

A large orange rectangular overlay with a white scalloped edge on the top-left corner. Inside, the text "Q1 2020 results" is written in white, bold, sans-serif font.

# Q1 2020 results

rare **strength**



29 April, 2020



# Forward looking statements

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**Guido Oelkers** | CEO




**Henrik Stenqvist** | CFO





**Milan Zdravkovic** | Head of R&D and CMO





# Taking charge in a challenging environment...

- 
**Take care of patients**

Secure supply for all key products, respond to increased demand in a flexible way
- 
**Protect team**

Early travel restrictions, enable a virtual office environment whenever possible
- 
**Continue access to HCPs**

Interactions with health care professionals transitioned to virtual pathways in a meaningful way
- 
**Enable a digital agenda**

Launch of Florio to enable haemophilia patients living a life with limited compromises – *liberating life*
- 
**Internationalise the Group in key markets**

Established a company in China and a new entity on the way in Japan

**...enabled by a strong financial profile**

*Financial strength and strong cash generation driven by diversified rare disease portfolio – highly resilient as demonstrated by Q1 results*

# Q1 2020: Strong start to year despite challenging period

Q1 2020 report

Strong demand...  
...across portfolio

## Immunology: 57% growth at CER year on year

- **Kineret:** Strong acceleration in growth due to COVID-19
- **Synagis:** Uplift on continued execution and seasonal demand
- **Gamifant:** Acceleration of uptake in younger pHLH patients

+39% CER	
+72% <sup>1</sup> CER	
+11% CER	

## Haematology: 34% growth at CER year on year

### Haemophilia products growing at 35% CER year on year

- Propelled by strong underlying patient growth and serving supply chain needs

- **Doptelet: First footprint in ITP**

- Despite limited market access our team has been able to build significant patient share in a difficult environment

	+33% CER
	+41% CER

Revenue Q1, SEK M

4,639

+42%

EBITA<sup>1</sup> Q1, SEK M

2,173

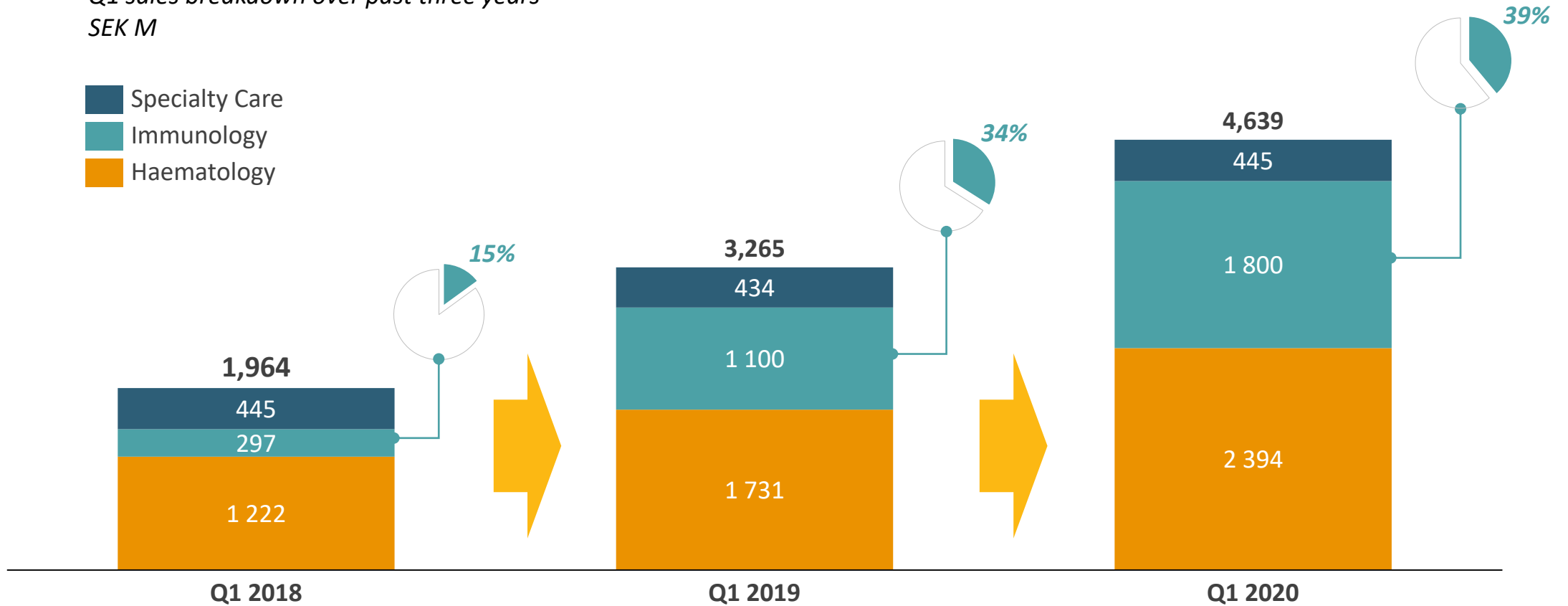
+44%

1. Growth compares full quarter in Q1 2020 vs partial quarter in Q1 2019 Q1 that only includes Sobi sales from 23 January, the date of acquisition. Organic growth calculated from 23 January in both quarters is 35%





# Progress in building a strong second leg in Immunology

Q1 sales breakdown over past three years  
SEK M

- Specialty Care
- Immunology
- Haematology



# A clear strategic focus for mid-term growth

		Strategic priorities	Q1 2020 update
Haematology	 <b>Maintain Innovate</b>	<b>1</b> <b>Maintain</b> haemophilia leadership	<i>Gained market share Launched digital platform <b>florio™</b></i>
	 <b>Diversify Build</b>	<b>2</b> <b>Build</b> Doptelet to scale	<i>ITP - First 450 patients treated in US; Filed ITP indication in the EU CLD - Planning for launch in the EU</i>
Immunology	 <b>Extend Expand</b>	<b>3</b> <b>Extend</b> Gamifant into sHLH and acute graft failure <b>4</b> <b>Expand</b> Kineret into additional indications	<i>Phase 2/3 study related to COVID-19 initiated sHLH – sJIA (MAS) completed recruitment Positive CHMP opinion for FMF indication</i>
	 <b>Grow</b>	<b>5</b> <b>Grow</b> Synagis	<i>Increased patient adherence and commercial excellence</i>

