

# Sobi: Update and Perspective

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# 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.*

# An International Specialty Healthcare Company Dedicated to Rare Diseases



# Quick Facts

**Market Cap:** \$3.0 Billion USD (SEK 19.3 Billion)

**Share:** SEK 72.80 (36.80 – 73.20)

**Listing:** NASDAQ OMX (STO:SOBI)

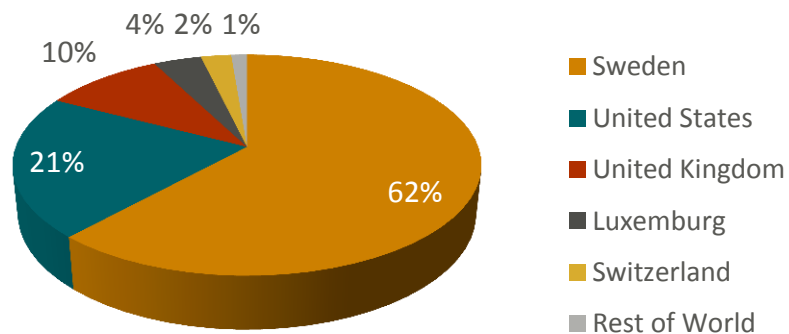
Outstanding shares: 270.4 M

## International Presence

- 500+ employees
- Sales and marketing organization which covers about 20 countries in Europe
- Growing organizations in US, Russia, Middle East

