Q1 2021 results

rare **strength**

4 May, 2021

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Guido Oelkers | CEO

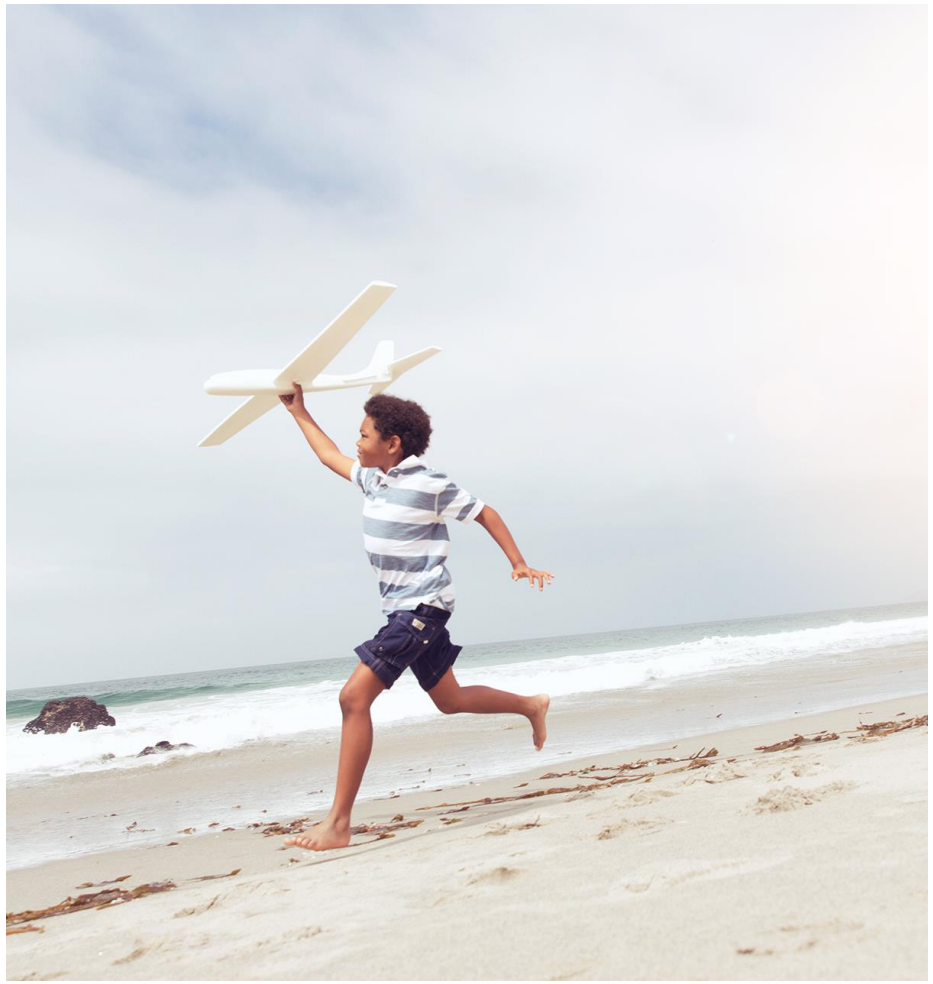
Henrik Stenqvist | CFO

Ravi Rao | Head of R&D and CMO

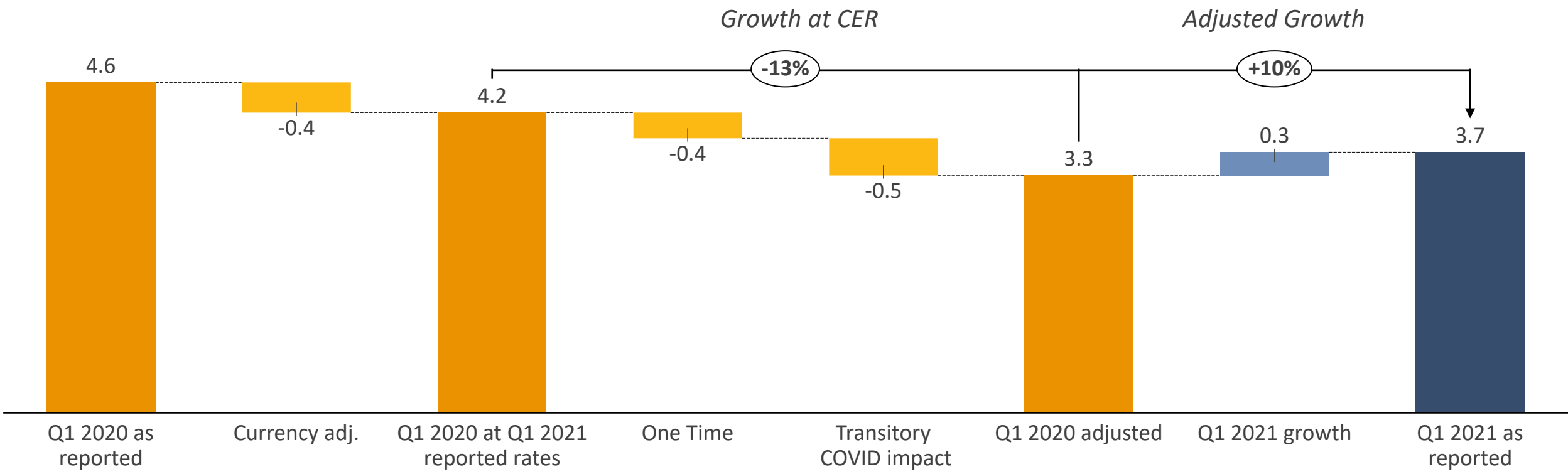
Presenters

Investing in growth - highlights in Q1

- **Financial outlook unchanged for 2021**
- **Strong growth for key products**
  - Doptelet growth, 222 per cent at CER
  - Kineret growth, 20 per cent at CER
  - Gamifant, 47 per cent at CER
- **Maintaining competitiveness in Haemophilia**
  - Patient growth:
    - 6 per cent for Elocta
    - 16 per cent for Alprolix
- **COVID-19 affects sales – but strong profitability**
  - Q1 2021 revenue of SEK 3,661 M and EBITA margin of 41%
- **Progress in R&D pipeline**
  - positive top line results show use of anakinra improved overall clinical outcomes by 64% in hospitalised patients with COVID-19 pneumonia



