Q4/FY 2019 results

rare **strength**

February 13, 2020

Forward looking statements

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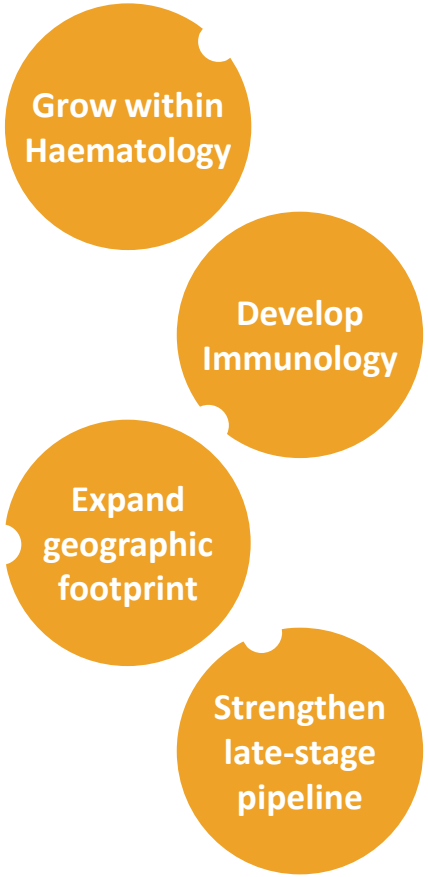
Guido Oelkers | CEO

Henrik Stenqvist | CFO

Milan Zdravkovic | Head of R&D and CMO

Presenters

Creating a rare disease leader



- **Transformation into broader Haematology franchise** Doptelet (avatrombopag) tablets
- **First launch success with Gamifant, solid growth of Synagis** gamifant emapalumab-lzsg; SYNAGIS PALIVIZUMAB
- **Step-change towards North America and beyond, e.g. entry into China**
- **Investing in a sustainable portfolio** e.g. **BIVV001, emapalumab and avatrombopag**

Over the past year we have continued to successfully execute on our strategy to ***diversify from Haemophilia into Haematology*** and ***increased investments in Immunology***

2019: A year of transformation and strong growth

Continued strong growth and launch execution…

- **Financial performance**: Strong organic top-line and earnings growth
  - Sales (**+56%** YoY) and adj. EBITA (**+72%** YoY)
- **Haemophilia**: Continued double-digit growth
  - **Elocta** (+34% CER YoY) & **Alprolix** (+46% CER YoY)
- **Immunology**: Strong performance across portfolio
  - **Synagis**: First-year execution on track
  - **Gamifant**: Ongoing launch, meeting a significant unmet medical need

…while driving transformation

- **Two transformational** acquisitions: Dova and emapalumab
- **Investing in R&D**: Built a **strong pre-market pipeline**
- **Geographic expansion** outside current territories into China
- **Restructuring** of Specialty Care/Partnering portfolio and focus on core business

