Q4 and FY 2020 results

rare **strength**

18 February, 2021

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

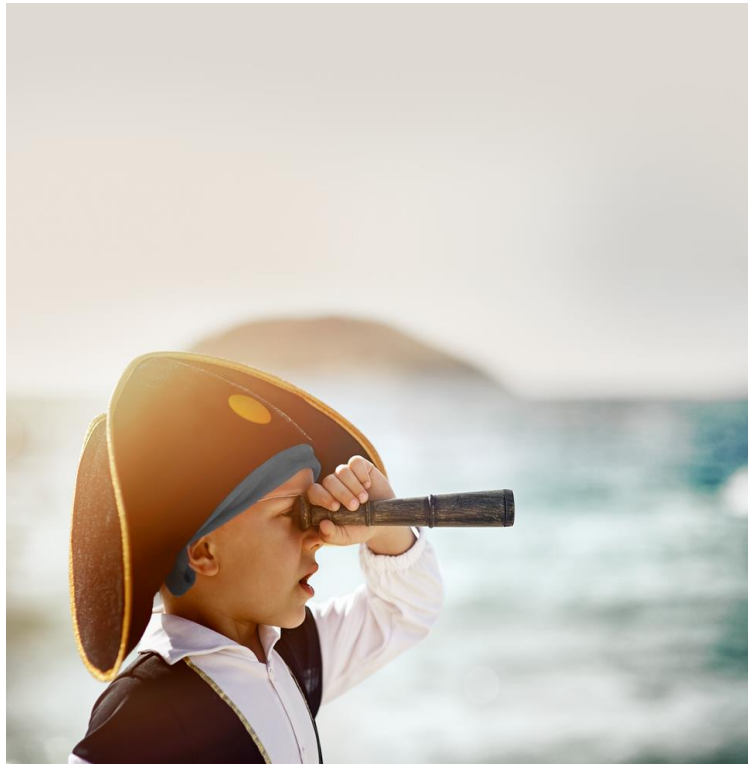
Henrik Stenqvist | CFO

Ravi Rao | Head of R&D and CMO

Presenters

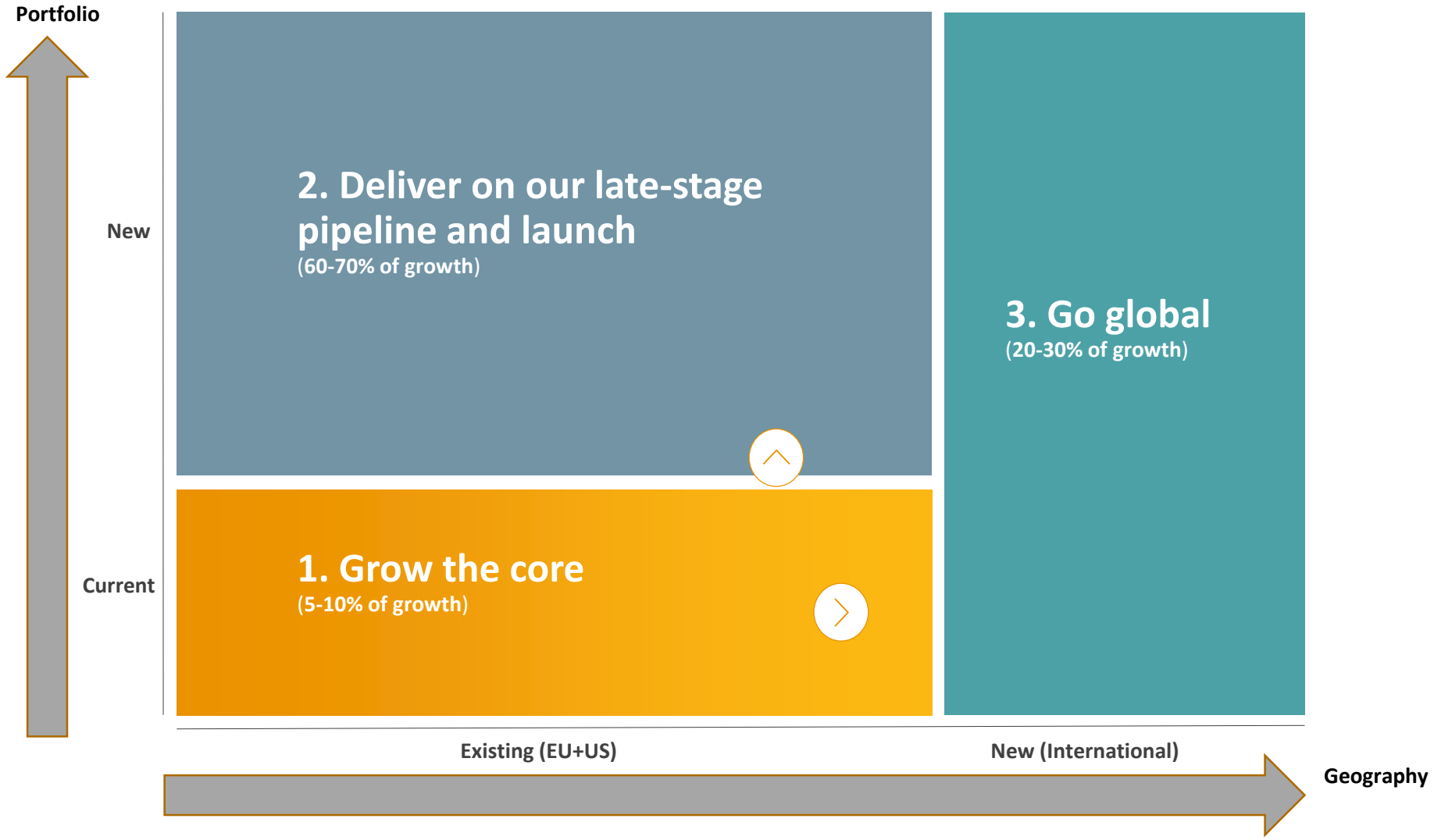
Expanding opportunities – strong growth and profitability

