Q2 2018 Results

18 July 2018

AGENDA

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Financials

Pipeline

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PRESENTERS

Guido Oelkers
Chief Executive Officer and President

Mats-Olof Wallin
Chief Financial Officer

Milan Zdravkovic
Head of Research & Development and
Chief Medical Officer

Forward looking statements

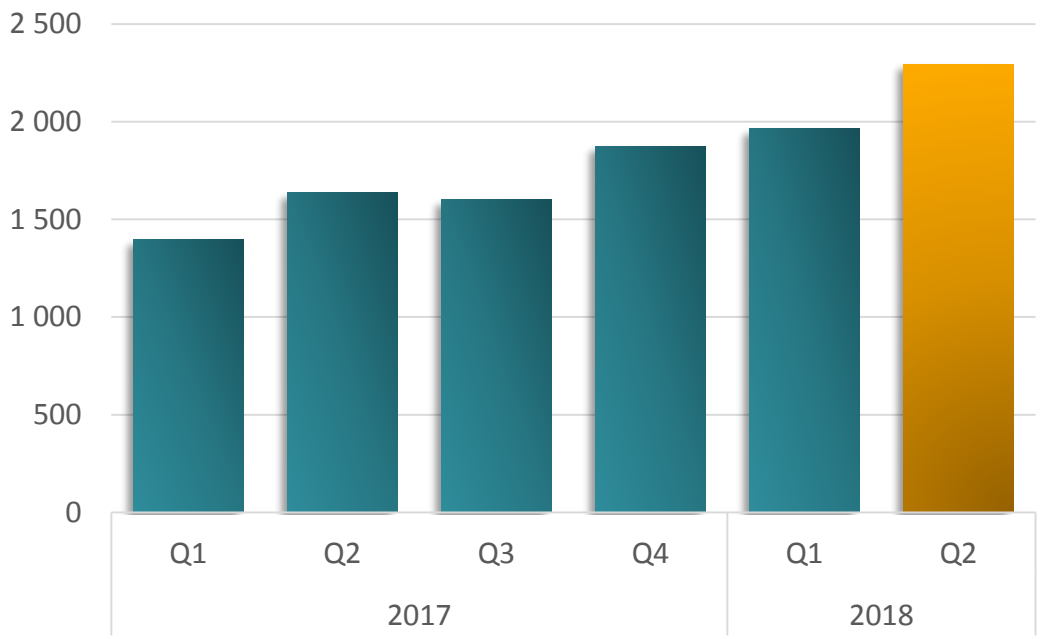
In order to utilize the 'Safe Harbor' provisions of the United States Private Securities Litigation Reform Act of 1995, Swedish Orphan Biovitrum AB (publ) is providing the following cautionary statement, This presentation contains forward-looking statements with respect to the financial condition, results 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.

Q2 highlights

- 40 per cent sales growth (36 per cent at CER)
- Total revenues of SEK 2,289 M (1,639)
- EBITA increased by 94 per cent to SEK 951 M (492)
- Net cash position of SEK 2,300 M (1,472 as of 31 December 2017)
- Revenues for Elocta® were SEK 794 M (351), an increase of 126 per cent
- Revenues for Alprolix® SEK 263 M (84), an increase of 215 per cent
- Kineret® sales were SEK 340 M (286) for Q2, an increase of 19 per cent
- Orfadin® sales reached their highest level yet, with revenue growth of 7 per cent to SEK 236 M (220)
- Advancements in the R&D portfolio (BIVV001, SOBI003, anaGO)
- Outlook revised

Financial highlights Q2 2018

Total Revenue (SEK M)

