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16 February 2017

Q4 and FY results presentation 2016

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 Q4 2016



- European commission approved marketing authorisation for Alprolix® to Sobi
- European Commission granted SOBI003 orphan designation for the treatment of MPS IIIA
- European study of real-life haemophilia treatment emphasises need to improve standard of care
- Data reinforcing the long-term safety and efficacy of Elocta® and Alprolix was highlighted at ASH meeting
- Sobi entered into distribution agreement with Horizon Pharma for Ravicti® and Ammonaps®



Significant events after the reporting period



- First patients enrolled in A-SURE, a 24 month study evaluating real-world effectiveness of Elocta
- Sobi and Bioverativ revealed new long-term safety and efficacy data of Elocta and Alprolix at EAHAD
- Long-term safety and efficacy data for Alprolix published in Lancet Haematology
- Health Canada approved Orfadin[®] capsules for the treatment of hereditary tyrosinaemia type-1 (HT-1)
- Sobi obtained approval from the EC for new dosing frequency for Orfadin
- First patient randomised in anaGO, a phase 2 study evaluating safety and efficacy of anakinra in the treatment of acute gout

Financial highlights Q4 2016



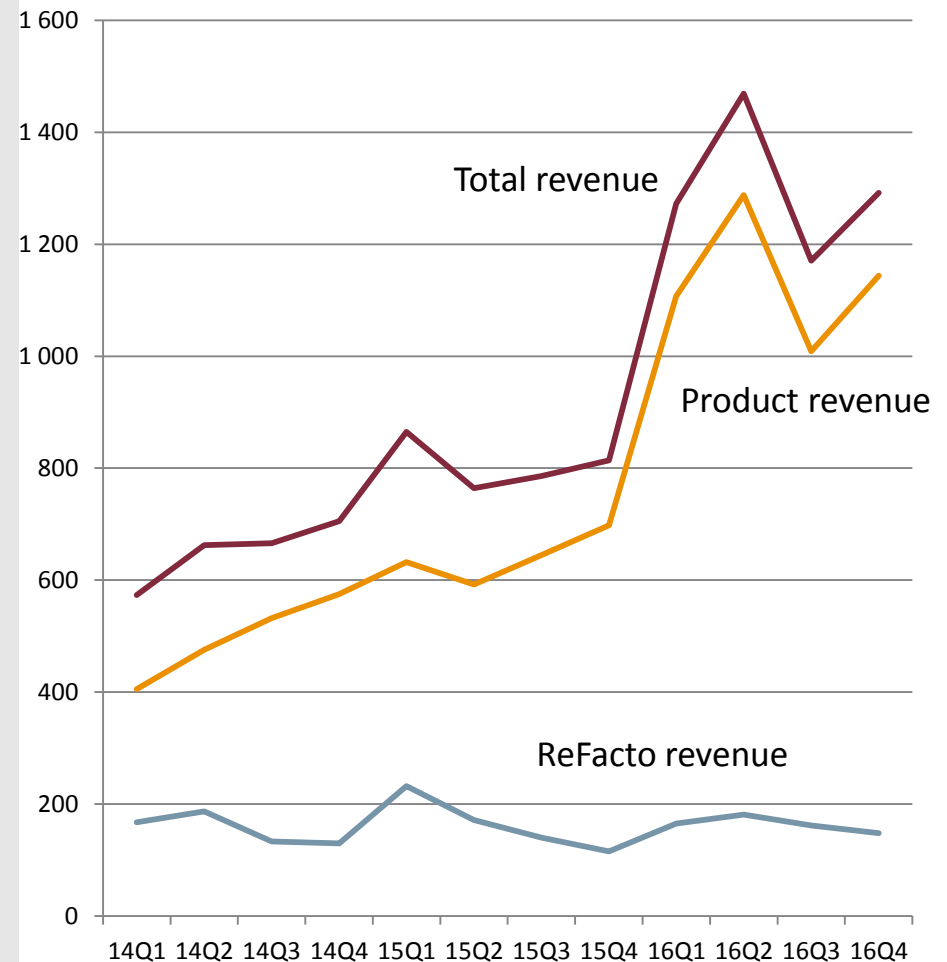
- Total revenue: SEK 1,292 M (814)
 - 59% growth (54% at CER)
- Product revenue: SEK 1,144 M (698)
 - 64% growth (58% at CER)
- ReFacto revenue: SEK 148 M (116)
- Gross margin: 67% (64%)
- EBITA: SEK 210 (90)
- Cash flow operations: SEK 26 M (13)



Financial highlights FY 2016



- Total revenue: SEK 5,204 M (3,228)
 - 61% growth
- Product revenue: SEK 4,548 M (2,568)
 - 77% growth
- ReFacto revenue: SEK 656 M (660)
- Gross margin: 70% (62%)
- EBITA: SEK 1,543 M (433)
- Cash flow operations: SEK 343 M (507)

