Q4 and FY results presentation 2015

Geoffrey McDonough | CEO

Alan Raffensperger | COO

Mats-Olof Wallin | CFO



Stockholm | 26 February 2016

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Pioneer in Rare Diseases

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 Q4 2015

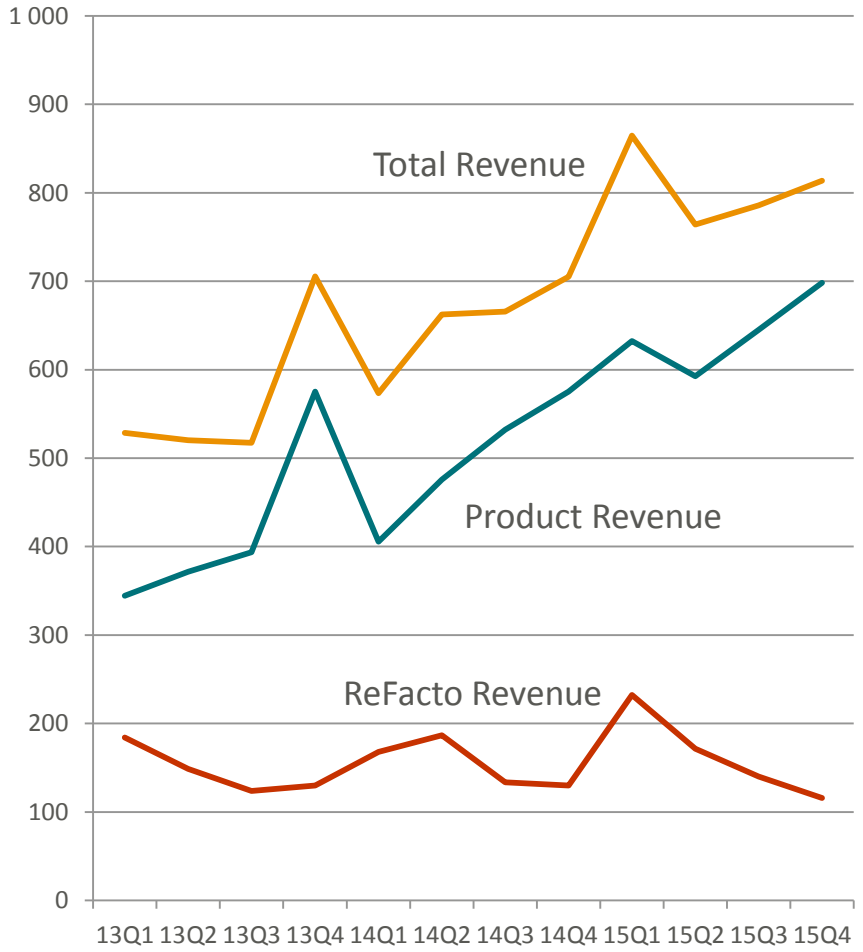
- Elocta® (efmoroctocog alfa) approved in Europe for the treatment of haemophilia A
- New data showed that Elocta and Alprolix® (rFIXFc) reduced target joint bleeds in people with haemophilia over a longer observation time
- Sobi and Biogen initiated deliveries of largest ever donation of haemophilia therapy
- European Medicines Agency approved Xiapex® for concurrent treatment of palpable cords
- Lars Dreiøe appointed Senior Vice President, Chief Quality & Compliance Officer

Significant events after the quarter

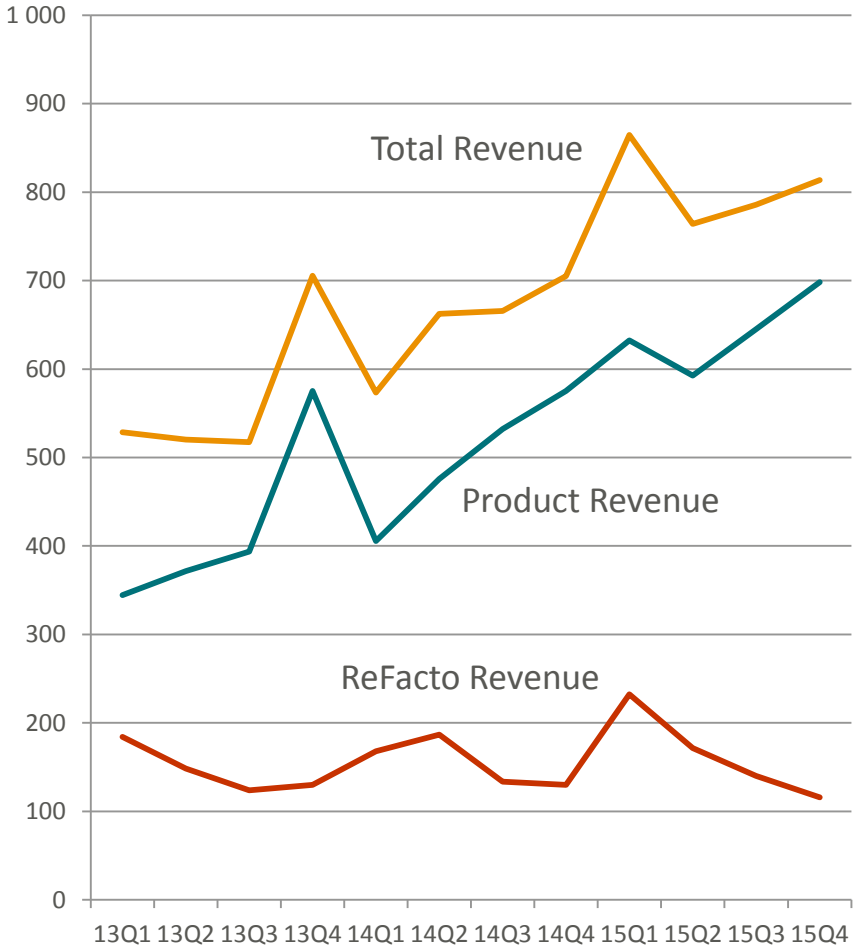
- Announced commercial launch of Elocta in first countries in EU
- Gained commercial rights for Relistor®, Deflux® and Solesta® from PharmaSwiss
- Sobi's Orfadin® oral suspension granted European patent
- Announced initiation of clinical development programs in acute gout and Still's disease
- Received US patent on new formulation for Kineret® (anakinra)

Highlights Q4 2015

- Total revenues: SEK 814 M (705)
  - 15% growth (9% at CER)
- Product revenues: SEK 698 M (575)
  - 21% growth (13% at CER)
- ReFacto® revenues: SEK 116 (130)
  - 11% decrease
- Gross margin 64% (60)
- EBITA: SEK 90 M (38)
- Cash flow operations: SEK 13 M (53)

