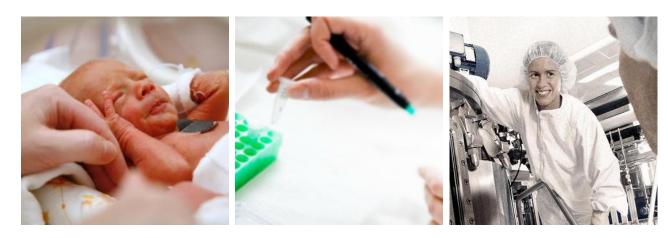
## Q4 and Full Year Results 2012

Geoffrey McDonough (CEO)

Alan Raffensperger (COO)

Annika Muskantor (Interim CFO)



Stockholm, 21 February 2013



## **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.



### Who We Are

# Sobi is an international specialty healthcare company dedicated to rare diseases.



Our key therapeutic areas are Inflammation and Genetic diseases, with a growing focus on Haemophilia and Neonatology.



We deliver products to specialist physicians and their patients through our integrated and focused team approach to sales and marketing, medical affairs and patient access.



We leverage our world-class capabilities in protein biochemistry and biologics manufacturing to develop next generation biological products.



## Q4 - 2012 Consolidated Results



<sup>&</sup>lt;sup>1)</sup> Adjusted for balance sheet write-downs in Q4-11.

#### **Financial**

- Total revenues SEK 472 M (436)
  - Increase of 8%
- Gross margin 57% (41)
- Operating expenses decreased
- Return to positive cash flow
- Write down of Multiferon



## Calendar Highlights Q4 and Full Year 2012

| Event  | H1<br>2012 | H2<br>2012 |
|--|------------|------------|
| Orfadin Liquid Formulation PIP Response        |            |            |
| Kineret CAPS¹ Pediatric Investigation Plan     |            |            |
| Complete Tech Transfer Kineret Manufacturing   |            |            |
| Kineret NOMID <sup>2</sup> Filing FDA          |            |            |
| Top-Line Data for rFIXFc Program (BIIB)        |            |            |
| Kineret CAPS <sup>1</sup> Filing EMA           |            |            |
| Top-Line Data for rFVIIIFc Program (BIIB)      |            |            |
| Kiobrina Complete Phase 3 Enrollment           |            |            |
| FDA Approval of Kineret for NOMID <sup>2</sup> |            |            |

<sup>&</sup>lt;sup>1</sup> Cryopyrin Associated Periodic Syndrome (CAPS)



<sup>&</sup>lt;sup>2</sup> Neonatal Onset Multisystem Inflammatory Disorder, a subset of CAPS

## **Progress Against Guidance**

#### Outlook 2012 Unchanged

#### Revenues

Total revenues expected to be about SEK 100 M lower than 2011, reflecting the divestment of the co-promotion rights.



#### **Gross Margin**

Gross margin expected to be in line with 2011 margin of 54% after adjustment for the balance sheet write-downs and the divestment of co-promotion rights.



Costs related to the transfer of Kineret production are estimated at SEK 60 M impacting gross margin primarily in the first half of the year.



#### OPEX

Operating expenses estimated at or below SEK 950 M.



#### Milestone Payment

Milestone payment to Amgen of USD 55 M expected in Q4 2012 or in Q1 2013.



The outlook was first published in the Q4 report on 23 February 2012.





## **Operational Priorities**

#### **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

+8% CER<sup>1</sup>

2. Ongoing cost discipline

-5%

3. Gross margin improvement

+3%2

Improving cash flow from operations and working capital

sobi

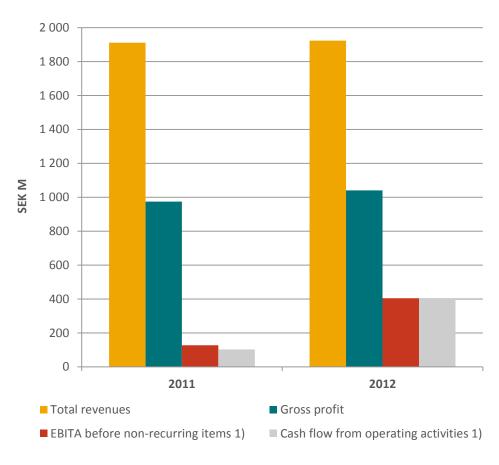
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<sup>1)</sup> Adjusted for currency effects, co-promotion, discontinued products and other revenues