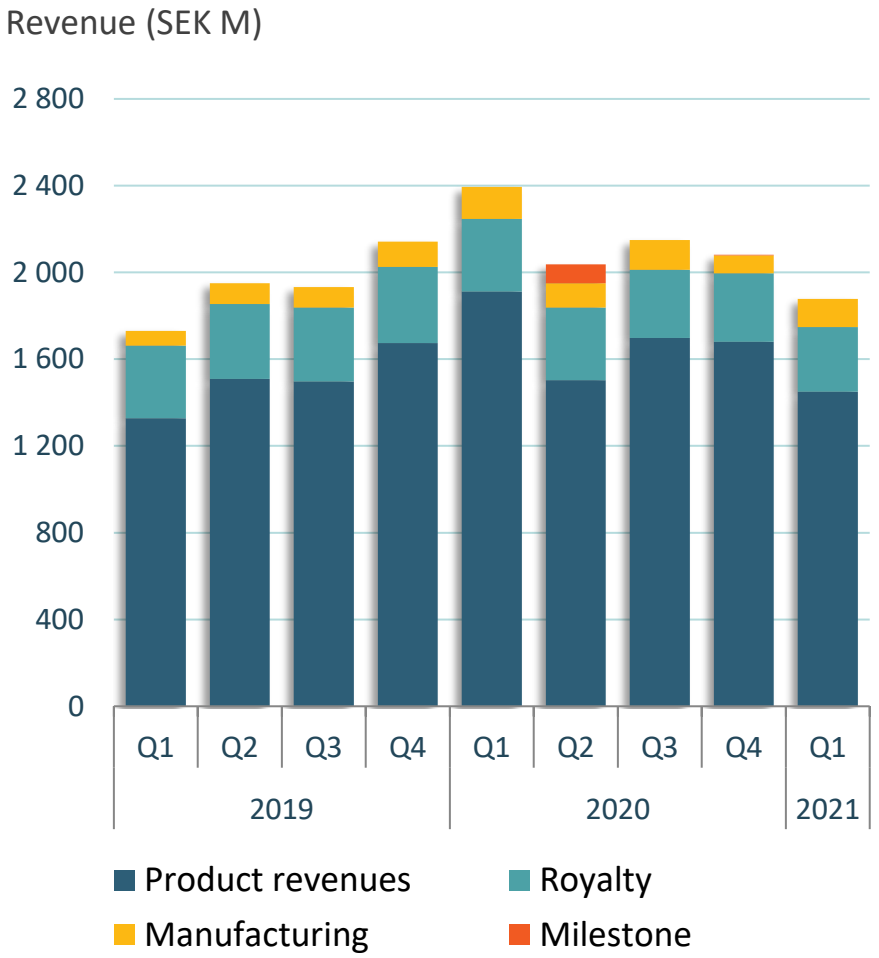
Perspective on Q1 revenue



Figures reported in SEK bn

Haematology

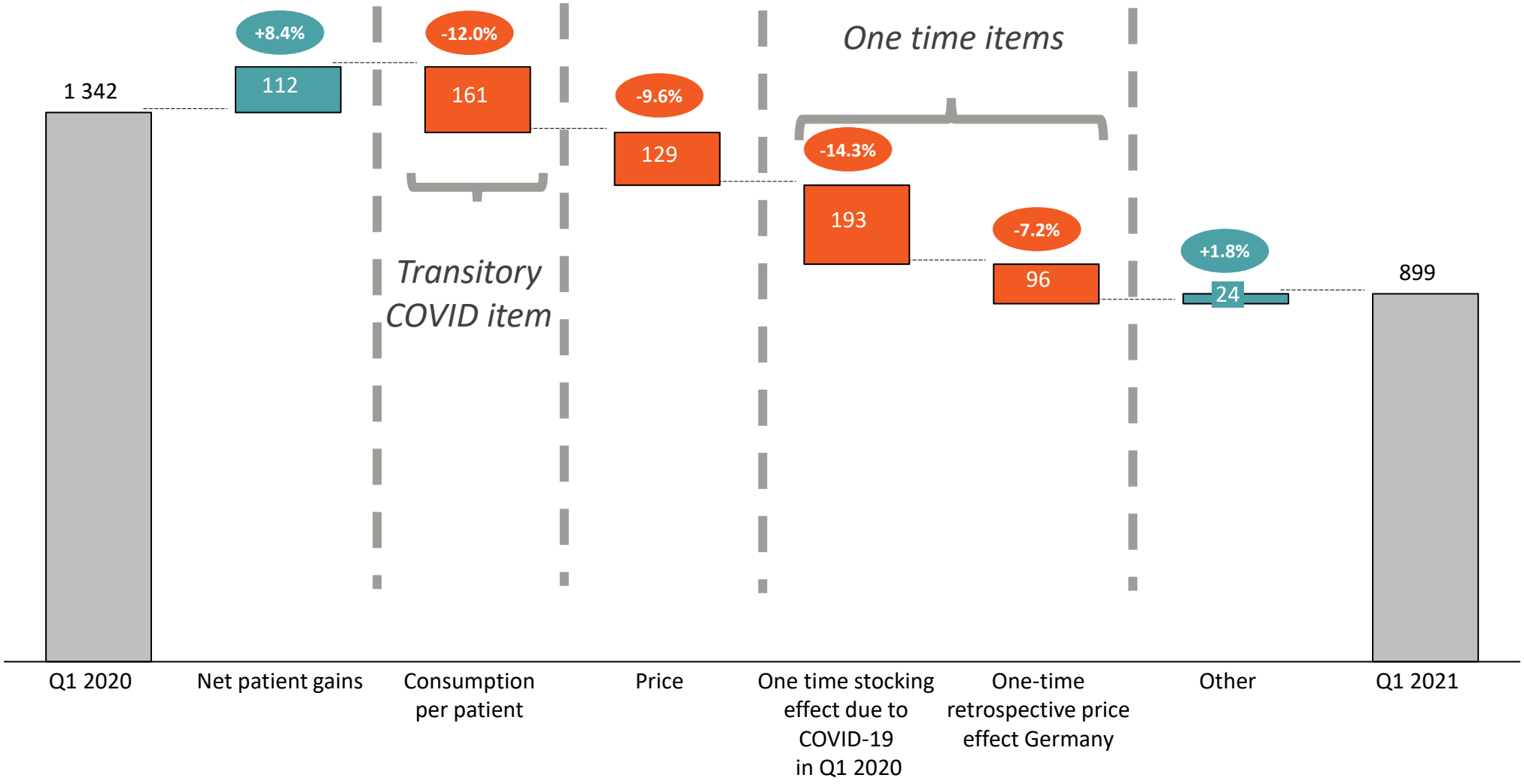
Haematology – continued patient gain for Elocta and Alprolix