Our strategic priorities focus on building a foundation for **double-digit growth** in the **mid-term** for the **core franchises**

# COVID-19 impact: We remain focused and agile

## Supply

Activities undergoing to ensure access to treatment and supply maintained

- Patient support activities
- Working closely with suppliers and partners to keep the supply chain up-and-running
- For now, production and supply of Sobi's products are not compromised by the current COVID-19 situation

## Regulatory

Environment for conducting clinical studies has changed given difficulties with clinical site interactions and patient enrolment

- Recruitment of CIT with avatrombopag remains on target
- Phase 2/3 study for anakinra and emapalumab on the way; study in MAS (SJIA) enrolment completed
- Potential delays in clinical programmes cannot be ruled out

## Commercial

- Access challenging
- Digital solution for haemophilia patients – Florio launched
- Proactive use of virtual tools to protect and support employees – early initiative taken to restrict travel and implement virtual office use

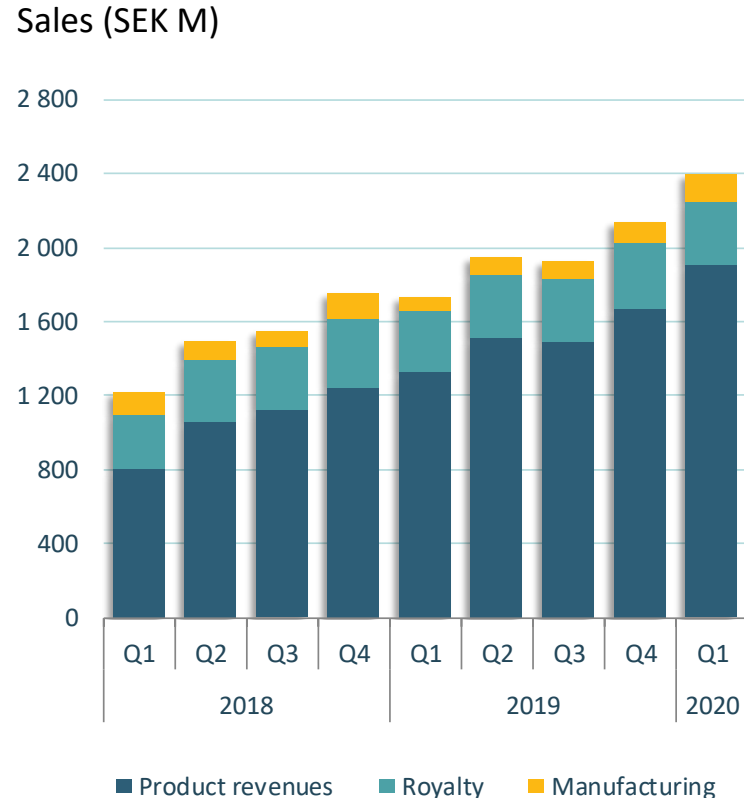




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Business review  
Haematology

# Haematology: Growth driven by haemophilia portfolio



- **Total Haematology revenue reached SEK 2,394 M (1,731) for the quarter, an increase of 38 per cent (34 per cent at CER)**
  - Royalty revenue amounted to SEK 335 M (334) for the quarter
- **Doptelet sales were SEK 65 M for the quarter**
  - First full quarter of sales since acquisition in November 2019
  - US: Still in early launch phase for ITP – first 450 patients
  - EU: Preparing for CLD launch
  - Strong recruitment of CIT trial with avatrombopag in Q1, promising evolution of patient acquisition in ITP

# Haemophilia portfolio: High single-digit patient growth QoQ

## Elocta

Sales (SEK M)



## Alprolix



- **Elocta** sales rose 37 per cent (33 per cent at CER) for the quarter to SEK 1,359 M (991)
  - Majority of growth derived from Spain and CEE
  - Largest part of growth emanates from continued patient growth and share gains, whilst additional supply requirements have been fulfilled
- **Alprolix** sales rose 45 per cent (41 per cent at CER) for the quarter to SEK 488 M (337)
  - Significant progress in patient growth in Q1
  - Continuing to grow in key markets
  - Approved for reimbursement in Spain
- **Florio** – an important enabler for haemophilia patients to live a life with fewer constraints

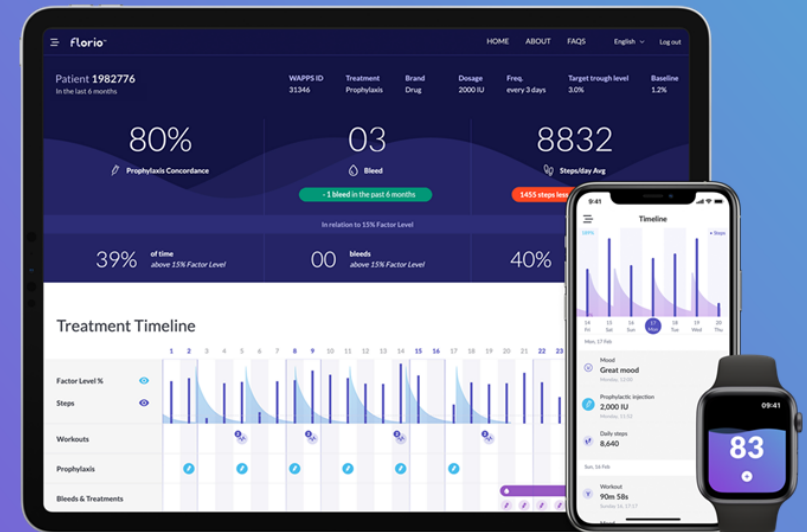
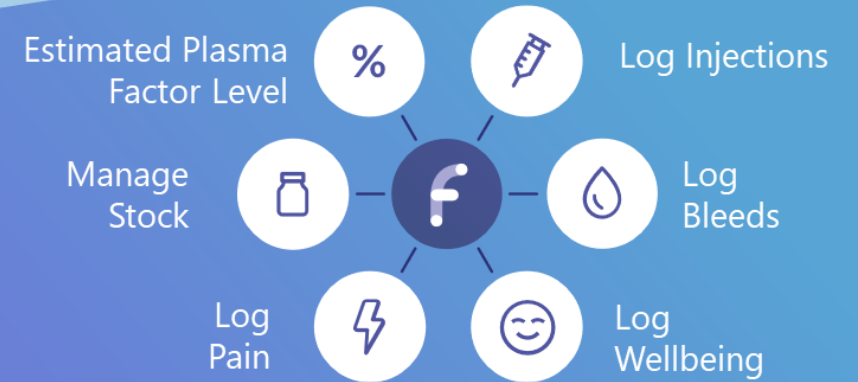
# florio™