## Ownership Summary:

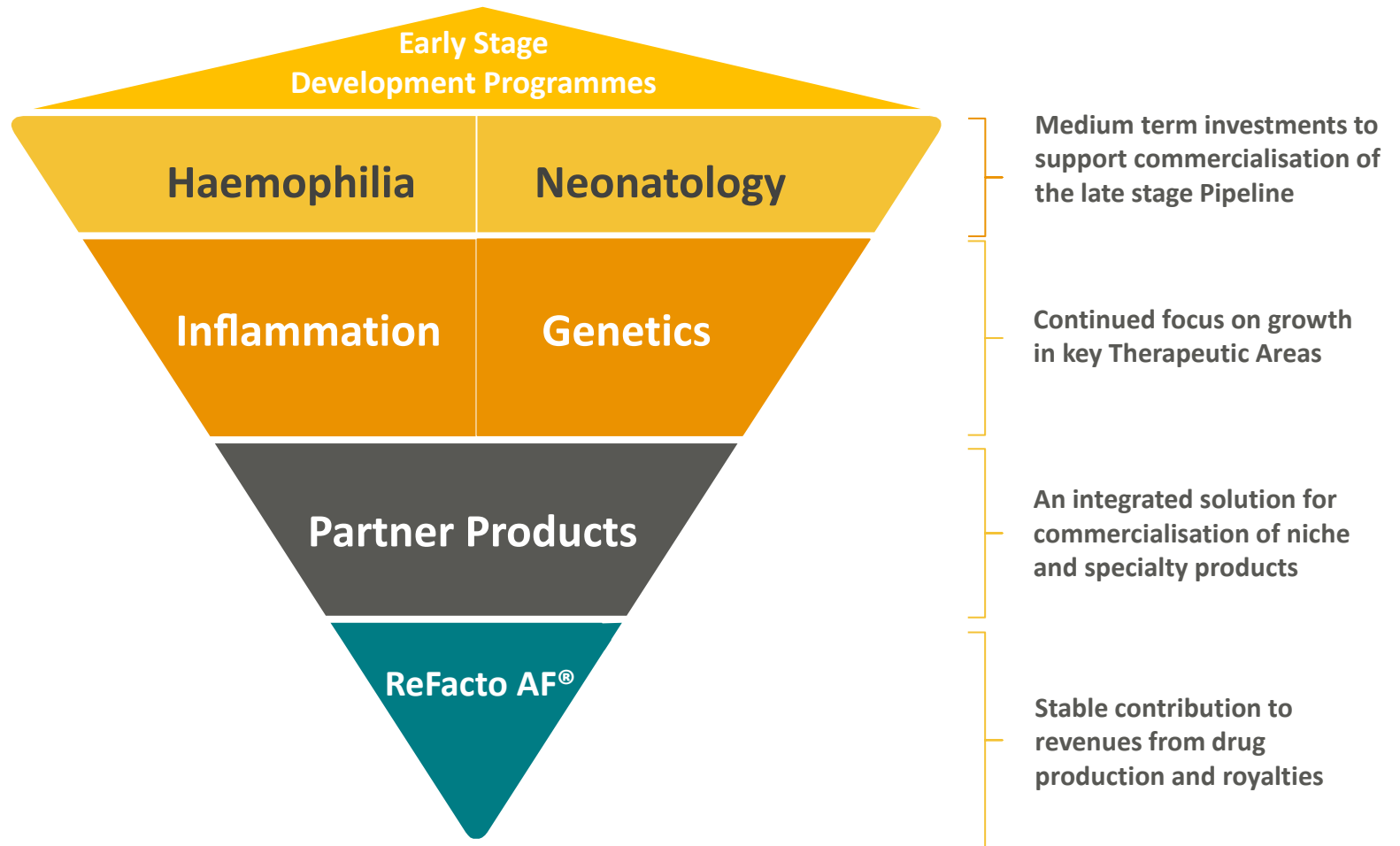
31 December 2013



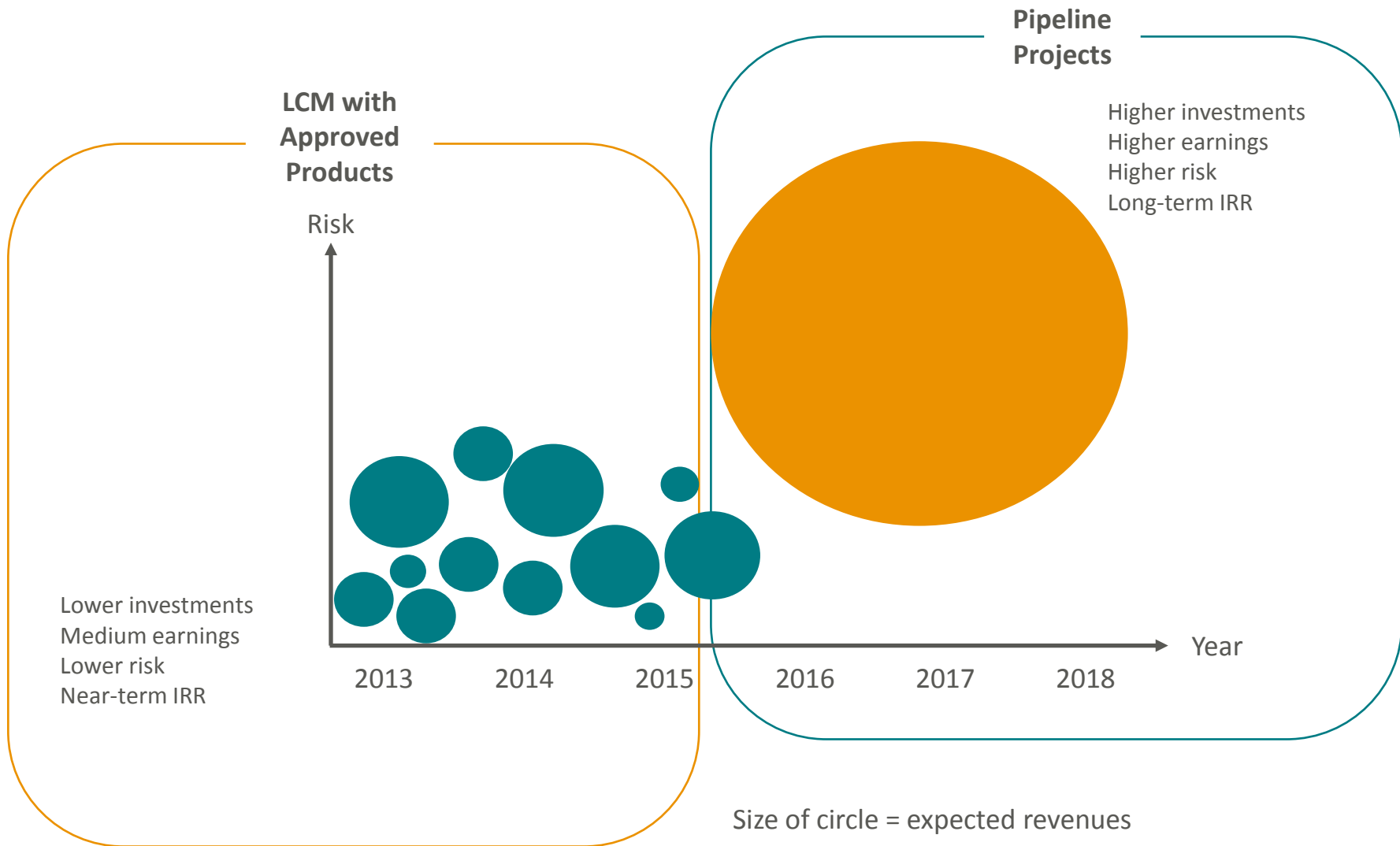
US\$ 1 = SEK 6.51 (Exchange rate January 7, 2013)




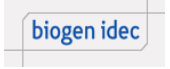
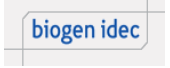








# A Diverse, Growing Business Platform



# A Balanced Approach to Risk + Allocation of Capital



# R&D Pipeline 2013

Indication	Project	Partner	Pre-Clin.	Phase I	Phase II	Phase III	Launch
CAPS	Kineret						
Hemophilia A	rFVIII Fc						
Hemophilia B	rFIX Fc						
Improve growth in preterm infants	Kiobrina						
Oral Mucositis in Head & Neck Cancer	Kepivance						
Hereditary Tyrosinemia Type 1	Orfadin Liquid						
Hereditary Tyrosinemia type 1	Orfadin 20mg capsule						
Alkaptonuria	Orfadin						
Complement – mediated disease	SOBI002						
ERT	SOBI003						
IL-1-driven disease	IL-1 Affibody						



