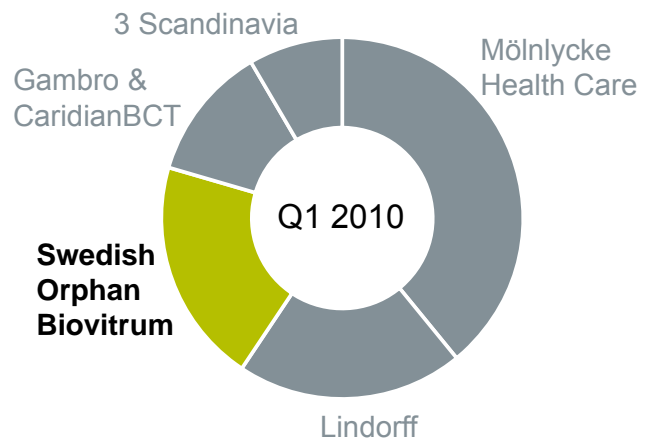


# SWEDISH ORPHAN BIOVITRUM

- > **Year of investment:** 2009
- > **Share of capital/votes:** 41%
- > **Value of holding:** SEK 3,271 m.
- > **Serving on the Board:**  
Hans Glemstedt and  
Lennart Johansson
- > Listed on the NASDAQ OMX  
Nordic Exchange



A Swedish based specialty pharmaceutical company with an international market presence. The company is focused on providing and developing orphan and niche specialist pharmaceuticals to patients with high medical needs.

Public

## SWEDISH ORPHAN BIOVITRUM Investor Capital Markets Day

2010-05-18

## DISCLAIMER

In order to utilize the 'Safe Harbor' provisions of the United States Private Securities Litigation Reform Act of 1995, 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 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.

## Strong industrial logic for merger



SWEDISH ORPHAN



### 1. Shared business strategy

- Rare disease focus
- Proprietary, in-licensed and distribution products

### 2. Complementary capabilities

- Swedish Orphan brings European commercial organization, business development track-record and products
- Biovitrum brings development pipeline, manufacturing expertise and products

### 3. Strong platform for profitable growth

- ~ 60 niche/orphan specialist pharmaceuticals
- Emerging late stage development pipeline
- Pan-European, and emerging US, commercial organization



**biovitrum.**



## Company development paths crossed

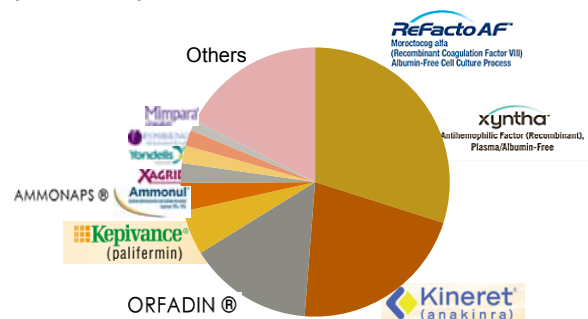
- Biovitrum growth strategy launched 2007
  - Focus on specialist pharmaceuticals
  - Take projects all the way to the market
  - Grow top- and bottom line
- 2008 - Transformation
  - Restructuring of R&D
  - Acquisition of Amgen products
  - M&S and supply chain infrastructure build-up in Europe, US, Canada, New Zealand, Australia
- 2009 - Continued Transformation
  - Development focus and capped costs
  - Out-licensing of primary care programs
  - Divestiture of CBT
  - Profit turn around

- Swedish Orphan International since 1988
  - Self-financed with sustained high growth
  - Product focus
  - In-depth orphan drug and market expertise
  - M&S expansion to pan-European presence
  - Goal to increase number of proprietary

**2010 - Creation of Swedish Orphan Biovitrum**

## Swedish Orphan Biovitrum corporate profile

- Focused on rare diseases
- Niche specialty pharmaceutical company with an international market presence
- Portfolio of ~60 marketed orphan and niche specialist products
- Emerging late stage development pipeline
- ~500 employees
- Head office in Stockholm, Sweden
- Share listed on NASDAQ OMX Stockholm (STO:BVT)