## Enabling life beyond haemophilia.

Sobi has invested in developing Florio, a digital medical device designed to improve the quality of life for people with haemophilia. It has recently been launched.

- Florio is a smartphone app for patients, which can be combined with a wearable device, and a web-based dashboard for physicians
- Florio allows patients to track, monitor and share data relating to their health in real-time with their healthcare teams to enable personalised care
- Florio aims to enable meaningful discussions between physicians and people living with haemophilia, aimed at reducing the uncertainty around treatment so patients with haemophilia are able to lead full and active lives.

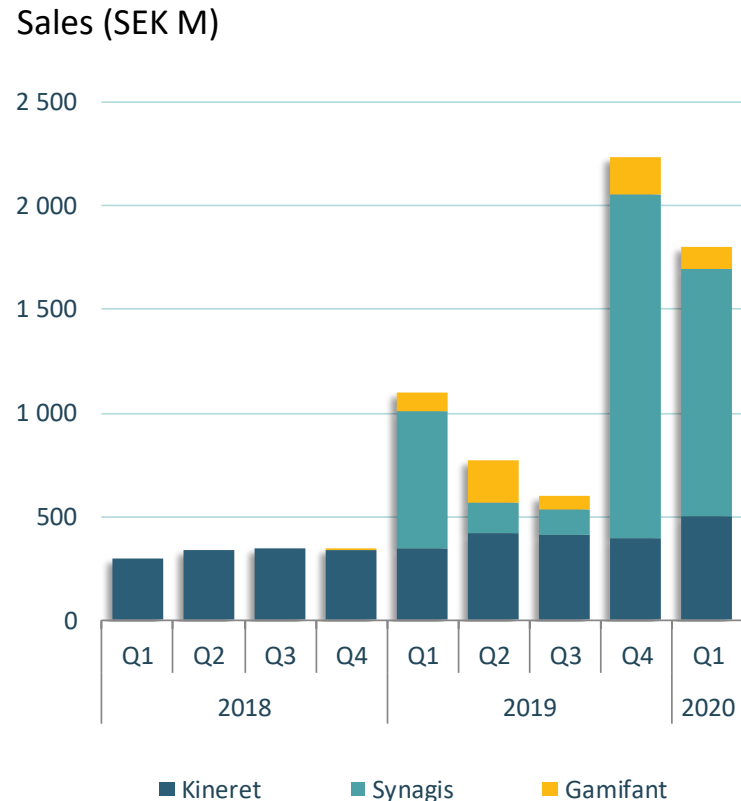
Florio was developed with extensive input from both healthcare professionals and people with haemophilia, further supporting Sobi's long-term commitment to the community. It has been developed by Florio GmbH, an affiliate within Sobi established as a separate company.



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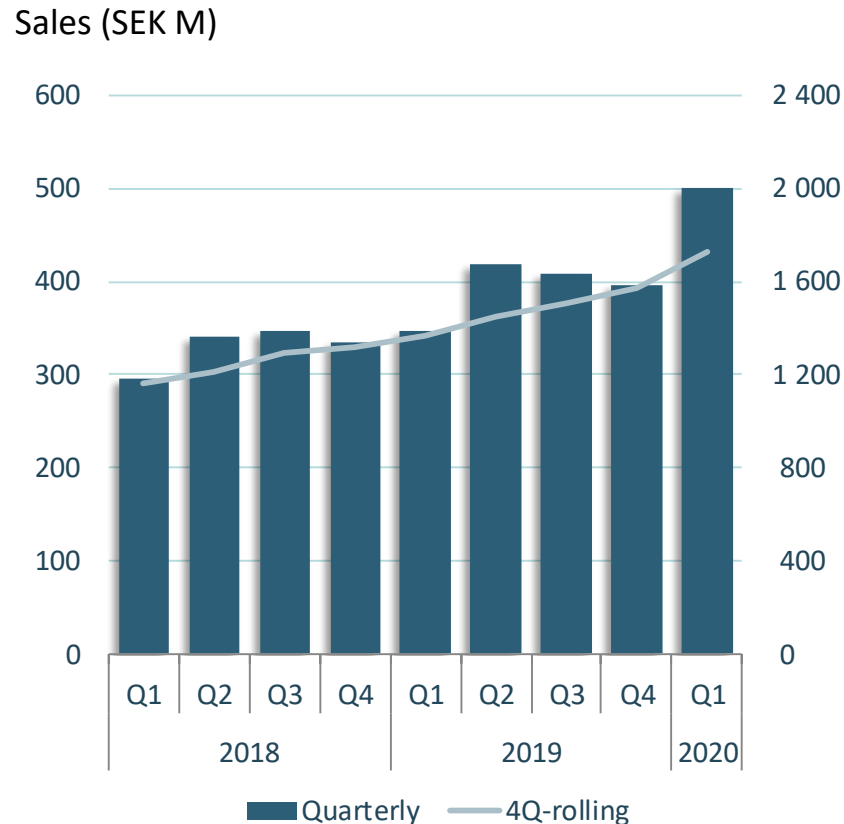
Business review  
Immunology

