Sobi Capital Markets Seminar

Solna, November 29 , 2011



Program

Capital Markets Seminar, 29 November 2011

13.00 **Company overview and direction, incl. Current product portfolio**
Geoffrey McDonough, President and CEO

14.00 **Financial review**
Lars Sandström, CFO

Coffee

14:45 **Development pipeline – Update on Kiobrina project**
Bertold Koletzko, MD, PhD, Professor at Ludwig-Maximilians-University of Munich
An van Es-Johansson, Head of Clinical Development
Anders Edvell, Head of Marketing & Sales

15.45 **Development pipeline – Update on Hemophilia projects**
Erik Berntorp, MD, PhD, Professor, Dept of Coagulation Disorders, University Hospital, Malmö
Glenn Pierce, MD, PhD, Senior Vice President of Hemophilia, Biogen Idec
Helena Rudberg, Global Director Hemophilia and Hematology

16:30 **Summary**
approx. Geoffrey McDonough, Presient and CEO

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.

CEO Introduction

Sobi Capital Day 2011

29 November 2011



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.

All the Components of a Great Company Are Here

R + D

1. World class protein biochemistry
2. Demonstrated early stage development from proof of concept to Phase III
3. In the heart of the Karolinska Life Science community
4. Balance of new and LCM projects

Manufacturing

1. Demonstrated competence in biologics manufacturing at pilot and commercial scale
2. Biologics process development, scale up, and tech transfer (w/ R+D)
3. Network of manufacturing partnerships

Our People
Our Partnerships

Commercial Capabilities

1. Portfolio of biologics and growth-oriented products
2. Maturing European commercial footprint, emerging US presence
3. Niche commercial approach

Positioning in Health Landscape

1. Orphan drug pioneer, with legacy of patient focus and commitment
2. "Not too big, not too small – nimble partner, and preferred partner for niche/orphan drug companies"

Our Objectives

1. To achieve **positive net cash flow and profitability** in our operations.
2. To efficiently commercialize **our proprietary innovative medicines** for rare disease patients globally.

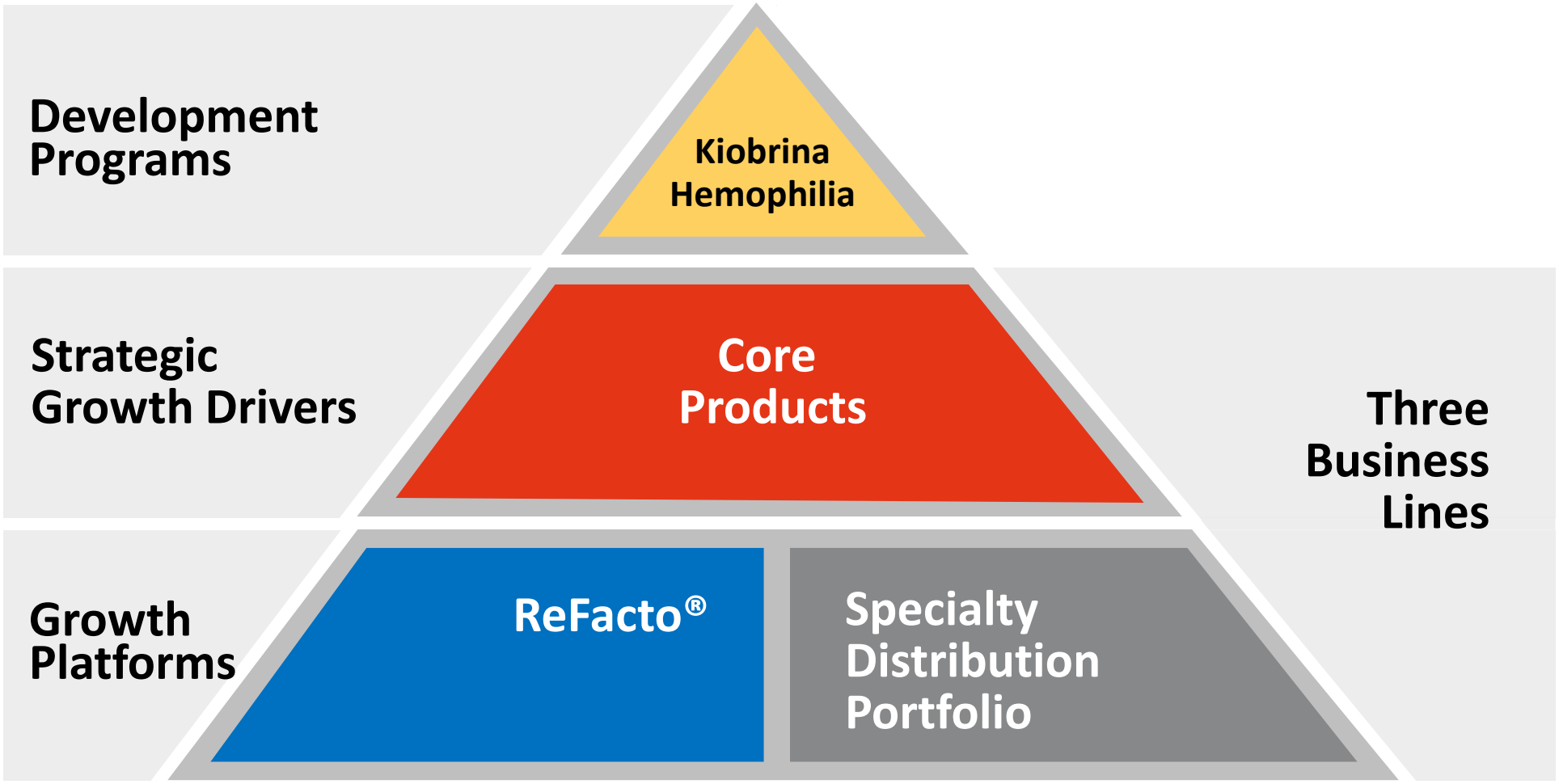
Actions to Reach Our Goals

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

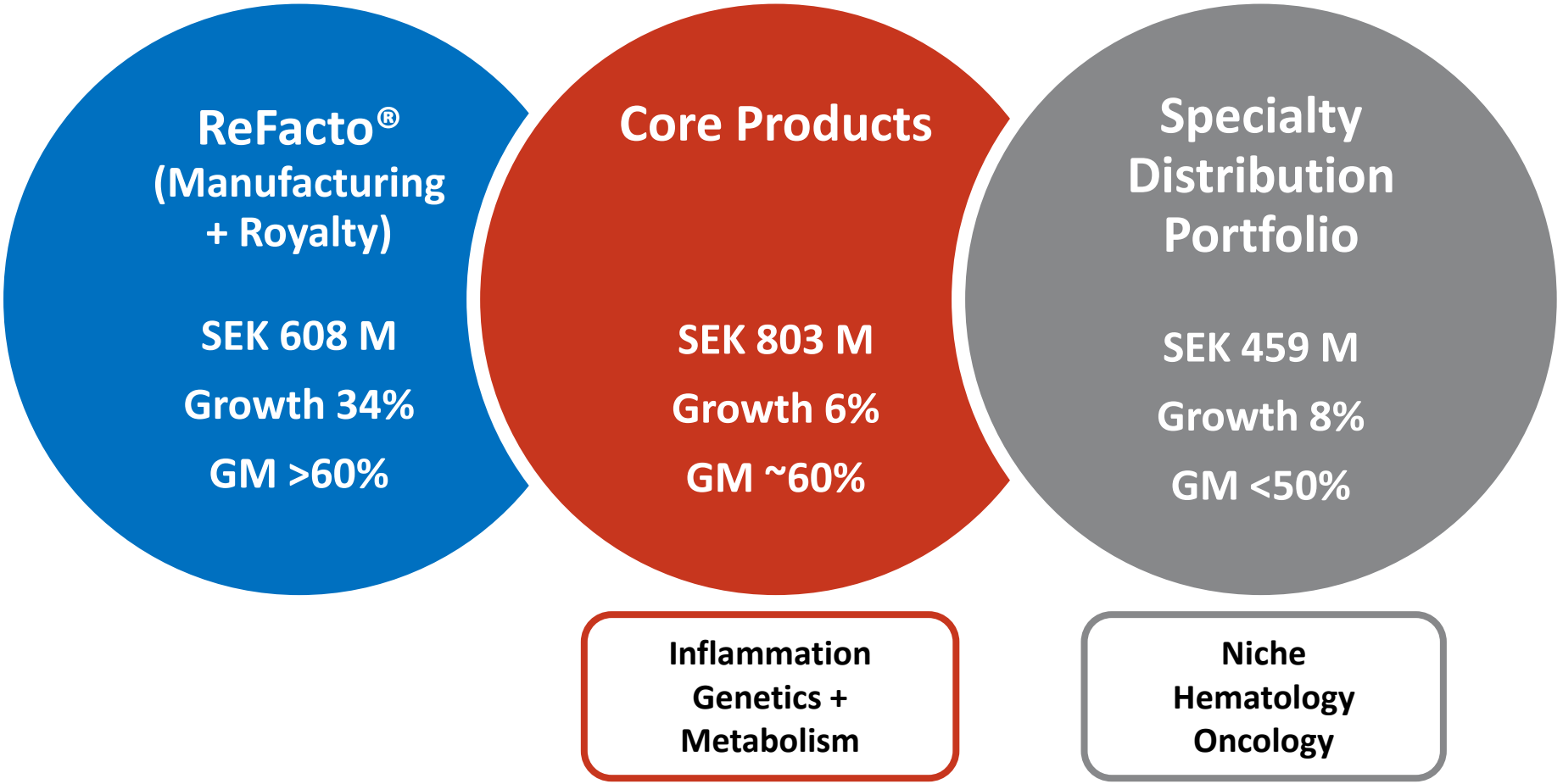
1. Revenue growth through focus on key products
2. Ongoing cost discipline
3. Gross Margin improvement

➔ Positive cash flow from operations and working capital

Focus the Business on Strategic Building Blocks

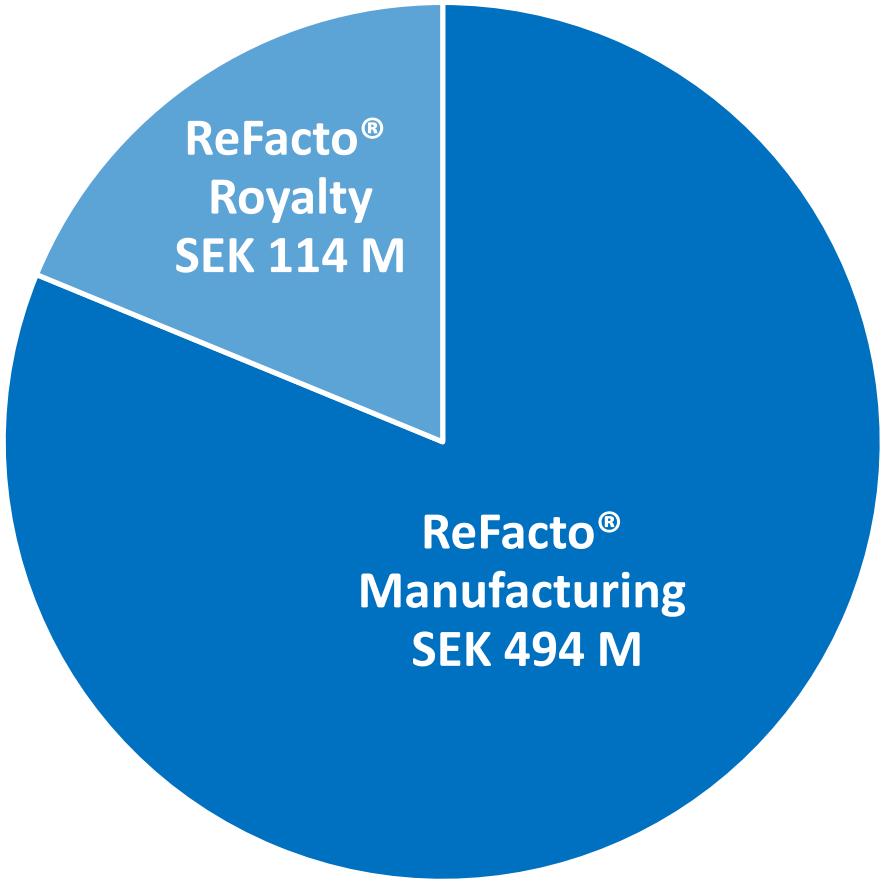


Aligning Resources in Three Business Lines



Note: 4 quarters rolling numbers, excl. discontinued products.
Sales growth September YTD at constant exchange rates.