- **Solid revenue and profitability growth**
  - FY 2020 revenue of SEK 15,261 M and an adjusted EBITA margin of 41%
  - Q4 revenue of SEK 4,581 M and an adjusted EBITA margin of 48%
- **Double-digit growth in Core business** FY 2020
  - Haematology 13 per cent at CER
  - Immunology 16 per cent at CER
- **Two important strategic partnerships**, fuelling pipeline, strengthening international footprint and enabling strong future growth.
  - **Sobi and Apellis** – global co-development and ex-US commercialisation of **systemic pegcetacoplan** in rare diseases; five programmes
  - **Global rights to SEL-212**



Two vectors of growth propel our business

Pipeline/launch of products and internationalisation fuel mid-term growth



Key pipeline catalysts

32 launches in key geographies by 2025 – 4 in 2021

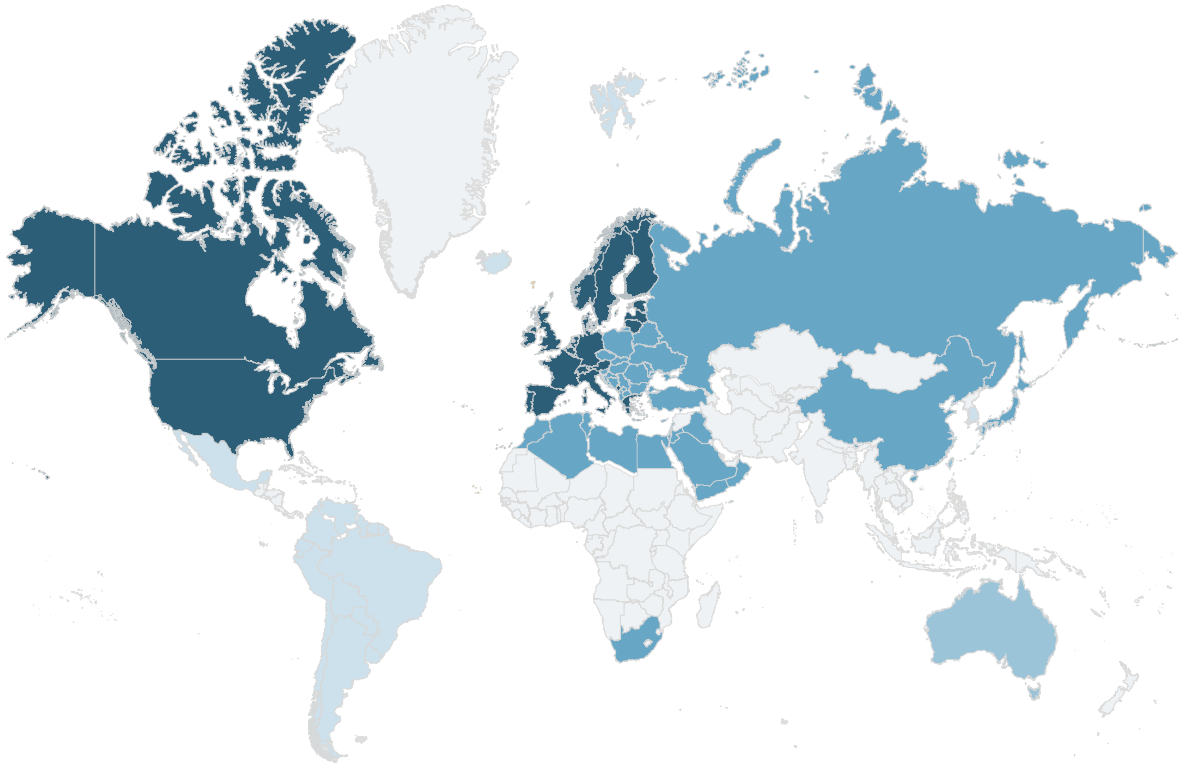
- ✓ Approval of Elocta in Russia
- ✓ Approval Kineret in Russia
- ✓ Approval of Doptelet ITP/CLD in EU
- Submitted Doptelet in Russia; potential approval in Q4
- Submitted Pegcetacoplan (PNH) in EU; potential approval in Q4

- ✓ SEL-212 progressing in Phase 3
- ✓ Efanesoctocog alfa (BIVV001) completed enrolment of phase 3

Emapalumab - start secondary rheumatology HLH study and enrol patients in acute graft failure study