<sup>2)</sup> Improvement of 3 absolute percentage points

### Full Year 2012 Consolidated Results

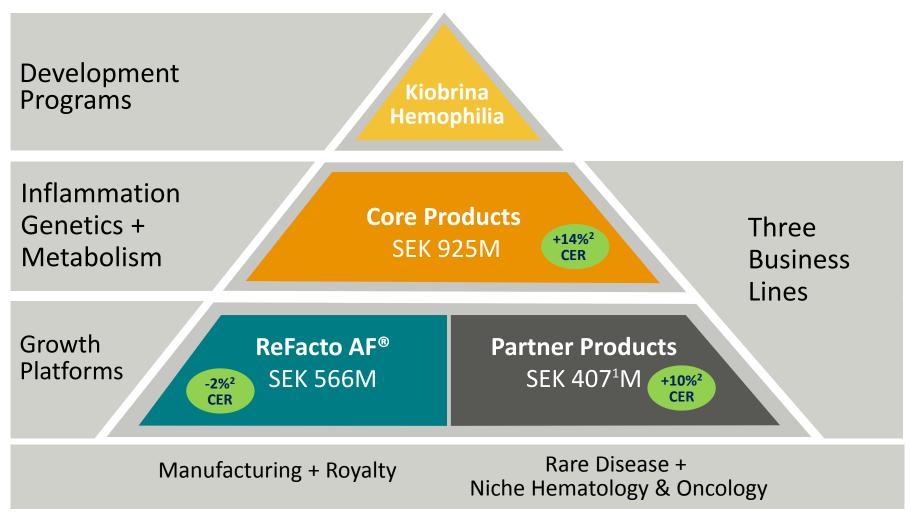


1) Adjusted for balance sheet write-downs in Q4-11

- Total revenues were SEK 1 923 M (1 911)
  - 2011 revenues included SEK 150 M from co-promotion and discontinued products
  - Adjusted revenues grew 8%
- Gross Margin was 54% (51%)
  - Efficiency gains in production
  - Completion of tech transfer for Kineret
- OPEX was SEK 941 M (995)
- Proceeds from sale of copromotion rights to Pfizer were SEK 307 M



## FY 2012 Revenues by Business Lines



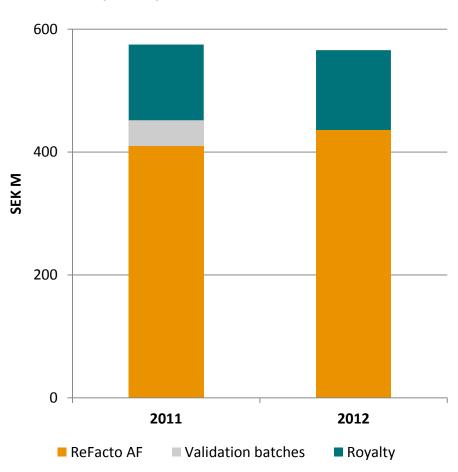
- 1) 2012 figures in SEK, excluding co-promotion revenues
- 2) YTD growth 2012 vs. 2011, adjusted for discontinued products and ReFacto/BeneFIX co-promotion



