

Pioneer & Partner in Rare Diseases



JP Morgan Healthcare Conference San Francisco, 10 January 2012



Safe Harbor Disclaimer

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.



Who We Are

Sobi is an innovative bio-pharmaceutical company with a leading position in the commercialization of niche and rare disease products.



Our operations are driven by a diversified and growth-oriented portfolio in niche and rare disease therapies.



We have a late-stage pipeline with substantial commercial potential.



We are a differentiated partner with world-class capabilities in protein biochemistry and biologics manufacturing development for rare diseases.



Our Vision

Sobi is recognized as the leading integrated bio-pharmaceutical company ...

dedicated to bringing innovative therapies and services ...

to improve the health of rare disease patients and their families.





Actions to Reach Our Goals

We intend to earn our way into our future based on operational performance.

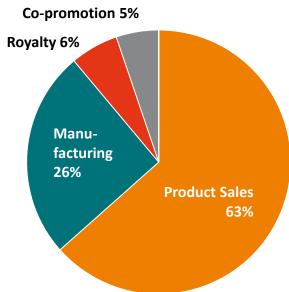
- 1. Revenue growth through focus on key products
- 2. Ongoing cost discipline
- 3. Gross Margin improvement
- Improving cash flow from operations and working capital



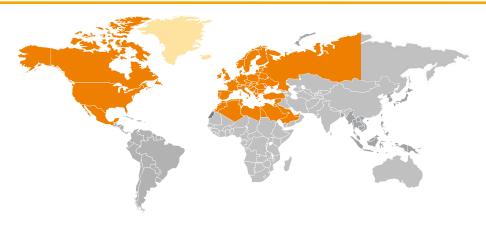
Diversified Base, European + Growing US Presence

- Traded on NASDAQ OMX: (STO:SOBI)
 - Sponsored ADR available through BNY Mellon
- Market Capitalization¹: USD 585 M
- Net Revenues²: USD 271 M
- Employees: ~ 500

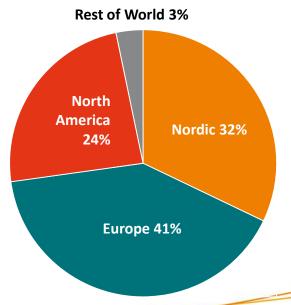
Sales by Revenue Type



¹⁾ Market capitalization as of December 31, 2011



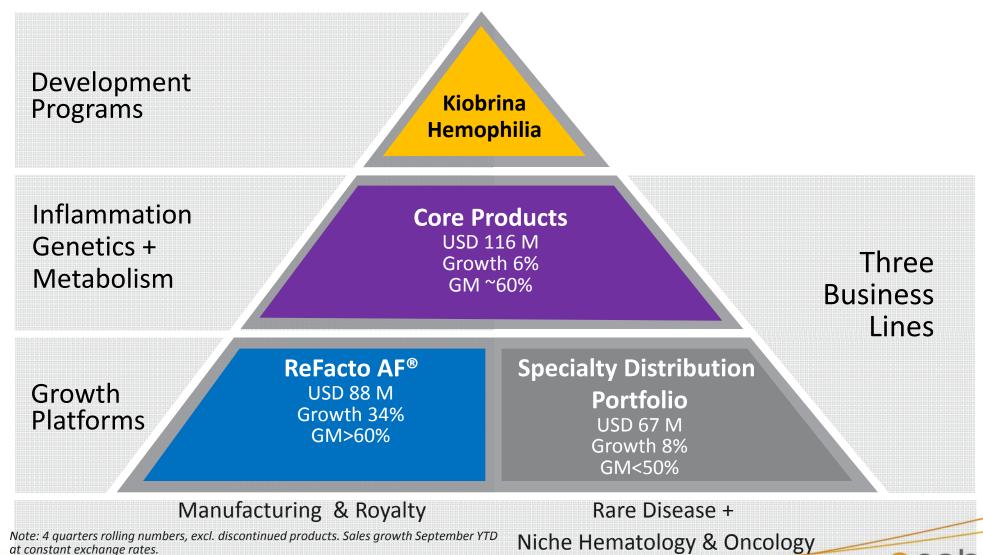
Product Sales and Co-promotion by Region





²⁾ 4 quarters rolling as of September 30, 2011

Our Future Built Upon Growing Base Operations









Note: 2011 numbers based on 4 quarters rolling as of September 30, 2011

- Partnership with Pfizer
 - Global sales 2010: USD 404 M
- As the exclusive supplier, we have:
 - Made ReFacto AF® (albumin free)
 - Substantially increased capacity
 - Enabled expansion of Pfizer's business
- 2011 an exceptional year
 - Pfizer built inventory for dual chamber syringe validation
 - Scale-up validation batches delivered in 2011

