

# Q3 2018 Results

31 October 2018

# AGENDA

- Introduction
- Business review
- Emapalumab
- Financials
- Summary



# PRESENTERS



**Guido Oelkers**  
Chief Executive Officer and President



**Henrik Stenqvist**  
Chief Financial Officer



**Armin Reiningger**  
Head of Medical & Scientific Affairs

# 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.*

# Q3 highlights

- Total revenues of SEK 2,315 M (1,601) in Q3 and SEK 6,568 M (4,636) YTD
- 45 per cent sales growth in the quarter compared with Q3 2017 (34 per cent at constant exchange rates (CER))
- EBITA increased by 74 per cent to SEK 933 M (536) in Q3 and 85 per cent to SEK 2,655 M (1,434) YTD
- Net cash position of SEK 2,483 M (1,472 as of 31 December 2017)
- Revenues for Elocta<sup>®</sup> and Alprolix<sup>®</sup> were SEK 873 M (417) and SEK 255 M (98) respectively for Q3<sup>1</sup>
- Kineret<sup>®</sup> revenues were SEK 347 M (272) in Q3, an increase of 28 per cent
- Orfadin<sup>®</sup> revenues were SEK 217 M (202) in Q3, an increase of 8 per cent
- Sobi strengthened inflammation franchise by acquiring the global rights to emapalumab
- First patients dosed in the phase 1/2 study with SOBI003

<sup>1</sup> Revenues as well as EBITA were positively affected by SEK 56 M, in Q3 2018, related to adjusted pharmaceutical taxes in France from 2017, whereof SEK 52 M relates to Elocta.

# Business review Q3

Guido Oelkers

# Haemophilia - capitalise on strong position and substantial potential

**Drive  
Haemophilia  
commercial  
effectiveness and  
international-  
isation**

**Expand access to patients in markets where treatment not yet available**

- ✓ Reimbursement for Alprolix gained in Sweden and Slovakia
- ✓ Portfolio with the most extensive EHL product real world experience

**Extend position in  
EMENAR**

**Achieve a leadership position in Europe, the Middle East and Africa**

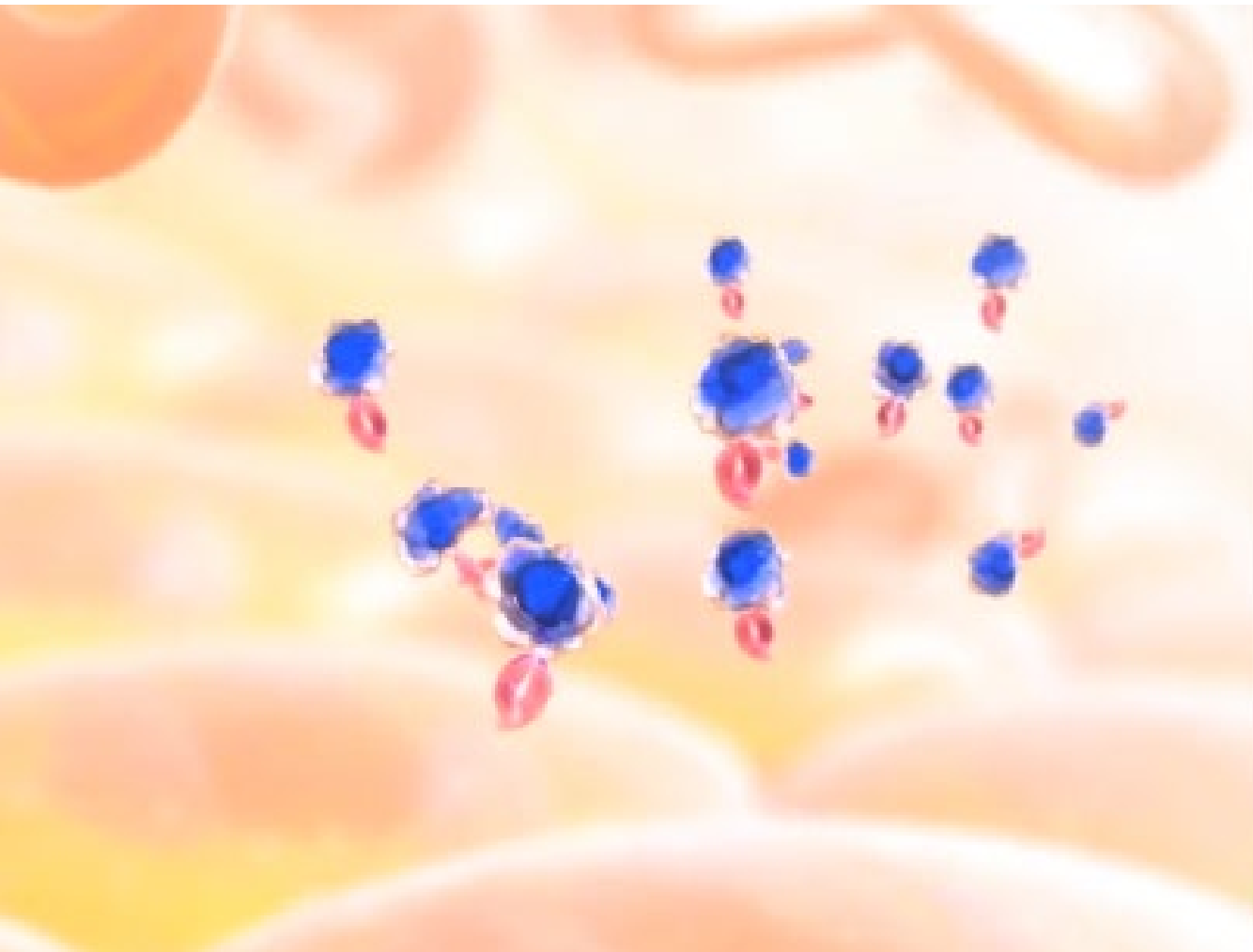
- ✓ + 12 per cent new patients on Elocta and Alprolix in Q3
- ✓ Elocta and Alprolix recognised as the standard of care in many countries

