Q2 2020 results

rare **strength**

July 16, 2020

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

Presenters

Preamble – significant progress in a difficult environment

Drivers facing the industry ex. US

(IQVIA 10 July, US Market):

COVID affecting the pharmaceutical market:

- Total prescriptions (TRx) down between 6 – 12 per cent between end of March and beginning of June
- Telemedicine having 30 – 40 per cent less productivity than face to face interactions
- New drug prescription (NRx) down between 30 – 40 per cent from end of March to beginning of June

Sobi's milestones in this environment

1. Half year top line growth: 20 per cent (17% at CER)
2. Half year adjusted EBITA growth: 20 per cent
3. Healthy cash flow: leverage below 2
4. Significant interest for anakinra related to COVID-19: approximately 2,500 patients in on-going clinical studies
5. Completed enrolment of two key studies
6. Gaining market share with Elocta and Alprolix
7. Substantial progress with Doptelet (52% growth QoQ and Gamifant 27% growth QoQ) with practically no face to face interaction
8. Building the future in line with strategy: acquisition of global rights to SEL 212[1]

[1]The transaction is subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act and other customary closing conditions.

Q2 2020: A robust quarter in challenging times

		Q2 2020 sales SEK M	
Haematology	**Haemophilia portfolio** *~4% patient growth QoQ*	1,403[1]	• Continued share gains of franchise; stocking effects from Q1 and decline in consumption/patient due to COVID-19 have impacted QoQ sales growth (see slide 6); patient growth: ~4% QoQ; > 24% YoY H1
Haematology	**Doptelet** *+52% growth QoQ*	99	• Strong and steady patient growth in the US built on demand creation • Recruitment of CIT completed
Immunology	**Gamifant** *+27% growth QoQ*	132	• Further increasing number of treated patients with new patients significantly younger vs 2019, please note price reductions affect YoY comparison
Immunology	**Kineret** *+24% growth at CER vs PY*	530	• Continued strong underlying growth, reduced no. of COVID patients in ICUs are reflected in the numbers • Three publications in Lancet Rheumatology to support Kineret in various settings
Immunology	**Synagis** *Sales of 52m in Q2*	52	• Out of season cycle

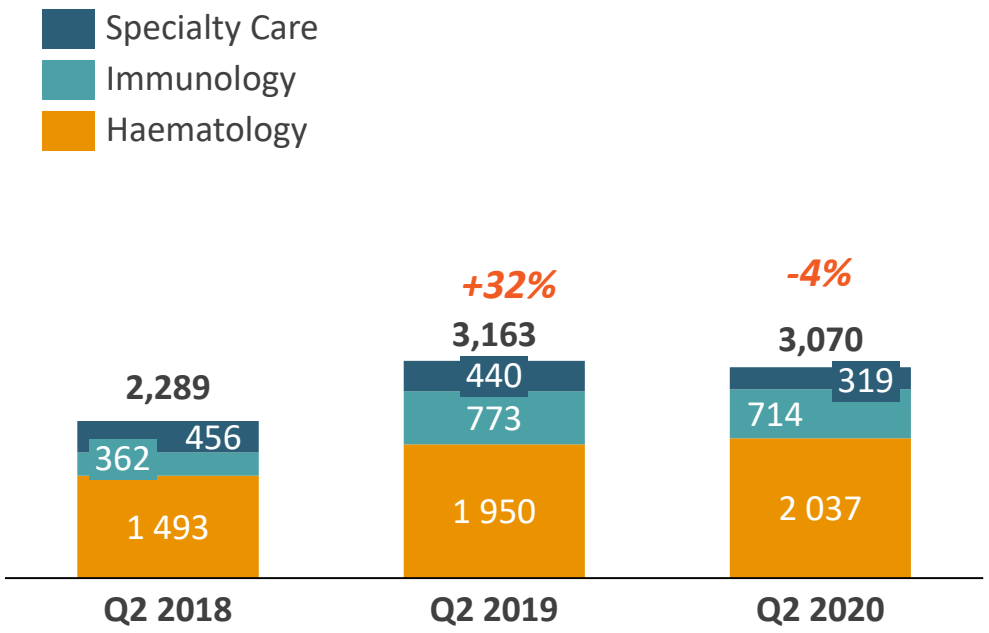
Solid EBITA margin of 33% and a strengthened gross margin of 78%; Strong cash flow generation

1. Refers to product sales only i.e. Elocta and Alprolix excluding Royalties and Refacto manufacturing

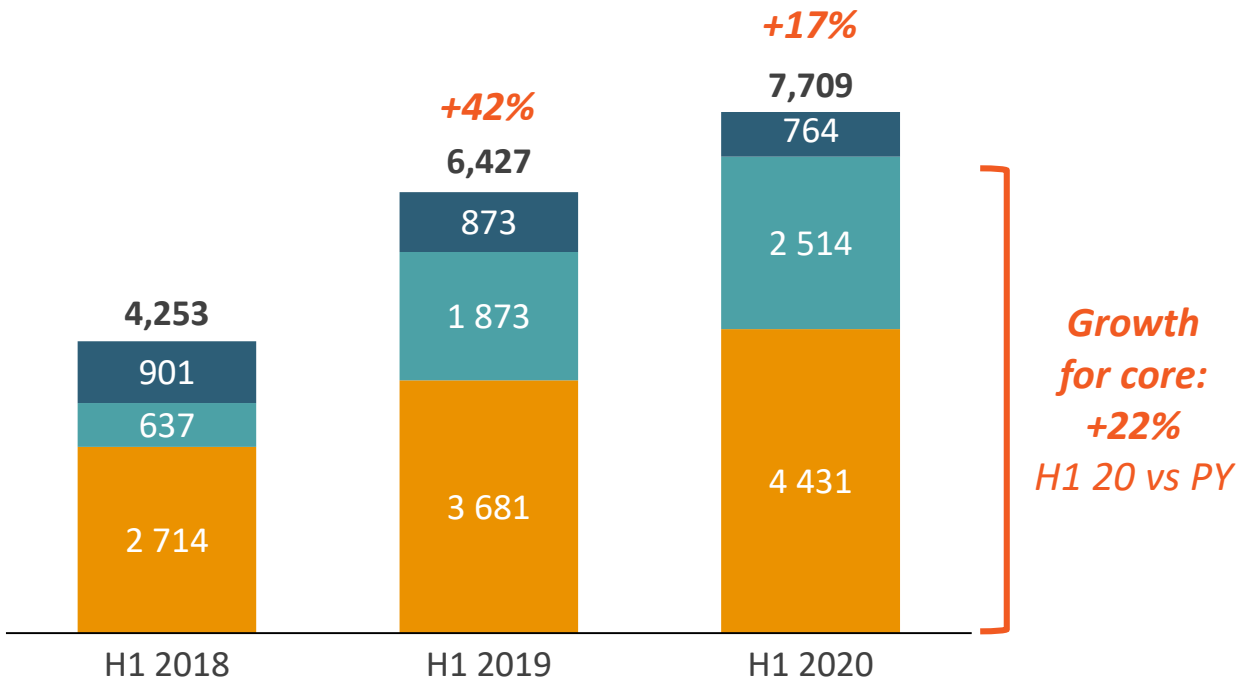
Q2/H1 2020 Group sales: Strong H1 despite COVID-19 impact on Q2

