Q3 results presentation 2015

Geoffrey McDonough | CEO

Alan Raffensperger | COO

Mats-Olof Wallin | CFO



Stockholm | 29 October 2015

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Business summary Q3 2015

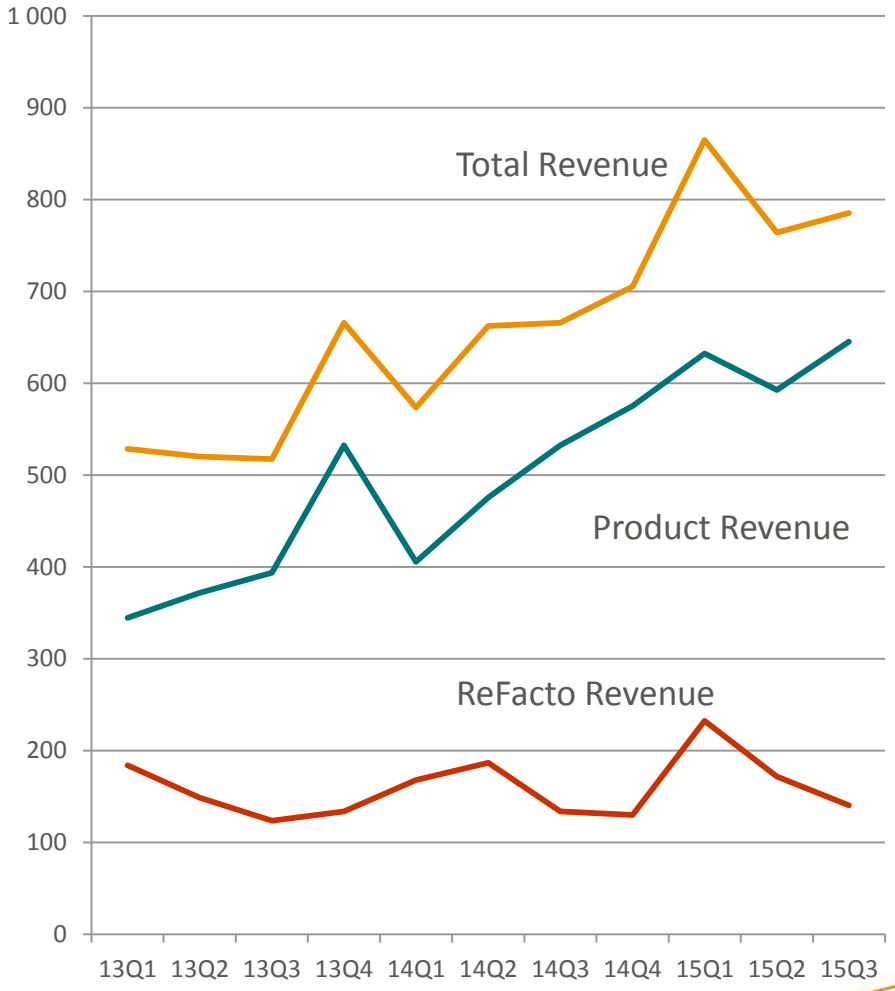
- Received positive opinion from CHMP for Elocta® for the treatment of Haemophilia A
- Exercised opt-in right for Alprolix®

- Received Australian regulatory approval for Kineret® for use in Systemic Juvenile Idiopathic Arthritis
- Kineret received Orphan Drug Designation for the treatment of Still's disease by the FDA

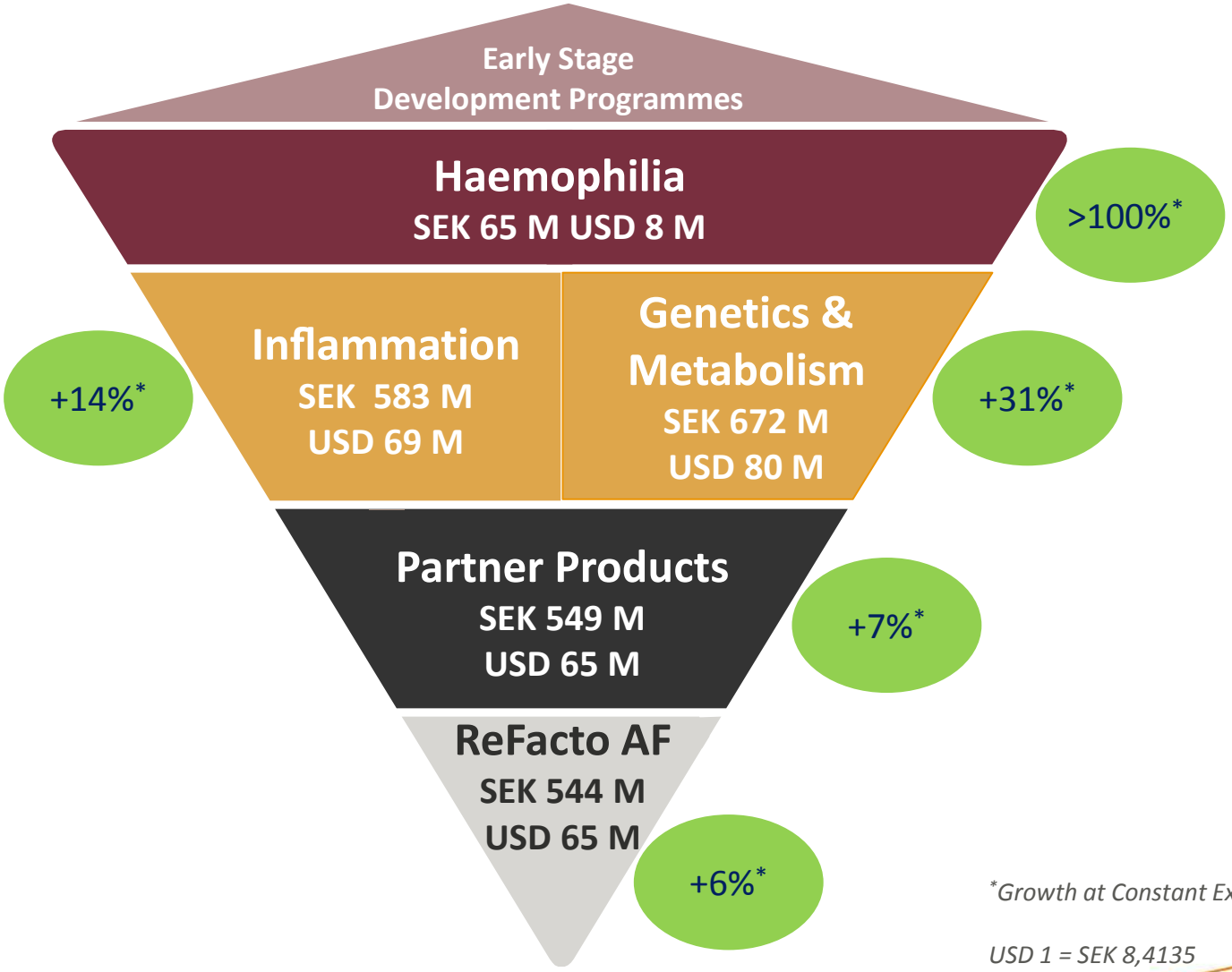
- FDA validated Orfadin® oral suspension filing