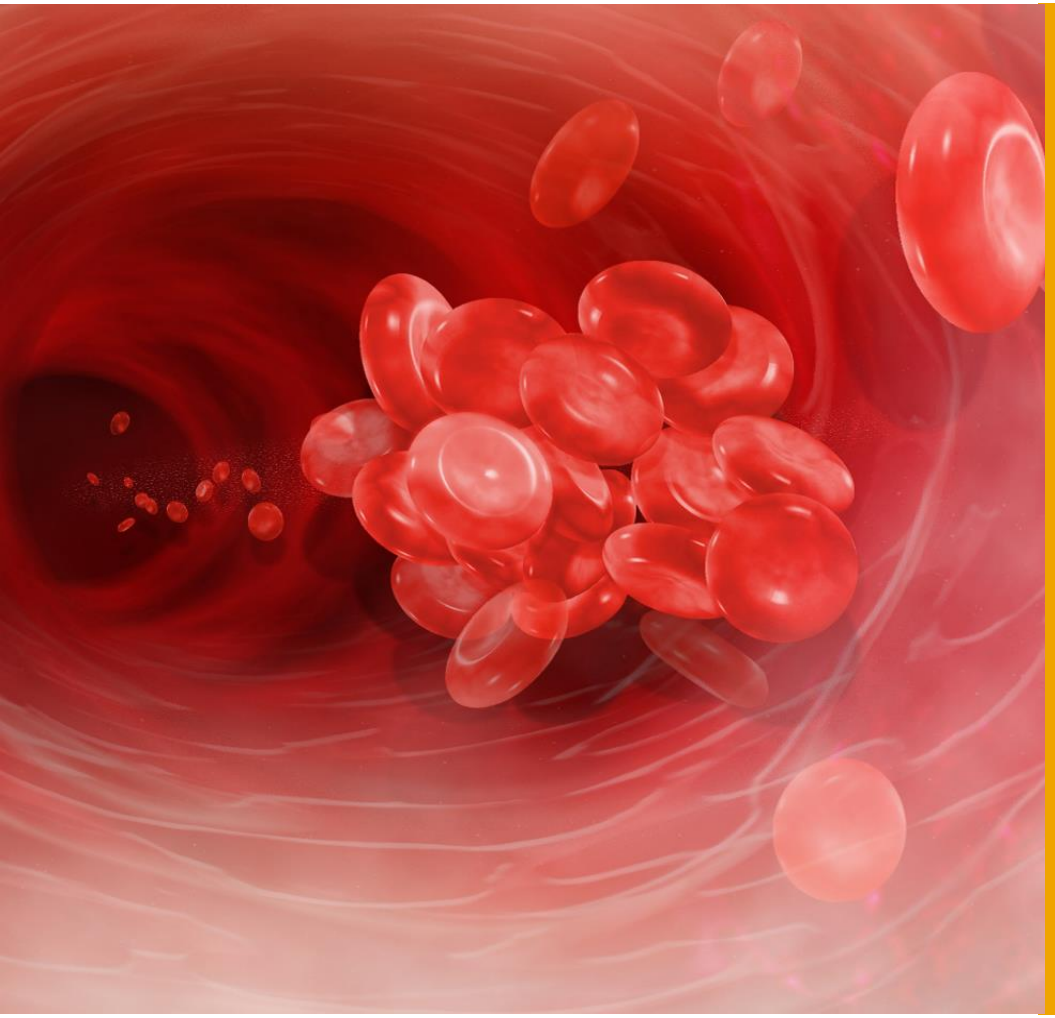


	Q2 2018	Q2 2017	Change (%)	H1 2018	H1 2017	Change (%)
Revenues (SEK M)	2,289	1,639	+40	4,253	3,035	+40
Gross margin	73%	71%		73%	72%	
EBITA (SEK M)	951	492	+94	1,722	898	+92
EBITA margin	42%	30%		40%	30%	
Cash flow from operations (SEK M)	564	173	+226	841	496	+70

Business review Q2

Guido Oelkers

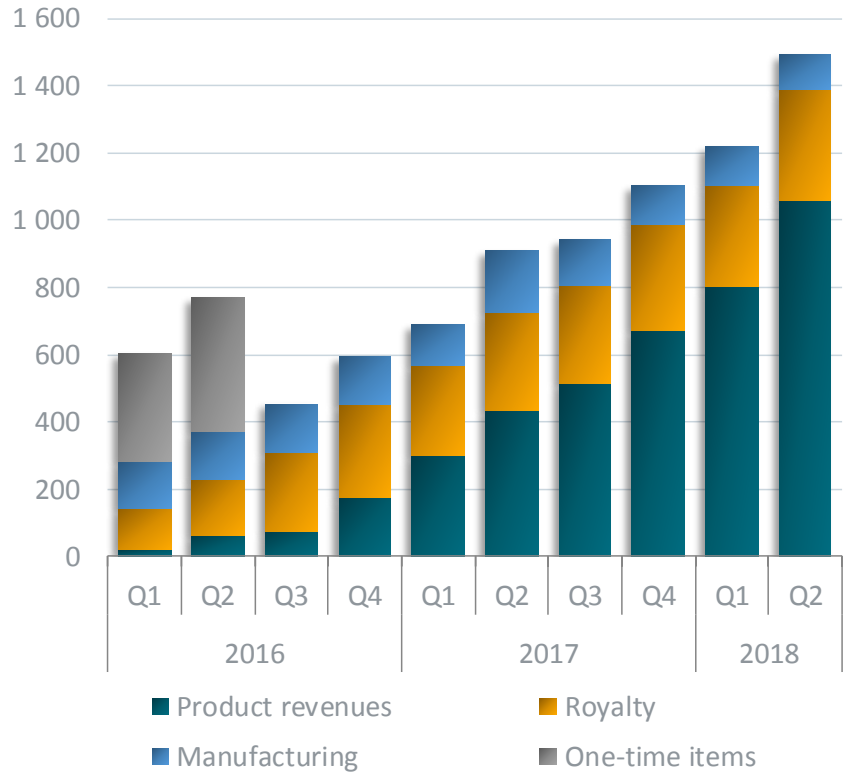
Haemophilia – growth based on innovation



- **Safety established in thousands of patients**
  - Unique use of Fc fusion technology in haemophilia utilising a natural pathway in the body
- **Provides opportunities for individualised treatment**
  - For all age groups, in prophylaxis, on-demand and surgery
  - Mode of action – a natural way of replacing factor
- **Evidence shows improved joint health**
  - Prophylactic treatment with Elocta demonstrates improved joint health

