



**Geoffrey McDonough, CEO**  
**Mats-Olof Wallin, CFO**

28 April 2017

# Q1 results presentation 2017

# Forward looking statements



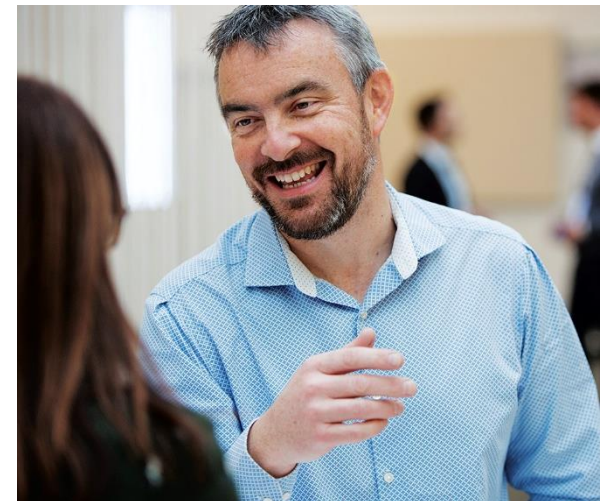
*In order to utilize the 'Safe Harbor' provisions of the United States Private Securities Litigation Reform Act of 1995, Swedish Orphan Biovitrum is providing the following cautionary statement. This presentation contains forward-looking statements with respect to the financial condition, results of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



# Business highlights Q1 2017



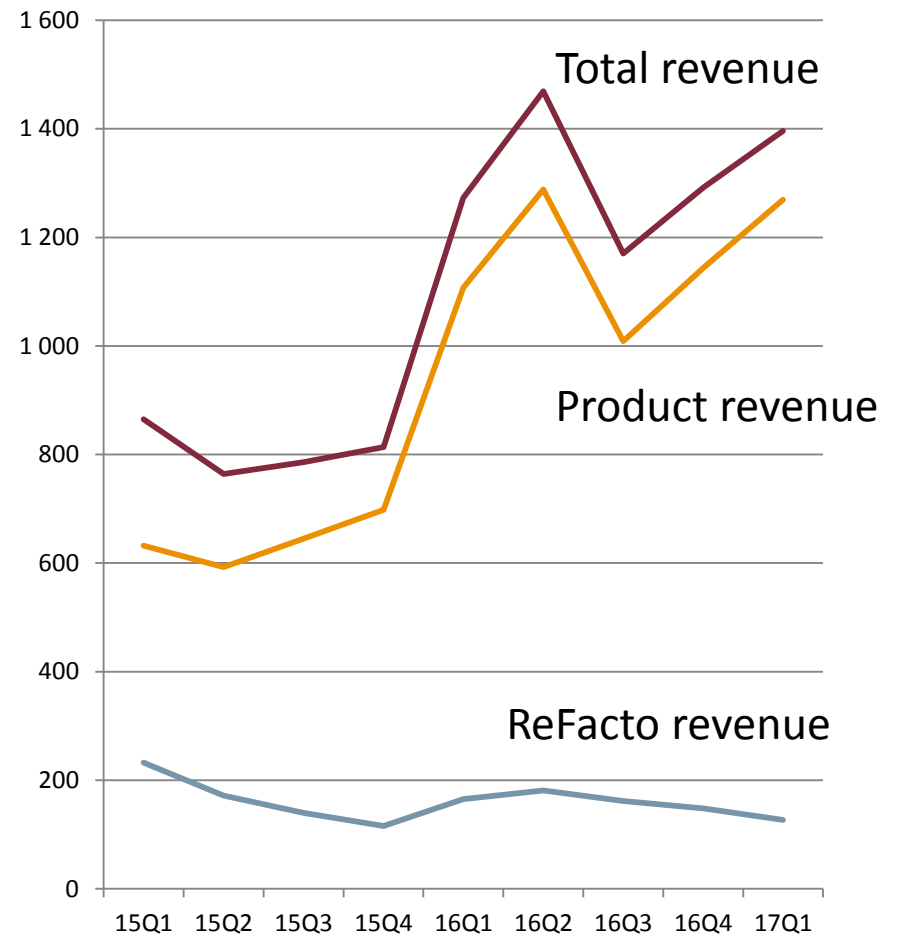
- First patients enrolled in a 24 month real-world study for Elocta®
- EMA approved higher capacity Elocta drug substance manufacturing
- New data for Alprolix® published in *Lancet Haematology* and in *Thrombosis and Haemostasis*
- Haemophilia B development portfolio expanded by adding rF9Fc-XTEN for subcutaneous injection to the collaboration agreement with Bioverativ
- Health Canada approved Orfadin® capsules for the treatment of hereditary tyrosinaemia type-1 (HT-1)
- EC approved new dosing frequency for Orfadin®
- First patient randomised in the Kineret (anakinra) phase 2 study, anaGo
- New distribution agreement signed for Ammonul®



# Financial highlights Q1 2017



- Total revenue: SEK 1,396 M (1,273)  
10% growth (6% at CER)
- Product revenue: SEK 1,269 M (1,108)  
15% growth (10% at CER)
- ReFacto revenue: SEK 127 M (165)
- Gross margin: 74% (74%)
- EBITA: SEK 406 M (502)
- Cash flow operations: SEK 324 M (235)

