



**Geoffrey McDonough | CEO**

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# Q2 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 Q2 2016



- Alprolix® approved in the EU; first sales reported in Germany
- Elocta® approved in Switzerland
- European patent granted for new Kineret® formulation
- Signed licensing agreement with Affibody for IL-1
- Signed manufacturing agreements with Pfizer
- Orfadin® Oral Suspension and 20 mg capsule approved in the US
- Bond redeemed and replaced with new financing on substantially better terms



# Significant events after the reporting period



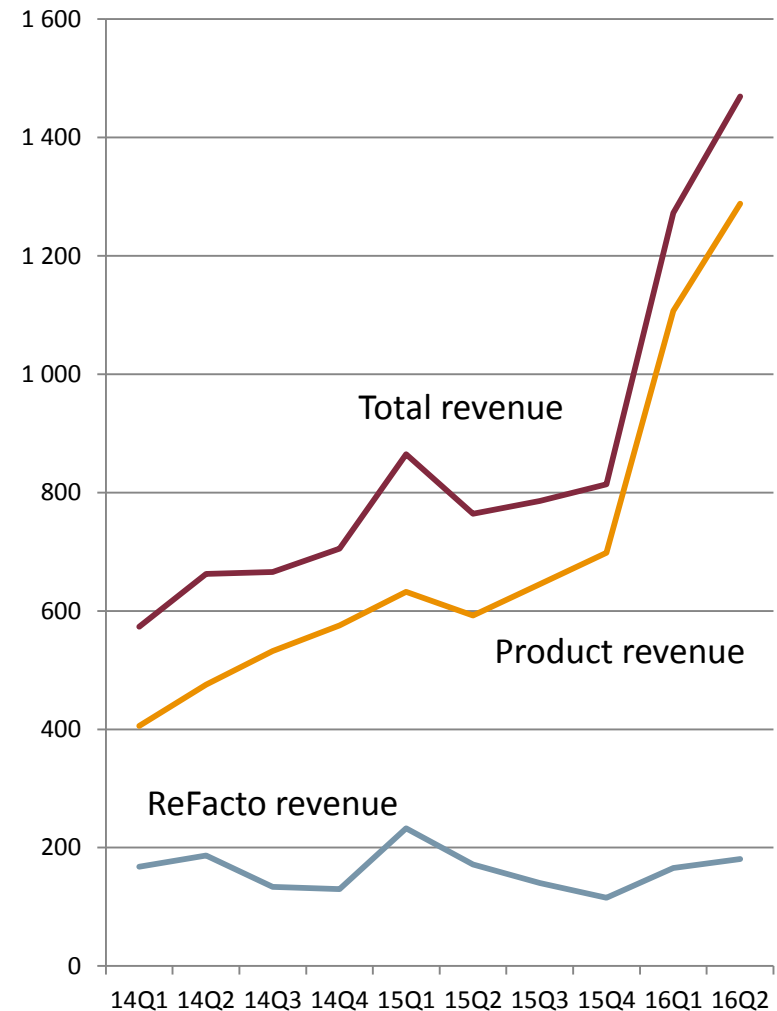
- Health Canada validates Orfadin® capsule filing