Pipeline Projects



LCM with Approved Products

# Two Years Ago at JP Morgan

## Actions to Reach Our Goals

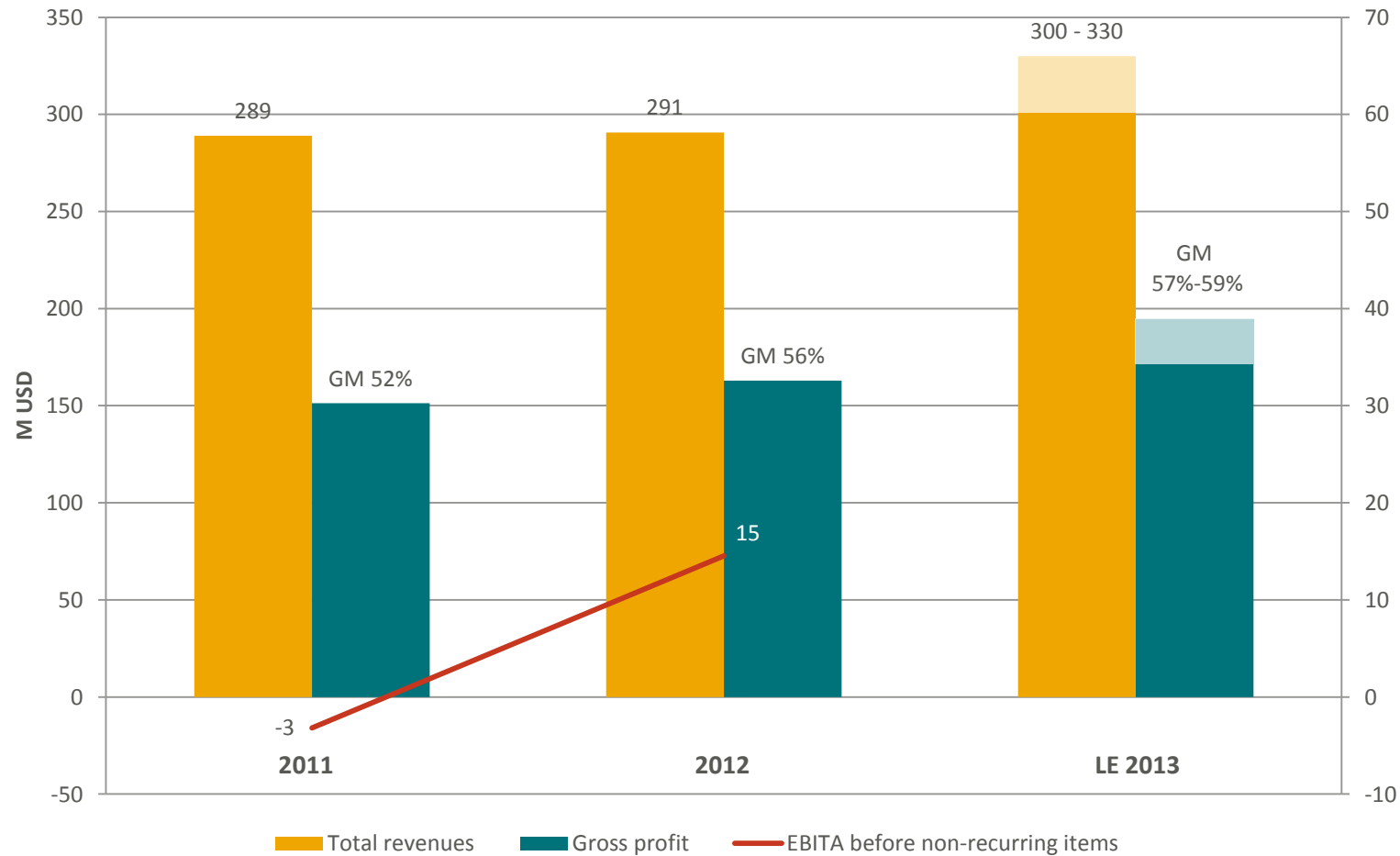
We intend to earn our way into our future based on **operational performance**.