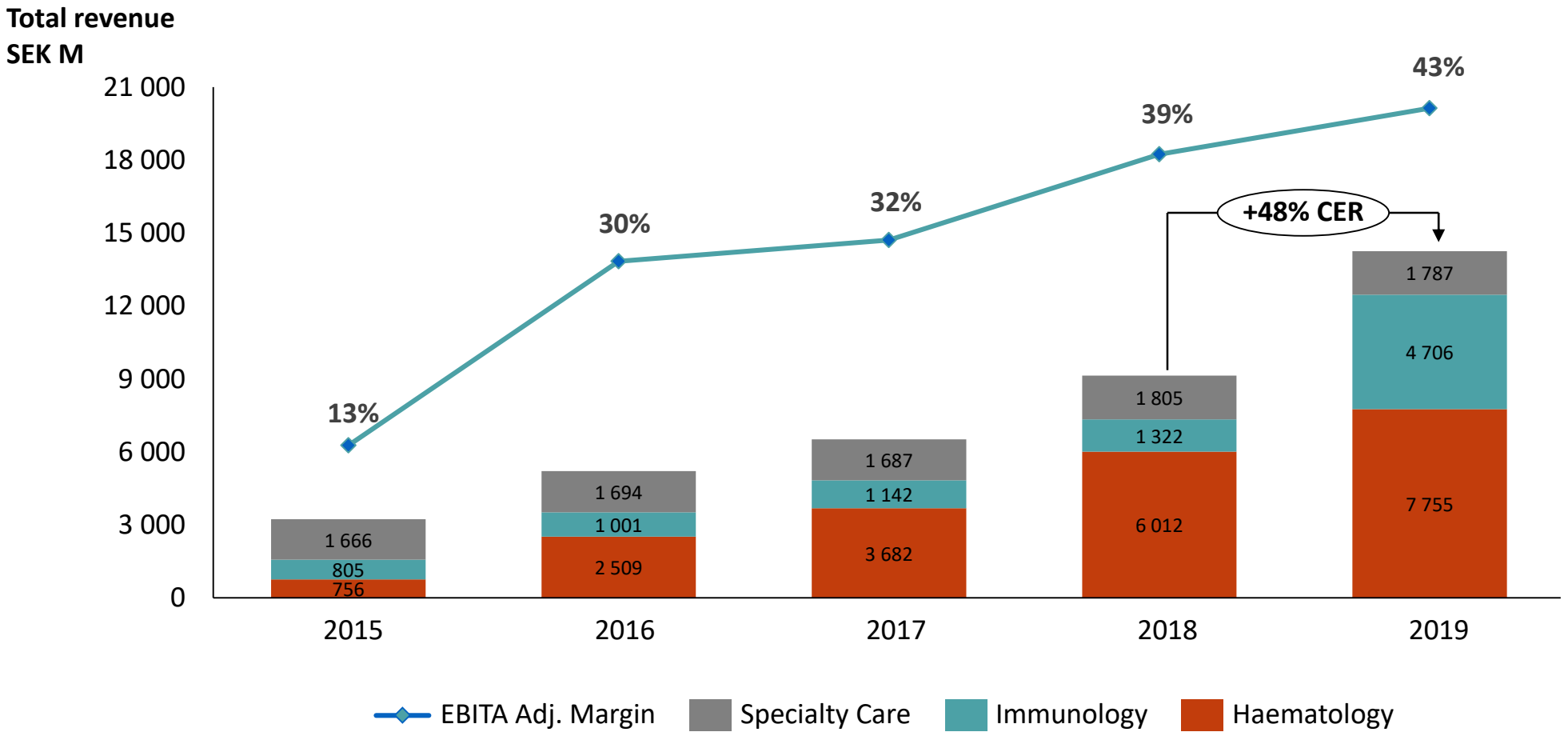
+20% CER organic growth

Double-digit growth across core franchises

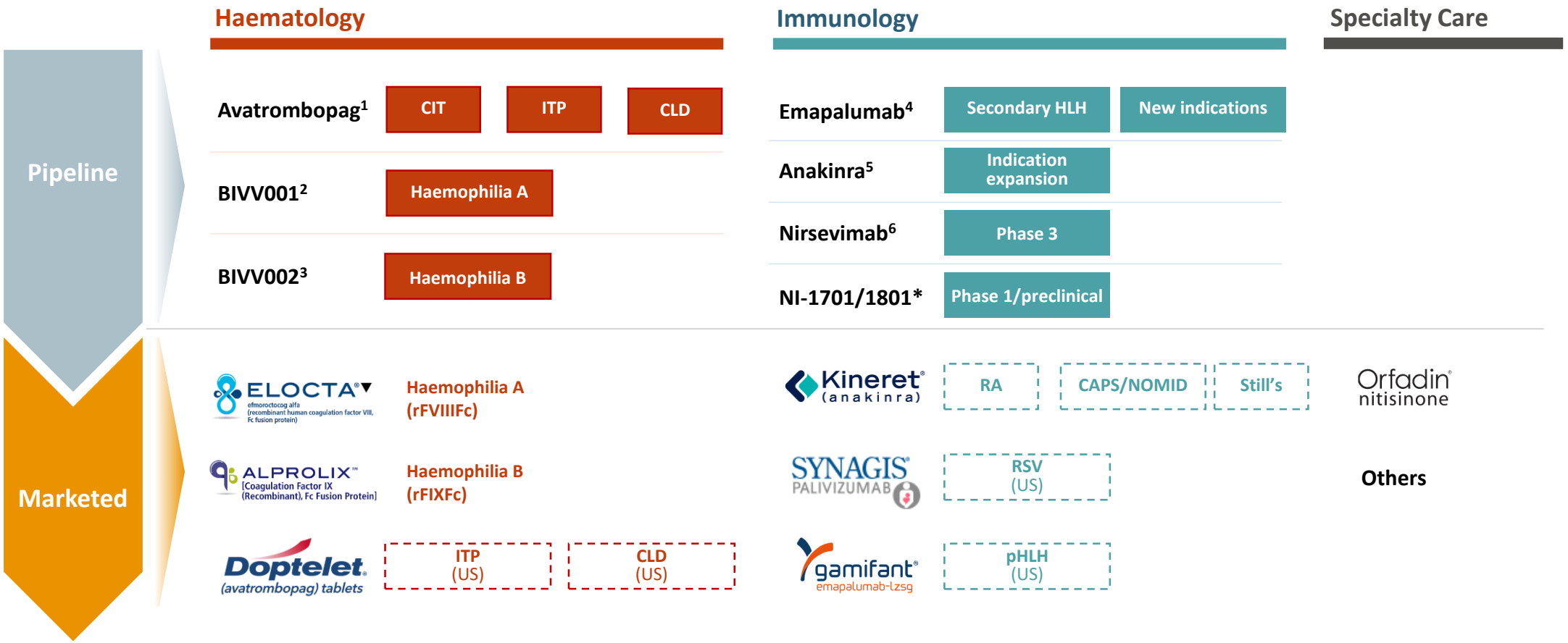
Executing on M&A strategy

R&D innovation model

Extraordinary performance: Double-digit growth and margin expansion

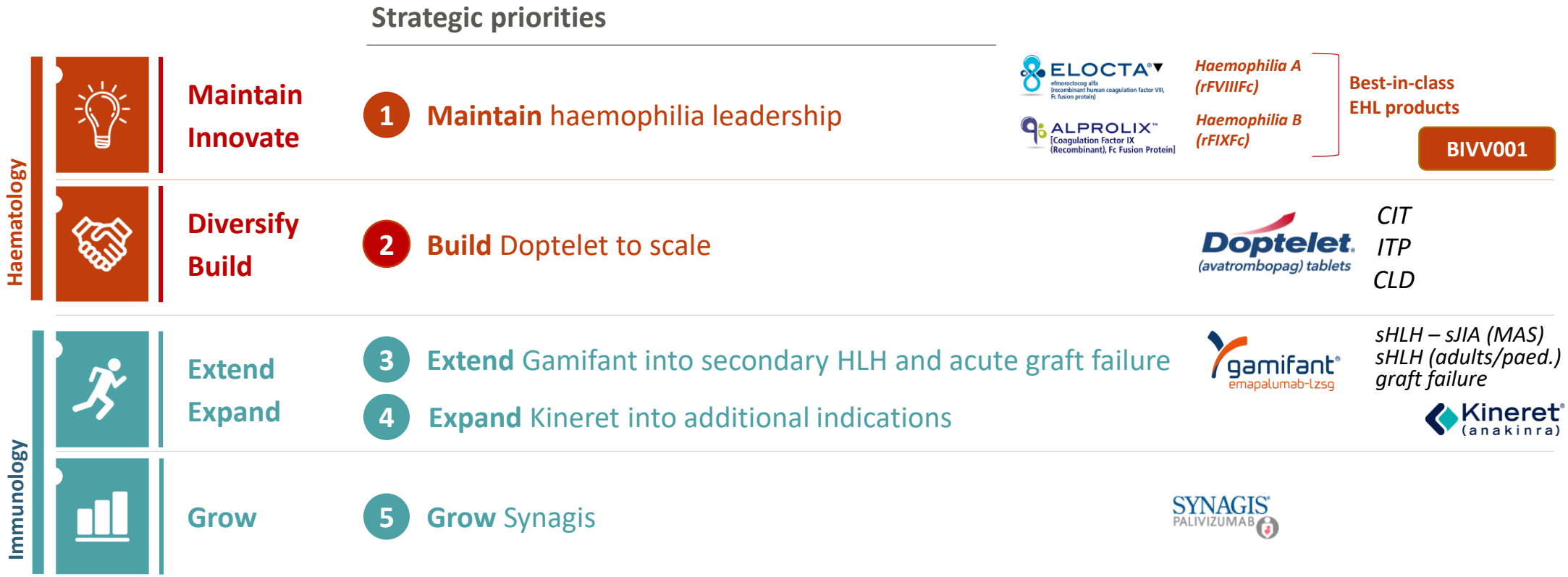


Recent acquisition strategy has led to a stronger, more diversified pipeline…



1. Avatrombopag – approved as Doptelet for thrombocytopenia in chronic liver disease (CLD) and chronic immune thrombocytopenia (ITP) in the US. 2. Developed in collaboration with Sanofi.
3. Sobi has elected to add the BIVV002 programme to the collaboration agreement with Sanofi but has not yet opted in. 4. Emapalumab – approved as Gamifant in the US for primary haemaphagocytic lymphohystiocytosis (HLH).
5. Anakinra – approved as Kineret in the US and in the EU for several autoinflammatory diseases. 6. Nirsevimab (MEDI8897), a follow-on compound to Synagis for respiratory syncytial virus (RSV)
*Options for the shared financial rights to NI-1701 and NI-1801, two product candidates in the field of immuno-oncology

…with a clear strategic focus for mid-term growth



Our five strategic priorities are focused on building a foundation for **double-digit growth** in the **mid-term** for our **two core franchises**

Haematology

Haematology: Reaching sales over SEK 2 bn in the quarter