# Highlights Q2 2016



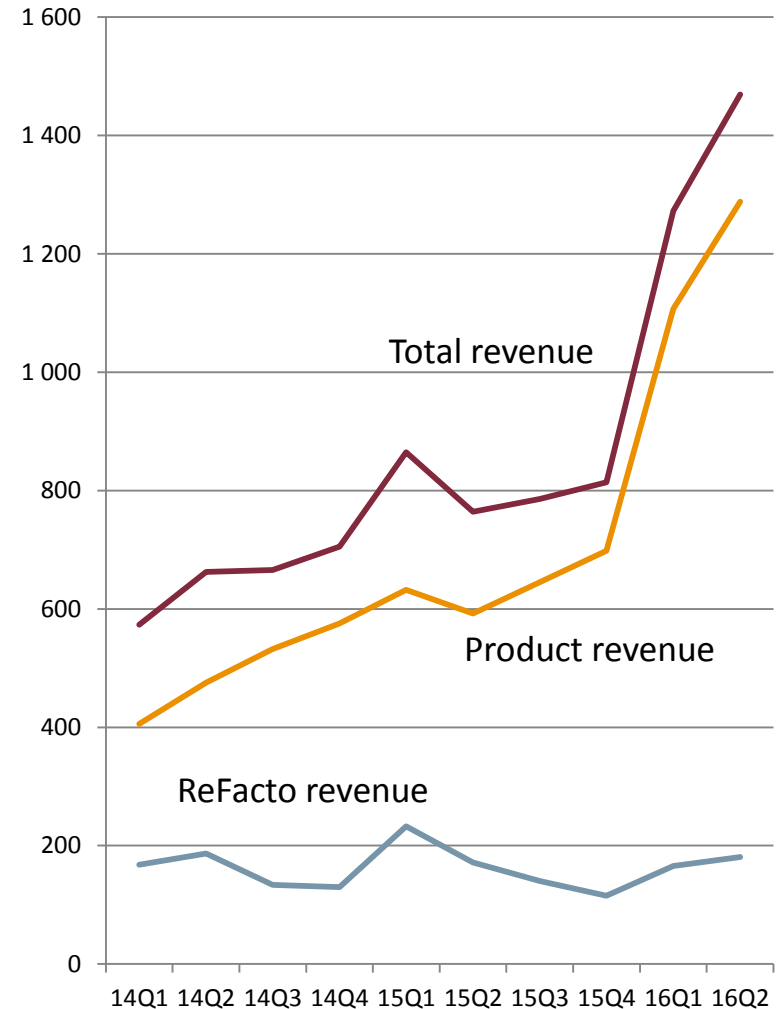
- Total revenue: SEK 1,469 M (764)
  - 92% growth (95% at CER)
- Product revenue: SEK 1,288 M (593)
  - >100% growth (>100% at CER)
  - incl. a one-time credit of SEK 386 M
- ReFacto revenue: SEK 181 (172)
  - 6% increase
- Gross margin 72% (63%)
- EBITA: SEK 550 M (74)
- Cash flow operations: SEK 0 M (79)



# Highlights H1 2016



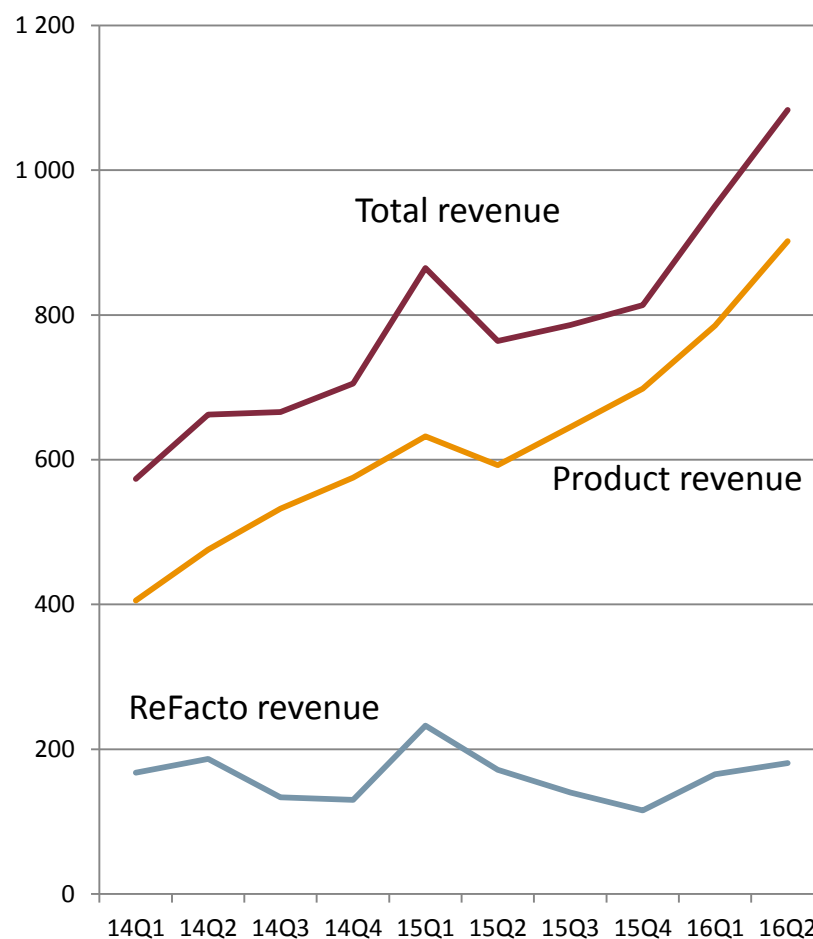
- Total revenue: SEK 2,742 M (1,629)
  - 68% growth (71% at CER)
- Product revenue: SEK 2,395 M (1,225)
  - 96% growth (98% at CER)
  - incl. one-time credits of SEK 708 M
- ReFacto revenue: SEK 346 (404)
  - 14% decrease
- Gross margin 73% (61%)
- EBITA: SEK 1,052 M (247)
- Cash flow operations: SEK 235 M (249)