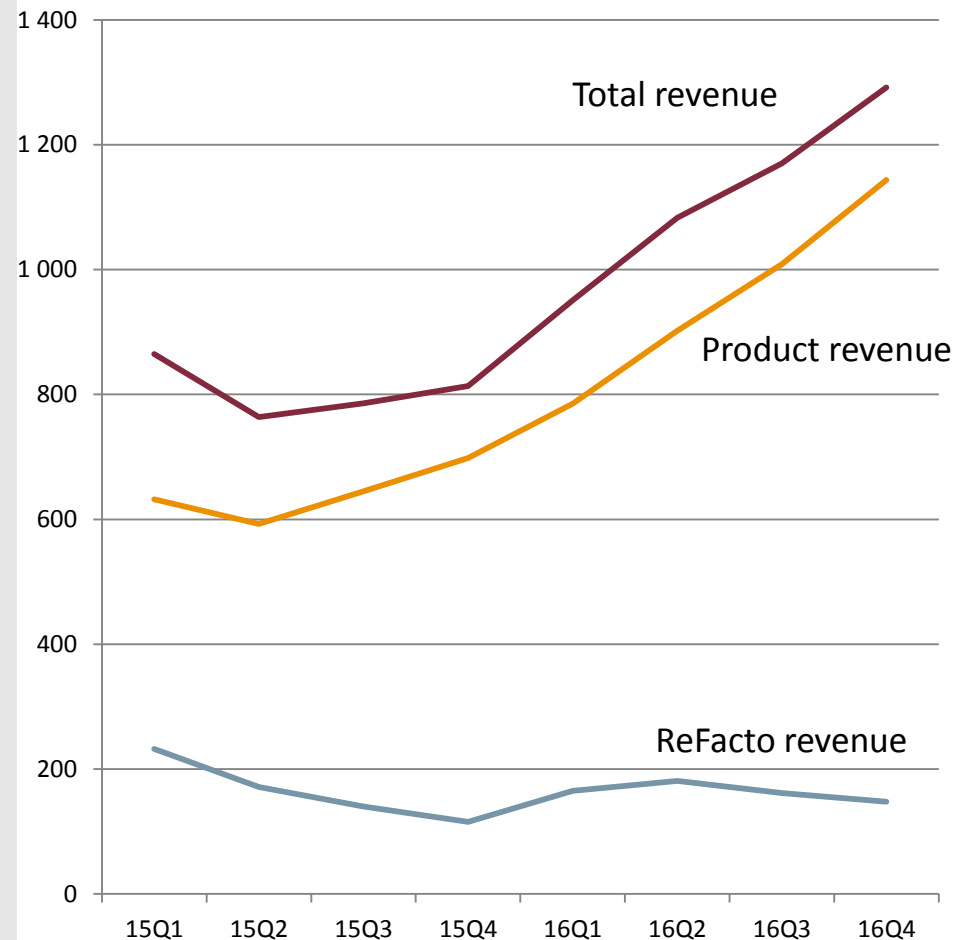


Financial highlights FY 2016

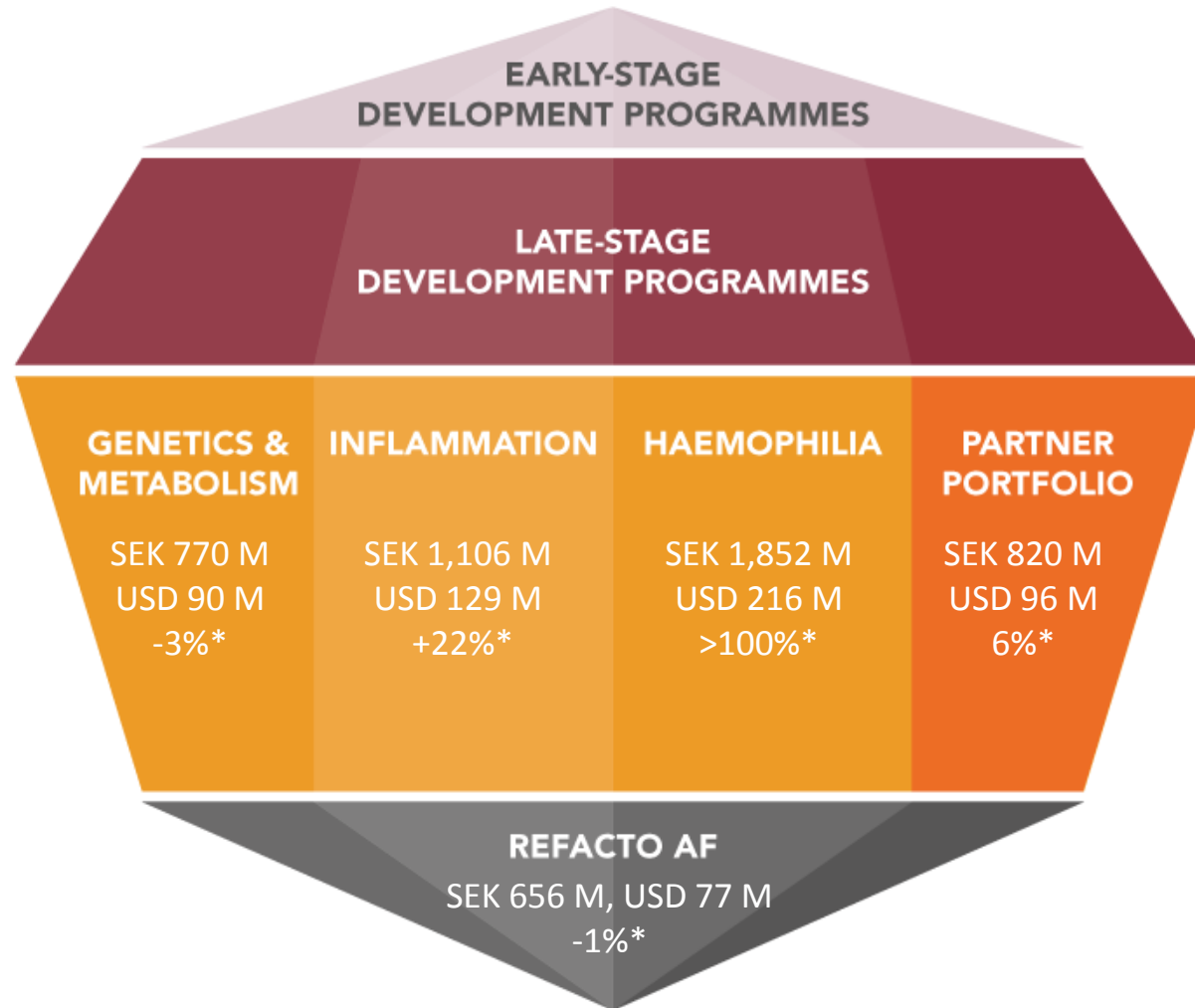


[excluding one-time credits of SEK 708 M]

- Total revenue: SEK 4,496 M (3,228)
 - 39% growth
- Product revenue: SEK 3,840 M (2,568)
 - 50% growth (49% at CER)
- ReFacto revenue: SEK 656 M (660)
- Gross margin: 66% (62%)
- EBITA: SEK 835 M (433)
- Cash flow operations: SEK 343 M (507)



Revenues by business line FY 2016



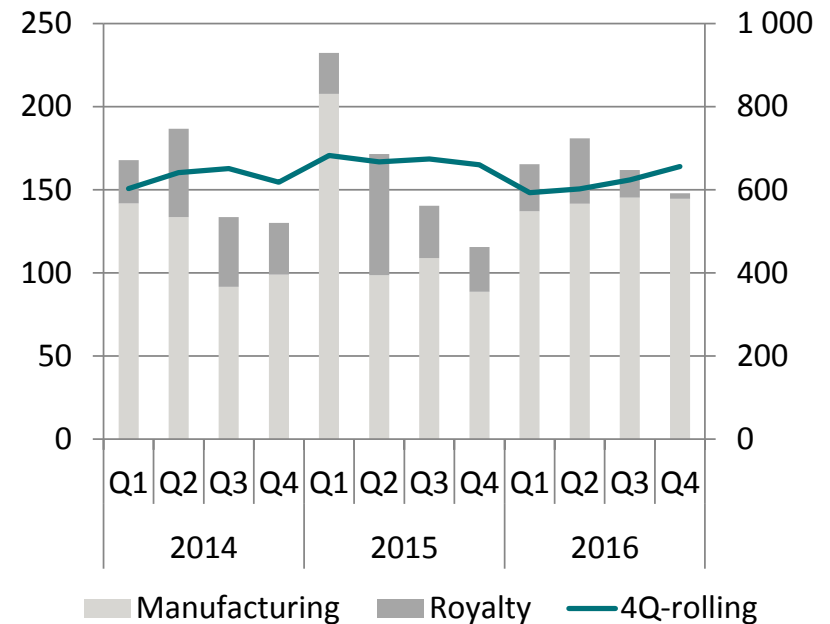
*Growth at Constant Exchange Rates
USD 1 = SEK 8,5613 (average year rate)