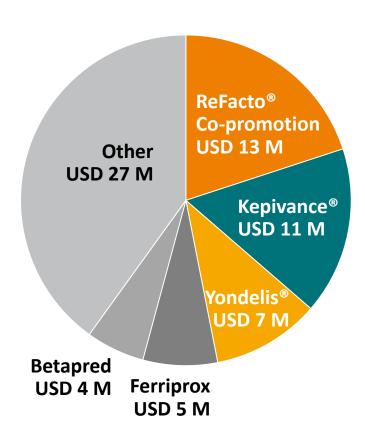


Specialty Distribution Portfolio – Regional Leadership + Diversified Growth



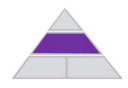
- Preferred partner for rare disease commercialization
- Rare Disease and Specialty Hematology/Oncology and Portfolio
- Create focus on the right deals
 - 1. Therapeutic Area overlap
 - 2. EBITA contribution
 - 3. Regional leverage

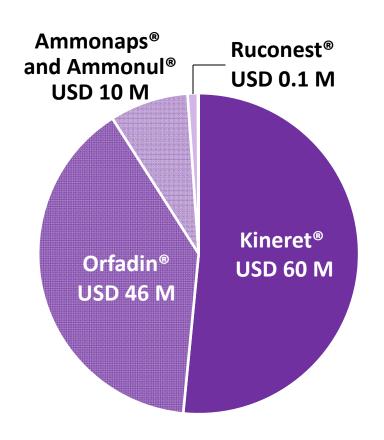






Core Products – Proprietary Strategic Growth Drivers





1. Niche Therapeutic Areas

- Genetics + Metabolism
- Inflammation

2. Focus for Growth

- Room to expand in existing markets
- Focus on growth in key markets (US, Russia, Middle East)

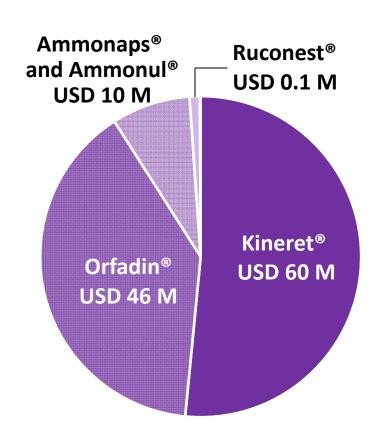
3. Fits Sobi Commercial Model

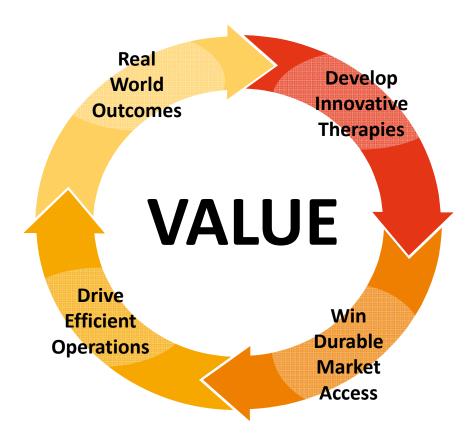
- Field focus on Centers of Excellence
- Medical focus on Health Outcomes



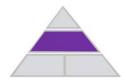
Core Products – Proprietary Strategic Growth Drivers











Kineret® – Repositioning is Creating Growth

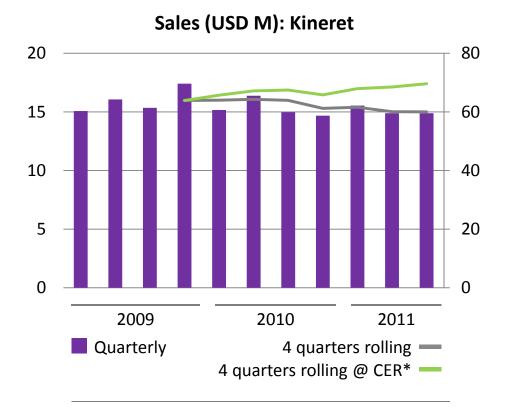
- We acquired Kineret® in 2008
- We identified a niche where Kineret addresses a significant medical need:

High risk RA-patients with co-morbidities for which the short half life and safety profile of Kineret are uniquely suitable

• Treated with biologics: 820 000

• Eligible Kineret patients: 200 000

• Current Kineret market share: 0.5%



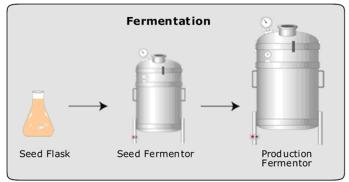
^{* 4} quarters rolling using average exchange rates for 2009 as base.