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

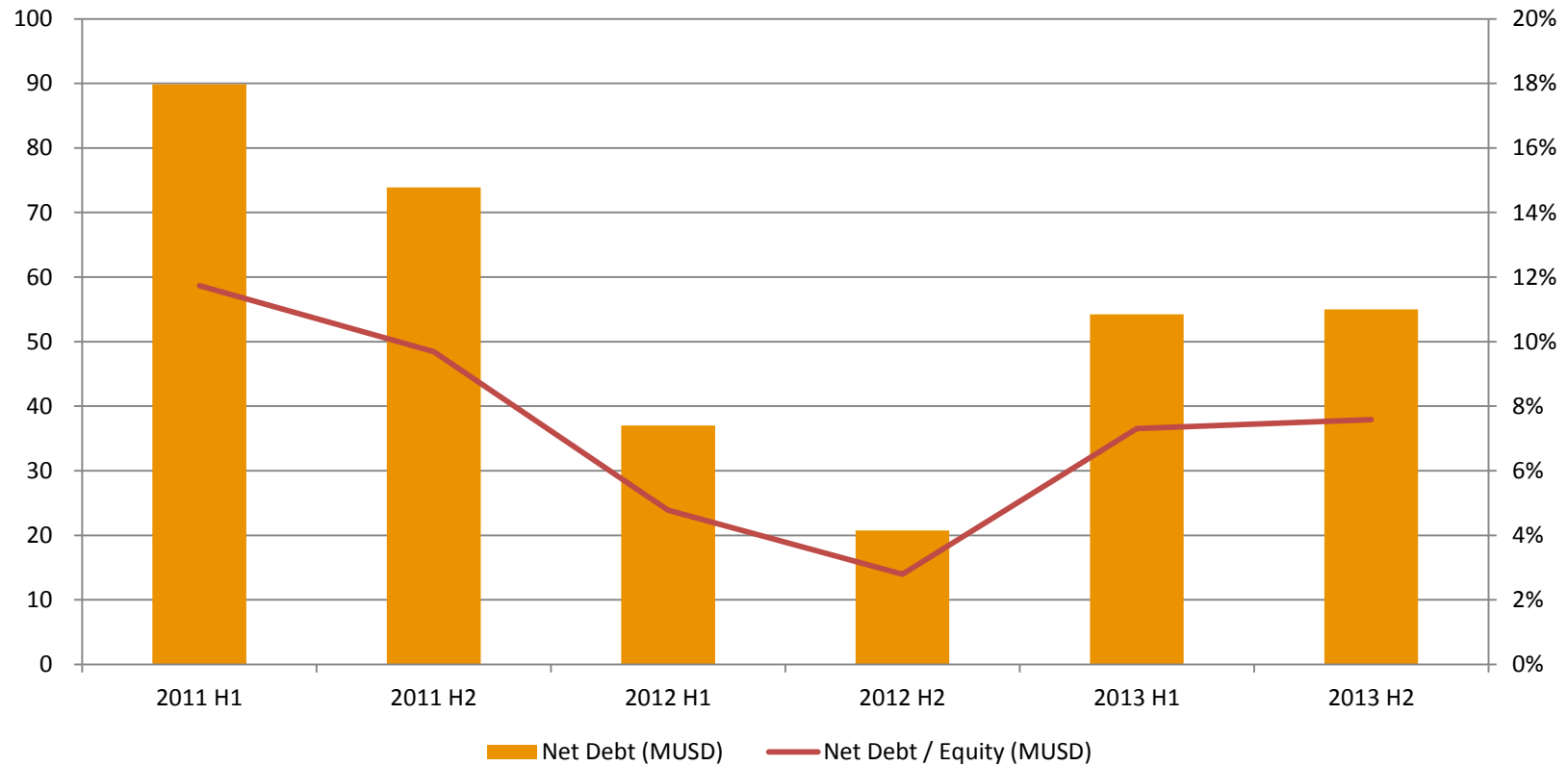


# Year End Revenue + GM Expectations\* 2013

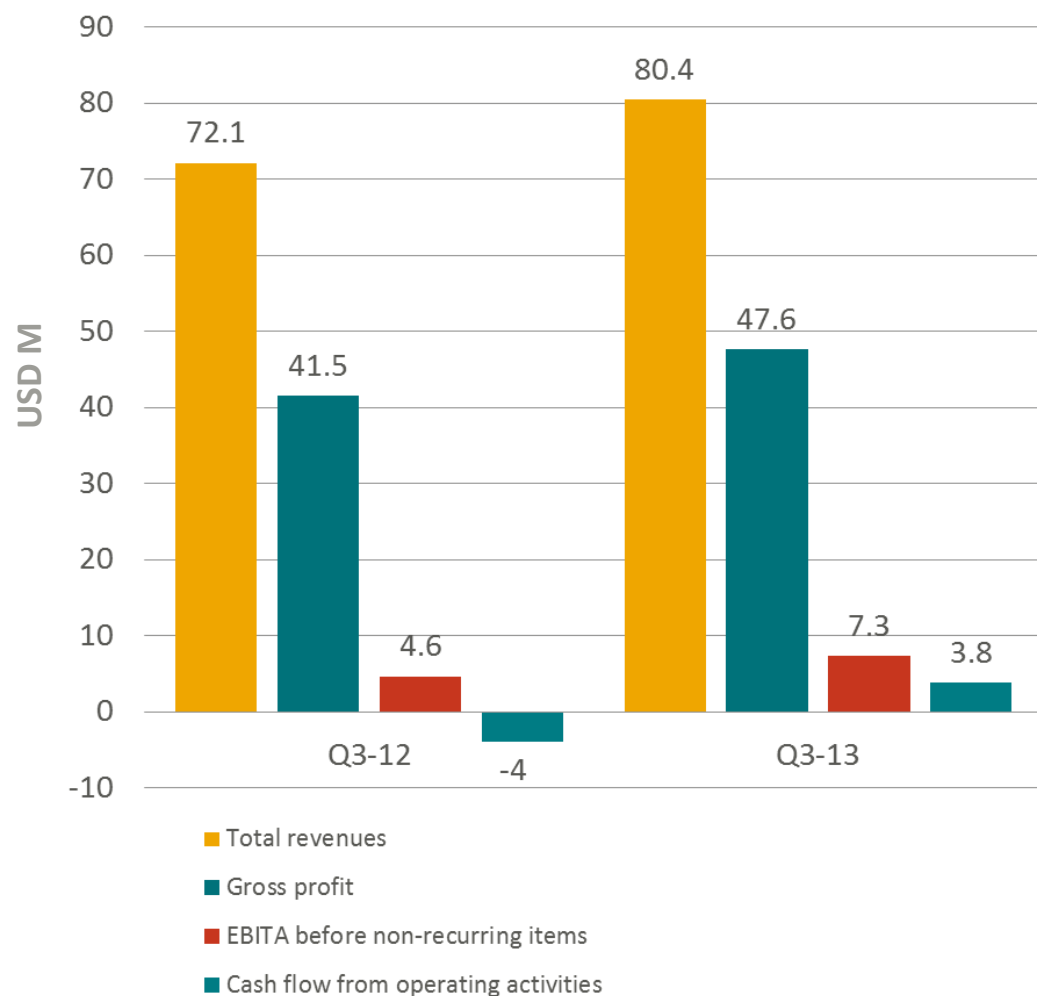