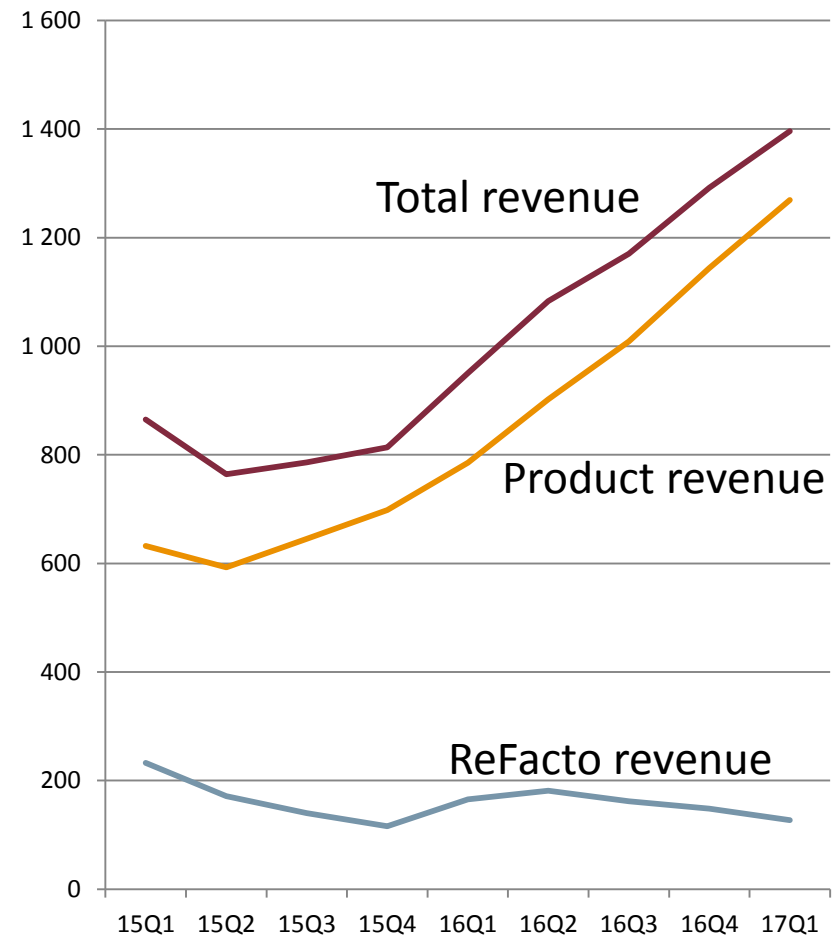


# Financial highlights Q1 2017

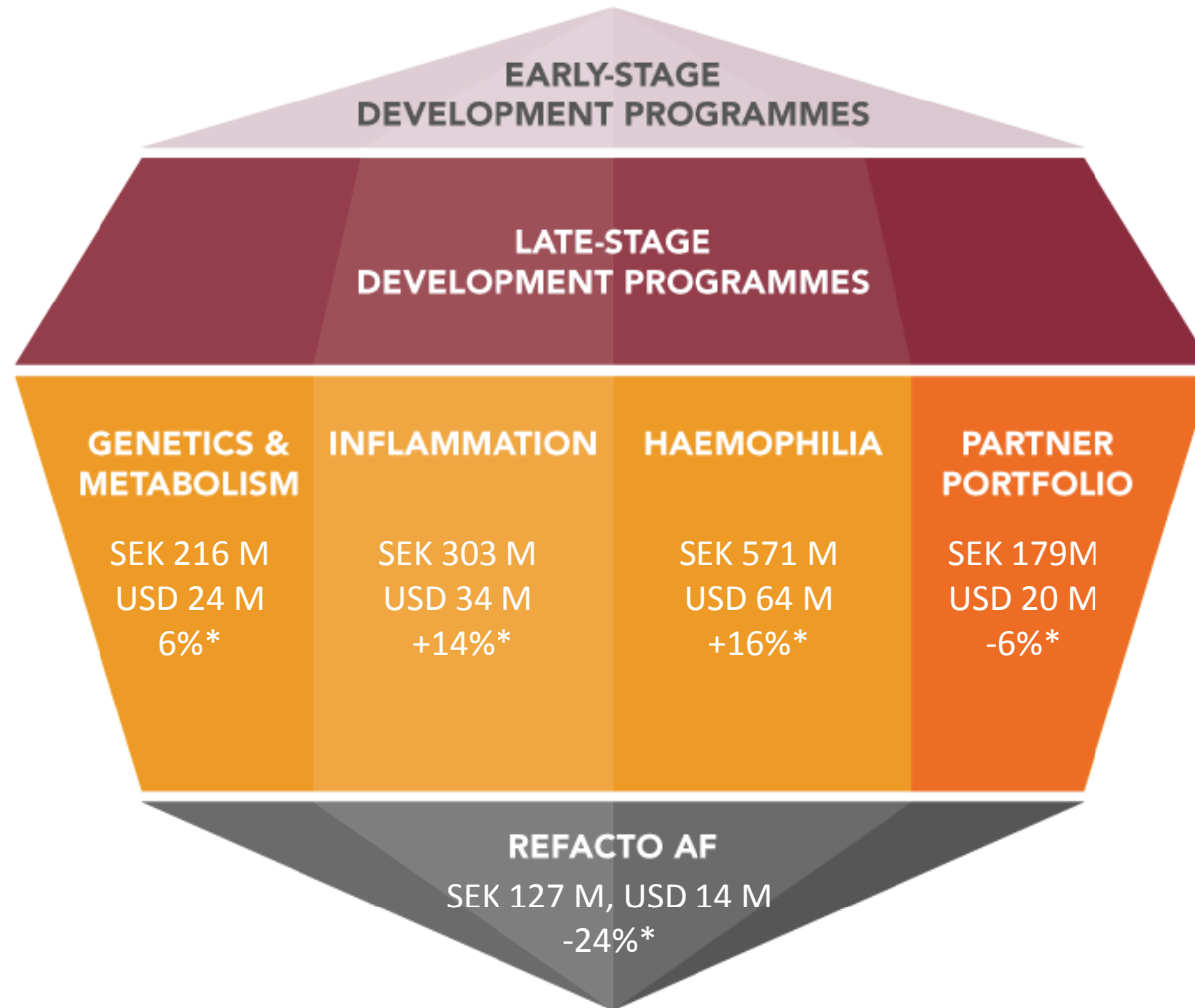


(adjusted for one-time inventory release Q1 2017 and credit in Q1 2016)