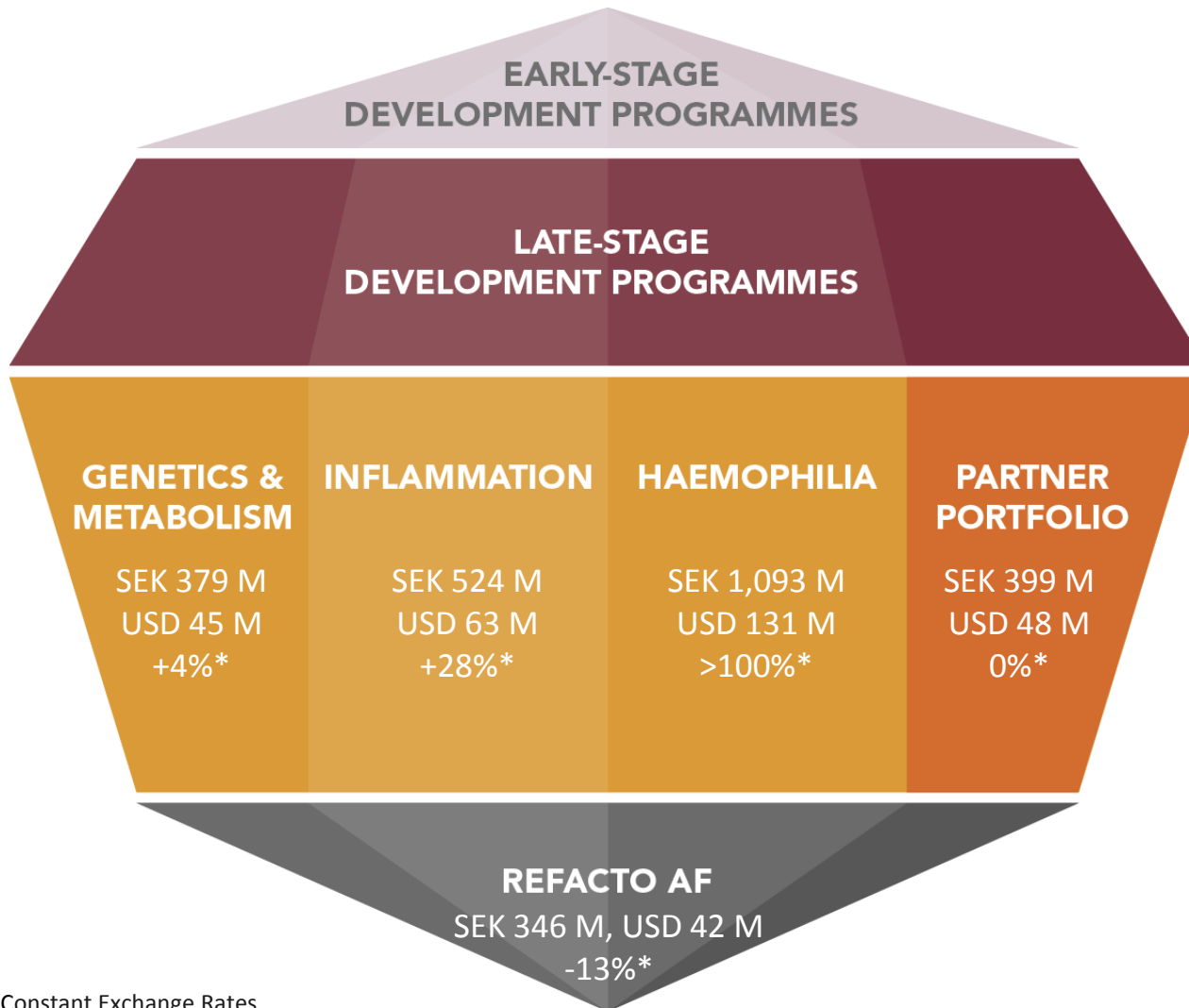
# Highlights H1 2016 excluding one-time credits