# Immunology: Kineret and Synagis driving growth in Q1



- **Q4 revenue** of SEK 1,800 M (1,100)
  - Revenue growth of 64 per cent (57 per cent at CER)
- **Two largest products driving growth**
  - **Synagis** sales for the quarter were SEK 1,196 M (665), corresponding to growth of 80 per cent (72 per cent at CER) over the previous RSV season
    - Strong underlying demand as well as recording of sales for a full quarter compared with Q1 2019, where sales were recorded from 23 January, the day the acquisition closed
    - Season-to-date sales of USD 312 M
  - **Kineret** continues to perform positively, with double-digit growth of 39 per cent at CER
  - **Gamifant** sales for the quarter amounted to SEK 104 M (89), an increase of 17 per cent (11 per cent at CER)
    - Continuous positive evolution of the number of patients
    - Sales continue to be volatile due to the product being in launch phase

# Kineret: Late increased demand driven by COVID-19



- Kineret sales for the quarter were SEK 501 M (346), an increase of 45 per cent (39 per cent at CER)
- Kineret continues to perform positively, with a very strong first quarter
- Growth is mainly driven by increased underlying demand across all regions as a result of the COVID-19 pandemic during the latter part of the quarter
  - Clinical interest for potential treatment of hyperinflammation related to COVID-19
- Positive CHMP opinion in Familial Mediterranean Fever (FMF)

# Gamifant: On the way to become an important drug for Sobi

## Q1 updates



**Compelling scientific evidence**

**1 Strong scientific evidence**, that IFN $\gamma$  contributes to clinical conditions seen in HLH patients

**Demonstrated efficacy**

**2 Demonstrated efficacy and effectiveness** in neutralising IFN $\gamma$  in conditions where excessive

**Development strategy well underway**

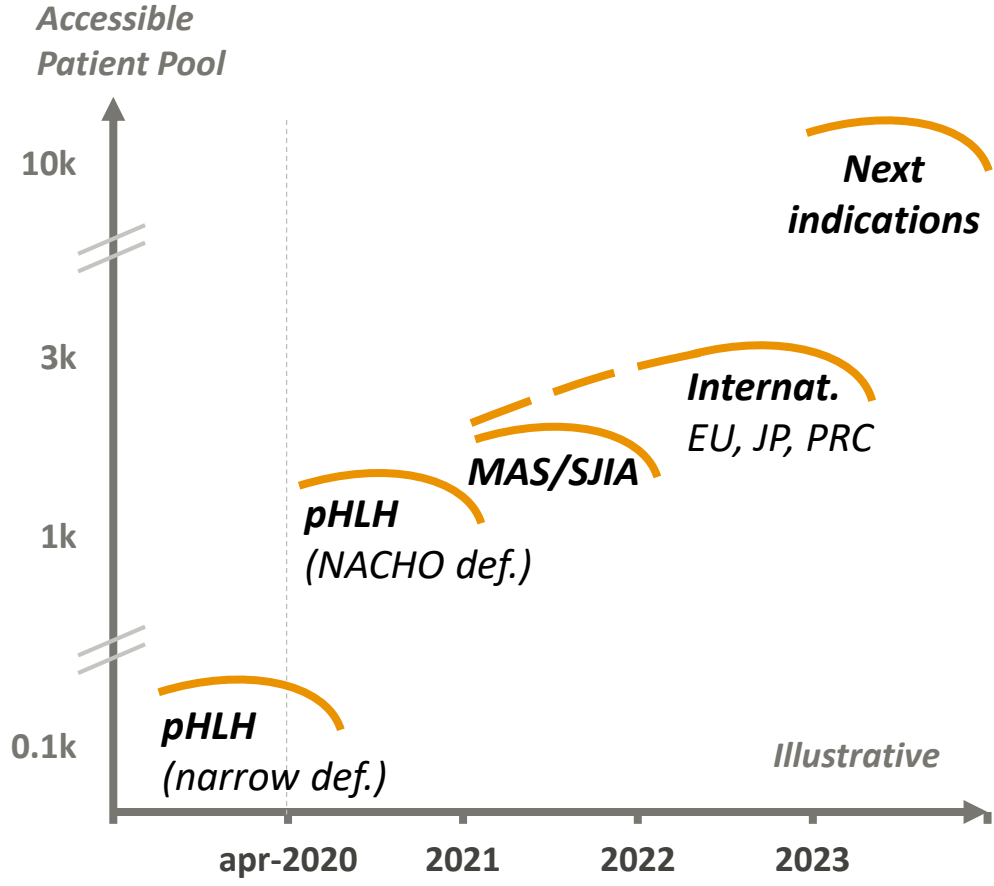
**3 Ongoing clinical plan** - develop emapalumab from narrow definition of pHLH to a broader HLH indication  
 → *MAS/SJIA study enrolment completed*  
 → *sHLH adults study opened for enrolment*  
 → *Preparing graft failure study*

**Role of IFN $\gamma$  in CSS**

**4 The role of IFN $\gamma$  in the cytokine storm syndrome** led us to initiate the study COVID-19 patients



# Gamifant: Q1 highlights and the journey ahead



## Q1, an exciting quarter for Gamifant (emapalumab)

- 1 Whilst sales increased by 17% at act. rate, we were able to increase no. of patients by 21% vs. Q4 2019
- 2 Completed enrolment in MAS/SJIA study
- 3 Included in phase 2/3 study in COVID-19-related hyperinflammation; study ongoing
- 4 Numerous research collaborations to broaden data on efficacy/safety in COVID-19-induced cytokine storm syndrome on the way
- 5 Preparing development of the “next” indications

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Pipeline



# Role of cytokine storm syndrome (CSS)



Accumulating evidence indicates that **hyper-inflammation caused by a cytokine storm** has been a serious complication associated with a subgroup of severe COVID-19 patients



**Current management of COVID-19 is mainly supportive...**

...and respiratory failure from acute respiratory distress syndrome (**ARDS**) is the **leading cause of mortality**<sup>1</sup>