Haemophilia – product revenues over SEK 1 Bn in Q2

Total Revenues (SEK M)



- Q2 revenues of SEK 1,493 M (923)
  - SEK 1,057 M (434) in product revenues
  - SEK 335 M (305) in royalty revenues
  - SEK 100 M (184) in manufacturing revenues

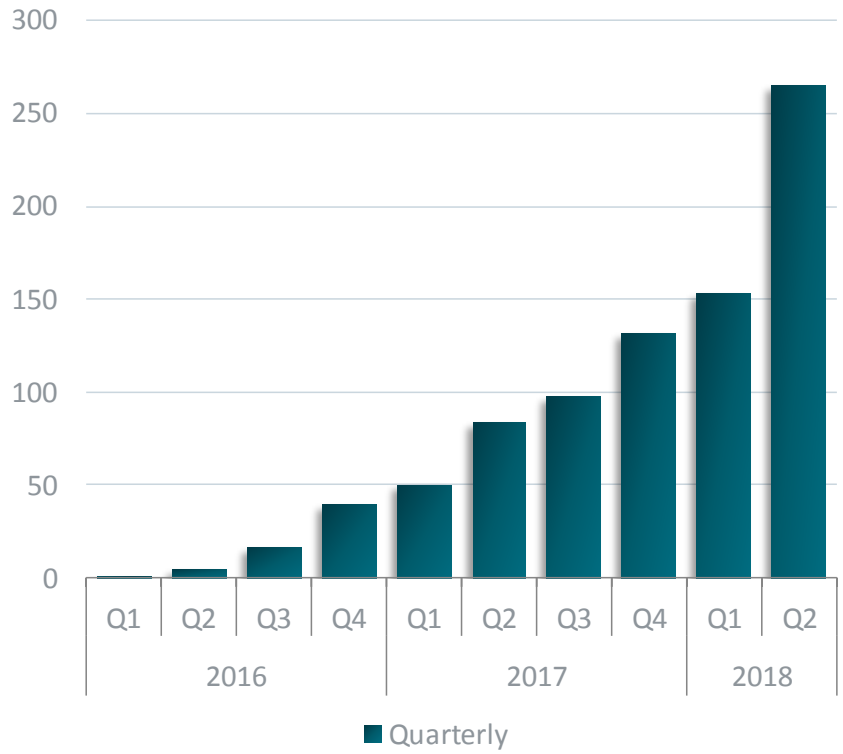
Elocta – acceleration continues

Product Revenues (SEK M)

- Q2 product revenues of SEK 794 M (351)
  - SEK 443 M (126 per cent) growth
  - Close to 60 per cent of the growth derived from France, Germany, Italy and UK
- Reimbursed in 25 countries

Alprolix – over 200 per cent revenue growth

Product Revenues (SEK M)



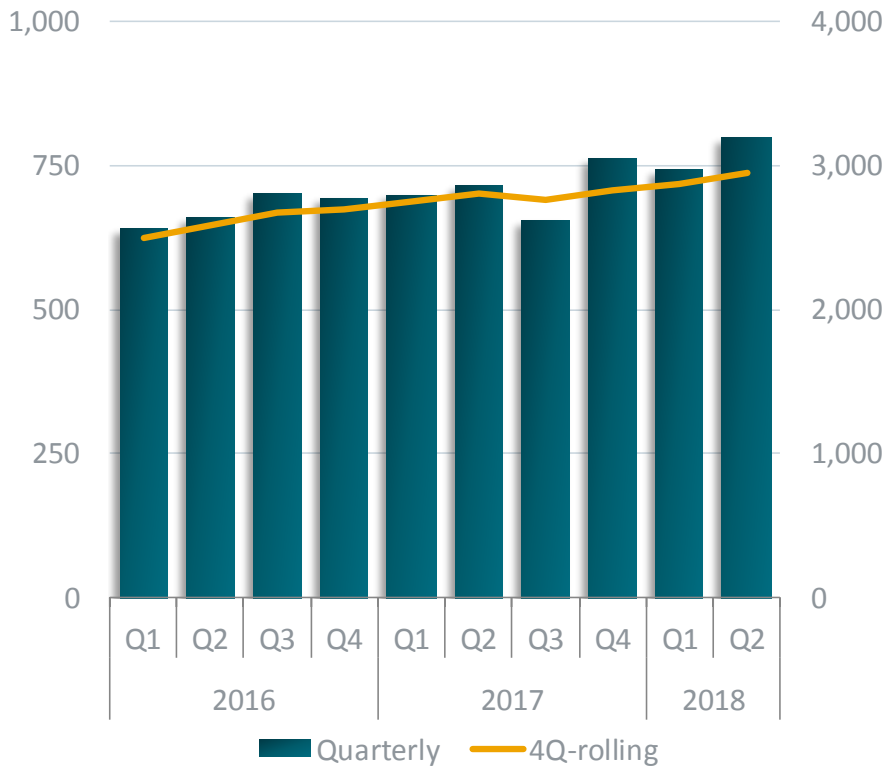
- Product revenues of SEK 263 M (84)
  - SEK 179 M (215 per cent) growth
  - More than 70 per cent of the growth derived from France, Germany, Italy and the Netherlands
- Reimbursed in 16 countries

