

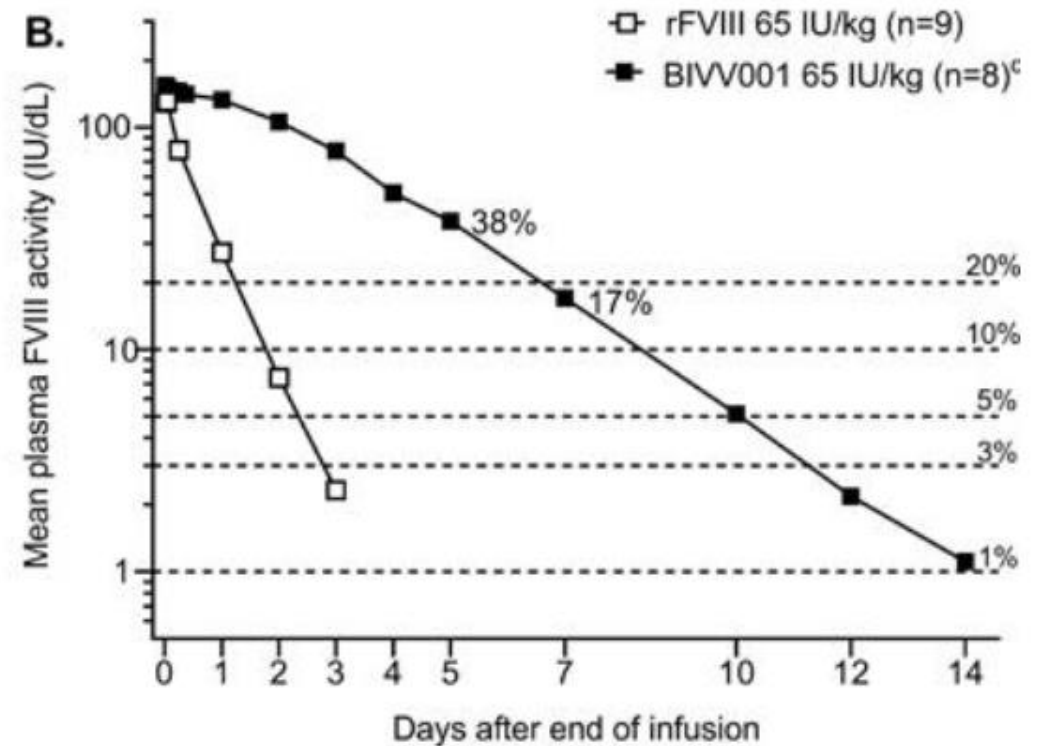
Sales revenue (SEK M)



- Q2 product sales of SEK 1,127 M (794)
 - Revenue growth of 42 per cent (37 per cent at CER)
 - Majority of the growth derived from France, Italy and Germany
 - Sales positively impacted by order patterns in the Middle East
- Reimbursed in 27 countries
- Confidence in further development of the product

Single 65 IU/kg dose of BIVV001 extends FVIII half-life to 43 h and shows 17% activity seven days post-infusion

- Mean $t_{1/2}$ for BIVV001 at a dose of 65 IU/kg was longer than for rFVIII (43 vs 13 h)
- Average FVIII activities at 5 and 7 days post 65 IU/kg BIVV001 were 38% and 17% respectively



Interim results from a prospective study of first-time ITI with Elocta

Background

- Immune Tolerance Induction (ITI) is the standard of therapy for eradication of inhibitors
- Experimental data suggests immunomodulatory effects of Fc-fused factor therapy
- Encouraging retrospective clinical data in ITI

Study

- Interventional, multi-centre study of Elocta for first-time ITI in subjects with severe haemophilia A & high-titre inhibitors (historical peak ≥ 5 BU/mL)
- Pre-planned interim analysis when 10 subjects received at least 6 months of ITI (data cut-off as of 23 Jan 2019)

Results & Conclusion

- 6 out of 15 patients had ITI success after a median of 11.7 weeks (8 patients still ongoing)
- Interim results indicate that Elocta may offer rapid time to tolerisation