\* Based on guidance 2013



# Net Debt Evolution



# Consolidated Results Q3

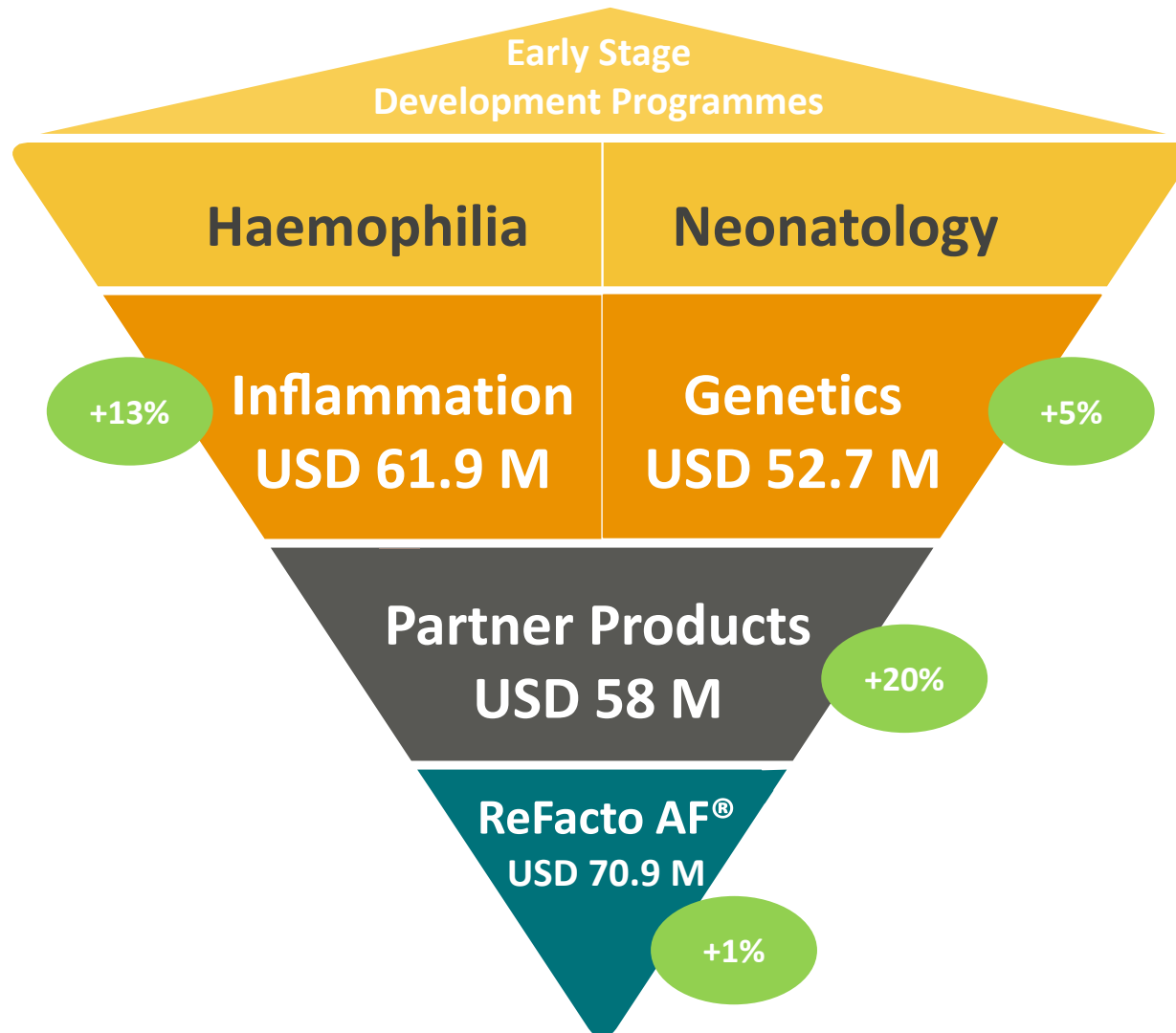


US\$ 1 = SEK 6.43 (Exchange rate September 30, 2013)