**Pattern similar to sHLH...**

**Progression to ARDS** is associated with the upregulation of pro-inflammatory cytokines and chemokines, known as **cytokines release syndrome (CRS)**, with a **pattern very similar to that of secondary haemophagocytic lymphohistiocytosis (sHLH)**



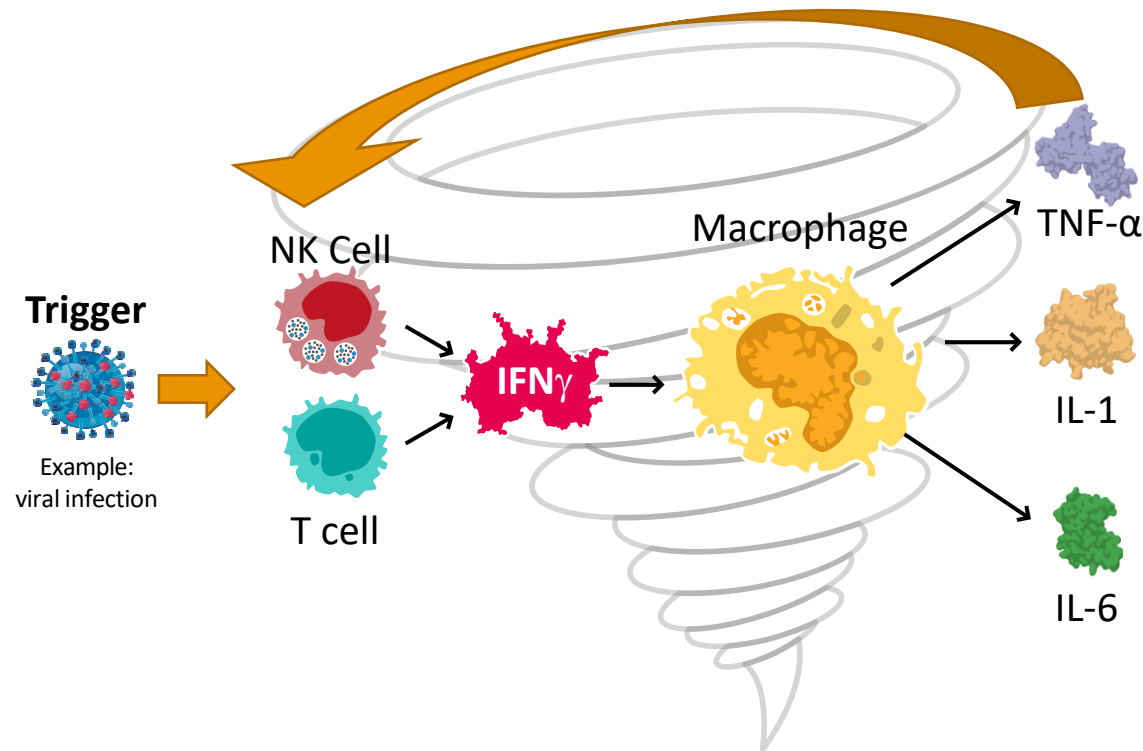
**Several potential targets...**

Specifically, this is **characterised by increased levels of a number of cytokines** resulting in unremitting fever, cytopenias and hyperferritinaemia

**The management of this cytokine storm is one of the major unmet needs regarding COVID-19 infection**

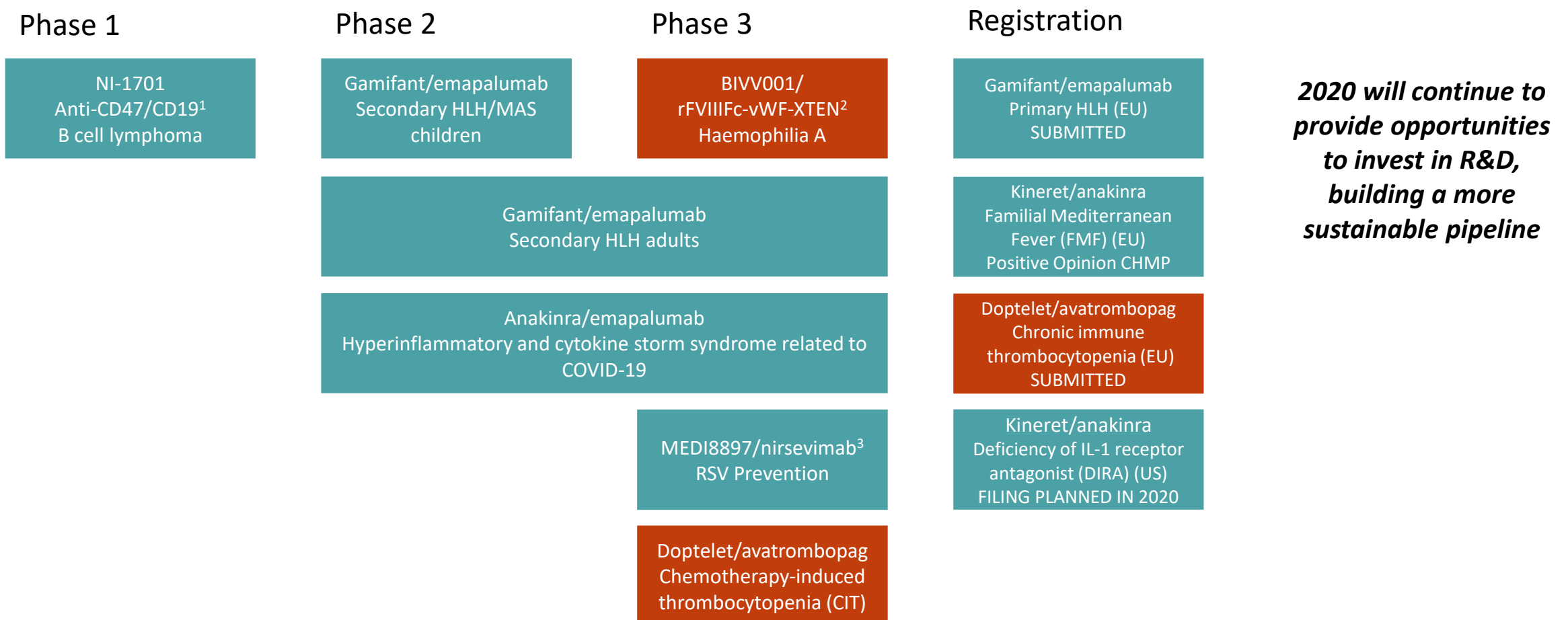
# Cytokine storm due to overactivation of the immune system: Proposed pathomechanism of severe viral infections