Specialty Care – core strengths continue to deliver

- **World-class commercialisation platform**
- **Lifecycle management & indication expansion**
- **Partner product portfolio with expansion possibilities**

Specialty Care – strong performance across portfolio

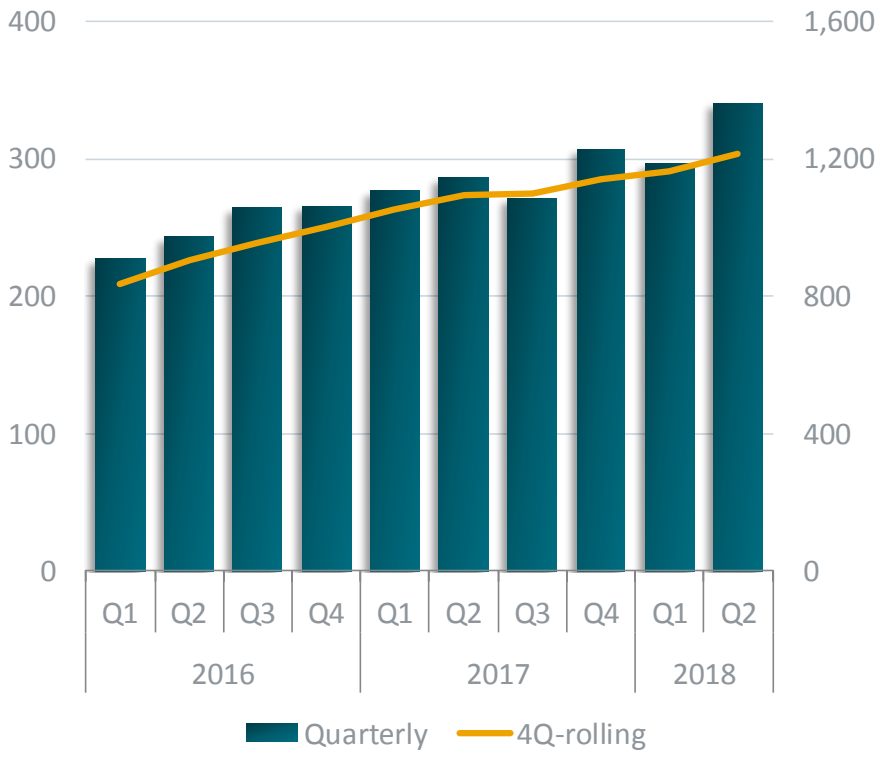
Product Revenues (SEK M)



- Q2 Revenues SEK 796 M (716)
  - increase of 11 per cent (9 per cent at CER)
- Kineret – strong double-digit growth
- Orfadin – continued strong growth
- Ravicti launched and gained reimbursement in first wave countries
- Xiapex growth mainly driven by Peyronie´s indication with Italy as a strong contributor

Kineret - strong growth driven by expansion of indications

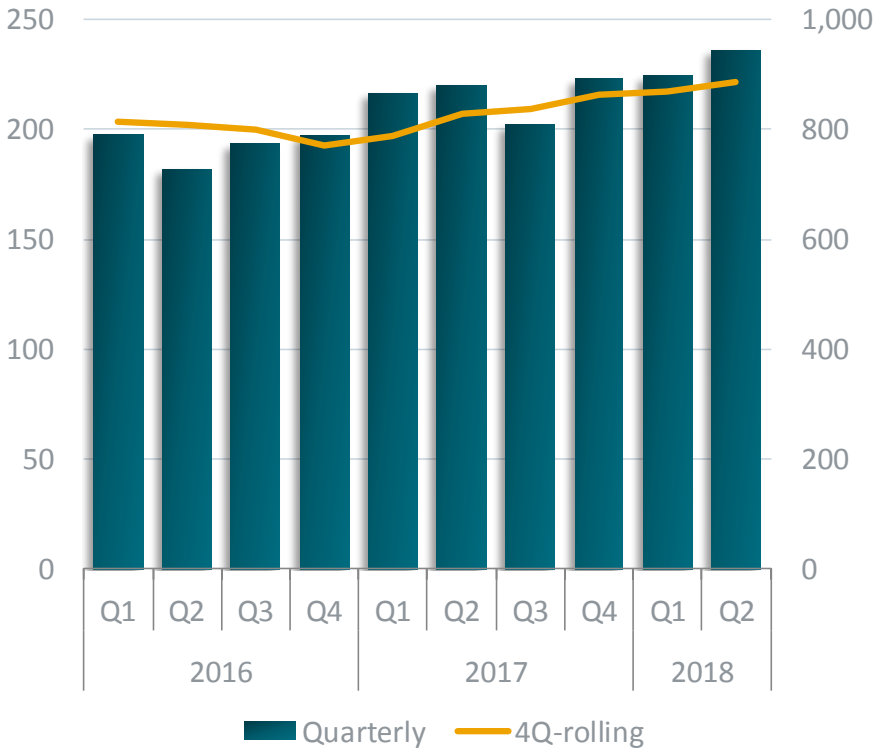
Product Revenues (SEK M)