Q2 sales breakdown over last three years

SEK M; Growth at CER



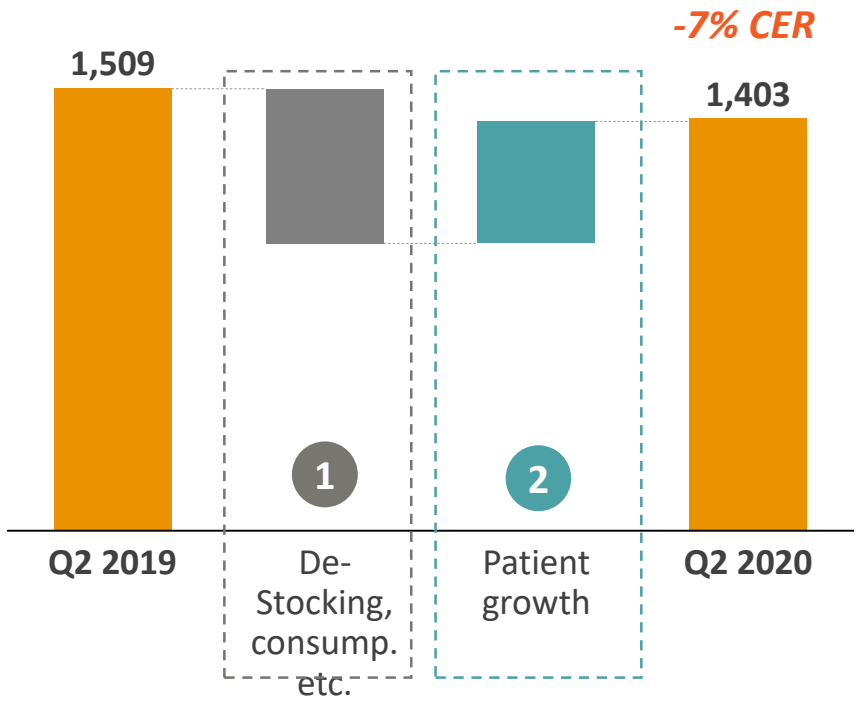
H1 sales breakdown over last three years



Q2 2020: Haemophilia - positive patient growth continues

Q2 revenue development/bridge

YoY Growth[1]: *Q2 2020 vs. PY*
SEK M



1 COVID-19 impacts

- Q2 sales impact driven by **inventory de-stocking** at wholesalers **following extraordinary stocking in Q1** and **lower patient consumption**
- **Temporary lower consumption by patient due to COVID-19 r**elated regional lockdowns, leading to the **postponement of elective surgeries and emergency procedures** and a **reduced activity levels** and consecutive reduced consumption

2 Patient development

- Despite limited or no face-to-face interactions due to the challenges caused by COVID-19, both Elocta and Alprolix continued to show **strong patient growth through all periods**

Patient growth

	QoQ	H1 vs PY
ELOCTA® efmoroctocog alfa (recombinant human coagulation factor VIII, Fc fusion protein)	*+3%*	*+21%*
ALPROLIX™ [Coagulation Factor IX (Recombinant), Fc Fusion Protein]	*+4%*	*+29%*

[1]Haemophilia product sales excluding Royalties and Refacto manufacturing

SEL-212[1]: Partnering towards further innovation in Immunology

Selecta Biosciences

SEL-212
ImmTOR
co-administered w/
Pegadricase

- **Worldwide** strategic license for SEL-212, **Phase 3 ready novel treatment** for **Chronic Refractory Gout**, a debilitating condition for patients
- SEL-212 consists of Selecta's **innovative targeted therapy** comprising ImmTOR technology and Pegadricase (recombinant uricase)
- SEL-212 is expected to be **best-in-class asset** without the immunogenicity risks of current available treatments

Investing in a sustainable portfolio while creating more breadth to our pipeline

[1]The transaction is subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act and other customary closing conditions.

Q2 2020: Significant progress in challenging times

Haematology

- **Haemophilia**
  - Continuous strong patient growth QoQ despite lack of face to face interactions
- **Doptelet**
  - Strong quarter on quarter growth and on a good trajectory despite no F2F interactions
  - CIT: Enrolment completed, read out in Q4 2020; ITP: Review in the EU ongoing; CLD: Ready for launch in the EU

Immunology

- **Gamifant**
  - Strong patient growth and continuing on our pathway to reposition the product towards broader pHLH indication; price effect on sales will be overcompensated by volume increases over time
- **Kineret**
  - Continued solid growth

R&D/Strategy

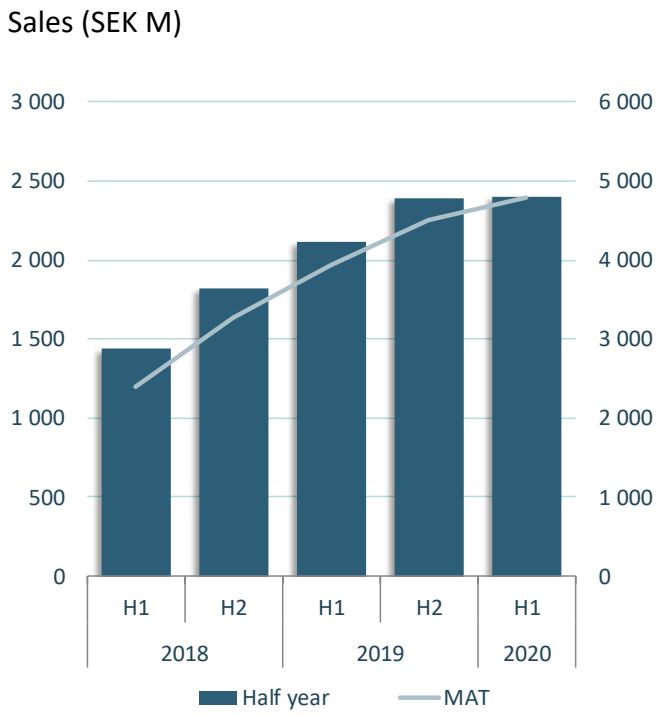
- **R&D milestones**
  - Strong delivery in R&D for key studies: completed enrolment of the study with **emapalumab in MAS in sJIA (06 study)** and to **CIT study with avatrombopag** despite the challenges related to COVID-19
- **Portfolio expansion and building the future**
  - Building on Sobi's mid-term future with SEL-212[1]

[1]The transaction is subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act and other customary closing conditions.