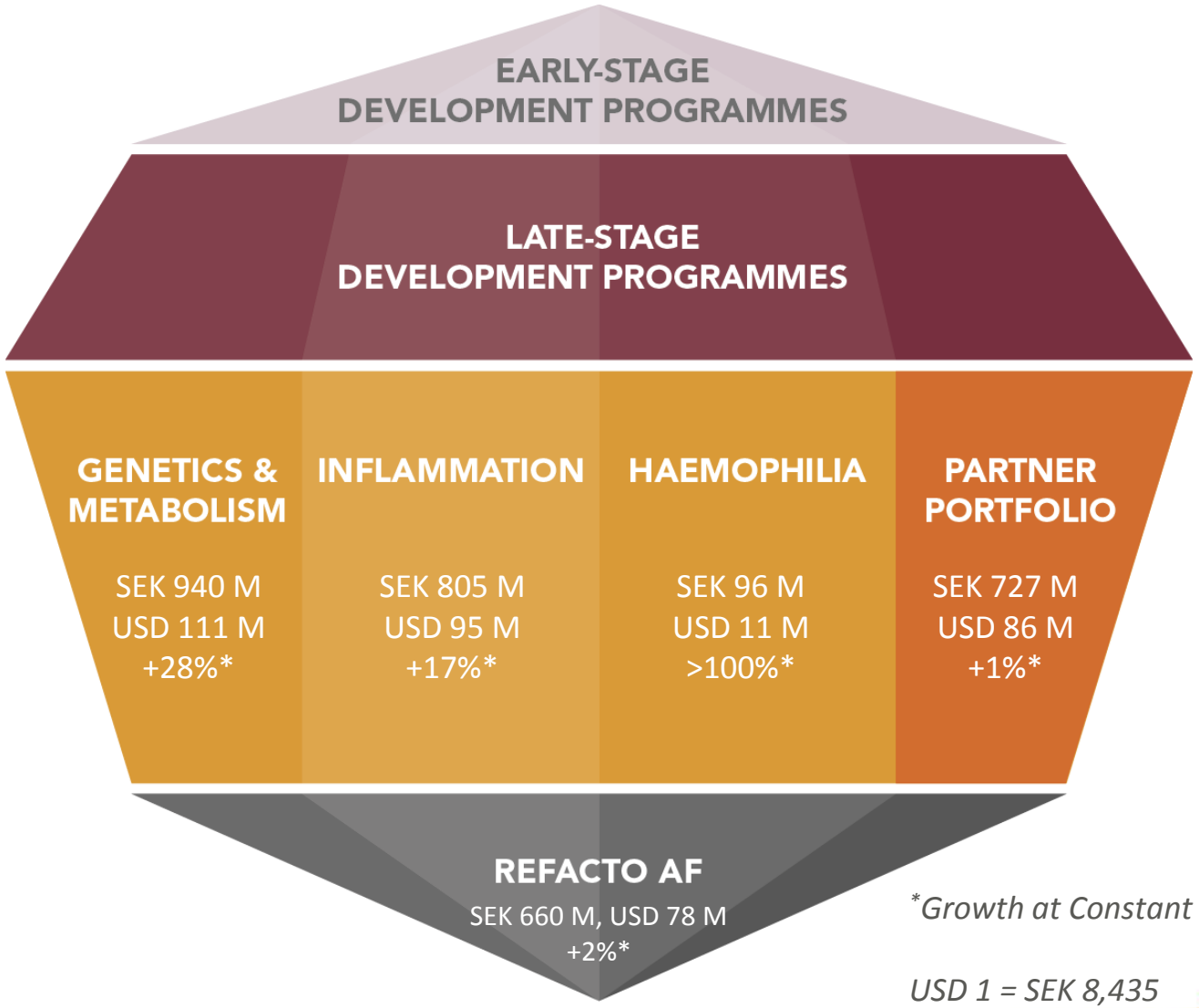


Highlights FY 2015



- Total revenues: SEK 3,228 M (2,607)
  - 24% growth (14% at CER)
- Product revenues: SEK 2,568 M (1,989)
  - 29% growth (18% at CER)
- ReFacto® revenues: SEK 660 (618)
  - 7% increase
- Gross margin 62% (59)
- EBITA: SEK 433 M (-43)
- Cash flow operations: SEK 507 M (234)

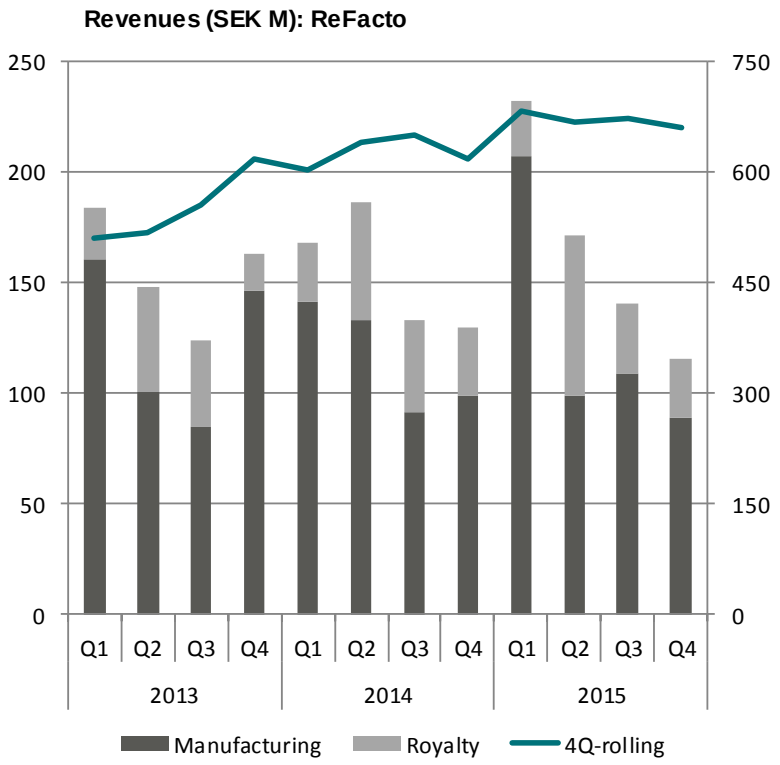
YTD 2015 revenue by business line



**Growth at Constant Exchange Rates*

USD 1 = SEK 8,435

ReFacto AF®



- Revenue for manufacturing and royalty SEK 116 M (130)
  - Decrease of 11%
  - Phasing effects caused by higher deliveries in the first half 2015
- Manufacturing revenue SEK 89 M (99)
- Royalty revenue SEK 27 M (31)
- FY was SEK 660 M (618)
  - Increase of 7%