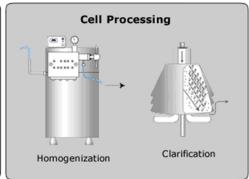


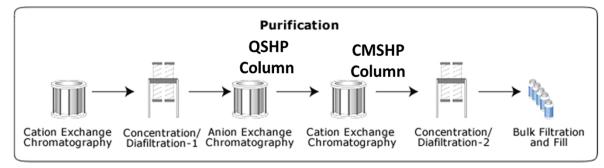
Key Success Factor: Kineret® Tech Transfer Delivery



- Sobi is transferring manufacturing for Kineret® to a CMO in Europe
- Sobi purchased 90M USD in Kineret® inventory from Amgen 2010 to support tech transfer
- Tech transfer has been delayed with additional costs in 2011 + 2012
- Process Validation runs to be completed in H1 2012
- We have retained a back-up supplier for Kineret®





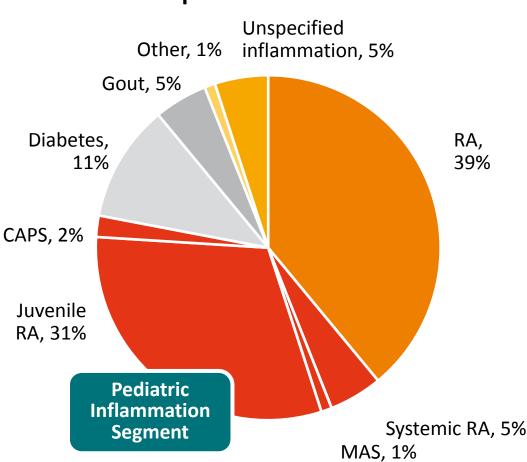




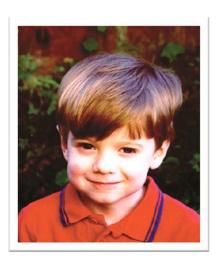
Kineret® – Strong Interest in Broader Inflammation











Pediatric Inflammation

- Sobi will file within CAPS in US and EU in 2012
- Critical to allow us to support clinical practice in children

Source: Wolters Kluwer Claims Database, (April 2010 – July 2011)





Orfadin® – Understanding the Growth Drivers

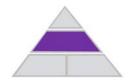


 ⁴ quarters rolling using average exchange rates for 2009 as base.

1. Addressing Clinical Needs in Adolescents

- Support Adequate Dosing
- Compliance
- 2. Monitoring
 - Substrate and drug levels
- 3. Newborn Screening
 - Gaining ground in US and Europe
- 4. Bringing Orfadin® to New Markets
 - Russia and Middle East





Orfadin® – Active Life Cycle Management









Liquid Formulation

- Drug Candidate available
- Manufacturing scale-up underway

EMA

- Pediatric Investigation Plan submitted May 2011
 - PIP approval could come in 2012
 - May extend orphan status in Europe until 2017

FDA

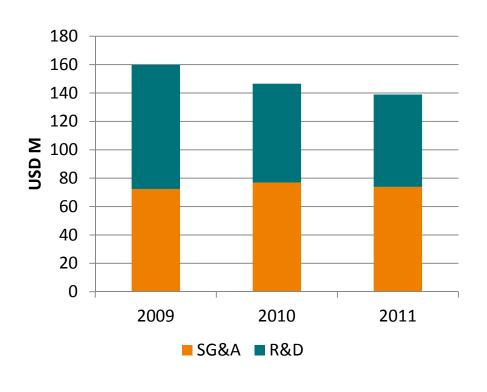
Discussion with FDA in 2012







Operating Expenses Have Decreased from 55% to 49% of Revenue



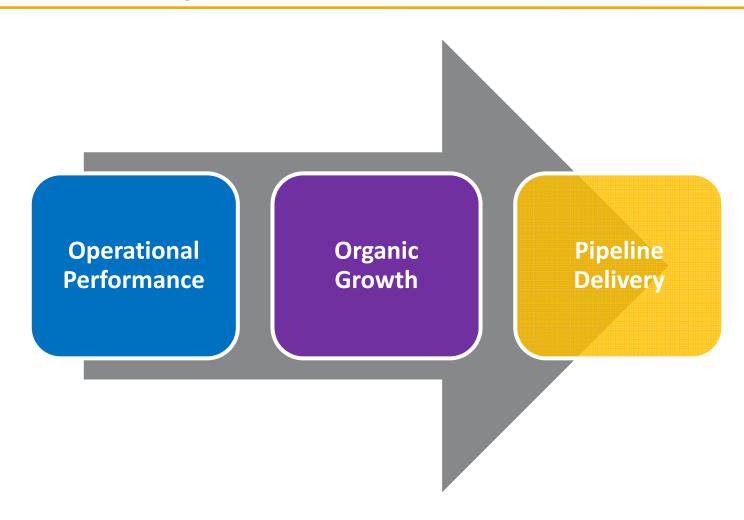
- 1. HQ personnel reduced by 40 FTEs in 2010
- 2. R&D restructuring 60 FTEs by year end 2011
- Two buildings to be closed in Q1 2012
- 4. Focus on late stage development and de-risking of R&D portfolio
- Transition to higher proportion of spending to support commercial effort

