A background image showing two female scientists in a laboratory. They are wearing white lab coats and safety glasses. One scientist in the foreground is wearing blue gloves and looking down at something in her hands. The other scientist is in the background, looking towards the first one. The background is slightly blurred, showing laboratory equipment.

Sobi Q4/FY
2018 report
presentation

rare **strength**

A solid orange circle.

20 February 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.



Gudio Oelkers, CEO



Henrik Stenqvist, CFO



Milan Zdravkovic, Head of R&D and CMO



Highlights Q4 2018

- Total revenues of SEK 2,571 M (1,875) in Q4 and SEK 9,139 M (6,511) for the full year
- 37 per cent sales growth in the quarter compared with Q4 2017 (29 per cent at CER)
- EBITA increased 48 per cent to SEK 916 M (619) in Q4 and 74 per cent to SEK 3,571 M (2,053) full-year
- Earnings per share of SEK 2.20 (1.33) in Q4 and SEK 8.97 (4.27) for the full year
- Net cash position of SEK 2,995 M (1,472 as of 31 December 2017)
- Revenues for Elocta[®] were SEK 945 M (540) for Q4 and SEK 3,261 M (1,557) for the full year
- Revenues for Alprolix[®] were and SEK 303 M (131) for Q4 and SEK 974 M (363) for the full year
- Sobi[™] entered into agreements to acquire the perpetual rights to Synagis[®] in the US from AstraZeneca and to participate in 50 per cent of the future earnings of the candidate drug MEDI8897 in the US. The closing of the acquisition was announced on 24 January 2019
- The US FDA approved Gamifant[®] for the treatment of primary HLH

The main graphic is a large white shape on an orange background. It is a circle with a small semi-circular notch at the bottom right. To its right is a smaller, solid white circle. The text 'Business review' is centered within the large white shape.

Business review

Elocta and Alprolix – liberates life for people with haemophilia



- Well established safety and efficacy profiles - real-world experience from thousands of patients
- Replacing the missing factor – fundamental in haemophilia treatment
- Standard of care in many countries
- Suitability for all patient groups and ages and flexibility to truly match treatment to outcomes
- Creates possibilities to live an active life with less worry about the safety and effectiveness of their therapy

Haemophilia - strong position with substantial potential

Exceptional momentum

- Recognition of therapeutic benefit more than doubled business
- Future growth driven by penetration and internationalisation

Individualised therapy

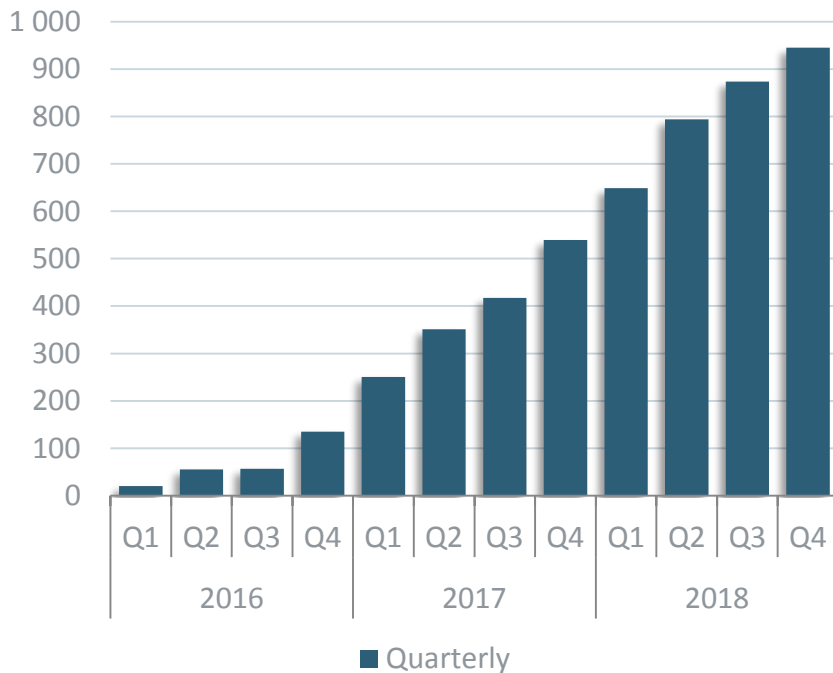
- Ensuring best outcome for patients

Significant promise for the future

- Impressive results from BIVV001

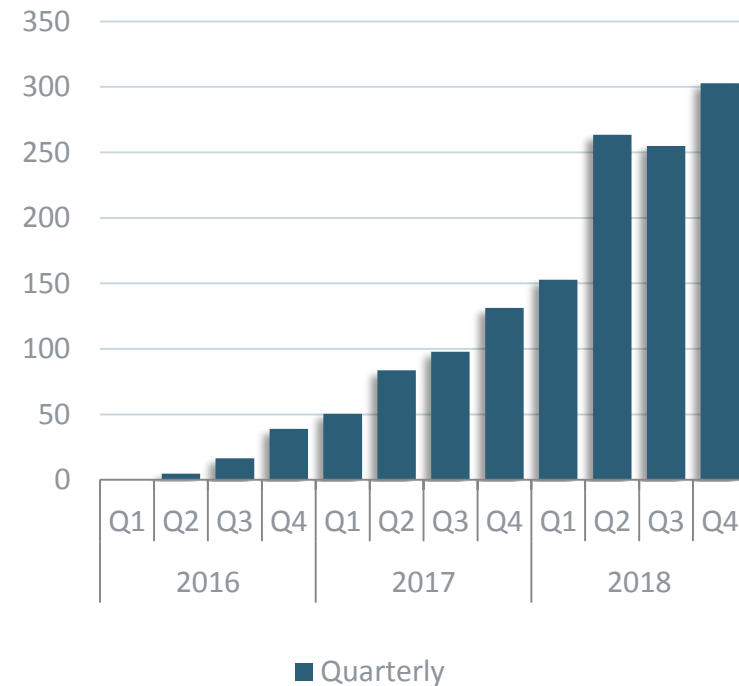
Exceptional momentum - strong sales growth in Q4