- **Q1 revenue** of SEK 1,877 M (2,394)
- Elocta and Alprolix **strengthened position** with continued patient gain
  - COVID-19 impacted consumption per patient
  - Price pressure in core markets
  - One off price adjustment in Germany of SEK 92 M
- **Doptelet** sales of SEK 180 M (65)

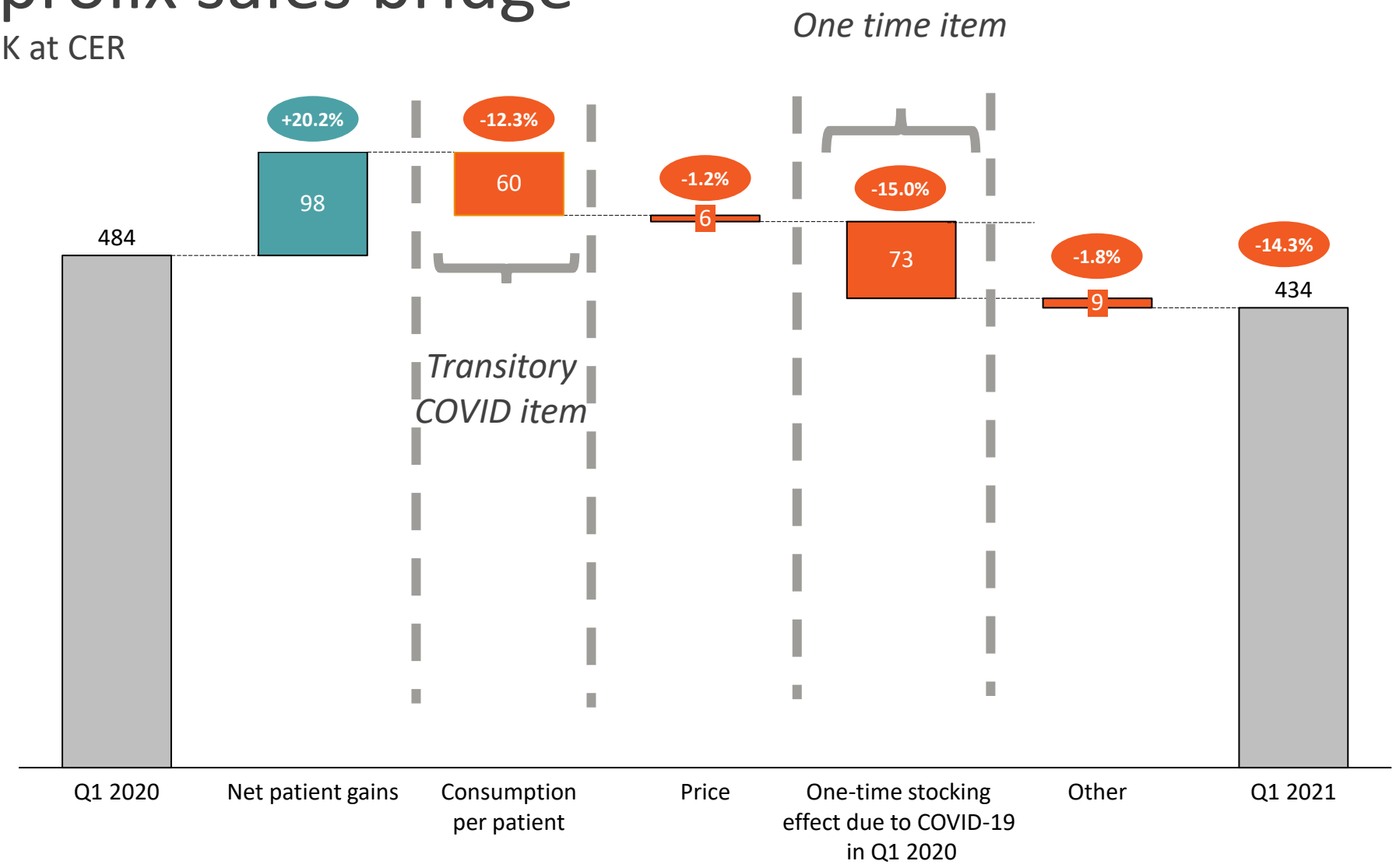
Elocta sales bridge

MSEK at CER

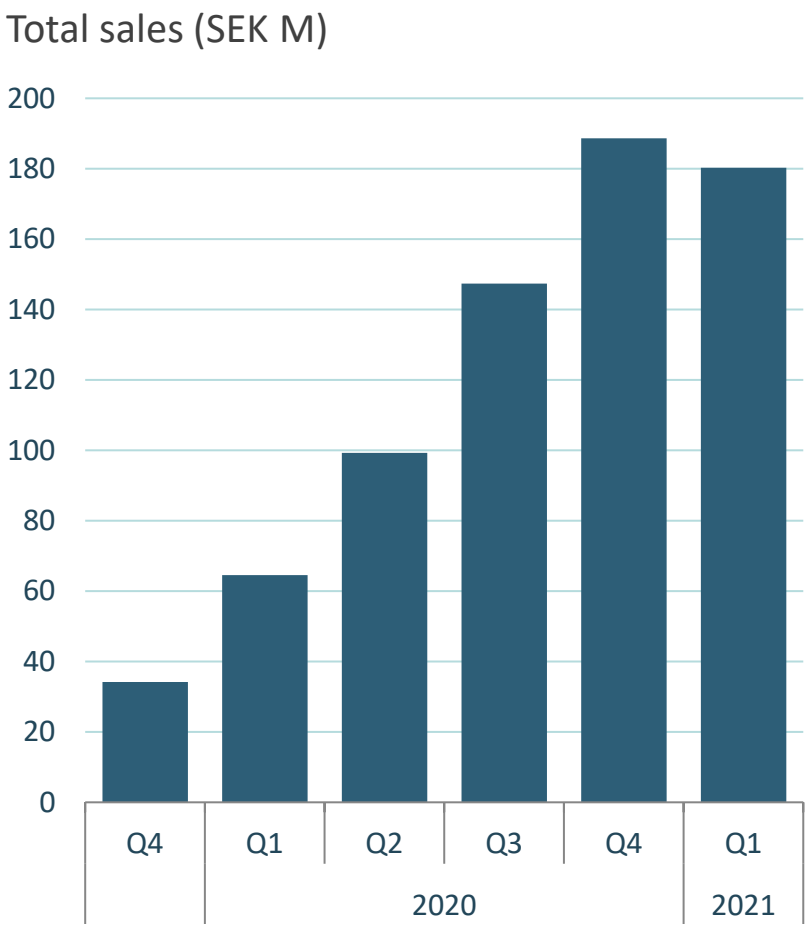


Alprolix sales bridge

MSEK at CER