Note: 2011 numbers based on 4 quarters rolling as of September 30, 2011



Focus on Delivery

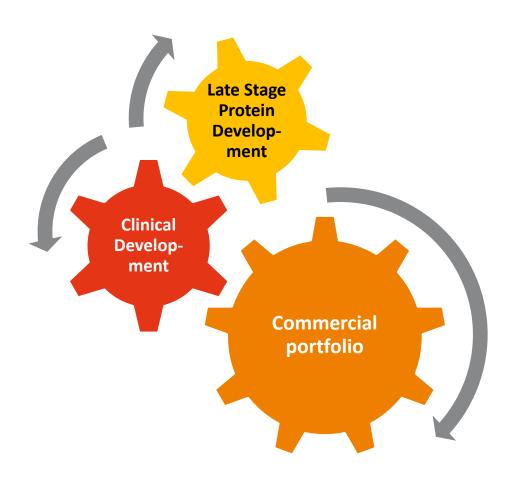


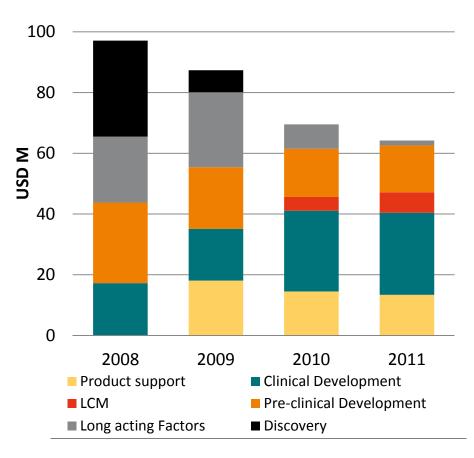






Increasing R+D Leverage: Phase 3 + Commercial

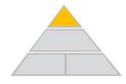




Note: 2008 only Biovitrum pre acquisition of Kineret® and Kepivance® Note: 2011 numbers based on 4 quarters rolling as of September 30, 2011

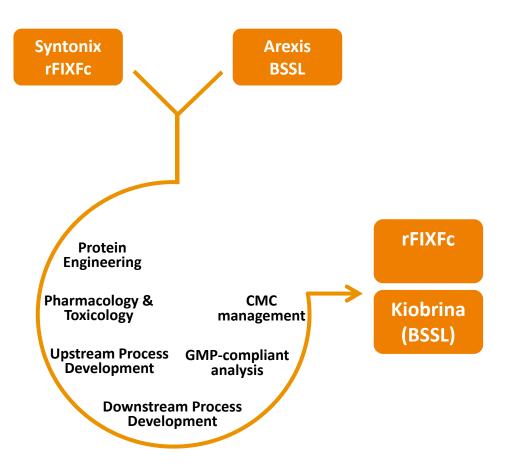


Sobi has Retained Strategic Development Capabilities



Value creation for innovative biologics therapies through:

- 1. Protein biochemistry capabilities in late preclinical development
- 2. GMP biologics process development and manufacturing scale-up



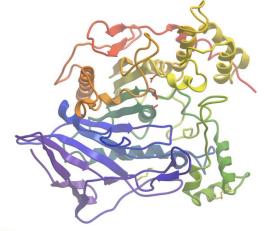


Kiobrina – Enzyme Replacement for Premature Infants





- Bile Salt Stimulated Lipase (BSSL) naturally occurs in mother's milk
- Infants do not produce BSSL
- BSSL not present in pasteurized milk or formula
- BSSL is important for growth and absorption of fatty acids, critical for brain development
- Lack of BSSL is correlated with slower growth



 Recombinant human BSSL (Kiobrina) is given orally together with formula or pasteurized milk to restore the BSSL activity

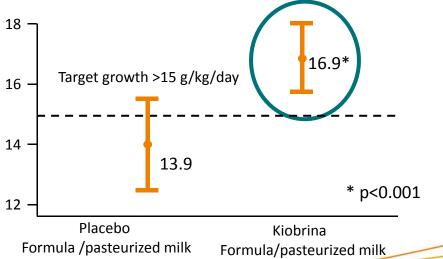




Potentially Significant Medical Value

- In the US approximately 24,000 infants born <32 weeks would be eligible for Kiobrina therapy
- Restoring growth in premature infants may reduce morbidy + NICU stay, and improve development outcomes
- Phase II data show Kiobrina accelerated growth after <u>one week</u> of treatment