- Total revenue: SEK 2,034 M (1,629)
  - 25% growth (27% at CER)
- Product revenue: SEK 1,687 M (1,225)
  - 38% growth (40% at CER)
- ReFacto revenue: SEK 346 (404)
  - 14% decrease
- Gross margin 64% (61)
- EBITA: SEK 344 M (247)
- Cash flow operations: SEK 235 M (249)



# YTD 2016 revenue by business line



\*Growth at Constant Exchange Rates  
USD 1 = SEK 8,3331

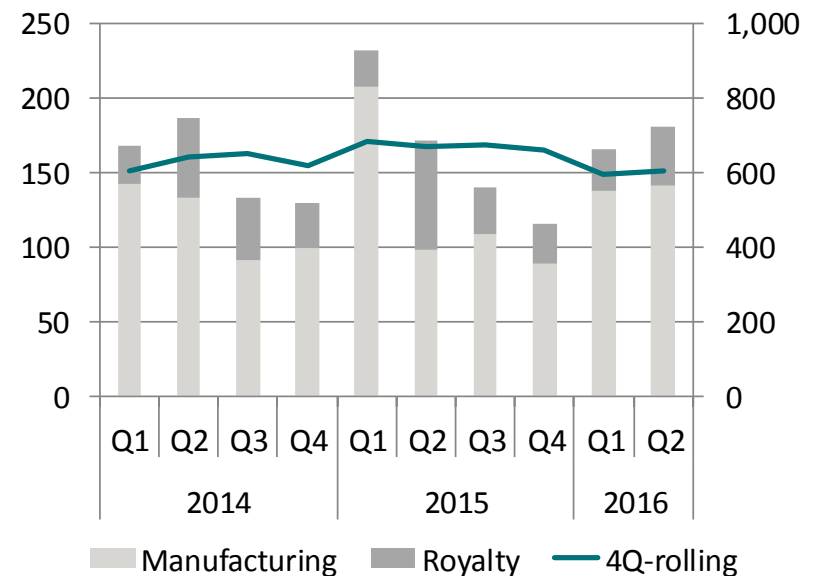


# ReFacto



- Revenue for manufacturing and royalty SEK 181 M (172)
  - Increase of 6%
- YTD revenue SEK 346 M (404)
  - Decrease of 14%
- Manufacturing revenue SEK 142 M (99)
- Royalty revenue SEK 39 M (73)
  - Royalty for ROW expired May 2016
  - YTD royalty ROW was SEK 47 M (74)

Revenues (SEK M): ReFacto

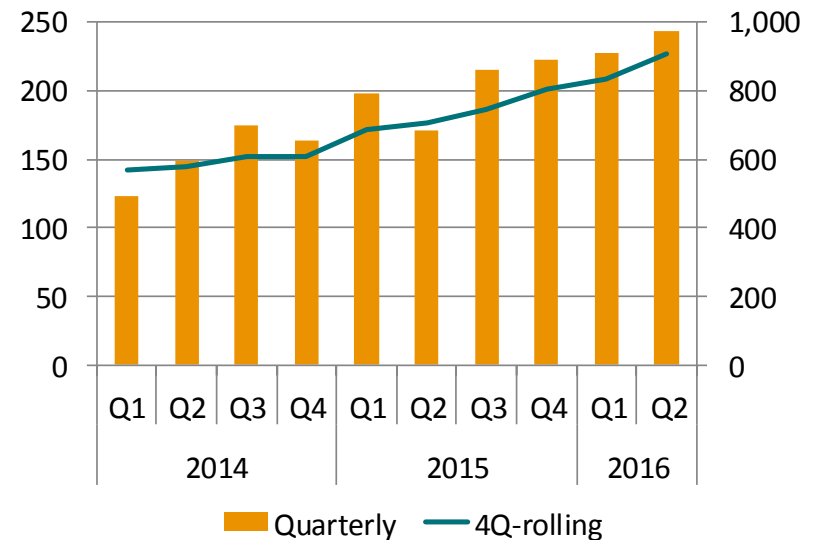


# Commercial results Q2 2016

Alan Raffensperger | COO

- Revenue SEK 243 M (171)
  - Increase of 43%
- YTD revenues SEK 471 M (369)
  - YTD increase of 28%
- Strong organic growth across markets