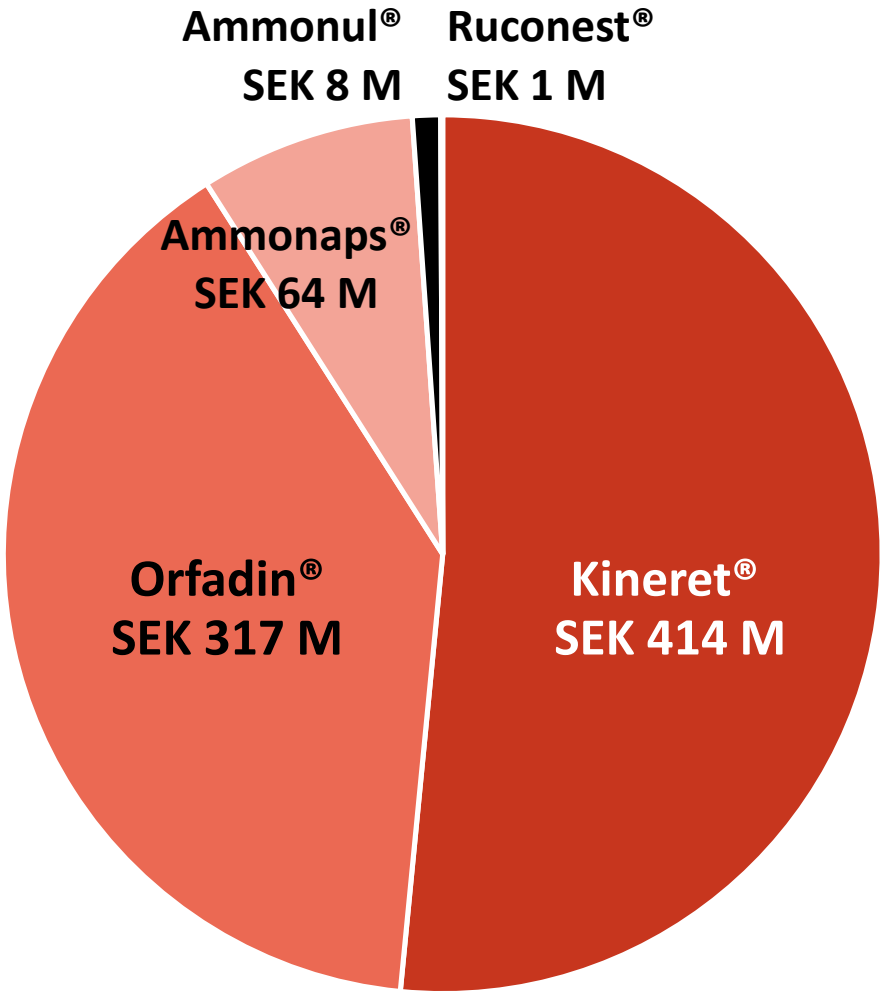
ReFacto® – A Durable Platform



- Partnership with Pfizer
  - Global sales 2010: USD 404 M
  - Pfizer expanding in established and emerging markets
- As the exclusive supplier, we have:
  - Made ReFacto® 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

Note: 4 quarters rolling sales numbers, excludes co-promotion

Core Products – Proprietary Strategic Growth Drivers



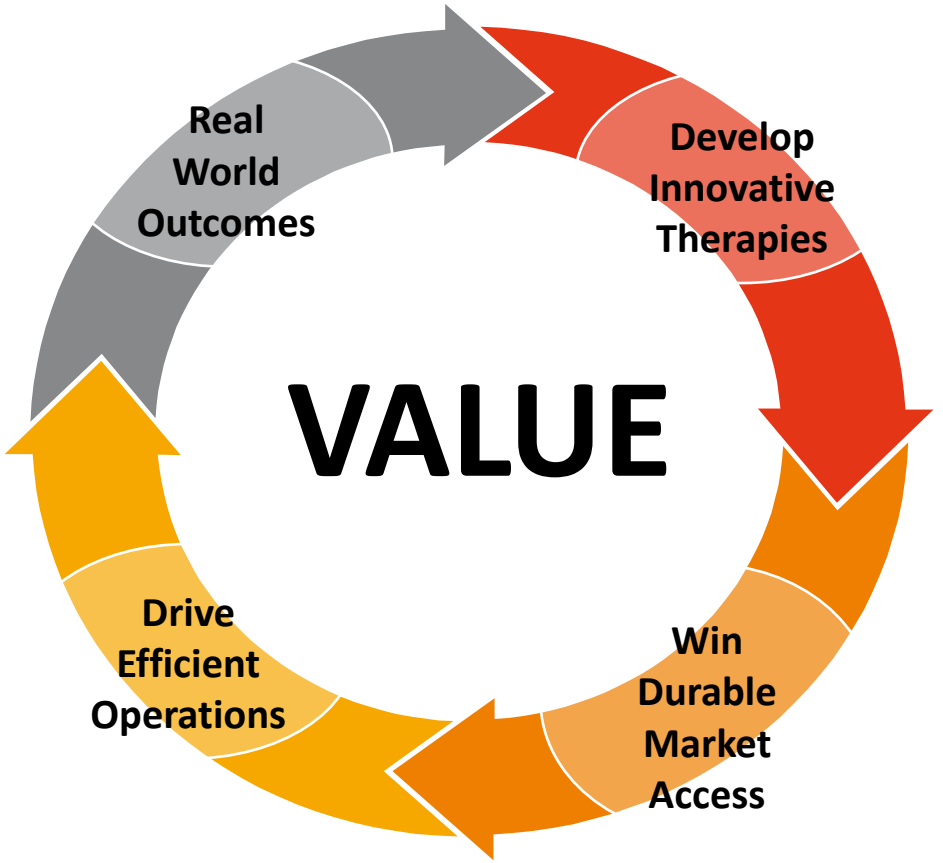
Note: 4 quarters rolling sales numbers

1. Therapeutic Areas
   - Genetics + Metabolism
   - Inflammation
2. Focus for Growth
   - Room to expand in existing markets
   - Additional key markets reachable by us (US, Russia, Middle East)
3. Fits our Commercial Model

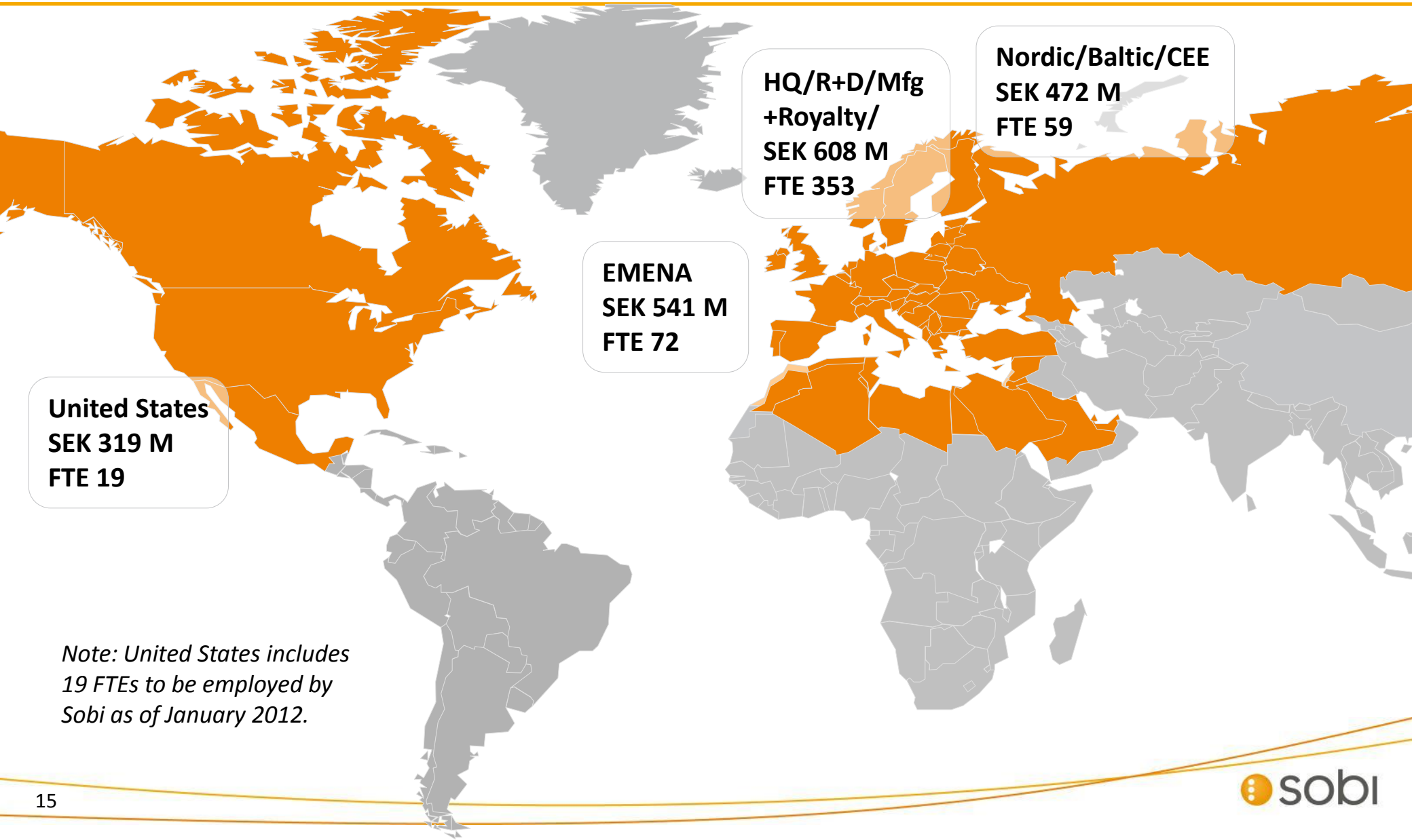
How We Deliver Value to Customers and Partners

- Price pressure will continue

1. Market Access is a continuous process throughout lifecycle
2. Centers of Excellence
3. Integrated value offering
   - Commercial focus Key Account Management
   - Medical focus on patient health outcomes



Infrastructure in Majority of Global Innovative Markets



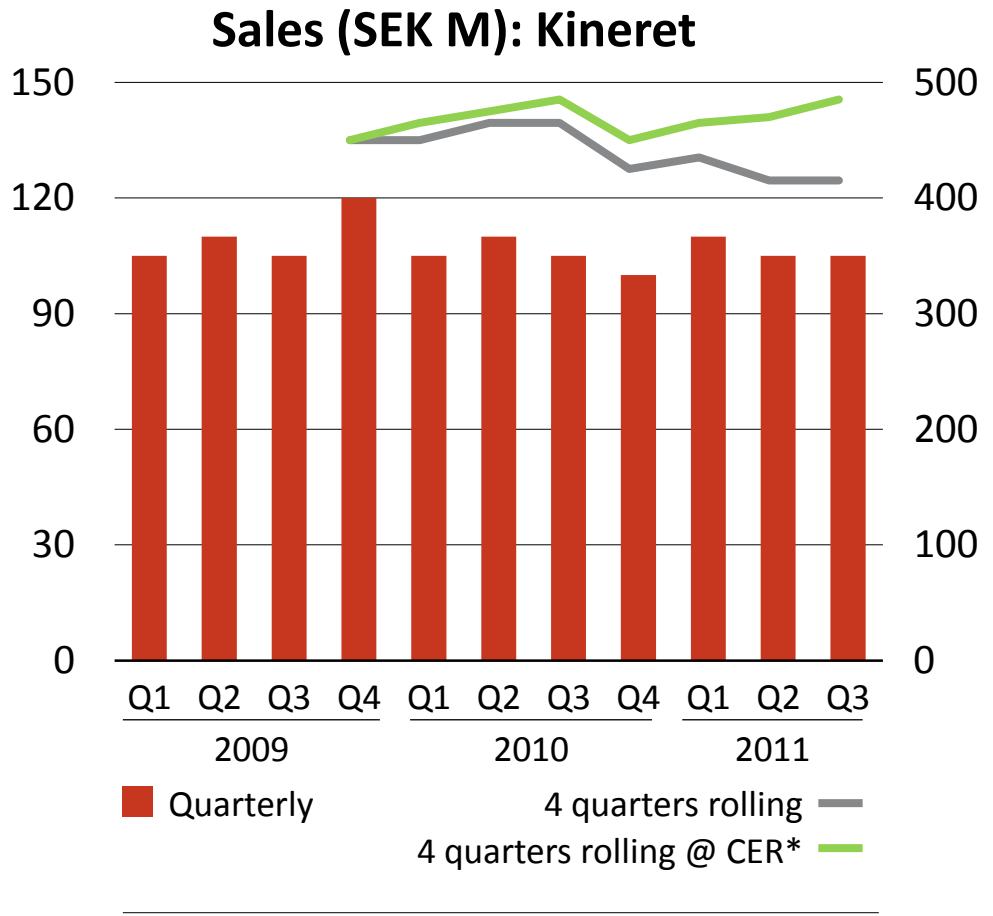
Note: United States includes 19 FTEs to be employed by Sobi as of January 2012.