Driving growth in Immunology

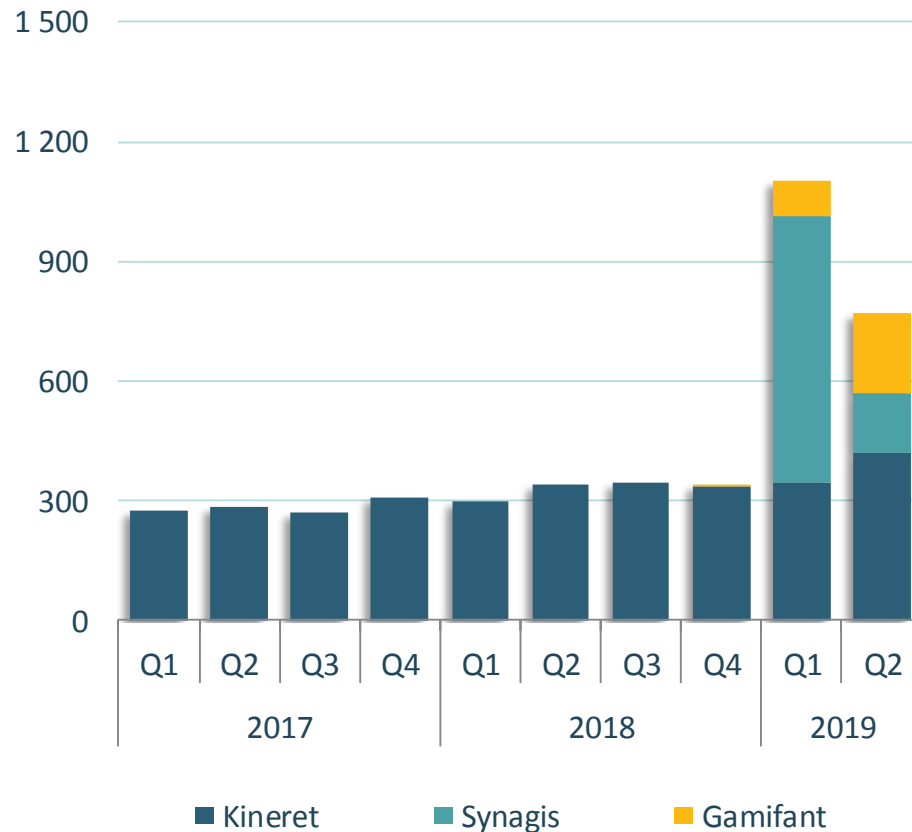
Strong base business with Kineret – back to double-digit growth

Gamifant – high unmet medical need driving growth

Continuously reviewing opportunities for external growth

Immunology – strong overall growth

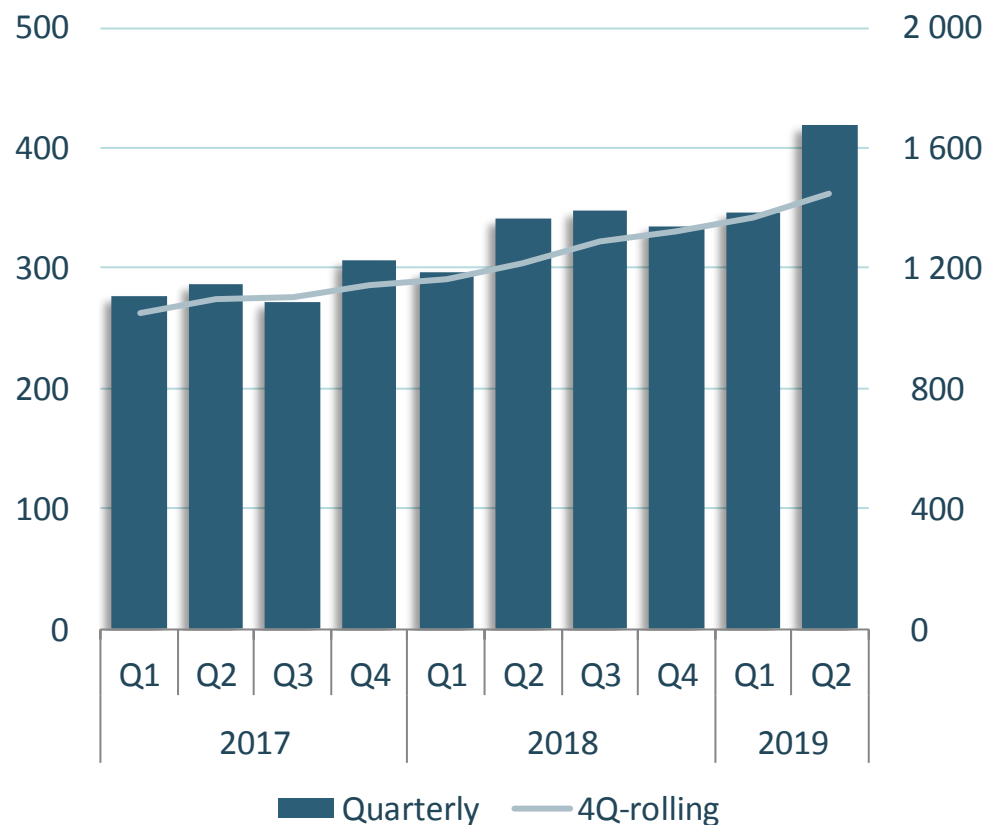
Sales revenue (SEK M)