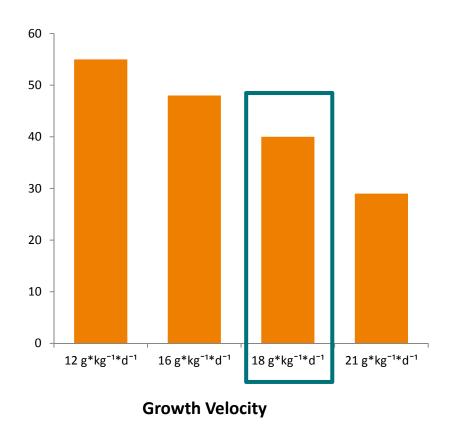




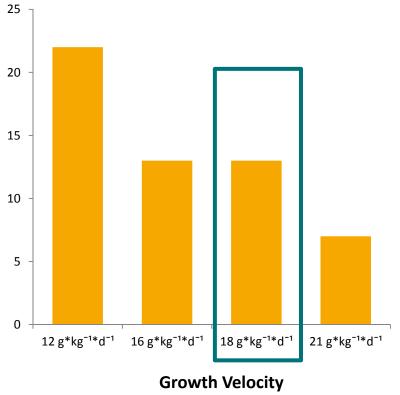


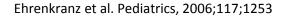
Growth Velocity Correlated With Risk of Impairment

% Patients w/ Impaired Neurodevelopment



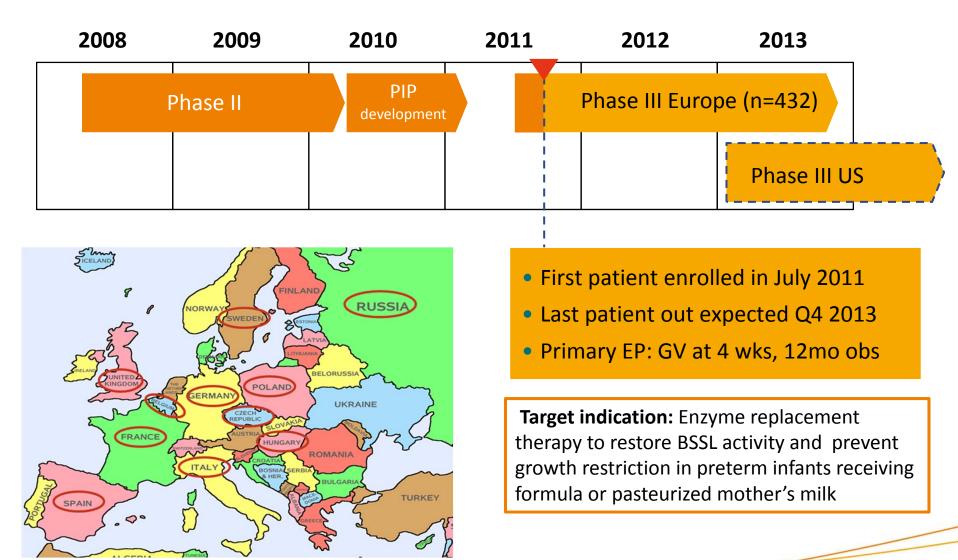
% Patients w/ Cerebral Palsy







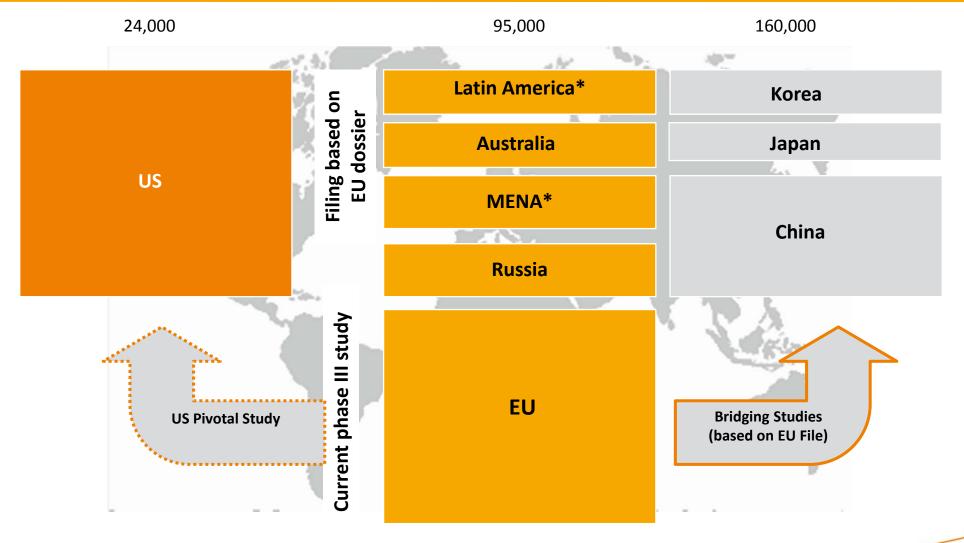
SPA-Approved Pivotal Trial Underway in Europe





Based on ongoing phase III study in Europe, Sobi can access >275,000 patients globally*





^{*}Lat AM: Brazil, Mexico, Argentina, Venezuela



^{*}MENA: Saudi, Iran, Israel, Egypt, Turkey



Improved growth will reduce the costs of treatment

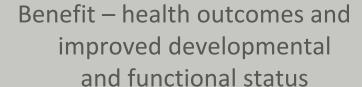
- Earlier discharge
- Reduced Hospital Utilization
- Reduced Illness due to prolonged hospitalization