Commercial results Q4 & FY 2015

Alan Raffensperger | COO

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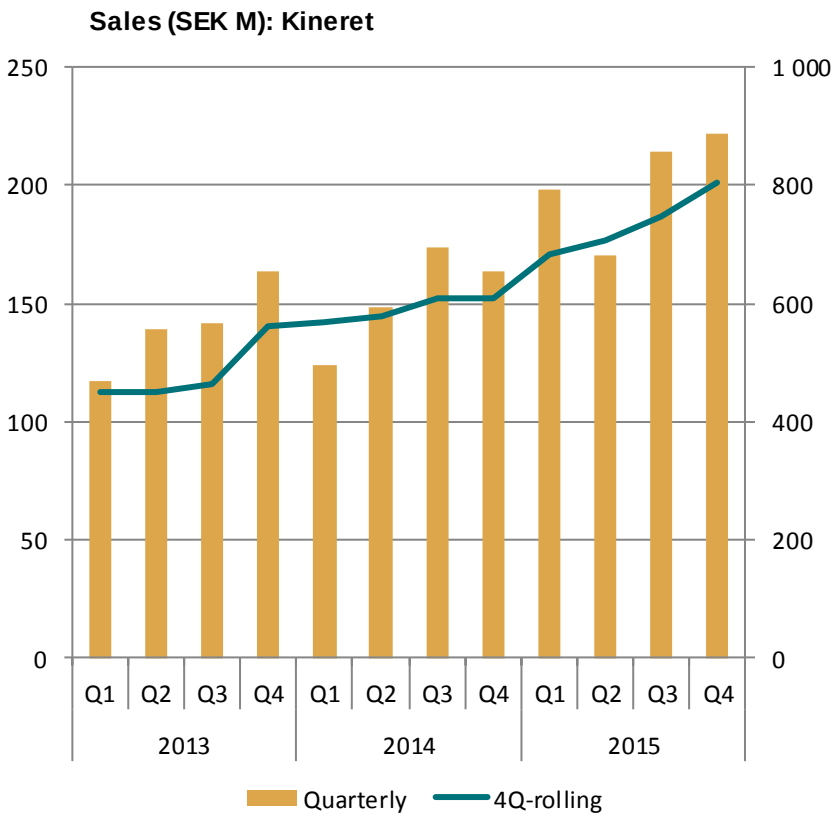
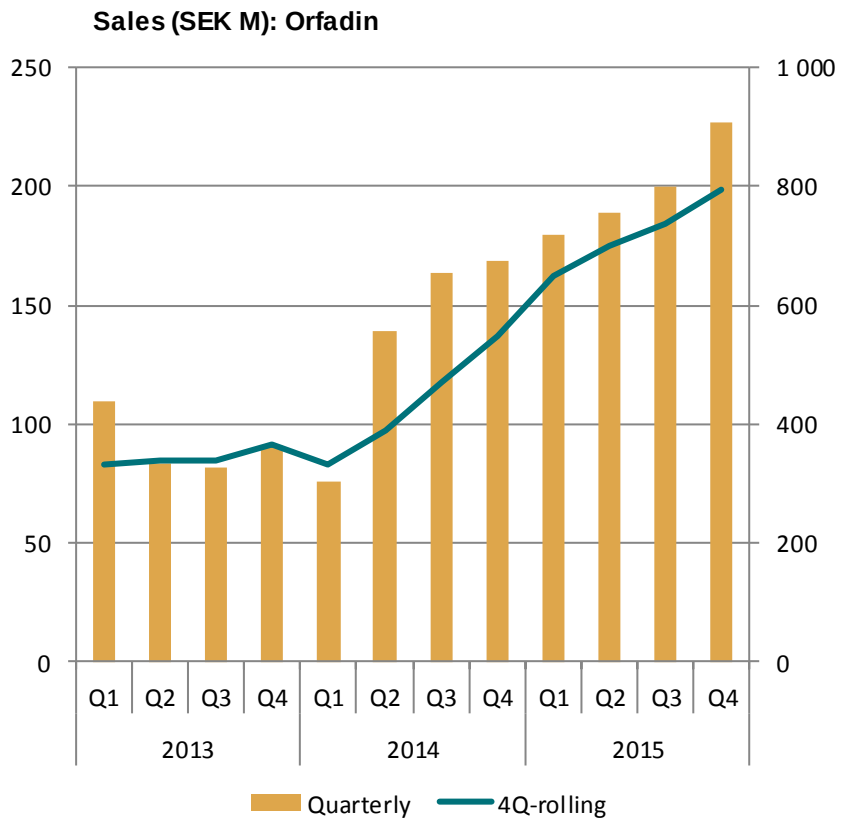
Kineret®



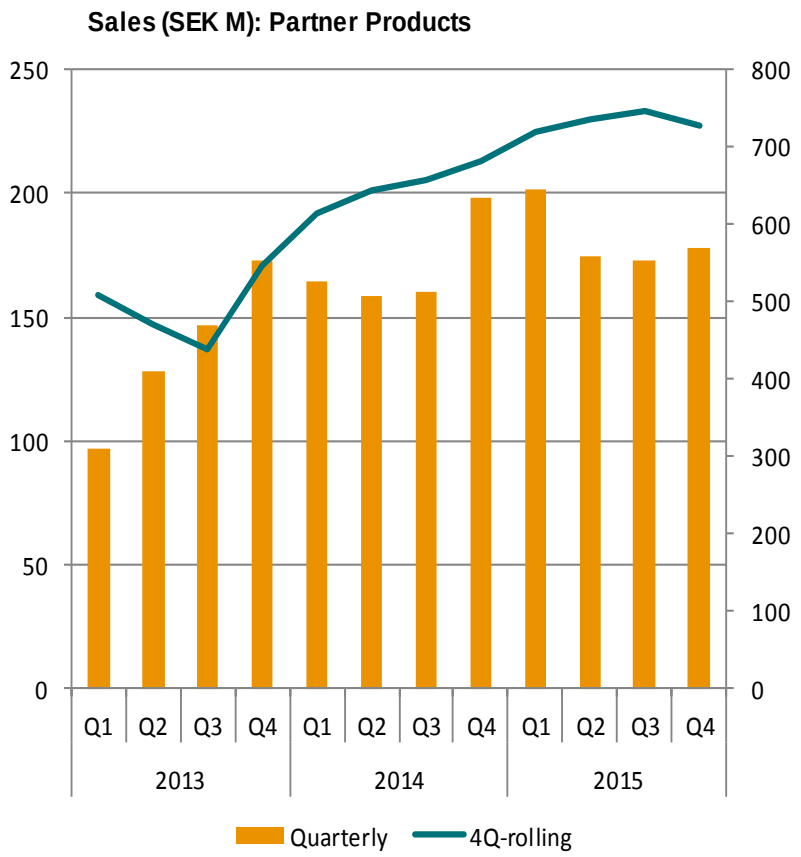
- Revenue SEK 222 M (163)
  - Increase of 36%
- YTD was SEK 805 M (609)
  - Increase of 32%
- Continued growth in major markets, in line with ongoing development of the CAPS and NOMID indications
- Shift in distribution in the US gaining traction