- Total Immunology revenue of SEK 773 M
- Synagis sales impacted by seasonal variations
- Purchase agreement of CHF 515 M (SEK 4,897 M) for the global rights to emapalumab and related assets was signed
- Double-digit growth for Kineret

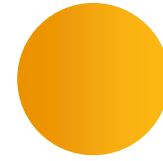
Kineret – continued solid growth

Sales revenue (SEK M)



- Revenue of SEK 419 M (340 M)
 - Increase of 23 per cent (16 per cent at CER) compared with Q2 2018
- Double-digit growth seen across all regions
- High demand in the US related to:
 - Changed distribution channel provider
 - New patient enrolments
 - More patients continuing on treatment
 - Improved prescription fill rates

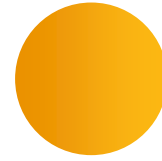
Synagis opportunity



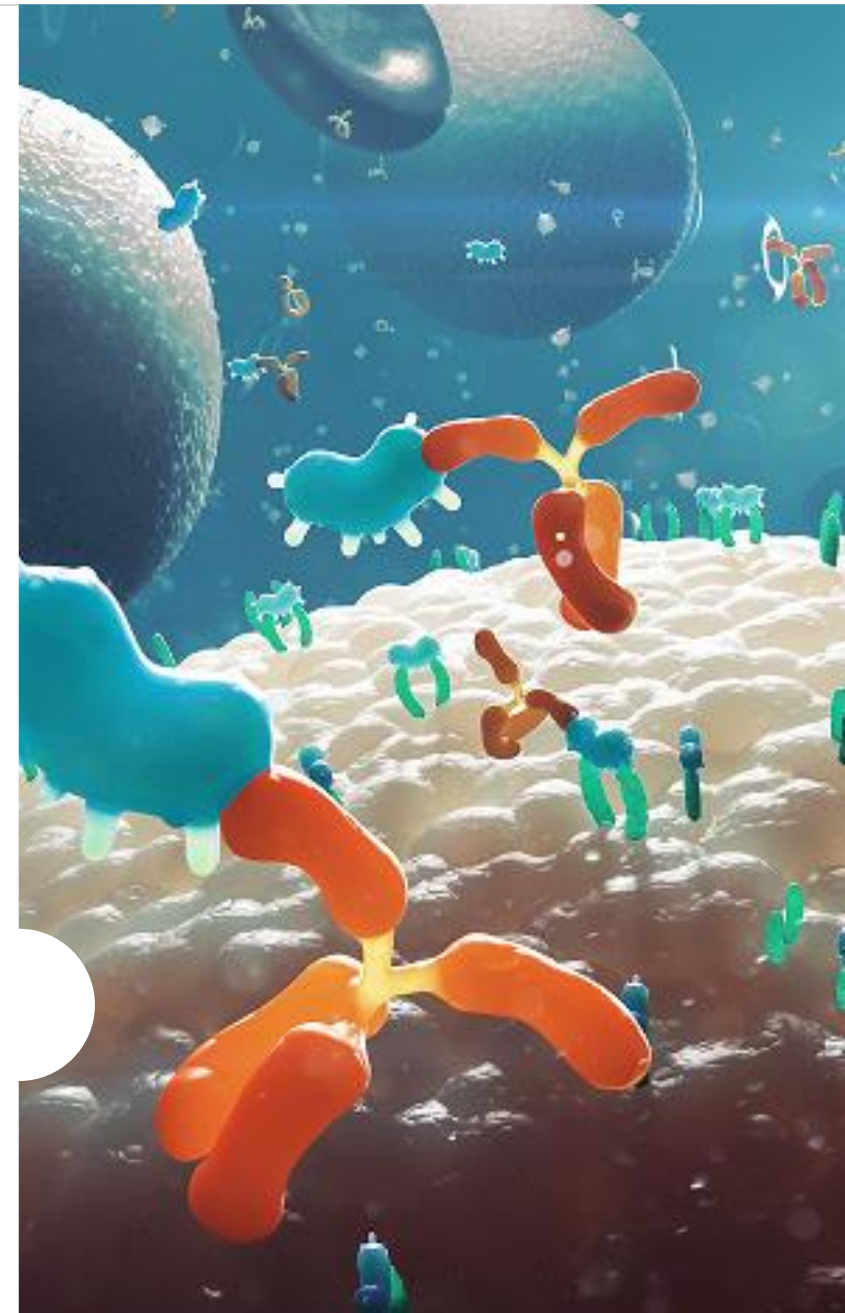
- Q2 sales of SEK 148 M
 - Sales strongly influenced by seasonal effects
 - Virus season lasted longer this year
 - Increased focus on achieving full adherence among patients.
 - Sales also include one-offs of SEK 81 M
- Underlying demand increasing (2.5%)
- Ongoing activities to unlock meaningful value across the patient funnel
 - Reduce leakages across the chain
 - Improve adherence