- Sales: SEK 1,396 M (951)
  - Increase of 47%
  - Excludes one-time credit SEK 322 M
- Product revenue: SEK 1,269 M (786)
  - Increase of 61%
  - Excludes one-time credit SEK 322 M
- Gross margin: 69% (65%)
  - Excludes one-time inventory release SEK 59 M
- EBITA: SEK 406 M (180)
- Cash flow operations: SEK 324 M (235)



# Revenues by business line Q1 2017



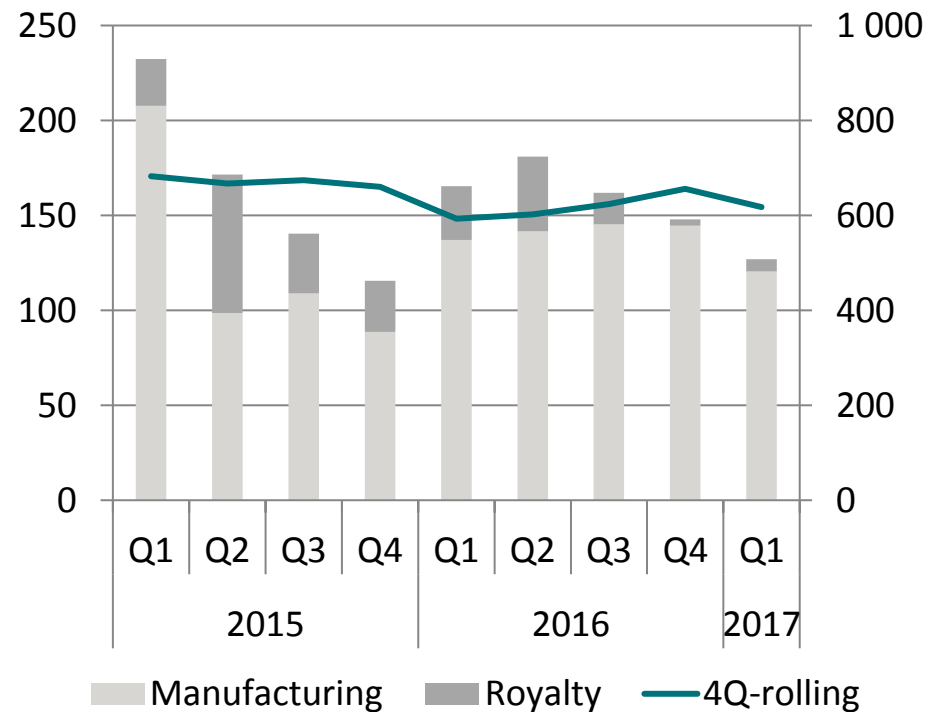
\*Growth at Constant Exchange Rates  
USD 1 = SEK 8,9229 (average year rate)

# ReFacto



- Revenue for manufacturing and royalty SEK 127 M (165)
  - decrease of 23%
- Manufacturing revenue SEK 121 M (137)
- Royalty revenue SEK 6 M (28)
  - Royalty to Sobi from ReFacto AF sales outside of the US ceased 1 June 2016