**Strengthen  
pipeline**

**Research into follow-on compounds and advancing care**

- ✓ Advancing the BIVV001 clinical programme in collaboration with Bioverativ, a Sanofi company
- ✓ Phase 3 studies demonstrate improved joint health
- ✓ Phase 4 studies ongoing to further accrue real world evidence

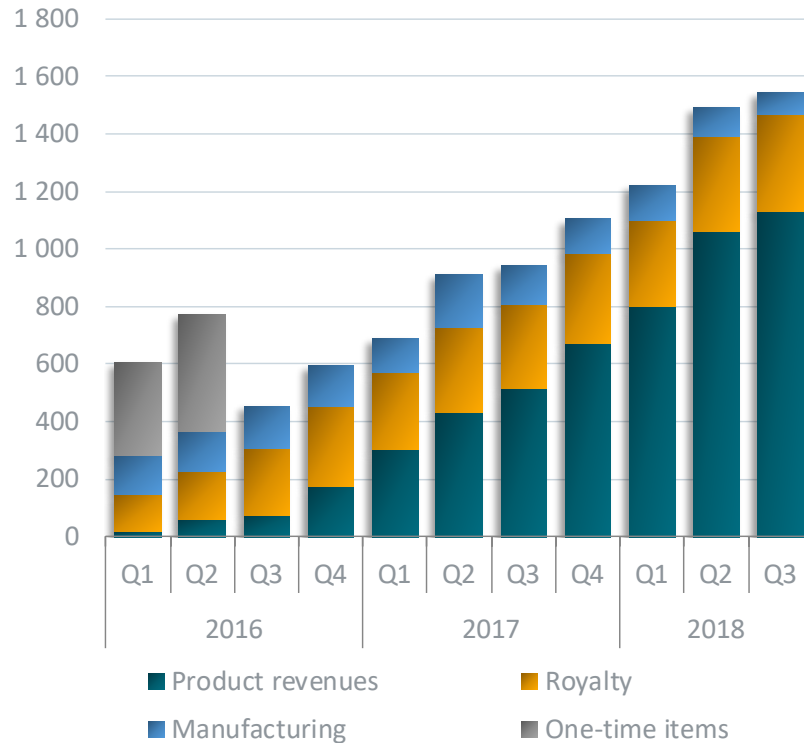
# Elocta and Alprolix – enable people with haemophilia to live well



- Well established safety and efficacy profiles - real-world experience from thousands of patients
- Replacing the missing factor – fundamental in haemophilia treatment
- Standard of care in many countries
- Suitability for all patient groups and ages and flexibility to truly match treatment to outcomes
- Creates possibilities to live an active life with less worry about the safety and effectiveness of their therapy

# Haemophilia – over SEK 1.5 Bn in revenues in Q3

## Total Revenues (SEK M)



- Q3 revenues of SEK 1,545 M (948)
- Revenue growth of 63 per cent (52 per cent increase at CER)
  - SEK 1,128 M (515) in product revenues
  - SEK 338 M (298) in royalty revenues
  - SEK 79 M (135) in manufacturing revenues



# Elocta – increasingly becoming the standard of care

## Sales Revenues (SEK M)



- Q3 product revenues of SEK 873 M<sup>1</sup> (417)
  - Revenue growth of 110 per cent (93 per cent at CER)
  - EU5 markets accounted for 76 per cent of the growth
- Reimbursed in 25 countries

<sup>1</sup> Revenues as well as EBITA were positively affected by SEK 56 M, in Q3 2018, related to adjusted pharmaceutical taxes in France from 2017, whereof SEK 52 M relates to Elocta.