ReFacto



- Q4 Revenue for manufacturing and royalty SEK 148 M (116)
 - increase of 28%
- Q4 Manufacturing revenue SEK 145 M (89)
- Q4 Royalty revenue SEK 3 M (27)
 - US royalty expires January 2018
 - ROW royalty expired May 2016
- FY was SEK 656 M (660)

Revenues (SEK M): ReFacto

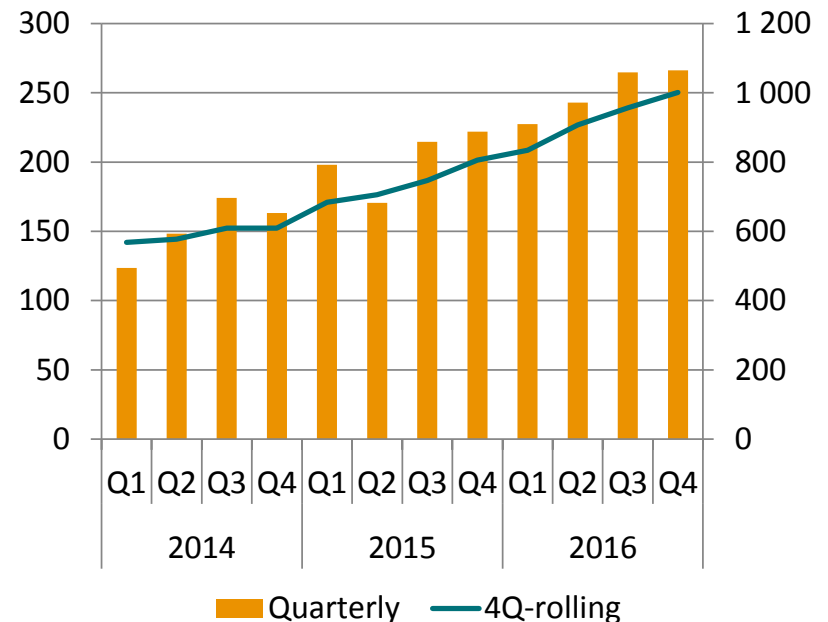


Commercial results Q4 & FY 2016

Alan Raffensperger | COO

- Q4 Revenue SEK 266 M (222)
 - Increase of 20%
- FY revenue SEK 1,001 M (805)
 - Increase of 24%
- US distribution model and patient support programme is driving growth
- Clinical programmes on track
 - First patient recruited to the phase 2 study, anaGo, for the treatment of acute gout

Revenues (SEK M): Kineret

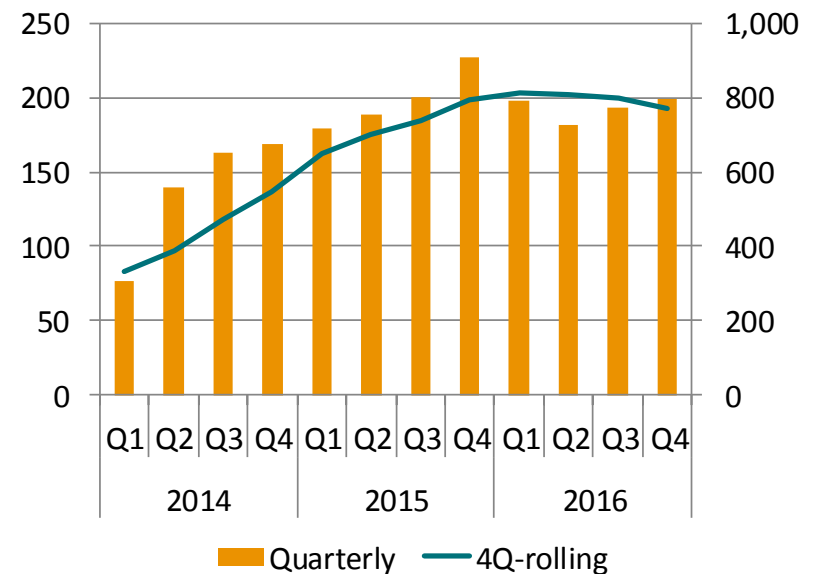


Orfadin



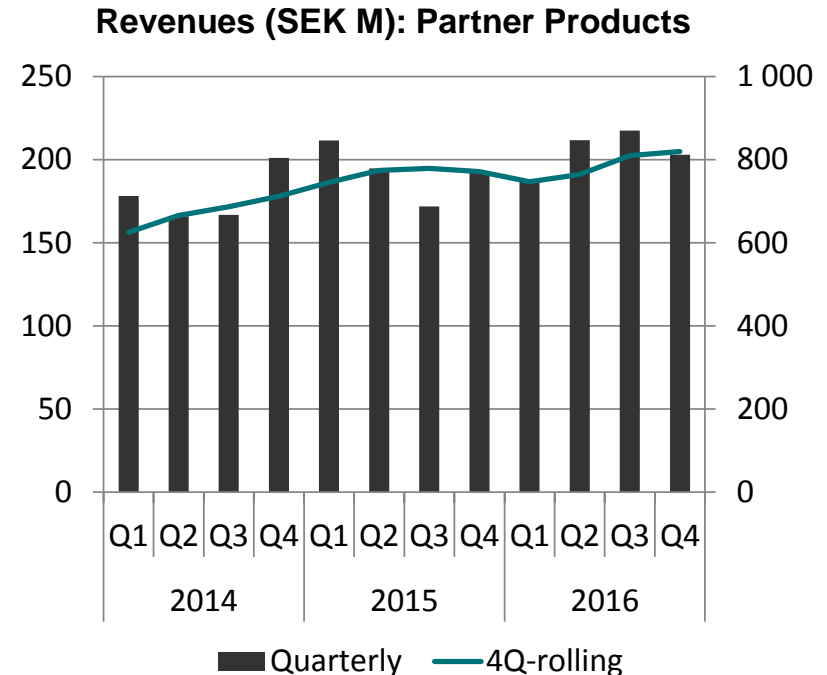
- Q4 Revenue SEK 197 M (227)
 - Decrease of 13%
- FY revenue SEK 770 M (796)
 - Decrease of 3%
- North America
 - Performance in the US supported by 20 mg and oral suspension launches
 - Orfadin approved in Canada
 - Revenue in Canada negatively impacted by generic approvals