Business summary Q3 2015

- Total revenues: SEK 786 M (666)
  - 18% growth (8% at CER)
- Product revenues: SEK 645 M (532)
  - 21% growth (10% at CER)
- ReFacto® revenues: SEK 140 (134)
  - 5% increase
- Gross margin 62% (59)
- EBITA: SEK 97 M (120)
- Cash flow operations: SEK 245 M (124)



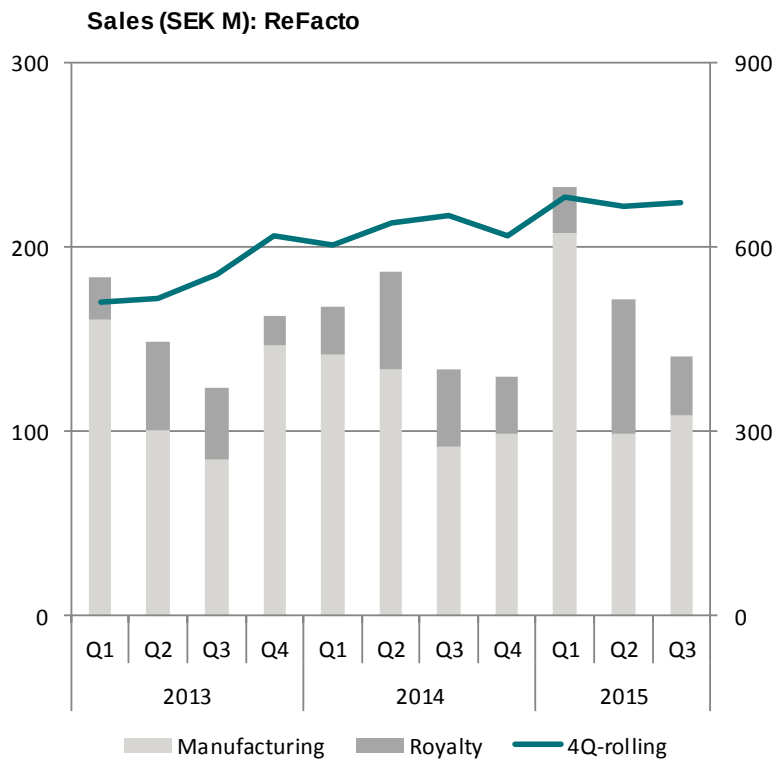
YTD 2015 revenue by business line



*Growth at Constant Exchange Rates

USD 1 = SEK 8,4135

ReFacto AF



- Revenue from manufacturing and royalty SEK 140 M (134)
  - Increase of 5%
  - Phasing effects caused by higher deliveries in the first half 2015
- YTD was SEK 544 M (488)
  - Increase of 12%
- Manufacturing revenue SEK 109 M (92)
- Royalty revenue SEK 31 M (42)

Commercial Results Q3 2015

Alan Raffensperger | COO

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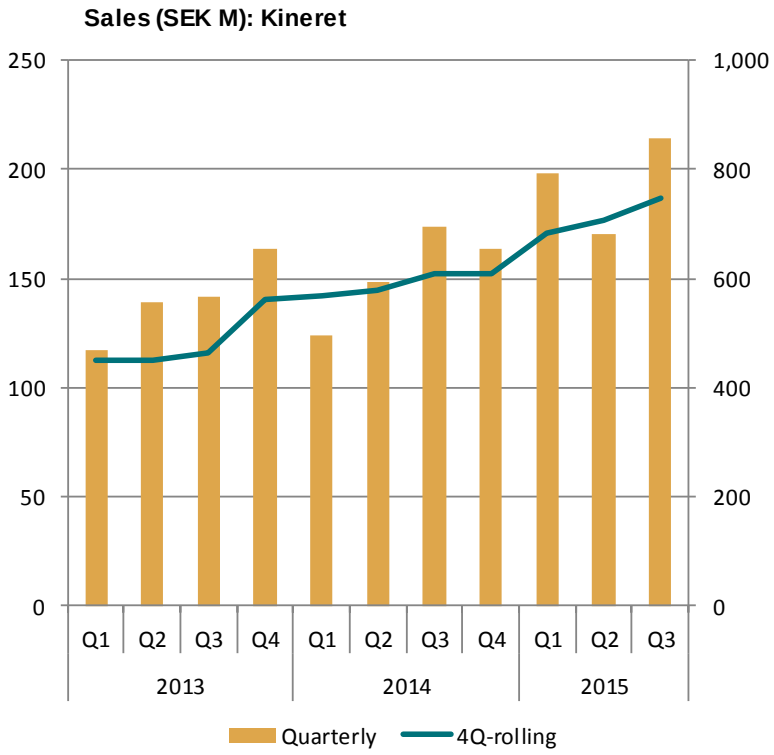
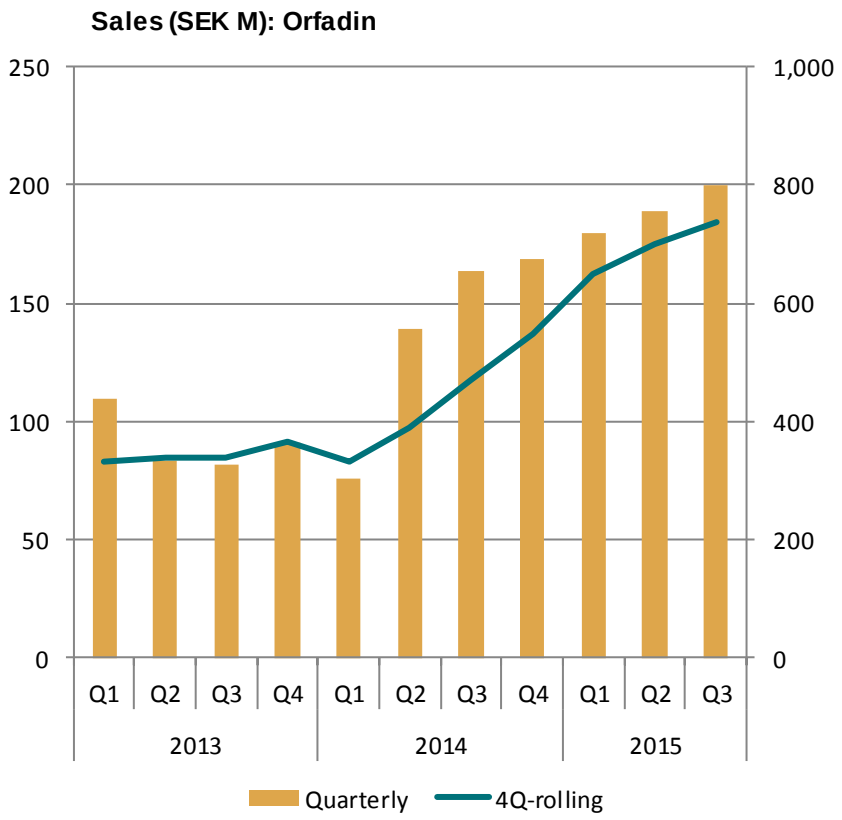
Kineret