Elocta revenues (SEK M)



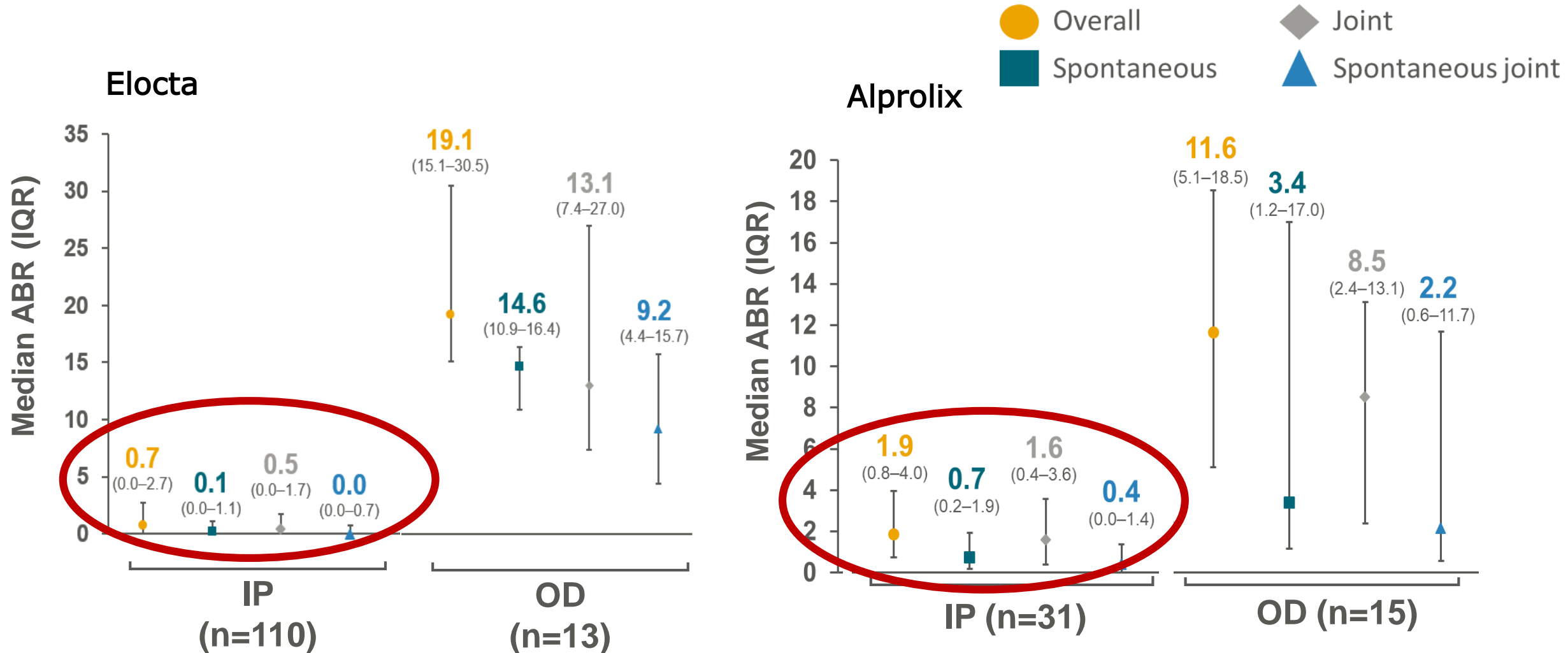
- Q4 product revenues of SEK 945 M (540)
 - Revenue growth of 75 per cent (65 per cent at CER)
 - Majority of growth derived from France, Germany and Italy
- FY product revenues of SEK 3,261 M (1,557)
- Reimbursed in 26 countries

Aprolix revenues (SEK M)



- Q4 product revenues of SEK 303 M (131)
 - Revenue growth of 131 per cent (118 per cent at CER)
 - Growth derived mainly from France, Germany and Italy
- FY product revenues of SEK 974 M (363)
- Reimbursed in 19 countries

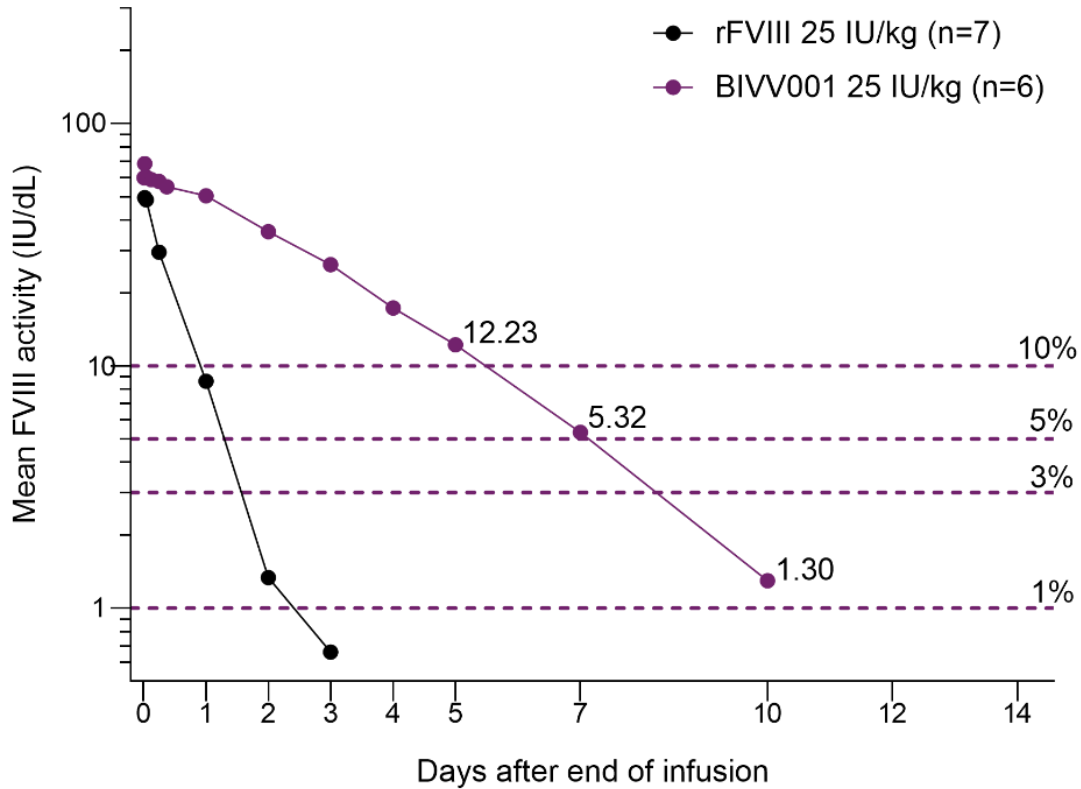
Individualising therapy improves patient outcome