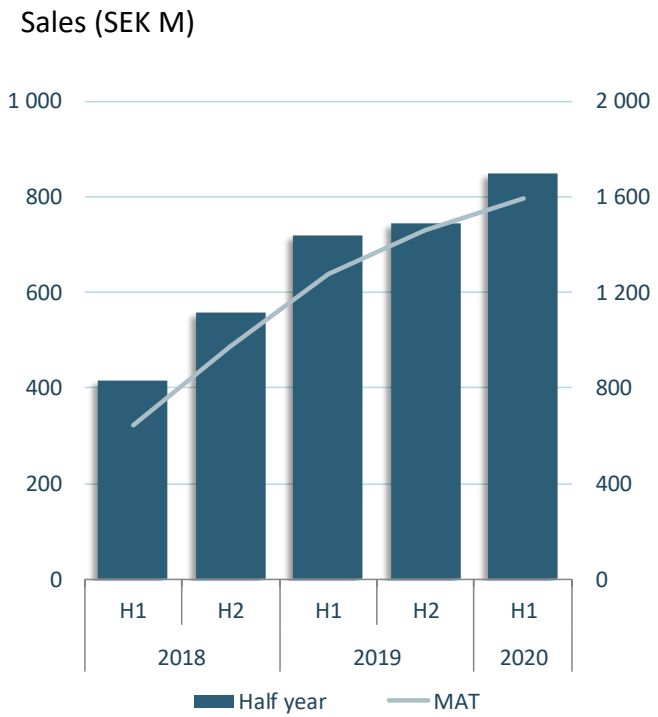
Business Review
Haematology

Haemophilia: Continued double-digit growth in H1

Elocta



Alprolix



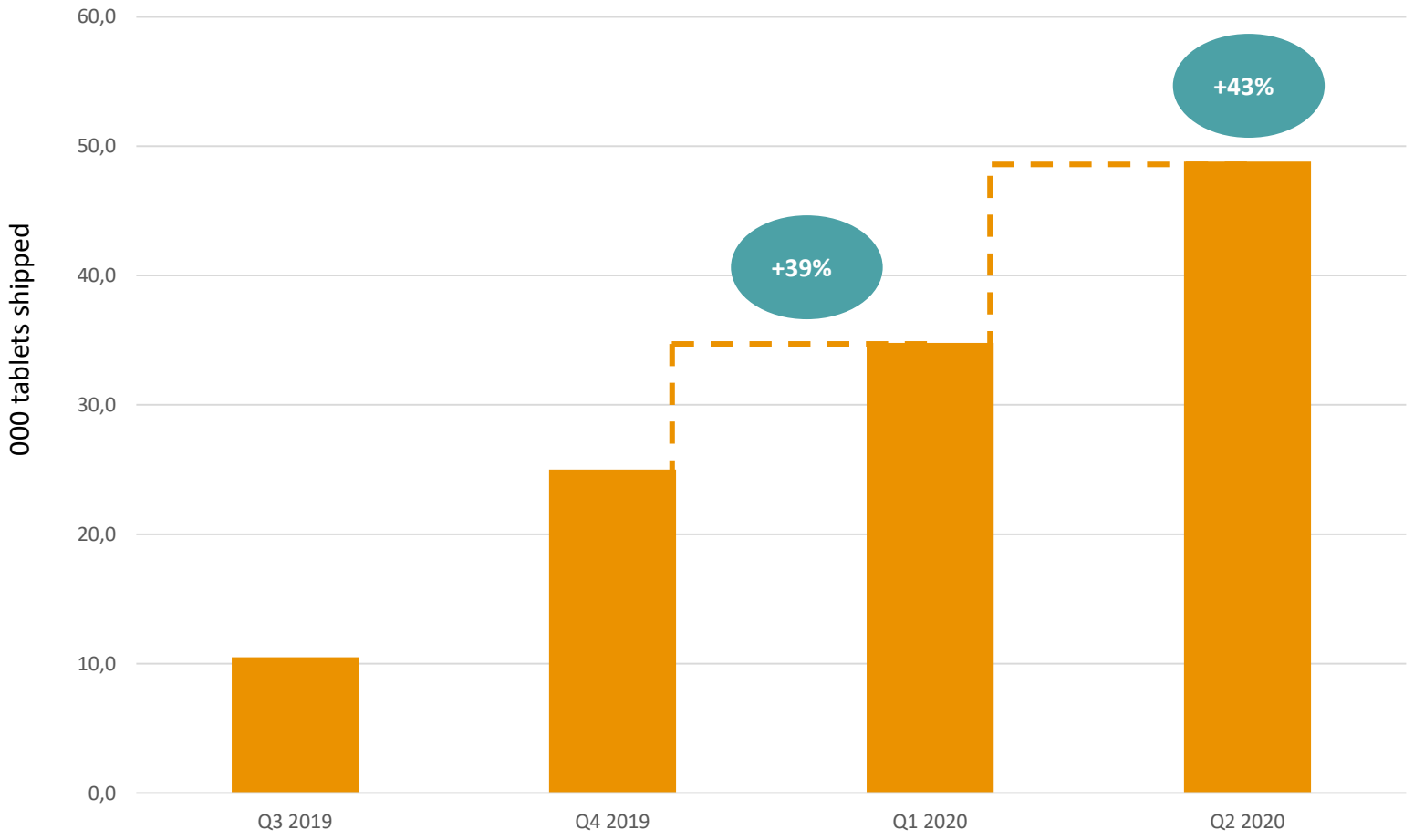
H1 development

- **Elocta** half-year sales amounted to SEK 2,399 M (2,118), up 13 per cent (11 per cent at CER)
- **Alprolix** half-year sales were SEK 851 M (718), up 18 per cent (17 per cent at CER)

Q2 development

- Sales decline driven by inventory de-stocking following extraordinary stocking in Q1 and lower demand due to COVID-19, leading to less surgeries & emergency procedures and lower consumption per patient
- Patient growth of 3-4 per cent
- Market leaders in France
- Elocta the no 1 prophylaxis treatment in Germany
- Successful bid in haemophilia A UK tender
- Florio digital platform
  - now available in 17 countries and 20 haemophilia treatment centres