Ongoing anakinra ISS study (SAVE MORE) read out in Q2 2021

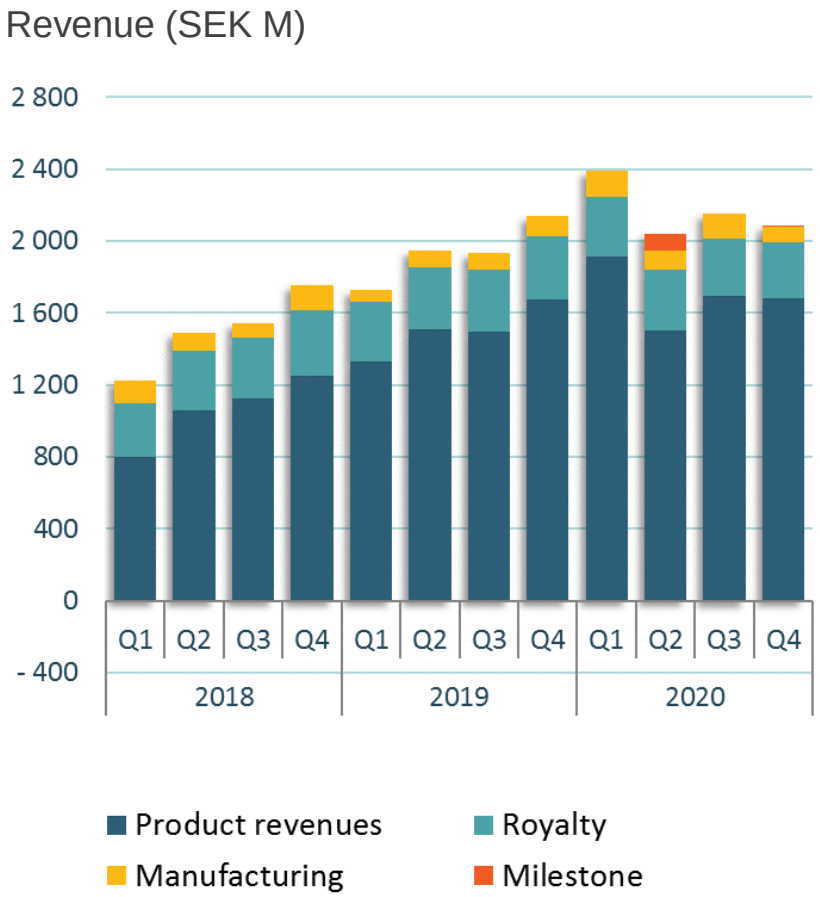
Ramping up our international expansion



- Created a presence in China, Japan and Australia and build out our representation in Russia
- **Russia:** Elocta approved, Kineret approved in CAPS, Doptelet submitted in Russia for ITP and CLD in Q4 2020
- **China:** Emapalumab and nitisinone submitted in 2020
- **Japan:** Phase 1 study initiated in 2021 for emapalumab, with potential approval in both primary and secondary HLH

Haematology

Haematology – continued market share gain



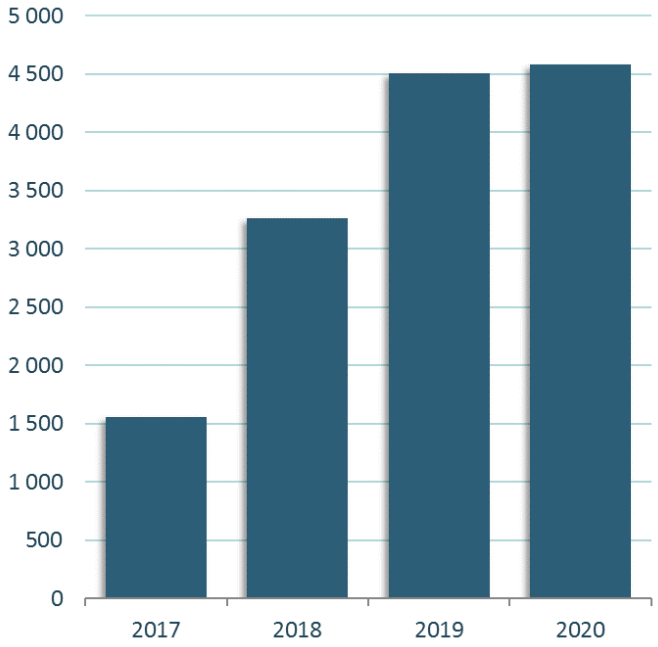
- **FY revenue** of SEK 8,660 M (7,755)
  - Revenue growth of 12 per cent (13 per cent at CER)
- Elocta **strengthened positions** in key markets with continued patient gain
  - Patient increase by > 10% in 2020
  - COVID-19 impacted consumption per patient
- **Doptelet** FY sales of SEK 587 M (34[1])

1) 12 November–31 December

Elocta and Alprolix

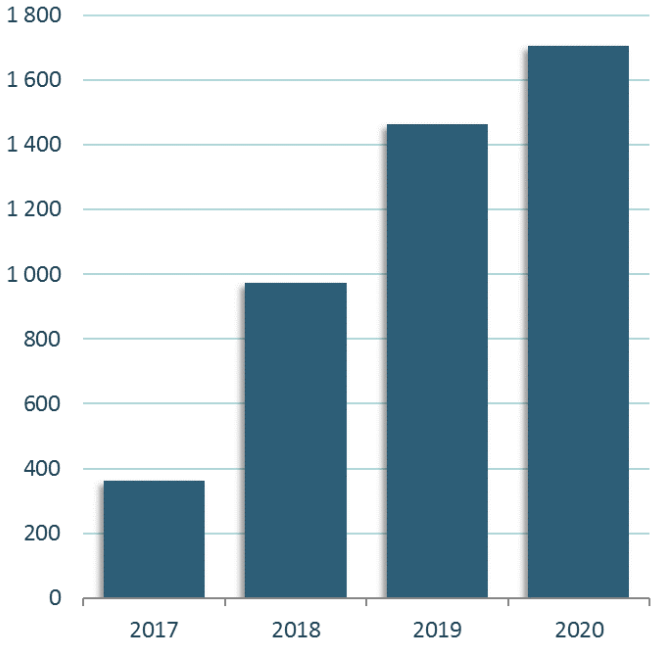
Competitive franchise – expansion of patient share in 2020

Elocta sales (SEK M)