- Q2 revenues SEK 340 M (286)
  - increase of 19 per cent (17 per cent at CER)
- Strong growth across all regions
- Still's indication granted EC approval on 6 April
  - Pricing and reimbursement for Still's disease secured for Germany, UK, Ireland, Netherlands and the Nordics
- Strong US growth continued due to patient support programmes and high demand in the IL-1 area

Orfadin – reached it's highest sales level

Product Revenues (SEK M)



- Q2 revenues SEK 236 M (220)
  - increase of 7 per cent (6 per cent at CER)
- Growth continued across EMENAR and North America due to solid patient support programmes and new formulations
- The first generics have entered some markets

Financial results

Mats-Olof Wallin

Profit & loss statement

Amounts in SEK M	Q2 2018	Q2 2017	H1 2018	H1 2017	Full-year 2017
Total revenues	**2,289**	**1,639**	**4,253**	**3,035**	**6,511**
Total cost of goods and services sold	-612	-475	-1,164	-844	-1,854
Gross profit	**1,677**	**1,163**	**3,089**	**2,191**	**4,657**
Gross margin	*73%*	*71%*	*73%*	*72%*	*72%*
Sales and administrative expenses	-483	-413	-916	-796	-1,644
Research and development expenses	-241	-247	-475	-465	-908
Other operating revenue/expenses	-1	-11	24	-32	-52
EBITA	**951**	**492**	**1,722**	**898**	**2,053**
EBITA margin	***42%***	***30%***	***40%***	***30%***	***32%***
Amortisation and write-downs	-111	-110	-221	-232	-453
EBIT	**841**	**381**	**1,500**	**666**	**1,600**
Financial income/expenses	-6	-21	-4	-36	-68
Profit before tax	**834**	**360**	**1,497**	**630**	**1,532**
Income tax expense	-149	-95	-297	-162	-384
Profit for the period	**685**	**265**	**1,200**	**468**	**1,149**

Balance sheet

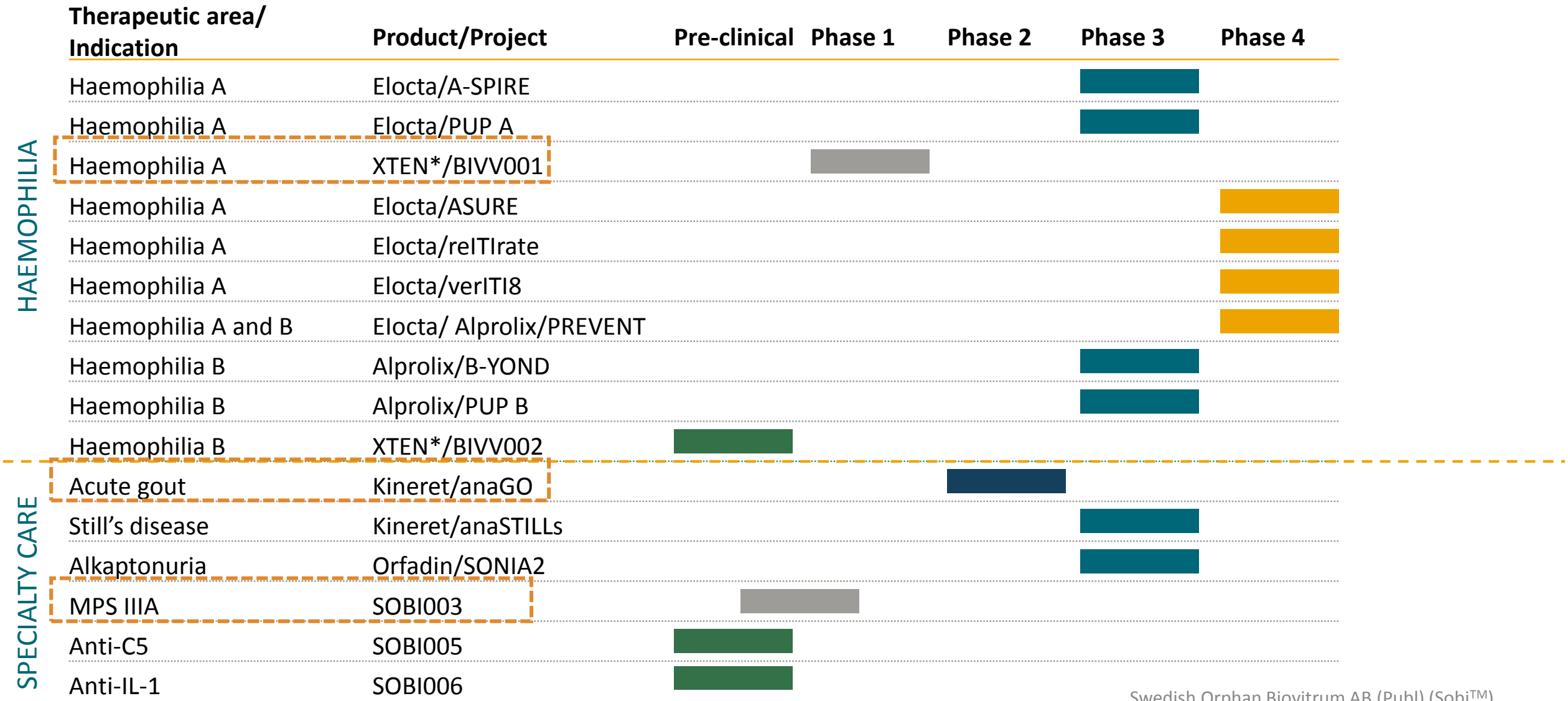
Amounts in SEK M	Jun 2018	Dec 2017	Jun 2017
Assets			
Intangible assets	6,240	6,445	6,643
Tangible and other non-current assets	328	301	270
Total non-current assets	6,567	6,746	6,913
Inventories	1,185	1,053	1,123
Accounts receivable	1,555	1,129	1,027
Other current receivable	512	496	430
Cash and cash equivalent	2,306	1,478	1,189
Total current assets	5,558	4,157	3,769
Total Asset	**12,124**	**10,903**	**10,682**