- **Q4 revenue** of SEK 2,142 M (1,752)
  - Revenue growth of 22 per cent (18 per cent at CER)
  - SEK 1,673 M (1,248) in product sales
  - SEK 352 M (367) in royalty revenue
  - SEK 116 M (137) in manufacturing revenue
- **Doptelet** sales of SEK 34 M (12 November-31 December)
  - US: Early launch phase for ITP
  - EU: Preparing for launch
- **FY 2019 revenue** of SEK 7,755 M (6,012)
  - Revenue growth of 29 per cent (24 per cent at CER)

Elocta: Continued strong double-digit growth

Sales (SEK M)

- **Q4 product sales** of SEK 1,235 M (945)
  - Sales growth of 31 per cent (26 per cent at CER)
  - Majority of the growth derived from France, Germany, Italy and the Middle East
- **FY product sales** of SEK 4,508 M (3,261)
  - Sales growth of 38 per cent (34 per cent at CER)
- Reimbursed in 27 countries
- Approval in Russia in January 2020

Haemophilia today: What did we learn from EAHAD?

Conviction amongst many KOLs: “Factor replacement remains the standard of care in patients with haemophilia A”

“Inhibitor prevention/eradication is important to ensure better bleed control in all clinical scenarios, even in this new therapeutic era”

“Risk-benefit ratio depends on significance of unmet needs.” This ratio has not been sufficiently established for new treatment options.

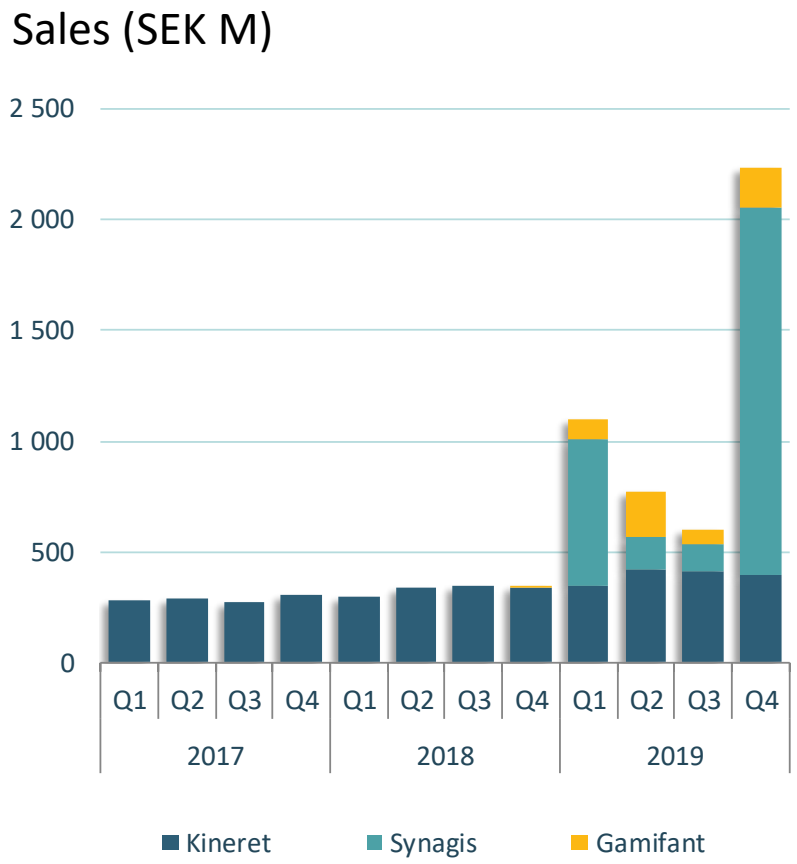
We are convinced we have the best-in-class haemophilia treatments in our portfolio