### ReFacto AF®



#### Sales (SEK M): ReFacto

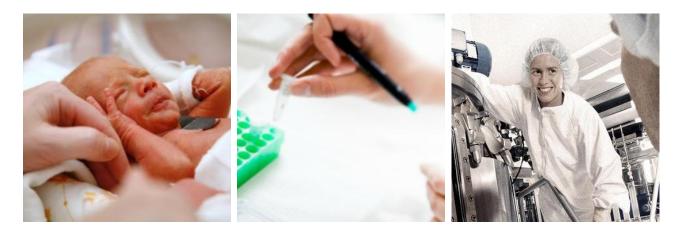


- Revenue from ReFacto AF manufacturing was SEK 436 M (410)
  - 2011 revenue from PV batches SEK 42 M
- Revenue from ReFacto royalty was SEK 130 M (123)
- Agreement with Pfizer extended to 2020



## **Business Update**

Alan Raffensperger (COO)

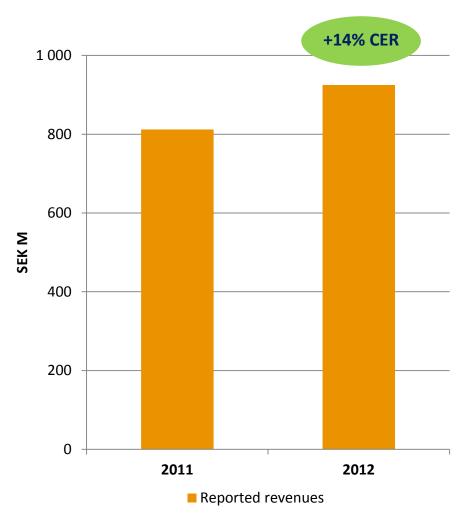


Stockholm, 21 February 2013



### **Core Products**





- Revenues from Core Products were SEK 925 M (812) an increase of 14%
- Sales momentum driven by Kineret and Orfadin
- Top line driven by a combination of volume and value gains

Note: Core Products include Kineret, Orfadin, Ammonaps, Ammonul and Ruconest



### Kineret<sup>®</sup>

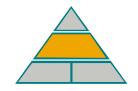




- Revenue for Kineret was SEK 485 M (422)
  - Growth of 14%
- Kineret approved for NOMID in December
  - US team now gearing up for launch to pediatric rheumatologists
- EMA Kineret CAPS Approval Possible in H2 2013
- Savient partnership in the US will enhance our ability to reach the Rheumatoid Arthritis market



## US Co-Promotion Agreement with Savient



- Doubling our share of voice for Kineret through the addition of Savient sales representatives
- Savient Pharmaceuticals; a specialty biopharmaceutical company
- Strong, established relationships with rheumatologists in the US
- KRYSTEXXA® (pegloticase) for the treatment of refractory chronic gout in the US
- Joint sales activities will commence in April 2013

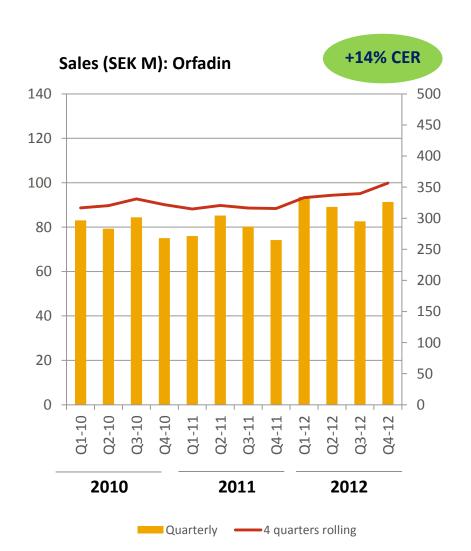






### Orfadin®





- Revenue for Orfadin was SEK 357 M (316)
  - Growth of 14%
- Sales driven by volume growth in new geographic regions: Middle East, North Africa and Russia
- Some phasing effects from Q4 2011 to Q1 2012 contributing to 2012 FY growth rate
- Orfadin Liquid Filing (EMA/FDA) planned H2 2013