Orfadin



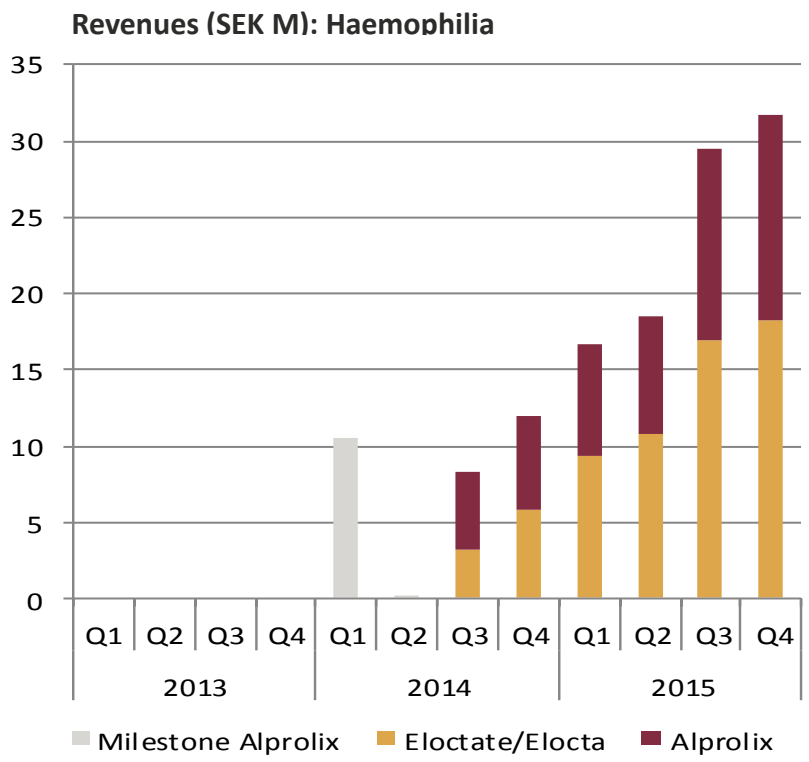
- Revenue SEK 227 M (169)
  - Increase of 35%
- YTD was SEK 796 M (548)
  - Increase of 45%
- Growth in all major markets
- Launch of liquid suspension underway

Partner Products



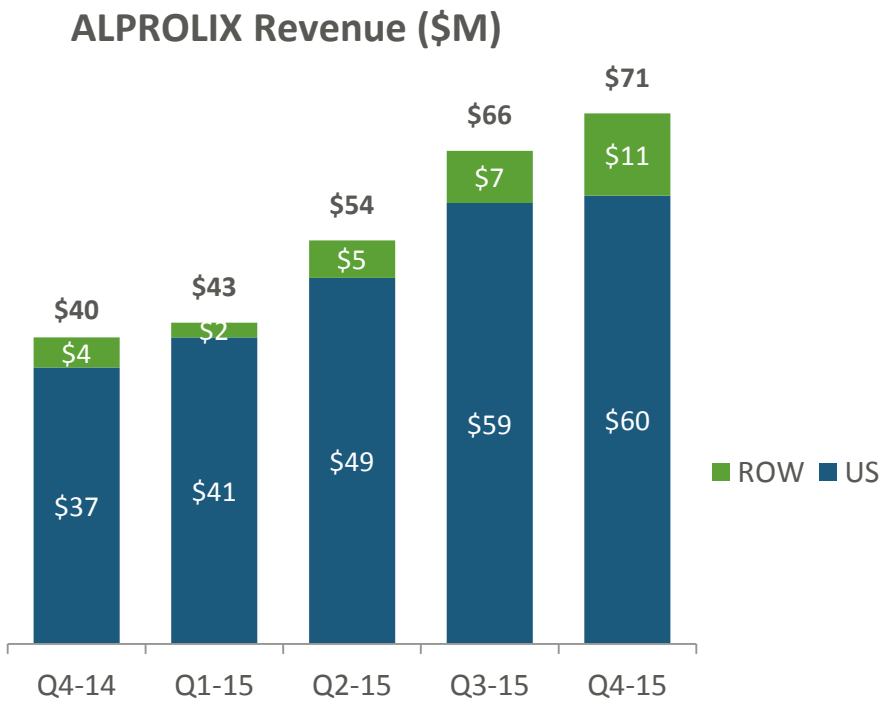
- Revenue SEK 178 M (198)
  - Decrease of 10%
  - Discontinued products account for quarter to quarter variation
- FY revenue SEK 727 M (682)
  - Increase of 7%
- Growth mainly driven by Xiapex, Cometriq® and Aloxi®

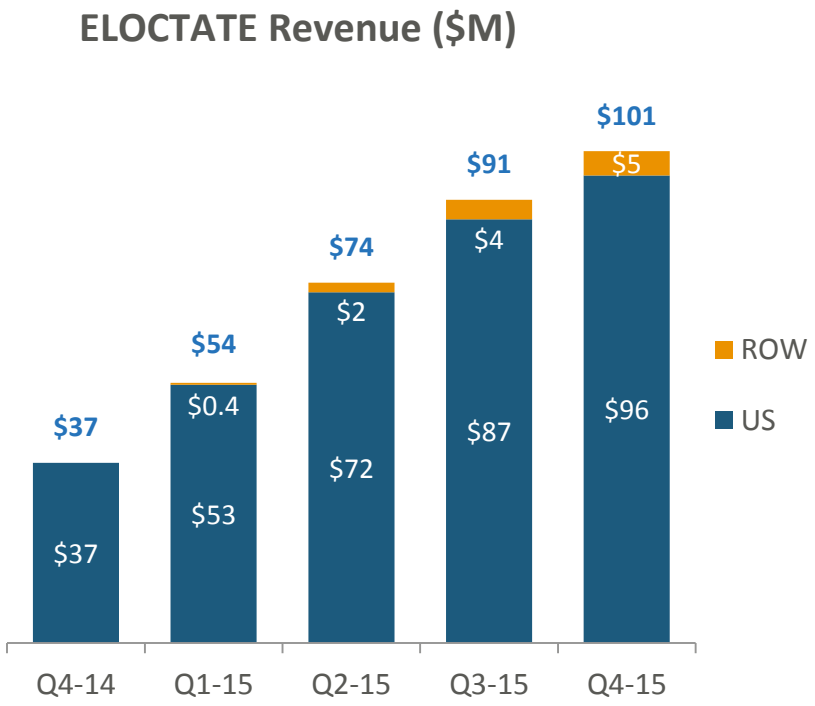
Haemophilia



- Revenue SEK 32 M (12)
  - SEK 30 M in royalty revenues and SEK 2 M in NPU sales
- Full year revenue of SEK 96 M (31)
  - SEK 94 M in royalty revenues and SEK 2 M in NPU sales
- Elocta received approval in Europe on 19 November 2015

Haemophilia – Biogen revenues





ALPROLIX®
[Coagulation Factor IX (Recombinant), Fc Fusion Protein]

ELOCTATE®
[Antihemophilic Factor (Recombinant), Fc Fusion Protein]

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Financial results Q4 & FY 2015