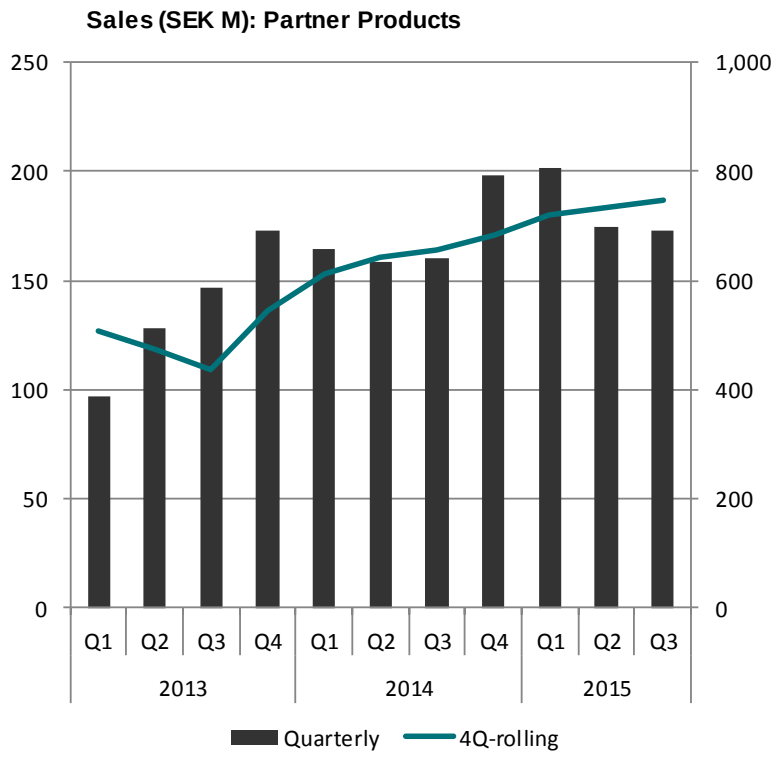
- Revenue SEK 215 M (174)
  - Increase of 23%
- YTD was SEK 583 M (446)
  - Increase of 31%
- Volume growth across most European markets
- The US market performed well driven by value and volume

Orfadin



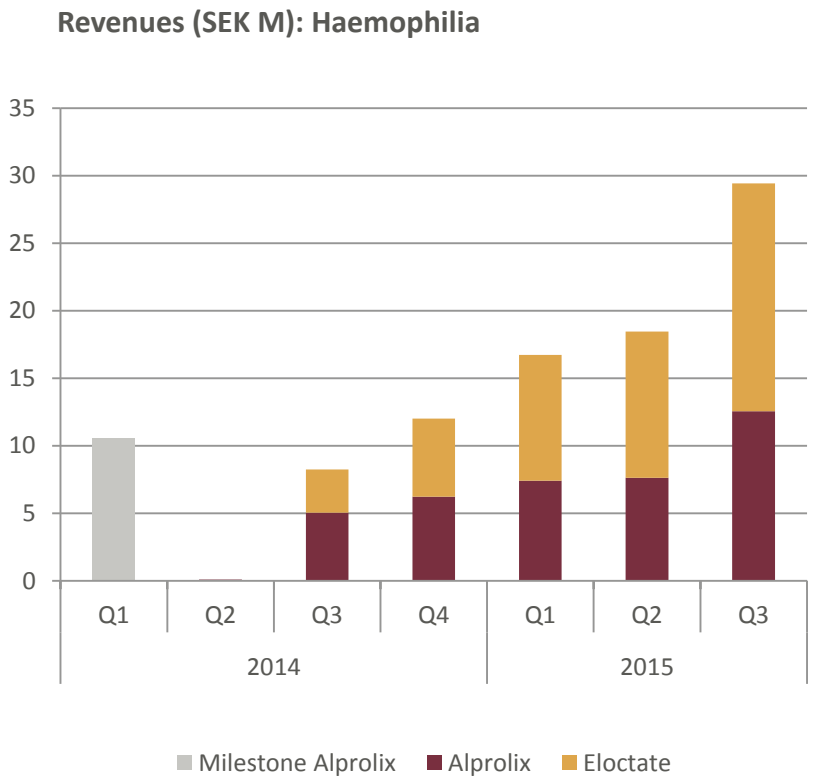
- Revenue SEK 200 M (164)
  - Increase of 22%
- YTD was SEK 568 M (379)
  - Increase of 50%
- Growth in all major markets
- FDA validated Orfadin oral suspension filing → PDUFA 2Q 2016
- Submitted MAA for Orfadin 20 mg capsule to the FDA

Partner Products



- Revenue SEK 173 M (160)
  - Increase of 8%
- YTD was SEK 549 M (484)
  - Increase of 14%
- Increase driven by growth of Cometriq® and Xiapex®
- Launch underway for Xiapex for Peyronie's disease