# Alprolix – continued strong patient conversion

## Sales Revenues (SEK M)



- Q3 product revenues of SEK 255 M (98)
  - Revenue growth of 161 per cent (140 per cent at CER)
  - 77 per cent of the growth derived from France, Germany, Italy and the UK
- Reimbursed in 18 countries

# Specialty Care - Acquisitions to further drive growth

## Develop Specialty Care

### **World-class commercialisation platform**

- ✓ Launches for Ravicti and Kineret for the treatment of Still's disease continued during the quarter

## Expand US business and extend position in EMENAR

### **Active strategic partnership management in order to continuously introduce novel therapies into our key markets: moving from distribution to ownership**

- ✓ The acquisition of the global rights to emapalumab strengthen Specialty care franchise and US presence

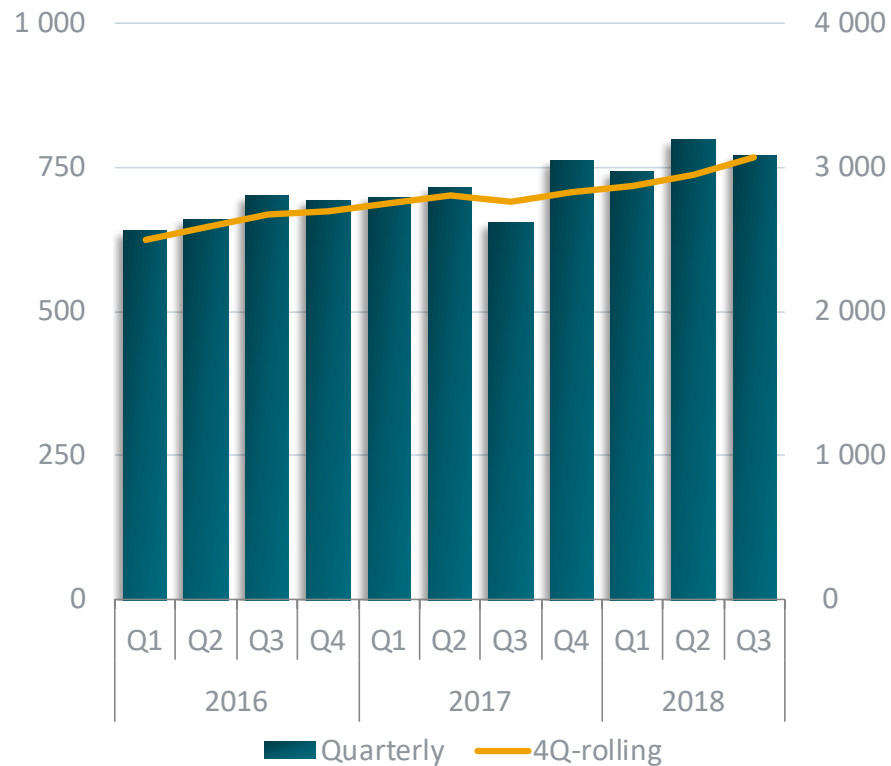
## Strengthen pipeline

### **Expand portfolio by strengthening R&D pipeline and business development efforts in order to further drive growth of the Specialty Care business**

- ✓ The acquisition of the global rights to emapalumab strengthen pipeline
- Lifecycle management & indication expansion**
- ✓ New indications for Kineret: Still's and gout

