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Q1 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 summary Q1 2016



- Commercial launch of Elocta[®] in the first European countries
- Sobi and Biogen received CHMP recommendation for Alprolix[®] for the treatment of haemophilia B
- Sobi received commercialisation rights to three products from PharmaSwiss
- European patent granted for Orfadin[®] Oral Suspension
- Clinical pipeline programmes for acute gout and Still's disease, and a new patent for a new formulation of Kineret[®]
- Håkan Björklund nominated as successor to Bo Jesper Hansen as Chairman of the Board of Sobi



Significant events after the quarter



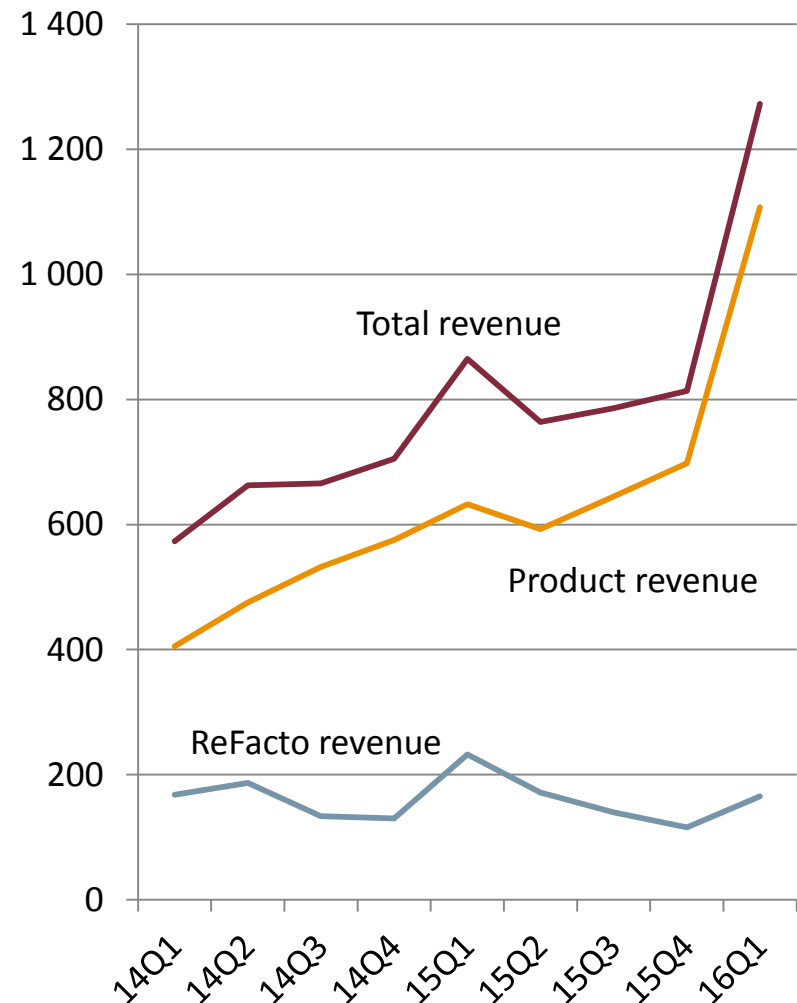
- COMP recommended to maintain orphan designation for Alprolix
- European patent granted on new formulation of Kineret
- Signed licensing agreement with Affibody for IL-1
- Orfadin Oral Suspension approved in the US



Highlights Q1 2016



- Total revenue: SEK 1,273 M (865)
 - 47% growth (48% at CER)
- Product revenue: SEK 1,108 M (632)
 - 75% growth (76% at CER)
- ReFacto[®] revenue: SEK 165 (232)
 - 29% decrease
- Gross margin 74% (60)
- EBITA: SEK 502 M (172)
- Cash flow operations: SEK 235 M (169)