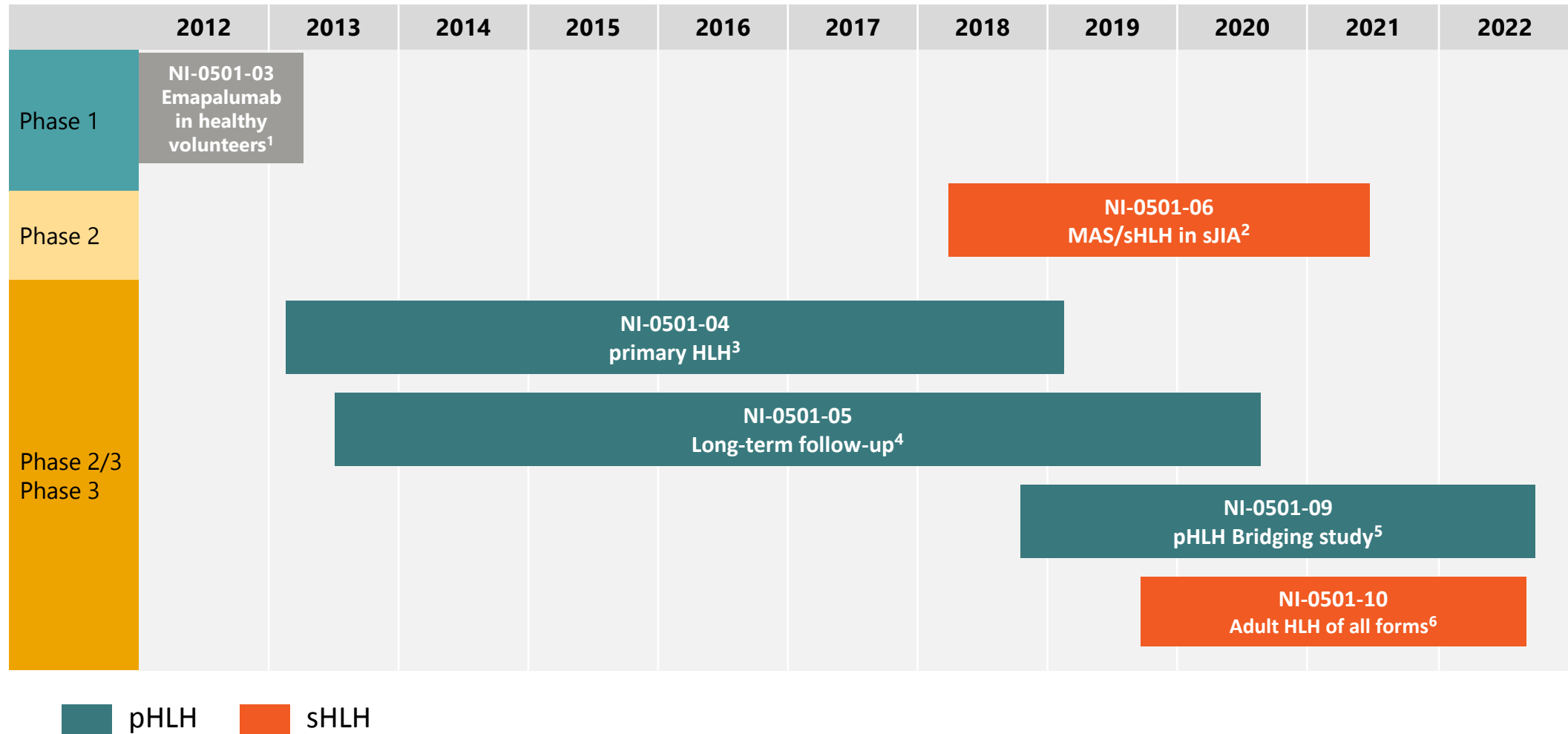
Gamifant – strong US growth



- Q2 sales of SEK 205 M
- Growth mainly driven by high demand due to unmet medical need
- The regulatory dialogue and process ongoing with CHMP in Europe for the potential approval of emapalumab for primary HLH
- Based on current estimates and anticipated timelines for questions and answers, approval expected around mid-2020.
- Continue investments into further indications and new markets