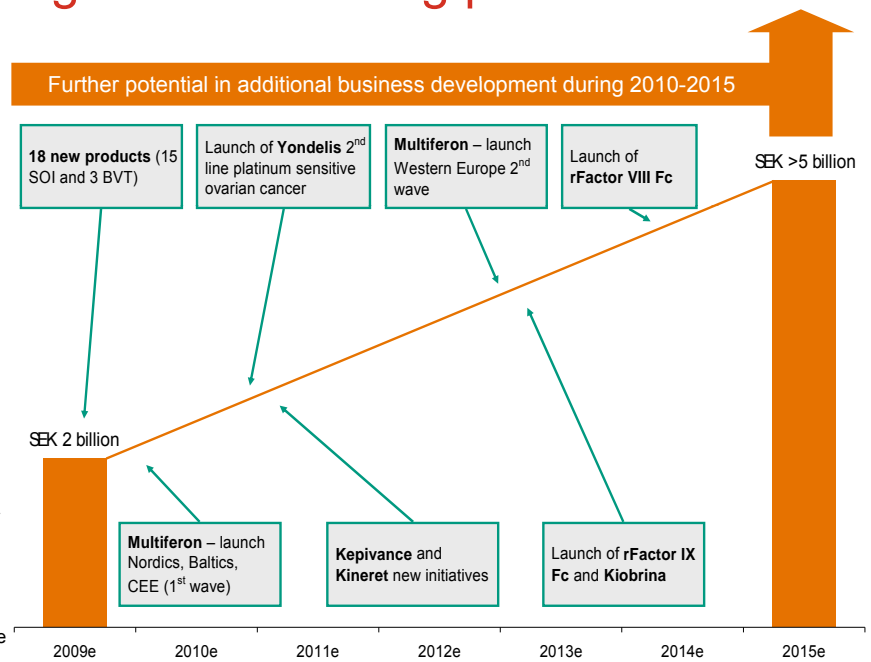


- Pro-forma revenues 2009 BSEK 2.066
- Pro-forma EBITA 2009 MSEK 283,8

# Strong platform for growth in existing portfolio

## Business goals

1. Deliver the top line
  - 2010-2011: 8-10% p.a. in CER
  - 2012-2015: >20% p.a. in CER
2. Ensure cost base reduction
  - Deliver development pipeline opportunities at capped budget
    - tight cost control and ruthless prioritization
  - Annual cost synergies >100 MSEK with full effect 2011
3. Gradual increase of EBIT\* margin to exceed 30%



\*) Excluding PPA amortizations arising from the Transaction

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## Why rare disease focus?

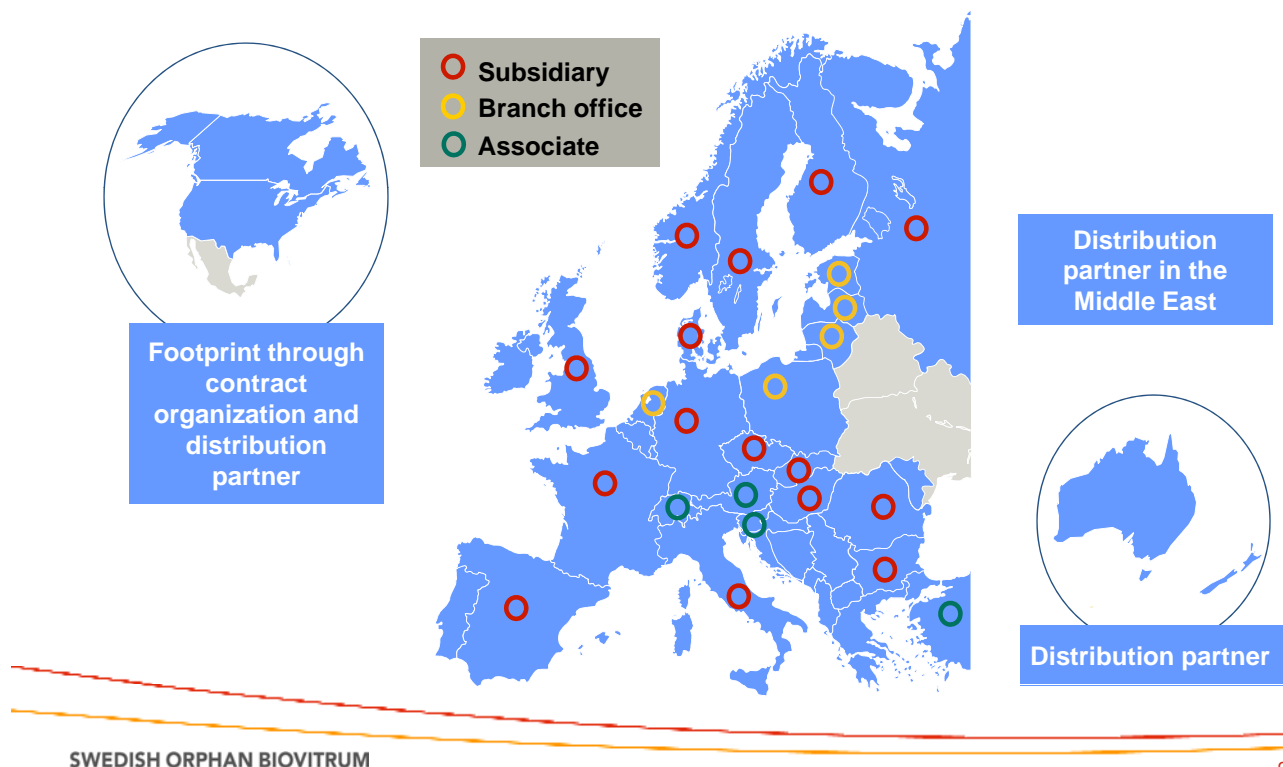
- High unmet medical needs
- Lower development risk and cost
  - Small programs
  - Science opportunities
  - Validated targets
- Favorable market access
- Premium price opportunities
- Less competition
- Orphan indications:
  - 7,000 known diseases affecting
    - 30 million people in the EU
    - 25 million people in the US
  - 400 existing therapies
  - Strong regulatory and political support