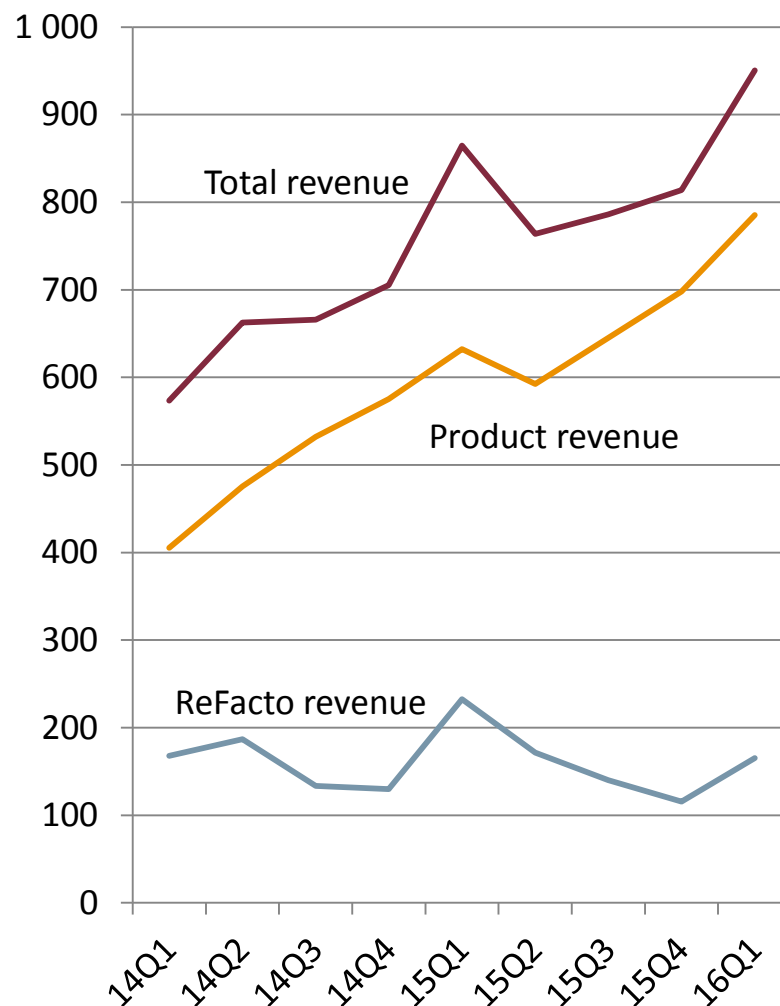


Highlights Q1 2016

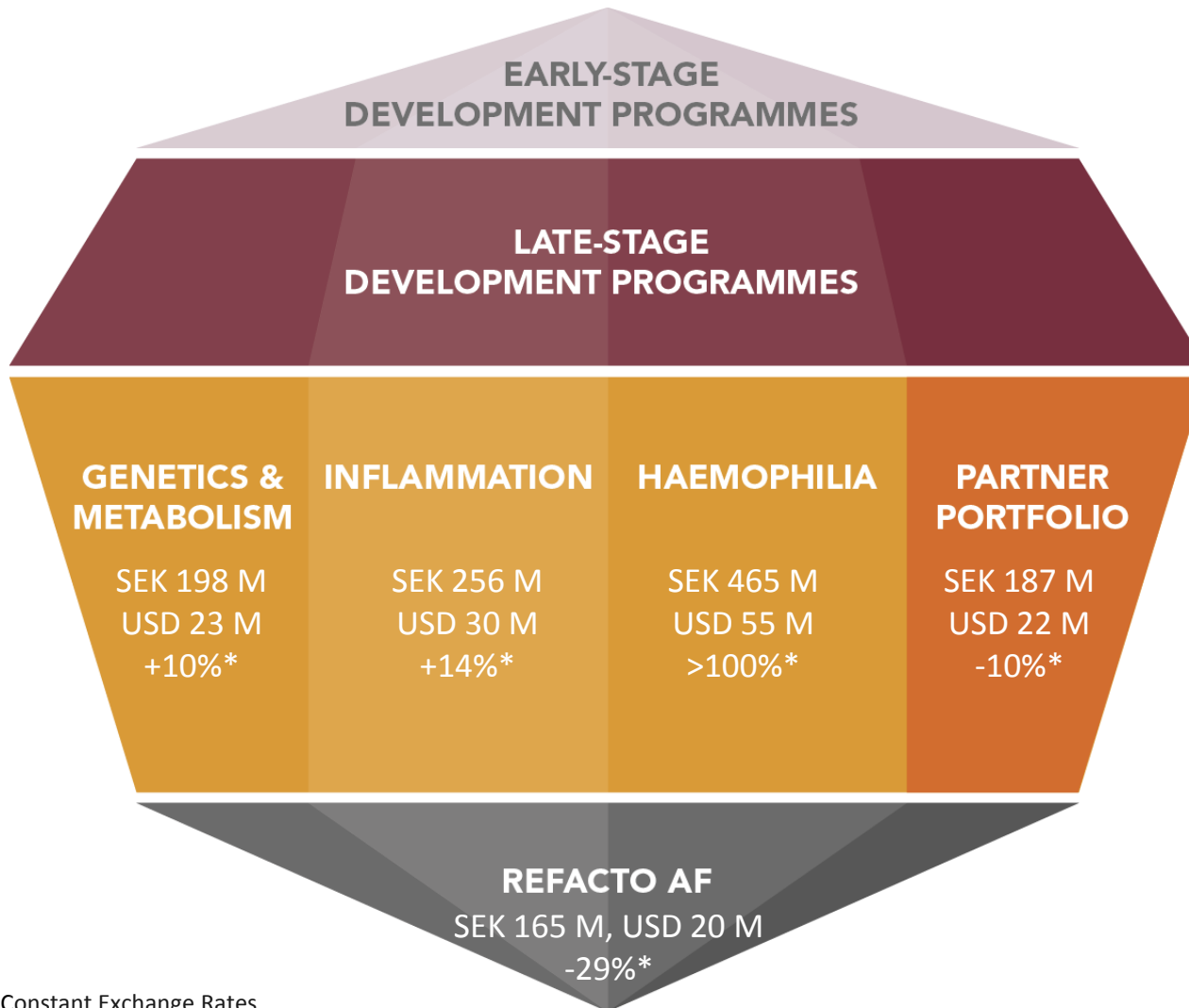
Excluding Elocta one-time credit



- Total revenues SEK 951 M (865)
 - 10% growth
- Product revenue: SEK 786 M (632)
 - 24% growth
- ReFacto revenue: SEK 165 (232)
 - 29% decrease
- Gross margin 65% (60)
- EBITA: SEK 180 M (172)
- Cash flow operations: SEK 235 M (169)