	Jun 2018	Dec 2017	Jun 2017
Equity and liabilities			
Shareholders' equity	7,851	6,701	5,963
Long-term liabilities	5	5	502
Long-term liabilities, non-interest bearing	1,489	1,832	2,021
Current liabilities	2	2	2
Total liabilities	2,778	2,363	2,194
Total equity and liabilities	**12,124**	**10,903**	**10,682**

Pipeline

Milan Zdravkovic

A rare disease pipeline with increasing value

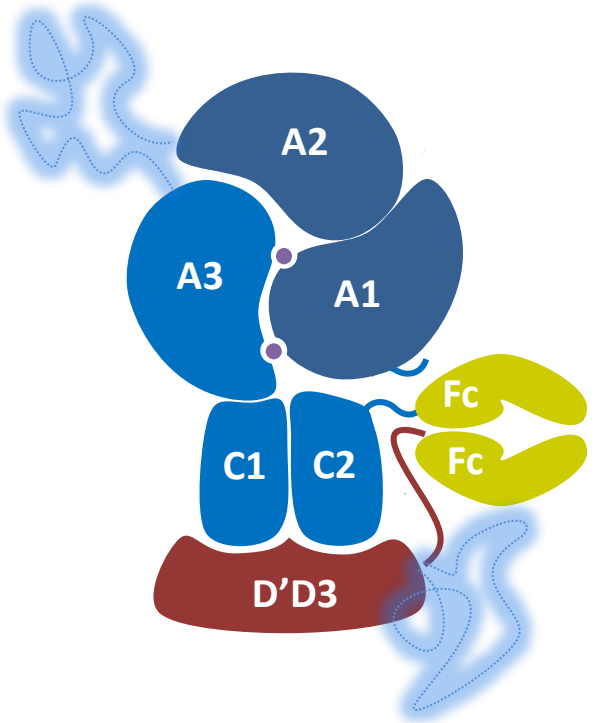


* XTEN are Bioverativ development program, Sobi has elected to add programs to the collaboration agreement but not yet opted-in

BIVV001 – the first, novel investigational FVIII therapy to break the VWF half-life ceiling

First-in-human study

- Phase 1/2a, open-label, dose-escalation, multicenter study to assess the safety, tolerability, and FVIII activity (PK) of a single dose of BIVV001 compared with rFVIII in previously treated adult males with severe hemophilia
- Data from first four patients of a single low-dose of 25 IU/kg showed a favorable safety profile of BIVV001
- Geometric mean half-life of 37 hours for BIVV001 (vs. 13 hours for rFVIII)
- Average FVIII activity was about 5.6% at 7 days post infusion of a single low dose BIVV001 while for conventional rFVIII it reduced to less than 1% within 3 days



Upon thrombin activation:
- Removes B domain XTEN
- Disrupts FVIII and D' D3 interaction
- Removes D' D3-XTEN
- **Results in same molecule as activated rFVIIIFc**

BIVV001 is a Bioverativ programme.