Revenues (SEK M): Orfadin



Partner Products

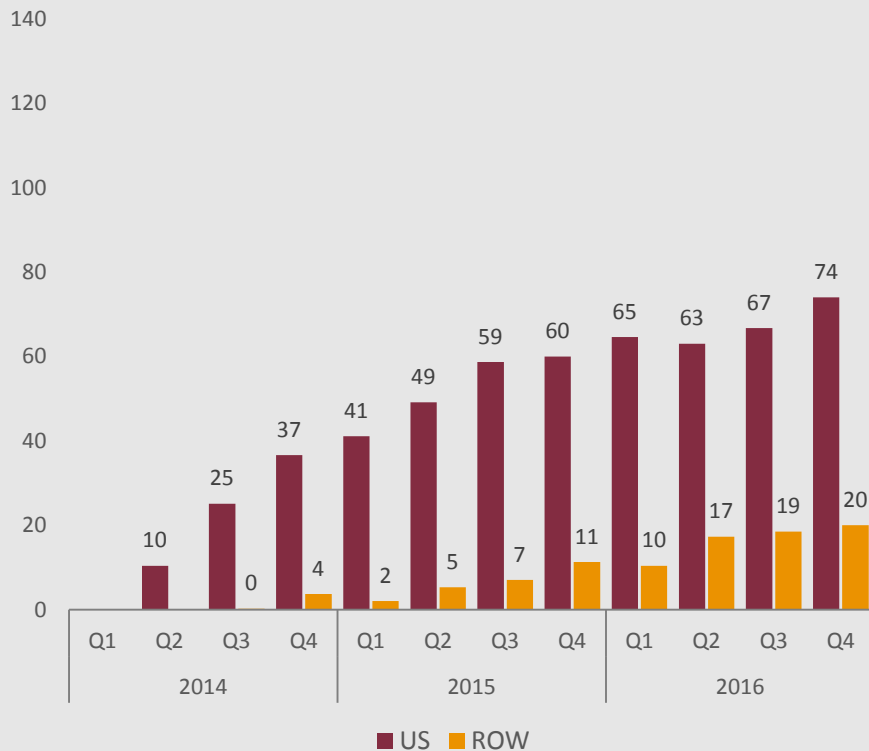
- Q4 Revenue SEK 203 M (193)
 - Increase of 5%
- FY revenues SEK 820 M (771)
 - Increase of 6%
- Revenue growth supported by new partnership with PharmaSwiss and Xiapex
- We are in discussions regarding a possible sale of Partner Products



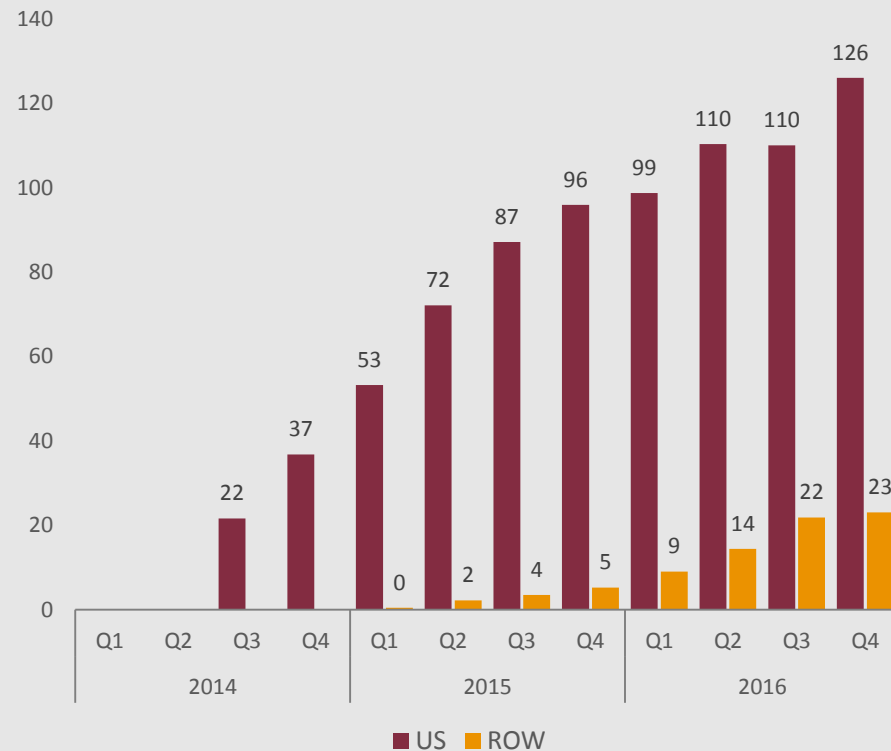
Haemophilia – Biogen Sales



Alprolix - Biogen Sales (million US\$)



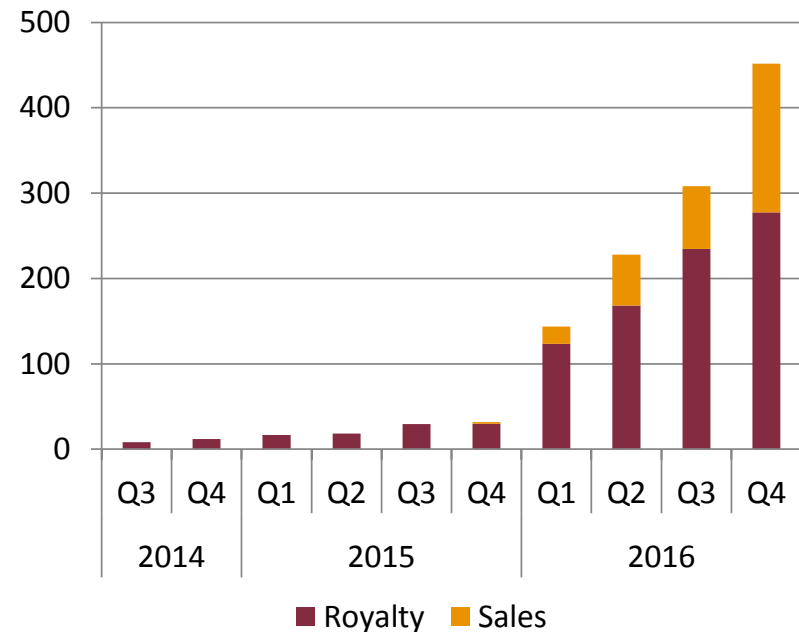
Eloctate - Biogen Sales (million US\$)