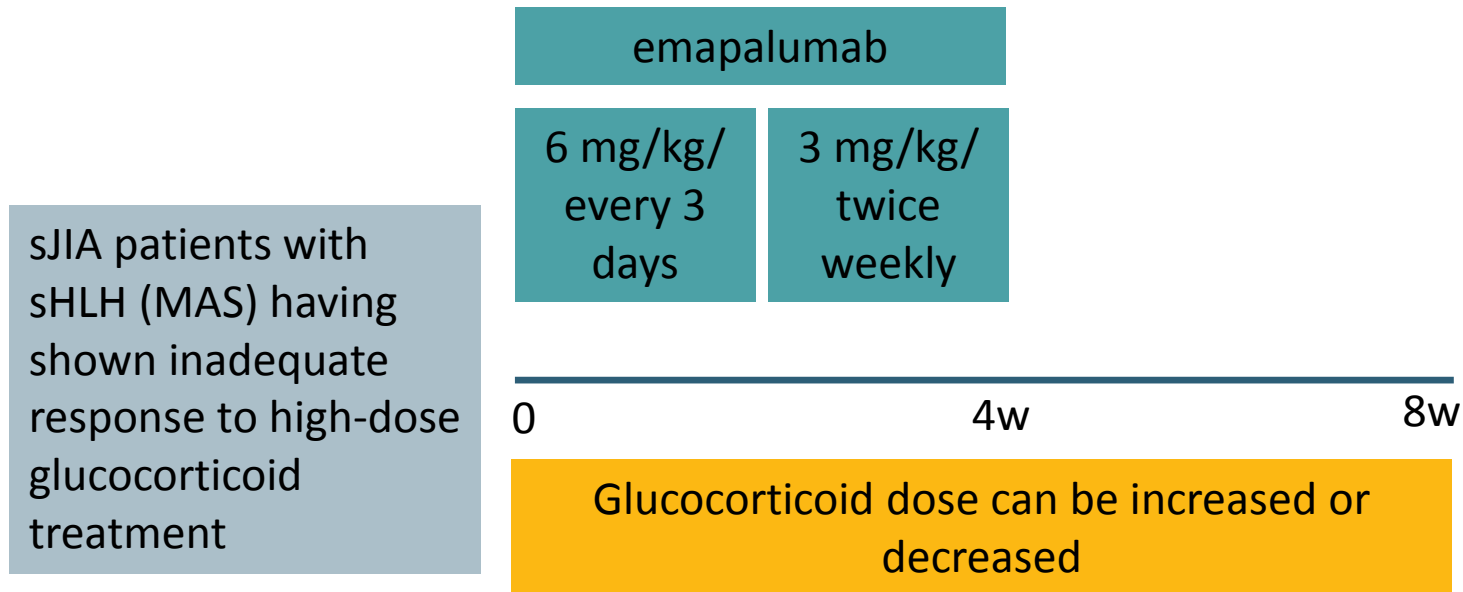
Emapalumab clinical trial programme (as of June 2019)



1. <https://clinicaltrials.gov/ct2/show/NCT01459562> 2. <https://clinicaltrials.gov/ct2/show/NCT03311854> 3. <https://clinicaltrials.gov/ct2/show/NCT01818492> 4. <https://clinicaltrials.gov/ct2/show/NCT02069899>
 5. <https://clinicaltrials.gov/ct2/show/NCT03312751> 6. <https://clinicaltrials.gov/ct2/show/NCT03985423>

Emapalumab leads to complete response in patients with secondary HLH (MAS) induced by sJIA