Illustrative view: **Continuous inflammatory feedback loop causing cytokine storm**



- Overproduction of immune cells and their activating compounds (cytokines)
- Surge of activated immune cells into the lungs
- Primary symptoms: incl. high fever, swelling, extreme fatigue and nausea
- Lung inflammation and fluid build-up can lead to respiratory distress and can be contaminated by a secondary bacterial pneumonia, often enhancing the mortality in patients

# Committed to building a sustainable R&D platform

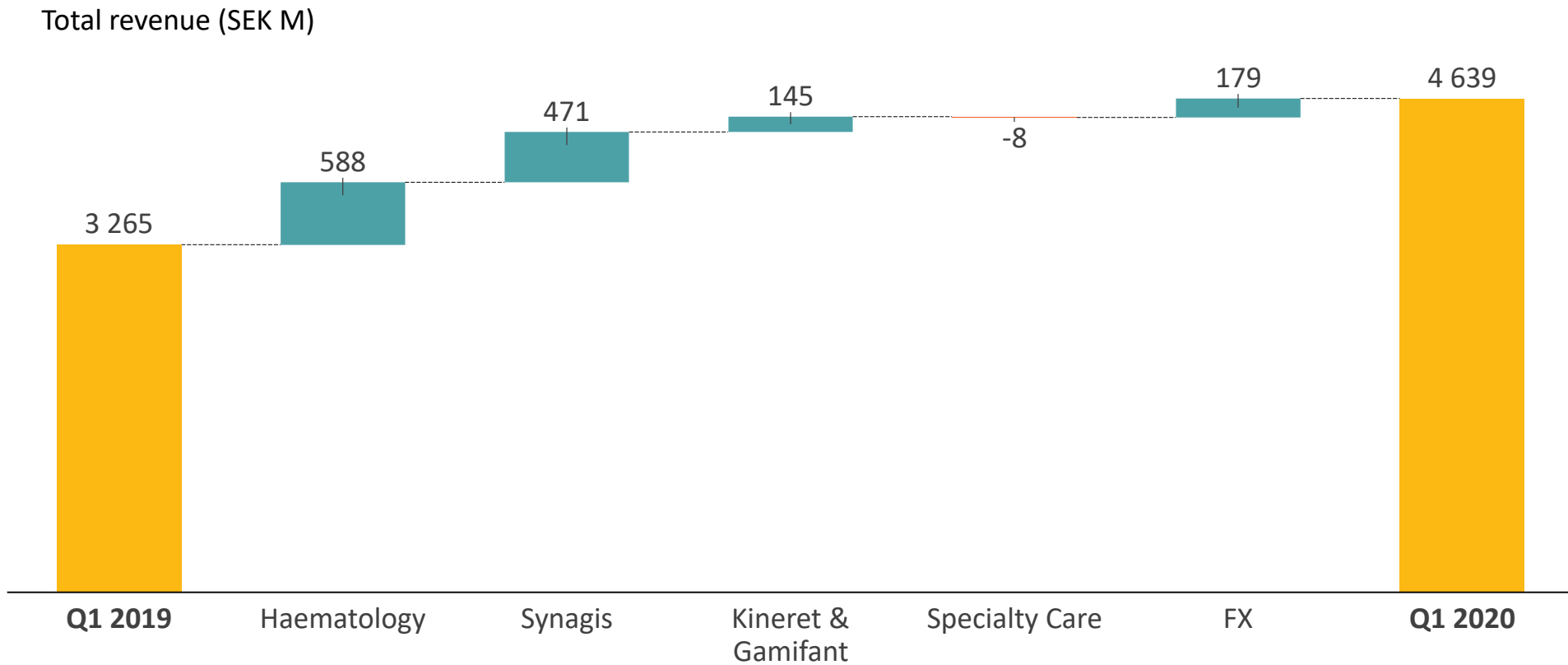


1. Options for shared financial rights to NI-1701  
 2. In collaboration with Sanofi  
 3. Developed by AstraZeneca and Sanofi. Sobi has rights to 50 per cent of US earnings.

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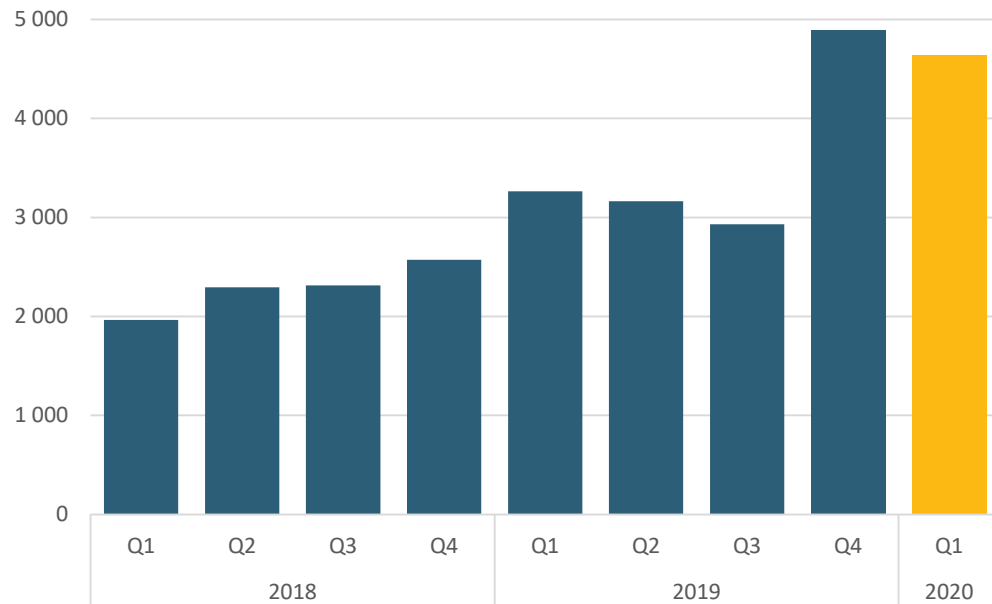
Q1 2020  
Financial results