Haemophilia

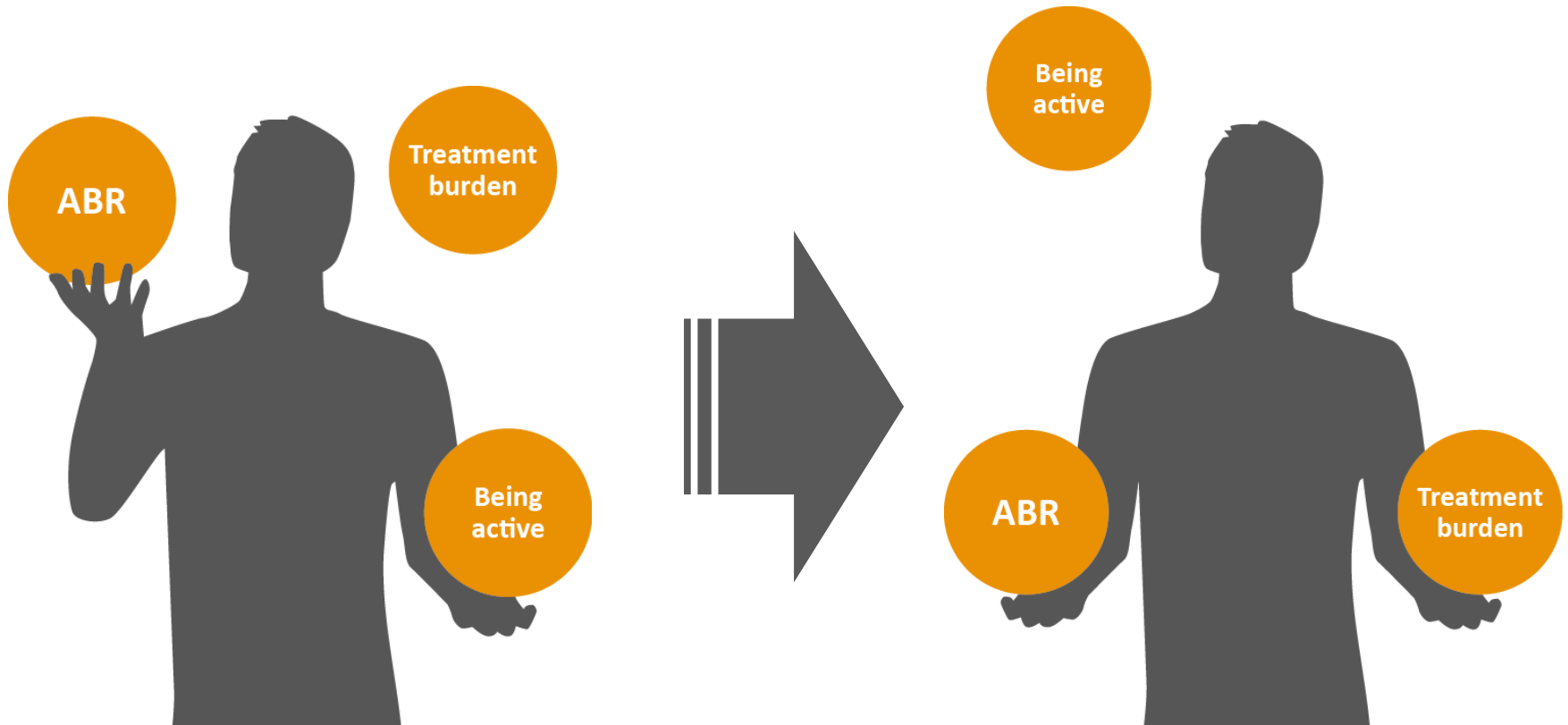
- Q4 Revenue of SEK 451 M (32)
 - SEK 174 M (2) in sales
 - SEK 277 M (30) in royalty revenue
- FY revenue of SEK 1,853 M (96)
 - SEK 327 M (2) in sales
 - SEK 803 M (95) in royalty revenue
 - SEK 708 M in one-time credits
 - SEK 14 M in milestone revenue

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



* Excluding one-time royalty credits and milestone revenues

Redefining protection in Haemophilia

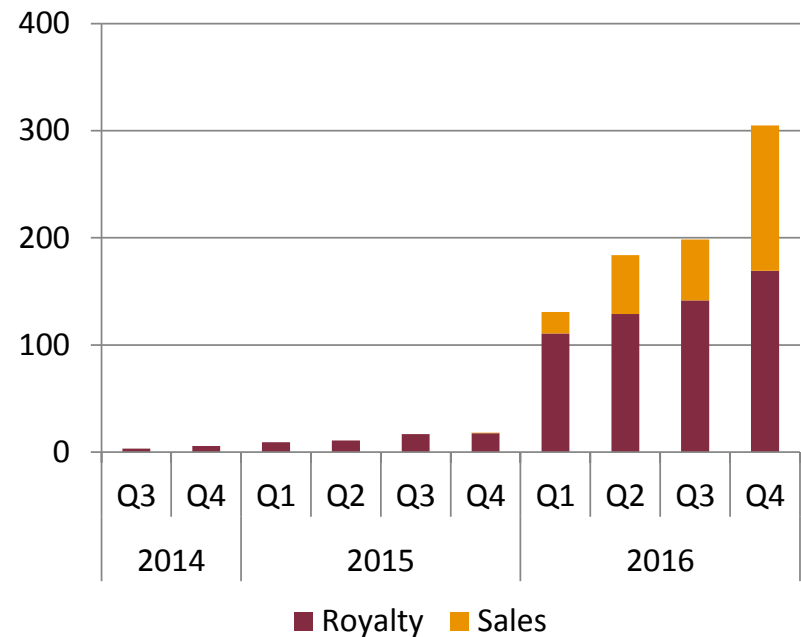


Adapted from Oldenburg J. *Blood* 2015.¹

- Q4 Revenue SEK 304 M (18)
 - SEK 135 M (1) in sales
 - SEK 169 M (18) in royalty revenue

- FY revenue of SEK 1,139 M (55)
 - SEK 267 M (1) in sales
 - SEK 550 M (55) in royalty revenue
 - One-time credit of SEK 322 M