Mats-Olof Wallin | CFO

Pioneer in Rare Diseases

Profit and Loss statement

Amounts in SEK M	Q4-15	Q4-14	FY 2015	FY 2014
Total revenues	**814**	**705**	**3 228**	**2 607**
Gross profit	**520**	**427**	**2 007**	**1 548**
Gross Margin	*64%*	*60%*	*62%*	*59%*
Sales and Administration	-293	-214	-1 057	-750
Research and development	-135	-149	-513	-501
Other operating revenues/expenses	-3	-25	-3	-341
EBITA	**90**	**38**	**433**	**-43**
Amortizations and write-downs	-73	-71	-287	-282
EBIT	**17**	**-33**	**146**	**-325**
Financial income/expenses	-26	10	-58	6
Income tax expense	0	5	-19	51
Profit/loss for the period	**-9**	**-17**	**68**	**-268**

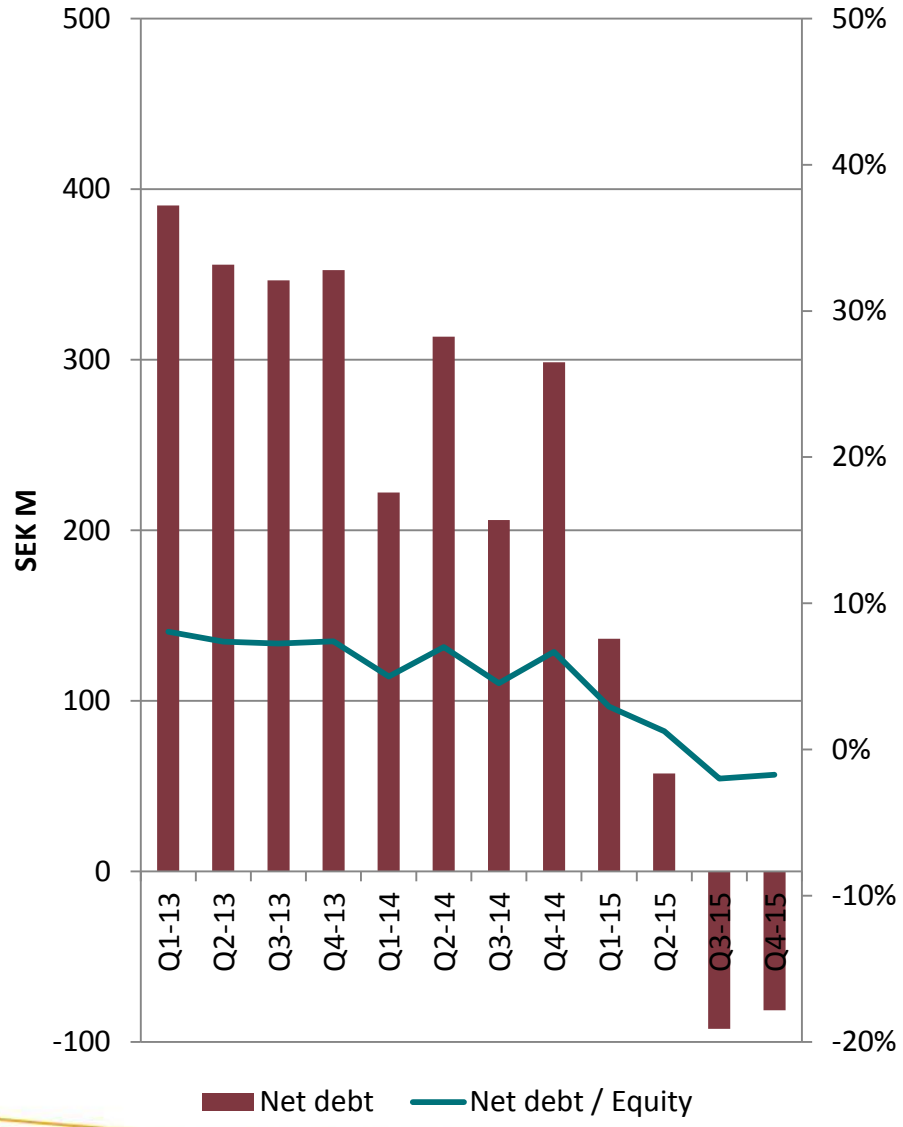
- Improved GM – favourable product mix and positive currency impact
- Increase in S&A expenses reflects build-up of haemophilia organisation
- EBITA improved – 2014 impacted by one-time write-offs of SEK 350 M (Kiobrina and Multiferon)

Balance Sheet

Amounts in SEK M	Dec 2015	Dec 2014
ASSETS		
Intangible	5 787	4 248
Tangible and financial	208	188
Total non-current assets	**5 995**	**4 436**
Inventories	776	764
Accounts receivable	451	480
Other Receivable	185	172
Cash and equivalent	904	519
Total current assets	**2 316**	**1 935**
Total Asset	**8 311**	**6 371**
EQUITY AND LIABILITIES		
Equity	**4 689**	**4 523**
Long term debt	800	816
Long term liabilities	1 501	285
Short term liabilities	1 320	747
Total liabilities	**3 621**	**1 848**
Total equity and liabilities	**8 311**	**6 371**

- Intangible assets and liabilities impacted by the approval of Elocta in Q4 2015
- Accounts Receivables improved
- Net cash at year end

Net cash/debt



- Cash SEK 904 M
- Net cash SEK 82 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: 2016

- Sobi will assume 50% development activity and costs in 2016
- Estimated repayment obligation to Biogen ~ USD 216 M

Outlook 2015

Revenues

Revenues for the full year were SEK 3,228 M, above the predicted range of SEK 3,000 to 3,200 M

Gross Margin

Gross margin for the full year was 62 per cent, above the expected range of 59 to 61 per cent

EBITA – range revised

EBITA for the full year was SEK 433 M above the set range of SEK 350-400 M

The outlook for 2015 excluded revenue from the potential European launch of Elocta.

The original outlook was first published in the 2014 Q4 and FY report on 19 February 2015.

Summary and outlook

Geoffrey McDonough | CEO

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Outlook 2016

Revenues

Sobi expects total revenues for the full year to be in the range of SEK 4,300 to 4,500 M

Gross Margin

Gross margin is expected 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 700 to 800 M

Note:

2016 will be impacted by a one-time credit for Elocta estimated to be SEK 300-325 M. This one-time credit will be reported in the Profit and Loss Statement but will not impact cash.

OPEX includes Sobi share of ongoing costs for Elocta, estimated to be SEK 200 to 250 M.

This outlook excludes the impact of an anticipated Alprolix approval and launch in 2016.

What happens at Alprolix launch?