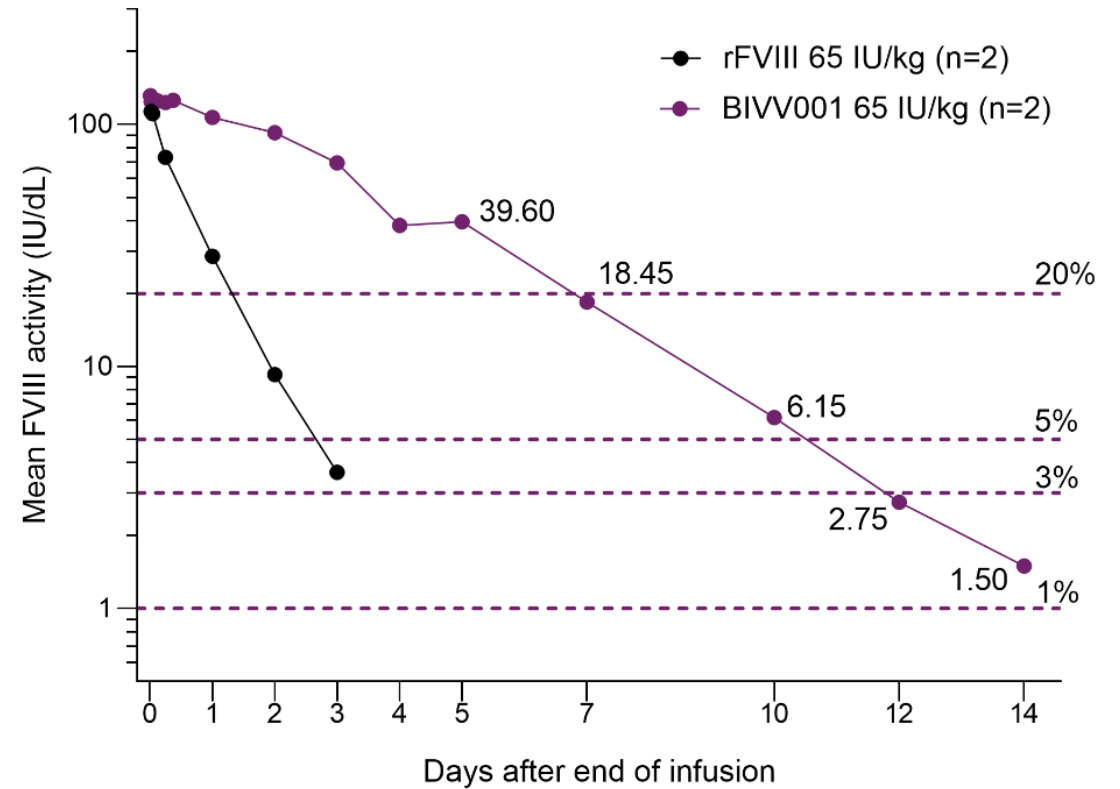
IP: Individualised prophylaxis; IQR: Interquartile range; OD: On-demand treatment
Adapted from Nolan et al. ASH 2018 Poster 1192

IP: Interval-adjusted prophylaxis; IQR: Interquartile range; OD: On-demand treatment
Adapted from Ragni et al. ASH 2018 Poster 1214