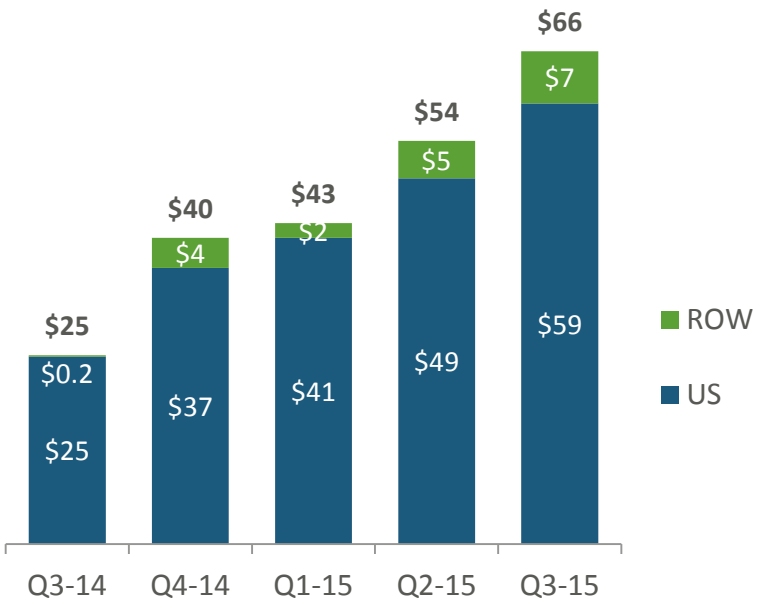
Haemophilia



- Revenue of SEK 29 M (8)
  - Based on 2% royalty of sales for Eloctate and Alprolix in Biogen territory
  - Q3 includes SEK 4 M (1) true-up from sales in the second quarter
- YTD was SEK 65 M (19)
- Exercised opt-in right for Alprolix
  - USD 10 M paid in the quarter
- Positive opinion from CHMP for Elocta - approval anticipated year end 2015

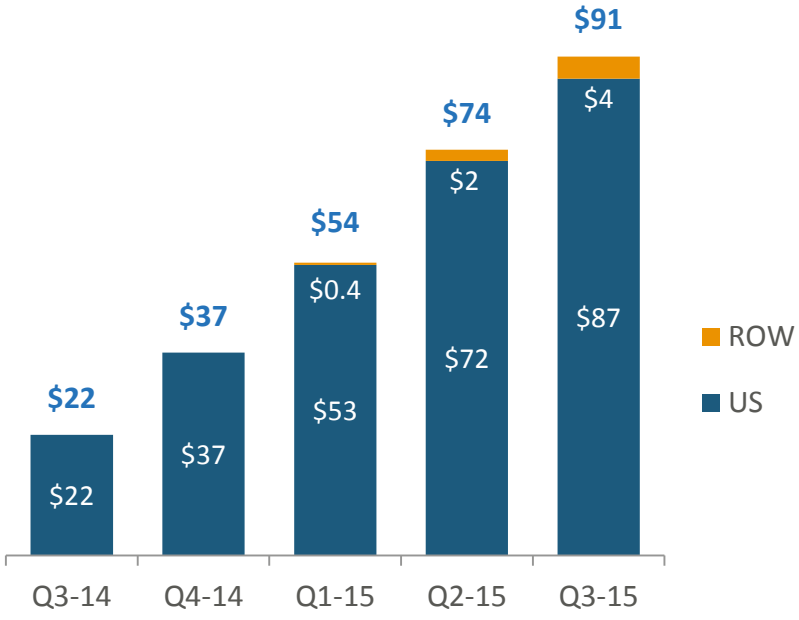
Haemophilia – Biogen revenues

ALPROLIX Revenue ($M)



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

ELOCTATE Revenue ($M)



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

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EU Elocta and Alprolix Launches in 2016

Time to reimbursement varies from country to country in Europe

- Launch will proceed country by country across Europe
  - Free access markets lead
  - Structured reimbursement markets follow
  - Tender markets lag
- Payer engagement underway since 2013
- Reimbursement dossiers submitted in eligible markets following CHMP opinion

Prophylaxis Therapy – Remaining Gaps

Patients on prophylaxis still bleed[2-5]

- UK registry data (all ages)[4]
  - Severe Haemophilia A: median ABR **4.0** (n=126)
  - Severe Haemophilia B: median ABR **4.0** (n=36)
- Canadian multi-centre study (≥18 years)[5]
  - Severe Haemophilia A: median ABR **5** (n=155)

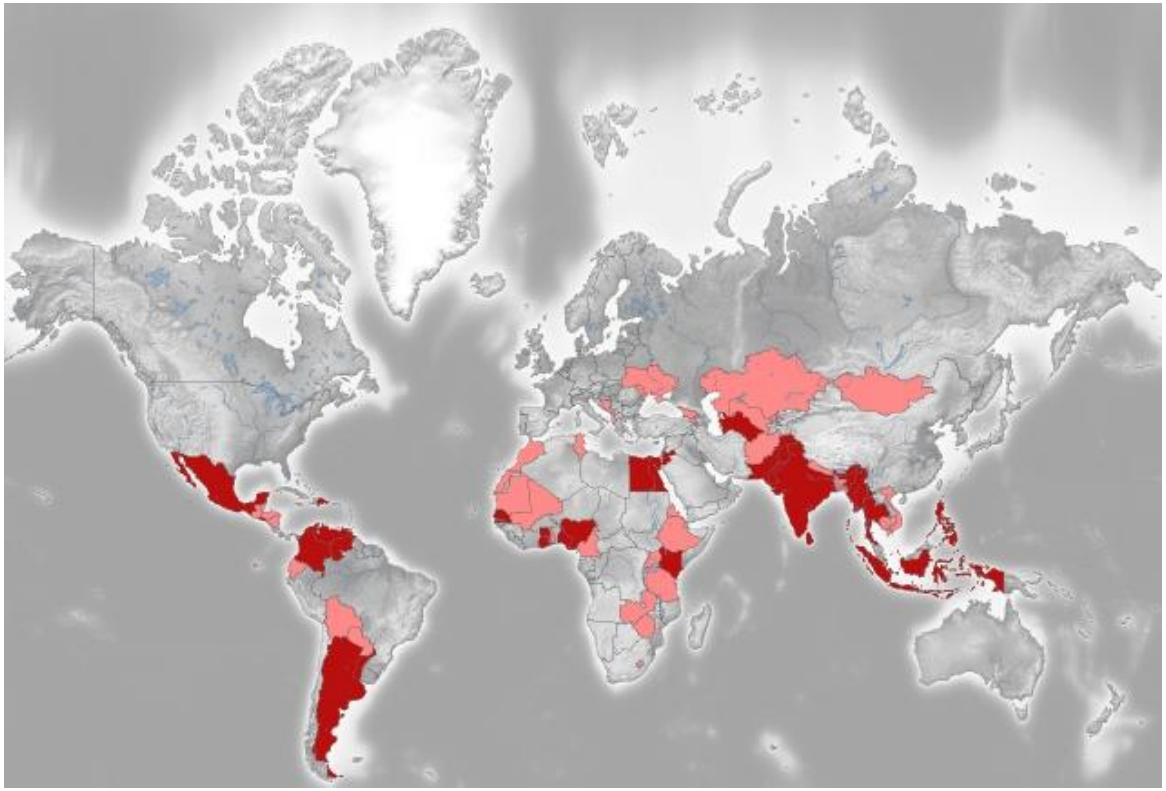
ABR: Annualised Bleeding Rate

Prophylaxis is not yet globally available[1,2]