Doptelet: Current and future opportunities

	CLD	ITP	CIT
Regulatory milestones	**Launch ongoing in the US** **Expected launch in the EU H2 2020**	**Launch ongoing in the US** **Submission in the EU H1 2020**	**Orphan Drug designation by the FDA in December 2019** **Phase 3 top-line read-out H2 2020**
Market	**Company estimates: market opportunity around USD 0.3 bn in the US**	**US market potential estimated at USD 1 bn** **Global TPO market estimated at USD 2 bn**	**US market potential estimated to exceed USD 1 bn** **No FDA-approved therapy for CIT today**

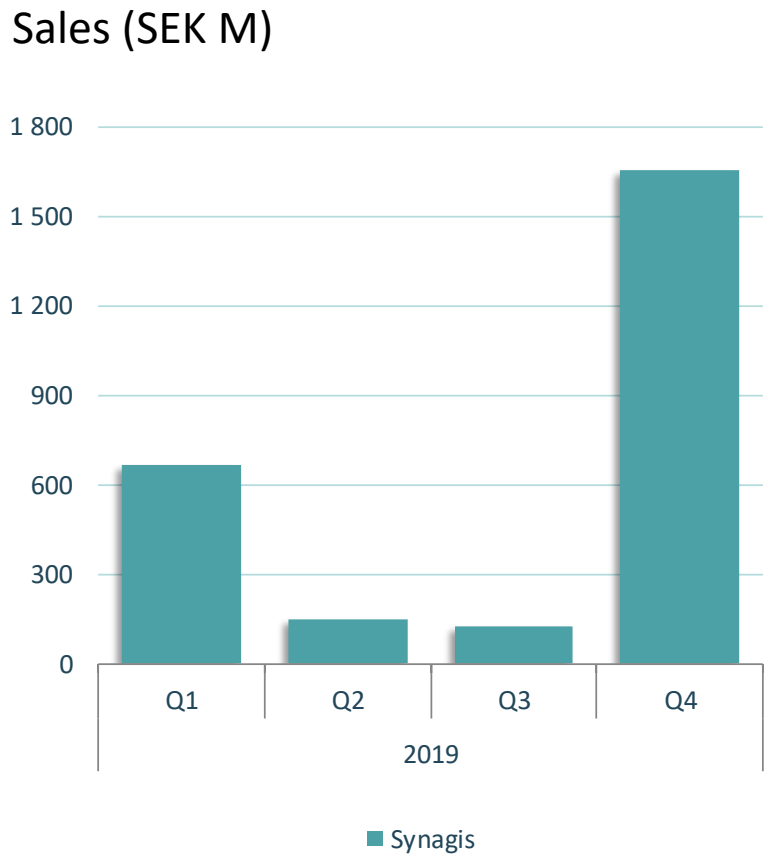
Immunology

Immunology: Strong overall growth across the franchise



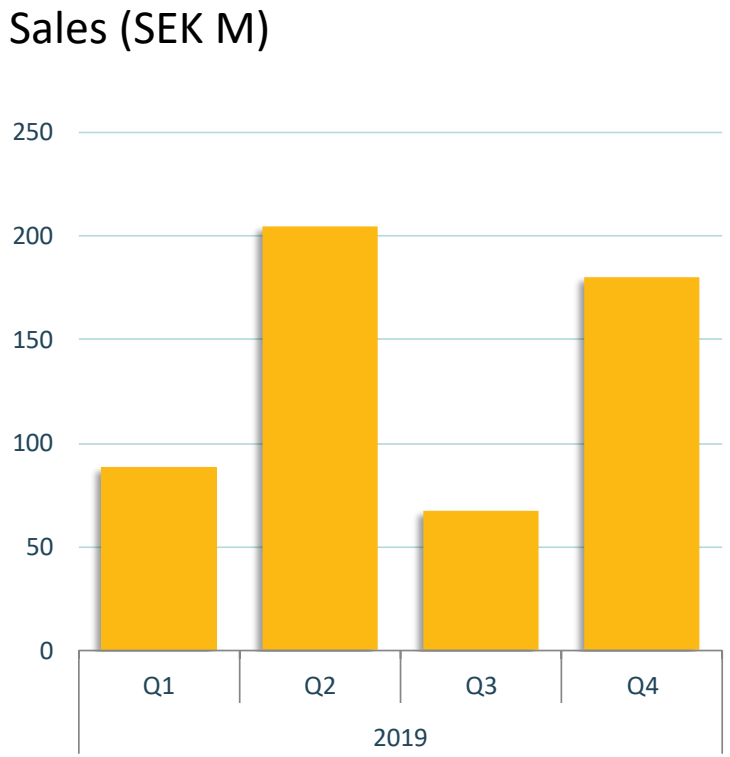
- **Total Immunology revenue** for the quarter was SEK 2,233 M (335 M)
- **FY revenues** were SEK 4,706 M (1,320 M)
- **Growth driven by all three products** within the portfolio
  - **Synagis** sales were better than expected due to several factors
  - **Gamifant** sales reached SEK 542 M in its first full year of launch
  - **Kineret** performed strongly with +12% FY growth at CER
- With the additions of Synagis and Gamifant to the portfolio, **Immunology is expected to be an important growth driver in the mid-term**

Synagis: Very strong Q4 sales –
Synagis is performing well under our ownership



- **Synagis sales** for the quarter were SEK 1,656 M
- **FY revenue** of Synagis were SEK 2,594 M
- **Very strong Q4 sales** mainly due to:
  - Overall increased demand/referrals as a result of improved commercial effectiveness and increased promotional effort
  - Mid single-digit underlying demand growth
  - A more severe RSV season
  - Demand and public holidays supported stocking at wholesaler level
  - Room for further improvements in the value chain