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

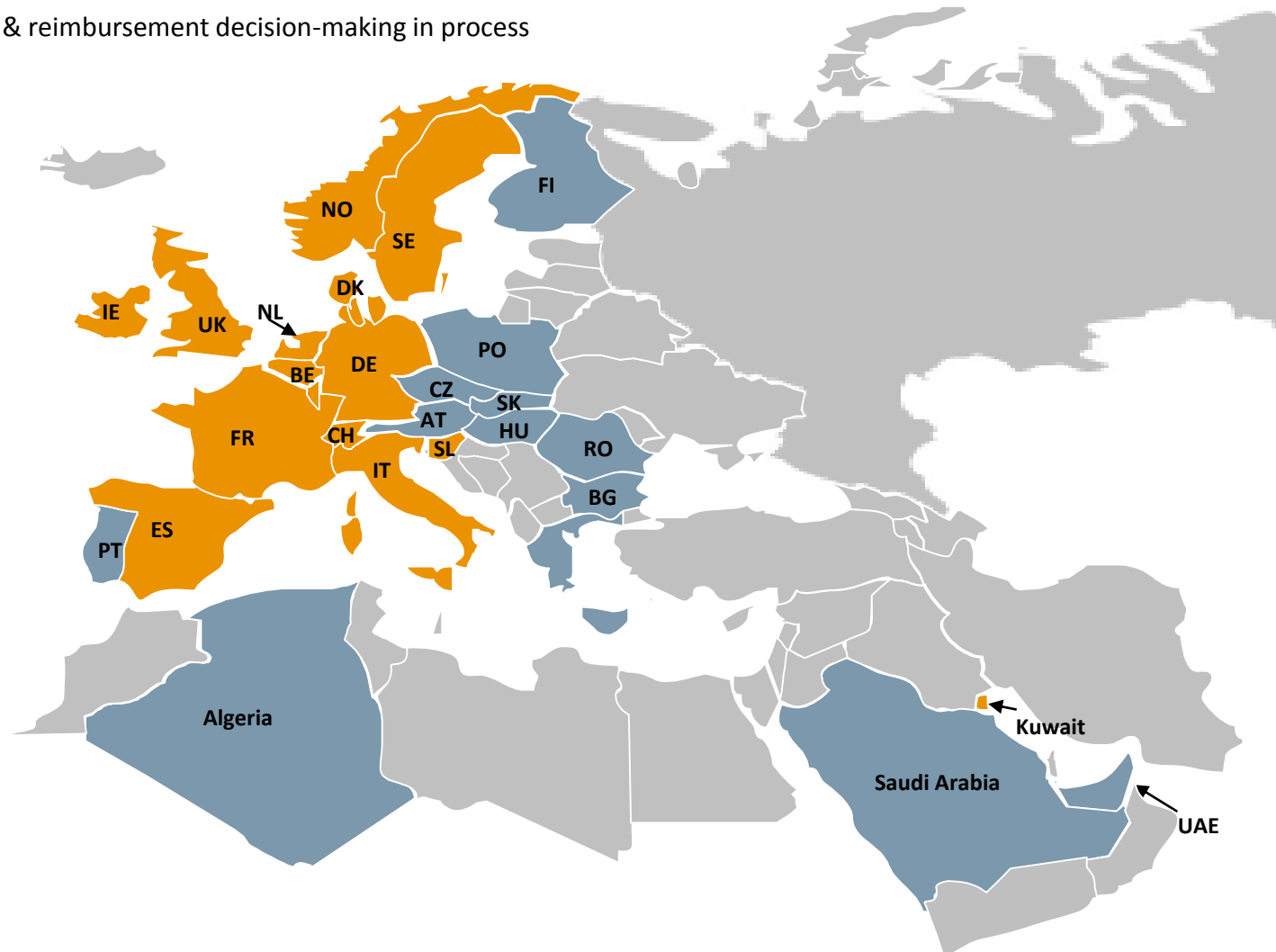


* Excluding one-time royalty credits

Elocta access update

- End of December 2016

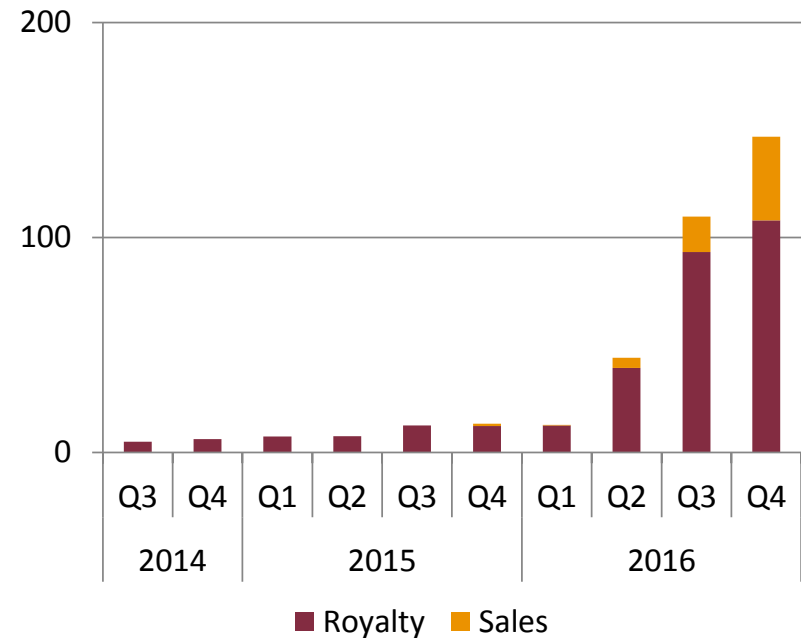
-  Reimbursement granted – treatment available
-  Pricing & reimbursement decision-making in process



- Q4 Revenue SEK 147 M (13)
 - SEK 39 M (1) in sales
 - SEK 108 M (12) in royalty revenue

- FY revenue of SEK 713 M (41)
 - SEK 60 M (1) in sales
 - SEK 253 M (40) in royalty revenue
 - SEK 14 M in milestone revenue
 - One-time credit of SEK 386 M