- Globally, only about 25% receive at least minimally adequate treatment[1]
- 47% of countries have less than half of haemophilia patients under 18 years on prophylaxis[2]

1. Skinner. *Haemophilia* 2012; **2.** WFH annual global survey 2013; **3.** Carcao. *Haemophilia* 2014; **4.** Hay et al. *J Thromb Haemost* 2015 (ISTH); **5.** Jackson et al. *BMC Hematology* 2015

WFH Close the Gap Programme in Action



- Estimated 2015 WFH donation countries*
- Estimated 2020 WFH donation countries*

Financial Results Q3 2015

Mats-Olof Wallin | CFO

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Profit and Loss Statement

Amounts in SEK M	Q3-15	Q3-14	Jan-Sep 2015	Jan-Sep 2014	FY 2014
Total revenues	**786**	**666**	**2,414**	**1,902**	**2,607**
Gross profit	**486**	**395**	**1,486**	**1,121**	**1,548**
Gross Margin	*62%*	*59%*	*62%*	*59%*	*59%*
Sales and Administration	-272	-187	-764	-536	-750
Research and development	-120	-91	-379	-351	-501
Other operating revenues/expenses	3	3	0	-315	-341
EBITA	**97**	**120**	**343**	**-82**	**-43**
Amortizations and write-downs	-72	-70	-214	-211	-282
EBIT	**25**	**50**	**129**	**-292**	**-325**
Financial income/expenses	-14	7	-33	-4	6
Income tax expense	-5	-4	-19	46	51
Profit/loss for the period	**5**	**53**	**77**	**-250**	**-268**

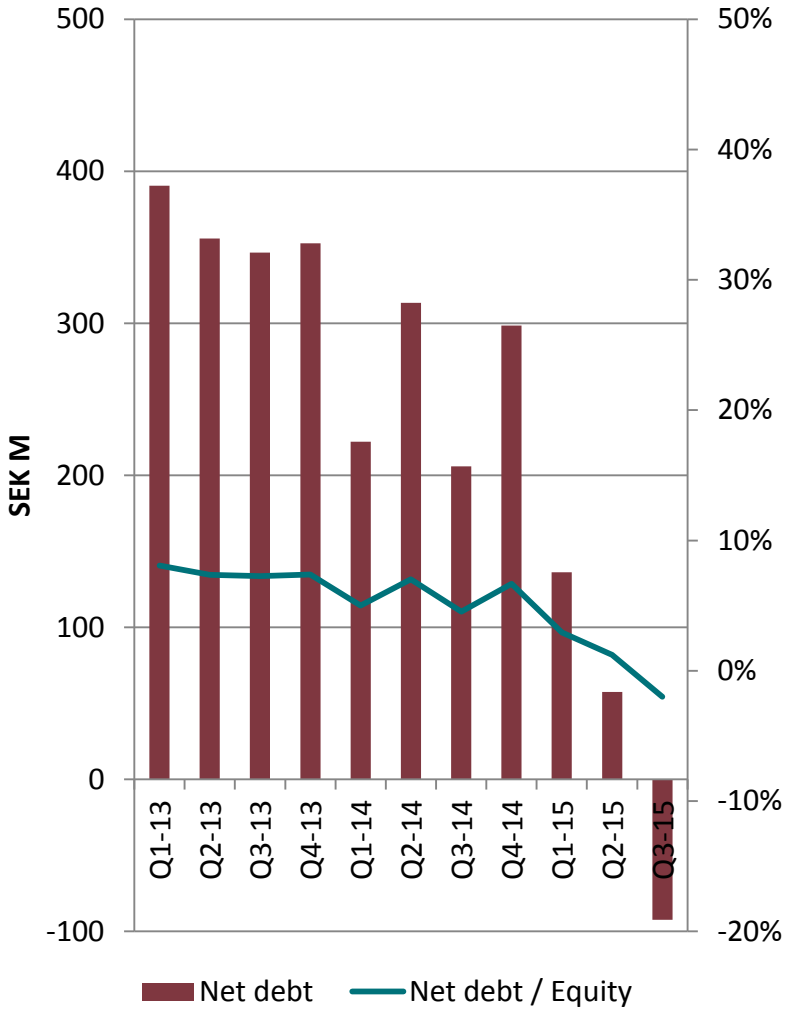
- One-time write-down in Q1, 2014 for Kiobrina®, SEK 325 M, with limited cash impact
- One-time accrual in Q4, 2014 for Multiferon®, SEK 25 M, with limited cash impact

Balance Sheet

Amounts in SEK M	Sept 2015	Sept 2014	Dec 2014
ASSETS			
Intangible	4,145	4,231	4,248
Tangible and financial	185	183	188
Total non-current assets	**4,330**	**4,414**	**4,436**
Inventories	758	726	764
Accounts receivable	498	451	480
Other Receivable	172	169	172
Cash and equivalent	914	611	519
Total current assets	**2,343**	**1,957**	**1,935**
Total Asset	**6,672**	**6,371**	**6,371**
EQUITY AND LIABILITIES			
Equity	**4,640**	**4,533**	**4,523**
Long term debt	820	815	816
Long term liabilities	308	292	285
Short term liabilities	906	730	747
Total liabilities	**2,033**	**1,838**	**1,848**
Total equity and liabilities	**6,672**	**6,371**	**6,371**

- Opt-In Alprolix USD 10 M
- Launch inventory of Elocta in place

Net cash/debt



- Cash SEK 914 M
- Net cash SEK 92 M

PnL impact of Elocta/Alprolix launches

Today

- Base cross royalty rate between Sobi and Biogen is 12%
- Sobi currently receives 2% royalty on sales in the Biogen territory
- The remaining 10% royalty is accumulated as a credit since launch – to be delivered at first commercial sale

On first commercial sale

- One-time credit equal to 10% of accumulated revenues from Biogen territory booked as revenue (no cash effect)
- Royalty rate increase to 12% whereof 7% has a cash impact

At MAH transfer

- Sobi will assume 50% development activity and costs in 2016
- Estimated to occur within 3-6 months of first commercial sale

Summary and Outlook

Geoffrey McDonough | CEO

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Outlook 2015 – EBITA range revised

Revenues

Sobi expects total revenues for the full year to be in the range of SEK 3,000 to 3,200 M

Gross Margin

Gross margin is expected be in the range of 59 to 61 per cent

Operating Costs

Operating costs are projected to increase as the company continues to prepare for the planned launch of Elocta

EBITA – range revised

Sobi now expects EBITA for the full year to be in the range of SEK 350-400 M (previously SEK 325-400 M)

The outlook for 2015 excludes 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.