Revenue

- One time credit
- Product sales
- Incremental royalty 2 ⟶ 12 per cent

Costs

- Incremental costs for Sobi's share of ongoing costs for Alprolix

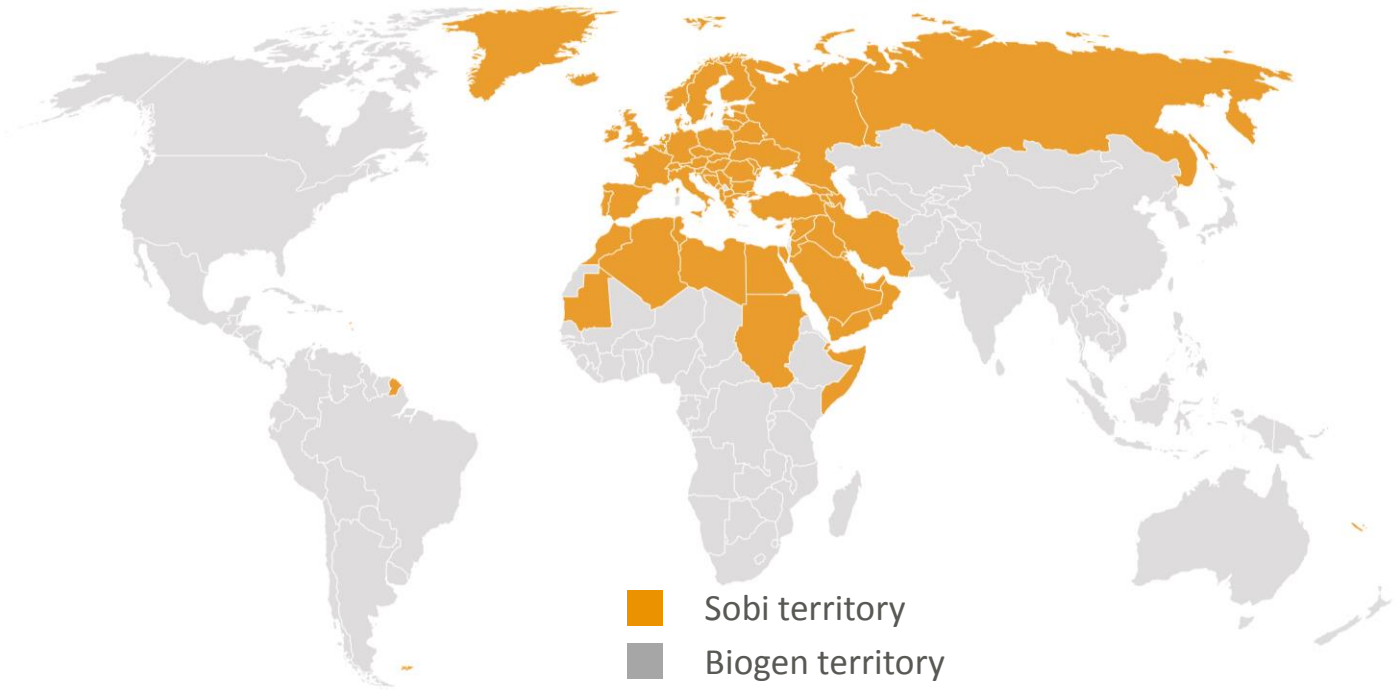
Haemophilia update

Haemophilia A in Sobi territory

Size of market in Sobi territory*

USD 3.3 B

SEK 23 B



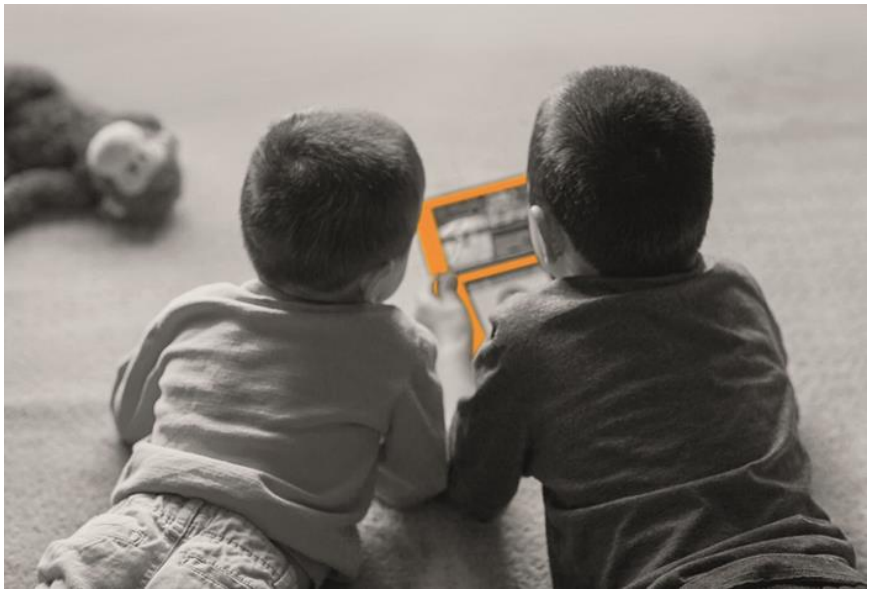
**Source: MRB, 2011, includes all patients (mild, moderate, severe)*

Elocta launch update

Elocta launch ongoing:

- Germany, UK, Denmark, Netherlands, Ireland
- Availability in the Middle East for commercial use

The importance of improved protection recognised by the community



Initial prescriber feedback:

"Lets my patients live more naturally"

- Abu Dhabi haemophilia physician

ELOCTA®
efmoroctocog alfa
(recombinant human coagulation factor VIII, Fc fusion protein)

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Elocta
Indication and prophylactic dosing guidance[1]

Elocta® is indicated for the <u>treatment</u> and <u>prophylaxis</u> of bleeding episodes in patients with haemophilia A (congenital factor VIII deficiency)

Elocta® can be used in <u>all age groups</u>

For long-term prophylaxis the recommended dose is:

50
IU/kg

The dose may be adjusted based on patient response:

In the range of
25–65
IU/kg

In some cases, especially in younger patients, shorter dosage intervals or higher doses may be necessary.

IU: International units

1. EMA. Elocta® Summary of Product Characteristics

A-LONG; Reduced ABRs with similar weekly Elocta consumption[1,2]

Sub-analysis of subjects with pre-study prophylaxis and on-study individualized prophylaxis for ≥ 6 months (n=80)