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## Strong European commercial presence



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## Products addressing needs of rare disease patients

Product	Disease indication	Commercial rights	Revenues 2009 (MSEK)
 	Hemophilia A	Nordics	617.8
	Rheumatoid arthritis	Global	440.7
ORFADIN®	Hereditary tyrosinemia type 1 (HT-1)	Global	308.5
	Oral mucositis in conjunction with chemotherapy and radiation	Global	109.9
 	Urea cycle disorders	Global	70.0
	Essential thrombocythemia	Nordics	48.9
	2nd line soft tissue sarcoma. 2nd/3rd line platinum sensitive ovarian cancer	Europe, Middle East, Russia	43.8
	Hyperphosphatemia of renal failure	Nordics	39.5
	Hypercalcemia in primary and secondary hyperparathyroidism	Nordics	26.2
Others			360,3
		<b>Total</b>	<b>2065,6</b>

# Kineret® growth opportunities

## 1. Kineret in Rheumatoid Arthritis (RA)

- Only registered IL-1 inhibitor against RA
- Significantly more efficacious than methotrexate alone
- Works well in patients failing one or more TNF $\alpha$  blockers
- Opportunity to define responder population
- Good safety profile compared to other biologicals

➤ RA re-launch Q2-Q3

## 2. Expansion into new territories

## 3. Expansion into orphan indications

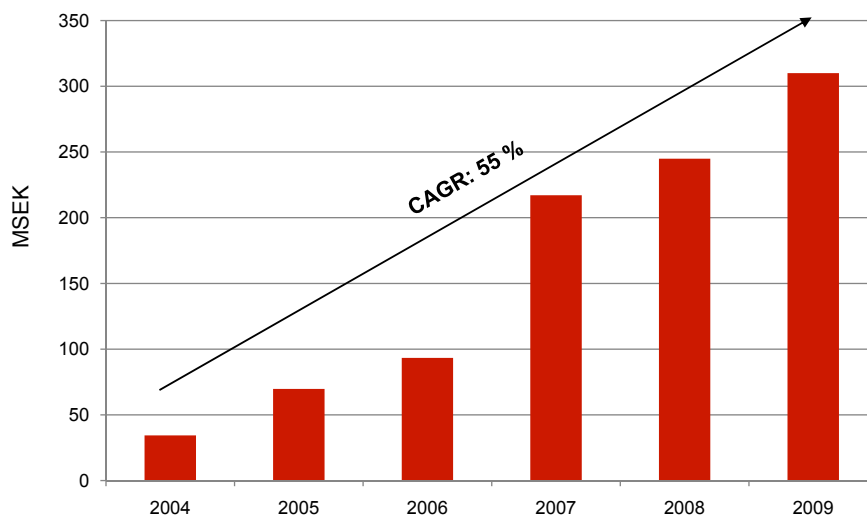
## 4. Modified anakinra



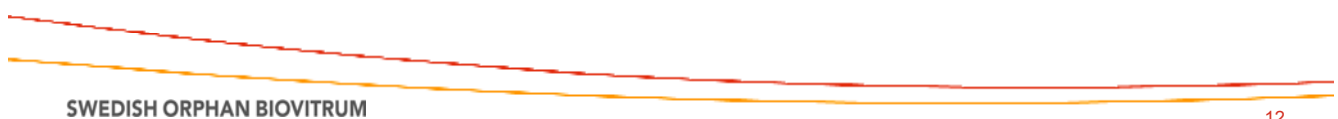
Kineret mimics endogenous IL-1Ra to help compensate for cytokine imbalance and control symptoms



# Orfadin®- impressive growth since orphan drug approval



Sales growth in 2006/07 due to take-over of product from Orphan Europe



## Orfadin®- key growth drivers

- Increased survival ⇒ Hereditary Tyrosinemia type 1 prevalence ↑
- Natural weight increase
  - Orfadin dosed in relation to bodyweight
  - Alone drives growth by 6-8% p.a.
- Improved dosing
- Improved neonatal HT-1 screening
- Further penetration in the US
  - Statistically large unmet need to be discovered by improved screening
- Expansion into new markets
  - Recently established operations in Russia and Northern Africa

Before Orfadin



After Orfadin



## Strong and low risk emerging development pipeline

Indication	Product/Project	Partner	Phase I	Phase II	Phase III	Reg phase
Hemophilia B	rFIXFc	BiogenIdec				
Fat malabsorption in premature infants	Kiobrina®					
Second line treatment of Hepatitis C	Multiferon®					
Hemophilia A	rFVIIIc	BiogenIdec				