Revenues (SEK M): Kineret

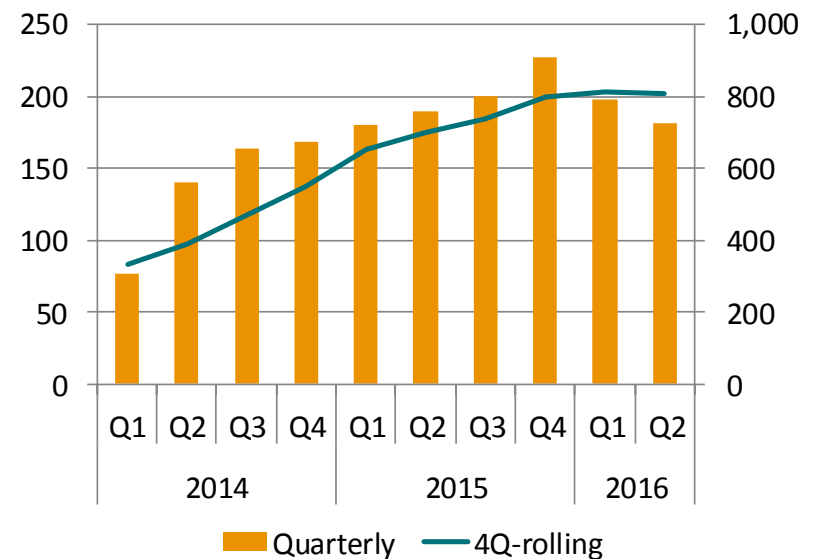


# Orfadin



- Revenue SEK 182 M (189)
  - Decrease of 4%
- YTD revenue SEK 379 M (369)
  - Increase of 3%
- Growth in Europe supported by the continued launch of oral suspension
- US lower due to higher than average Medicaid rebates in June
- Orfadin Oral Suspension and 20 mg approved by FDA

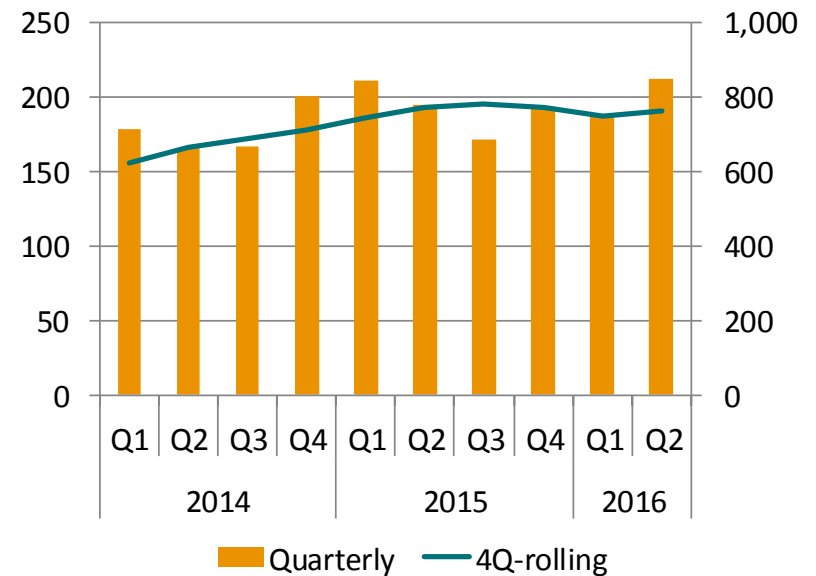
Revenues (SEK M): Orfadin



# Partner Products

- Revenue SEK 212 M (195)
  - Increase of 9%
- YTD revenue SEK 399 M (406)
  - Decrease of 2%
- Continued strong growth for Xiapex®
- Revenue growth also supported by new PharmaSwiss partnership