Q1 2016 revenue by business line

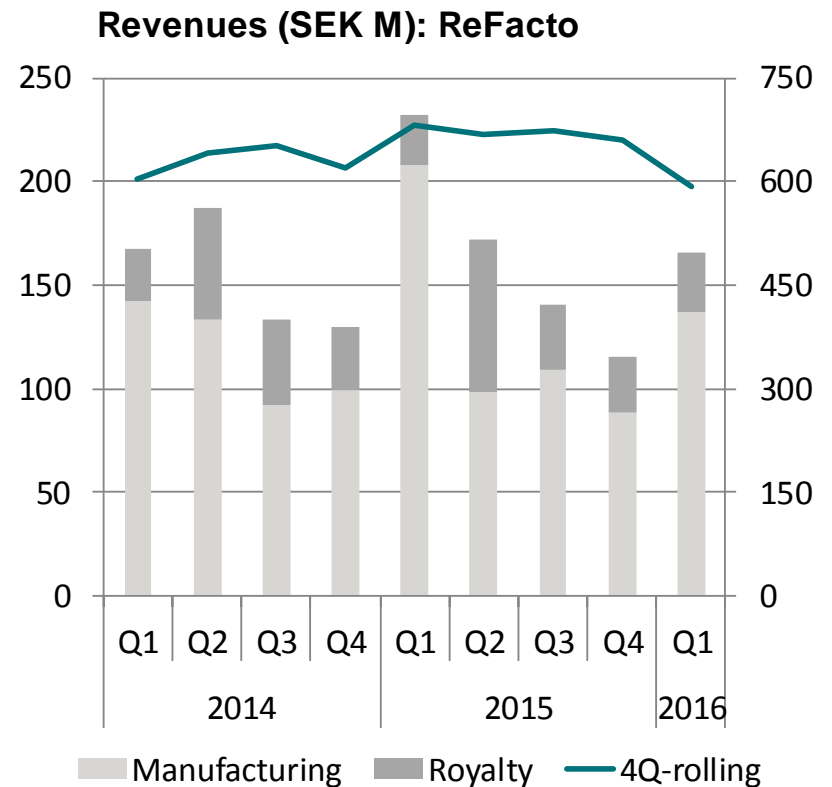


*Growth at Constant Exchange Rates
USD 1 = SEK 8,4567

ReFacto



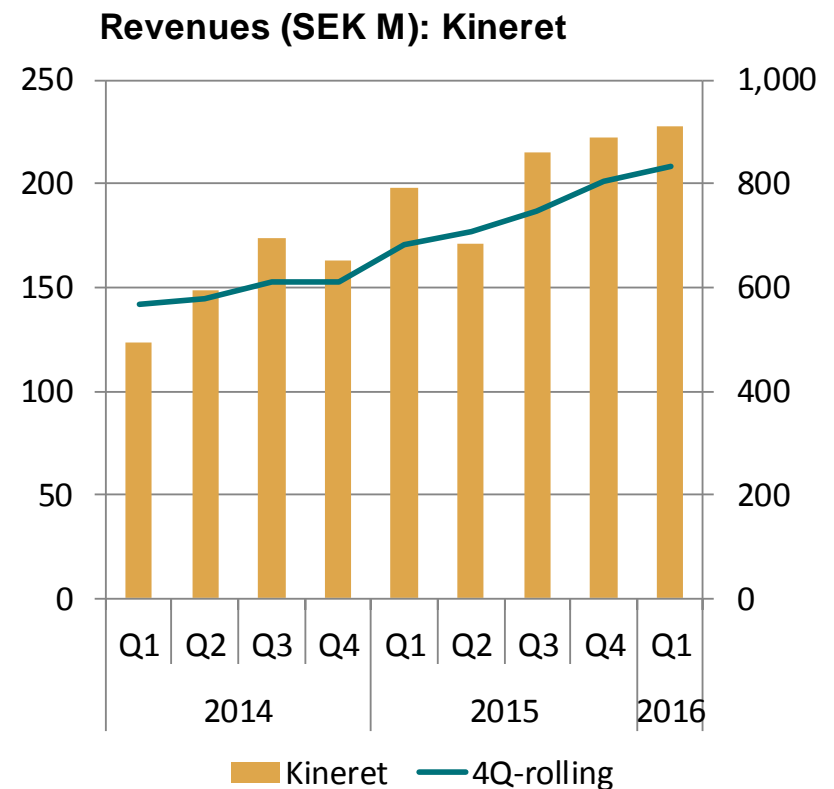
- Revenue for manufacturing and royalty SEK 165 M (232)
 - Decrease of 29%
 - Phasing effects caused by higher deliveries in the first half 2015
- Manufacturing revenue SEK 137 M (208)