## Financial Highlights Q3

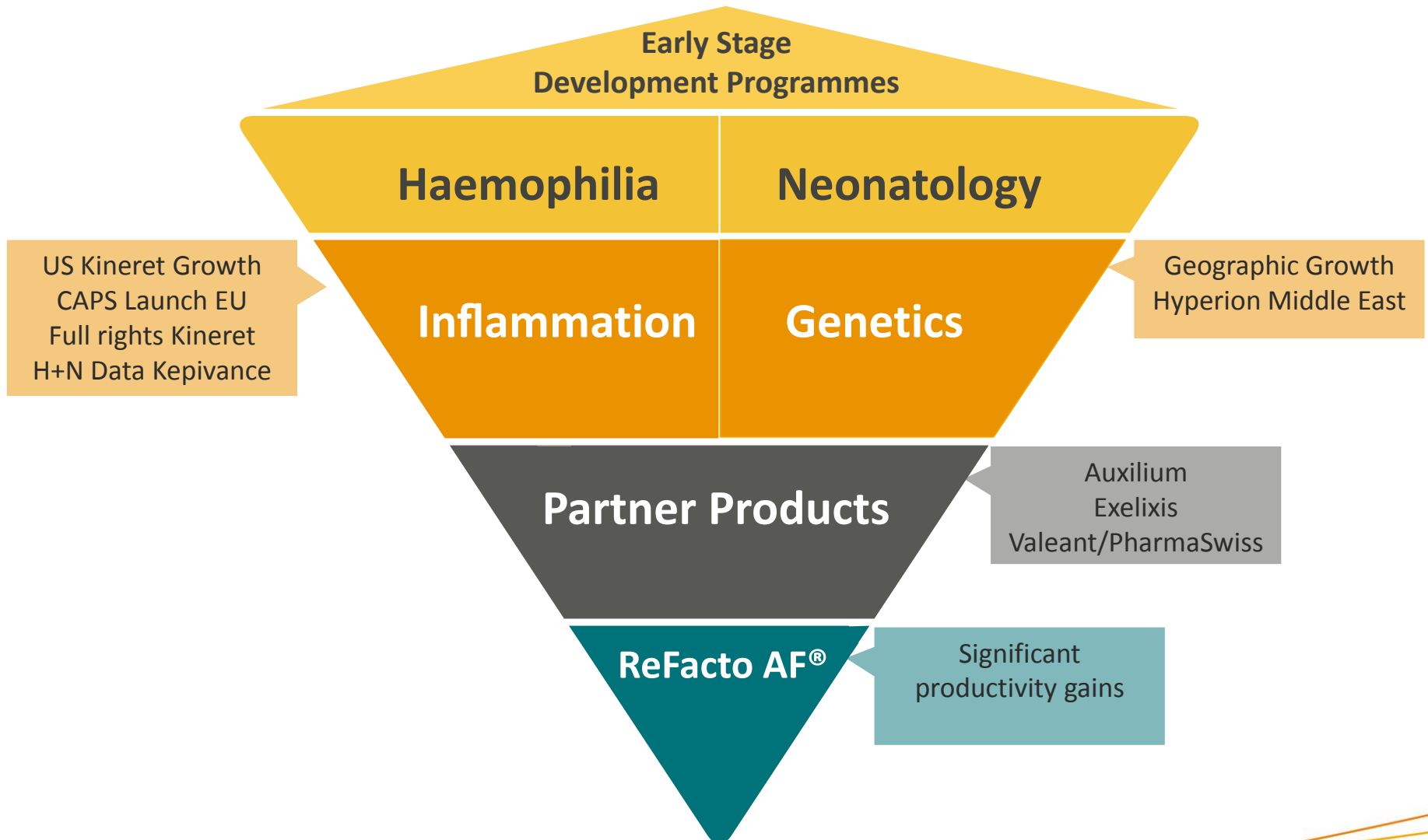
- Total Revenues: USD 80.4 M
  - Year over Year increase of 12%
  - Year to Date increase of 8%
- Gross Margin: 59%
  - YTD Gross Margin: 59%
- EBITA before non-recurring items: USD 7.3 M (4.6)
- Cash Flow from operating activities: USD 3.8 M (-4)
- Cash Position: USD 70 M

# YTD Q32013 Revenue by Business Line



US\$ 1 = SEK 6.43 (Exchange rate September 30, 2013)

# Key Events and Drivers 2013



# The Share – Past Two Years

SEK 72.80



# Strategic Priorities

1. **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.