E.g. cost saved if discharged 1 week earlier from NICU 14,000-28,000 USD



- Improved functional outcomes
- Reduced risk of neurodevelopment delay







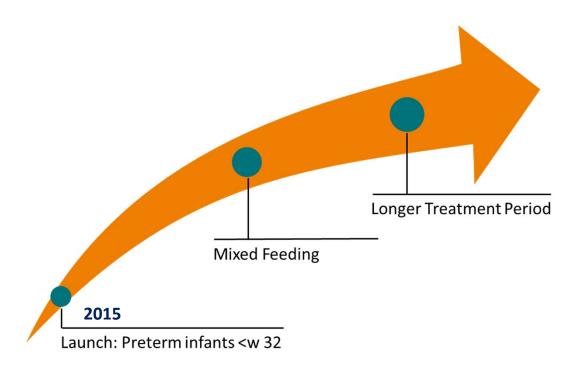
Global Proprietary Innovation in Neonatology

Pioneers in neonatology

- Potentially significant medical value
- Our own product
- Global potential

Neonatology is attractive

- Low competition
- Able to support innovation
- Addressable audience

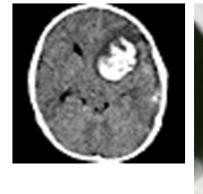




Hemophilia A and Hemophilia B: Lifelong IV Therapy







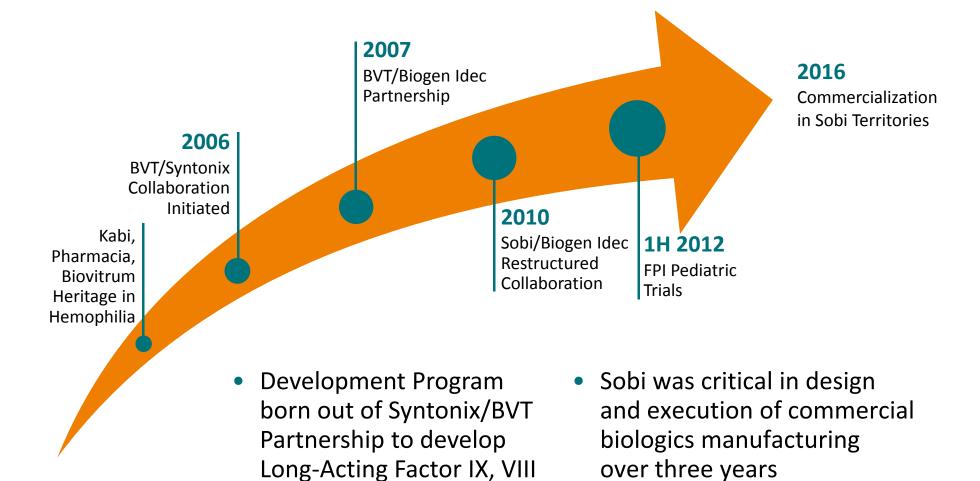




Hemophilia:

Demonstrates Potential of Biologics Expertise





BVT: Biovitrum



Strong Alignment with Biogen Idec to Deliver Value



 Potential to deliver the first long-acting recombinant factors to the global market

Sobi repays its share of development costs:

- 1. Milestone for each program at MAA filing
- 2. Cross-Royalties
- 3. True-up payment at six years







Hemophilia is a \$3.4B USD Market in Sobi Territory

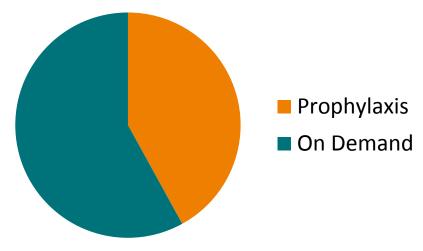
Hemophilia A

- Europe 3B USD
 - 55% of global \$ sales
 - > 50 Brands
 - ~ 73% recombinant
- ~22 000 patients on regular treatment

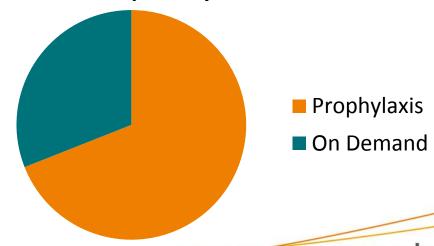
Hemophilia B

- Europe 380M USD
 - 44% of global \$ sales
 - >10 Brands
 - ~55 % recombinant
- ~ 4000 patients on regular treatment

Factor Consumption by Patients



Factor Consumption by Units

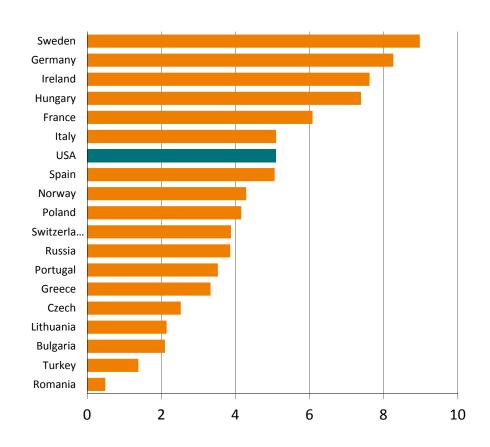


Source: Company Annual Reports, MRB 2008, WFH 2009, UKHCDO 2011, Internal estimates



Factor Use for Prophylaxis High in Sobi Territory

Per Capita consumption of FVIII (IU/Inhab.)