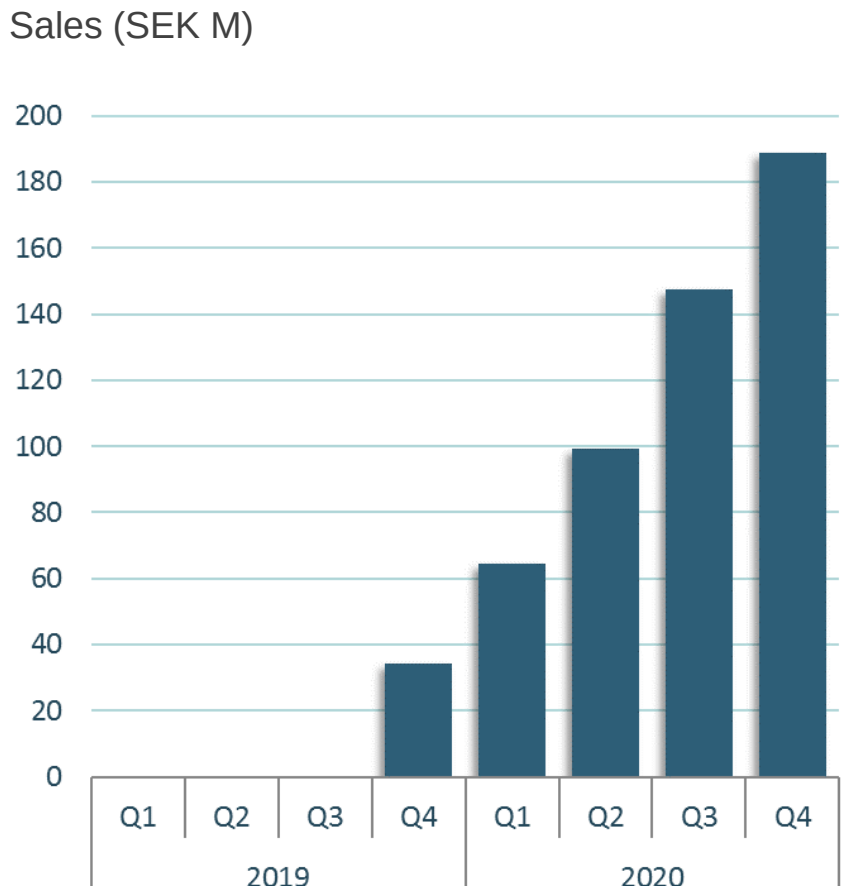
Continued strong growth of patients offset to a large extent by reduced consumption/patient; sales growth 3 per cent at CER and 10 per cent patient growth FY 2020

Alprolix sales (SEK M)



Patients on Alprolix grew by 25 per cent FY 2020 and 4 per cent in Q4 vs Q3

Doptelet – having an impact on the TPO RA market in US

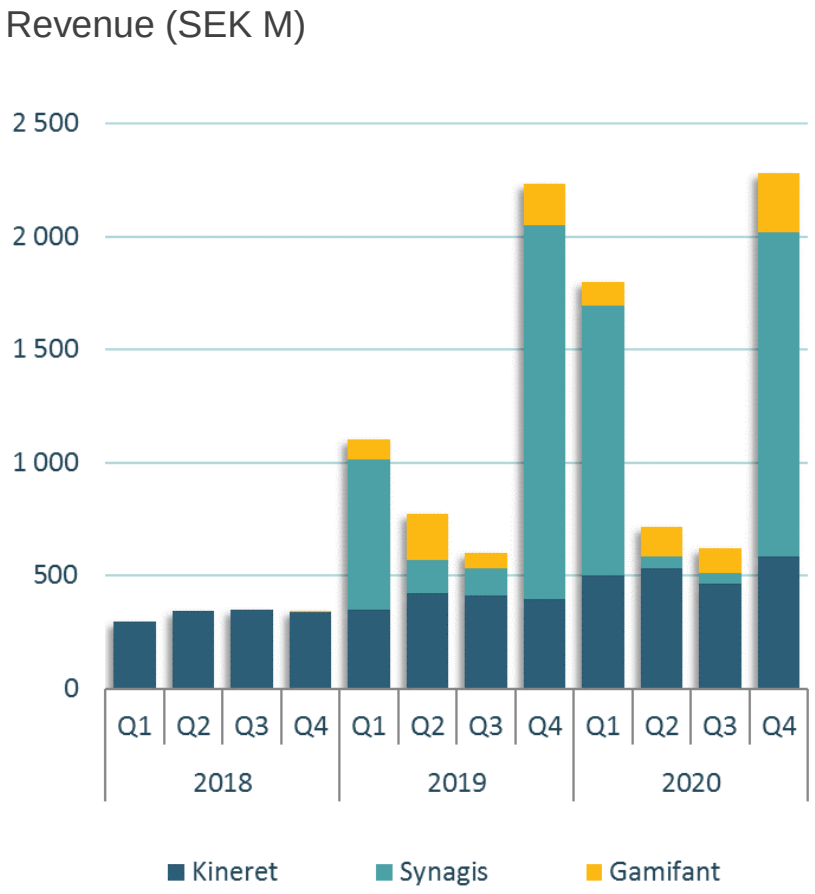


- **FY sales** of SEK 587 M (34[1])
- **Q4 sales** of SEK 191 M (34[1])
- **US:** strengthened market share in Q4 (7% in ITP)
- **International:**
  - Product makes good progress in China by Fosun
  - EMA approval of ITP indication in January 2021