Gamifant: Strong Q4 sales

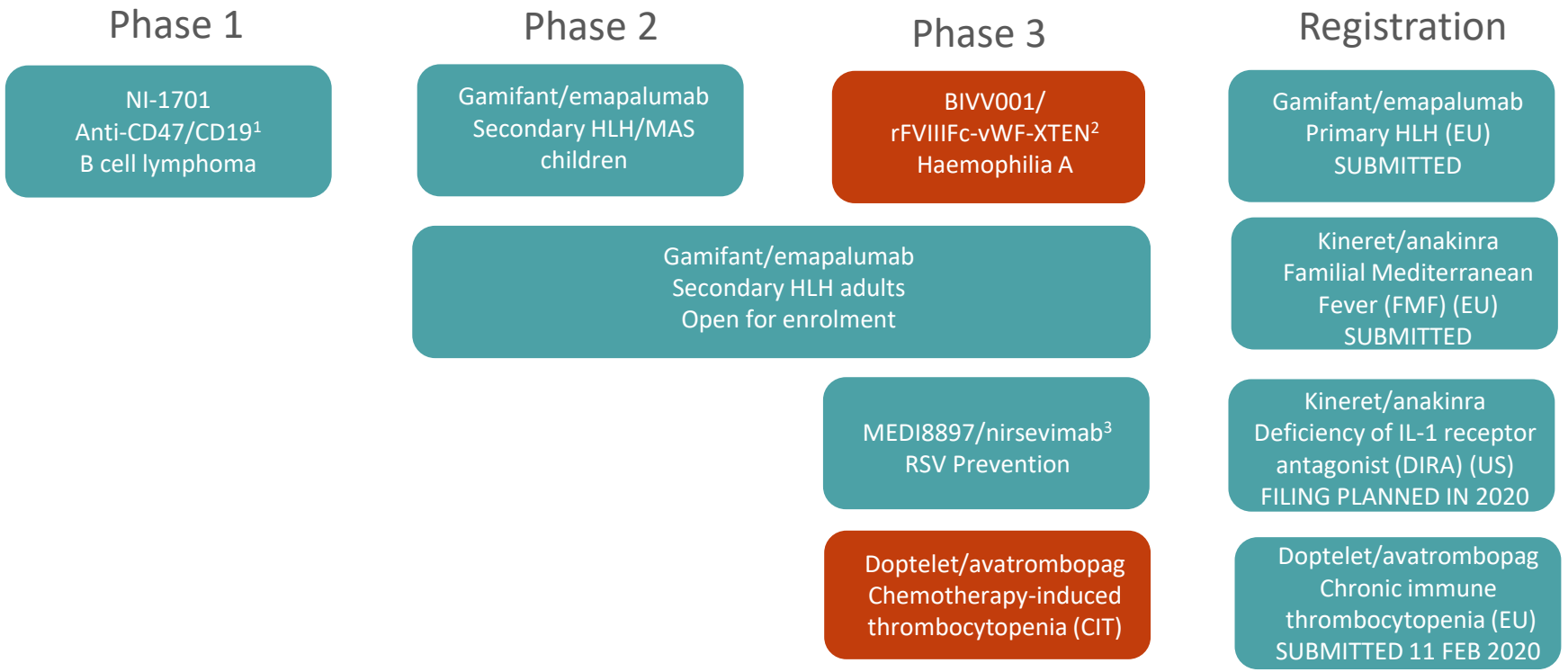


- **Gamifant sales** for the quarter amounted to SEK 180 M. FY 2019 Gamifant sales were SEK 542 M.
- **Strong sales** reflect a demand increase and increasing experience with the product's benefits
- Consumption by patient also increased due to average dose, duration of treatment and average weight
- Still at an early stage of launch to a broader HLH population; hence product sales will not allow for a linear extrapolation
- Adoption of the NACHO definition[1] of primary HLH
- Continuous strong underlying demand

1. Jordan MB, Allen CE, Greenberg J, et al. Challenges in the diagnosis of hemophagocytic lymphohistiocytosis: recommendations from the North American Consortium for Histiocytosis (NACHO). *Pediatr Blood Cancer*. 2019;66:e27929. https://doi.org/10.1002/pbc.27929**)**

Pipeline

Significantly strengthened and diversified pipeline



1. Options for shared financial rights to NI-1701
2. In collaboration with Sanofi
3. Developed by AstraZeneca and Sanofi. Sobi has rights to 50 per cent of US earnings.

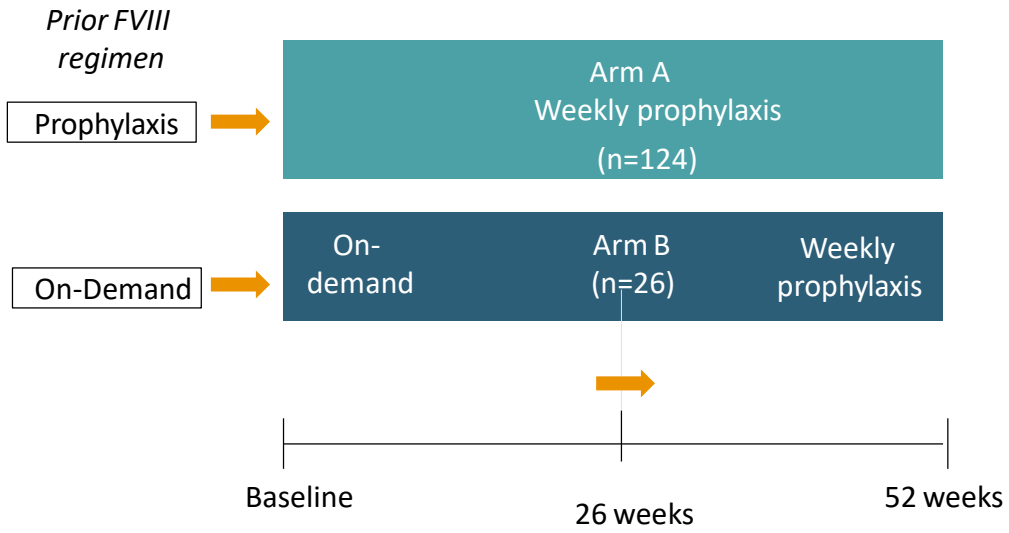
…And with a significant near-term news flow