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

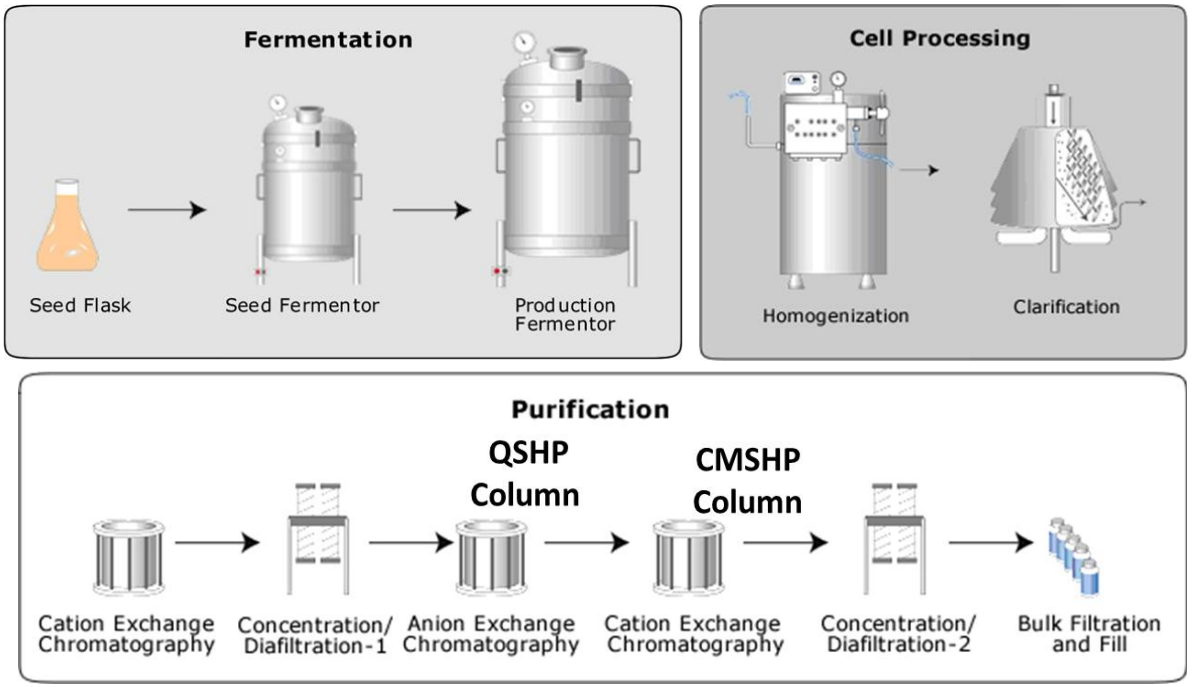
- Treated with biologics: 820 000
- Eligible Kineret patients: 200 000
- Current Kineret market share: 0.5%



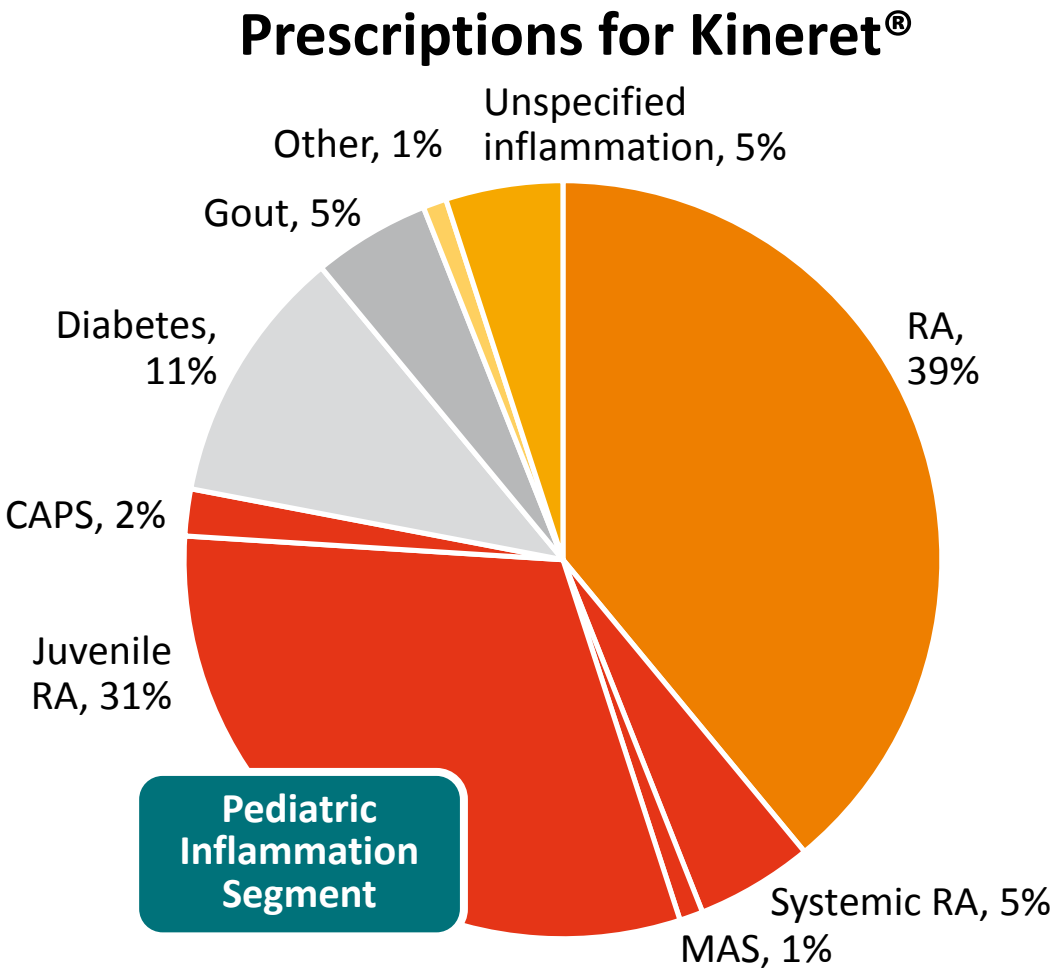
* *4 quarters rolling using average exchange rates for 2009 as base.*

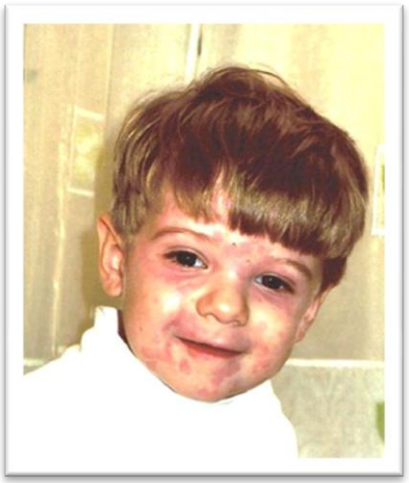
Key Success Factor: Kineret® Tech Transfer Delivery

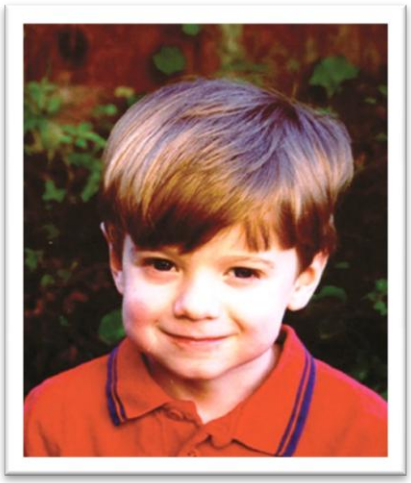
- Sobi is transferring manufacturing for Kineret® to a CMO in Europe
- Sobi purchased 500M SEK in Kineret® inventory from Amgen 2010 to support tech transfer
- The tech transfer has costs in 2011
  - Ordinary cost of TT
  - Cost of delay in TT
  - Validation Batch Write Down
- Process Validation runs to be completed in Q1 2012
- We have retained a back-up supplier for Kineret®



Kineret® – Strong Interest in Broader Inflammation





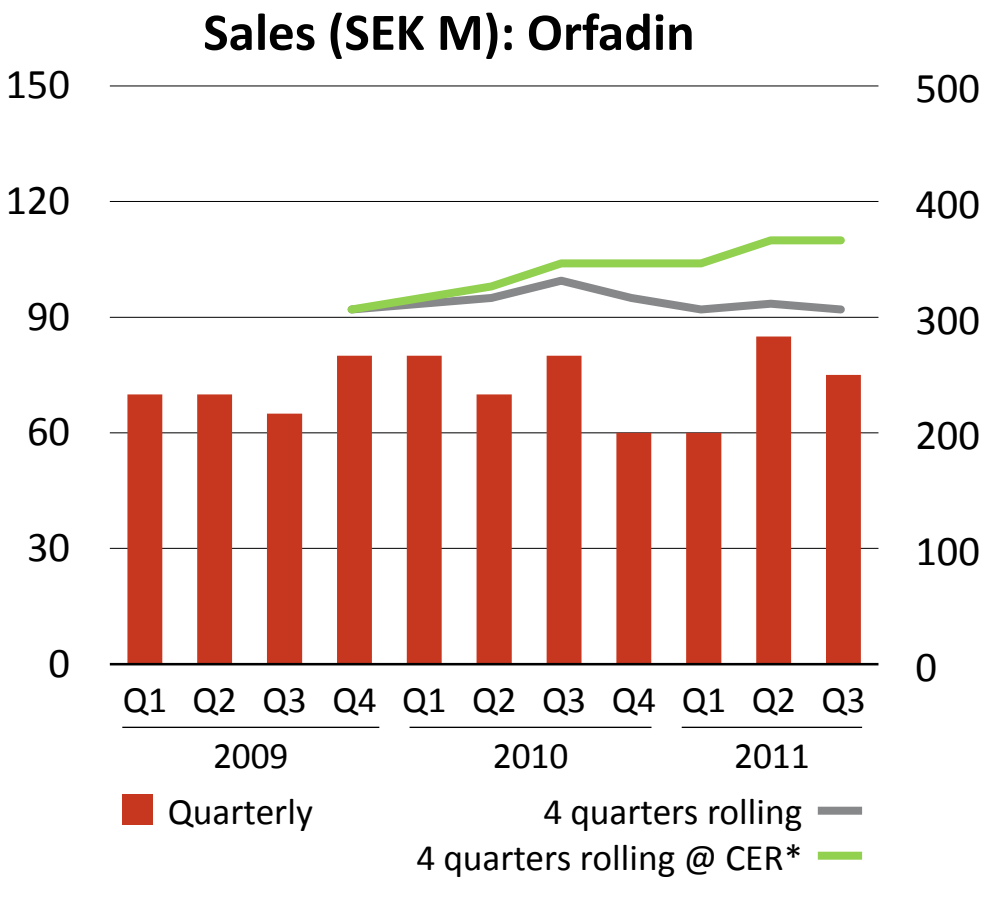


Pediatric Inflammation

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

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

Orfadin® – Understanding the Growth Drivers

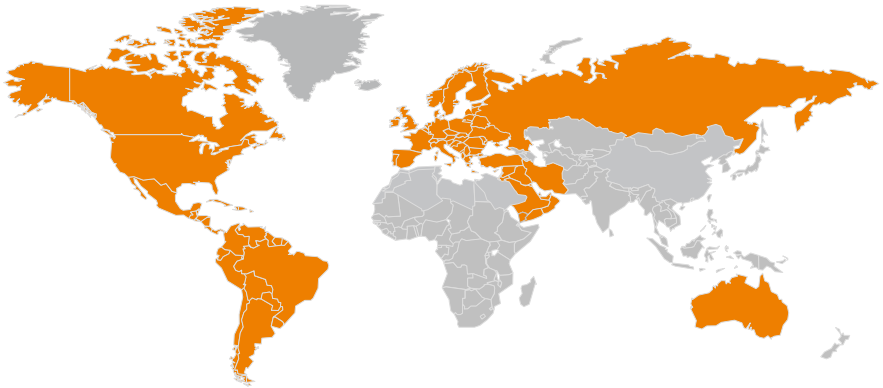


* *4 quarters rolling using average exchange rates for 2009 as base.*

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

Orfadin® – Russia and MENA Key Growth Markets

Estimated patients treated with Orfadin®: 850



RDT	Sobi
Canada: 80	Europe: 480
USA: 150	Middle East: 50
South America: 34	Israel: 20
	Australia: 10
	Rest of the world: 26