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

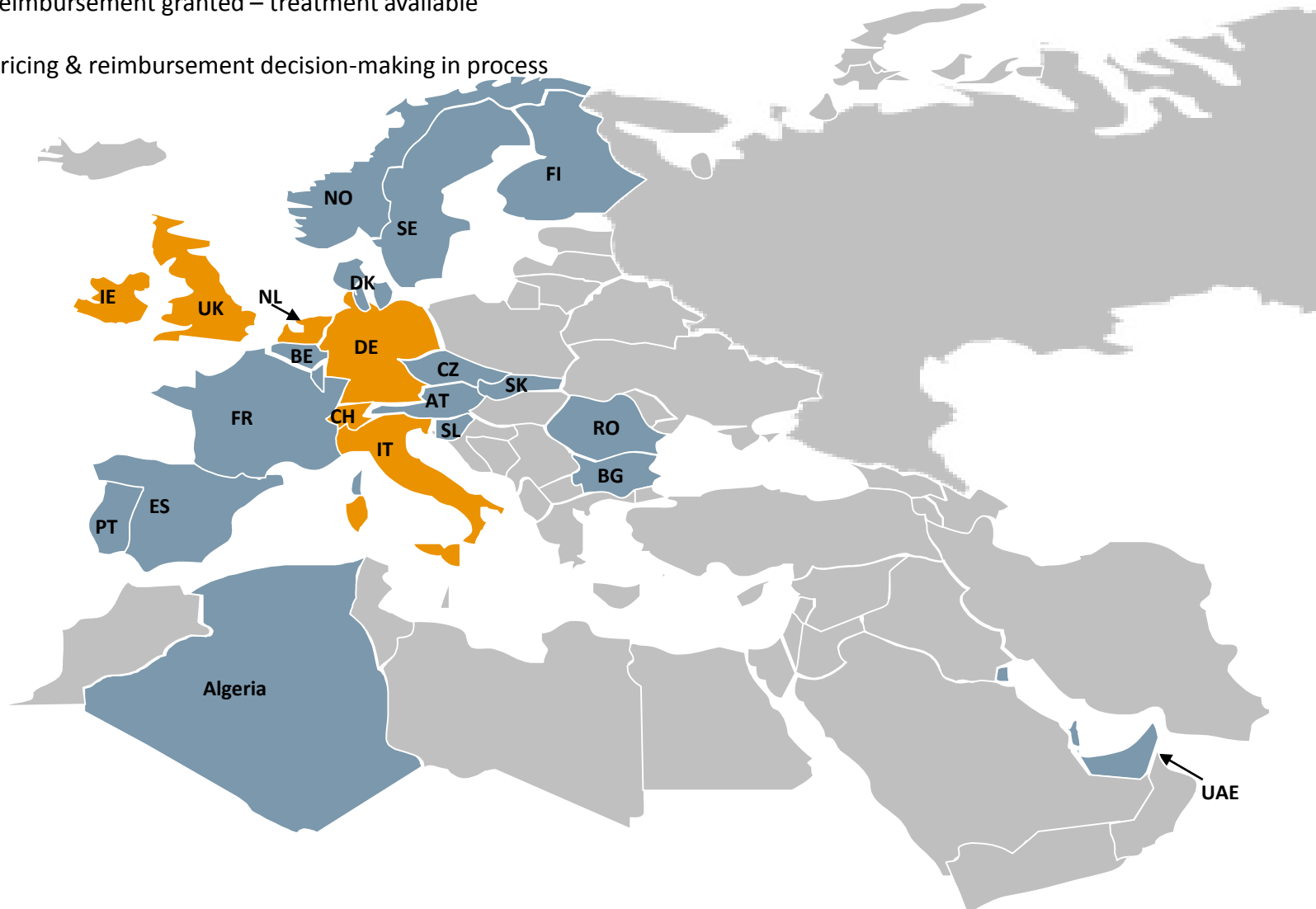


* Excluding one-time royalty credits and milestone revenues

Alprolix access update

- *End of December 2016*

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



Financial results
Q4 and FY 2016
Mats-Olof Wallin | CFO

Profit and loss statement



<i>Amounts in SEK M</i>	Q4-16	Q4-15	FY 2016	FY 2015
Total revenues	1,292	814	5,204	3,228
Gross profit	860	520	3,651	2,007
<i>Gross Margin</i>	<i>67%</i>	<i>64%</i>	<i>70%</i>	<i>62%</i>
Sales and Administration	-399	-293	-1,366	-1,058
Research and development	-258	-135	-778	-513
Other operating revenues/expenses	7	-3	36	-3
EBITA	210	90	1,543	433
Amortizations and write-downs	-110	-73	-410	-287
EBIT	100	17	1,133	146
Financial income/expenses	-12	-26	-85	-61
Profit before tax	88	-10	1,048	84
Income tax expense	12	-1	-239	-19
Profit/loss for the period	100	-10	809	65

Balance sheet



<i>Amounts in SEK M</i>	Dec 2016	Sep 2016	Dec 2015
ASSETS			
Intangible	6,806	6,893	5,787
Tangible and other	257	257	212
Total non-current assets	7,063	7,151	5,999
Inventories	870	798	776
Accounts receivable	769	628	451
Other Receivable	487	398	185
Cash and equivalent	786	824	904
Total current assets	2,911	2,647	2,316
Total Asset	9,974	9,798	8,315
EQUITY AND LIABILITIES			
Equity	5,354	5,340	4,660
Long term debt	502	502	800
Long term liabilities	2,360	2,466	1,534
Short term liabilities	1,758	1,490	1,320
Total liabilities	4,620	4,458	3,654
Total equity and liabilities	9,974	9,798	8,315

Outlook 2016*



All elements exceeded or met

Revenues

Revenues for the full year were **SEK 5,204 M**, above the predicted range of SEK 5,125 to 5,200 M

Gross margin

Gross margin for the full year was **70 per cent**, according what was predicted

EBITA

EBITA for the full year was **SEK 1,543 M** above the predicted range of SEK 1,475 to 1,525 M

*The original outlook was published in the 2015 Q4 and FY report 26 February 2016.

*The outlook was raised on 27 October 2016, the date for publication of the Q3 2016 report

*Results include non-recurring, one-time credits of SEK 708 M associated with the launch of Elocta and Alprolix