# Q1 2020: Revenue build



# Q1 2020: Financial results

Total revenue (SEK M)



Amounts in SEK M	Q1 2020	Q1 2019	Change	Full-year 2019
Total revenue	4,639	3,265	42%	14,248
Gross profit	3,598	2,494	44%	10,913
Gross margin <sup>1</sup>	78%	76%		77%
EBITA adjusted <sup>1,3</sup>	2,173	1,471	48%	6,145
EBITA margin adjusted <sup>1,3</sup>	47%	45%		43%
Profit for the period	1,182	903	31%	3,304
Earnings per share, SEK adjusted <sup>1,3,4</sup>	4.02	3.03	32%	11.89
Operating cashflow	2,001	388	516%	3,634
Net debt (+)/net cash (-)	14,198	5,552		15,404

<sup>1</sup>Alternative Performance Measures (APMs)

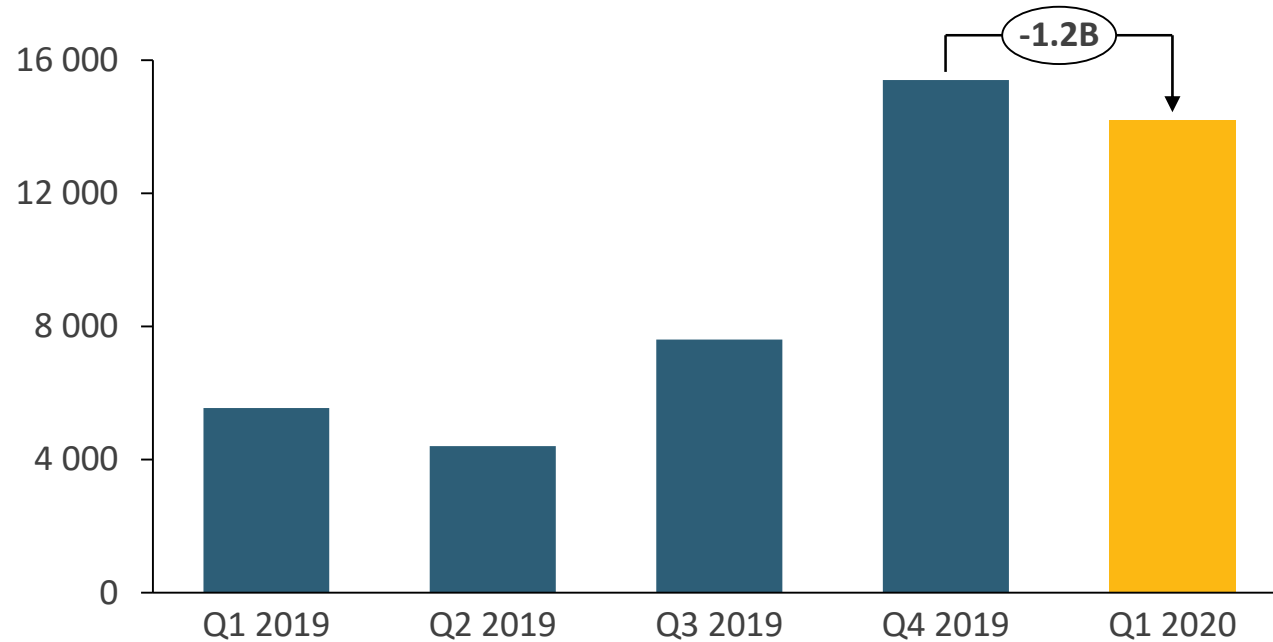
<sup>3</sup>EBITA full-year 2019 excluding non-recurring items; transaction costs related to the acquisition of Dova in Q4 of SEK 92 M, restructuring costs of SEK 157 M in Q2 2019 and gain from divestment of SOBI005 in Q1 2019 of SEK 37 M.

<sup>4</sup>EPS full-year 2019 excluding impairment of intangible assets of SEK 18 M related to restructuring in Q2 2019.



# Continued strong operating cash flow in Q1 2020, leverage < 2.5x

Net debt (SEK M)



## Q1 2020 update

- **Operating cash flows** of 2B SEK
- **Net debt** reduction of -1.2B
- **Leverage** < 2.5x
- **Available liquidity** of ~7B SEK

Acquisitions



& related assets

# Sobi stands strong in the current COVID-19 environment

-  Unchanged or increased demand
-  Ability to supply product
-  Receivables under control
-  Strong liquidity reserves