1) 12 November–31 December

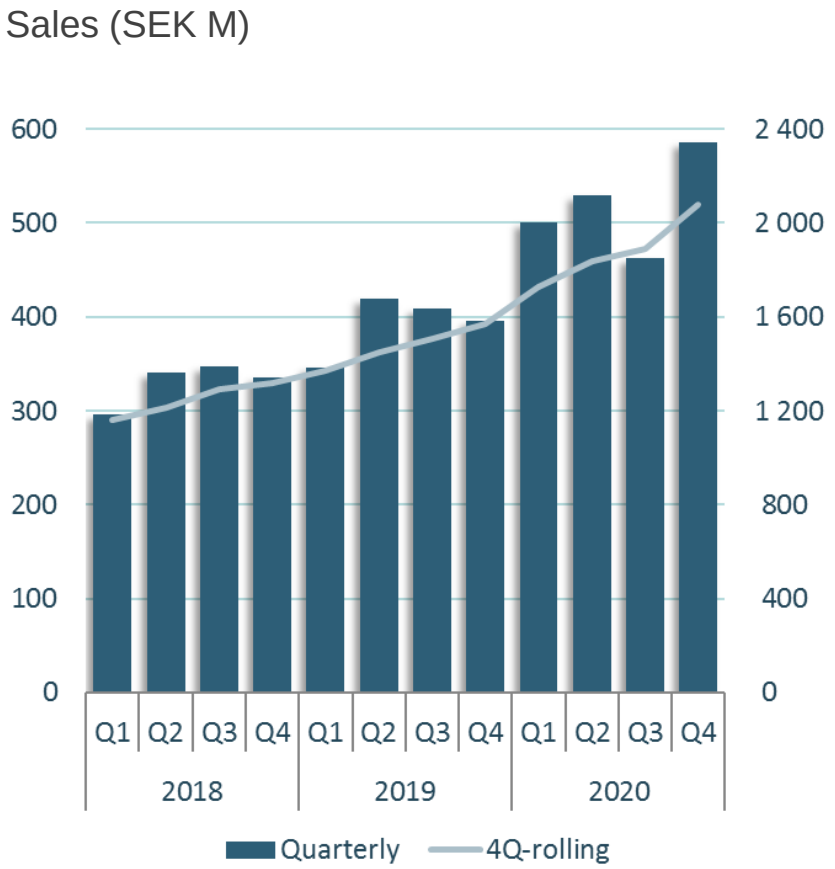
Immunology

Immunology – solid growth



- **Q4 revenue** of SEK 2,281 M (2,233)
  - Revenue growth of 2 per cent (6 per cent at CER)
- FY revenue of SEK 5,415 M (4,706)
  - Revenue growth of 15 per cent (16 per cent at CER)
- **Synagis has performed well**, even though the incidence of RSV was heavily impacted by COVID-19
- **Kineret and Gamifant –** impressive growth in the quarter

Kineret – accelerated sales growth



- **Q4 sales** of SEK 586 M (396)
  - Sales growth of 48 per cent (59 per cent at CER)
- **FY sales** of SEK 2,079 M (1,571)
  - Sales growth of 32 per cent (35 per cent at CER)
- **New indication for DIRA** (deficiency of the interleukin-1 receptor antagonist) granted by FDA in Q4
- **Various ISS programmes ongoing** to establish Kineret in the area of hyperinflammation related to COVID

Gamifant – strong patient growth

- **Q4 sales** of SEK 263 M (180)
  - Sales growth of 46 per cent (56 per cent at CER)
- **FY sales** of SEK 609 M (542)
  - Sales growth of 12 per cent (16 per cent at CER)
- Number of **patients grew by 67 per cent** FY 2020, driven by education and awareness
- **Emapalumab submitted in China**

R&D

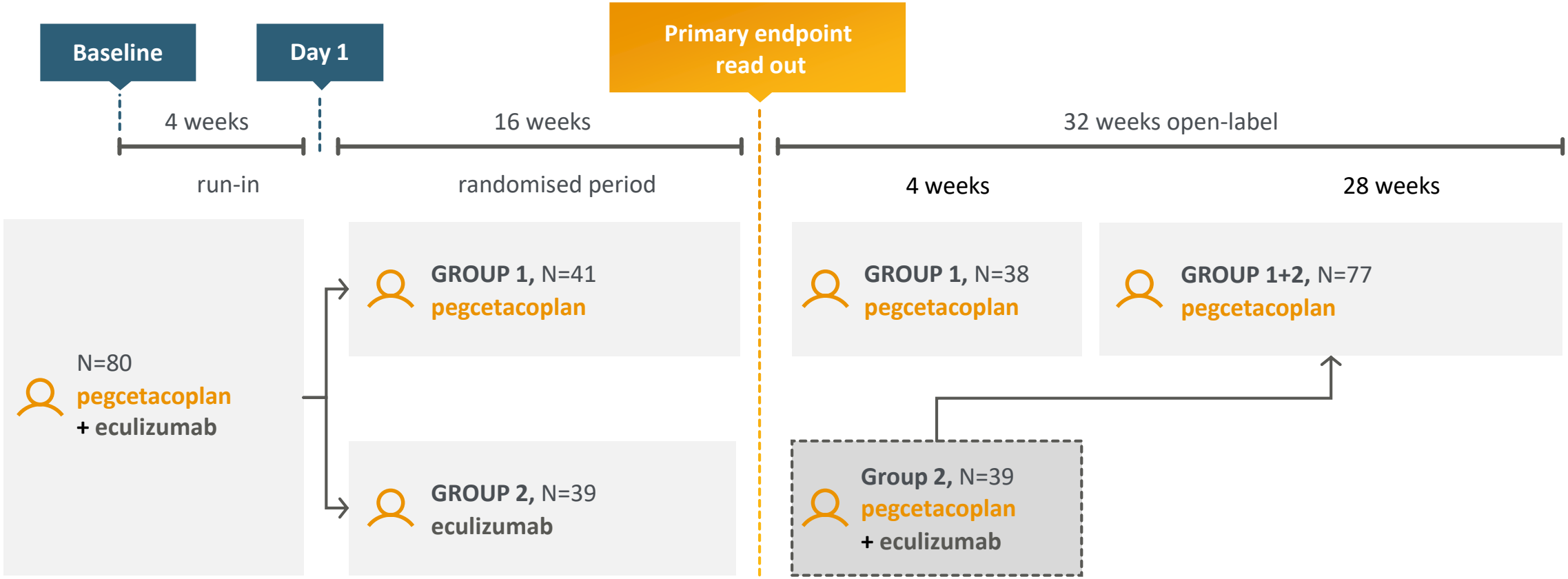
Substantial value in our late-stage pipeline[1]

Phase 2	Phase 3	In registration
Gamifant / emapalumab Secondary HLH malignancy	**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
Gamifant / emapalumab Graft failure (GF)	**MEDI8897 / nirsevimab[4]** RSV prevention	
pegcetacoplan[2] HSCT-TMA	**BIVV001 / rFVIIIFc-VWF-XTEN2[5]** Haemophilia A	
pegcetacoplan[2] ALS	**pegcetacoplan[2]** CAD	
	pegcetacoplan 1st line[2] Paroxysmal nocturnal haemoglobinuria	
	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

Pegcetacoplan: potential to elevate the standard of care in PNH

PEGASUS: Phase 3 head -to-head study of pegcetacoplan vs eculizumab



APL2-302; NCT03500549

Sobi has global co-development with Apellis and ex-US commercialisation of systemic pegcetacoplan