Significant promise for the future: BIVV001 protection in a once weekly dosing



**BIVV001 FVIII activity at 5 days was 12% and at 7 days was 5%
Half-life was 37.56 hours**



**BIVV001 FVIII activity at 5 days was 40% and at 7 days was 18%
Half-life was 43.76 hours**

Driving growth in Immunology

Build upon a strong base - Kineret

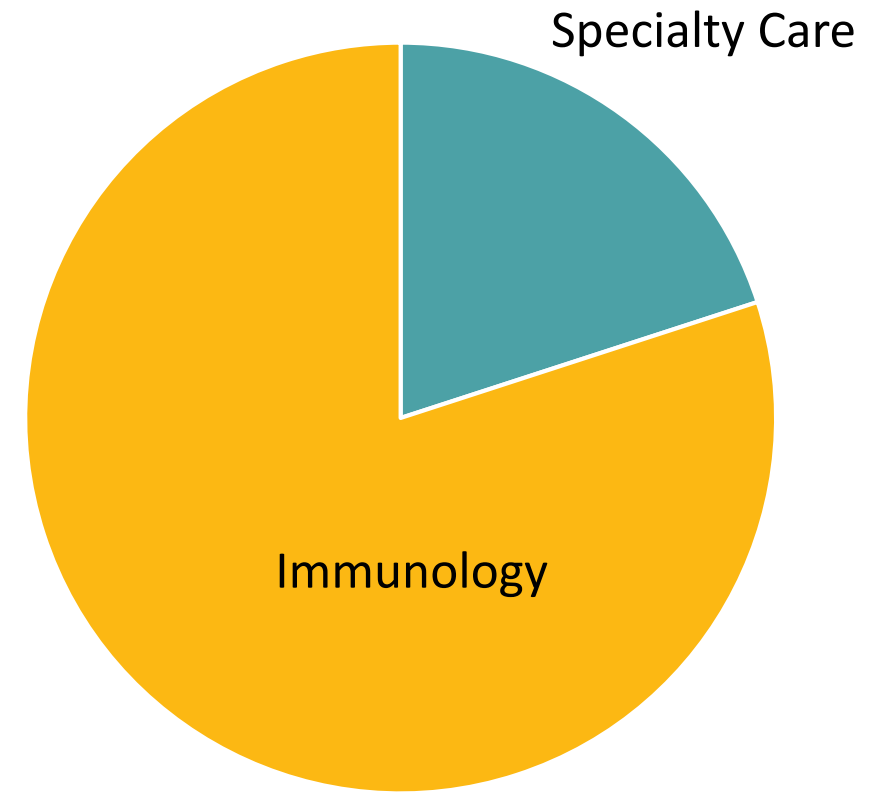
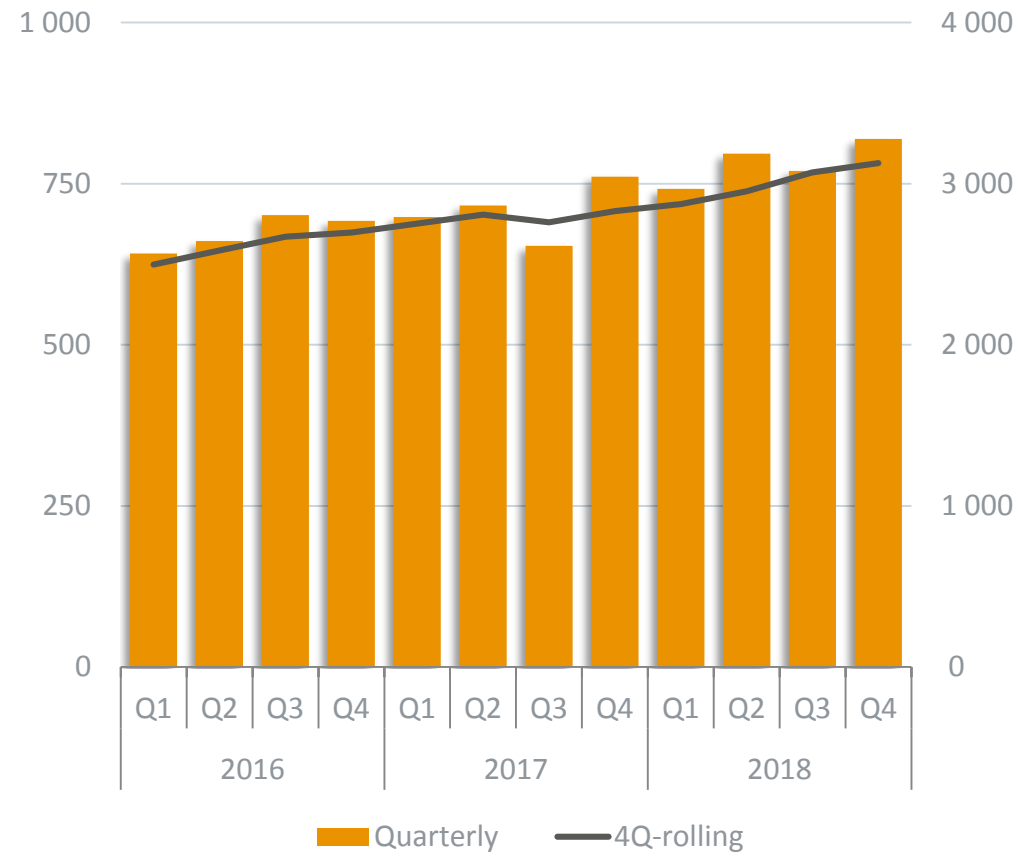
Expand the product platform and footprint
- Integration of Synagis business in the US