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# Q1 summary

# Q1 2020: Significant progress achieved

## Strategic actions

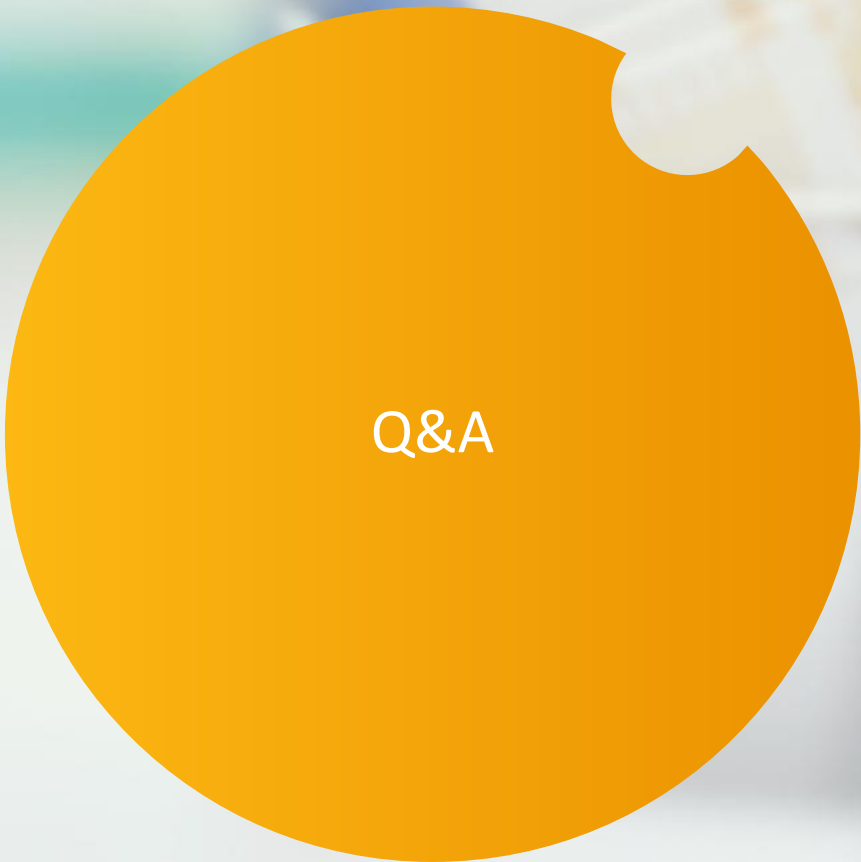
Haematology	Establishing leadership	Florio launch	<ul style="list-style-type: none"> <li>• Launch of <b>Florio</b>, our digital solution for Haemophilia patients to live a life with fewer compromises -- <i>Liberate life</i></li> </ul>
		Avatrombopag	<ul style="list-style-type: none"> <li>• <b>CIT</b>: Over 100 patients enrolled in study</li> <li>• <b>ITP</b>: Filing in EU</li> <li>• <b>CLD</b>: Approval in China</li> </ul>
Immunology	Building broader foundation	COVID-19 study	<ul style="list-style-type: none"> <li>• <b>Anakinra</b>: Included in various clinical studies in COVID-19-related CSS; Positive opinion from CHMP for FMF</li> </ul>
		Extend & Expand	<ul style="list-style-type: none"> <li>• <b>Emapalumab</b>: Completed enrolment in the sJIA/MAS study; Initiated phase 2/3 study for CSS in COVID-19 patients</li> <li>• <b>Synagis</b>: Improved effectiveness of our value chain to ensure correct dosing cycle</li> </ul>
International	Building global presence	International Division formation	<ul style="list-style-type: none"> <li>• <b>Emerging market player</b>: Building global footprint, focusing on Japan and China</li> </ul>

# Financial outlook 2020: unchanged

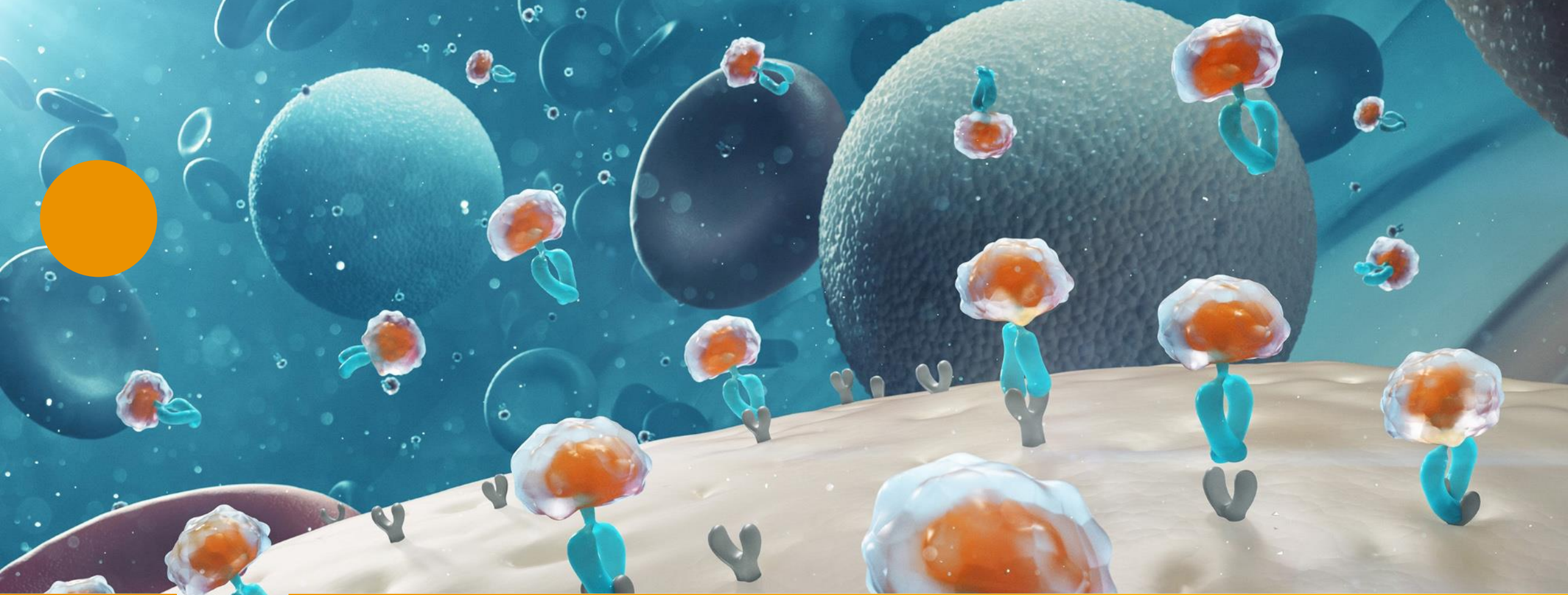
**Revenue** for full-year 2020 is expected to be in the range of SEK 15,000 – 16,000 M reflecting double-digit growth in the two core businesses, **Haematology** and **Immunology**.

**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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