- Royalty revenue SEK 28 M (25)



Commercial results Q1 2016

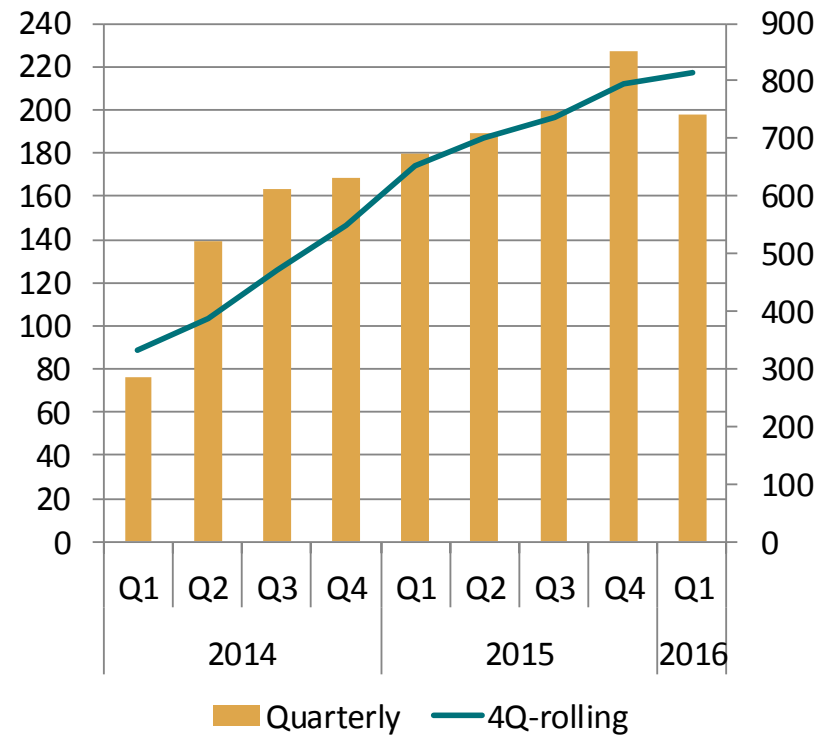
Alan Raffensperger | COO

- Revenue SEK 227 M (198)
 - Increase of 15%
- Solid growth in major markets
 - Continued launch in CAPS indication in Europe
 - New specialty distribution model in North America
- New clinical development programs
 - Acute gout
 - Still's disease