Launch of a new promising monoclonal antibody - emapalumab

Bolster pipeline
- Indication development for emapalumab and access to MEDI8897

Specialty Care – our future is in Immunology

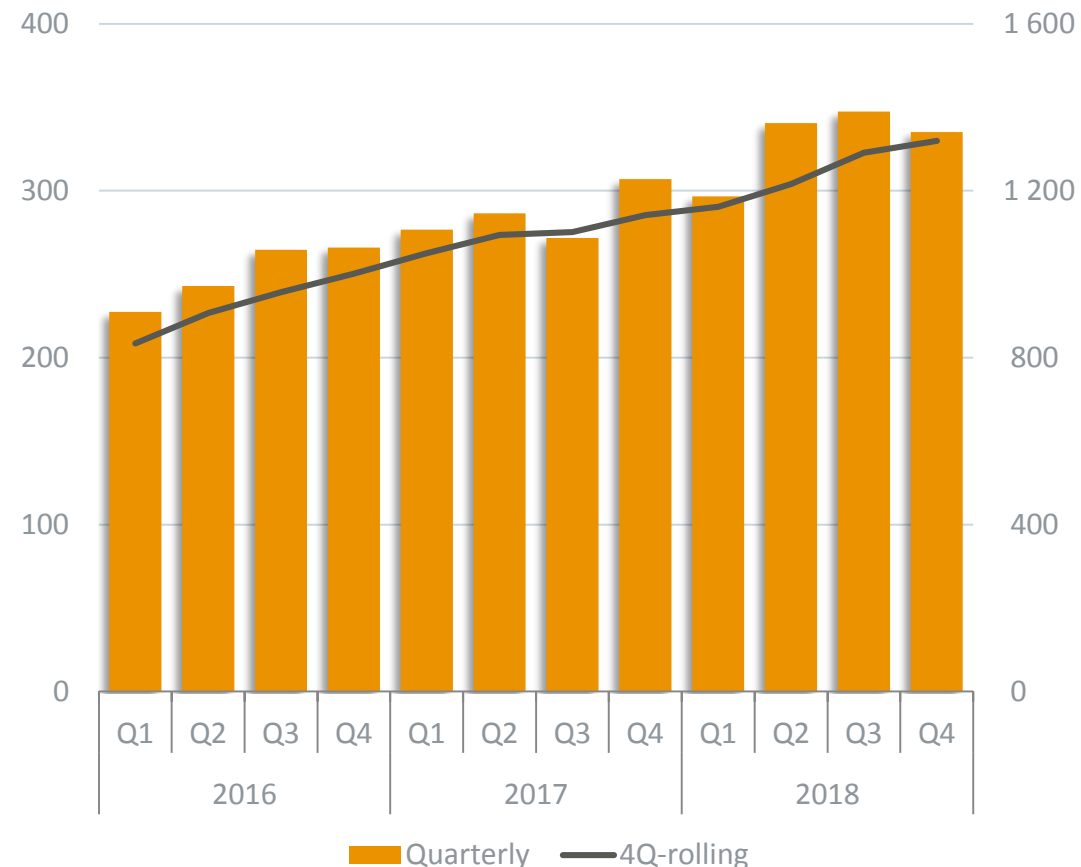
Revenues (SEK M)



Expected contribution of Immunology in 2019

Kineret – new indications drive growth in Europe

Revenues (SEK M)



- Q4 revenue SEK 335 M (307)
 - An increase of 9 per cent (2 per cent at CER)
- Full-year revenue SEK 1,320 M (1,142)
 - An increase of 16 per cent (12 per cent at CER)
- Revenue growth slowed down in Q4, reflecting phasing of sales after the strong performance in Q3
- Stills indication launched in nine EU countries

Synagis opportunity

Will be Sobi's largest product in Immunology

A growing business – demand growth 1.5% in Q4

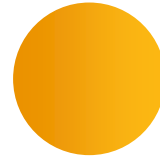
Expansion of sales force will drive further growth

Will create scalability in the US and will provide useful leverage points into the paediatric setting

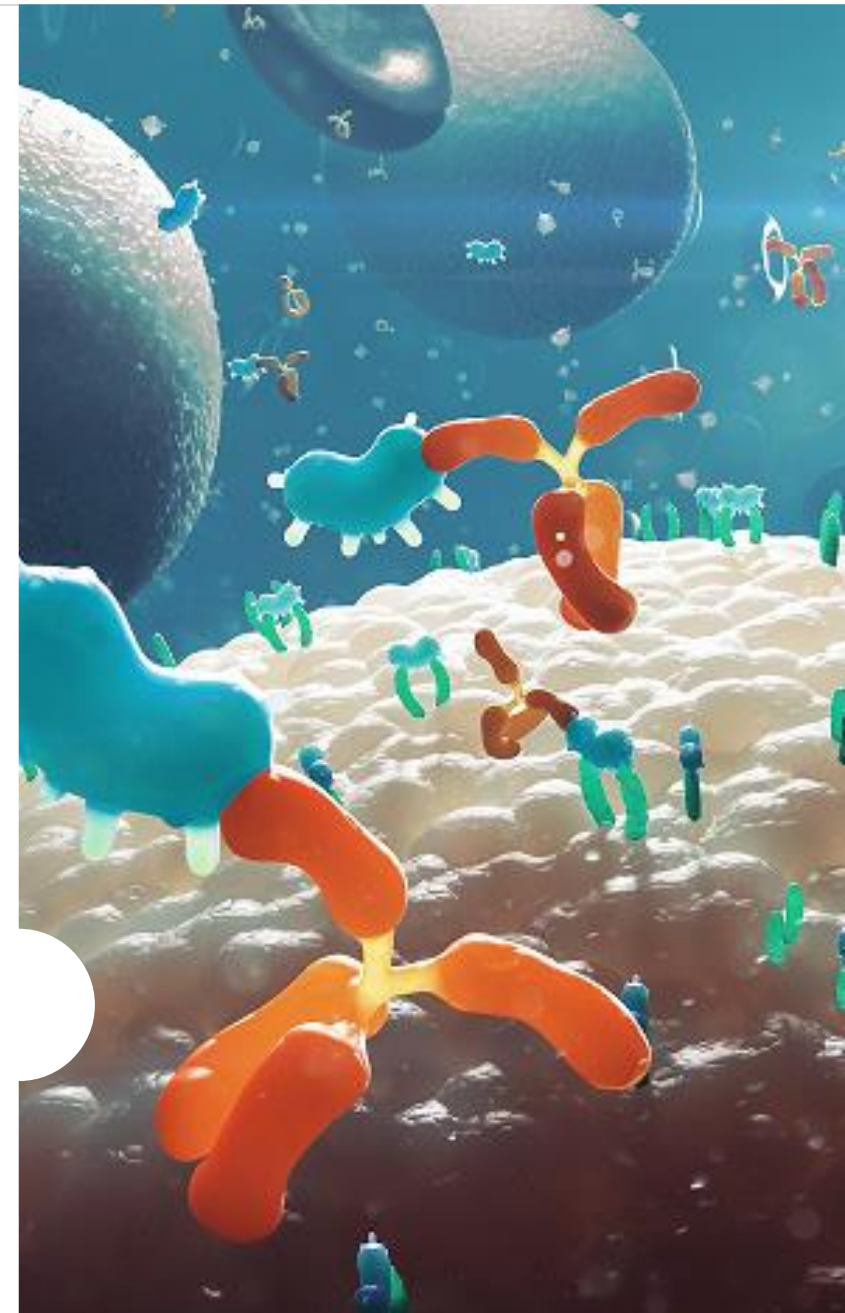
Promising future outlook based on access to
MEDI8897