12 months prior to study **≥ 6 months on rFVIIIFc**

1 **Median weekly factor consumption (IU/kg)**

78.0 vs. **79.2***

Similar weekly consumption

2 **Median ABR**

6.0 vs. **0.0*†**

Increased protection

3 **Weekly dosing frequency**

~ 3 vs. **2** times

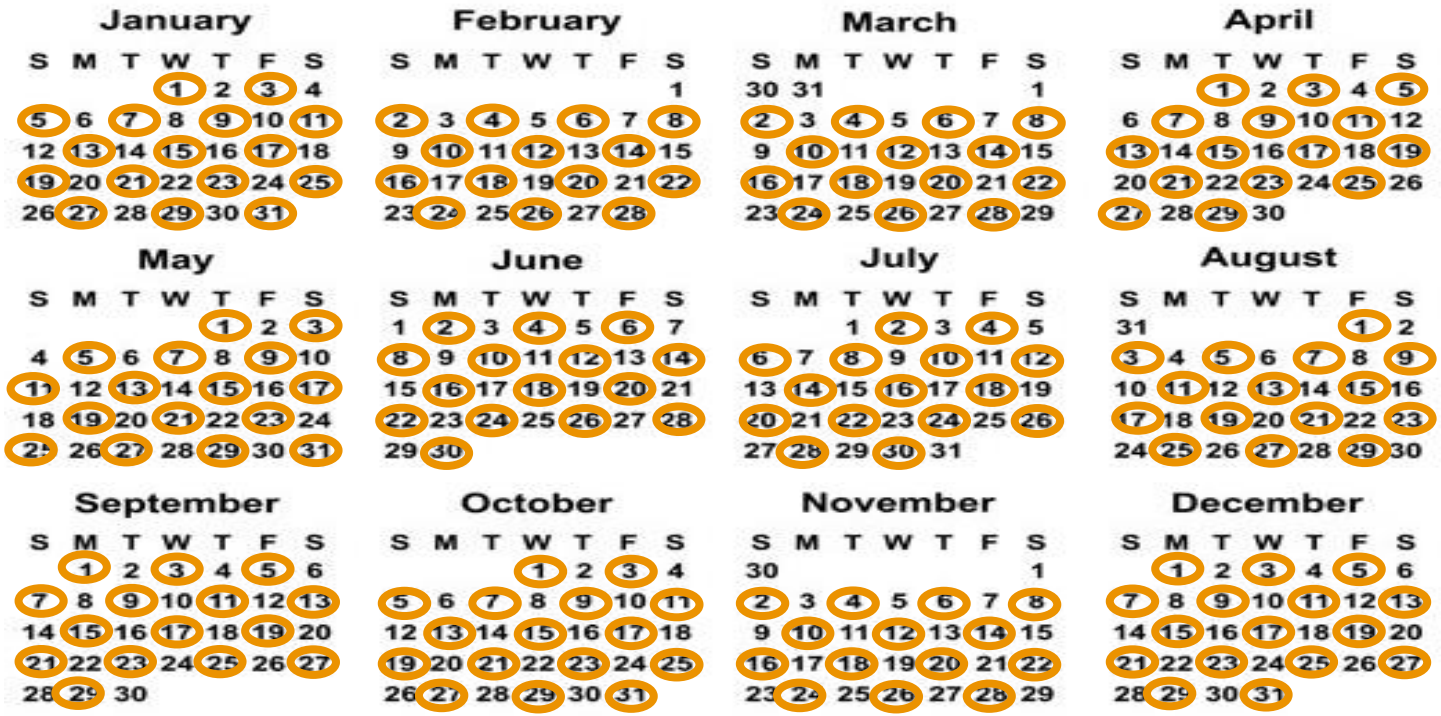
Fewer injections

ABR: Annualised bleeding rate; FVIII: Factor VIII;
* Over the last 3 months on-study; † $p \leq 0.003$
1. Mahlangu et al. *Blood* 2014; **2.** Shapiro et al. *J Thromb Haemost* 2014

A year of prophylaxis with conventional FVIII

(every other day dosing)*

In practice most commonly used dosing regimens with conventional FVIII are three times per week or every other day[1, 2, 3]



* Slide from M. Carcao

1. Meunier et al. *International Society on Thrombosis and Haemostasis*, 29 June–4 July 2013, Amsterdam, Netherlands;
2. Hay et al. *International Society on Thrombosis and Haemostasis*, 20–25 June 2015, Toronto, Canada;
3. Ahnström et al. *Haemophilia* 2004

A year of prophylaxis with extended half-life FVIII

(twice per week dosing)*

Median dosing frequency with rFVIIIFc in A-LONG was twice weekly[1]

* Slide from M. Carcao

1. Mahlangu et al. *Blood* 2014 (individualised prophylaxis arm)

EAHAD Congress Malmö 3rd – 5th February 2016

European Association for Haemophilia and Allied Disorders

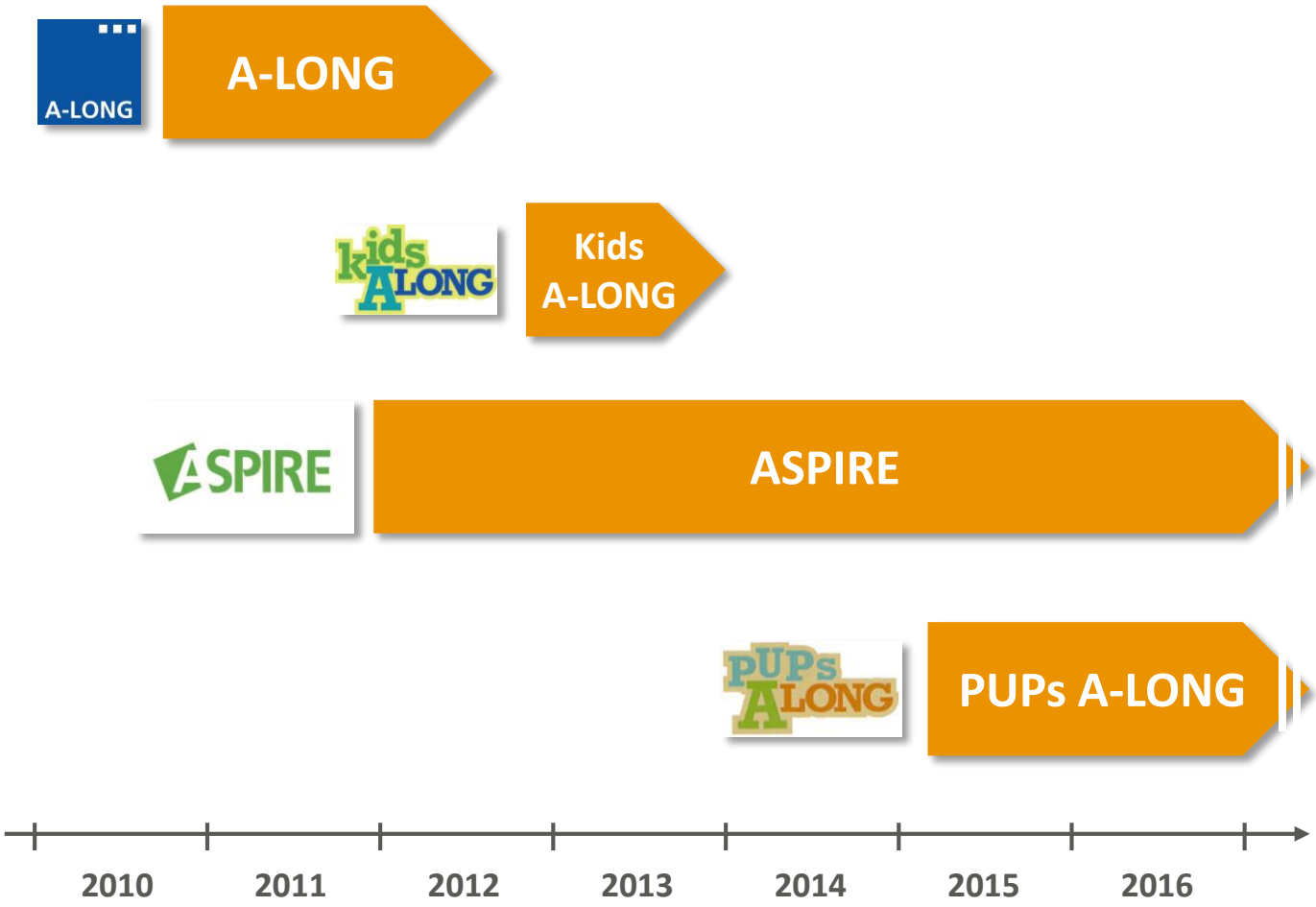
- 1600 delegates from across Europe and beyond