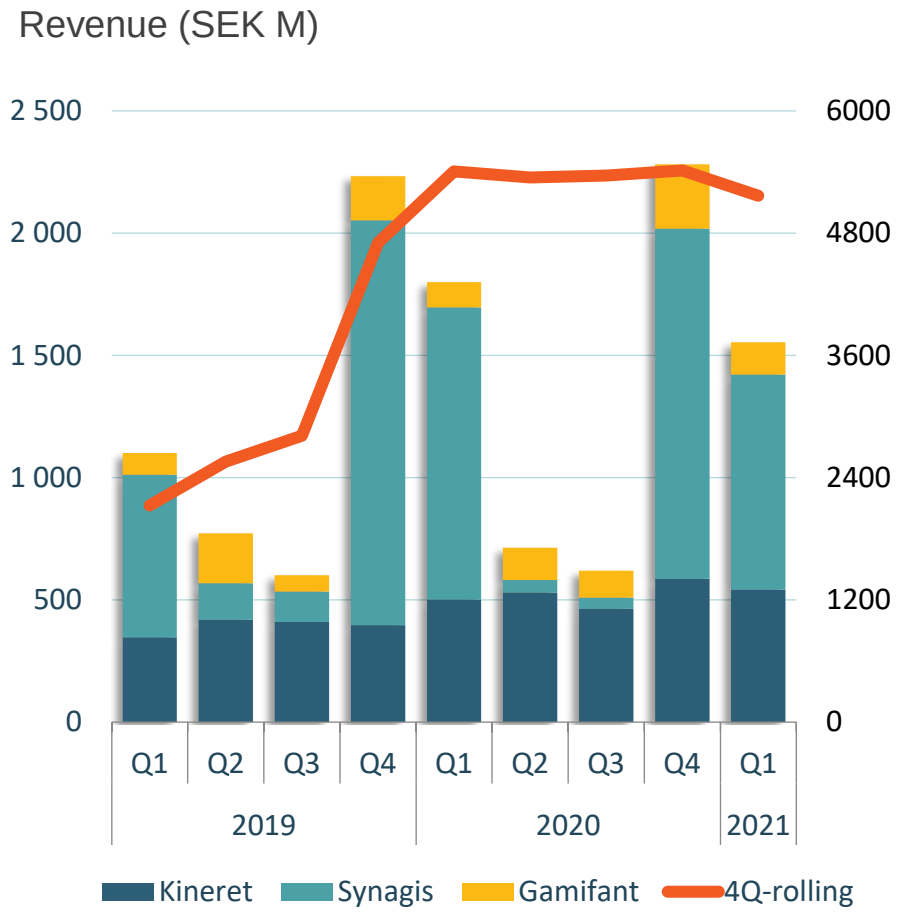
Doptelet – growth driven by new patients and sites



- **Q1 sales** of SEK 180 M (65)
- **EU:** EMA approval of ITP indication
- **US:** expanded market share in Q1

Immunology

Immunology – solid growth



- **Q1 revenue** of SEK 1,554 M (1,800)
- **Synagis** impacted by low virology of RSV; epidemic levels have been reached in 3 states in April
- Strong underlying demand for **Kineret and Gamifant**