# Specialty Care - solid performance across portfolio

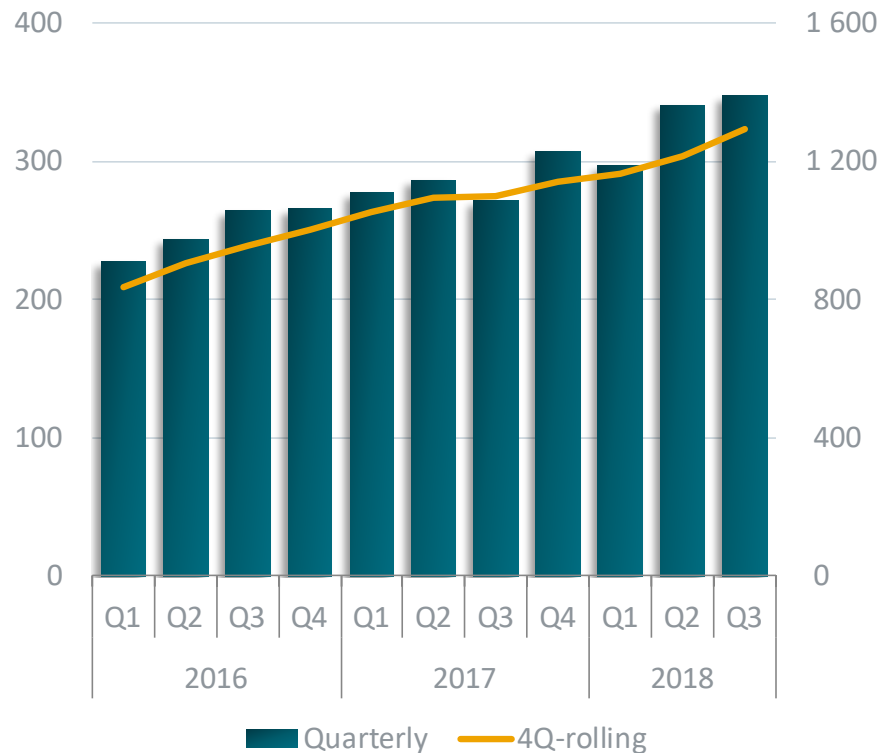
## Sales Revenues (SEK M)



- Q3 revenues SEK 770 M (653)
  - Revenue growth of 18 per cent (8 per cent at CER)

# Kineret – new indications drive growth

## Sales Revenues (SEK M)



- Q3 revenues SEK 347 M (272)
  - Revenue growth of 28 per cent (17 per cent at CER)
- Continued solid growth across NA and EMENAR
- Stable double-digit growth across EU5 and Turkey
- Commercial launch for Kineret Still's disease ongoing
- Primary efficacy results from anaGO, the phase 2 study of anakinra in patients with acute gout, were released

# Orfadin – continued solid performance

## Sales Revenues (SEK M)



- Q3 revenues SEK 217 M (202)
  - Revenue growth of 8 per cent (decrease of -2 per cent at CER)
- The first generics have entered the market, however the impact was not material