- Revenue SEK 198 M (180)
 - Increase of 10%
- Growth in all major markets
- Launch of oral suspension in first countries in Europe
 - Oral Suspension now launched and generating revenue in Finland, Germany, the Netherlands, Norway, and the UK

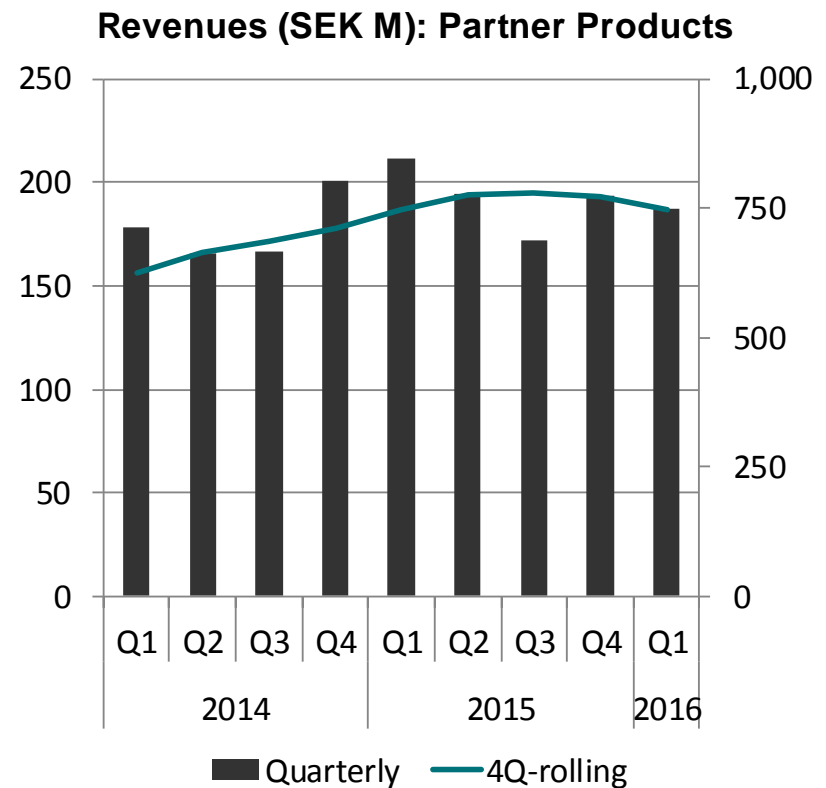
Revenues (SEK M): Orfadin



Partner Products

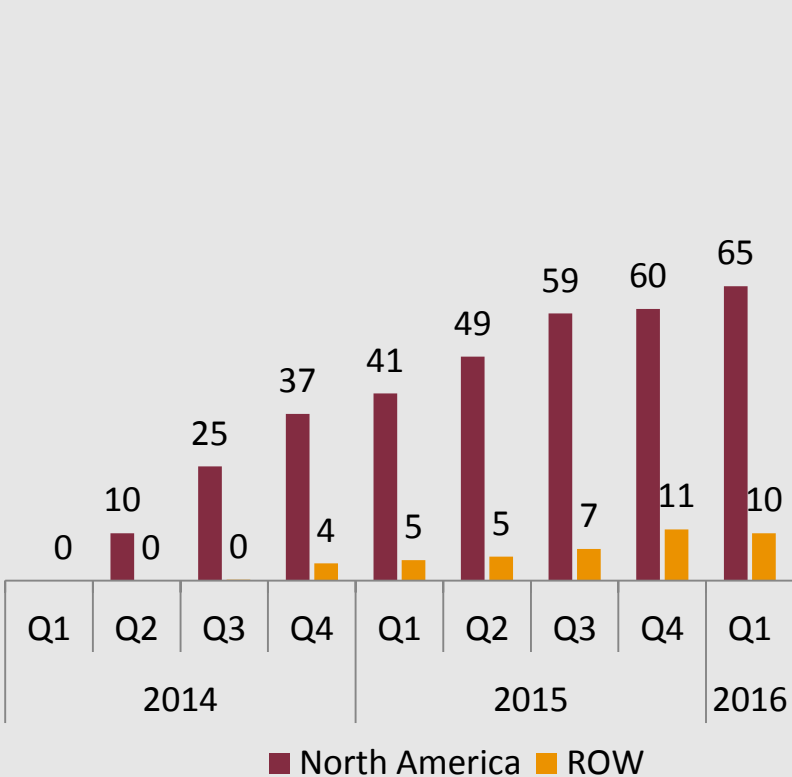