Revenues (SEK M): ReFacto



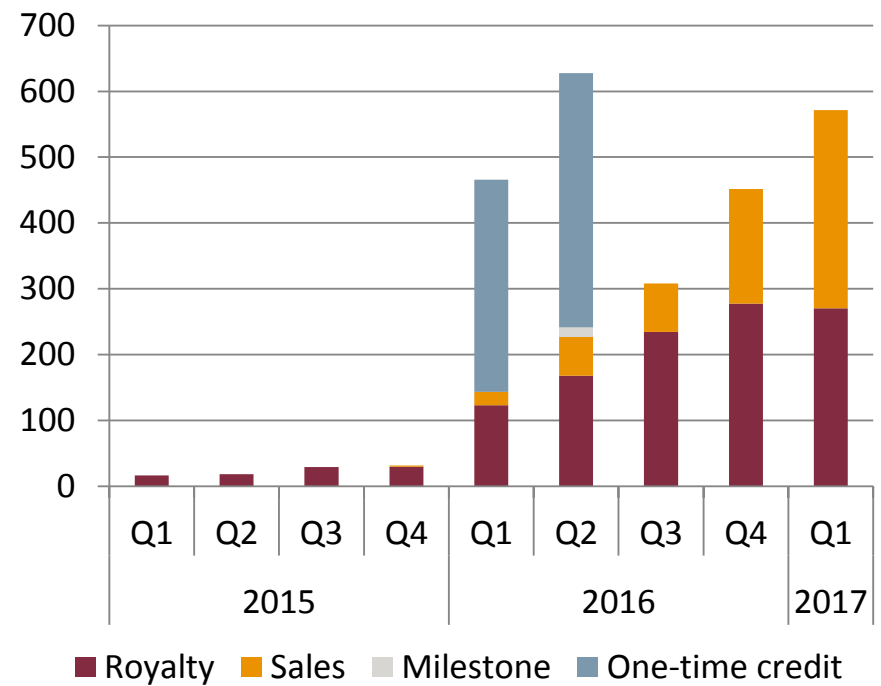
# Commercial results Q1 2017



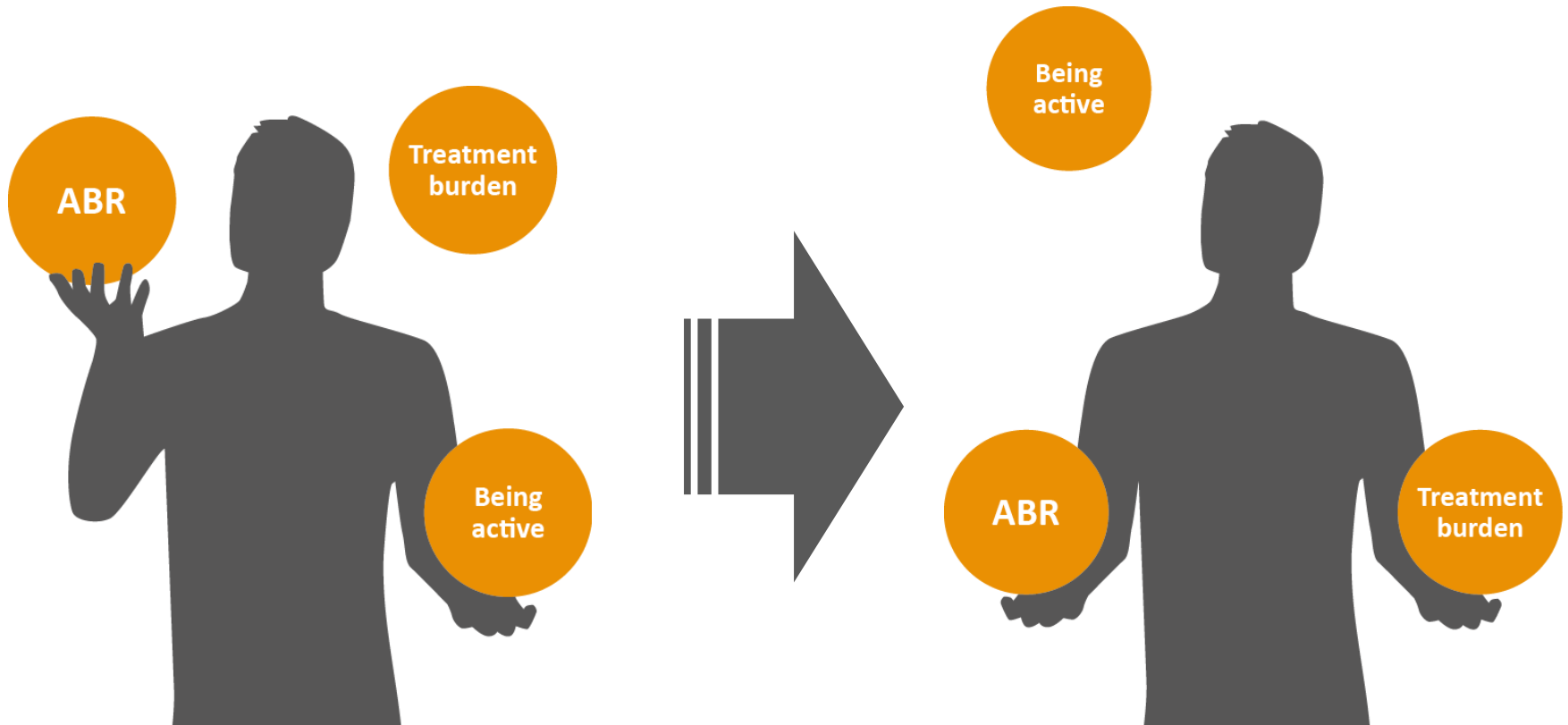
# Haemophilia

- Total revenue SEK 571 M (466)
  - SEK 300 M (20) in sales
- SEK 270 M (445) in estimated royalty revenue