Pegcetacoplan: potential to elevate the standard of care in PNH

Met primary endpoint in phase 3 PEGASUS study vs eculizumab at week 16

superior

to eculizumab on improving hemoglobin levels

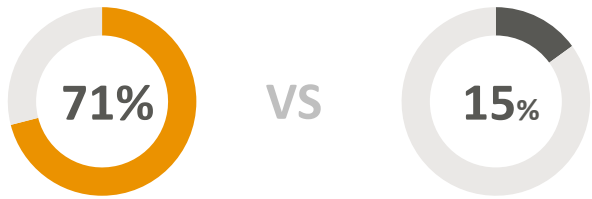
3.8 g/dL improvement in adjusted means pegcetacoplan vs eculizumab p<0.0001

Meaningful improvements across key markers of disease*

Patients were transfusion-free

pegcetacoplan | eculizumab

Patients with normalised LDH



pegcetacoplan | eculizumab

FACIT-fatigue score

12-point difference

pegcetacoplan over eculizumab

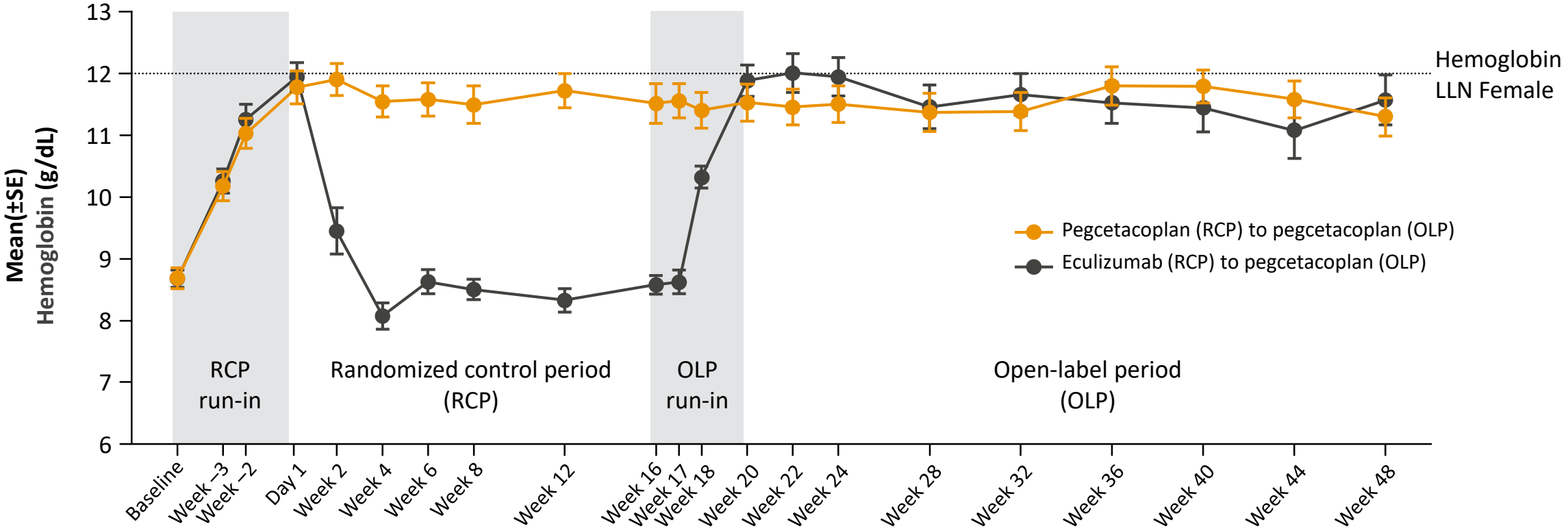
APL2-302; NCT03500549

*Refer to Apellis' January 7, 2020 investor presentation and press release for additional detail on key secondary endpoints. Refer to Apellis' June 12, 2020 EHA presentation for additional detail on other secondary endpoint analyses.

Sobi has global co-development with Apellis and ex-US commercialisation of systemic pegcetacoplan

Pegcetacoplan demonstrated sustained improvements in hemoglobin and clinical measures at week 48

Hemoglobin increase from baseline at week 48 equal to increase at week 16



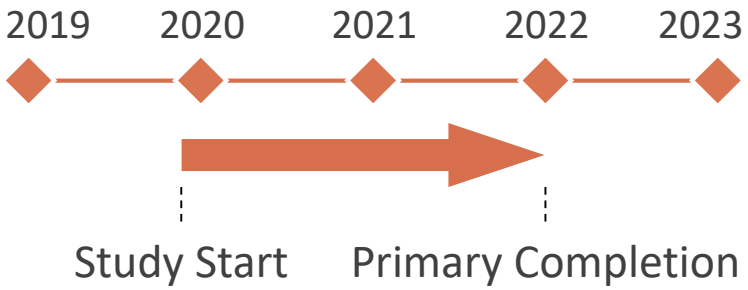
- Sustained improvements in transfusion avoidance, reticulocyte count, LDH level, and FACIT-fatigue score
- No cases of meningitis
- Safety profile comparable to eculizumab at week 16; consistent throughout 48-week study
- 24 of 80 pegcetacoplan monotherapy-treated patients (30%) experienced a serious adverse event (SAE); 5 SAEs (6%) assessed to be possibly related to study treatment. One death reported due to COVID-19 and unrelated to study treatment

Sobi has global co-development with Apellis and ex-US commercialisation of systemic pegcetacoplan

Efanesoctocog alfa (BIVV001) expected to be submitted in US in 2022

Phase 3 in adults & adolescents
N= 150
≥12 year old

Study timeline

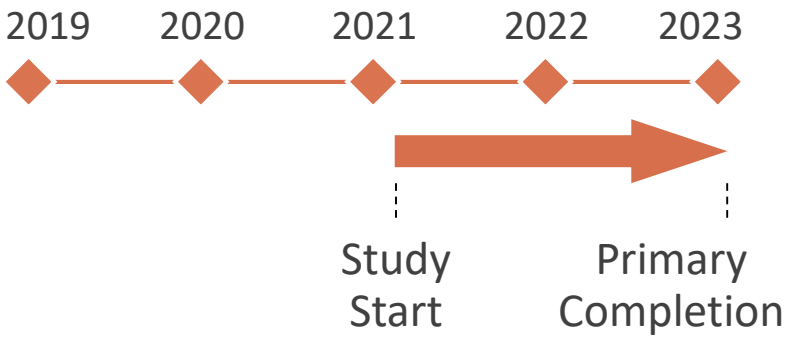


Key design aspects

Arms: Multi-centre, open-label, non-randomized 2-arm (prophylaxis and on-demand); previously treated patients with severe haemophilia A