– interim results from a pilot phase 2 study



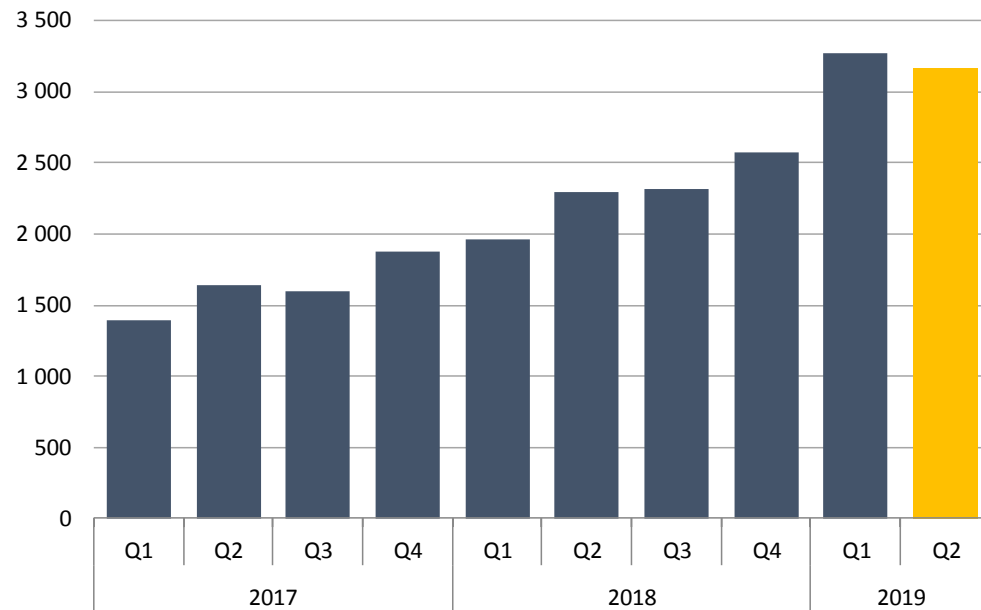
- Complete response to emapalumab was observed in 6 out of 6 patients, all of whom had failed conventional therapy
- Rapid decrease in CXCL9 demonstrating complete neutralisation of IFN γ
- Response occurred early with clinically meaningful tapering of glucocorticoids observed from week 1
- Emapalumab was well tolerated; a few infections emerged (mostly positive tests); one CMV reactivation was considered related and serious

The graphic features a large white circle on the left side of the slide, containing the text 'Financial Results'. To its right is a smaller white circle. The background is a solid orange color with a vertical gradient, transitioning from a lighter shade on the left to a darker shade on the right.

Financial Results

Financial results

Total revenue (SEK M)



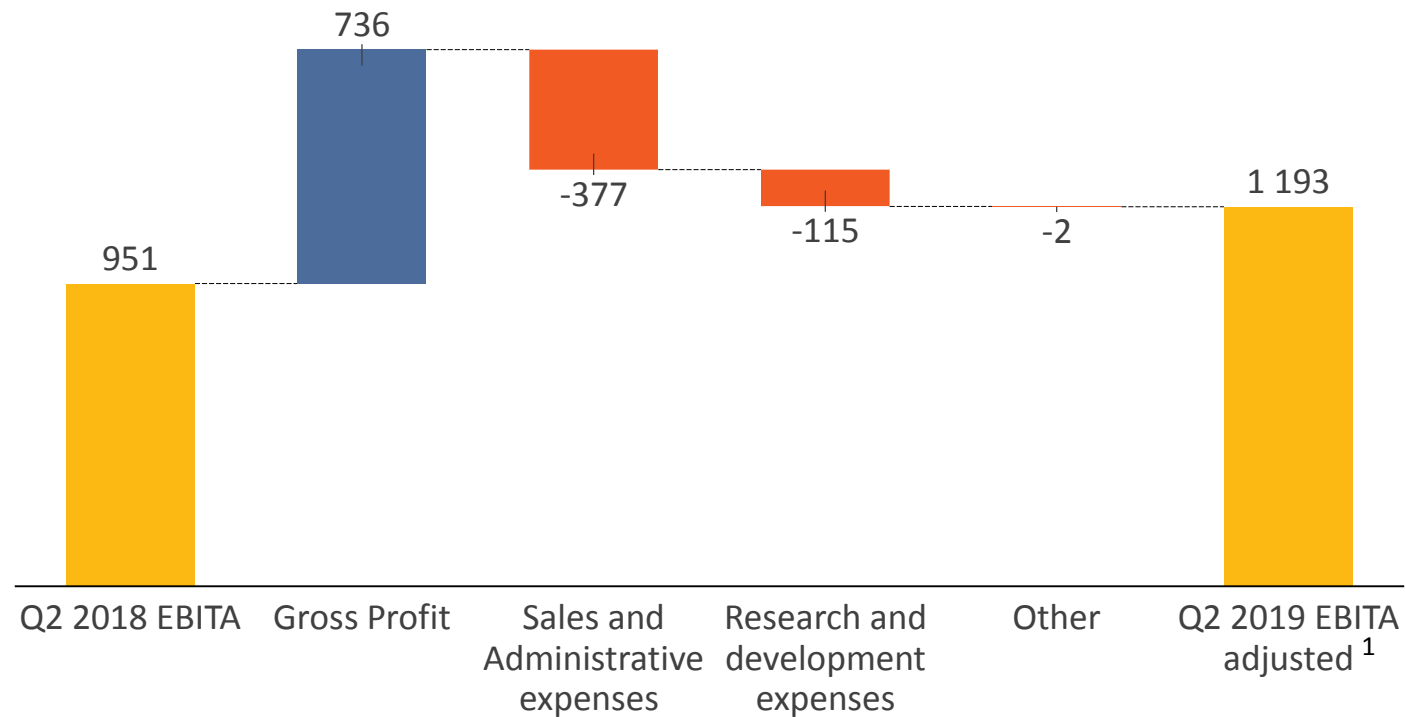
Amounts in SEK M	Q2	Q2	Change	H1	H1	Change	FY
	2019	2018		2019	2018		2018
Total revenue	3,163	2,289	38%	6,427	4,253	51%	9,139
Gross profit	2,413	1,677	44%	4,907	3,089	59%	6,723
Gross margin	76%	73%		76%	73%		74%
EBITA adjusted ¹	1,193	951	25%	2,665	1,722	55%	3,571
EBITA margin adjusted ¹	38%	42%		41%	40%		39%
Profit for the period	499	685	-27%	1,402	1,200	17%	2,418
Earnings per share, SEK adjusted ^{1,2}	2.12	2.54	-17%	5.14	4.45	16%	8.97
Operating cash flow	1,275	564	126%	1,663	841	98%	2,090
Net debt(+) / Net cash(-)	4,403	-2,300		4,403	-2,300		-2,999