30%

56%

13%

Russia

- Orfadin® included in new orphan legislation
- Sobi affiliate in place
- 7 patients identified
- 15–20 newborns/yr

Middle East + North Africa

- Sobi to establish direct presence
- High incidence of genetic disease
- Skilled reference centers
- 30–35 newborns/yr

Orfadin® – Active Life Cycle Management

Liquid Formulation

- Drug Candidate available
- Manufacturing scale-up underway

EMA

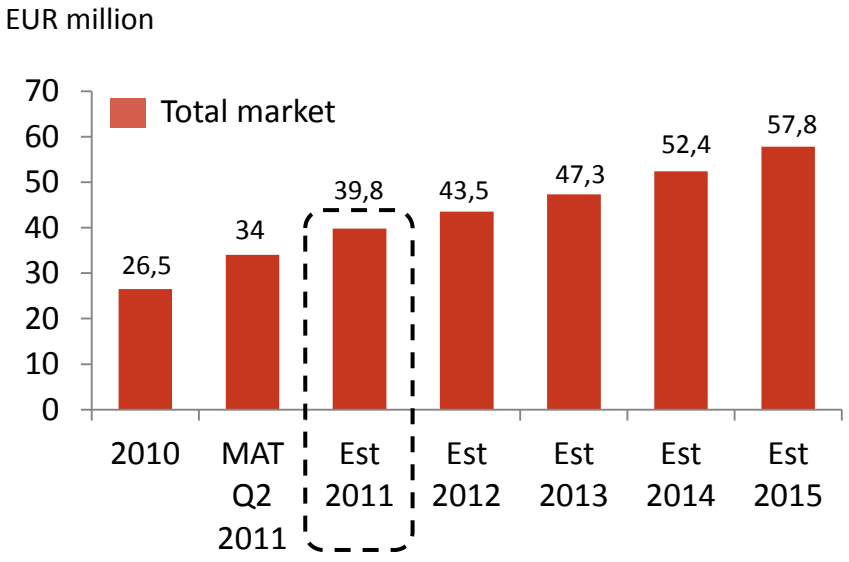
- Pediatric Investigation Plan submitted May 2011
- Approval could come in 2012
- May extend orphan status in Europe until 2017

FDA

- Discussion with FDA in 2012

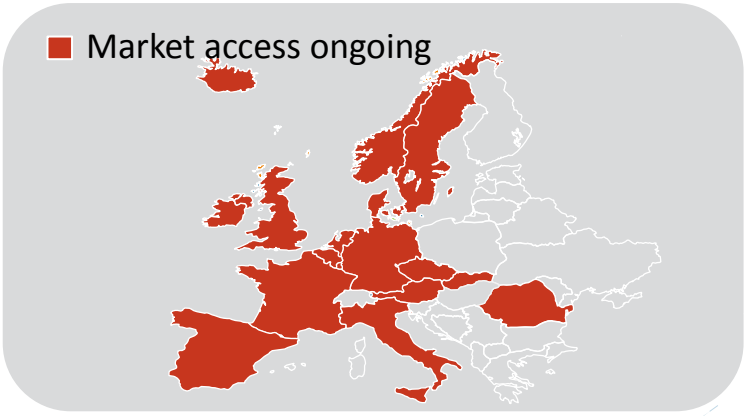
Ruconest™: Potential in Growing HAE Market

Total HAE market: Actual 2010 and expected growth rate 2011-2015 (EUR million)

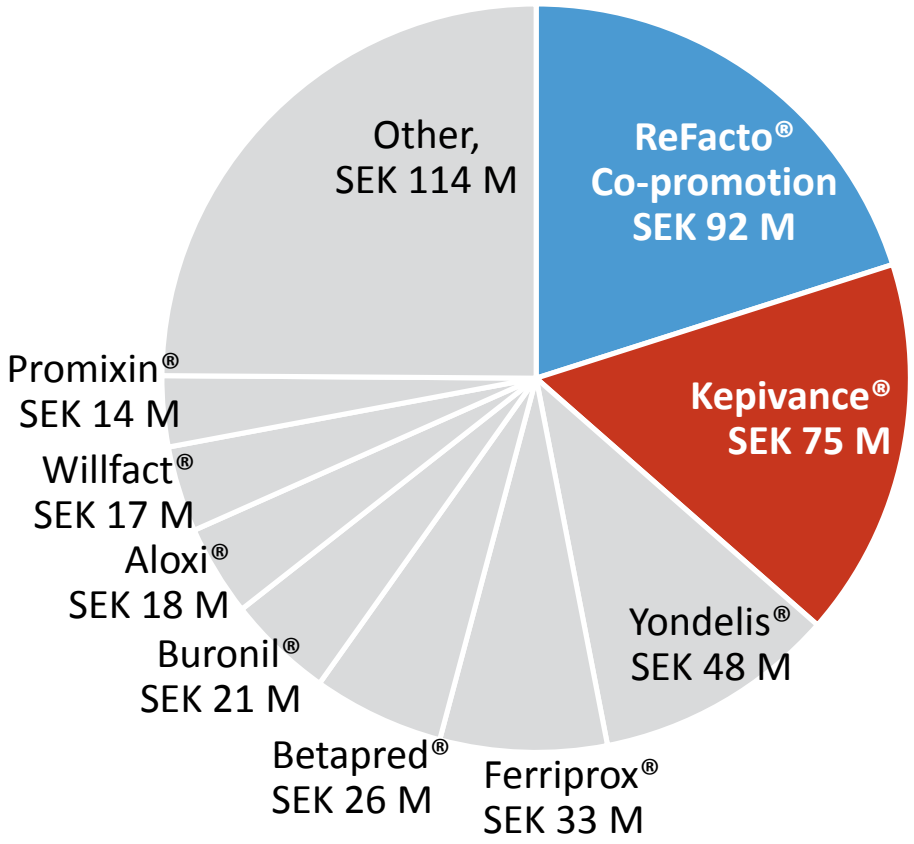


Source: IMS Health (2010 MAT 201 Q2), EU, Switzerland, Luxemburg and Norway

- First and only recombinant replacement therapy for hereditary angioedema (HAE) patients
- Best in class efficiency:
  - High response rate
  - No relapses

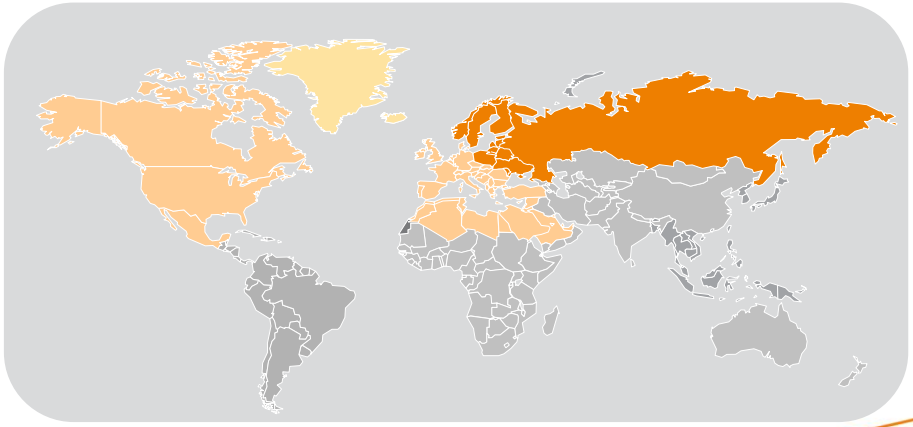


Specialty Distribution Products – Regional Leadership + Diversified Growth



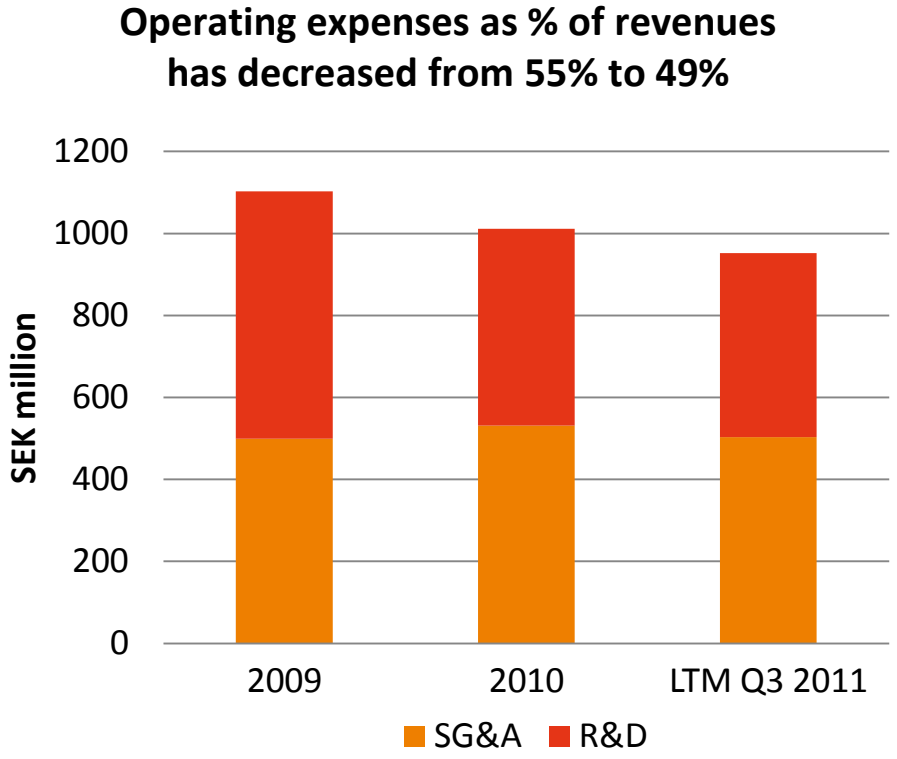
Note: 4 quarters rolling sales numbers, excluding discontinued products

1. Building on strong leadership position from Swedish Orphan International
2. Specialty Hematology/Oncology Portfolio
3. Create focus on the right deals
   1. Therapeutic Area overlap
   2. Strong contribution
   3. Regional leverage