Fat malabsorption	Exinalda®					
Rh-Immunezation	Sym001	Symphogen				
Autoimmune platelet disorder (ITP)	Sym001	Symphogen				
Oral mucositis, pediatric (1-16 years)	Kepivance®					

## Hemophilia – a franchise poised for growth

- ReFacto (hemophilia A), BeneFIX (hemophila B), Willfact (von Willebrands disease) in current product portfolio
- Long-acting fFVIII Fc for Hemophilia A in phase I/II
  - prevalence 5.4-14.5 per 100,000 males
  - ~4.7 BUSD 2010 (CAGR ~6%)
  - 2015 forecast 6 BUSD
  - Estimated peak year sales potential >1.5 BUSD
- Long-acting rFIX Fc for Hemophilia B in phase III (B-Long)
  - prevalence 0.9-3.2 per 100,000 males
  - ~1.2 BUSD 2010 (CAGR ~5.5%)
  - 2015 forecast USD ~1.5 billion
  - Estimated peak year sales potential >500 MUSD
- Increased prophylactic use a growth opportunity
  - Prophylaxis vs. on-demand reduces e.g. joint bleedings and extends life expectancy
  - Compliance improved



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## Kiobrina<sup>®</sup> phase III decision taken

- Medical need: improve lipid absorption in premature infants not receiving fresh mothers milk
- Lack of lipase for lipid uptake may lead to:
  - insufficient growth
  - Impaired cognitive function development risk
- Clinical phase II results showed significantly improved growth after 1 week treatment
- ~ 90,000 pre-term infants <1,500 grams born annually in Europe and USA
- Estimated market potential USD 400 million in Europe and USA
  - no product on the market today



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## Strong biopharmaceuticals heritage

- Sole global manufacturer of ReFacto® AF drug substance
- Manufacturing processes for 6 products developed to market
- More than 30 processes developed and manufactured for clinical phase



**xyntha**  
Antihemophilic Factor (Recombinant),  
Plasma/Albumin-Free

**ReFactoAF**  
Moroctocog alfa  
(Recombinant Coagulation Factor VIII)  
Albumin-Free Cell Culture Process

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## Outlook 2010 and long term objectives

- Operating income (EBITA) expected to increase 30-35% in CER
- Revenue growth of 8-10% in CER
- Gross profit margin expected to be between 63-65%
- Operating expenses expected to decrease by 10-12%

### Long term business target is to by 2015:

- Grow revenues to 5 BSEK
- Reach an EBITA margin of >30 %.

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