¹EBITA excluding non-recurring items; restructuring costs of SEK 157 M in Q2 2019 and gain from divestment of SOBI005 in Q1 2019 of SEK 37 M.

²EPS excluding impairment of intangible assets of SEK 18 M related to the restructuring in Q2 2019.

Q2 Adjusted EBITA¹ walk-through

Total EBITA (SEK M)



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

¹ EBITA excluding non-recurring items; restructuring costs of SEK 157 M in Q2 2019

Important events – financial impact

Intention to discontinue early research and programmes outside of core areas:

- Restructuring costs for the quarter amounted to SEK 175 M, whereof SEK 157 M impacted EBITA and SEK 18 M related to impairment of intangible assets
- Expected to generate annual savings of SEK 200 – 300 M in 2020, with the intention to invest the freed up capital in strategic core areas

Sobi signed a purchase agreement for emapalumab and related assets

- Consideration for the acquisition is CHF 515 M (SEK 4,897 M), of which CHF 400 M was previously committed in the exclusive license agreement
- The acquisition is debt-financed, with new credit facilities made available by current funding banks
- Sobi has net debt of SEK 4,403 M at 30 June 2019. Pro forma leverage remains under 2. Additional debt capacity remains for further M&A.

A large white graphic on the left side of the slide. It is a circle with a small semi-circular notch at the bottom right. To its right is a smaller, solid white circle.