Primary endpoint: Annualized bleeding rate (ABR) in prophylaxis treatment arm (time frame: baseline to 52 weeks)

Phase 3 in Paediatric
N= 65
<12 year old



Arms: Multi-centre, open-label 1-arm; previously treated patients with severe haemophilia A

Primary endpoint: Inhibitor development (time frame: baseline to 52 weeks)

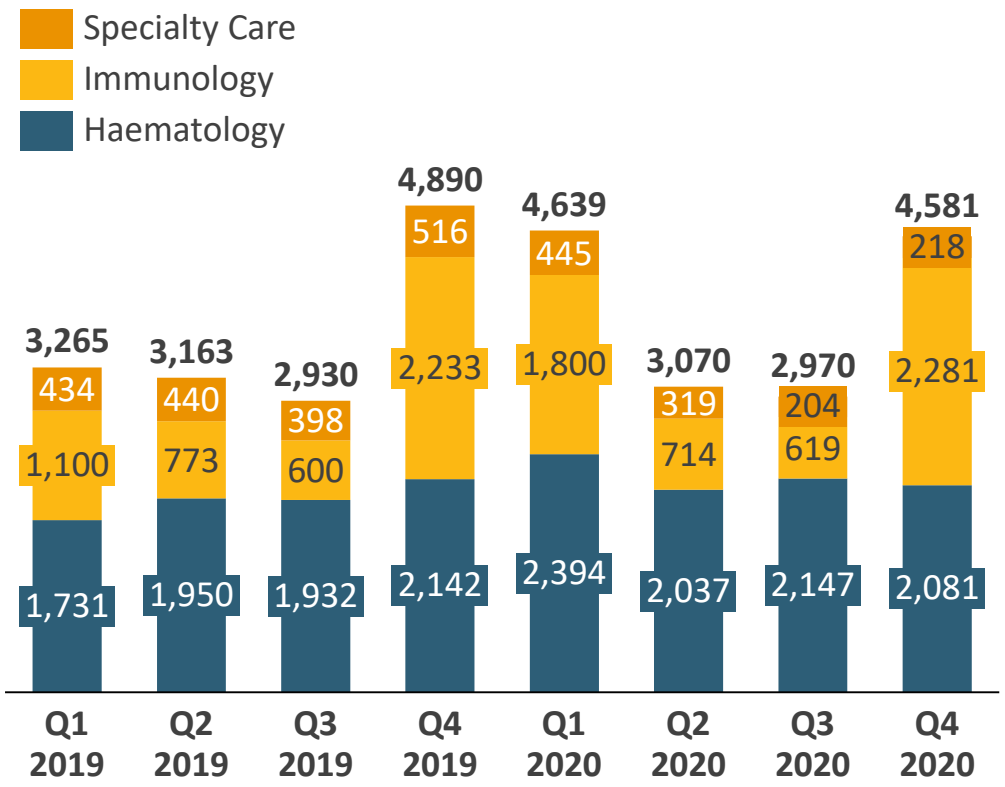
- Phase 3 enrolment completed
- Top-line pivotal results in early part of H1 2022
- Fast Track Designation for efanesoctocog alfa (BIVV001) in the US
- Earliest approval in EU 2023 or early 2024

Efanesoctocog alfa (BIVV001) is developed and, if approved, will be commercialised in collaboration with Sanofi

Q4 and FY 2020 Financial Results

Q4 2020: Financial results

Total revenue (SEK M)



Amounts in SEK M	Q4 2020	Q4 2019	Change	Full-year 2020	Full-year 2019	Change
Total revenue	**4,581**	4,890	-6%	**15,261**	14,248	7%
Gross profit	**3,718**	3,833	-3%	**12,036**	10,913	10%
Gross margin[1]	**81%**	78%		**79%**	77%	
EBITA adjusted[1,2]	**2,177**	2,380	-9%	**6,301**	6,145	3%
EBITA margin adjusted[1,2]	**48%**	49%		**41%**	43%	
Profit for the period	**1,502**	1,360	10%	**3,245**	3,304	-2%
Earnings per share, SEK adjusted[1,2,3]	**3.74**	4.90	-24%	**9.66**	11.89	-19%
Operating cashflow	**858**	976	-12%	**5,214**	3,634	43%
Net debt (+)/net cash (-)	**13,748**	15,404		**13,748**	15,404	

[1]Alternative Performance Measures (APMs)
[2]EBITA Q4 and full-year 2020 excluding non-recurring items; other operating income related to reversal of the CVR liability of SEK 399 M. EBITA 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 Q4 and full-year 2020 excluding the reversal of the CVR liability of SEK 399 M. EPS 2019 excluding impairment of intangible assets of SEK 18 M related to restructuring in Q2 2019.

Outlook

Guido Oelkers

CEO

Impact of COVID-19 on our business

48 per cent of our business impacted directly/indirectly by COVID-19

Elocta

- Currently lower consumption per patient compared to pre COVID-19 levels
- Due to economic pressure on health systems and increased competition prices for Haemophilia products will be adjusted
- Continued single digit patient growth

Synagis

- Lack of international travel and social distancing has significantly reduced the RSV prevalence in the US

Financial outlook 2021

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

At constant exchange rates this range corresponds to a revenue growth of between -2,5 and 4,5 per cent

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

R&D expenses as share of revenue are expected to grow to 13–15 per cent reflecting increased investments in SEL-212 and pegcetacoplan and support for our 12 late-stage programmes

The outlook for 2021 is expressed at end of January 2021 closing exchange rates. The negative currency impact on 2021 performance is expected to be 5-7 per cent on revenues and 6- 8 per cent on EBITA compared to average full year 2020 exchange rates.