Gamifant – first FDA approved therapy for primary HLH



- Approved by the FDA on 20 November 2018 for the treatment of primary HLH - and first patient treated by the end of 2018
- Marketing Authorisation Application submitted in Aug 2018 in Europe
- In 2019 we will make investments into clinical activities:
 - primary HLH
 - secondary HLH in children with autoimmune Systemic Juvenile Idiopathic Arthritis (sJIA) Developing Macrophage Activation Syndrome
 - adult patients with malignancy and non-malignancy induced HLH (in planning)
 - preemptive treatment of graft failure in children undergoing hematopoietic stem cell transplantation (in planning)

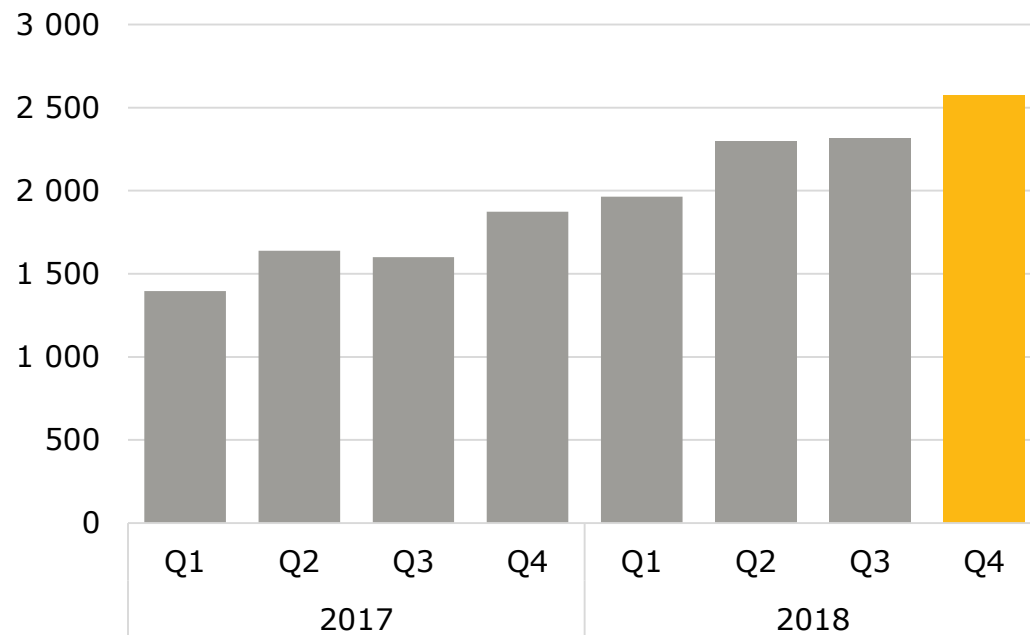


The graphic features a large white circle on the left side of the slide, containing the text 'Financial results'. To its right is a smaller white circle. The background is a solid orange color with a vertical line on the left side.

Financial results

Financial summary

Total revenue (SEK M)