Building our future

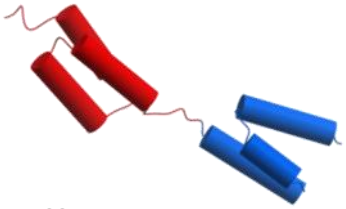
Continued focus on our business and capabilities within rare diseases

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 territories – 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

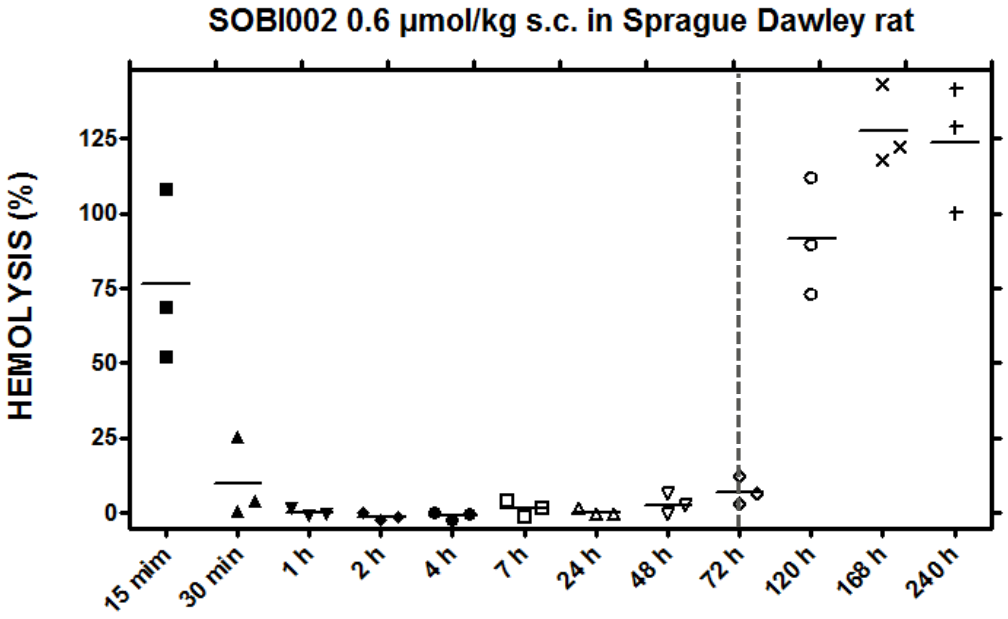
Anticipated early R&D pipeline end 2016

Indication	Product/Project	Partner	Exploratory	Preclin.	Phase I	Phase II	Phase III	Registration
C5-driven disease	Z-Fc	Affibody						
MPSIIIA	SOBI003	sobi						
IL-1-driven disease	Modified Anakinra	sobi						
IL-1 –driven disease	Z molecule IL-1R antagonist	Affibody						
Lysosomal Diseases	GlyMod ERT	sobi						
Haemophilia A	XTEN-Factor VIII-Fc	Biogen						
Inflammation/ autoimmunity	Proprietary platform	sobi						

SOBI002: C5 Affibody:ABD inhibitor

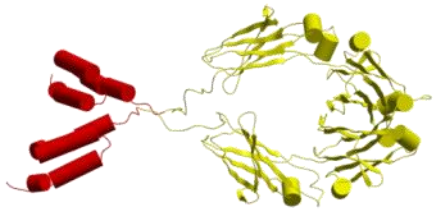


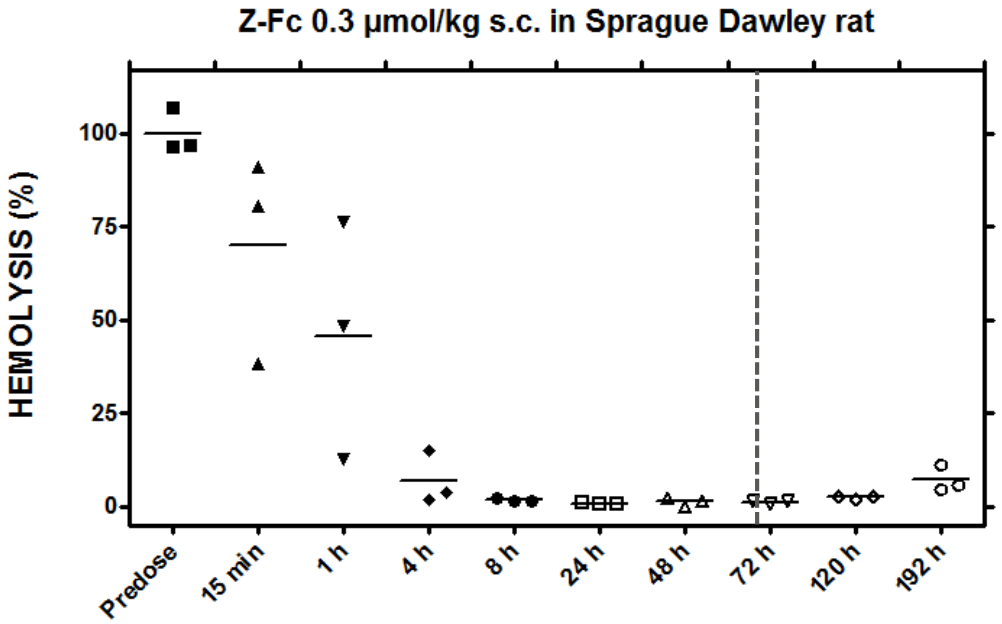
Affibody-ABD



- SOBI002 comprises a C5-binding Z domain and an albumin-binding domain
- Half-life in animal models showed extended inhibition of C5 inhibitory Affibody
- SOBI002 withdrawn from clinical trials in 2014