# Momentum Across Business Lines Through Q3 2013

## Inflammation

- US Volume + Price
- CAPS launch in Europe

## Genetics & Metabolism

- Growth in Middle East, North Africa, + Europe
- Assume direct responsibility for North America 1 April 2014
- Preparation for liquid formulation launch in 2015

## Partner Products

- Execution on recent partnership deals
- Selected new deals based on synergy

## ReFacto

- **Focus on operating improvements**



# Strategic Priorities – 2014: A Pivotal Year

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# Hemophilia – Long-Lasting Factor Programs



## Key Milestones

- rFIXFc US Launch est. Q2 2014
  - KIDS B-LONG study on-going
- rFVIII Fc US Launch est. MY 2014
  - KIDS A-LONG study on-going
  - Sobi expects to opt-in on rFVIII Fc in 2H2014

## A \$3.7B Market in Sobi Territory Today



•Albania	•Denmark	•Iraq	•Monaco	•Somalia
•Algeria	•Djibouti	•Ireland	•Morocco	•Spain
•Andorra	•Egypt	•Italy	•Norway	•Sudan
•Armenia	•Estonia	•Jordan	•Oman	•Sweden
•Austria	•Finland	•Kuwait	•Poland	•Switzerland
•Azerbaijan	•Former Yugoslav Republic of Macedonia	•Latvia	•Portugal	•Syria
•Bahrain	•France	•Lebanon	•Qatar	•The Netherlands
•Belarus	•Georgia	•Libya	•Romania	•Tunisia
•Belgium	•Germany	•Liechtenstein	•Russia	•Turkey
•Bosnia Herzegovina	•Greece	•Lithuania	•San Marino	•UAE
•Bulgaria	•Hungary	•Luxembourg	•Saudi Arabia	•Ukraine
•Croatia	•Iceland	•Malta	•Serbia & Montenegro	•United Kingdom
•Cyprus	•Iran	•Mauritania	•Slovakia	•Vatican City
•Czech Republic		•Moldova	•Slovenia	•Yemen

# Updates from ASH December 2013 and ISTH July 2013

## Kids B-LONG poster presented by Biogen Idec<sup>1</sup> at ASH

- Compared with currently available FIX products, rFIXFc had an extended half-life (>3-fold increase) and reduced CL (>60% reduction) in children
- These results are in agreement with those previously observed in adults and adolescents
- The final analysis of the Kids B-LONG study will provide additional PK information and evaluate the safety and efficacy of rFIXFc in children

## Kids A-LONG poster presented by Biogen Idec<sup>2</sup> at ASH

- Compared with currently available FVIII products, rFVIIIIFc had an extended half-life and reduced clearance in children, suggesting that rFVIIIIFc can potentially be dosed less frequently than FVIII
- These results are in agreement with those previously observed in adults and adolescents
- The final analysis of the Kids A-LONG study will provide additional PK information, and evaluate the safety and efficacy of rFVIIIIFc in children

## X-TEN fusion protein data presented by Biogen Idec and ISTH<sup>3</sup>

Pre-clinical findings, presented by Sobi's partner Biogen Idec at the ISTH conference in Amsterdam in July 2013, from new factor VIII molecules showed that the XTEN Fusion Protein achieved a circulating half-life of 30 hours in mice, representing a 4-fold half-life extension over factor VIII

1. Pharmacokinetics of Recombinant Factor IX Fc Fusion Protein (rFIXFc) in Pediatric Subjects with Hemophilia B: An Interim Analysis of the Kids B-LONG Study - Poster #3599 – Monday, December 9 – 6:00-8:00 PM (CST)

2. Pharmacokinetics of Recombinant Factor VIII Fc Fusion Protein (rFVIIIIFc) in Pediatric Subjects with Hemophilia A: An Interim Analysis of the Kids A-LONG Study - Poster #3609 – Monday, December 9 – 6:00-8:00 PM (CST)

3. Liu et al., AS 45.1, J. Thromb Haemost 2013;11 (Suppl. 2), 71 and Chhabra et al., OC37.5, J. Thromb Haemost 2013;11 (Suppl. 2), 170