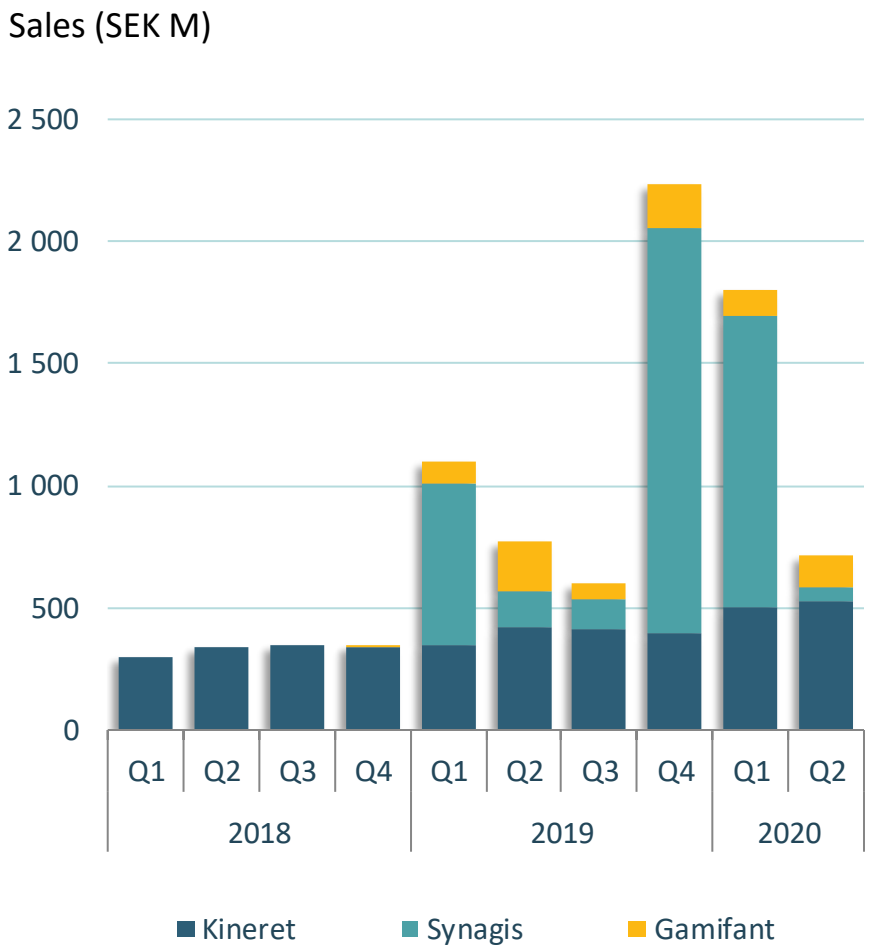
Doptelet: Strong underlying demand



- Doptelet revenue reached SEK 186 M for the quarter.
  - Includes a milestone revenue related to the approval of the CLD indication in China of SEK 87 M
- Recruitment of CIT study completed in Q2
- Doptelet half-year revenue amounted to SEK 251 M

Business Review
Immunology

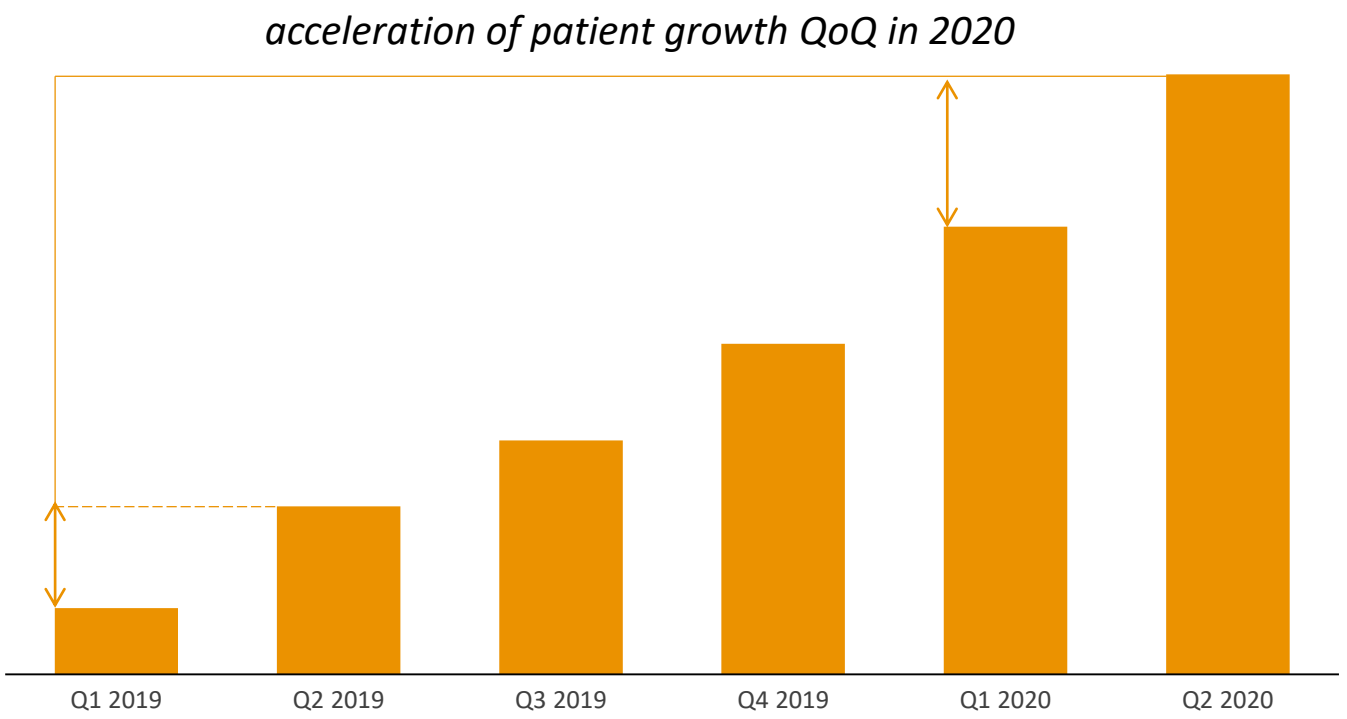
Immunology: Strong H1 growth +30%



- Immunology revenue for the quarter was SEK 714 M (773) a decrease of 8 percent (-10 per cent at CER)
  - **Gamifant** sales for the quarter amounted to SEK 132 M (205) a decrease by 36 per cent (-38 per cent at CER)
    - The average weight of patients and a lower price impacted total sales
  - **Synagis** sales for the quarter were SEK 52 M (148), a decrease by 65 per cent (-65 per cent at CER)
    - Decrease is explained mainly by remaining late season sales in Q2 2019
    - Half-year revenue was SEK 2,514 M (1,873), up 34 per cent (30 per cent at CER)
- Half-year sales of Gamifant were SEK 236 M (294) a decrease of 20 per cent (-23 per cent at CER)
- Half-year sales of Synagis were SEK 1,248 M (SEK 813 M for period 23 January-30 June 2019)

Gamifant – acceleration of patient uptake in Q1 and Q2

Cumulative patients, Q1 2019-Q2 2020



Gamifant performance

Progress of patient uptake
Financial impact not as favourable yet due to

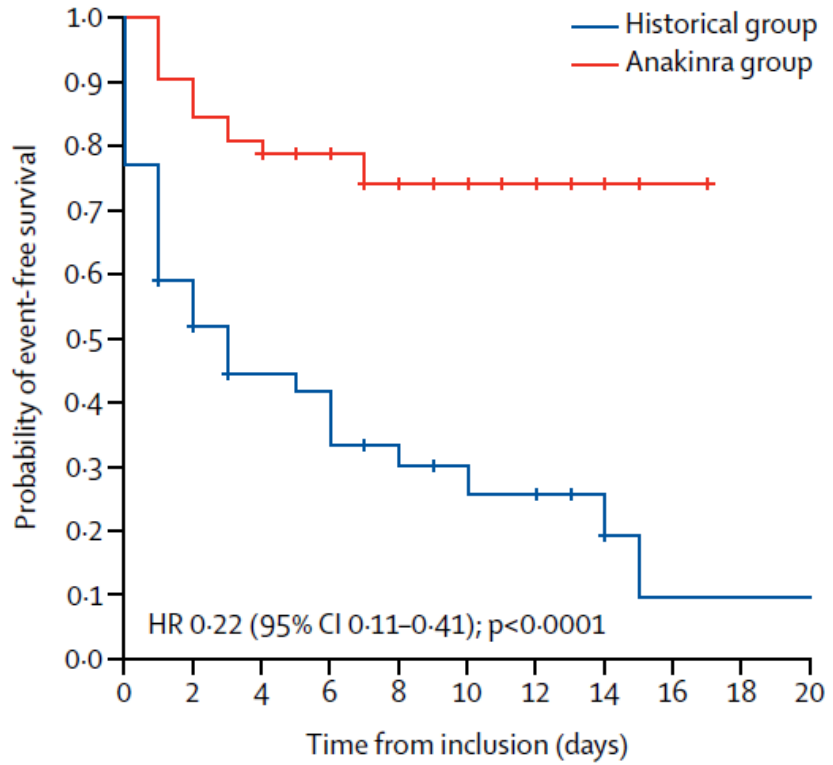
- lower price in 2020
- lower consumption by patient – mainly due to lower weight