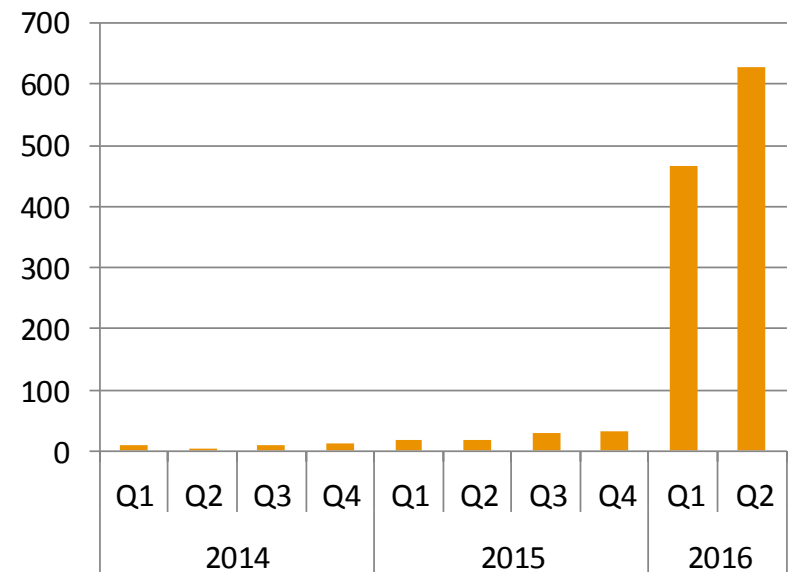
Revenues (SEK M): Partner Products



# Haemophilia

- Revenue SEK 627 M (18)
- YTD revenue SEK 1 093 M (35)

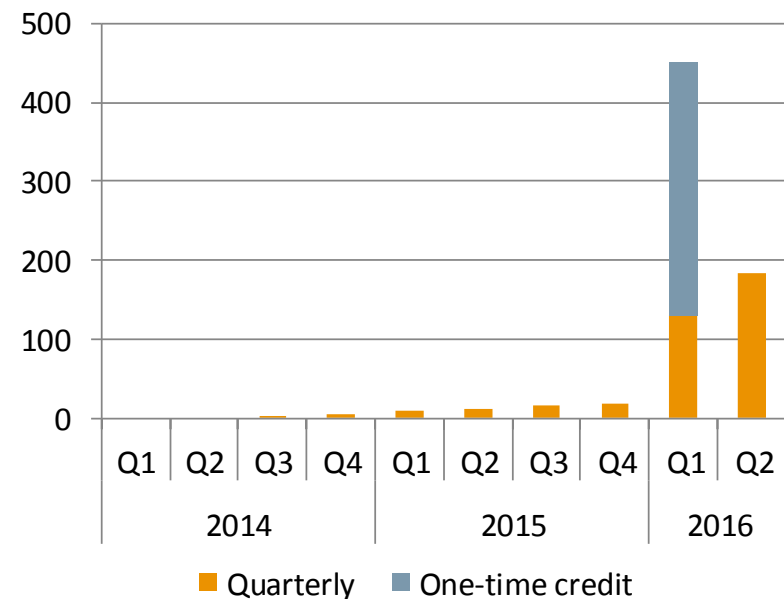
Revenues (SEK M): Haemophilia



- Revenue SEK 184 M (11)
  - SEK 129 M (11) estimated royalty revenue\*
  - SEK 55 M (0) in sales
- YTD revenue SEK 637 M (20)
- Approved in Switzerland in June

\*Royalty estimated prior to Biogen financial reporting

**Revenues (SEK M): Elocta/Eloctate**



# Elocta launch progress

## Q2 2016 update



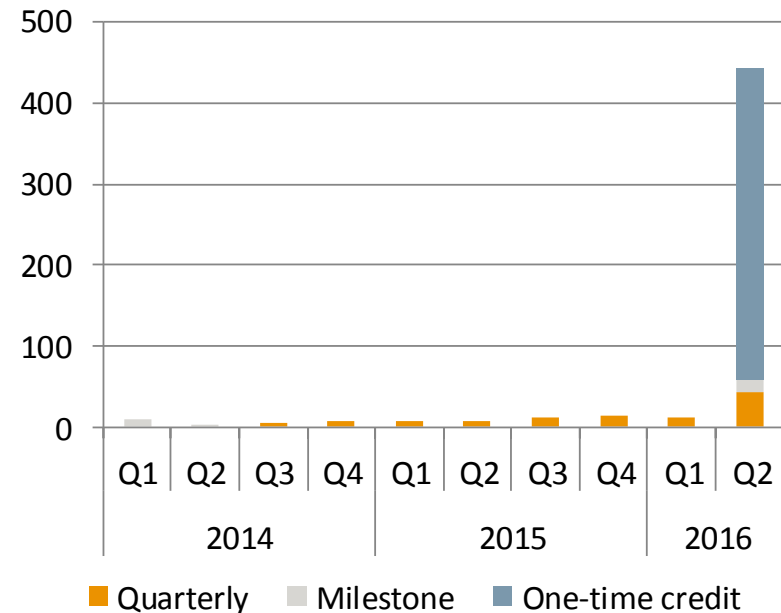
- Revenue from the quarter derived mainly from Germany and the Middle East, with first sales also in UK, Ireland and Sweden
- Reimbursement for Elocta now granted in Germany, the Netherlands, Ireland, and Sweden
- UK: NHS Framework agreements in place for Elocta in Northern Ireland, Wales and Scotland; final commissioning guidance under development in England
- Preparations on track to enter remaining markets over the coming year