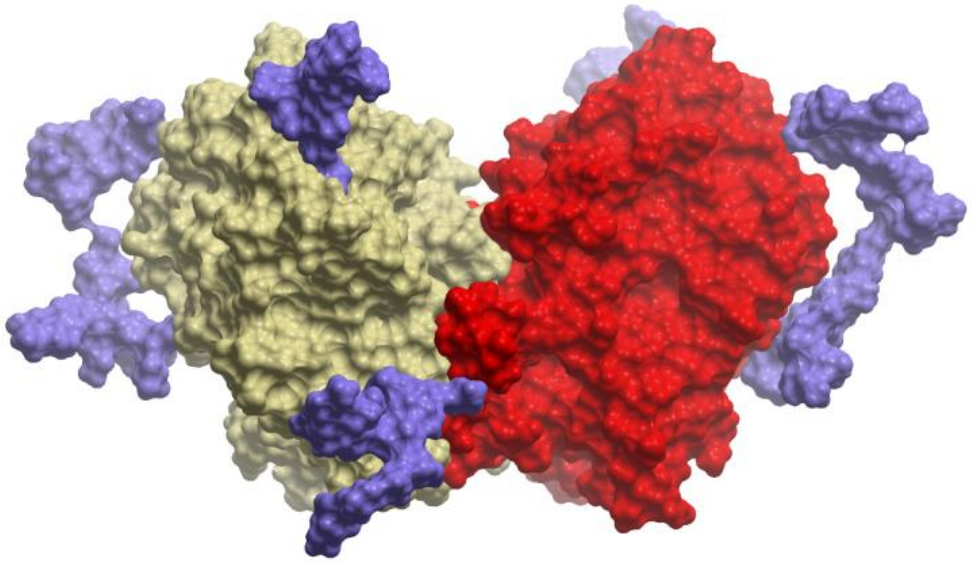
Sobi elected to add BIVV001 to the collaboration agreement with Bioverativ, a Sanofi company in September 2014, but has not yet opted in.

Bioverativ
A SANOFI COMPANY

SOBI003 for Mucopolysaccharidosis IIIA (MPS IIIA)

Mucopolysaccharidosis IIIA (MPS IIIA)

- A rare systemic disease with a significant CNS component due to incomplete breakdown and increased lysosomal storage of heparan sulfate (HS)
- Increased morbidity and mortality
- Caused by mutations in gene for sulfamidase enzyme
- Up to about 2000 people are estimated to live with MPS IIIA in the EU and US
- There is currently no treatment available for MPS IIIA
- SOBI003: a recombinant sulfamidase using proprietary Modifa™ technology with potential to address an unmet needs in MPS IIIA



SOBI003 - chemically modified recombinant human sulfamidase

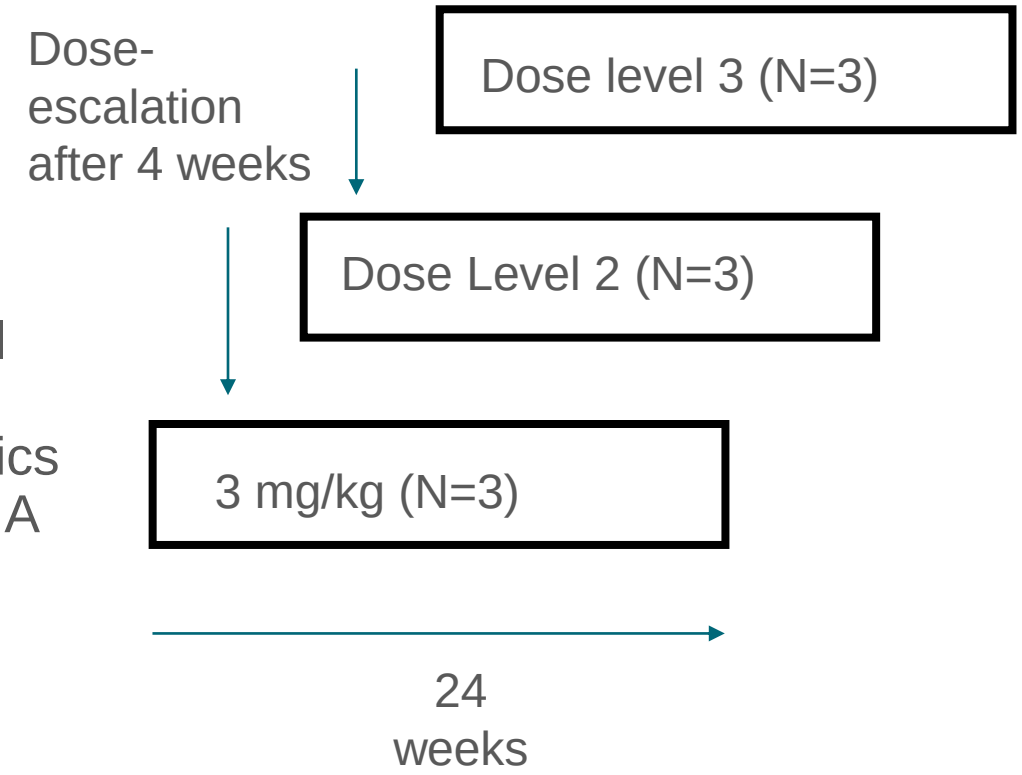
First patient screened in first-in-human study with SOBI003

Development status

- Orphan Drug Designation in the EU and US
- US FDA Fast Track Designation

First-in-man study

- Open-label, non-controlled, parallel, sequential ascending multiple dose, study to assess the dose related safety, tolerability, pharmacokinetics and pharmacodynamics of SOBI003 in MPS IIIA patients (1-6 years of age)
- Patients completing 24 weeks will be offered enrolment into a 80 weeks extension study