Kineret: Continued strong growth

- Kineret sales for the quarter were SEK 530 M (419), an increase of 26 per cent (24 per cent at CER)
- Half-year sales were SEK 1,030 M (765), an increase of 35 per cent (31 per cent at CER) driven by higher demand
- Kineret continues to perform well, with double-digit growth
- Growth is mainly driven by increased underlying demand across all regions but also as a consequence of the COVID-19 pandemic
- Recruitment for study related to COVID-19 ongoing. More sites to open in Q3
- EMA approval of FMF indication. Preparing for launch

Increasing evidence of anakinra's utility in severe forms of COVID-19 – *ex. a cohort study: Huet et al. 2020*

Death or invasive mechanical ventilation[1]



Historical group = Standard of care group (including oral hydroxychloroquine, azithromycin, antibiotics, thromboembolic prophylaxis.

Significant interest for anakinra related to COVID-19: approximately 2,500 patients in on-going clinical studies

Anakinra[2] has shown strong clinical data in supporting patients with severe COVID-19 infection and hyperinflammation

Medical Experts authorities have issued Immune-based treatment recommendations and refer to anakinra recognising its increasing body of evidence[3]

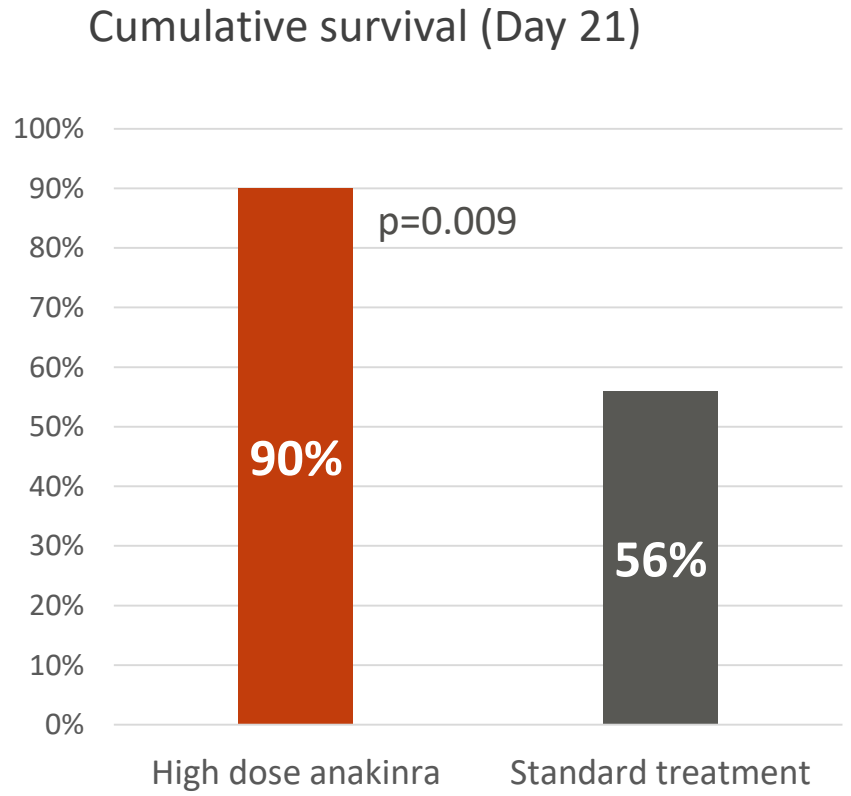
1.Huet et al. Lancet Rheumatol 2020;2:e393–400 ("Anakinra for Severe forms of COVID-19" a Cohort Study: *Huet et al. 2020)*

2. Anakinra is not approved for treatment of COVID-19.
3. NIH: Available at https://www.covid19treatmentguidelines.nih.gov/. Accessed 11 July 2020; 2. WHO COVID consultation report, 25 March 2020; 3. NICE Evidence Summary, May 2020, "Anakinra for COVID-19 associated secondary haemophagocytic lymphohistiocytosis" Commissioned by NHS England, ISBN: 978-1-4731-3800-1.

Growing evidence regarding anakinra –

Cumulative survival was higher in patients with COVID-19 at 21 days, with high dose intravenous anakinra[1]

- High dose anakinra 5 mg/kg (IV) BID:
  - was associated with prompt reductions in serum CRP
  - dampened systemic inflammation
  - was associated with progressive improvement in respiratory function in patients with moderate-to-severe ARDS, and hyperinflammation*



1. Retrospective Cohort Study, n=45: Cavalli et al. Lancet Rheumatol 2020;2:e325–31.

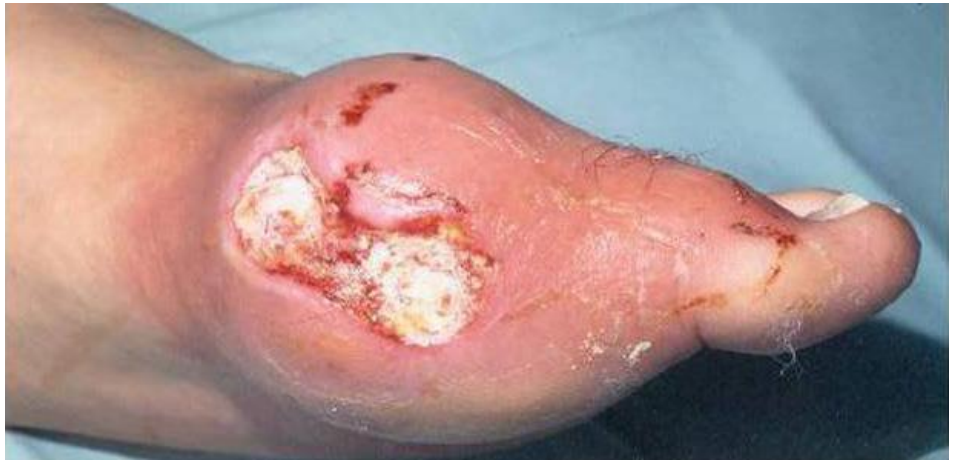
*Defined as serum CRP ≥100 mg/L, ferritin ≥900 ng/mL, or both. ARDS, acute respiratory distress syndrome; BID, twice daily; CRP, C-reactive protein; Standard treatment: hydroxychloroquine, lopinavir, ritonavir.