	Compound	Indication/Expected Milestone Event	Status
Haematology	BIVV001	Phase 3 study in adults and adolescents (≥12 years)	Initiated
		Phase 3 study in children (< 12 years)	Expect to be initiated by year-end 2020
	avatrombopag	Chronic immune thrombocytopenia (ITP)	Approved in the US EU: Submitted on 11 February 2020
		Chemotherapy-induced thrombocytopenia (CIT)	Phase 3 read-out expected H2 2020
Immunology	anakinra	Familial Mediterranean Fever (FMF)	Submitted in EU
		Deficiency of Interleukin-1 receptor antagonist (DIRA)	Expected US FDA submission mid 2020
	emapalumab	Primary HLH	Approved in the US Submitted in the EU
		Secondary HLH – sJIA (MAS)	Study ongoing; following enrolment of 10 evaluable patients. FDA meeting to be scheduled (expected by year-end 2020
		Secondary HLH (adults)	Study open for enrolment
		Phase 2 study in pre-empting haematopoietic stem cell transplantation graft failure	Study initiation by year-end 2020

BIVV001[1]: Registration study initiated

Phase 3 study in previously treated patients ⩾ 12 years (n=150)

- Primary endpoint: Annualised bleeding rate
- Novel endpoints include joint health via ultrasound and physical activity monitoring
- Dose: 50 IU/kg once weekly
- Rapid enrollment expected (prospective study + community excitement)



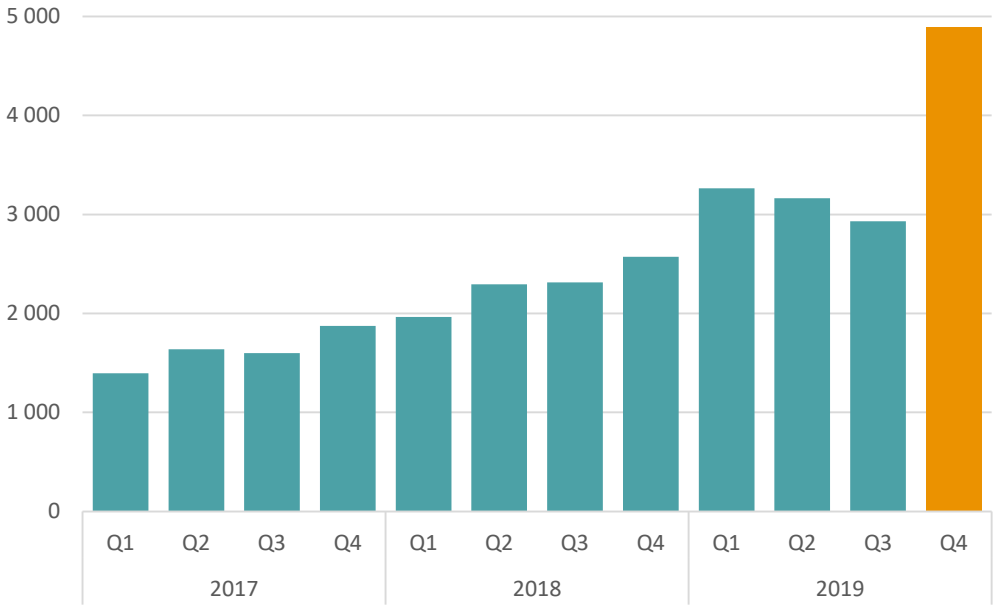
Pivotal results expected in H2 2021

[1]BVV001 is a joint Sobi and Sanofi development programme

Financial results

Financial results

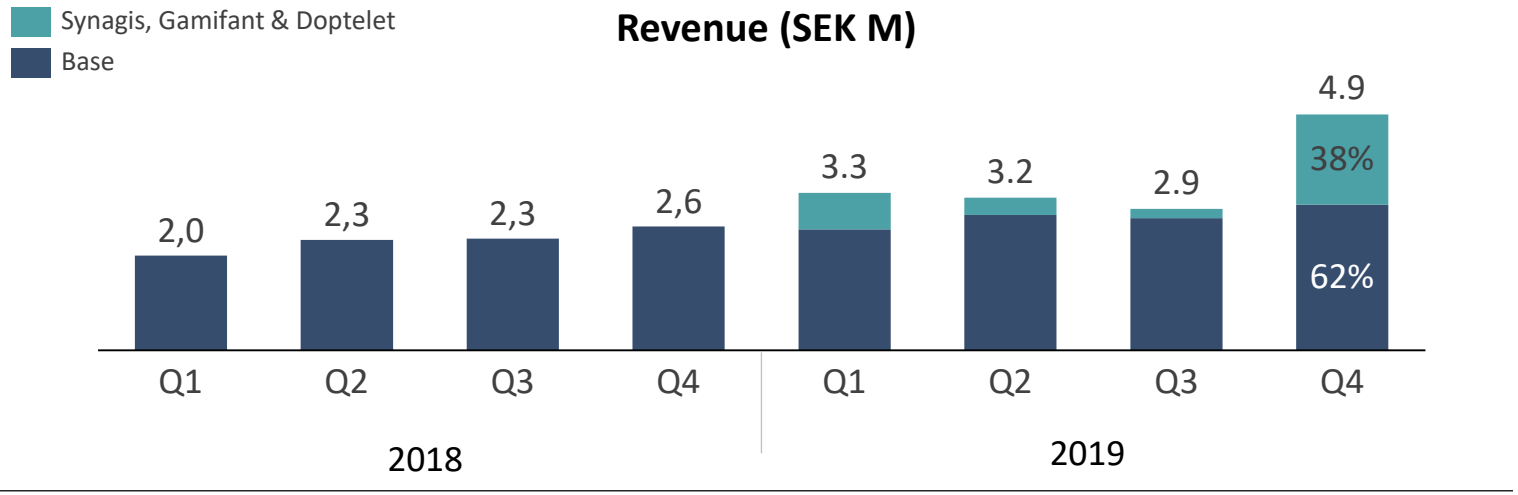
Total revenue (SEK M)