- Highly developed Centers of Excellence
- Early recognition of the value of prophylaxis
 - "Not accepting a bleed"
- Strong Patient Advocacy groups

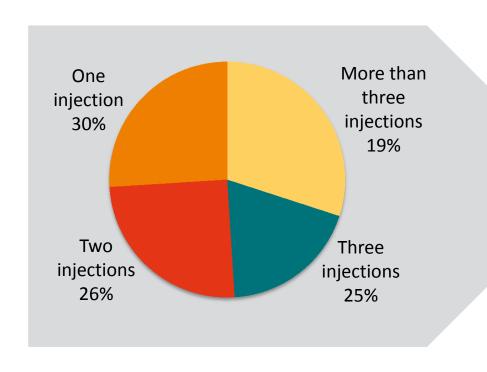
Source: WFH 2009



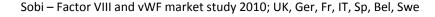
Significant Opportunity to Improve On-Demand Care



No. of injections given when bleedings occur.



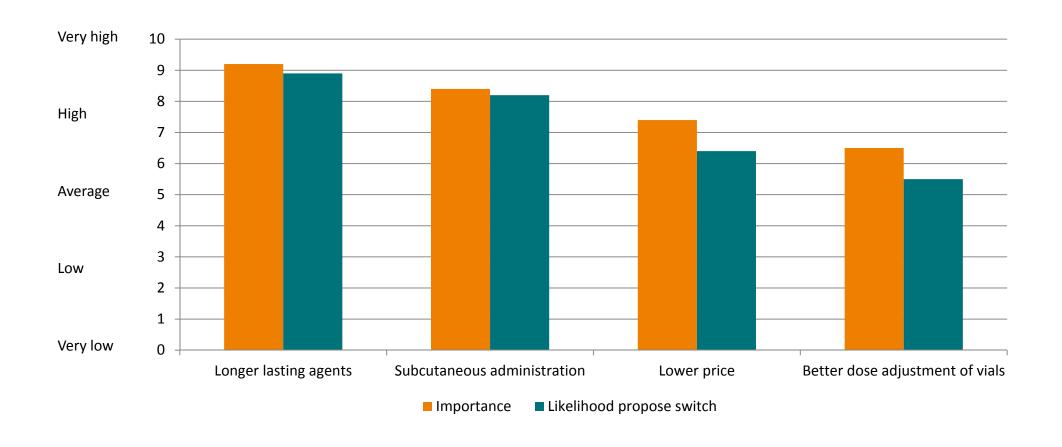
70% of EU patients
treated on-demand
use
more than
1 injection per bleed

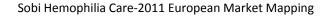




Longer Lasting Agents Most Appealing as Improvement and Most Likely to Generate Switch



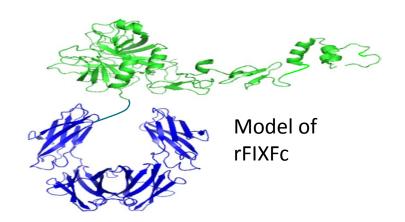








Phase Two Studies Confirm Long Half-Life



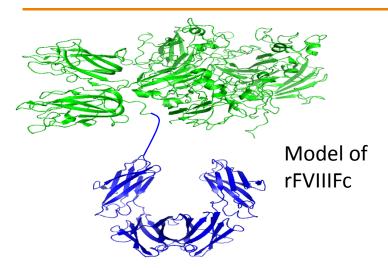
Phase I/II Trial: rFIXFc

PK parameter Elimination $T_{1/2}$ (hours)²

rFIXFc n=11 mean 57 h (42–75 h)

BeneFIX^{®1} n=56 mean 19 h (11–36 h)

 ~3 x increase in half-life relative to historical data for BeneFIX®



Phase I/II Trial: rFVIIIFc

PK parameter Elimination $T_{1/2}$ (hours)³

rFVIIIFc n=15 mean 19 h (18-22 h)

Advate® n=15 mean 11,5 h (10–13 h)

- rFVIIIFc ~1,5-1,75 fold increase in half-life versus Advate®
- All patients had a longer half life with rFVIIIFc