### **Partner Products**



#### Sales (SEK M): Partner Products



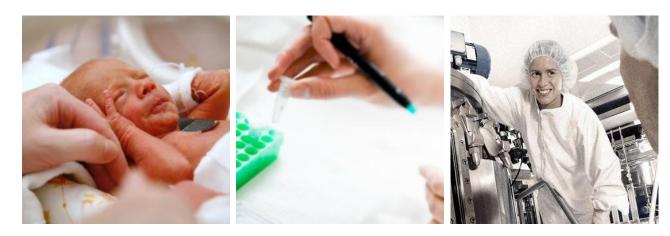
- Revenue for Partner Products was SEK 419 M (524)
  - 2011 included SEK 150 M from copromotion and discontinued products
  - Adjusted revenue grew 10% CER
- Key growth drivers: Aloxi, Mezavant and Defibrotide (Nordic)
- Valeant/PharmaSwiss partnership validates European platform



<sup>&</sup>lt;sup>1</sup> Growth of base business versus 2011 (adjusted for SEK 150 M from co-promotion and discontinued products)

## **Financials**

Annika Muskantor (Interim CFO)



Stockholm, 21 February 2013

## **Income Statement**

|                                   | Reported | Reported |        |
|-----------------------------------|----------|----------|--------|
| SEK M                             | 2011     | 2012     | Change |
| <b>-</b>                          | 4.044    | 4 000    | 40/    |
| Total revenues                    | 1 911    | 1 923    | 1%     |
| Gross profit                      | 975      | 1 040    | 7%     |
| Gross margin                      | 51%      | 54%      |        |
| OPEX                              | -995     | -941     |        |
| Other operating revenues/expenses | 147      | 305      |        |
| EBITA before non-recurring items  | 127      | 404      | >100%  |
| Non-recurring items               | -78      | -37      |        |
| Amortizations 1)                  | -368     | -422     |        |
| EBIT                              | -319     | -54      | 83%    |
| Net financial items               | -52      | -51      |        |
| Tax                               | 389      | 4        |        |
| Profit/loss                       | 18       | -101     | <-100% |

<sup>1)</sup> Adjusted for write-down of Multiferon



### **Balance Sheet**

|                                | Dec   | Dec   |
|--------------------------------|-------|-------|
|                                | 2012  | 2011  |
| ASSETS                         |       |       |
| Intangible <sup>1)</sup>       | 4 533 | 4 885 |
| Tangible and financial         | 130   | 167   |
| Total non-current assets       | 4 663 | 5 052 |
|                                |       |       |
| Inventories                    | 700   | 894   |
| Other Receivable <sup>2)</sup> | 498   | 534   |
| Cash and equivalent            | 457   | 219   |
| Total current assets           | 1 655 | 1 647 |
| Total Asset                    | 6 319 | 6 699 |

- Inventory reduction
- Decrease in operating receivables
- Cash increase
- Long term debt constant since Q2

#### **EQUITY AND LIABILITIES**

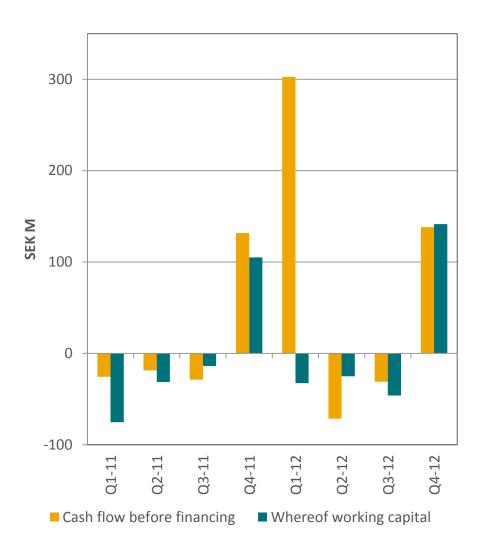
| Equity                               | 4 838 | 4 963 |
|--------------------------------------|-------|-------|
| Long term debt                       | 600   | 701   |
| Long term liabilities <sup>2)</sup>  | 372   | 359   |
| Short term liabilities <sup>2)</sup> | 509   | 677   |
| Total liabilities                    | 1 481 | 1 736 |
| Total equity and liabilities         | 6 319 | 6 699 |