- Revenue SEK 444 M (8)
  - SEK 39 M (8) estimated royalty revenue\*
  - SEK 386 M (0) one-time credit
  - SEK 5 M (0) sales
  - SEK 14 M (0) milestone revenue for EMA approval of Alprolix
- YTD revenue SEK 456 M (15)
- Alprolix approved in EU 12 May 2016

\*Royalty estimated prior to Biogen financial reporting

Revenues (SEK M): Alprolix



# Alprolix launch preparations

## Q2 2016 update



- Revenue from the quarter derives mainly from Germany and the Middle East, with first sales also in UK
- Reimbursement for Alprolix now granted in Germany, the Netherlands, and Ireland
- UK: NHS Framework agreements in place for Alprolix (effective 1 September) in Northern Ireland, Wales and Scotland; final commissioning guidance under development in England
- Preparations on track to enter remaining markets over the coming year
- Launch sequence similar to Elocta

# Financial results Q2 2016

Geoffrey McDonough | CEO

# Profit and Loss statement



| <i>Amounts in SEK M</i>           | Q2-16        | Q2-15      | H1-16        | H1-15        | FY 2015      |
|-----------------------------------|--------------|------------|--------------|--------------|--------------|
| <b>Total revenues</b>             | <b>1 469</b> | <b>764</b> | <b>2 742</b> | <b>1 629</b> | <b>3 228</b> |
| <b>Gross profit</b>               | <b>1 065</b> | <b>482</b> | <b>2 009</b> | <b>1 001</b> | <b>2 007</b> |
| <i>Gross margin</i>               | 72%          | 63%        | 73%          | 61%          | 62%          |
| Sales and Administration          | -325         | -274       | -640         | -493         | -1 057       |
| Research and development          | -202         | -127       | -340         | -259         | -513         |
| Other operating revenues/expenses | 12           | -7         | 23           | -3           | -3           |
| <b>EBITA</b>                      | <b>550</b>   | <b>74</b>  | <b>1 052</b> | <b>247</b>   | <b>433</b>   |
| Amortisations and write-downs     | -97          | -72        | -189         | -142         | -287         |
| <b>EBIT</b>                       | <b>453</b>   | <b>3</b>   | <b>862</b>   | <b>105</b>   | <b>146</b>   |
| Financial income/expenses         | -28          | -17        | -51          | -19          | -58          |
| <b>Profit before tax</b>          | <b>425</b>   | <b>-15</b> | <b>812</b>   | <b>86</b>    | <b>88</b>    |
| Income tax expense                | -159         | 13         | -245         | -13          | -19          |
| <b>Profit/loss for the period</b> | <b>265</b>   | <b>-2</b>  | <b>567</b>   | <b>73</b>    | <b>68</b>    |

- Improved Gross margin due to increased royalty revenues
- Increase in S&A expenses reflects build-up of Haemophilia organisation
- Increase in R&D expenses reflects incremental development costs from Biogen
- Financial net reflects costs for repayment of bond