**Royalty and Sales Revenues (SEK M):  
Haemophilia**



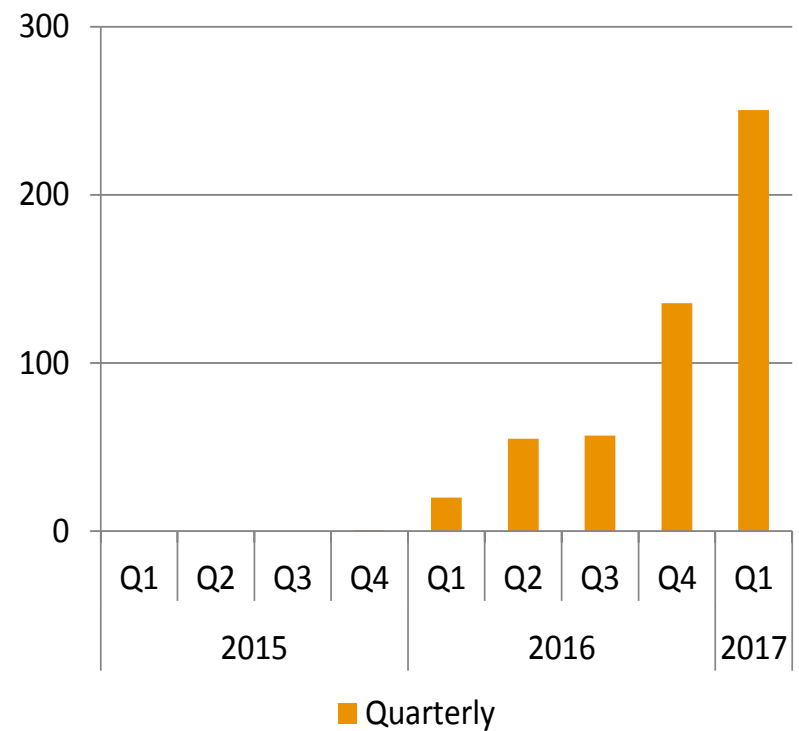
# Redefining protection in Haemophilia



Adapted from Oldenburg J. *Blood* 2015.<sup>1</sup>

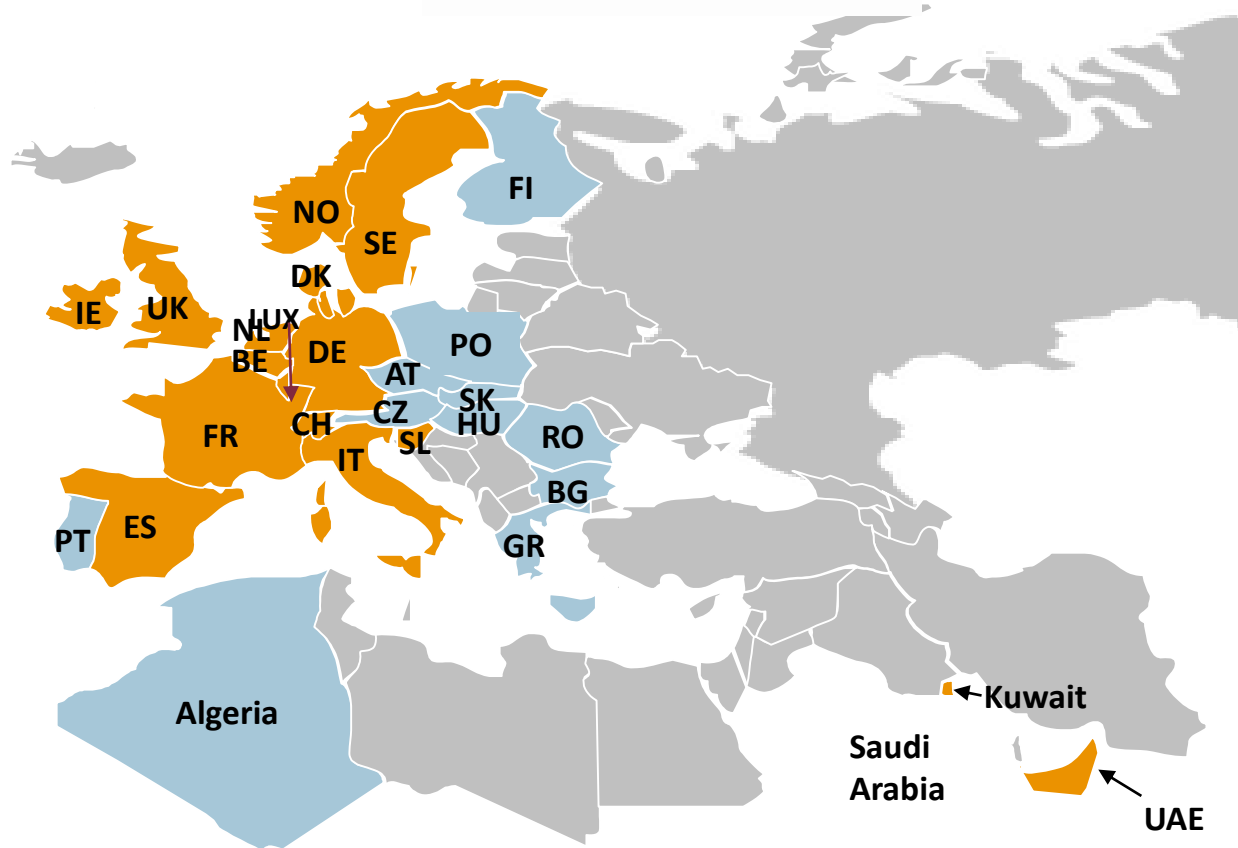
- Sales revenue SEK 250 M (20)
  - Increase of 85% compared to Q4 2016
  - Derived mainly from France, UK, Germany and Italy
  - Now reimbursed in 16 countries



**Sales Revenues (SEK M): Elocta**



# Elocta launch update

March 2017



-  Reimbursement granted – treatment available
-  Pricing & reimbursement decision-making in process