# Neonatology – Kiobrina (rh-BSSL)



## Key Milestones

- Kiobrina EU topline phase 3 data 1Q 2014
- Kiobrina US phase 3 FPI 1H 2014

Annual no of live births  
11 300 000

Preterms <W 37  
1 070 000

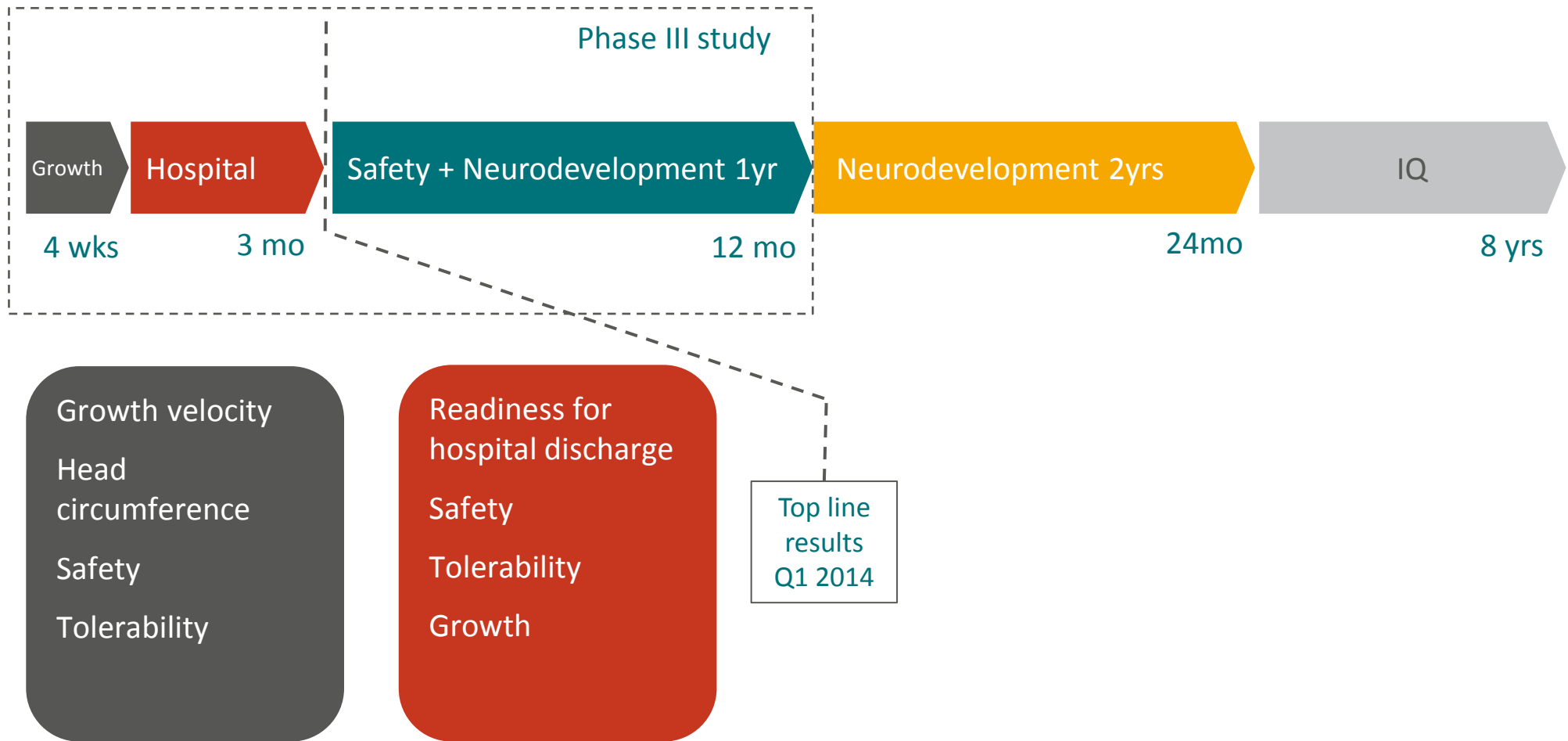
Preterms <W 32  
160 000

PBM/Formula  
56 000 (34%)

Mixed feeding  
38 000 (24%)

Breast milk  
68 000 (42%)

# Top Line Results Q1 2014: Growth, Safety, Hospital Outcomes



# Planned Key Events\* 2014 -- 2016

## Sobi's Key Milestones

Kineret	Orfadin	Kepivance	Factor VIII	Factor IX	Kiobrina	SOBI002
<ul style="list-style-type: none"> <li>✓ NOMID approval US</li> <li>✓ NOMID launch US</li> <li>✓ CAPS approval EU</li> <li>1 European launch CAPS</li> </ul>	<ul style="list-style-type: none"> <li>✓ Filling of liquid formulation in US and EU</li> <li>1 Assume direct Orfadin sales in NA</li> <li>2 Decision on approval of liquid formulation in EU</li> <li>3 Decision on approval of liquid formulation in US</li> </ul>	<ul style="list-style-type: none"> <li>✓ Phase I</li> <li>✓ Phase II</li> <li>✓ Phase III</li> <li>1 Discussion with FDA on possible label expansion for Head/Neck CA</li> </ul>	<ul style="list-style-type: none"> <li>✓ Phase I</li> <li>✓ Phase II</li> <li>✓ Phase III</li> <li>1 US launch</li> <li>2 EMA Filing + Opt-In</li> <li>3 European approval</li> </ul>	<ul style="list-style-type: none"> <li>✓ Phase I</li> <li>✓ Phase II</li> <li>✓ Phase III</li> <li>1 US launch</li> <li>2 EMA Filing + Opt-In</li> <li>3 European approval</li> </ul>	<ul style="list-style-type: none"> <li>✓ Phase I</li> <li>✓ Phase II</li> <li>1 Results of European phase III trial</li> <li>2 Beginning US Phase III trial</li> <li>3 File for EU approval</li> <li>4 European launch</li> </ul>	<ul style="list-style-type: none"> <li>1 Phase I</li> </ul>

## Sobi's Milestones by Timeline

Completed	2014										2015					2016
✓	1	1	1	1	1	2	1	2	3		2	3	2	4	3	3

\*Timing is illustrative within years.

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Pioneer in Rare Diseases

Q4 2013 + Full Year Earnings; 2014 Guidance: 20 February 2014