<sup>1)</sup> Including write down of Multiferon



<sup>2)</sup> Including non-interest bearing

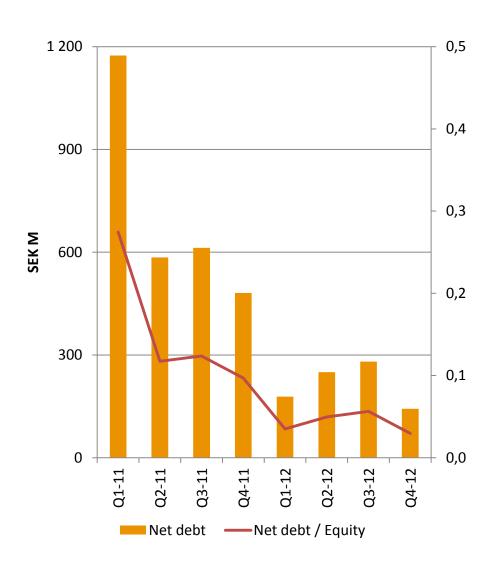
## Cash Flow – Q4



- Improved cash flow from operations
- Reduction in inventory and operating receivables continues somewhat offset by phasing of operating payables
- Pfizer co-promotion proceeds of SEK 307 M in Q1



### Net Debt

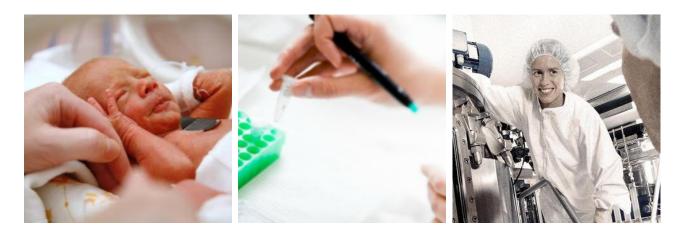


- Decrease in net debt from Q4 due to higher cash balance at year end
- Amgen milestone will be paid in late
   February 2013 in amount of US 55 M
- Bond issue of up to SEK 200 M will support our readiness for the Haemophilia programmes



## Outlook

Geoffrey McDonough (CEO)



Stockholm, 21 February 2013



### Outlook 2013

#### Revenues

Total revenues are expected to be in the range of SEK 2.0 to 2.2 B

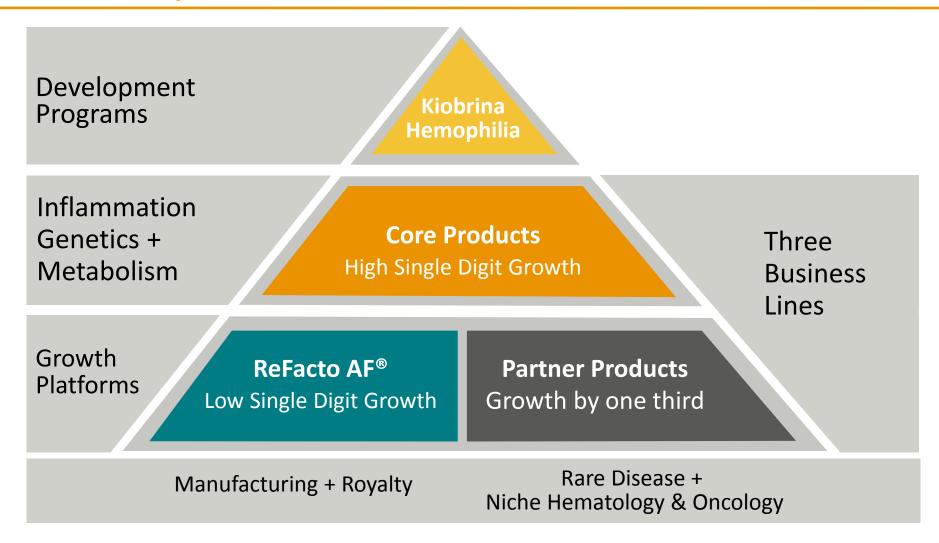
- Core Products high single-digit growth
- Partner Products growth by about one third (~30%)
- ReFacto<sup>®</sup> manufacturing and royalty low to mid single-digit growth