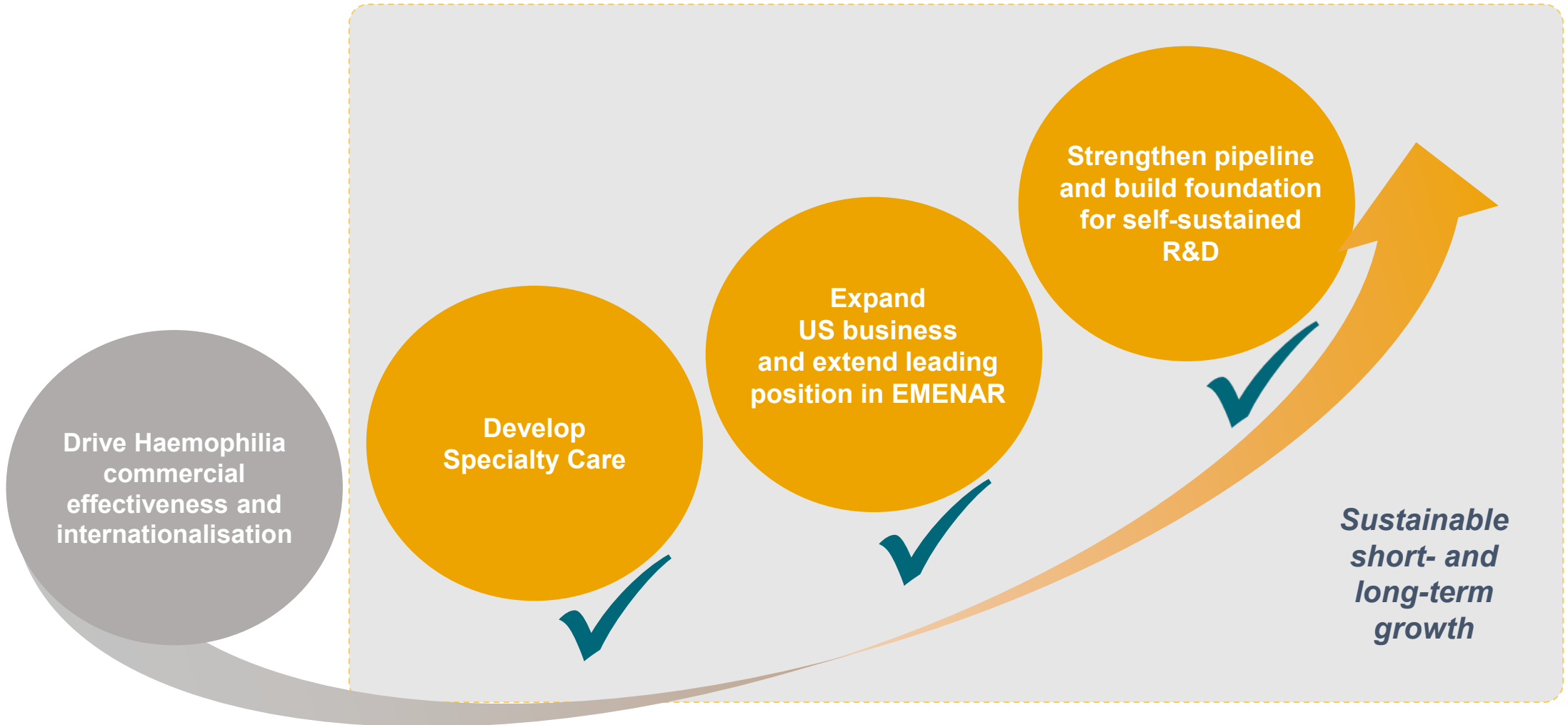
# Emapalumab – a strategic deal

# Sobi licenses emapalumab from Novimmune

- Progress toward becoming a global leader in rare diseases
  - Builds Specialty Care and strengthens immunology focus
  - Increases US footprint
  - Bolsters R&D pipeline
- Emapalumab in review for rare disease primary haemophagocytic lymphohistiocytosis (HLH)
  - FDA approval expected H2 2018
  - MAA filing to EMA validated Aug 2018
- Purchase price of CHF 450 M (CHF 50 M cash upon signing)
- The license agreement to emapalumab is expected to add of around SEK 200 M to the Sobi cost base in 2018.



# Emapalumab – a product that is right on our strategic focus



# Emapalumab

## Fully human monoclonal antibody that targets IFN-gamma, a central mediator of inflammation

- Strategic partnership to develop and commercialise emapalumab, a highly attractive late stage orphan drug candidate that addresses a high unmet medical need in Haemophagocytic lymphohistiocytosis (HLH)
- Targets HLH, a rare, life-threatening syndrome of extreme immune activation (cytokine storm)
- Near-term commercial opportunity with sales potential from 2019 onwards

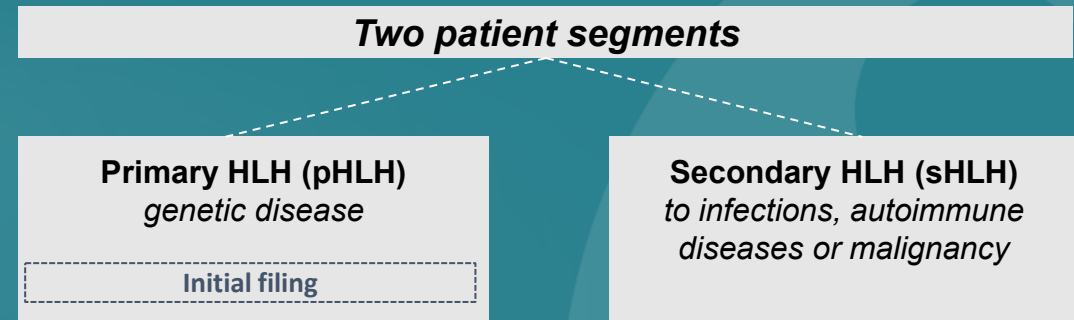


# Haemophagocytic lymphohistiocytosis (HLH)

HLH is a rare and life-threatening syndrome of extreme immune activation

## High unmet medical need

- Fatal with median survival of <2 months without treatment
- No approved drug treatments
- Current widely accepted treatment protocols apply a combination of dexamethasone and chemo-immunotherapy (incl. etoposide)



**ca. 5,000+**

Patients in the  
US, EU and Japan  
(primary and  
secondary HLH)

# The transaction is an excellent fit with our strategy

## Develop Specialty Care

- ✓ Late stage orphan drug, in the area of inflammation, addressing a high unmet medical need
- ✓ Provides an attractive near-term commercial opportunity with USD 300 M peak sales potential
- ✓ Expected to support sustainable sales growth from 2019 onwards