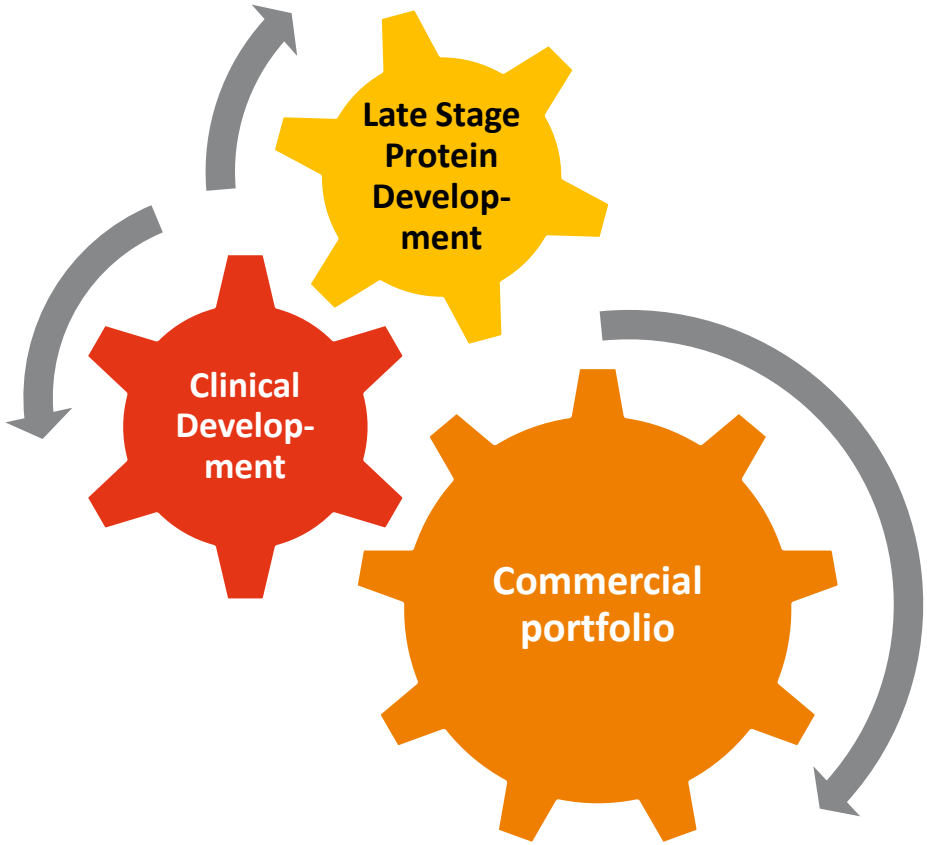


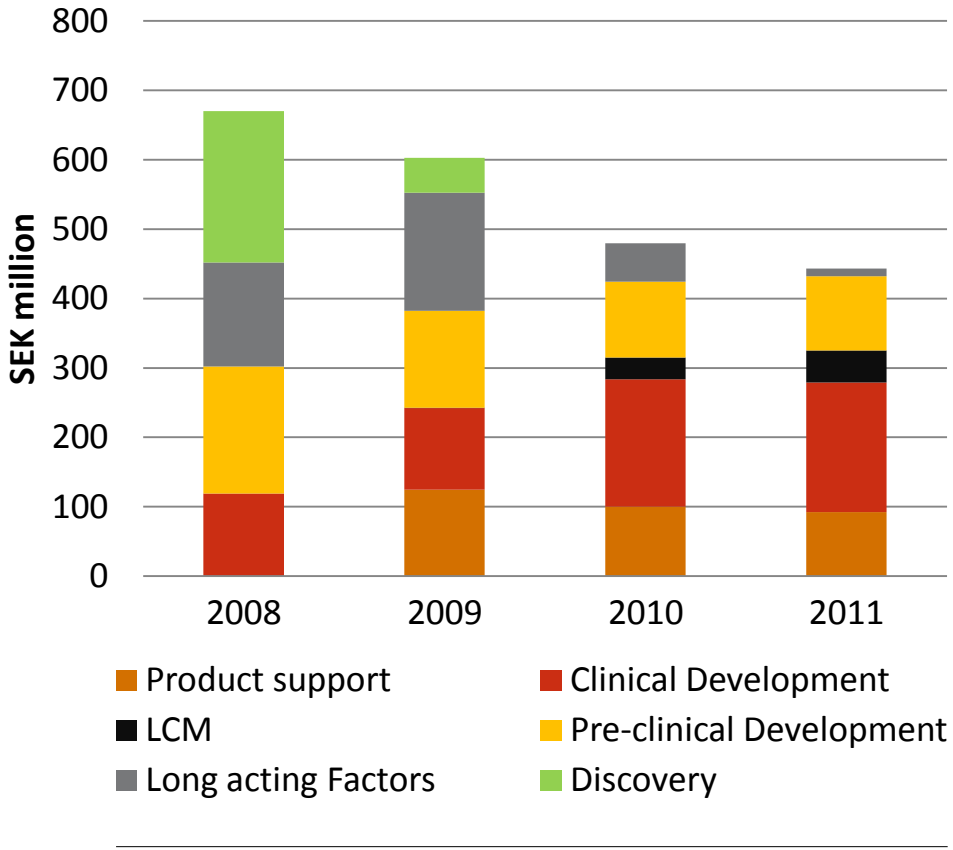
Continued Focus on Cost Discipline

1. HQ personnel reduced by 40 FTEs in 2010
2. R&D restructuring 60 FTEs by year end 2011
3. Two buildings to be closed in Q1 2012
4. Transition to higher proportion of spending to support commercial effort



Increasing Leverage of R+D for Late Stage + Commercial



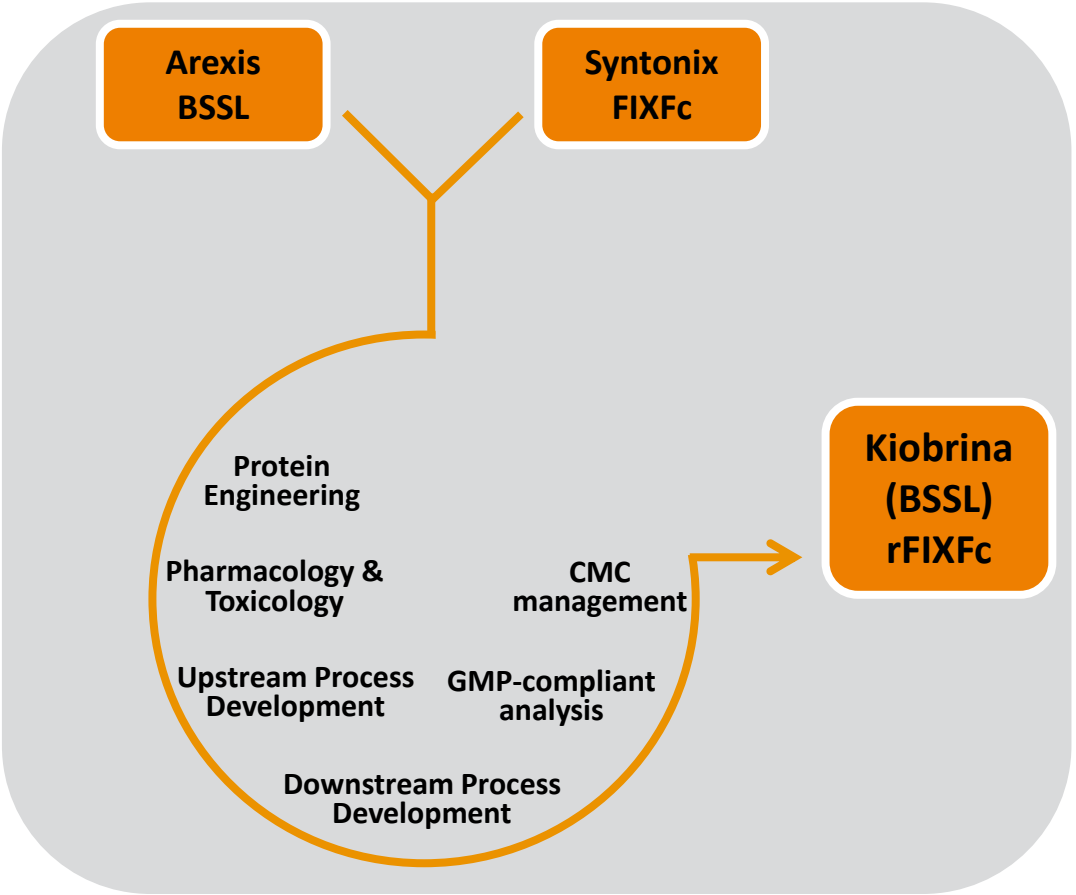


Note: 2008 only Biovitrum pre acquisition of Kineret® and Kepivance®

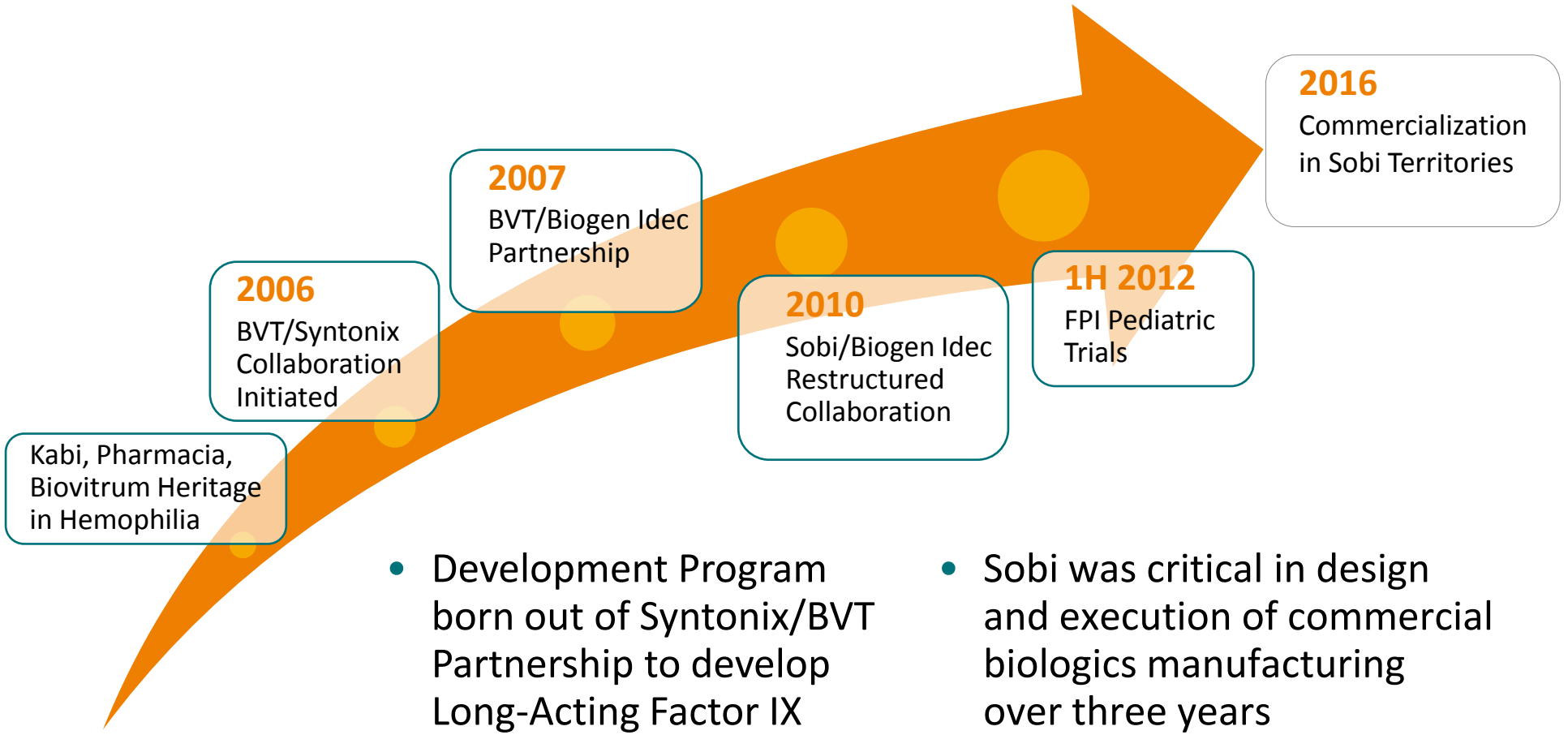
Sobi has Retained Strategic Development Capabilities

Value creation for innovative biologics therapies through:

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



Hemophilia: Demonstrates Potential of Biologics Expertise

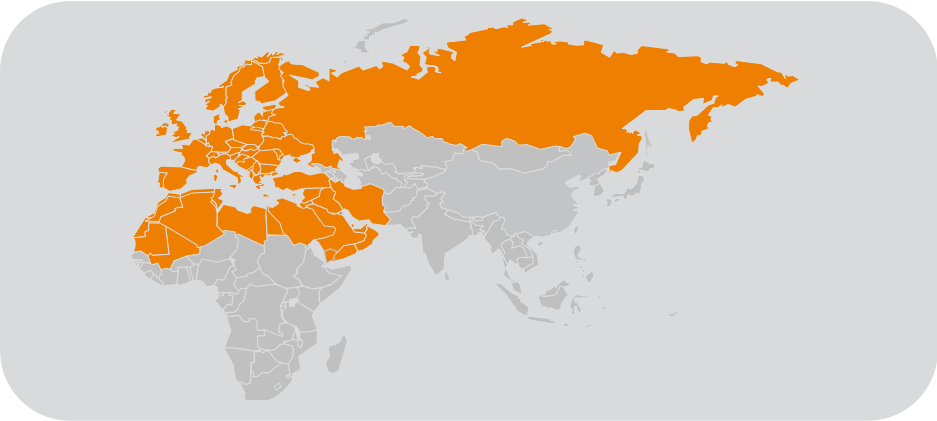


- Development Program born out of Syntonix/BVT Partnership to develop Long-Acting Factor IX
- Sobi was critical in design and execution of commercial biologics manufacturing over three years

BVT: Biovitrum

Strong Alignment with Biogen Idec to Deliver Value

- Potential to deliver the first long-acting factors to the global market
- Hemophilia market USD 3.4B in Sobi territory
- Market Development underway to support commercialization in our territories



Sobi repays Sobi share of development costs:

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

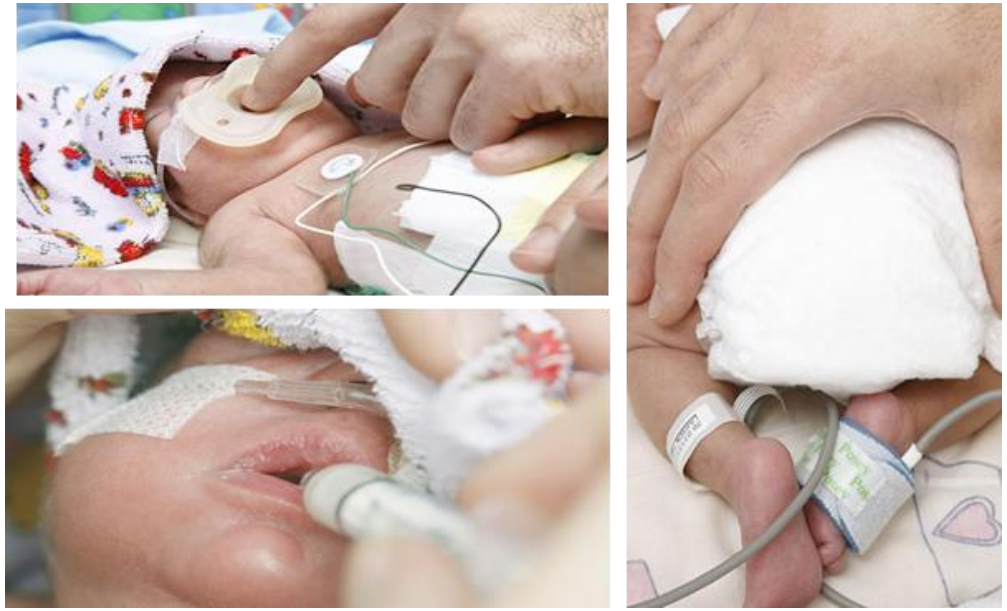
Kiobrina – Neonatal Enzyme Replacement for Prematurity

Pioneers in neonatology

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

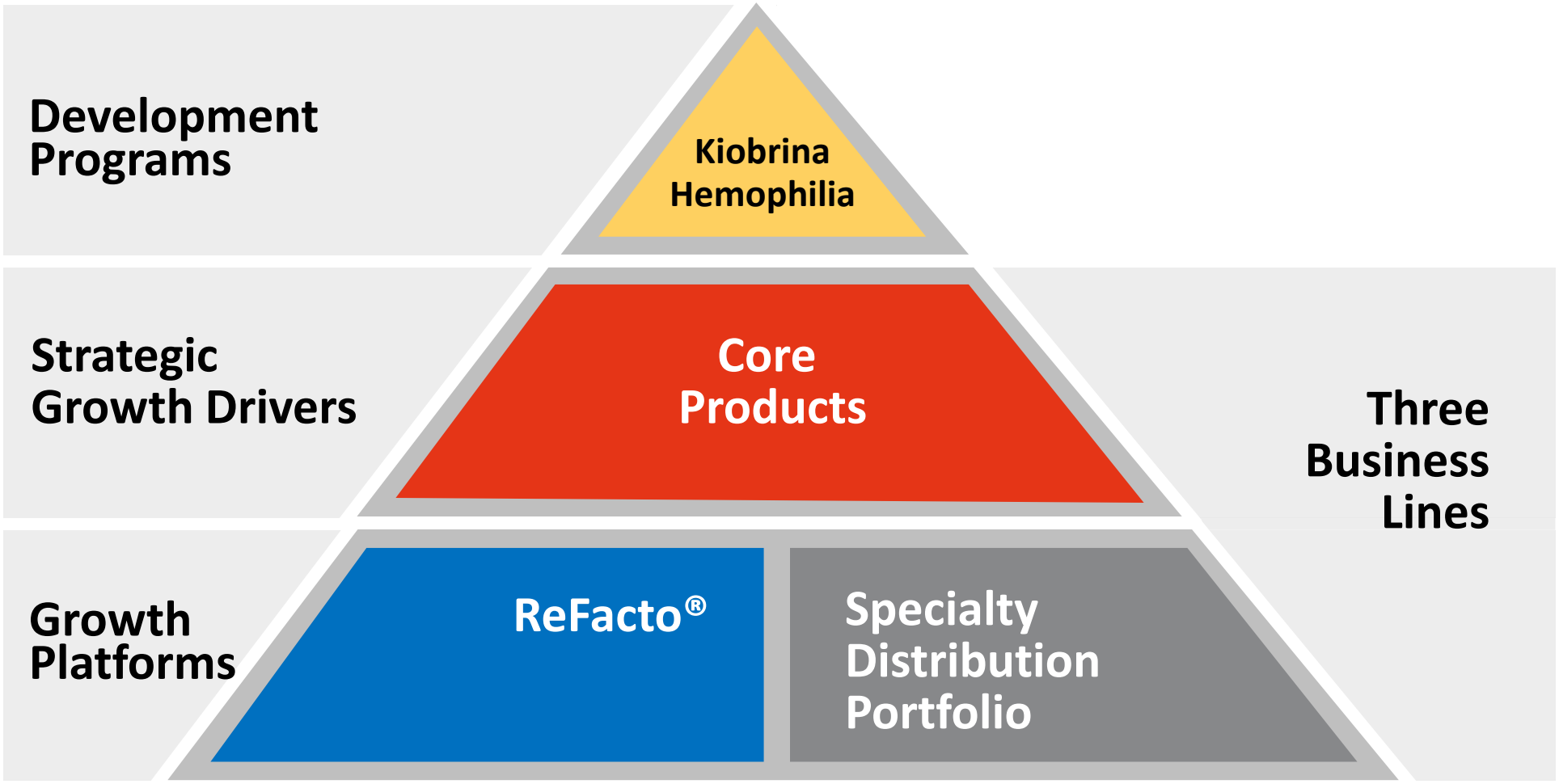
Neonatology is attractive

- Low competition
- Able to support innovation
- Reachable audience

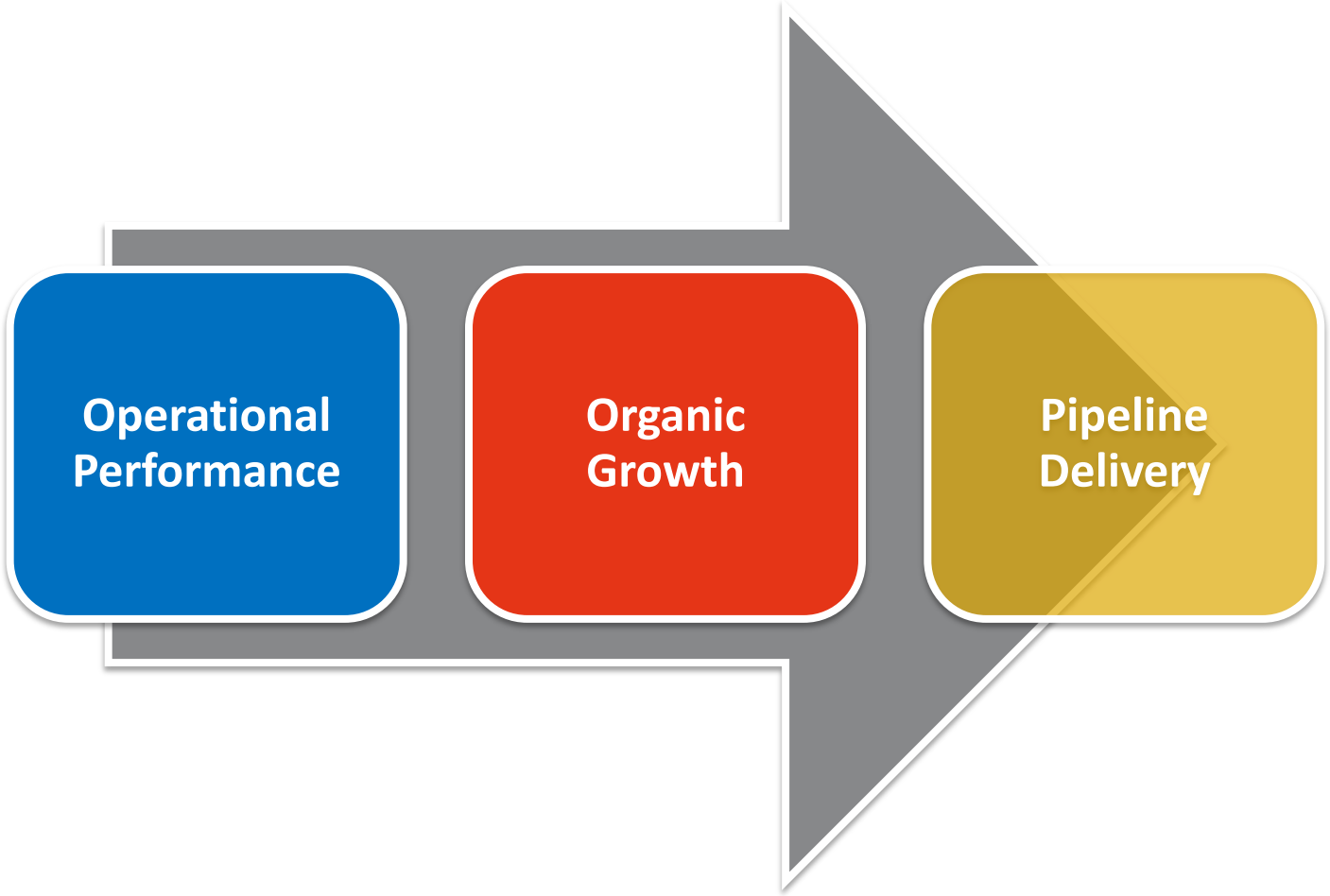


Sobi can bring Kiobrina to 100,000 patients based on EMA filing

Putting It All Together



Focus on Delivery



Summary

1. To achieve **positive net cash flow and profitability** in our operations.

2. To efficiently commercialize **our proprietary innovative medicines** for rare disease patients globally.

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Pioneer & Partner in Rare Diseases