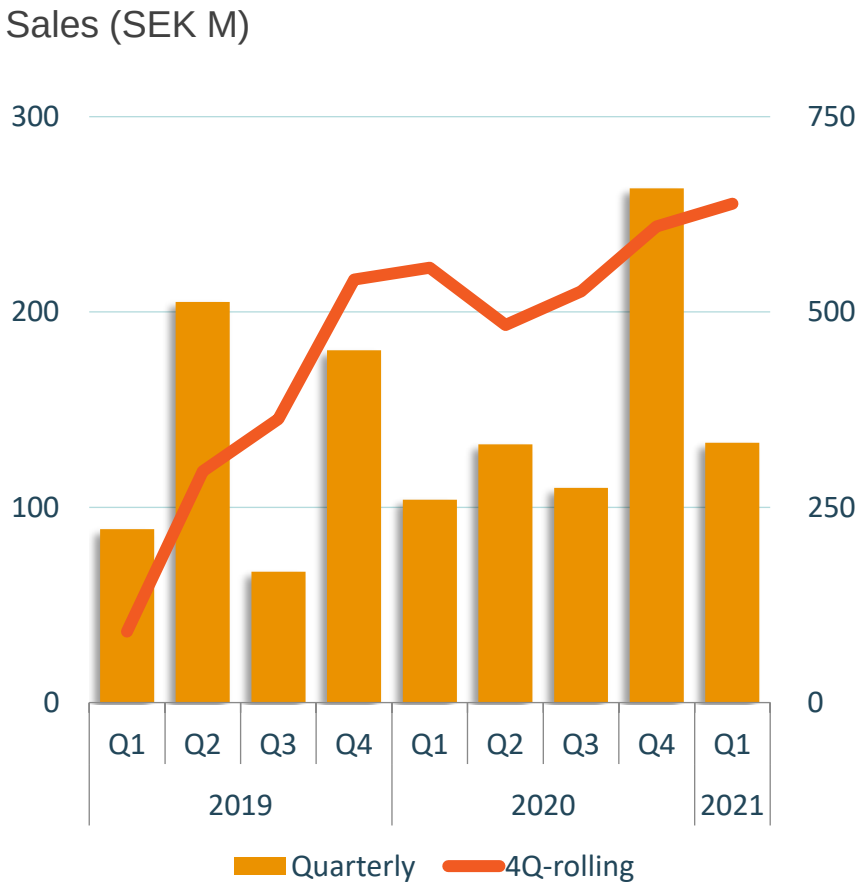
Kineret – strong double digit growth in Q1

- **Q1 sales** of SEK 542 M (501)
- Strong underlying demand
- Approved in Russia for treatment of CAPS
- **SAVE MORE**: results for Kineret in treatment of COVID-19 related severe respiratory failure; strong benefit vs. SOC

~ 6000 patients/day
newly hospitalized in Europe (April)

50 to 60% likely to meet
suPAR > 6 ng/ml

Gamifant – strong patient growth



- **Q1 sales** of SEK 133 M (104)
  - Sales growth of 47 per cent at CER
- Growth driven by number of new **patients,** progress in patient identification process
- Volatility still subject to weight difference in patient population by quarter

R&D

R&D progress in Q1

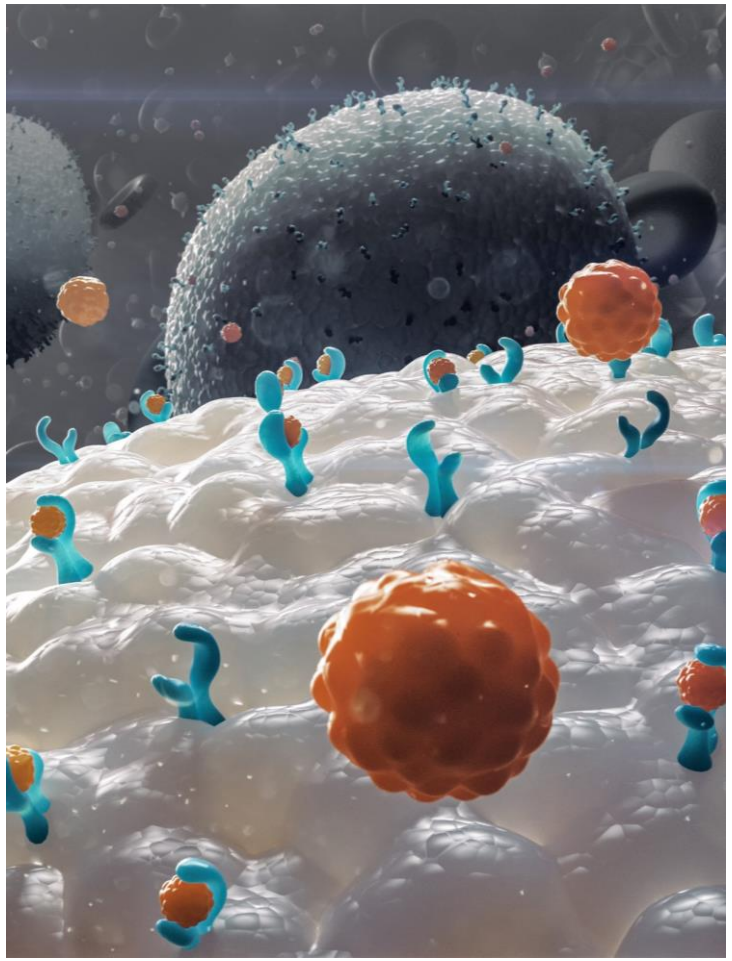
- Kineret (anakinra)– SAVE MORE demonstrated positive results in management of COVID19 pneumonia
- Kineret – approved in Russia for treatment of CAPS
- Doptelet – approved for ITP in Europe
- Efanesoctocog alfa (BIVV001) paediatric study – first patient dosed in April 2021, on the back of enrolment of the adult study
- Nirsevimab – MELODY Phase III trial met primary endpoint of reduction in the incidence of medically attended lower respiratory tract infections (LRTI) caused by RSV