# Sobi and Bioverativ to investigate Elocta/ ELOCTATE for Immune Tolerance Induction in 2017



## 'First ITI attempt' Study

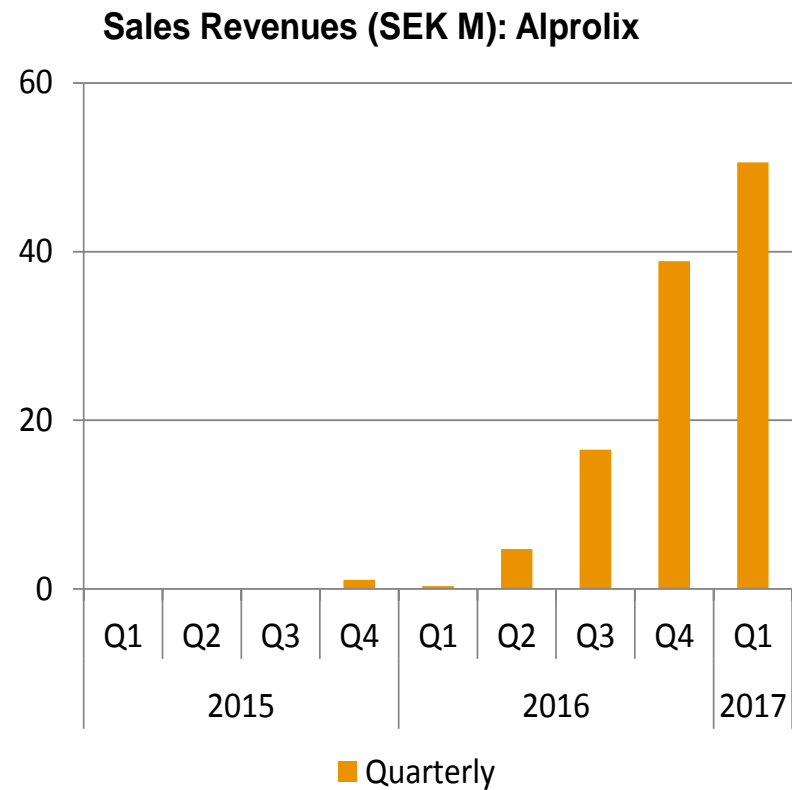
**Objective:** To investigate rFVIII Fc for ITI in patients with severe haemophilia A with inhibitors undergoing ITI for the first time

## 'Rescue ITI' Study

**Objective :** To investigate rFVIII Fc for ITI in patients with severe haemophilia A with inhibitors who have failed previous ITI therapies

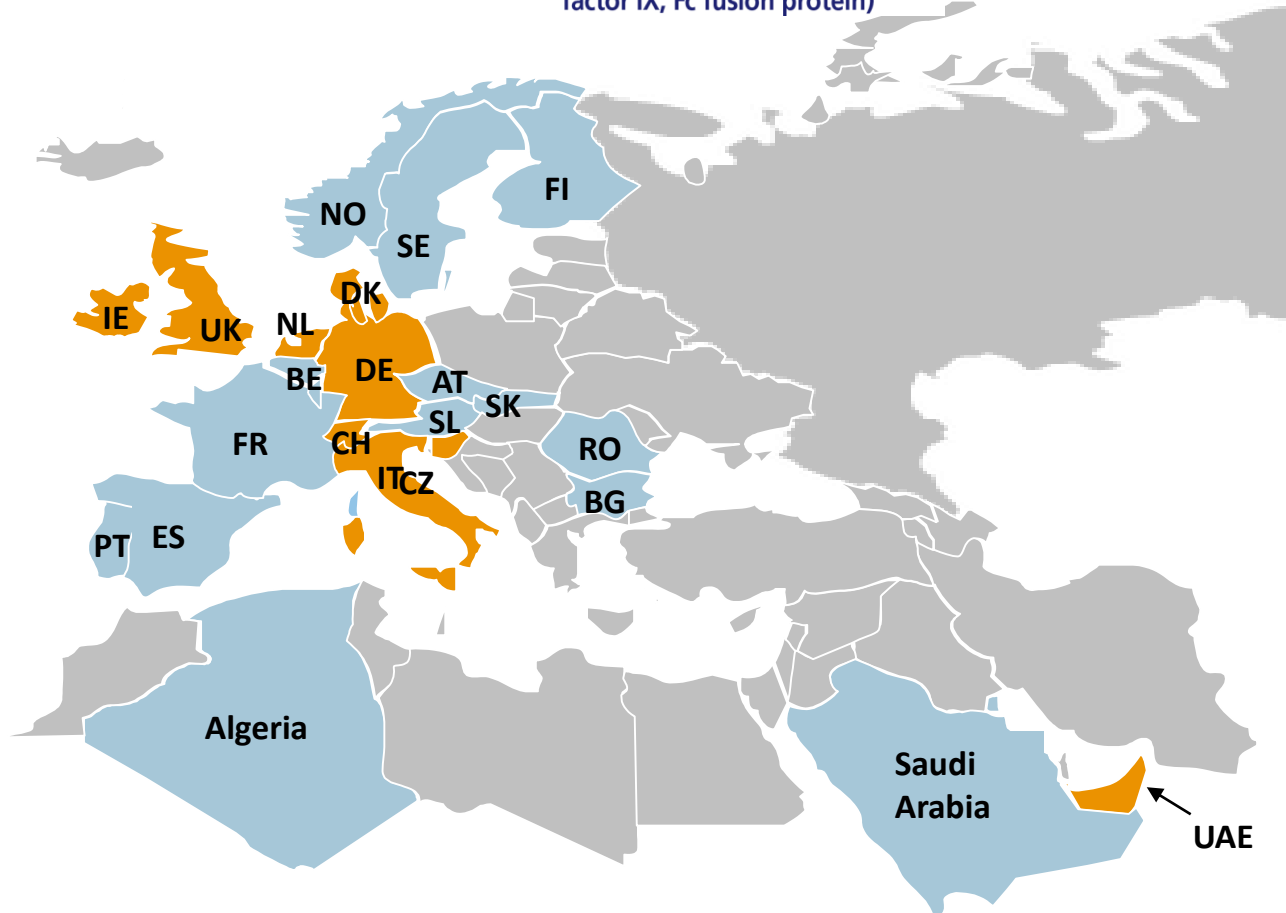
**Both studies expected to start in mid-2017**