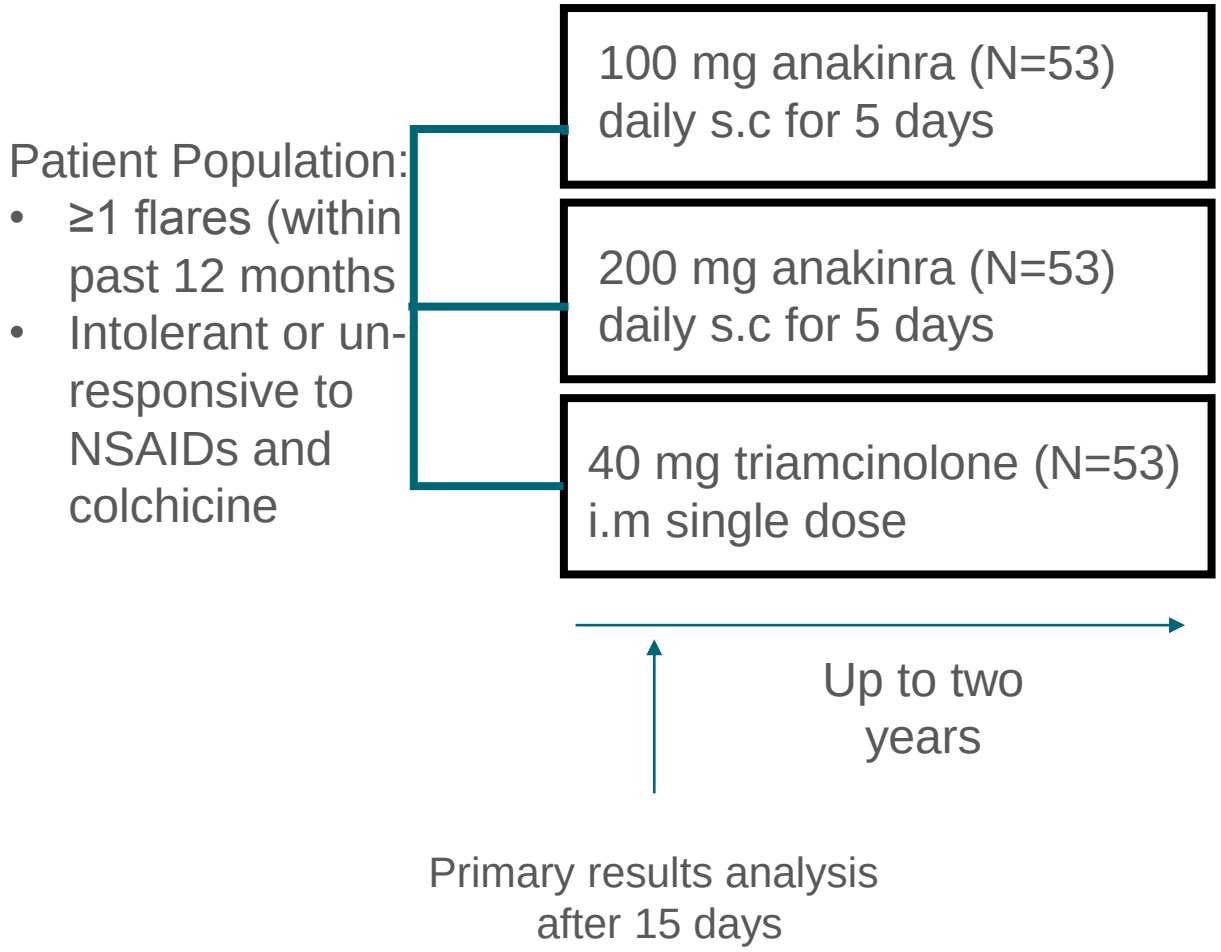


SOBI003 will be administered once weekly (i.v.)

Enrolment completed in the phase 2 study anaGO, with anakinra in patients with acute gout

Phase 2 study

- A randomized, double-blind, active-control, multicenter, efficacy and safety study of 2 dose levels of subcutaneous anakinra compared to intramuscular triamcinolone in the treatment of acute gouty arthritis, followed by an extension period of up to 2 years for treatment of subsequent flares
- Primary objective: to evaluate efficacy of anakinra compared to triamcinolone with respect to patient-assessed pain intensity in the treatment of a gouty arthritis flare (first flare in study)



Summary

Guido Oelkers

Outlook 2018[1,2] – revised

- Sobi expects total revenues for the full-year to be in the range of SEK 8,600 – 8,800 M (7,900 – 8,100)
- Gross margin is expected to be at least 70 per cent (unchanged)
- Sobi expects EBITA for the full-year to be in the range of SEK 3,400 – 3,600 M (2,800 – 3,000)

[1]At current exchange rates as of 18 July 2018
[2]The latest outlook was published on 26 April 2018

Our strategic direction

Further internationalisation
and commercialisation of Haemophilia

Build Specialty Care
as the preferred partner

Strengthen position
in the US and EMENAR

Build pipeline
and self-sustained R&D

Vision

To be recognised as a global leader in providing innovative treatments that transform lives for individuals with rare diseases

Q&A


sobi
Pioneer in Rare Diseases