- ✓ Launch progress Doptelet and Gamifant
- ✓ Strong underlying growth for Kineret
- ✓ Elocta impacted by COVID-19
- ✓ Synagis impacted by lower virology levels

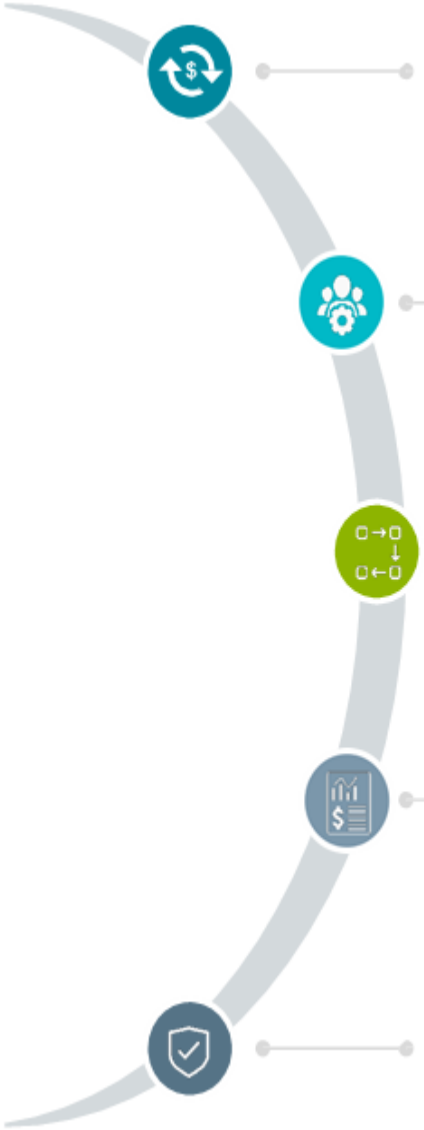
SG&A expenses will growth slightly reflecting international expansion and product launches

Revenue outlook of 14.0 to 15.0 bn (@ Jan closing rates) equals -2.5 to 4.5 % growth @CER (average 2020 rates)

	2021 Revenues (SEK bn)		
	Guidance at Jan closing rates	At CER[1]	CER Growth
Low end →	14.0	14.9	-2.5%
Mid point →	14.5	15.4	1.0%
High end →	15.0	15.9	4.5%

[1] CER is 2020 average rates

Conclusions



Proven track record; demonstrated strong impact against large competitors

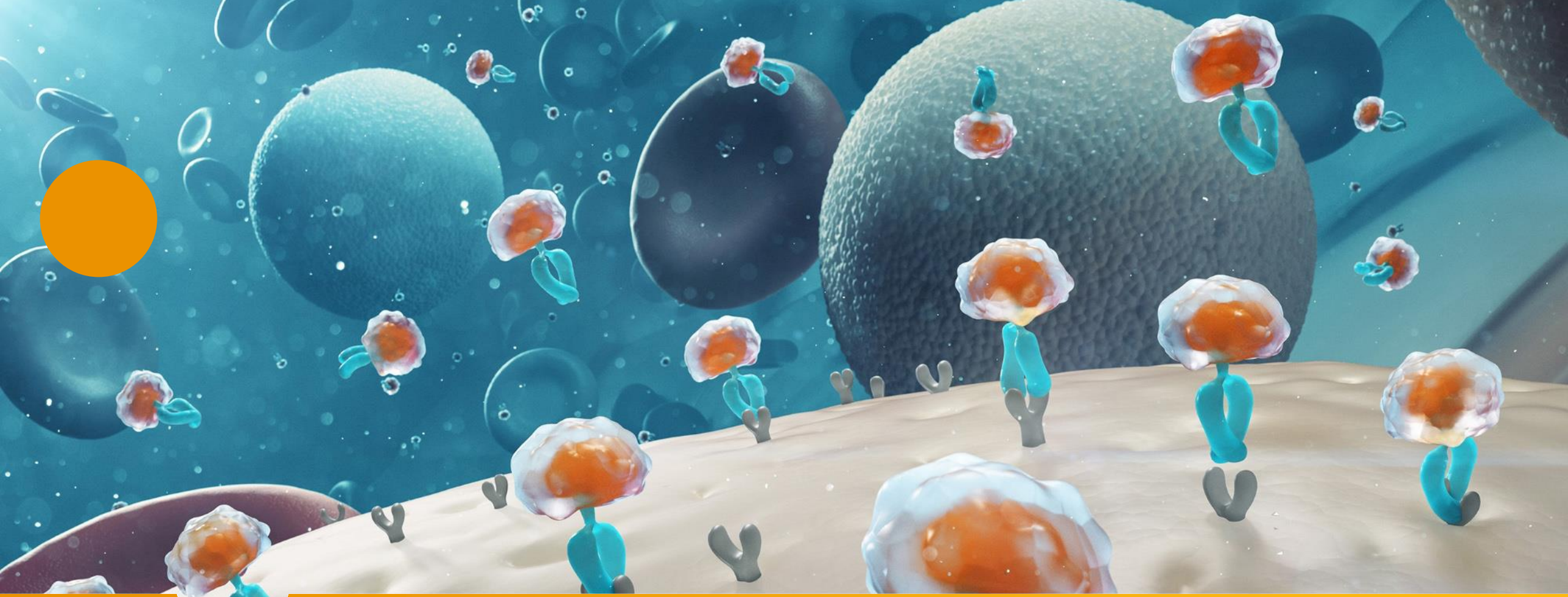
Robust and diversified in 2 therapeutic areas

Strong cash flows out of the operating business

12 late stage projects; great opportunities for growth requiring funding

Various catalysts for sustainable value creation

Q&A



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