- Sales revenue SEK 50 M (0)
  - Increase of 28% compared to Q4 2016
  - Derived mainly from Germany, UK and Switzerland
  - Reimbursed in 8 countries



# Alprolix launch update

March 2017

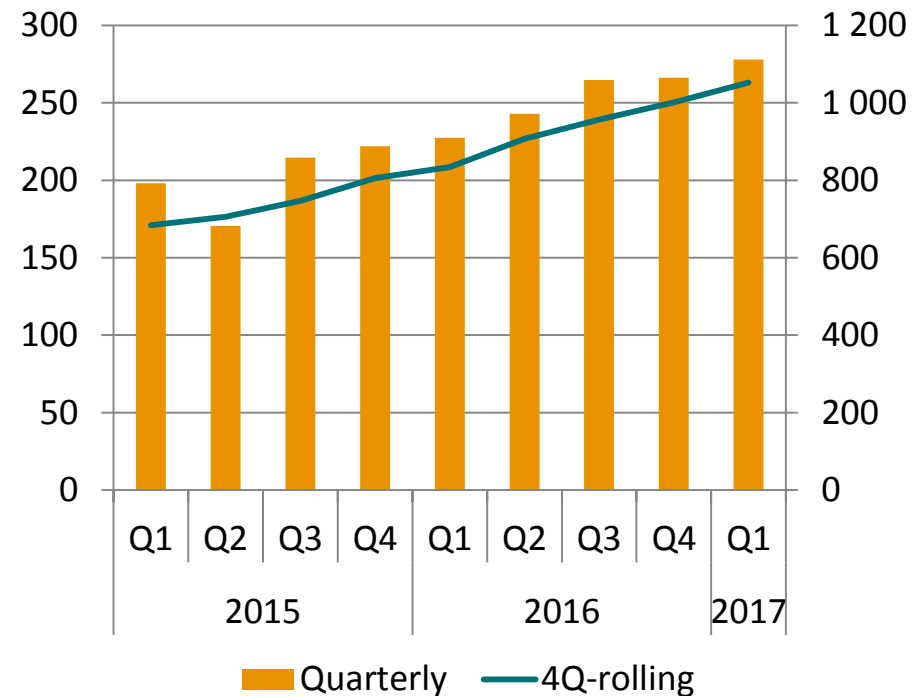


- Reimbursement granted – treatment available
- Pricing & reimbursement decision-making in process

# Kineret

- Revenue SEK 277 M (227)
  - Increase of 22%
- Growth driven by
  - Implementation of new US patient support program
  - EMENAR highlights were Turkey, France, Germany and Italy
- First patient randomised in the phase 2 study anaGO, to evaluate efficacy and safety of Kineret (anakinra) for the treatment of acute gout

Revenues (SEK M): Kineret



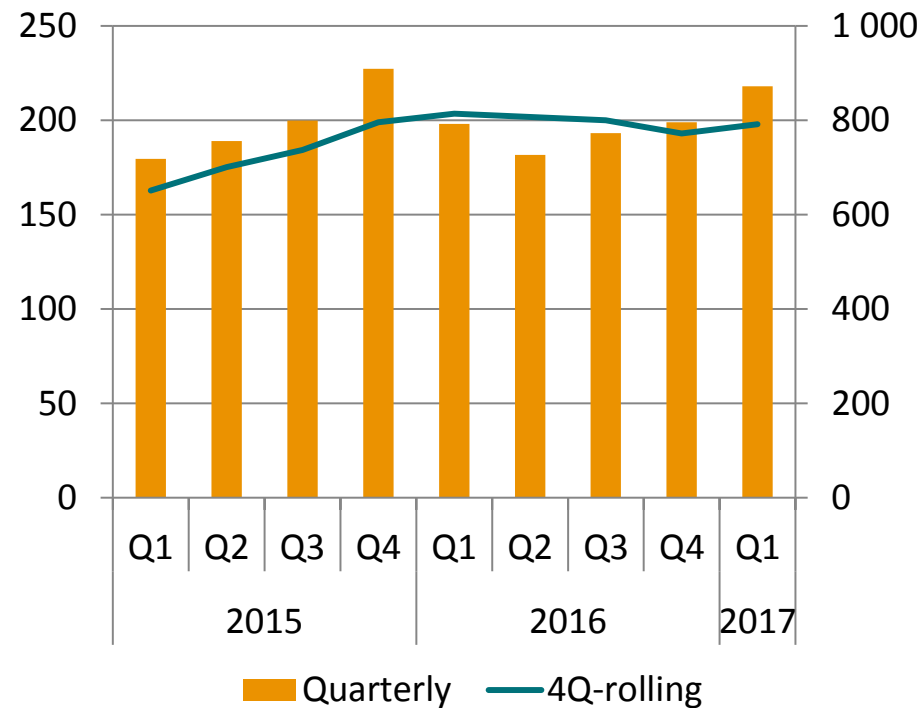


# Orfadin



- Revenue SEK 216 M (198)
  - increase of 9%
- North America
  - Performance in the US supported by 20 mg and oral suspension launches
- In-use storage at room temperature approved by the FDA
- Once daily dosing frequency approved by the EC