## Expand US business and extend position in EMENAR

- ✓ Sobi to gain full global rights to emapalumab
- ✓ Utilises Sobi's strengths in market access and product launch
- ✓ US expansion – Potential to double Sobi's sales in the US market
- ✓ BLA filed with FDA in March 2018

## Strengthen pipeline and build foundation for self-sustained R&D

- ✓ Currently planning studies in follow-on indications

# Emapalumab will be a catalyst for creating a strong Immunology franchise in Specialty Care

## Haemophilia



**ELOCTA**<sup>®</sup> ▼  
efmoroctocog alfa  
(recombinant human coagulation factor VIII, Fc fusion protein)

**ALPROLIX**<sup>®</sup> ▼  
eftrenonacog alfa  
(recombinant human coagulation factor IX, Fc fusion protein)

## Specialty Care

### Immunology



**Emapalumab**

**Kineret**<sup>®</sup>  
(anakinra)

### GenMet/ Other



**Orfadin**<sup>®</sup>  
nitisinone

**RAVICTI**<sup>®</sup>  
(glycerol phenylbutyrate) Oral Liquid

**XIAPEX**<sup>®</sup>  
collagenase clostridium histolyticum

# Pipeline October 2018 – continuous expansion of possible indications

HAEMOPHILIA

SPECIALTY CARE

Therapeutic area / Indication	Product / Project	Pre-clinical	Phase 1	Phase 2	Phase 3	Phase 4
Haemophilia A	Elocta/A-SPIRE <sup>1</sup>				█	●
Haemophilia A	Elocta/PUP <sup>1,2</sup>				█	
Haemophilia A	BIVV001 <sup>3</sup> /EXTEN-A		█			●
Haemophilia A	Elocta/ASURE					█
Haemophilia A	Elocta/reITrate					█
Haemophilia A	Elocta/verIT18					█
Haemophilia A and B	Elocta/Alprolix/PREVENT					█
Haemophilia B	Alprolix/B-YOND <sup>1</sup>				█	
Haemophilia B	Alprolix/PUP <sup>12</sup>				█	
Haemophilia B	BIVV002 <sup>3</sup> /EXTEN-B	█				
Primary HLH	Emapalumab				█	●
Secondary aHLH	Emapalumab			█		●
Acute gout	Anakinra/anaGO			█		●
Still's disease	Anakinra/anaSTILLS				█	
Alkaptonuria	Nitisinone/SONIA2				█	
MPSIIIA	SOBI003		█			●
Anti-C5	SOBI005	█				
Anti-IL-1	SOBI006	█				

Interim data published in *Haemophilia* show improvements in long-term joint health for haemophilia A patients after prophylactic treatment with Elocta. (30 Oct 2017)

Preliminary safety and pharmacokinetic data showed that a single low dose of BIVV001 extended the half-life of factor VIII to 37 hours with high factor activity levels and was generally well tolerated. (21 May 2018, presented at WFH by Bioverativ, a Sanofi company)

Sobi acquired the global rights to emapalumab from Novimmune. (20 July 2018)

Primary efficacy results from the phase 2 study anaGO released. ( 2 Oct 2018)

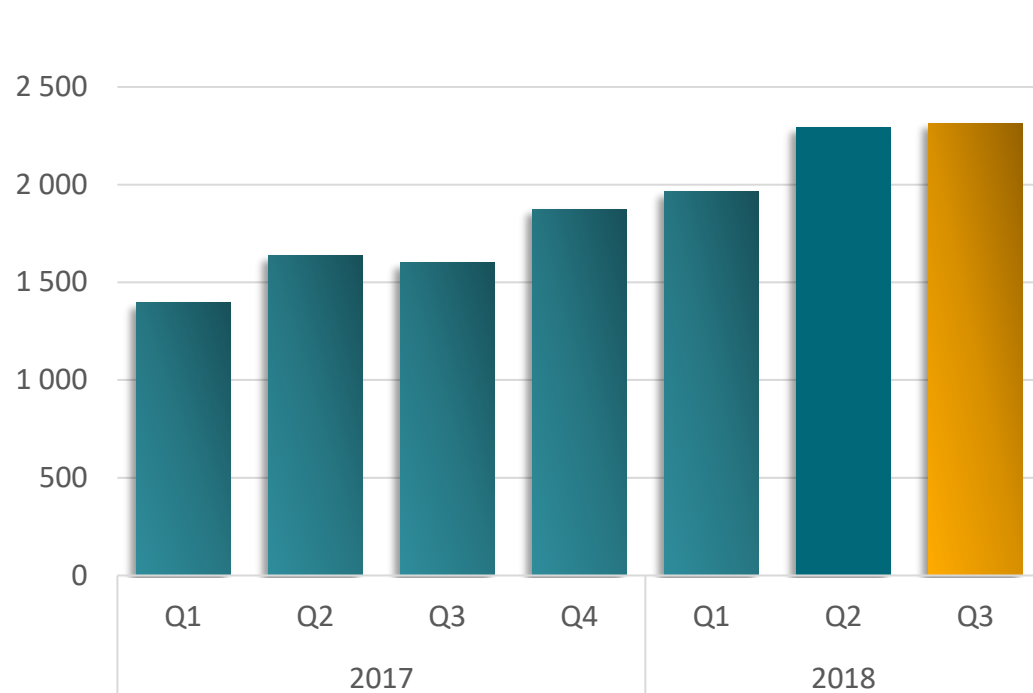
First patient dosed in the phase 1/2 study with SOBI003. (10 Aug 2018)