- Sobi symposium:

"TREATMENT GOALS IN HAEMOPHILIA: REDEFINING PROTECTION"

  - 800 plus attendees
  - Pivotal Elocta data: A-LONG & Kids A-LONG
  - Long-term Elocta data: ASPIRE
  - Real world data from US

Long term outcomes data from ASPIRE



Long term outcomes data from ASPIRE*

- Median time on ASPIRE: **126.9 weeks**
- Median cumulative duration on A-LONG + ASPIRE: **158.2 weeks**
- 87.3 % had ≥150 Elocta EDs

	A-LONG†[1]	ASPIRE data cut 1†[2]	ASPIRE data cut 2†[3]
Median ABR	1.6	0.7	0.8
Injection Frequency	3.5 days (median)	93.8% same or lengthened	93.8% same or lengthened
Median weekly consumption	77.9 IU/Kg	79.6 IU/Kg	79.2 IU/Kg
Inhibitors	Zero	Zero	Zero

* Slide shows adult/adolescent data; † In individualised prophylaxis group

1. Mahlangu et al. *Blood* 2014; **2.** Nolan et al. *Haemophilia* 2015; **3.** Pasi et al. *EAHAD* 2016 Poster P070

Elocta has a favourable safety profile after long-term exposure[1,2]

No inhibitors* were observed on-study, as of the 2nd interim data cut

Adverse events were typical of a haemophilia A population

Most common TEAEs[1]

- Nasopharyngitis (20.7%)
- Upper respiratory tract infection (11.3%)
- Arthralgia (10.0%)

No serious adverse events were considered to be related to Elocta

*Inhibitors are defined as anti-FVIII neutralising antibodies. A positive inhibitor test result was defined as a neutralising antibody value ≥0.6 BU/mL (by Nijmegen-modified Bethesda assay) and confirmed on retesting within 2–4 weeks

TEAE: treatment emergent adverse event; BU: Bethesda units; mL: Millilitre

1. Pasi et al. *EAHAD* 2016 Poster P070 (adults/adolescents data); **2.** Nolan et al. *EAHAD* 2016 Poster P072 (paediatric data)

Alprolix approval & launch planning

- Alprolix CHMP opinion imminent
- European Commission decision anticipated H1 2016
- Would enable launch mid-year 2016

Kineret update

Evolution of Kineret

Kineret features

- Strong evidence of effect in treating IL-1 mediated diseases
- Rapid onset + short duration of action
- Well-characterized safety profile
- Combines IL-1 α and β blockade
- Prefilled, graduated s.c syringes

Systemic/Joint

- Adult Onset Still's Disease
- Myositis
- PAPA syndrome
- SJIA
- Macrophage Activation Syndrome
- Osteomyelitis (incl. CRMO, SAPHO, Majeed)
- AID Family
- Kawasaki Disease
- Early-onset sarcoidosis/Blau syndrome
- Schnitzler's syndrome
- Henoch-Schönlein purpura
- Behcets
- Polyarteritis nodosa
- Erosive Osteoarthritis
- Granulomatosis w/ polyangiitis
- Urticarial vasculitis

Masters SL et al, Annu. Rev. Immunol. 2009. 27:621-68

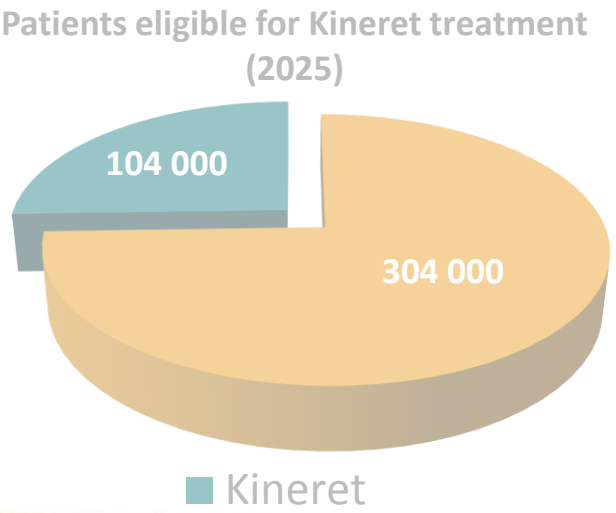
Acute Gout and Still's disease

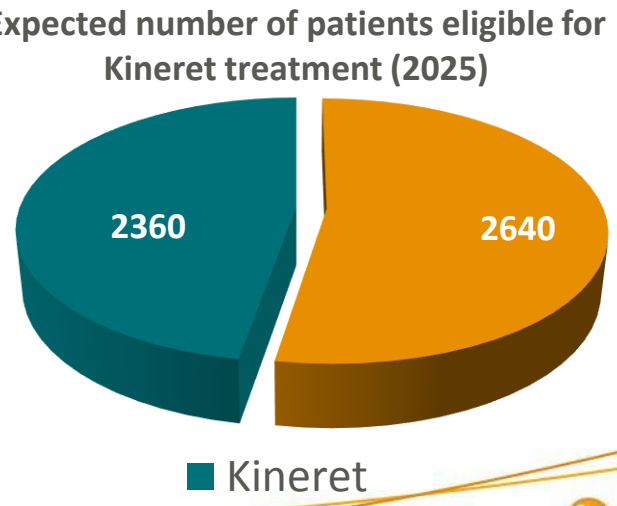
Acute Gout

- Quick onset and short duration of immunosuppression preferred
- Targeted segment unsuitable for standard therapy and have ≥ 3 comorbidities
- In average 1.42 flares per year, a flare is treated for 5 days with 1 syringe per day

Still's disease (SJIA & AOSD)

- No approved pharmaceutical treatment for AOSD
- Targeting patients who are eligible for IL-1 blocking agents
- In average treated for 7 months per year with 1 syringe per day

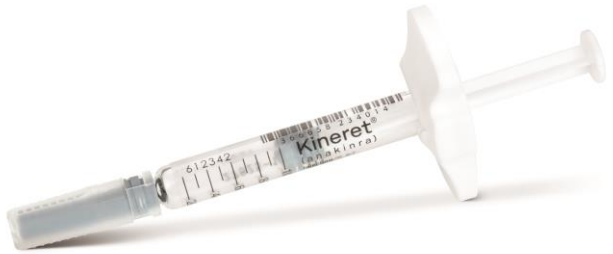




Patent BV-1228: citrate free anakinra composition

Kineret – a citrate free formulation

- Meets a need in the patient community
- Patent granted in **US, China and New Zealand** to date
- **EU and Hong Kong patent applications** have been allowed
- **Patent expiry in February 2032**



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