SEL-212[1] for the potential treatment of refractory gout

- Gout is an inflammatory arthritis caused by hyperuricemia and deposition of monosodium urate (MSU) crystals in synovial fluid and other tissues
- People with chronic gout have frequent gout flares and a significant deposition of MSU crystals
  - Deposition can occur anywhere in the body
  - Tophi represent a significant burden (e.g. high pain and restricted mobility)
- Refractory gout occurs when patients are not well controlled on conventional therapies and / or have considerable tophi burden resulting in progressive physical disability and poor health-related quality of life

Chronic Gout can lead to complications including:

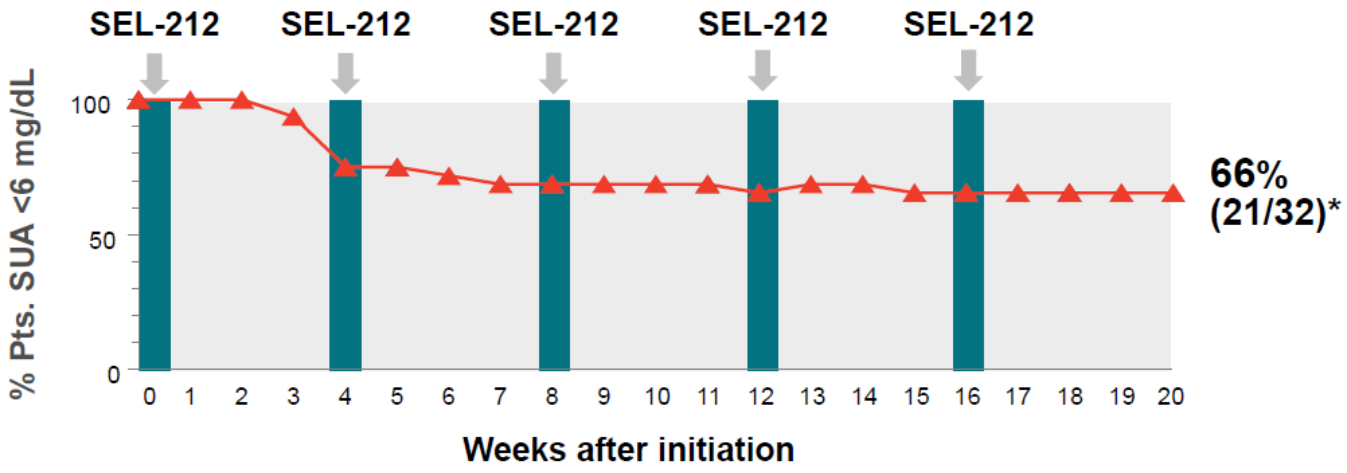
- Chronic pain
- Joint deformities
- Loss of function/joint motion
- Disability
- Kidney stones including renal obstruction and infection



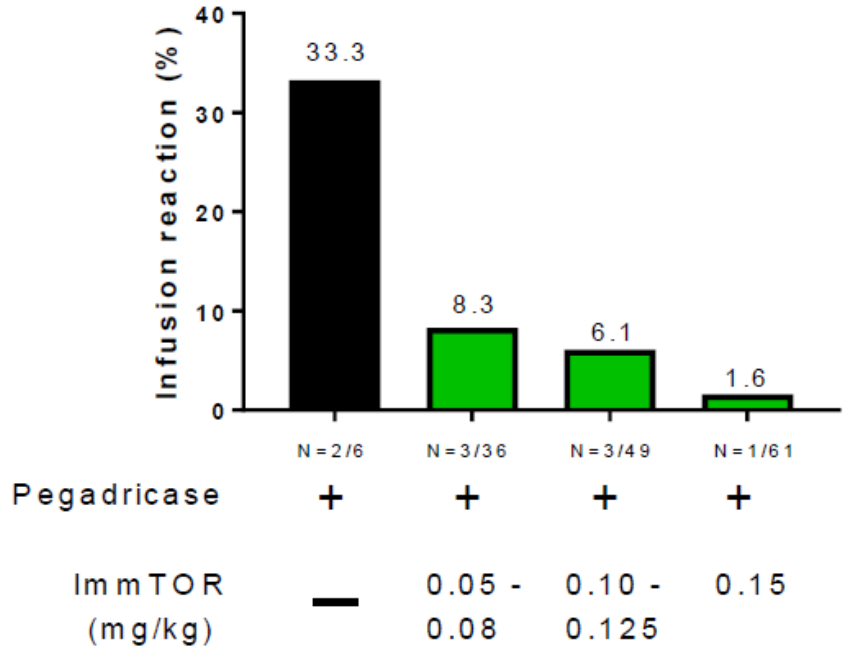
[1]The transaction is subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act and other customary closing conditions.

SEL-212[1] shows encouraging phase 2 data supporting efficacy and reduction of infusion related reactions

Phase 2 results after 20 weeks of once-monthly SEL-212 treatment:



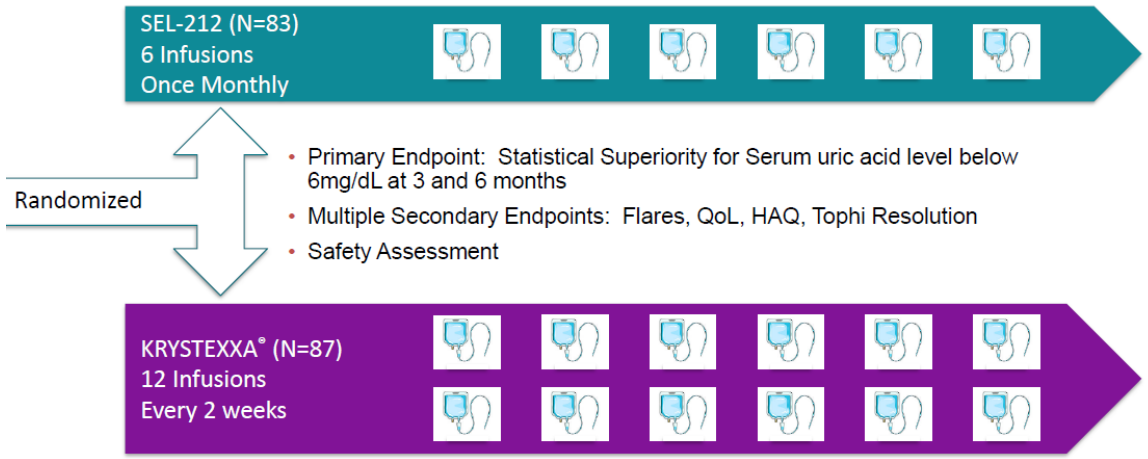
Serious infusion reactions (%)