Early, targeted anakinra treatment improves COVID-19 outcome

Positive results from the SAVE MORE investigator sponsored study

- **Anakinra vs placebo** on a background of standard of care
  - Includes remdesevir, dexamethasone, anticoagulants
- **Hospitalised** patients with COVID19 pneumonia
- Moderate-severe patients **not on assisted ventilation**
- Poor prognosis demonstrated by a **raised plasma suPAR***

- Despite recent advances in treatment, there is still a very high medical need for COVID-19.
- We will continue our ongoing dialogue with EMA



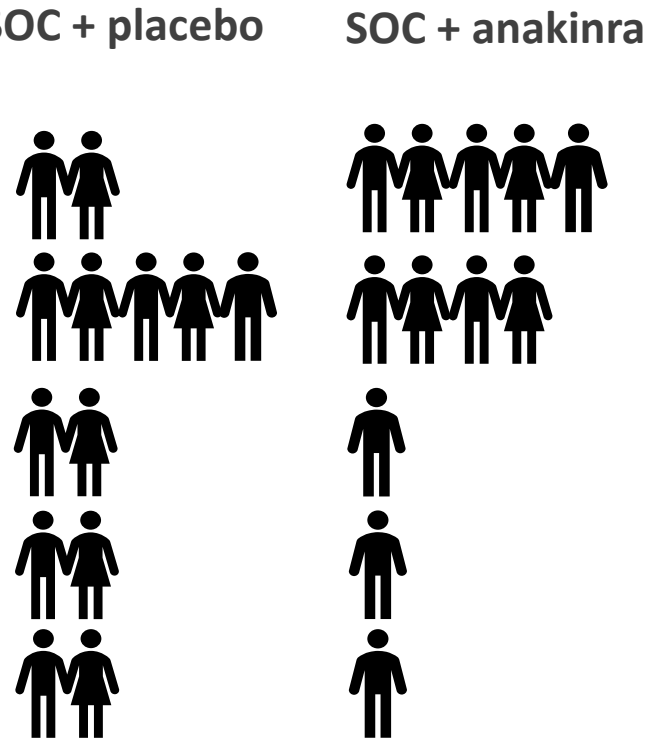
**soluble urokinase plasminogen activator receptor*

SAVE-MORE study: key highlights

606 patients randomised across 40 centres in Greece and Italy

- **60%** of screened patients were **suPAR+**

Patient status at D28 Modified WHO CPS
Uninfected
Ambulatory, mild disease
Hospitalised, moderate disease
Hospitalised, severe disease
Dead



Europe (April 2021)

~175,000 patients hospitalised

~25,000 patients in ICU

Odds Ratio was 0.36 (p< 0.001) in **favour of anakinra**

anakinra 2.8 times more likely to improve overall clinical status

Substantial value in our late-stage pipeline[1]

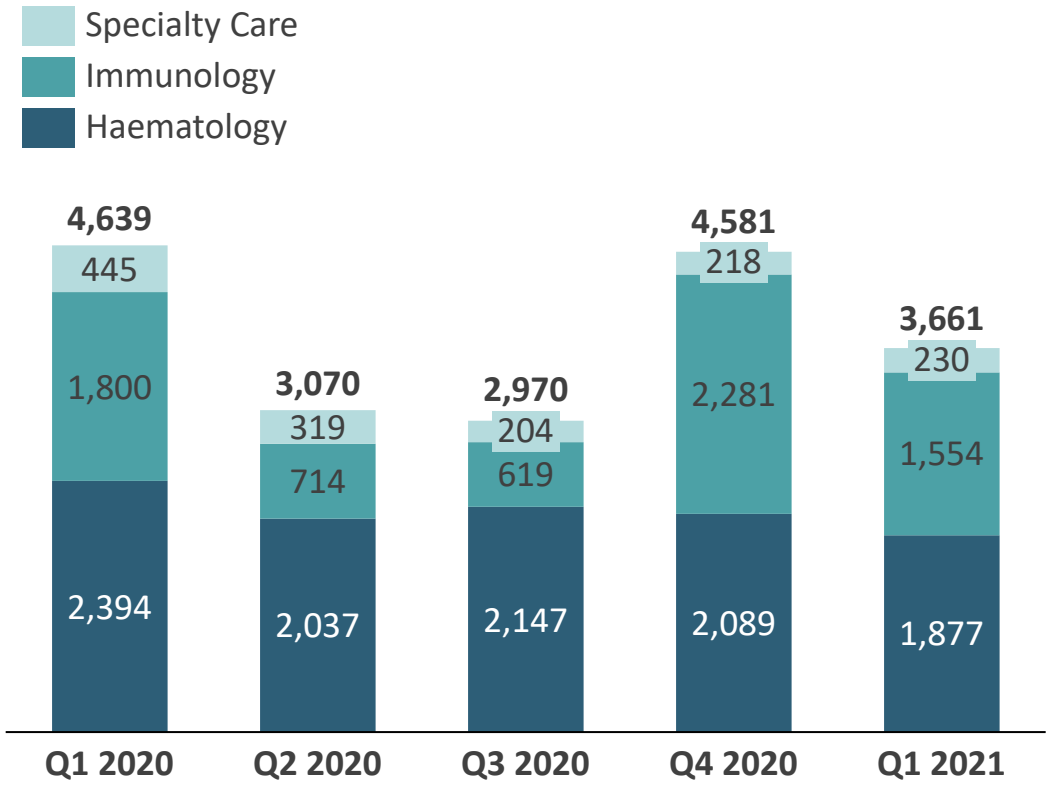
Phase 2	Phase 3	In registration
Gamifant / emapalumab Graft failure (GF)	**Gamifant / emapalumab** Secondary HLH rheumatology	**Gamifant / emapalumab** Primary HLH (RoW)
Gamifant / emapalumab GvHD	**SEL-212 / pegadricase[3]** Chronic refractory gout	**pegcetacoplan 2nd line[2]** Paroxysmal nocturnal haemoglobinuria (PNH)
pegcetacoplan[2] ALS	**MEDI8897 / nirsevimab[4]** RSV prevention	
pegcetacoplan[2] HSCT-TMA	**efanesoctocog alfa / BIVV001[5]** Haemophilia A	
	pegcetacoplan[2] CAD	
	pegcetacoplan 1st line[2] Paroxysmal nocturnal haemoglobinuria (PNH)	
	pegcetacoplan[2] IC-MPGN and C3G	