# Balance sheet

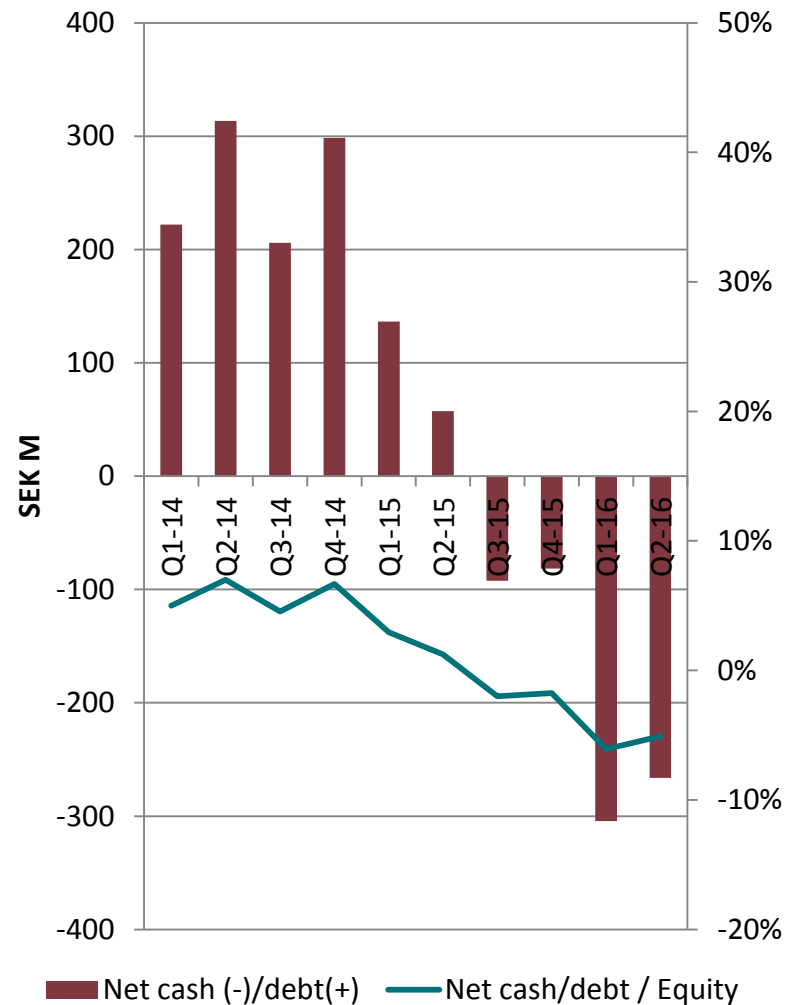


| <i>Amounts in SEK M</i>             | June 2016    | Dec 2015     | June 2015    |
|-------------------------------------|--------------|--------------|--------------|
| <b>ASSETS</b>                       |              |              |              |
| Intangible                          | 6 974        | 5 787        | 4 128        |
| Tangible and other                  | 192          | 208          | 199          |
| <b>Total non-current assets</b>     | <b>7 165</b> | <b>5 995</b> | <b>4 327</b> |
| Inventories                         | 751          | 776          | 742          |
| Accounts receivable                 | 558          | 451          | 523          |
| Other Receivable                    | 346          | 185          | 194          |
| Cash and equivalent                 | 770          | 904          | 763          |
| <b>Total current assets</b>         | <b>2 426</b> | <b>2 316</b> | <b>2 222</b> |
| <b>Total Asset</b>                  | <b>9 591</b> | <b>8 311</b> | <b>6 549</b> |
| <b>EQUITY AND LIABILITIES</b>       |              |              |              |
| <b>Equity</b>                       | <b>5 247</b> | <b>4 689</b> | <b>4 630</b> |
| Long term debt                      | 502          | 800          | 819          |
| Long term liabilities               | 2 461        | 1 501        | 316          |
| Short term liabilities              | 1 382        | 1 320        | 784          |
| <b>Total liabilities</b>            | <b>4 344</b> | <b>3 621</b> | <b>1 919</b> |
| <b>Total equity and liabilities</b> | <b>9 591</b> | <b>8 311</b> | <b>6 549</b> |

- Increase in intangible assets and liabilities due to Elocta/Alprolix approvals
- Reduction in long term debt reflects repayment of bond and draw down of new term loan

# Net cash

- Cash SEK 770 M
- Net cash SEK 266 M
- The bond of SEK 800 M called and repaid in the quarter
- New term loan of SEK 500 M established in the quarter
- Substantially better terms with new financing structure



# PnL impact of Alprolix 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: June 2016

- One-time credit booked as revenue (no cash effect); ~USD 46 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: expected in Q3 2016

- Sobi will assume 50% development activity and costs in 2016
- Estimated total repayment obligation to Biogen USD 186 M
- Current liability is USD 130 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 SEK

## Gross margin

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

## EBITA - updated

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

# 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