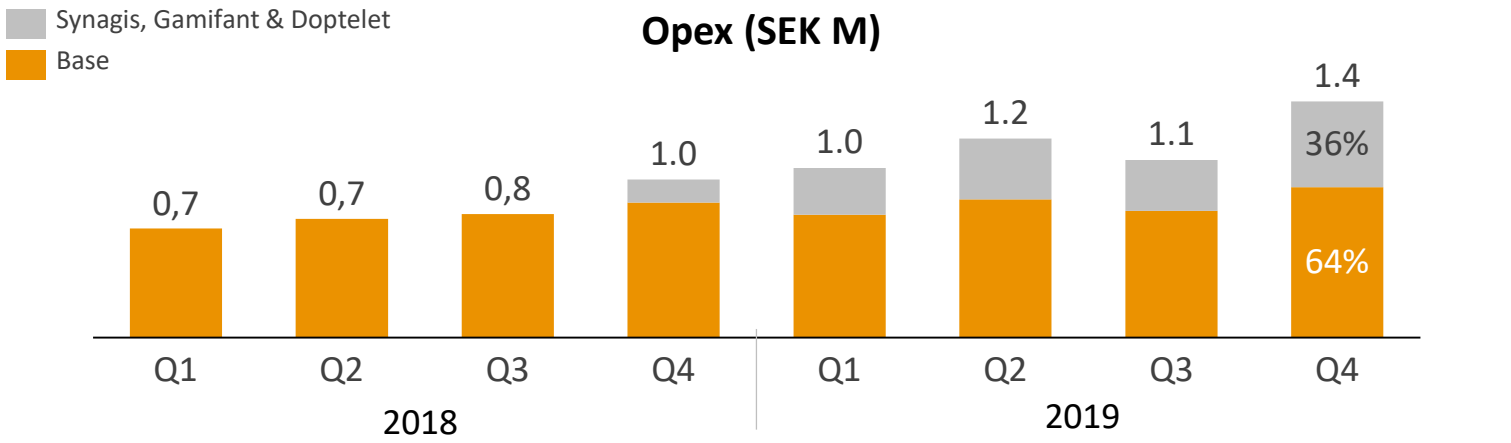


Amounts in SEK M	Q4 2019	Q4 2018	Change	Full-year 2019	Full-year 2018	Change
Total revenue	4,890	2,571	90%	14,248	9,139	56%
Gross profit	3,833	1,894	102%	10,913	6,723	62%
Gross margin[1]	78%	74%		77%	74%	
EBITA adjusted[1,2]	2,380	916	160%	6,145	3,571	72%
EBITA margin adjusted[1,2]	49%	36%		43%	39%	
Profit for the period	1,360	595	129%	3,304	2,418	37%
Earnings per share, SEK adjusted[1,2,3]	4.90	2.20	122%	11.89	8.97	33%
Operating cashflow	976	538	81%	3,634	2,090	74%
Net debt (+)/net cash (-)	-15,404	2,999		-15,404	2,999	

[1]Alternative Performance Measures (APMs)
[2]EBITA full-year 2019 excluding non-recurring items; transaction costs related to the acquisition of Dova in Q4 of SEK 92 M, restructuring costs of SEK 157 M in Q2 2019 and gain from divestment of SOBI005 in Q1 2019 of SEK 37 M.
[3]EPS full-year 2019 excluding impairment of intangible assets of SEK 18 M related to restructuring in Q2 2019.

