## PRESS RELEASE



Stockholm, 29 November, 2011

# Sobi holds Capital Markets Seminar

The program for today's Capital Markets Seminar includes a company overview by CEO Geoffrey McDonough, a financial update by CFO Lars Sandström and a presentation of the phase III projects in neonatology (Kiobrina®, an enzyme replacement therapy to prevent growth restriction in preterm infants), and in hemophilia (long acting recombinant Factor VIII FC and Factor IX FC for hemophilia A and B). All presentations are streamed live at <a href="www.sobi.com">www.sobi.com</a>.

The purpose of the seminar is to provide insight to Sobi's operations and late-stage development projects. No other long-term financial goals or guidance for 2012 other than described in this press release will be provided. Given the adjusted timeline for the hemophilia projects as a result of the new guidelines from the European Medicines Agency, the previous long-term financial targets are no longer valid.

In his company overview, CEO Geoffrey McDonough will focus on Sobi's objectives to achieve positive cash flow and profitability, and to commercialize its pipeline of proprietary innovative medicines for rare diseases. The company will prioritize greater operational efficiency, growth of the product portfolio in existing and in selected new geographies, and the execution of the research projects according to plan.

The commercial business will be presented in three lines:

- ReFacto® with net revenues of SEK 608 M, including royalty, and a gross margin above 60%.
- Core Products (Kineret®, Orfadin®, Ammonaps®, Ammonul® and Ruconest®) with net revenues
  of SEK 803 M and a gross margin of approximately 60%.
- Specialty Distribution Products with revenues of SEK 459 M and a gross margin below 50%.

Product area	Revenues	Growth	Gross margin, %
ReFacto®	608	34%	>60%
Core Products	803	6%	~60%
Specialty Distribution Portfolio	459	8%	<40

Revenues are rolling 12 months as of 30 September 2011 in reported exchange rates, adjusted for discontinued products. Growth figures are based on YTD 9 months 2011, adjusted for currency and discontinued products.

CFO Lars Sandström will comment on the development of revenues, gross margin and working capital from 2009 to September 2011:

- Adjusted for changes in exchange rates and discontinued products, total revenues during this period
  increased by an annual average of approximately 7%, despite price reductions imposed by the authorities
  in many European countries.
- The high growth rate for ReFacto® in 2011 is due to exceptionally high production as a result of the delivery of validation batches in the amount of approximately SEK 40 M.
- The gross margin from 2009 to September 2011 was negatively impacted by approximately SEK 120 M or 6 percentage points relating to currency effects due to the strengthening of the Swedish krona.

- The gross margin was also negatively affected by an additional amount of approximately SEK 120 M or 6 percentage points by various short-term effects, in particular the transfer of Kineret® production and the building up of stock in the amount of approximately SEK 500 M in preparation for the tech transfer, as well as by the production of validation batches for ReFacto®.
- Conversion of the Kineret® substance into finished product has been largely completed in 2011 and this will have a positive impact on working capital as stock levels will gradually fall in 2012 and 2013. The goal is to be back at normal stock levels in line with 2009 by 2013.

#### Write-down of balance sheet items

As reported in the interim report for Q3 2011, a number of balance sheet items will be written down in Q4 2011. The write-downs will amount to an estimated SEK 300-320 M and the items to be written down are listed in the table below. The write-downs will have a limited impact on cash flow.

Asset	Product	mount, SEKm	
Inventory	Kineret®	70-80	Revaluation of validation batches for Kineret® in order to value inventory at commercial value.
	Kepivance®	30	Reduced but stabilized revenues require write-down of inventory bought in 2008.
Trade receivable		20	Write-down of overdue receivables.
			Write-down of Leptin project outlicensed to Astra Zeneca due to reduced probability of commercial
Intangibles		130	success.
Real estate		50-60	Valuation of liability related to previous premises. Write-down of assets related to new premises.
Total		300-320	

## Transfer of Kineret® production

As previously announced, the transfer of Kineret® production from manufacturer Amgen Inc. in the US to a contract manufacturer in Europe has been delayed due to technical issues. The costs relating to the transfer during the first nine months of 2011 amounted to SEK 30 M. Final process validation runs are scheduled to be completed in the first quarter of 2012. Sobi has maintained the option to purchase additional supply from Amgen should a further delay occur, and will make this decision by the second quarter of 2012.

### Phase III projects progressing according to plan

#### Kiobrina

Kiobrina® is a recombinant human bile salt stimulated lipase (rhBSSL) being developed by Sobi as an enzyme replacement therapy to improve growth in preterm infants who receive pasteurized breast milk or infant formula. Data from this project is expected during 2013 and Sobi expects to commercialize Kiobrina during 2015. Kiobrina is a unique project with a potential to reach approximately 100 000 patients based on the ongoing study.

Kiobrina, Phase III study			
	Placebo-controlled, double blind study		
	4 weeks treatment		
	430 patients, <32 weeks		
	11 countries, 70 sites		

### Hemophilia

Sobi's and Biogen Idec's rFIXFc and rFVIIIFc hemophilia projects are advancing according to plan with recruitment of patients in both phase III studies (B-LONG and A-LONG, respectively). Data from both studies are expected to be delivered during the second half of 2012. The pediatric studies are expected to start in the first half of 2012. Following the initiation of the pediatric studies, Sobi expects the total development program, including regulatory review, to be completed within three to four years i.e. 2016 would be the first year with significant revenues. The total market for hemophilia within Sobi's territories is growing and is currently USD 3.4 billion.

Hemophilia projects	rFIXFc	rFVIIIFc
Phase III studies	B-LONG	A-LONG
No. of patients	105	150
Start date	dec-09	nov-10
Phase III data	H2 2012	H2 2012
Start of pediatric studies in previously treated patients	H1 2012	H1 2012
Orphan drug designation	USA and Europe	USA and Europe

No. of patients required in the European studies	rFIXFc	rFVIIIFc
Previously treated patients >12 years	20	50
Previously treated patients 6- <12 år	10	25
Previously treated patients <6 years	10	25

Ref. EMA (European Medicines Agency)

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### Swedish Orphan Biovitrum (Sobi)

Sobi is a leading integrated biopharmaceutical company dedicated to bringing innovative therapies and services to improve the health of rare disease patients and their families. The product portfolio comprises about 60 marketed products as well as projects in the late clinical phase. Key therapeutic areas are Inflammation and Genetics & Metabolism. In 2010 Sobi had revenues of SEK 1.9 billion and around 500 employees. The share (STO: SOBI) is listed on OMX NASDAQ Stockholm. More information is available at <a href="https://www.sobi.com">www.sobi.com</a>.

The information above has been published pursuant to the Swedish Securities Market Act and/or the Financial Instruments Trading Act. The information was released for public distribution on 29 November 2011 at 1.15 p.m. CET.

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.