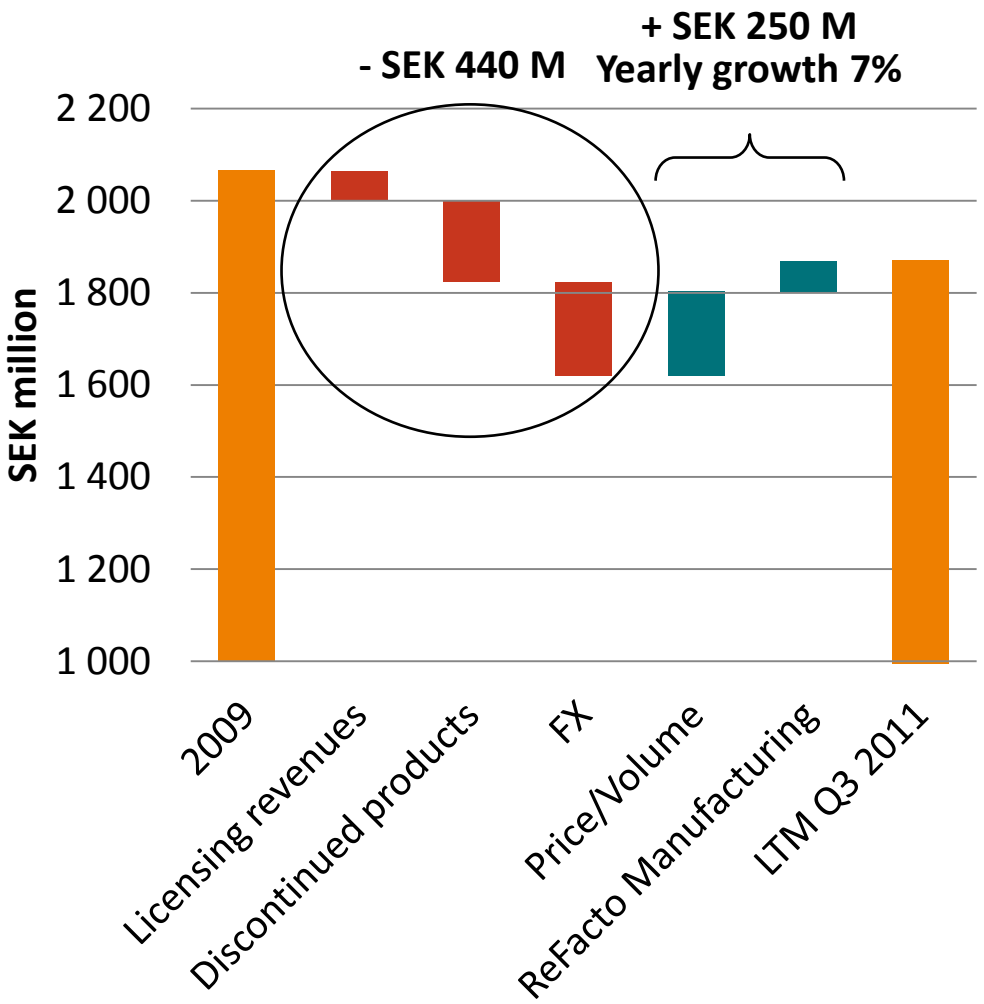
Capital Markets Day – Financials

Lars Sandström CFO

29 November 2011

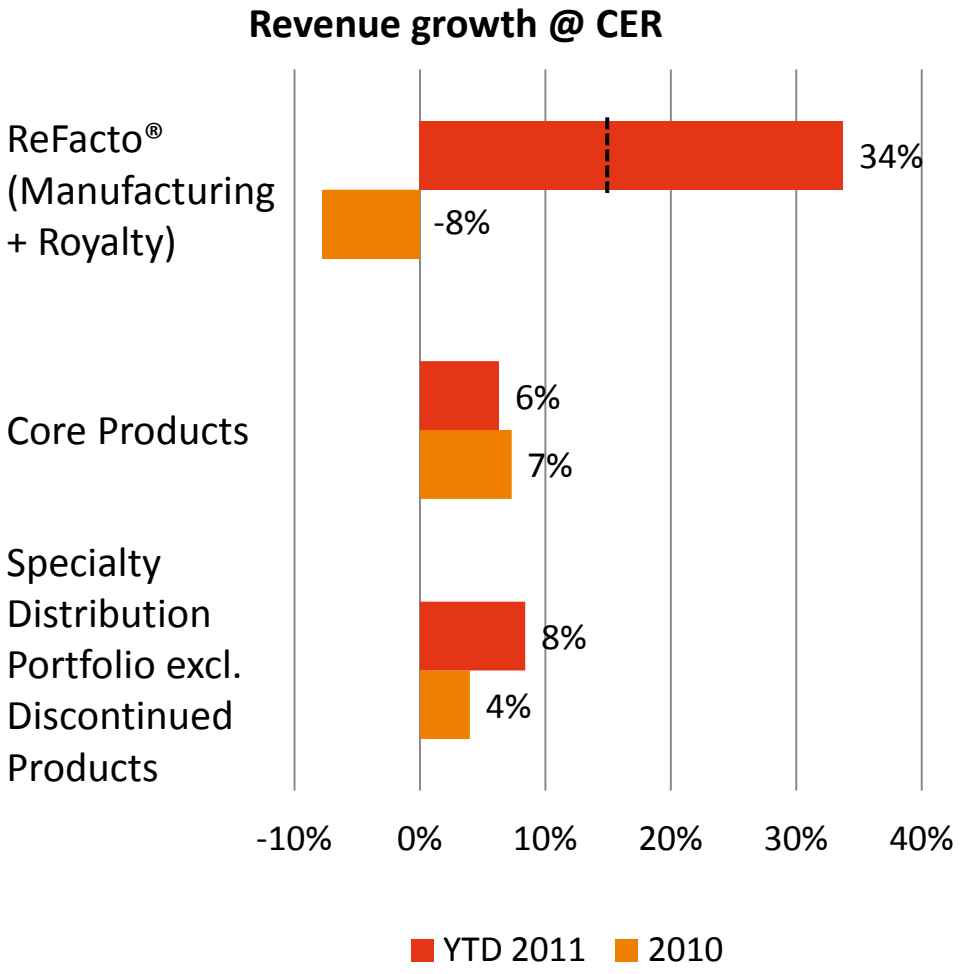


Underlying Business Growing 7%



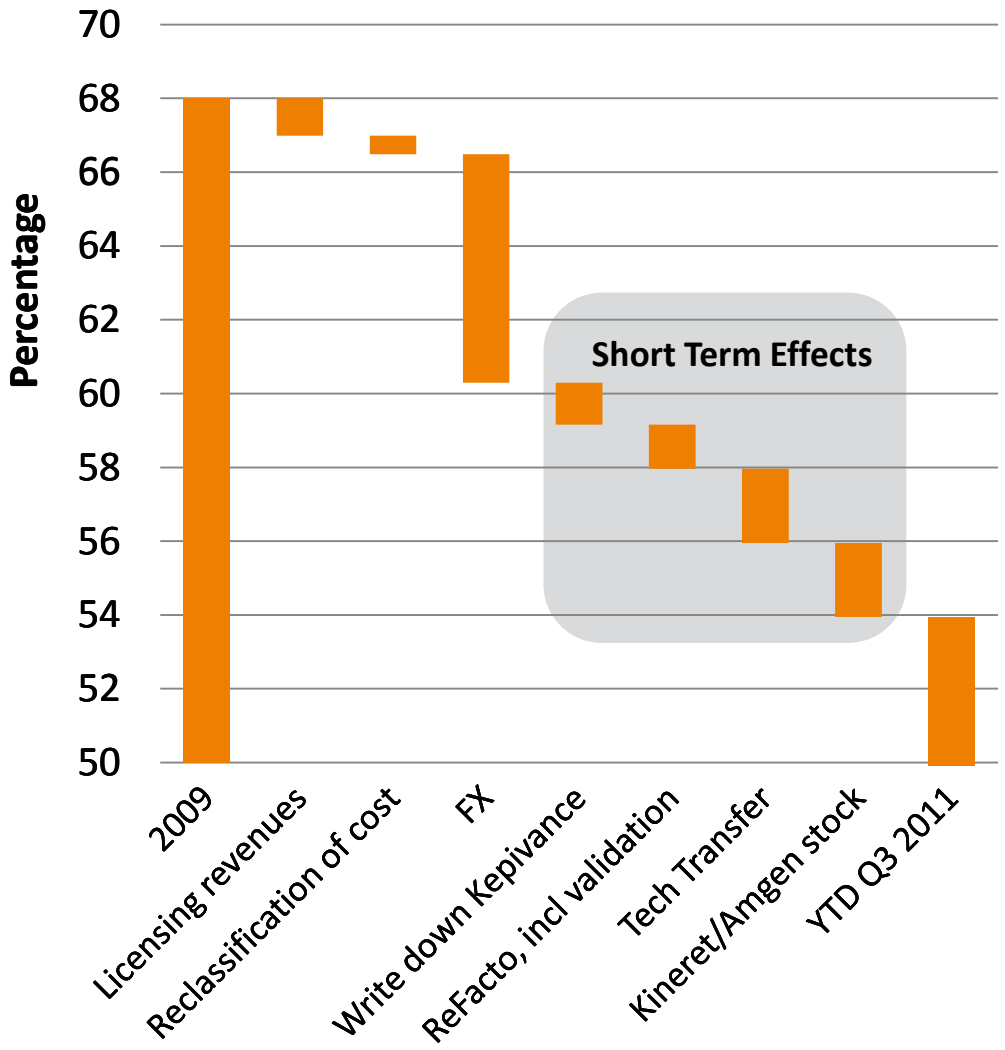
- Currency headwind , discontinued products and licensing revenues have decreased revenues with approx. SEK 440 M
- Organic revenue growth have increased revenues with more than SEK 250 M implying a growth of 7% per year
- Validation batches for scale-up, SEK 40 M

All segments showed growth 2010 and 2011



- ReFacto 2011 is **exceptional**
  - Validation batches for scale-up (SEK 40 M)
  - Inventory build-up to support dual chamber syringe for Pfizer
- Strong sales efforts have increased sales for Kineret®
- Emerging markets contributing to growth for Orfadin®
- Ammonaps® negatively effected by supply disturbance in 2011, now solved
- Effect of restricted label on Kepivance® more than offset by underlying growth in portfolio

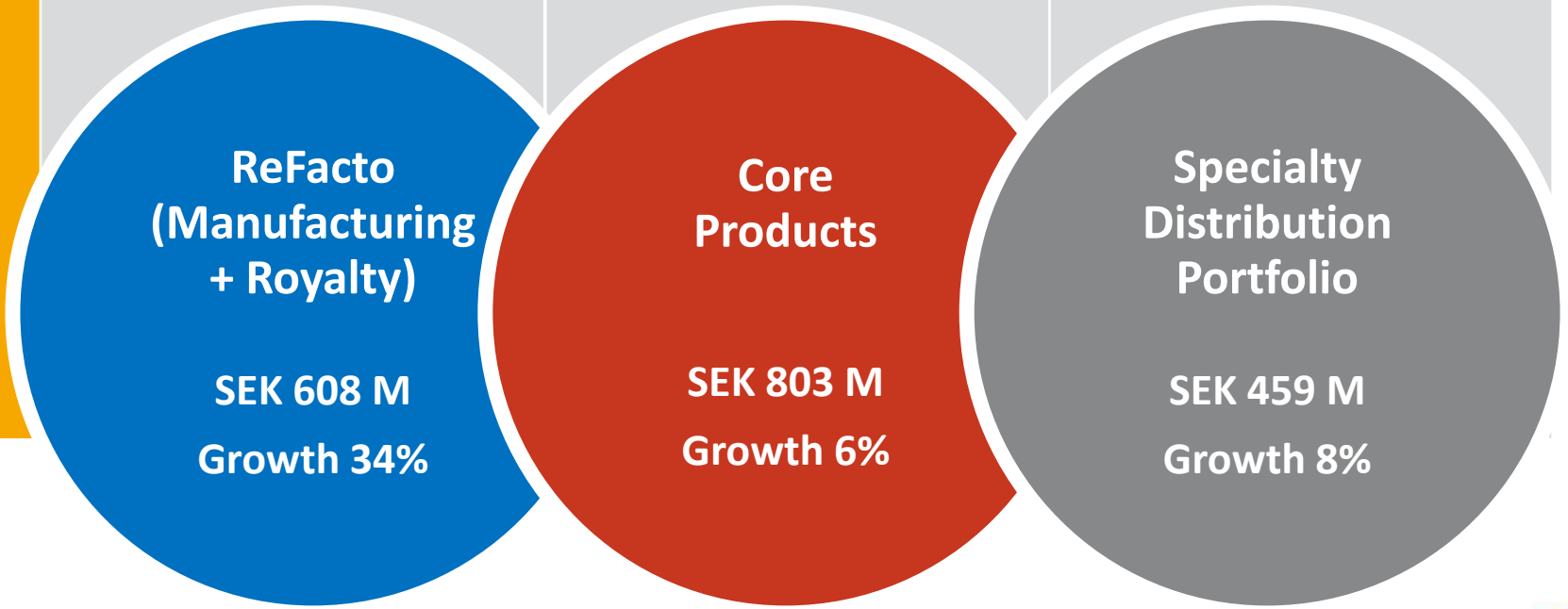
Gross Margin Impacted by Currency and Non-recurring Items



- Currency impact 6 percentage points
- Tech Transfer costs and higher supply cost from Amgen for Kineret® impact with 4 percentage points
- In 2011 the average price for ReFacto® Manufacturing has been lower than current agreement due to delivery of validation batches

Drivers of Growth and Profitability by Segment

Revenues	Strong underlying growth as Pfizer focus on emerging markets.	Geographical expansion and life cycle management contributing to growth.	Growth from launch products and addition of new products.
Gross margin	Leverage effect of larger volumes.	New CMO for Kineret®, reduce margins short term, improve margins long term.	Continuous efficiency improvement in distribution costs.