Revenue and opex[1] development – diversifying into new areas of growth

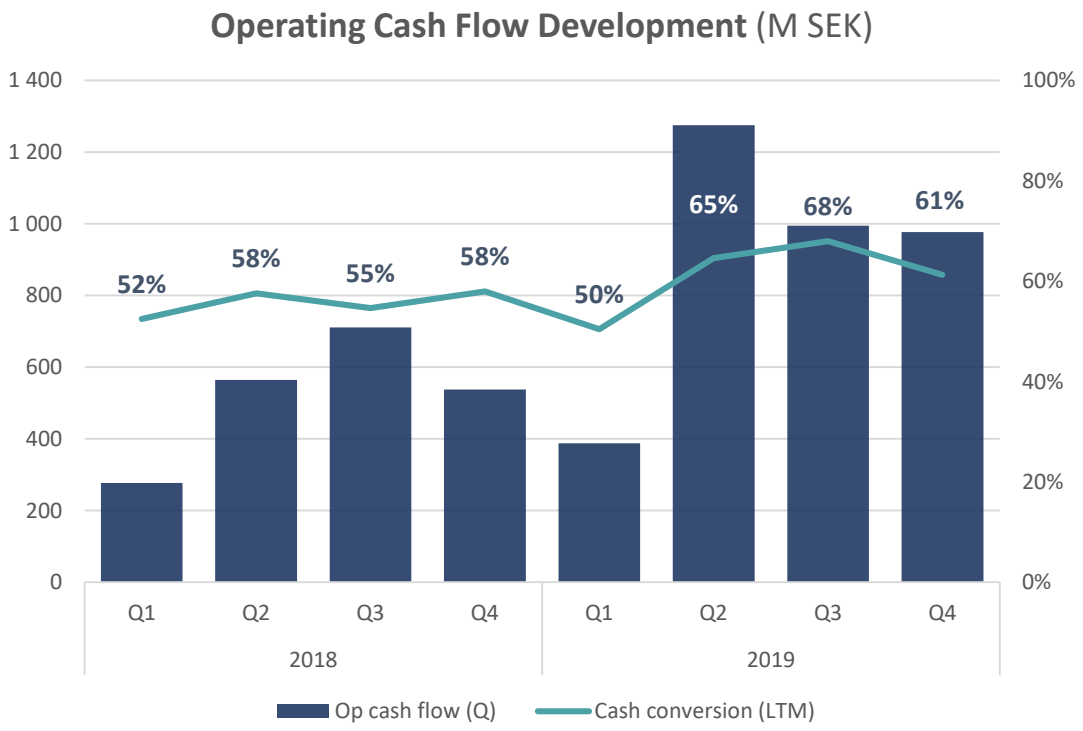




- Opex spend on base business[2] is stable with increased investments driven by Haemophilia
- Increase in Opex coming from acquisitions[3] – in order to achieve long-term growth and profitability
- US commercial investments in Synagis, Gamifant and Doptelet
  - R&D projects of Gamifant and Doptelet
  - Internationalisation
- A larger driver of the 2019 Opex increase from Q3 to Q4 is due to Dova

[1] Opex excluding non-recurring items; [2] Base business is Sobi total excluding acquisitions of Synagis, Gamifant and Doptelet; [3] Acquisitions of Synagis, Gamifant and Doptelet

Historical operating cash flow and net debt



- Acquisition of Dova in Q4 19
- Q4 19 Net debt increase to SEK 15.4B (vs. Q3 19 of SEK 7.6B)
  - Q3 19 Net debt / EBITDA < 1.5x
  - Q4 19 Net debt / EBITDA < 3.0x
- Expect rapid deleveraging due to continued strong cash conversion
- Cash conversion and operating cash flow will have seasonal fluctuations due to Synagis

Financial outlook

Further investment in 2020 will lay the foundation for future growth…

Haematology

- **Doptelet** and **Gamifant** – *future growth drivers*
  - Investment into market penetration and clinical trials with a view to expand indications for both products will affect our results in 2020
  - Doptelet and Gamifant have **potential peak sales beyond USD 500 M each** and their evolution needs to be adequately resourced during this critical phase

Immunology

- The **development and launch of Doptelet** will **negatively affect <u>2020 EBITA</u>** by **around SEK 500 M**

Specialty Care

- **Non-core Specialty Care** *expected to* ***decline***
- Focusing on the two core areas catalysed discontinuation of various less profitable products
  - Expected **negative impact of SEK 300 - 400 M** on **<u>2020 revenues</u>**

Mid-term outlook

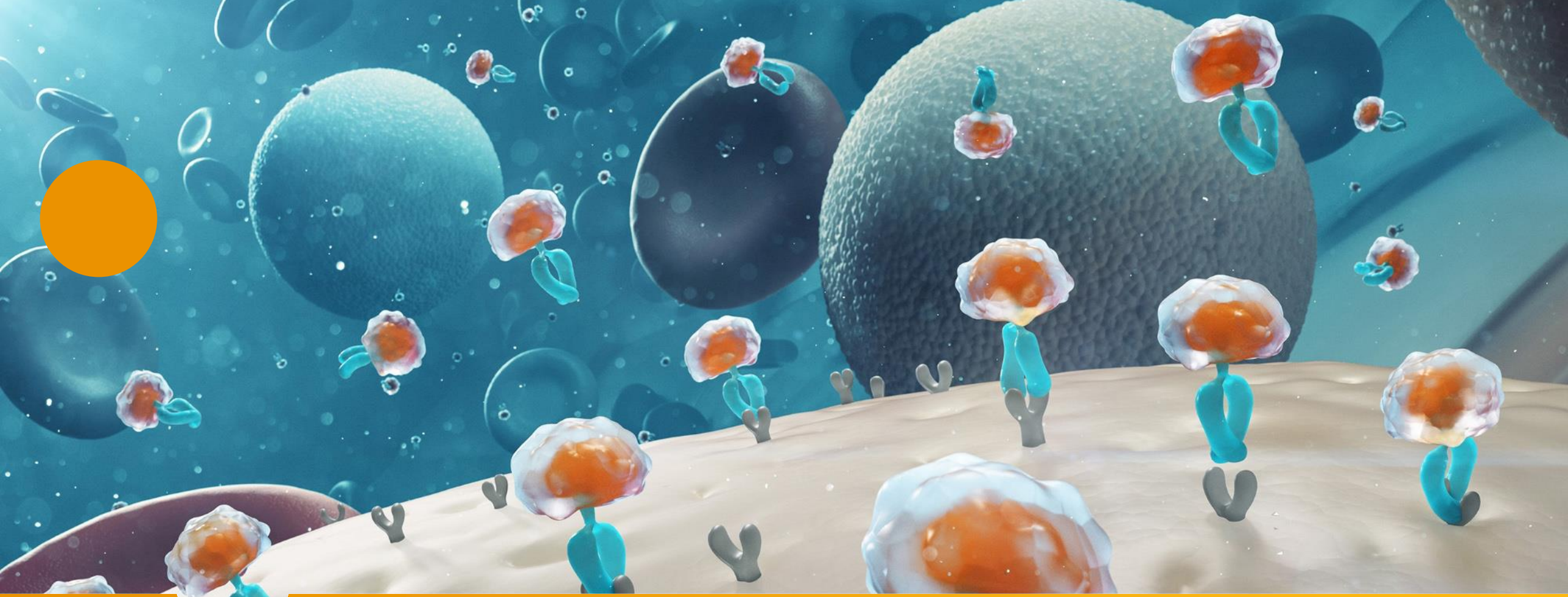
…driving **continuous annual double-digit growth** in **Haematology** and **Immunology in the mid-term**

Financial outlook 2020

Revenue for the full-year 2020 is expected to be in the range of SEK 15,000 – 16,000 M reflecting double-digit growth in the two core businesses, **Haematology** and **Immunology**.

EBITA is expected to be in the range of SEK 5,500-6,300 M, including the development and launch of Doptelet which will negatively affect EBITA by around SEK 500 M in 2020.

Q&A



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