- Revenue SEK 187 M (212)
 - Decrease of 11%
- Signed agreement with PharmaSwiss
- Growth especially driven by Xiapex®
- Q1 2015 included:
 - SEK 22 M Cometriq® milestone and service fee
 - SEK 10 M revenue from products no longer in the portfolio

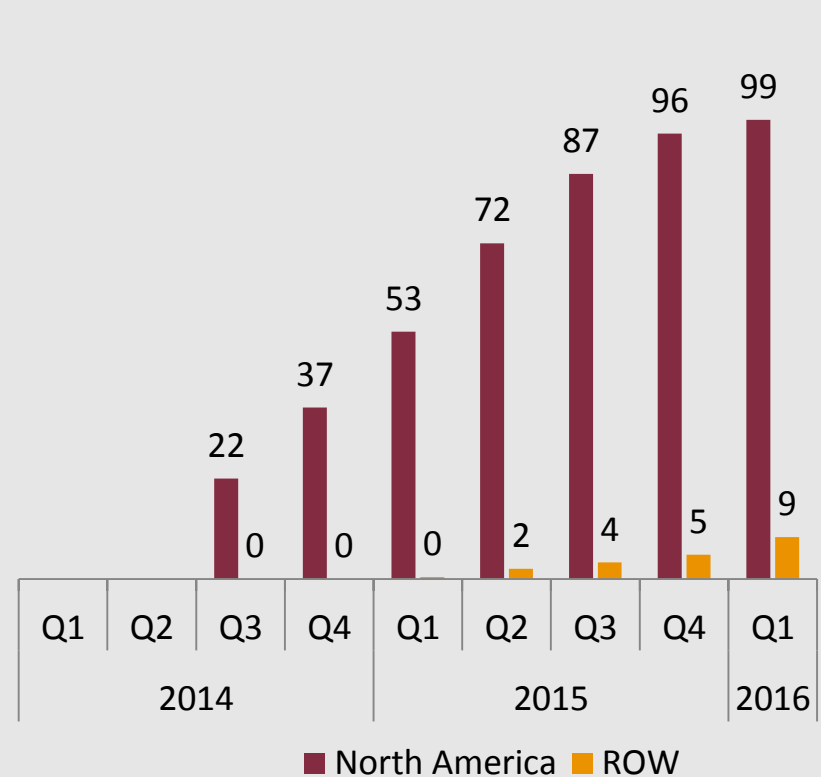


Haemophilia – Biogen revenues

Alprolix - Biogen Sales (million US\$)