1. Not all programmes have been started 2. In collaboration with Apellis 3. Strategic licensing agreement with Selecta 4. Financial interest only, in collaboration with AstraZeneca 5. BIVV001 is developed and, if approved, will be commercialised in collaboration with Sanofi

Q1
financial results

Q1 2021: Financial results

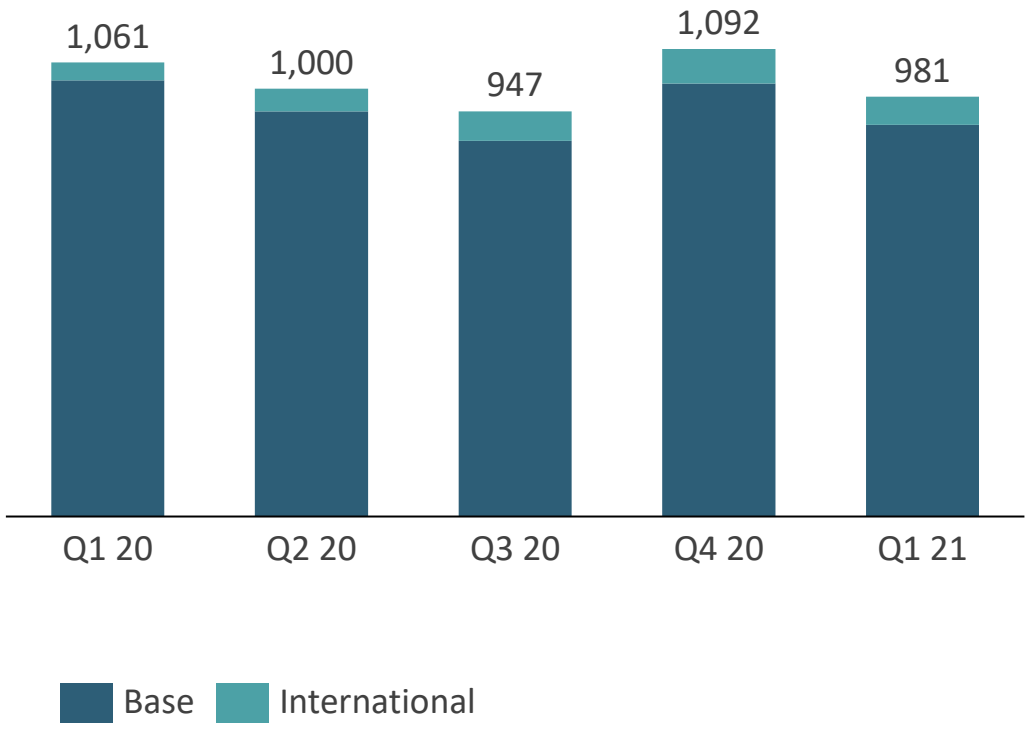
Total revenue (SEK M)



Amounts in SEK M	Q1 2021	Q1 2020	Change	Full-year 2020
Total revenue	3,661	4,639	-21%	15,261
Gross profit	2,935	3,598	-18%	12,036
Gross margin[1]	80%	78%		79%
EBITA adjusted[1,2]	1,484	2,173	-32%	6,301
EBITA margin adjusted[1,2]	41%	47%		41%
Profit for the period	696	1,182	-41%	3,245
Earnings per share, SEK adjusted[1,2,3]	2.36	4.02	-41%	9.66
Operating cashflow	1,699	1,886	-10%	4,925
Net debt (+)/net cash (-)	12,674	14,198		13,748

[1]Alternative Performance Measures (APMs)
[2]EBITA full-year 2020 excluding non-recurring items; other operating income related to the reversal of the CVR liability of SEK 399 M.
[3]EPS full-year 2020 excluding the reversal of the CVR liability of SEK 399 M.