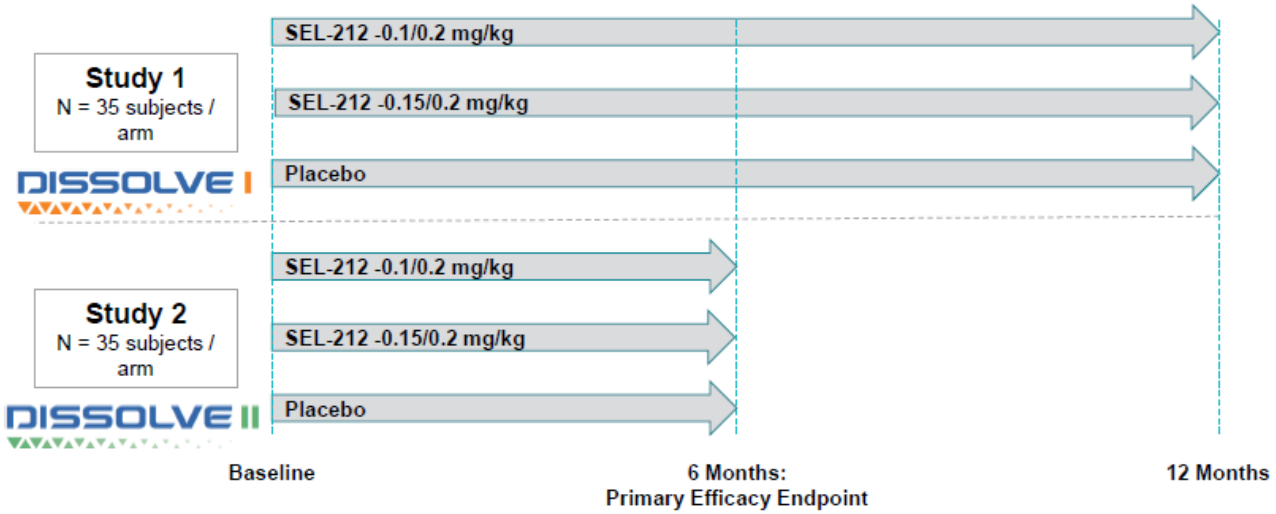


**Week 20 Evaluable patients = patients who received a full first dose and did not discontinue due to any measure other than drug effectiveness or drug related safety; Selecta Corporate Presentation June 2020 (http://ir.selectabio.com/static-files/94be5462-b385-454b-8454-84d619cce139)*

[1]The transaction is subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act and other customary closing conditions.

Further clinical Ph2 and Ph3 data being generated





Selecta Corporate Presentation June 2020 (http://ir.selectabio.com/static-files/94be5462-b385-454b-8454-84d619cce139)

Committed to building a sustainable R&D platform

Phase 1	Phase 2	Phase 3	Registration
NI-1701 Anti-CD47/CD19[1] B cell lymphoma	Gamifant/emapalumab Secondary HLH/MAS children	BIVV001/ rFVIIIFc-vWF-XTEN[2] Haemophilia A	Gamifant/emapalumab Primary HLH (EU) SUBMITTED
	Gamifant/emapalumab Secondary HLH adults		Kineret/anakinra Deficiency of IL-1 receptor antagonist (DIRA) (US) SUBMITTED (validation ph)
	Anakinra/emapalumab Hyperinflammatory and cytokine storm syndrome related to COVID-19		Doptelet/avatrombopag Chronic immune thrombocytopenia (EU) SUBMITTED
	SEL-212[4] Chronic refractory gout	MEDI8897/nirsevimab[3] RSV Prevention	
		Doptelet/avatrombopag Chemotherapy-induced thrombocytopenia (CIT)	

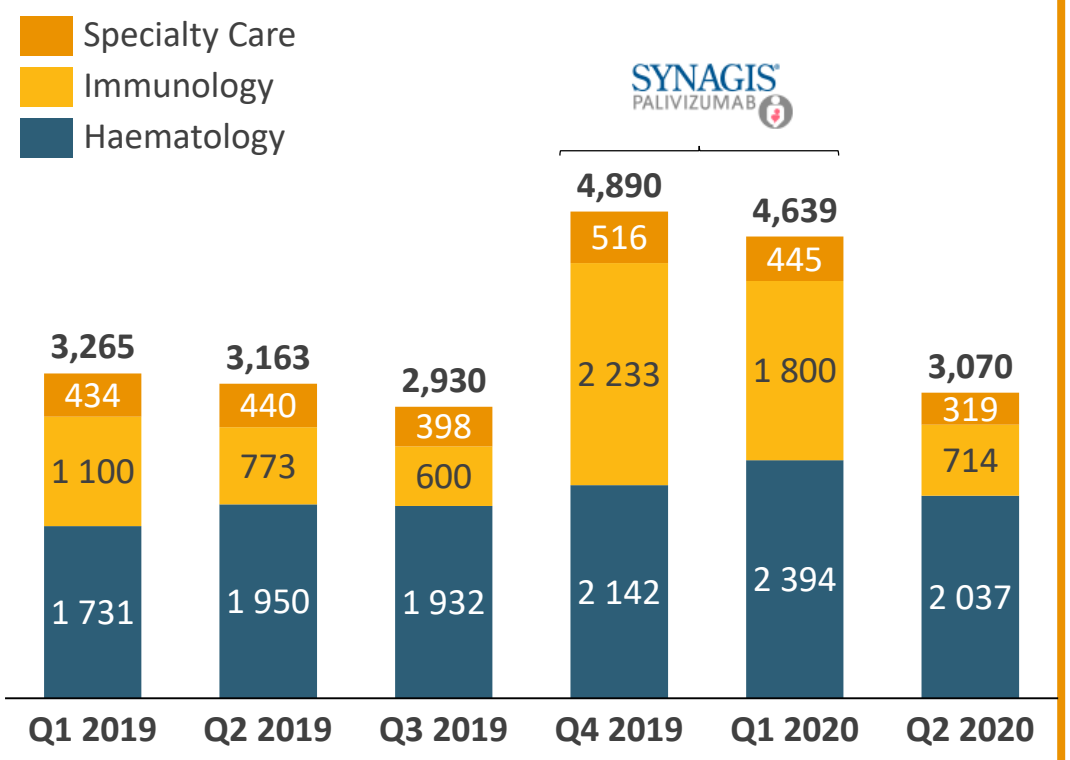
2020 will continue to provide opportunities to invest in R&D, building a more sustainable pipeline

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.
4. The transaction is subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act and other customary closing conditions.

Q2 2020
Financial results

Q2 2020: Financial results

Total revenue (SEK M)



Amounts in SEK M	Q2 2020	Q2 2019	Change	H1 2020	H1 2019	Change	Full-year 2019
Total revenue	**3,070**	3,163	-3%	**7,709**	6,427	20%	**14,248**
Gross profit	**2,381**	2,413	-1%	**5,979**	4,907	22%	**10,913**
Gross margin[1]	**78%**	76%		**78%**	76%		**77%**
EBITA adjusted[1,2]	**1,018**	1,193	-15%	**3,191**	2,665	20%	**6,145**
EBITA margin adjusted[1,2]	**33%**	38%		**41%**	41%		**43%**
Profit for the period	**283**	499	-43%	**1,465**	1,402	4%	**3,304**
Earnings per share, SEK adjusted[1,2,3]	**0.96**	2.12	-55%	**4.98**	5.14	-3%	**11.89**
Operating cashflow	**1,911**	1,275	50%	**3,912**	1,663	>100%	**3,634**
Net debt (+)/net cash (-)	**11,802**	4,403		**11,802**	4,403		**15,404**