Summary results 2016



With and without one-time credits of SEK 708 M

Revenues
SEK 5,204 M

Gross margin
70 per cent

EBITA
SEK 1,543 M

Revenues
SEK 4,497 M

Gross margin
65 per cent

EBITA
SEK 836 M

Summary and outlook

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

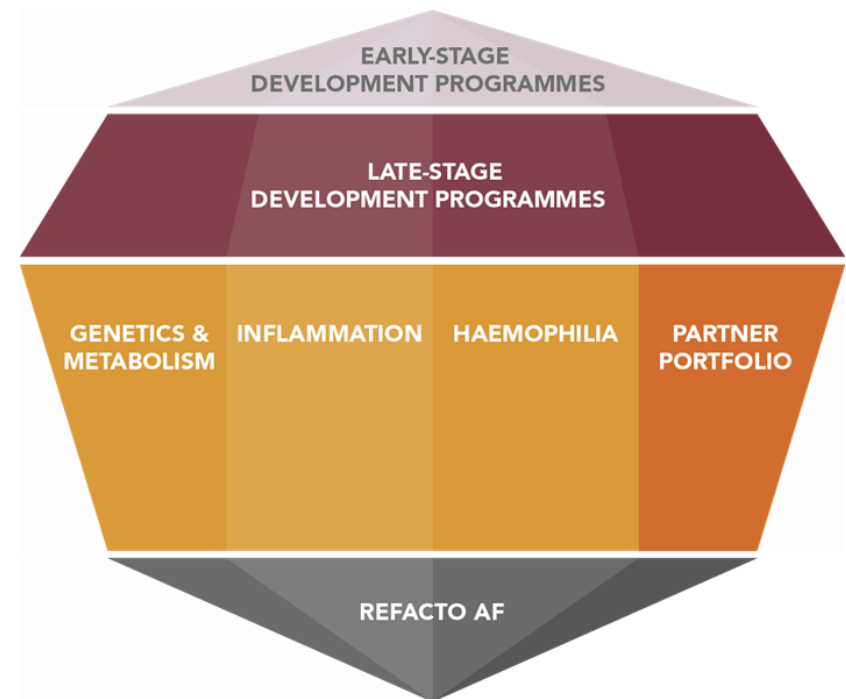
*At current exchange rates

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



R&D pipeline



Therapeutic area/Indication	Product/Project	Pre-clinical	Phase 1	Phase 2	Phase 3
Haemophilia A	Elocta/A-SPIRE*				
Haemophilia A	Elocta/PUP ¹ *				
Haemophilia B	Alprolix/B-YOND*				
Haemophilia B	Alprolix/PUP ¹ *				
Acute gout	Kineret/anaGO				
Still's disease	Kineret/anaSTILLS				
Alkaptonuria	Orfadin/SONIA2				
MPSIIIA	SOBI003				
Anti-C5	SOBI005				
Anti-IL-1	SOBI006				

*Extension trial for an already approved indication

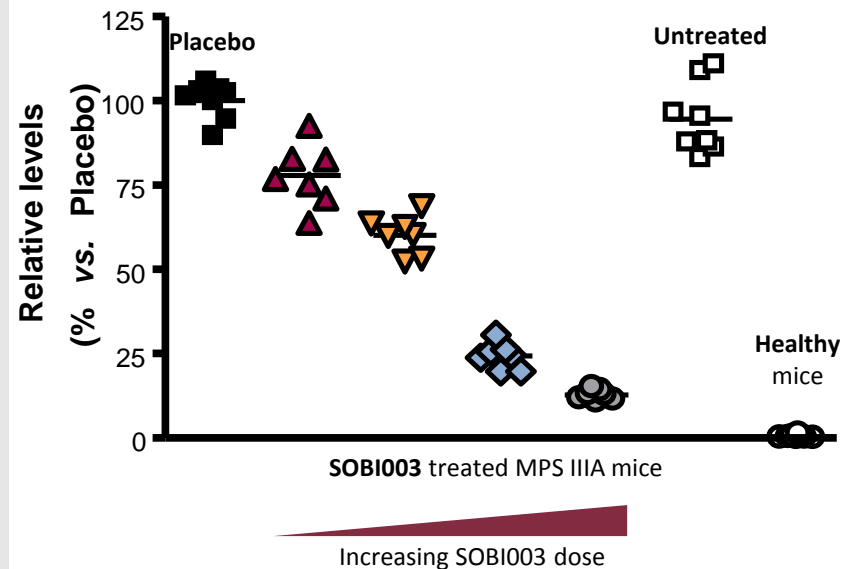
¹ PUP = Previously untreated patients

SOBI003 for MPS IIIA



- Systemic ERT with CNS penetration

- MPS IIIA is a Lysosomal Storage Disease – heparan sulfate accumulates and causes significant CNS morbidity and mortality
- SOBI003 is a recombinant human sulfamidase enzyme which has been modified to facilitate CNS uptake
- Orphan designation for SOBI003 was granted by the EC (Oct 2016)



Dose dependent reduction of tetrasaccharide storage in the brain of MPS IIIA mice following treatment with SOBI003

Sobi and Bioverativ to investigate Elocta 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

First patient in for both studies: mid 2017

Bioverativ to advance BIVV 001 in H2 2017

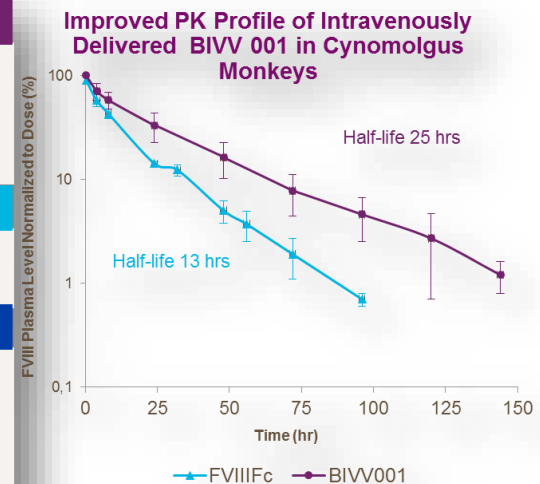


- Programme to advance to clinic in H2 2017
- Bioverativ development programme
- Sobi has opt-in right at European filing
- Financial terms similar to those for Elocta and Alprolix

BIVV 001 has Potential to Extend Hemophilia A Prophylaxis to Once Weekly or Less Frequently

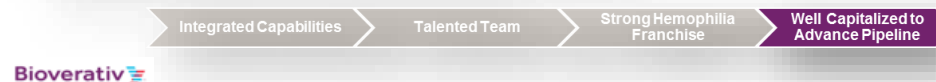
rFVIII_{FC}-VWF-XTEN

Technology
<p>Uniquely engineered factor VIII molecule with a region of Fc dimer, VWF, and XTEN polypeptides</p> <ul style="list-style-type: none"> - Fc monomer, like Elo, enables recycling to extend time in circulation - D'D3 inhibits binding to VWF which limits the ceiling for current FVIII products - XTEN insertions increase half-life by protecting from clearance/ proteolysis
Potential Clinical Profile
<p>Potential to enable prophylaxis intervals in Hemophilia A of <u>once weekly or less frequent dosing</u></p>
Competitive Positioning
<p>Only next gen FVIII molecule that can potentially achieve goal of weekly prophylaxis as it removes the 1/2 life limit found with all other EHL products caused by their binding to VWF. Known biology, MOA can potentially achieve full correction to stop bleeds and use in surgery</p> <p>Other novel MOAs will require bypass agents or factor to treat bleeds</p>
Timing
<p>Intend to move into the clinic in H2 2017</p>



BIVV 001 showed 2-fold improvement in pharmacokinetic property compared to rFVIII_{FC} in cyno monkeys

Note: BIVV 001 is currently BIIB073, XTEN technology licensed from Amunix



External pipeline development

- ✓ expertise in biologics - engineering, process development and manufacturing
- ✓ experienced in commercialization for rare disease products
- ✓ a strong portfolio in
 - ✓ Genetic and Metabolic disease
 - ✓ Inflammation
 - ✓ Haemophilia
- ✓ launch capacity in North America today, in Europe 2018+