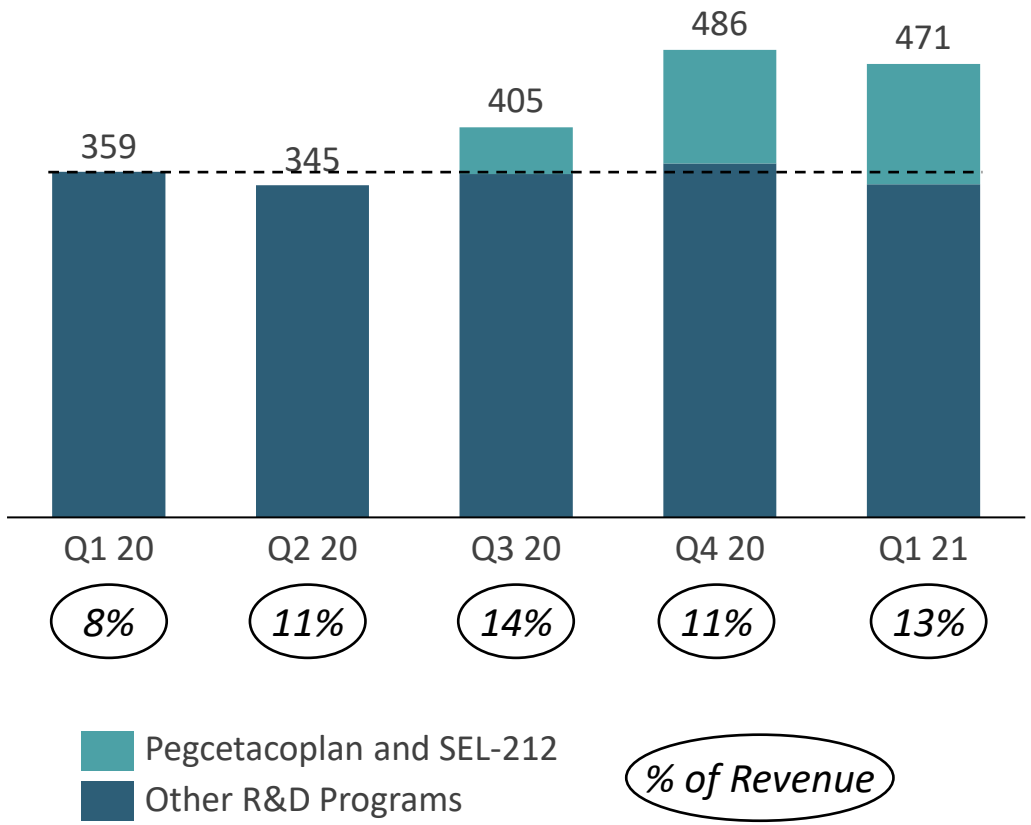
SG&A – opex evolution



- **SG&A expected to gradually increase in the remainder of 2021 due to:**
  - Doptelet CLD & ITP launch in Europe
  - Increased investments in launch activities for pegcetacoplan
  - Increased investments in geographic expansion (Russia, China & Japan)
  - “Return to normal” as COVID restrictions ease

Base SG&A is defined as SG&A excluding International region

R&D – opex evolution



- **Q1 R&D** in line with guidance at 13-15% of revenue
- **FY guidance remains at 13-15% of revenue**, incremental spend is expected from:
  - Pegcetacoplan, various indications
  - SEL-212 to increase in future quarters as Phase 3 trials progress

Base R&D is defined as all R&D except APL-2 and SEL-212

Conclusion

Financial outlook unchanged for 2021

Revenue for the full-year 2021 is expected to be in the range of SEK 14–15 bn

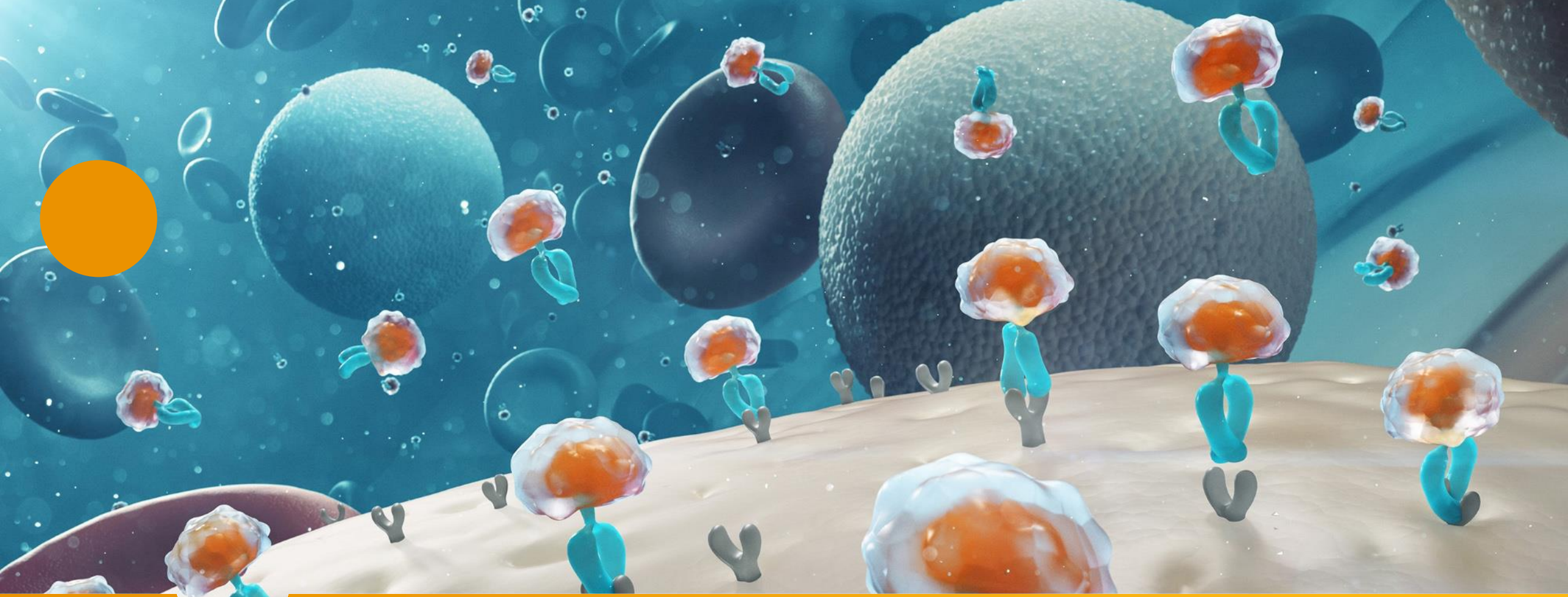
EBITA margin is expected to be in the range of 30–35 per cent of revenue

Increasing confidence to grow the company at CER

based on…

1. Traction with launch and growth products
2. Positive signals to overcome transitory COVID related effects
3. Delivery in R&D
4. Material opportunity related to Kineret

Q&A



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