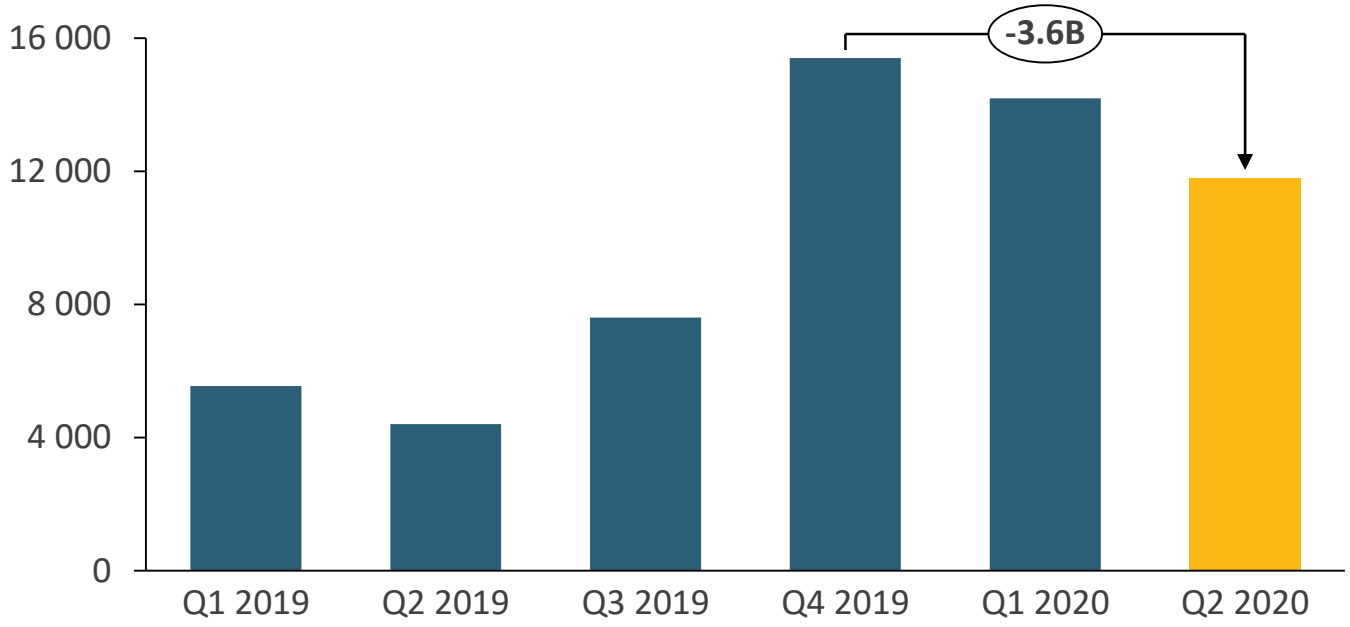
[1]Alternative Performance Measures (APMs)

[2]EBITA Q2 and 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 Q2 and full-year 2019 excluding impairment of intangible assets of SEK 18 M related to restructuring in Q2 2019.

Continued strong operating cash flows in H1 2020, leverage < 2.0x

Net Debt (SEK M)



Acquisitions ❯ SYNAGIS PALIVIZUMAB, gamifant emapalumab-lzsg & related assets, Dova PHARMACEUTICALS

Q2 2020 update

- **Operating cash flows** of 1.9B SEK
- **Net Debt** reduction of -2.4B
- **Leverage** < 2.0x
- **Available liquidity** of ~7B SEK

Q1 summary

Q2 2020: Further advancing market position organically and through acquisitions

Strategic actions

Haematology

Establishing leadership

Florio launch

- **Florio**, our digital solution for Haemophilia patients to live a life with fewer compromises -- *Liberate life* available in 17 countries

Avatrombopag

- **CIT**: Enrolment completed, read out in Q4 2020
- **ITP**: Under review in EU
- **CLD**: Ready for launch in the EU H2

Immunology

Building broader foundation

Extend & Expand

- **Anakinra**: Included in various clinical studies in COVID-19-related CSS;
- **Emapalumab**: Enrolment into secondary HLH adult study ongoing
- **SEL-212[1]:** Licensing agreement with Selecta for the product candidate SEL-212 for the potential treatment of chronic acute gout, an important addition to the late-stage pipeline. Phase 2 read out in Q3 and phase 3 to start in H2

International

Building global presence

International Division formation

- **Emerging market player**: Now established in Japan

[1]The transaction is subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act and other customary closing conditions.

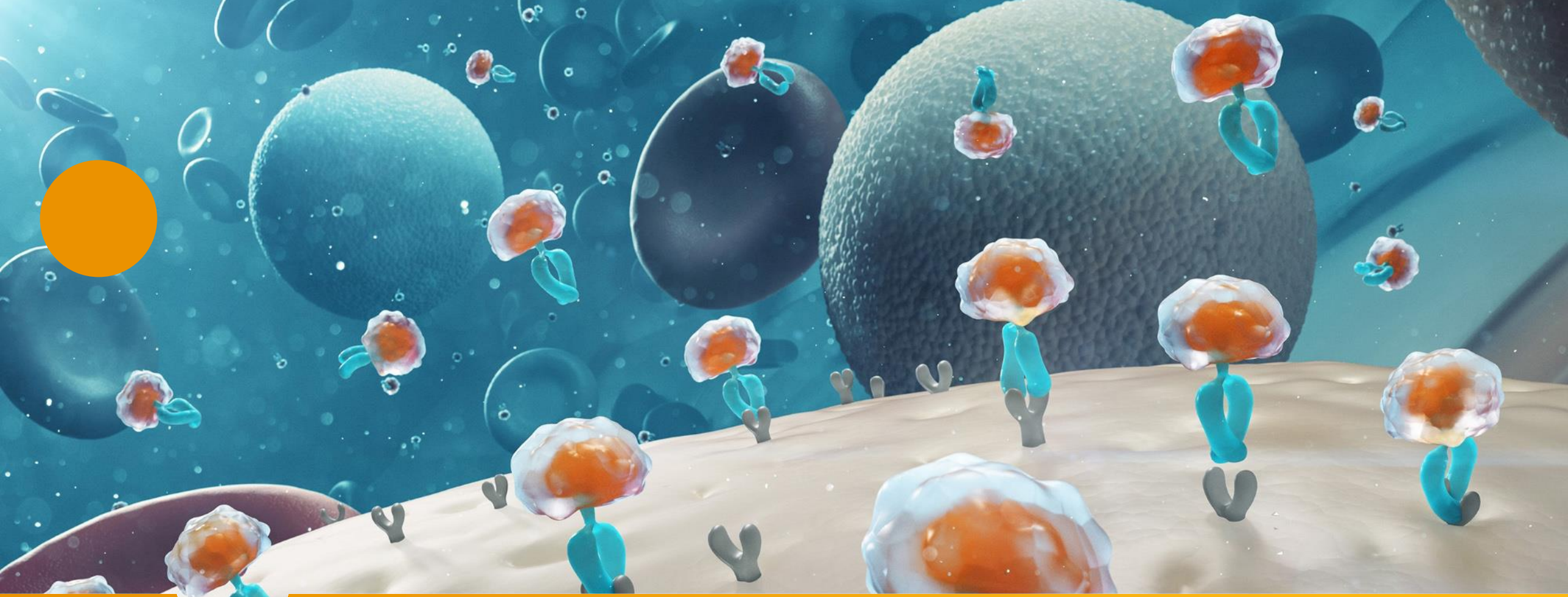
Financial outlook 2020[1,2] – unchanged

Revenue for full-year 2020 is expected to be in the range of SEK 15,000 – 16,000 M reflecting double-digit growth in each of 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.

[1]At exchange rates as of 13 February 2020.
[2]Financial outlook excludes any impact from the potential acquisition of Selecta Biosciences, Inc. announced on 11 June 2020; in the event of completion of the transaction, R&D expenses are expected to increase by up to SEK 150 M in H2 2020

Q&A



Swedish Orphan Biovitrum AB (publ)
SE-112 76 Stockholm • Sweden
www.sobi.com

sobi
rare **strength**