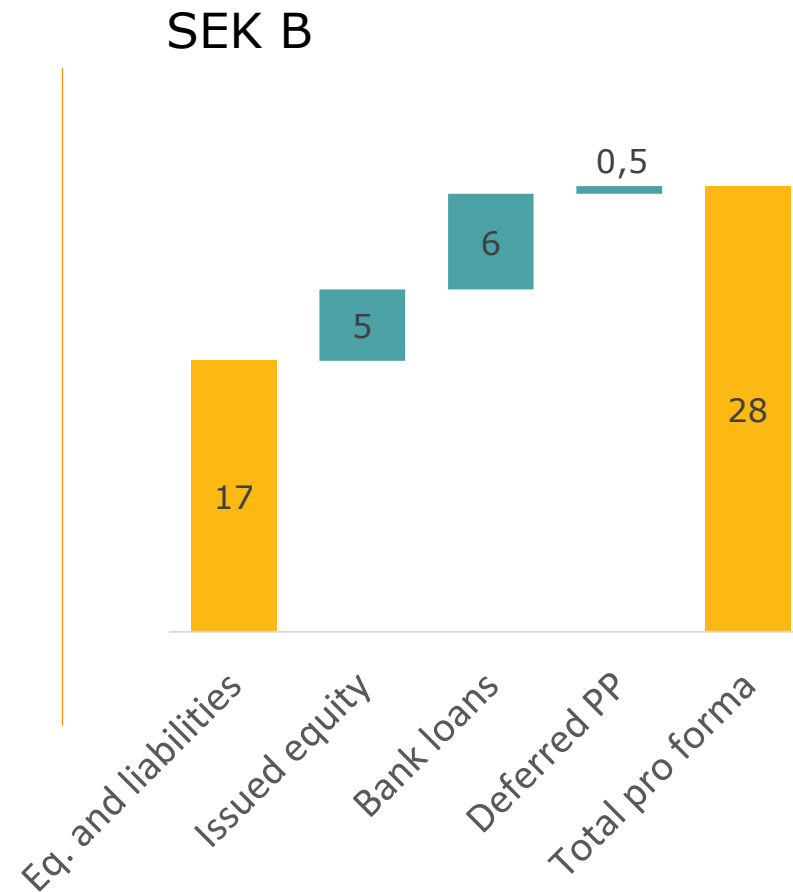
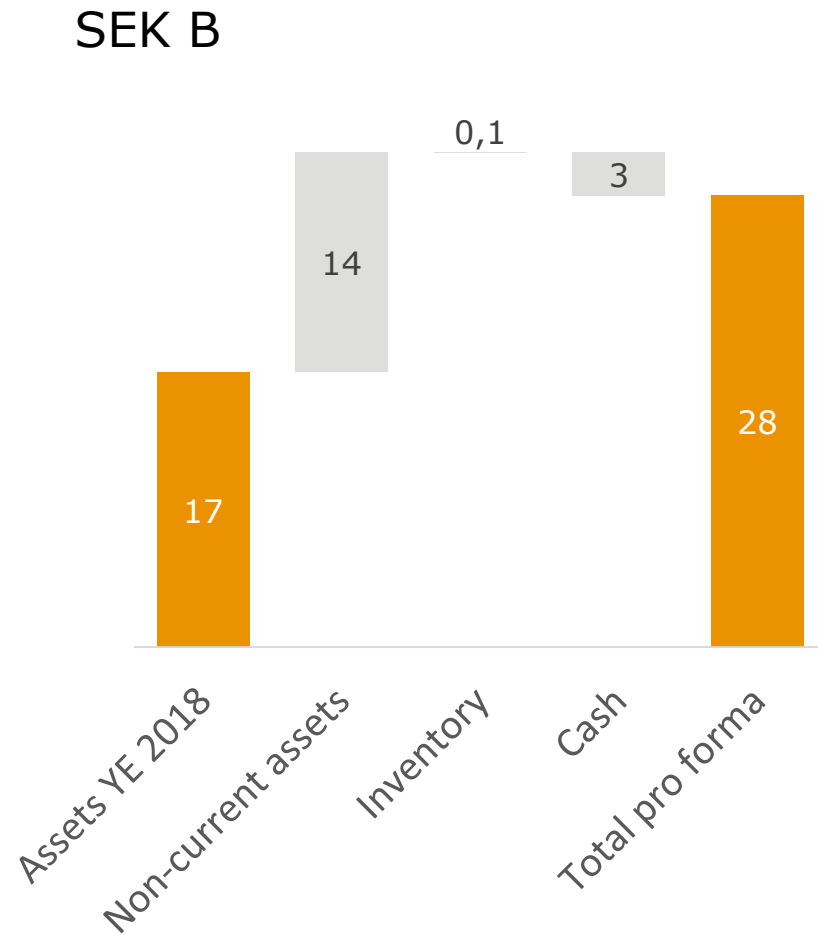
Amounts in SEK M	Q4	Q4	Change	Full-year	Full-year	Change
	2018	2017		2018	2017	
Total revenues	2,571	1,875	37%	9,139	6,511	40%
Gross profit	1,894	1,337	42%	6,723	4,657	44%
Gross margin	74%	71%		74%	72%	
EBITA	916	619	48%	3,571	2,053	74%
EBITA margin	36%	33%		39%	32%	
EBIT (operating profit)	802	509	58%	3,122	1,600	95%
Profit for the period	595	357	67%	2,418	1,149	110%
Earnings per share, SEK	2.20	1.33	66%	8.97	4.27	110%
Operating cash flow	538	257	109%	2,090	1,333	57%

Balance sheet

Amounts in SEK M	Dec 2018	Dec 2017
ASSETS		
<i>Non-current assets</i>		
Intangible assets	10,159	6,445
Tangible assets	136	134
Financial assets	286	167
Total non-current assets	10,581	6,746
<i>Current assets</i>		
Inventories	1,284	1,053
Accounts receivable	1,665	1,129
Current receivables, non-interest bearing	654	496
Cash and cash equivalents	2,999	1,478
Total current assets	6,602	4,157
Total assets	17,183	10,903

	Dec 2018	Dec 2017
EQUITY AND LIABILITIES		
Shareholders' equity	9,040	6,701
<i>Long-term liabilities</i>		
Long-term liabilities	3	5
Long-term liabilities, non-interest bearing	1,189	1,832
Total long-term liabilities	1,192	1,838
<i>Current liabilities</i>		
Current liabilities	1	2
Current liabilities, non-interest bearing	6,950	2,363
Total current liabilities	6,951	2,365
Total equity and liabilities	17,183	10,903

Pro forma balance sheet impact of Synagis/ MEDI8897



- Net Debt: SEK 6 B
- Net debt / EBITDA: >1X
- Headroom for further expansion:
 - Organic
 - M&A activity

A large white circular graphic is positioned on the left side of the slide. It has a small notch at the bottom right. To its right is a smaller, solid white circle. The text 'Strategy and Outlook' is centered within the large white circle.