New candidate: C5 Affibody:Fc Fusion inhibitor

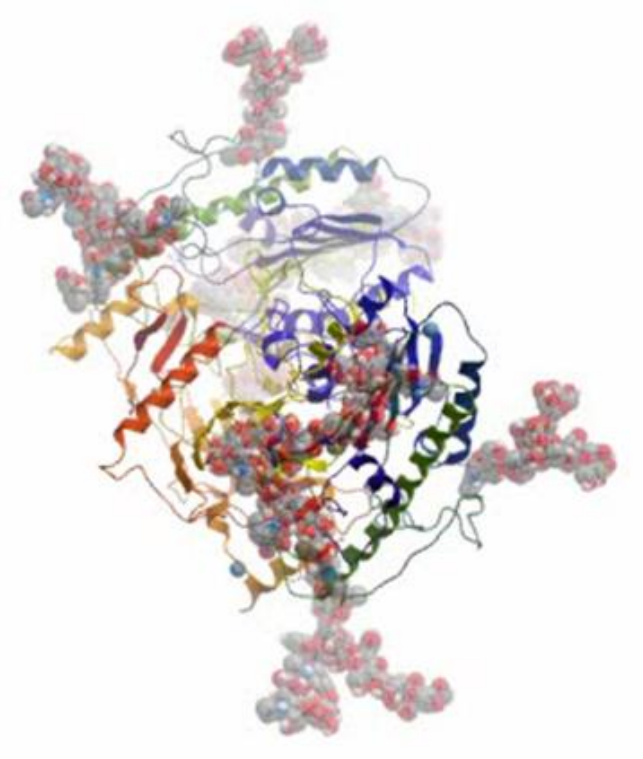




- More stable version of C5-binding Z-domain identified
- Fc fusion to Z-domain yields significant half-life extension over SOBI002
- Pre-CD selection in early 2016 will allow first-in-human studies in 2018

Mucopolysaccharidosis IIIA: Sanfilippo A

- Rare disease with incidence of approx. 1 in 70,000 live births
- Behavioral and motor-sensory disturbances in early childhood, with cognitive decline leading to death in the second decade of life
- Current treatment is palliative
- No treatments available which ameliorate or modify the neuoronopathic symptoms