#### **Gross Margin**

Approximately 57-59%

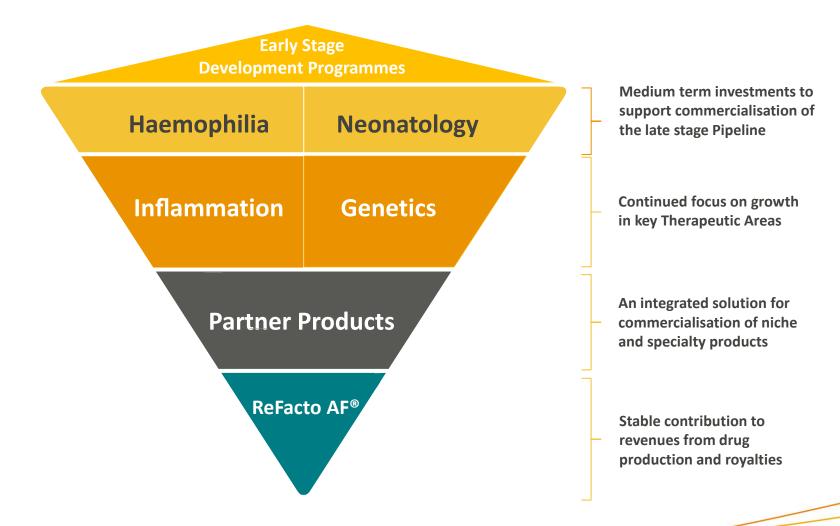


## Outlook by Business Lines





## Entering the Mid-Term





## Hemophilia Update – EAHAD Warsaw 2013



Recombinant Fc fusion proteins show potential to transform care by providing long-lasting protection from bleeding with fewer injections than the current standard of care

- A-LONG data indicate that rFVIIIFc has the potential to become the first product to offer hemophilia A patients long-lasting protection from bleeding with less frequent dosing than the current standard of care
- Recombinant FVIIIFc was generally well-tolerated and no inhibitors to rFVIIIFc were detected

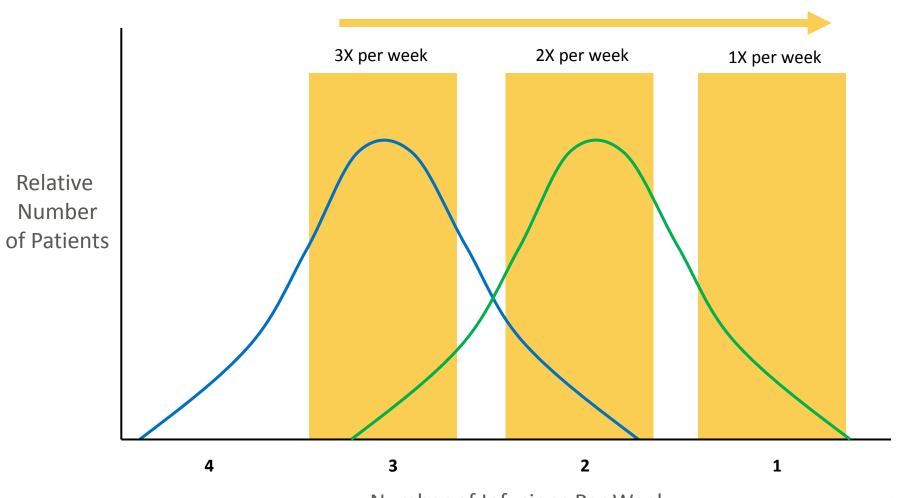
- B-LONG data support the potential for rFIXFc to become the first product to offer hemophilia B patients long-lasting protection from bleeding with less frequent dosing than the current standard of care
- Recombinant FIXFc was generally welltolerated and no inhibitors to rFIXFc were detected