# Financial results

Henrik Stenqvist

# Financial highlights Q3 2018

## Total Revenue (SEK M)



	Q3 2018	Q3 2017	Change (%)	Jan-Sep 2018	Jan-Sep 2017	Change (%)
Revenues (SEK M)	2,315	1,601	+45	6,568	4,636	+42
Gross margin	75%	70%		74%	72%	
EBITA (SEK M)	933	536	+74	2,655	1,434	+85
EBITA margin	40%	33%		40%	31%	
Cash flow from operations (SEK M)	712	580	+23	1,553	1,076	+44



# Profit & loss statement

<i>Amounts in SEK M</i>	Q3 2018	Q3 2017	Jan-Sep 2018	Jan-Sep 2017	Full-year 2017
<b>Total revenues</b>	<b>2,315</b>	<b>1,601</b>	<b>6,568</b>	<b>4,636</b>	<b>6,511</b>
Total cost of goods and services sold	-574	-473	-1,738	-1,316	-1,854
<b>Gross profit</b>	<b>1,741</b>	<b>1,129</b>	<b>4,830</b>	<b>3,320</b>	<b>4,657</b>
<i>Gross margin</i>	<i>75%</i>	<i>70%</i>	<i>74%</i>	<i>72%</i>	<i>72%</i>
Sales and administrative expenses before amortisation and write-downs	-509	-371	-1,425	-1,167	-1,644
Research and development expenses	-287	-214	-762	-679	-908
Other operating revenue/expenses	-12	-8	12	-40	-52
<b>EBITA</b>	<b>933</b>	<b>536</b>	<b>2,655</b>	<b>1,434</b>	<b>2,053</b>
<i>EBITA margin</i>	<i>40%</i>	<i>33%</i>	<i>40%</i>	<i>31%</i>	<i>32%</i>
Amortisation and write-downs	-113	-110	-335	-342	-453
<b>EBIT</b>	<b>820</b>	<b>426</b>	<b>2,320</b>	<b>1,092</b>	<b>1,600</b>
Financial income/expenses	-13	-17	-17	-53	-68
<b>Profit before tax</b>	<b>807</b>	<b>409</b>	<b>2,303</b>	<b>1,038</b>	<b>1,532</b>
Income tax expense	-183	-85	-480	-247	-384
<b>Profit for the period</b>	<b>623</b>	<b>324</b>	<b>1,823</b>	<b>791</b>	<b>1,149</b>

# Balance sheet

<i>Amounts in SEK M</i>	Sep 2018	Dec 2017	Sep 2017		Sep 2018	Dec 2017	Sep 2017
<b>Assets</b>				<b>Equity and liabilities</b>			
Intangible assets	10,242	6,445	6,535	Shareholders' equity	8,499	6,701	6,352
Tangible and financial assets	362	301	277	Long-term liabilities	4	5	503
<b>Total non-current assets</b>	<b>10,604</b>	<b>6,746</b>	<b>6,812</b>	Long-term liabilities, non-interest bearing	1,213	1,832	1,880
Inventories	1,174	1,053	1,095	<b>Total long-term liabilities</b>	<b>1,217</b>	<b>1,838</b>	<b>2,283</b>
Accounts receivable	1,511	1,129	941	Current liabilities	1	2	2
Other current receivable	488	496	469	Current liabilities, non-interest bearing	6,548	2,363	2,339
Cash and cash equivalent	2,488	1,478	1,758	<b>Total current liabilities</b>	<b>6,550</b>	<b>2,365</b>	<b>2,341</b>
<b>Total current assets</b>	<b>5,662</b>	<b>4,157</b>	<b>4,263</b>	<b>Total equity and liabilities</b>	<b>16,266</b>	<b>10,903</b>	<b>11,075</b>
<b>Total asset</b>	<b>16,266</b>	<b>10,903</b>	<b>11,075</b>				