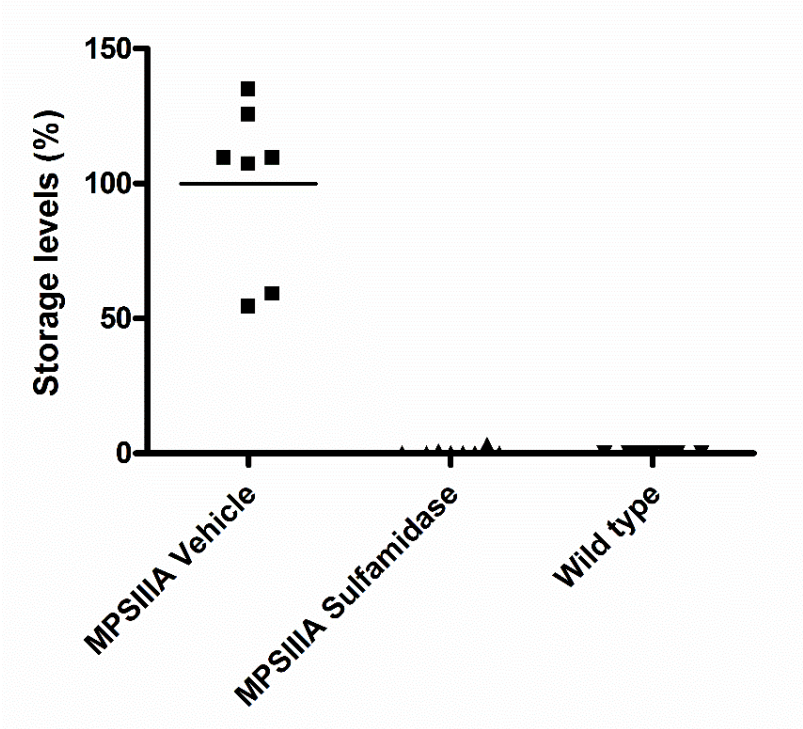
MPSIIIA Mouse Model

MPSIIIA mouse **Wild type**

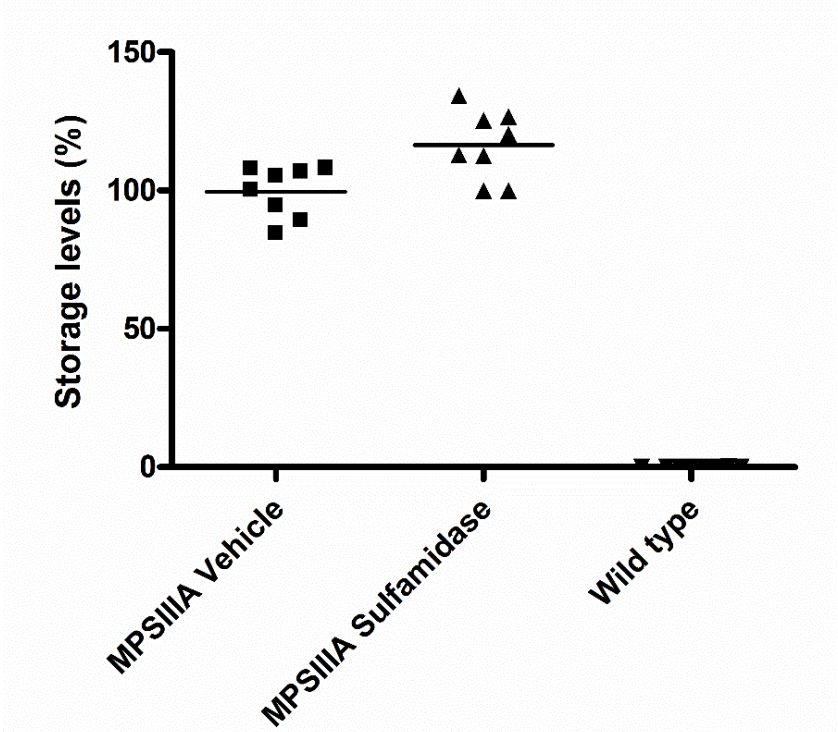
Native Sulfamidase Does Not Access CNS

- Recombinant sulfamidase doesn't get to the brain

Liver

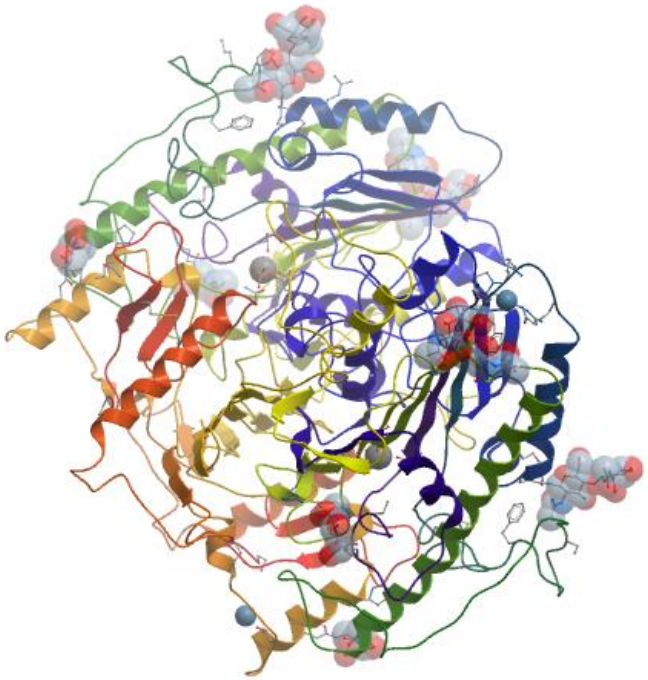


Brain



Data on file

SOBI003: Modified Sulfamidase

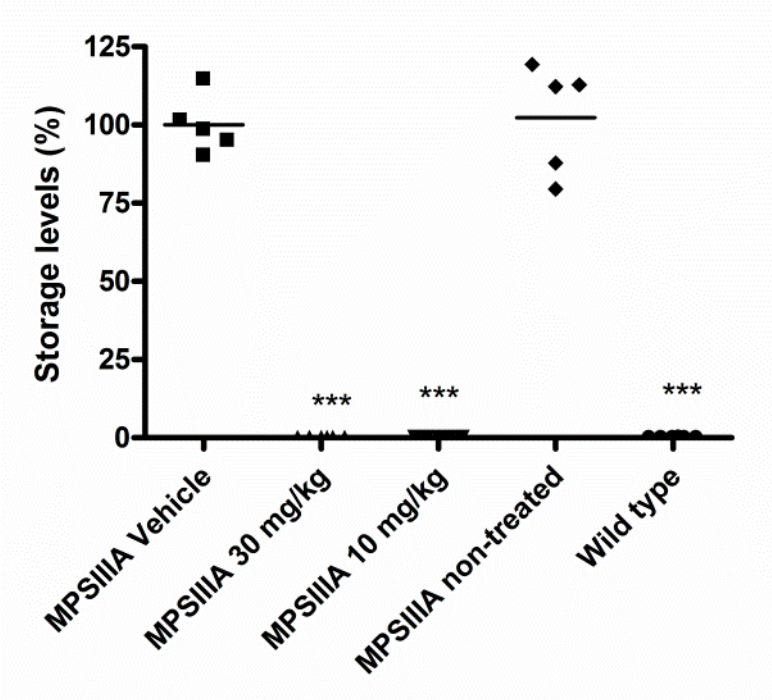


- Sulfamidase with proprietary modification approach
- Goal is to enable penetration of the CNS with systemic IV treatment
- Patent applications surrounding SOBI003 technology pending

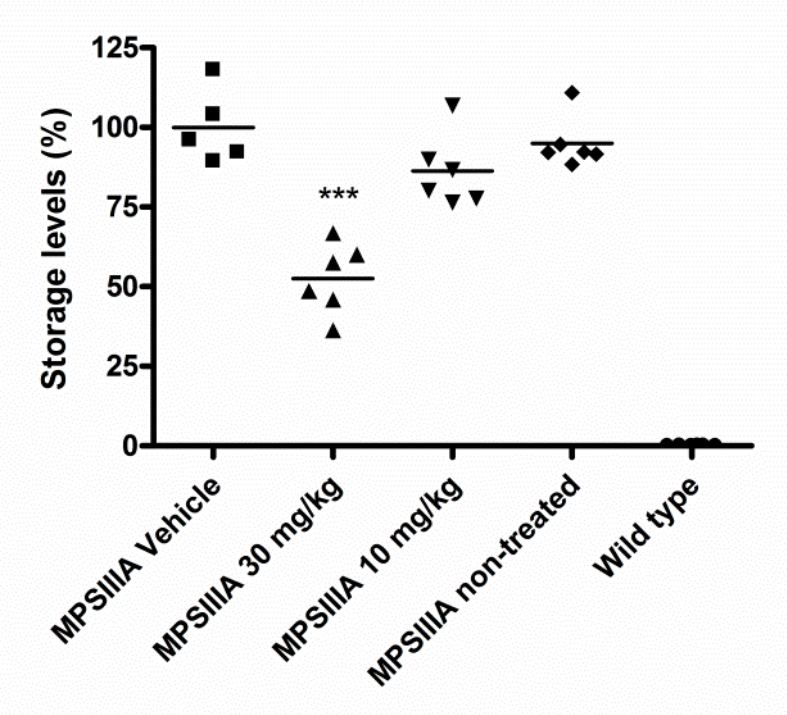
Substrate Reduction in Brain in Mouse Model

- Treatment with intravenously administered SOBI003

Liver



Brain



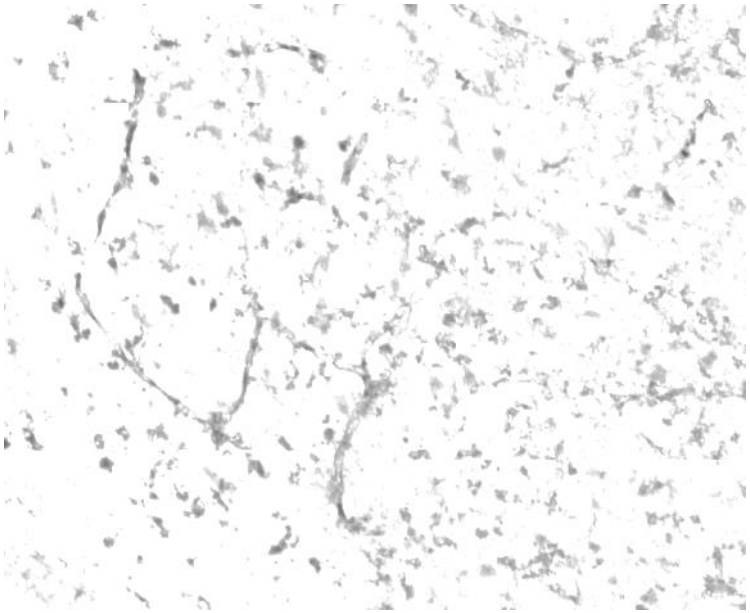
Data on file

SOBI003 present in brain tissue after IV administration

- MPSIIIA mouse cortex

6 h following vehicle

6 h following SOBI003



Data on file

Next steps

- Process development for SOBI003 ongoing (challenging)
- Clinical material will be manufactured in Sobi's facility in 2016 to enable GLP toxicity testing
- First-in-human studies planned for 2018

Summary

- Solid momentum in base business based on growth across the portfolio
- Significant achievement of milestones for our extended half-life Haemophilia franchise
- Elocta launch preparations on track for YE 2015 approval
- Alprolix filing and opt-in in place
- Early rare disease programs underway