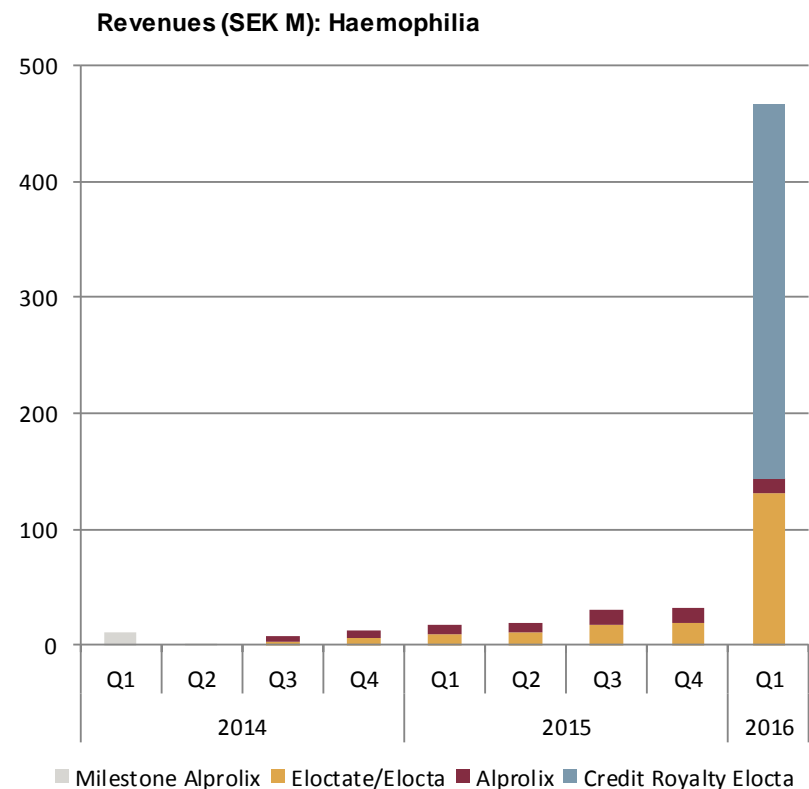


Eloctate - Biogen Sales (million US\$)



Haemophilia

- Revenue SEK 465 M (17)
 - SEK 445 M in royalty revenues
 - SEK 123 M royalty
 - SEK 322 M was a one-time royalty credit
 - Elocta sales SEK 20 M
- Marketing authorisation in the EU transferred to Sobi
- Alprolix received a positive recommendation from CHMP and from COMP



Elocta launch progress

Q1 2016 update



- Revenue from the quarter derives almost exclusively from Germany, the only market in the EU where pharmaceuticals are immediately reimbursed upon EU approval
- Reimbursement is available in the UK for a limited number of patients until the framework agreement becomes effective at mid-year
- Reimbursement granted in the Netherlands and Ireland at the end of Q1
- Reimbursement pending in Denmark and Sweden. We expect to secure full reimbursement for both markets at mid-year
- Preparations for entering other markets and securing reimbursement during 2016 on track

Alprolix launch preparations

Q1 2016 update



- Alprolix CHMP Positive Opinion received 25th February 2016
- Positive opinion to maintain OMP status received 5th April 2016
- European Commission decision anticipated shortly
- Launch sequence will be similar to Elocta

Financial results Q1 2016

Mats-Olof Wallin | CFO

Profit and Loss statement



<i>Amounts in SEK M</i>	Q1-16	Q1-15	FY 2015
Total revenues	1,273	865	3,228
Gross profit	944	519	2,007
<i>Gross Margin</i>	74%	60%	62%
Sales and Administration	-315	-219	-1,057
Research and development	-138	-132	-513
Other operating revenues/expenses	11	4	-3
EBITA	502	172	433
Amortizations and write-downs	-92	-71	-287
EBIT	410	102	146
Financial income/expenses	-23	-1	-58
Profit before tax	387	101	88
Income tax expense	-86	-26	-19
Profit/loss for the period	301	75	68

- Improved GM due to increased royalty revenues
- Increase in S&A expenses reflects build-up of haemophilia organization
- EBITA improved primarily due to increased royalty revenues