Strategy and Outlook

Strategic direction



**Drive Haemophilia
Penetration**

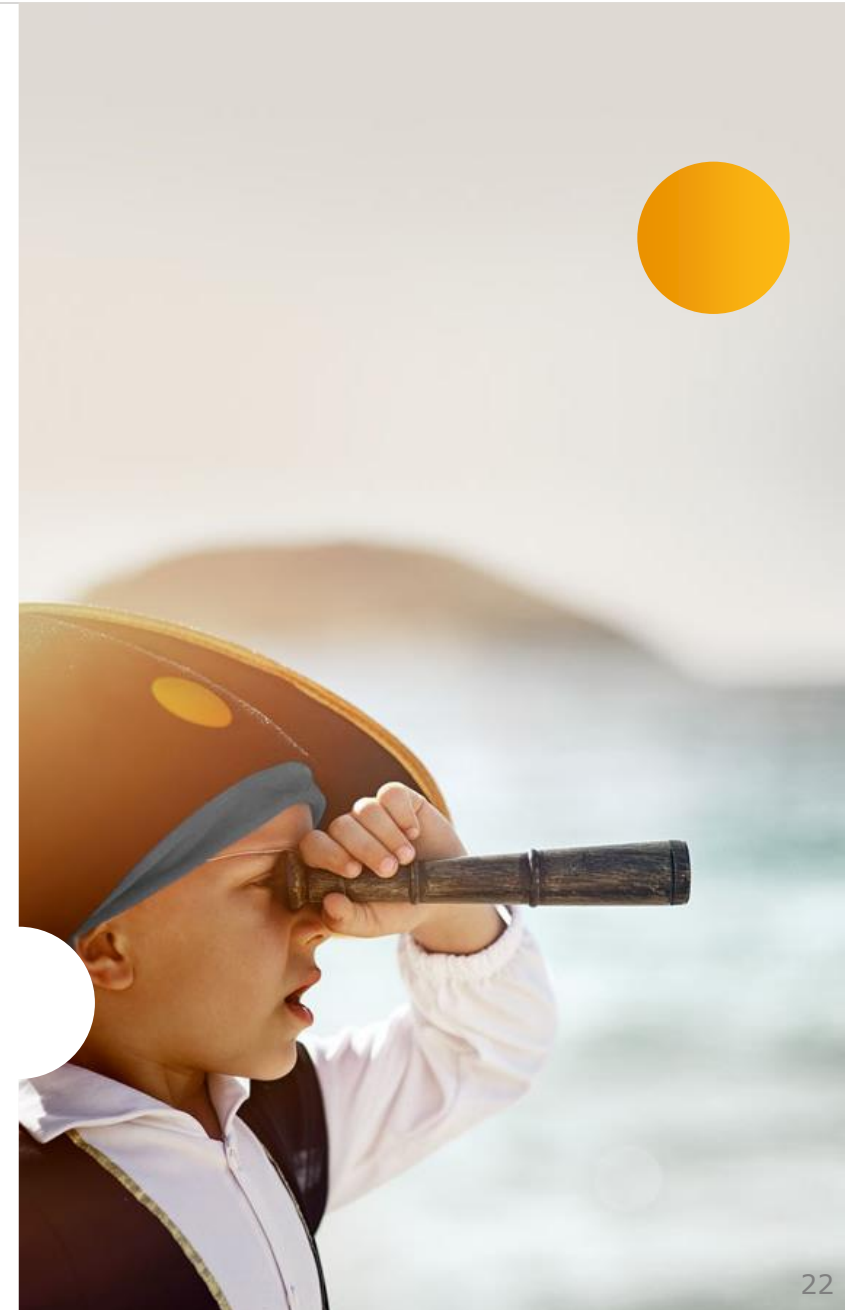
**Develop
Specialty Care and
Immunology**

**Grow US business and
strengthen position in
EMENAR**

**Strengthen R&D
pipeline**

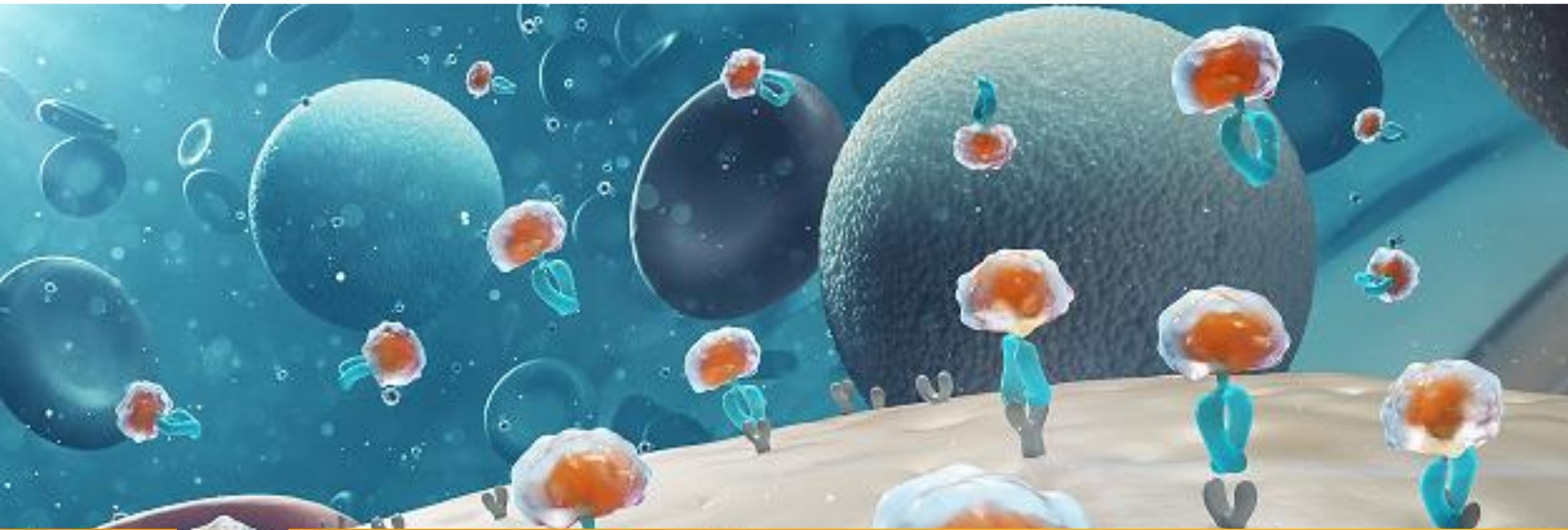
Outlook 2019¹

- Sobi expects revenue for the full year to be in the range of SEK 12,500 - 13,000 M.
- Main drivers of revenue growth are: continued market share growth of our haemophilia franchise with Elocta and Alprolix, the acquisition of Synagis and growth of this franchise in the US and the launch of Gamifant in the US.
- EBITA for the full year is expected to be in the range of SEK 5,000 - 5,300 M.
- In 2019, we will increase market investments in the haemophilia franchise and in the commercial launch of Gamifant. Furthermore, we will expand clinical activities for emapalumab.
- ¹At current exchange rates as of 20 February 2019.





Q&A



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