## What Does Shifting the Curve Mean?



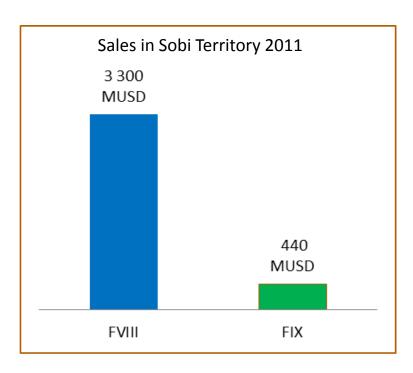
#### ILLUSTRATION ONLY - NOT DATA





## Sobi Territory Update





Source: Marketing Research Bureau 2011 (http://www.marketingresearchbureau.com)



| Aigeria                      |
|------------------------------|
| •Andorra                     |
| •Armenia                     |
| •Austria                     |
| <ul><li>Azerbaijan</li></ul> |
| •Bahrain                     |
| •Belarus                     |
| •Belgium                     |
| •Bosnia                      |
| Herzegovina                  |
| •Bulgaria                    |
| •Croatia                     |
| •Cyprus                      |
| •Czech Republic              |
|                              |
|                              |

Albania

Algeria

Denmark
Dibouti
Egypt
Estonia
Finland
Former Yugoslav
Republic of
Macedonia
France
Georgia
Germany
Greece
Hungary
Iceland

•Iraq
•Ireland
•Italy
•Jordan
•Kuwait
•Latvia
•Lebanon
•Libya
•Liechtenstein
•Lithuania
•Luxembourg
•Malta
•Mauritania

•Somalia Monaco •Morocco •Spain Norway •Sudan •Sweden •Oman Poland Switzerland Portugal •Syria •Qatar •The Netherlands •Tunisia •Romania •Russia Turkey •San Marino •UAE •Saudi Arabia •Ukraine •Serbia & United Kingdom Montenegro Vatican City

•Slovakia

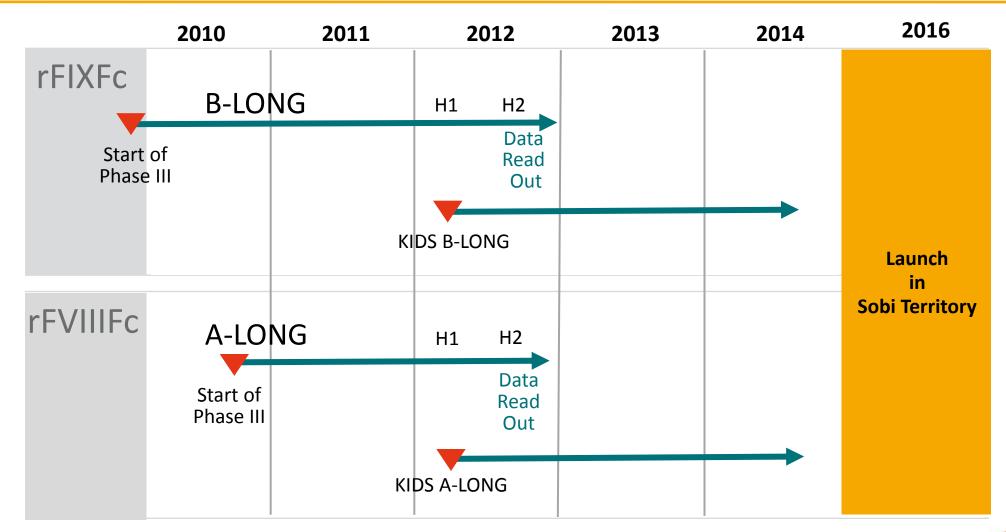
•Slovenia



•Yemen

### Launch in Sobi Territories will follow US





## **Strategic Priorities**

- Near-term focus on growth in key therapeutic areas, with sustainable positive cash flow from operations.
- 2. Medium-term investments to ensure successful commercialization of our late-stage pipeline.
- 3. Long-term growth will come organically and through acquisitions in key therapeutic areas.