1Summary of product characteristics of BeneFIX® (Nov 18, 2009)
2 Blood 2011 blood-2011-07-367003; published ahead of print November 22, 2011, doi:10.1182/blood-2011-07-367003
3 15/16 PTPs were included for PK analysis (1 subject did not complete PK profiling); In press, Blood 2011



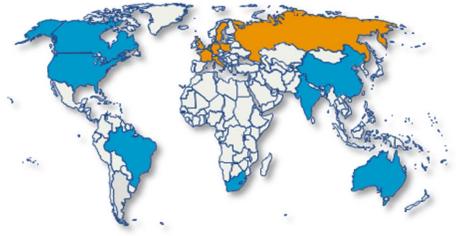


Pivotal Studies To Assess Prophylaxis + On Demand



B-LONG: An Open-Label, Multicenter study

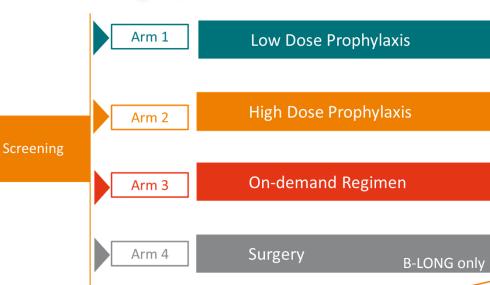
 Evaluation of the Safety, Pharmacokinetics and Efficacy of rFIXFc in the Prevention and Treatment of Bleeding in Previously Treated Subjects With Severe Hemophilia B



A-LONG An Open-Label, Multicenter study

 Evaluation of the Safety, Pharmacokinetics and Efficacy of rFVIIIFc in the Prevention and Treatment of Bleeding in Previously Treated Subjects With Severe Hemophilia A

More information, please visit : www.clinicaltrials.gov www.biogenidechemophilia.com

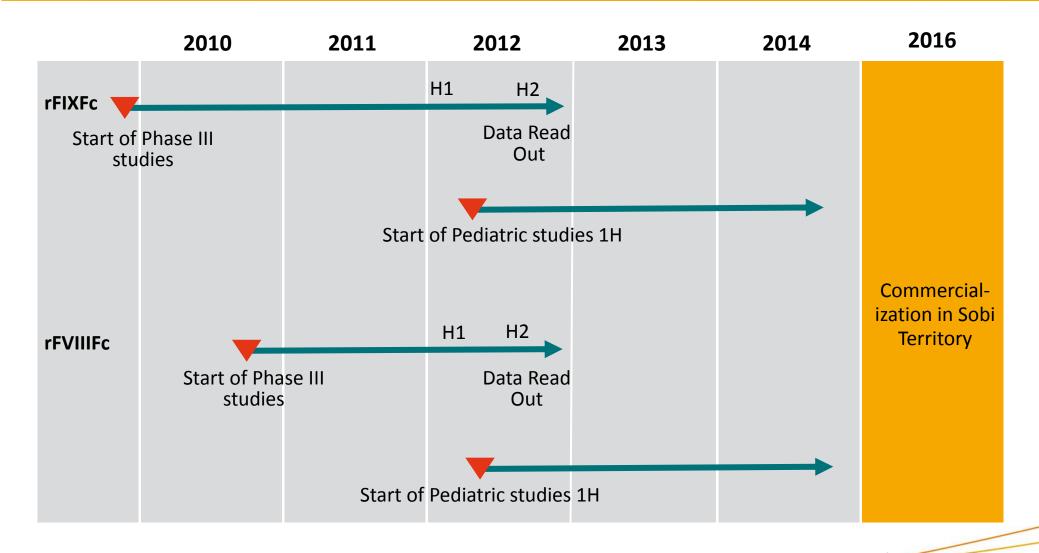






Pivotal Program Timelines: Sobi Territories Follow US









Sobi has Significant Experience in the Market

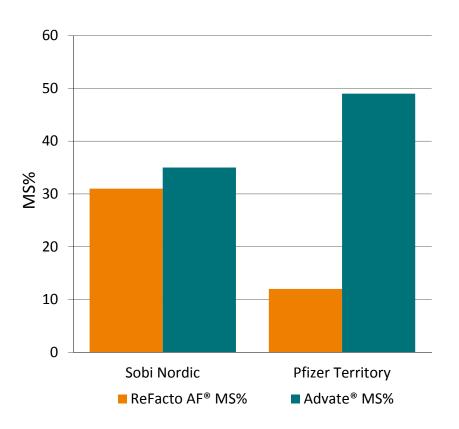








Sobi Market Share in Co-Promotion Territory



Source: Analyst report internal analysis wholesaler data



Summary

- Diversified commercial portfolio focused on improving cash flow and profitability
- 2. Working to efficiently commercialize our proprietary innovative medicines for rare disease patients globally
- 3. Business model oriented to **building** value through partnerships from global early stage biologics development to late stage specialty distribution in Europe.



Pioneer & Partner in Rare Diseases