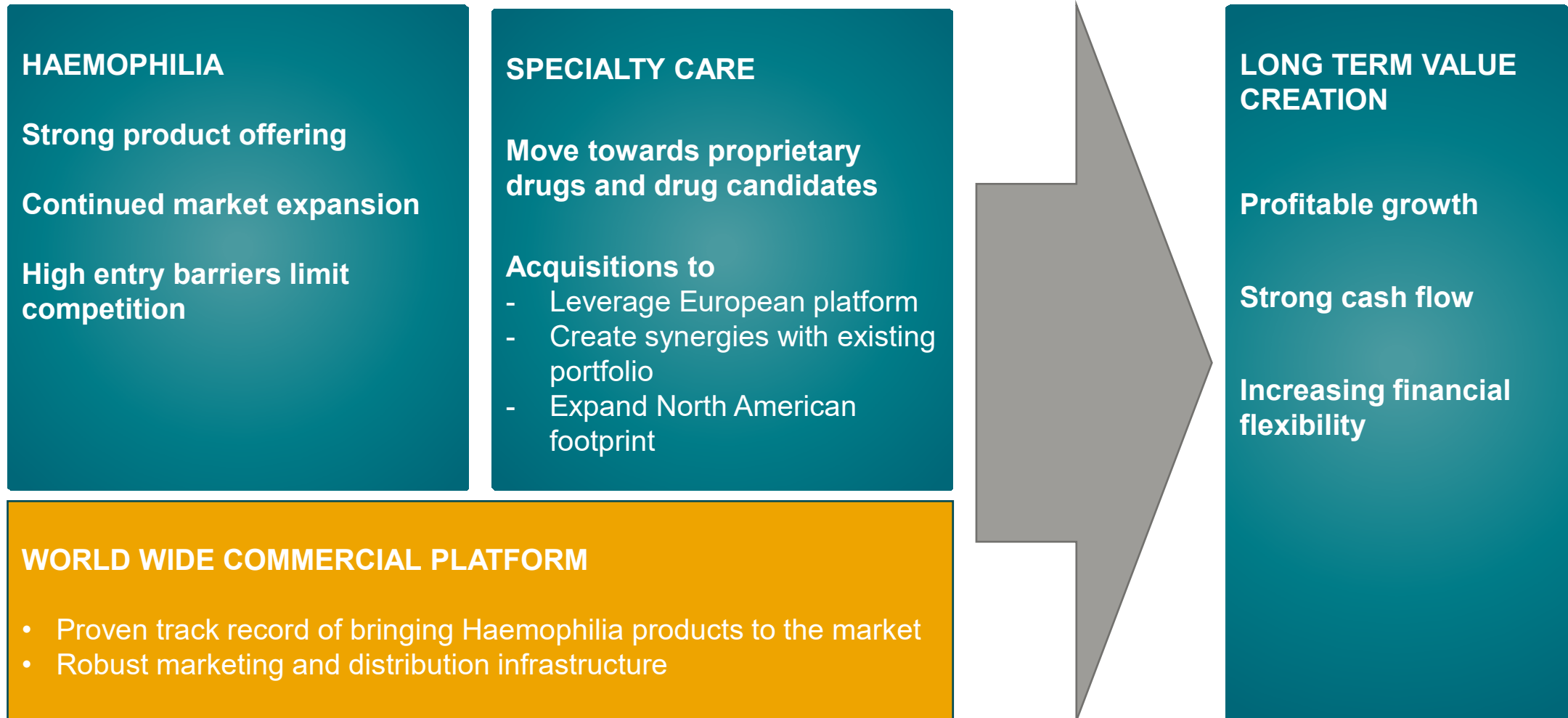
# Summary

Guido Oelkers

# Strategic direction



# Strong growth and positive outlook in the rare disease market segment



# Outlook 2018 - revised

- Sobi expects total revenues for the full year to be in the range of SEK 8,900 - 9,000 M (8,600 - 8,800)
- The gross margin is expected to be in the range of 73 - 74 per cent (at least 70)
- Sobi expects EBITA for the full year to be in the range of SEK 3,400 - 3,500 M (3,400 - 3,600), including development and commercialisation costs for emapalumab of around SEK 200 M

# Q&A



Pioneer in Rare Diseases