Balance sheet

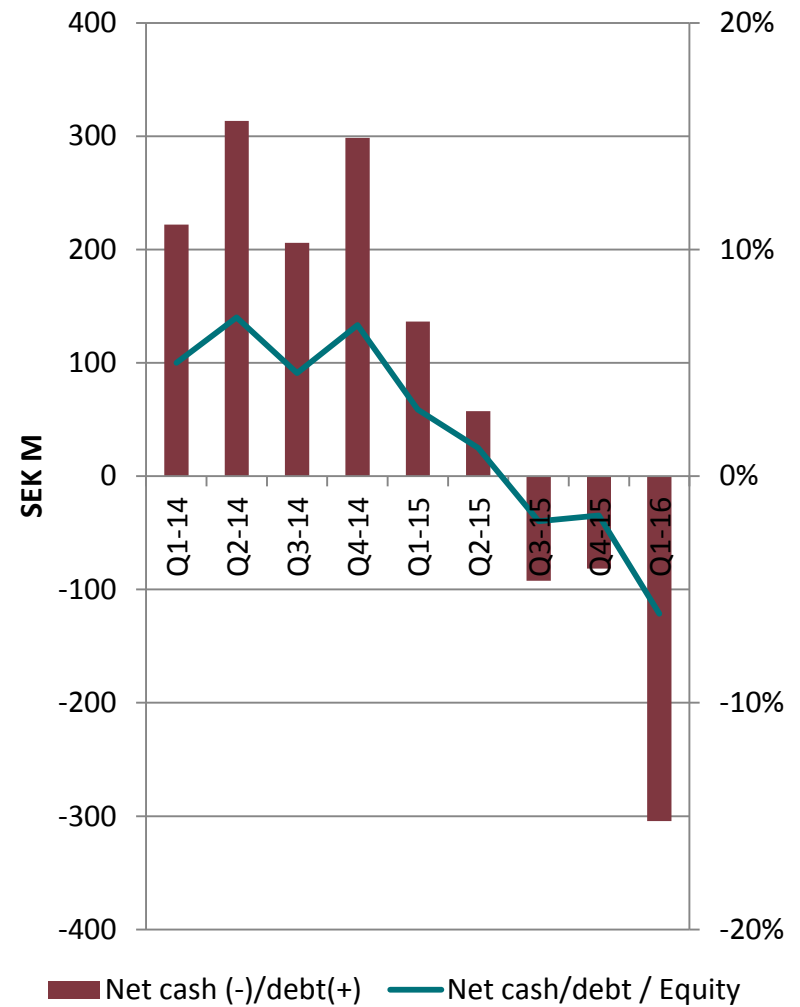


<i>Amounts in SEK M</i>	March 2016	Dec 2015	March 2015
ASSETS			
Intangible	5,661	5,787	4,192
Tangible and other	194	208	189
Total non-current assets	5,854	5,995	4,380
Inventories	810	776	765
Accounts receivable	505	451	647
Other Receivable	260	185	133
Cash and equivalent	1,108	904	682
Total current assets	2,684	2,316	2,226
Total Asset	8,538	8,311	6,606
EQUITY AND LIABILITIES			
Equity	5,016	4,689	4,614
Long term debt	802	800	817
Long term liabilities	1,457	1,501	313
Short term liabilities	1,263	1,320	862
Total liabilities	3,522	3,621	1,992
Total equity and liabilities	8,538	8,311	6,606

- Inventory build up to reflect ongoing haemophilia launch
- Positive cash flow in the quarter reflects improved net cash at quarter end

Net cash

- Cash SEK 1,108 M
- Net cash SEK 305 M



PnL impact of Elocta launch



Up to Launch

- Base cross royalty rate between Sobi and Biogen is 12%
- Royalty to Sobi of 2% on sales in the Biogen territory booked as revenue
- The remaining 10% royalty is accumulated as a credit since launch – not booked until first Sobi commercial sale

Launch: January 2016

- One-time credit booked as revenue (no cash effect); ~USD 38 M
- Royalty to Sobi is 7%, 12% is booked as revenue and 5% is credited to dev. obl.
- Royalty to Biogen on Sobi territory sales is 17%, 12% is booked as COGS and 5% is credited to dev. obl.

MAH transfer: March 2016

- Sobi has assumed 50% development activity and costs in 2016
- Estimated total repayment obligation to Biogen USD 210 M
- Current liability is USD 162 M

Summary

Geoffrey McDonough | CEO

Outlook 2016 (unchanged)



Revenues

Sobi expects total revenues for the full year to be in the range of SEK 4,800 to 5,000 M

Gross Margin

Gross margin is expected to be in the range of 68 to 70 per cent

EBITA

Sobi expects EBITA for the full year to be in the range of SEK 1,200 to 1,300 M

Revenue will include one time credits for Elocta of SEK 300-325 M, and for Alprolix SEK 300-325 M, which will not impact cash.

Sobi will continue to invest in the launches of Elocta and Alprolix and will also take on incremental cost of SEK 250–300 M, reflecting its 50 per cent share of Biogen's ongoing development costs for the products.

The outlook was published on 29 February 2016.

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 – providing forward cash flow to continue to build company
3. Growing the business organically with new partner products, and with a pipeline of early stage rare disease biologics