Summary

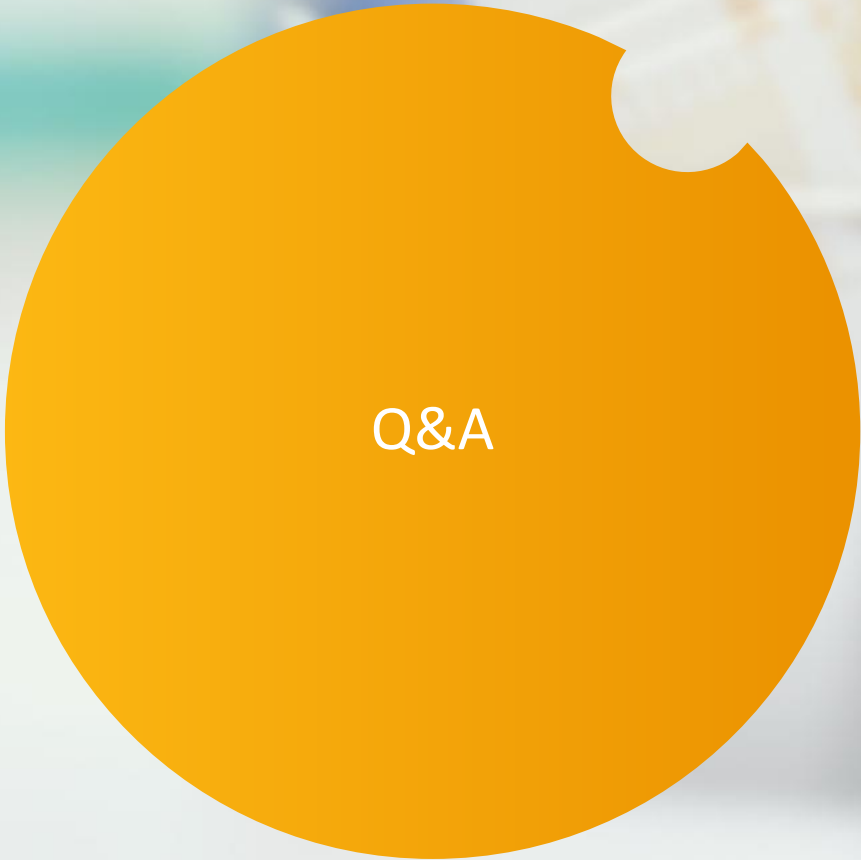
Key messages

- Committed to our strategic direction
- Develop Immunology and expand within Haematology
 - Drive Haemophilia penetration
 - Grow US business and strengthen position in EMENAR
 - Strengthen late-stage pipeline
 - Committed to M&A
- Updated 2019 guidance:
 - Sobi expects revenue for the full year to be in the range of SEK 13,000 - 13,500 M¹ (12,500 - 13,000)².
 - EBITA for the full year is expected to be in the range of SEK 5,300 - 5,500 M¹ (5,000 - 5,300)², excluding restructuring costs.
 - The updated outlook reflects the continued strong product sales in Haemophilia and the promising uptake of Gamifant in the US.

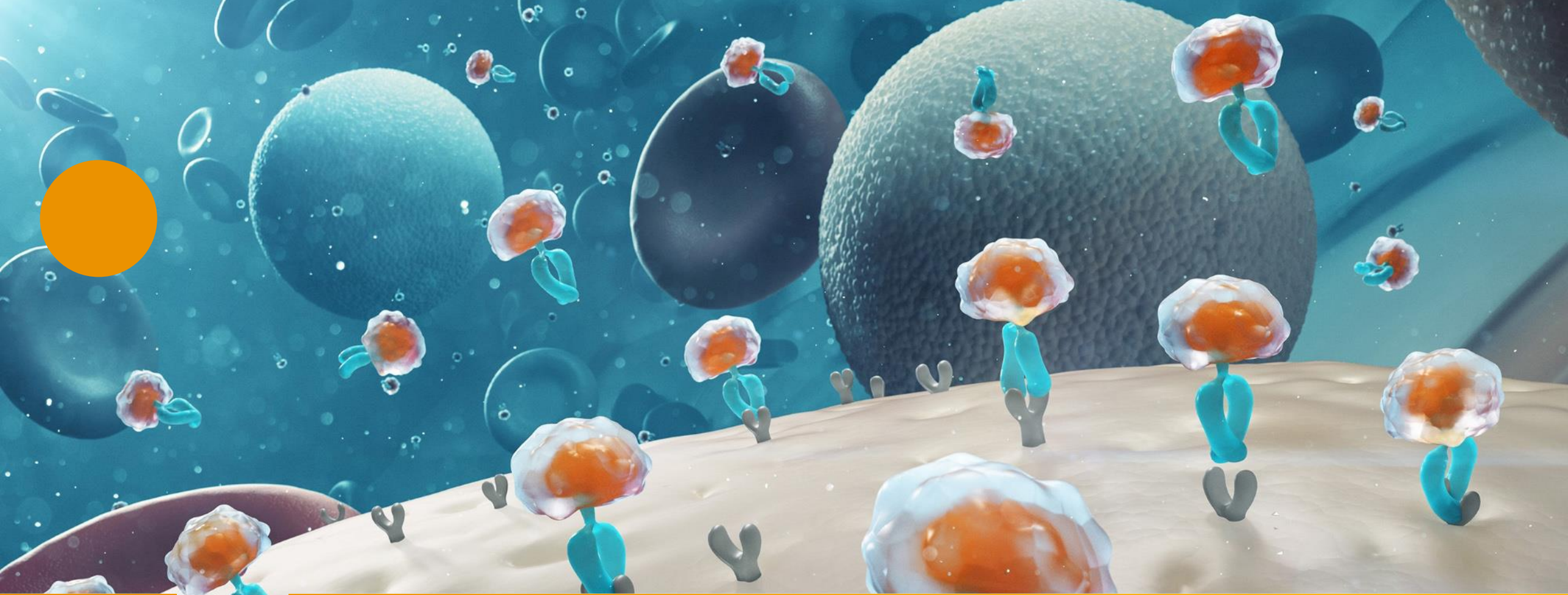


¹At current exchange rates.

²The initial outlook was first published on 20 February 2019.



Q&A



Sobi is a trademark of Swedish Orphan Biovitrum AB (publ).
© 2019 Swedish Orphan Biovitrum AB (publ) – All rights reserved
Swedish Orphan Biovitrum AB (publ)
SE-112 76 Stockholm • Sweden
www.sobi.com

 **sobi**
rare **strength**