Revenues (SEK M): Orfadin

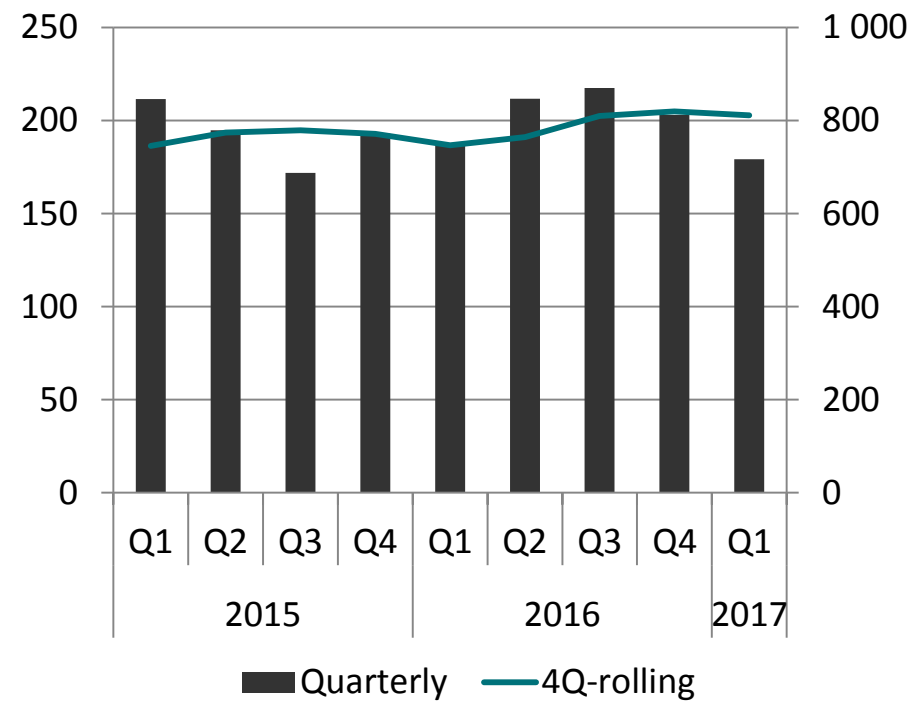


# Partner Products



- Revenue SEK 179 M (187 M)
  - Decrease of 5%
  - Due to Ammonul and Ravicti phasing
- Consistent base business growth led by Xiapex
  - Overall portfolio growing 4%
- Divestment discussions ongoing

Revenues (SEK M): Partner Products



# Financial results Q1 2017

Mats-Olof Wallin

# Profit & loss statement



<i>Amounts in SEK M</i>	Q1-17	Q1-16	FY 2016
<b>Total revenues</b>	<b>1,396</b>	<b>1,273</b>	<b>5,204</b>
<b>Gross profit</b>	<b>1,028</b>	<b>944</b>	<b>3,651</b>
<i>Gross Margin</i>	<i>74%</i>	<i>74%</i>	<i>70%</i>
Sales and Administration	-382	-315	-1,366
Research and development	-218	-138	-778
Other operating revenues/expenses	-21	11	36
<b>EBITA</b>	<b>406</b>	<b>502</b>	<b>1,543</b>
Amortizations and write-downs	-122	-92	-410
<b>EBIT</b>	<b>284</b>	<b>409</b>	<b>1,133</b>
Financial income/expenses	-15	-23	-85
<b>Profit before tax</b>	<b>269</b>	<b>387</b>	<b>1,048</b>
Income tax expense	-74	-86	-239
<b>Profit/loss for the period</b>	<b>196</b>	<b>301</b>	<b>809</b>

Adjusted gross margin  
69% (65%) excluding  
one-time events:

- Inventory adjustment of SEK 59 M in Q1 2017
- Credit of SEK 322 M in Q1 2016.

*\*one-time adjustment to inventory due to delayed release of Kineret drug substance manufactured in 2016*

# Balance sheet



<i>Amounts in SEK M</i>	<b>Mar 2017</b>	<b>Dec 2016</b>	<b>Mar 2016</b>
<b>ASSETS</b>			
Intangible	6,747	6,806	5,661
Tangible and other	281	257	198
<b>Total non-current assets</b>	<b>7,028</b>	<b>7,063</b>	<b>5,858</b>
Inventories	988	870	810
Accounts receivable	888	769	505
Other Receivable	396	487	260
Cash and equivalent	1,032	786	1,108
<b>Total current assets</b>	<b>3,304</b>	<b>2,911</b>	<b>2,684</b>
<b>Total Asset</b>	<b>10,332</b>	<b>9,974</b>	<b>8,542</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>	<b>5,592</b>	<b>5,354</b>	<b>4,987</b>
Long term debt	502	502	802
Long term liabilities	2,216	2,360	1,491
Short term liabilities	2,022	1,758	1,263
<b>Total liabilities</b>	<b>4,740</b>	<b>4,620</b>	<b>3,555</b>
<b>Total equity and liabilities</b>	<b>10,332</b>	<b>9,974</b>	<b>8,542</b>

# Summary

Geoffrey McDonough, CEO

# Outlook 2017\*



## Revenues

Sobi expects total revenues for the full year to be in the range of SEK 5,800 to 6,000 M

## Gross margin

Gross margin is expected to be in the range of 66 to 68 per cent

## EBITA

Sobi expects EBITA for the full year to be in the range of SEK 1,600 to 1,700 M

\*The outlook was first published on 16 February 2017 and is based on the exchange rate as of that date.

# Building our future

Strong focus on our business and capabilities within rare diseases

1. Diverse, growing, and profitable base business in Europe and North America focused on rare diseases
2. Launching first-to-market long-acting haemophilia factors in Sobi territory\*
3. Growing the business organically and through M&A, while developing our pipeline of early stage rare disease biologics

\* Europe, North Africa, Russia and certain countries in the Middle East