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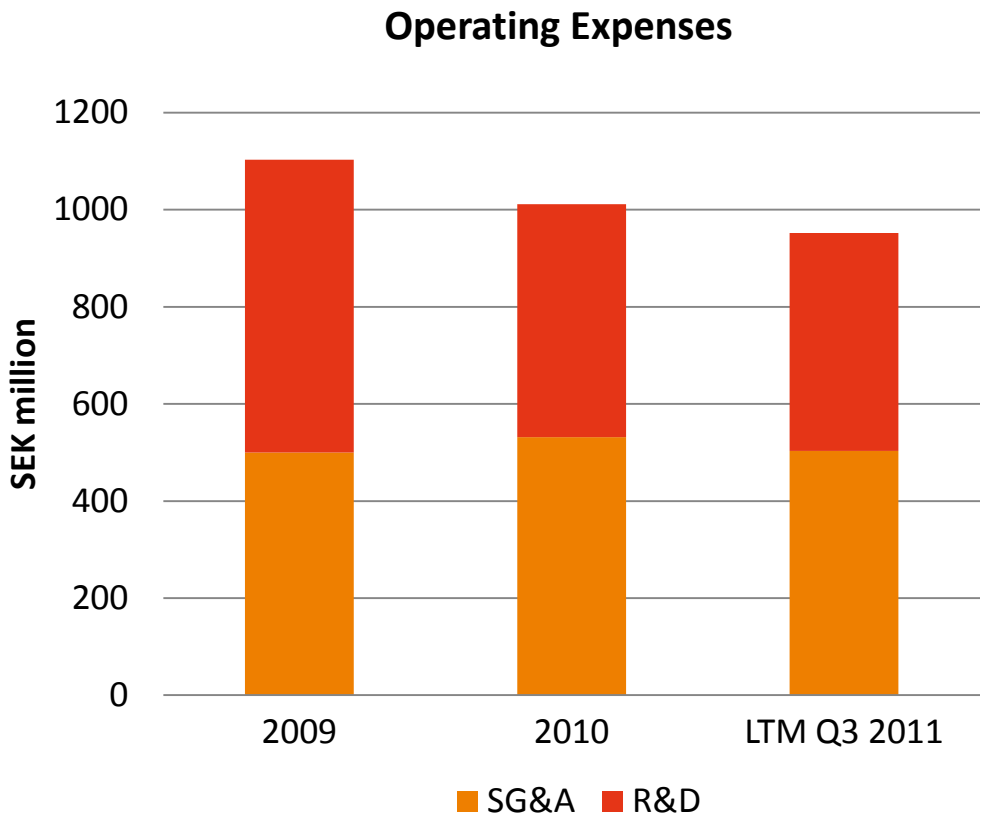
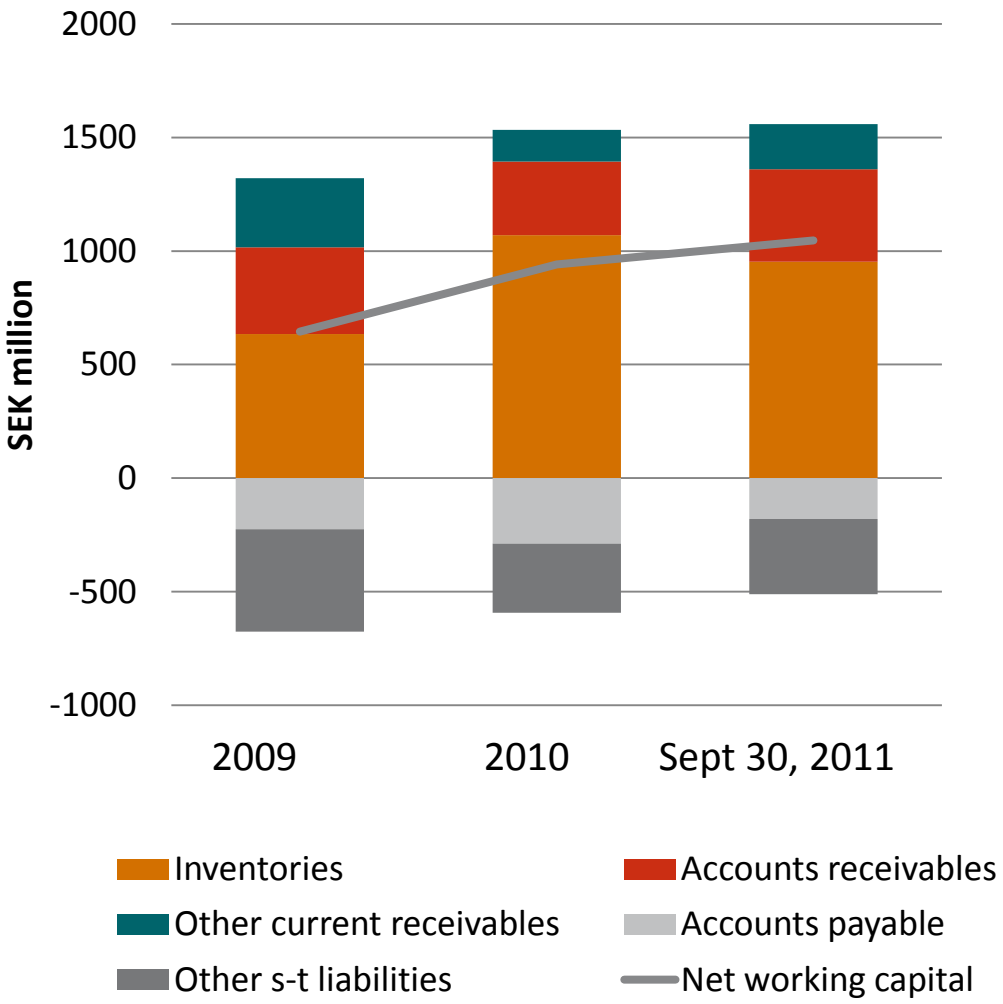
Sales growth September YTD at constant exchange rates.

Spending Control and Leveraging Infrastructure



- Synergies SEK 100 M from Biovitrum/Swedish Orphan International merger
  - Investments in Marketing & Sales organization have off-set savings in Administration
- Restructuring 2011 with full effect as of 2012
- Focus on late stage development and de-risking of R&D portfolio
- Operating expenses as % of revenues has decreased from 55% to 49%

Factors Influencing Working Capital



- The build up of inventory is mainly due to the supply of Kineret® in 2010
- Increase in 2011 of receivables related to ReFacto®

Balance Sheet Write Downs Q4-11, Limited Cash Flow Effects

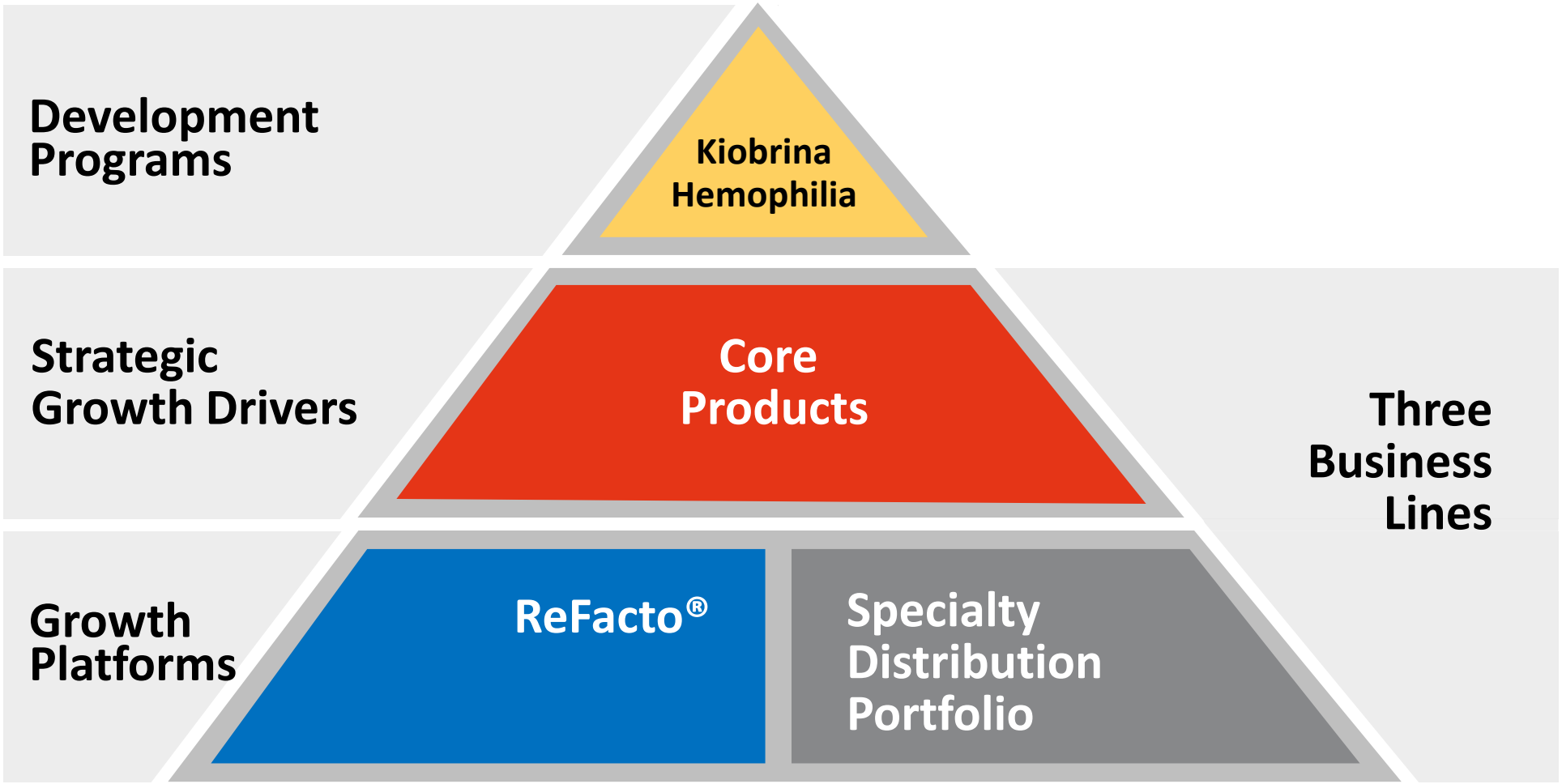
Asset	Product	Amount	Comments
Inventory	Kineret®	SEK 70-80 M	Re-valuation of validation batches of Kineret® from tech transfer in order to value inventory at commercial value
	Kepivance®	SEK 30 M	Reduced, but stabilized revenue, requires write-down of inventory bought in 2008
Trade receivables		SEK 20 M	Write-down of overdue receivables
Intangibles		SEK 130 M	Write-down of Leptin modulation program, out licensed to AstraZeneca, due to reduced probability of commercial success
Real estate		SEK 50-60 M	Valuation of liability related to previous premises. (Will be paid over 13 yrs). Write-down of assets related to new premises
Total		**SEK 300-320 M**	

Summary

- Underlying growth in all business lines
- Short term effects impacting margin during the year
- Continued operating discipline

→ Focus on positive cash flow and profitability

Q + A


Development Programs
Kiobrina Hemophilia
Strategic Growth Drivers
Core Products
Growth Platforms
ReFacto®
Specialty Distribution Portfolio
Three Business Lines

Kiobrina

Sobi Capital Seminar, 2011



We provide valuable medicines to patients with rare diseases

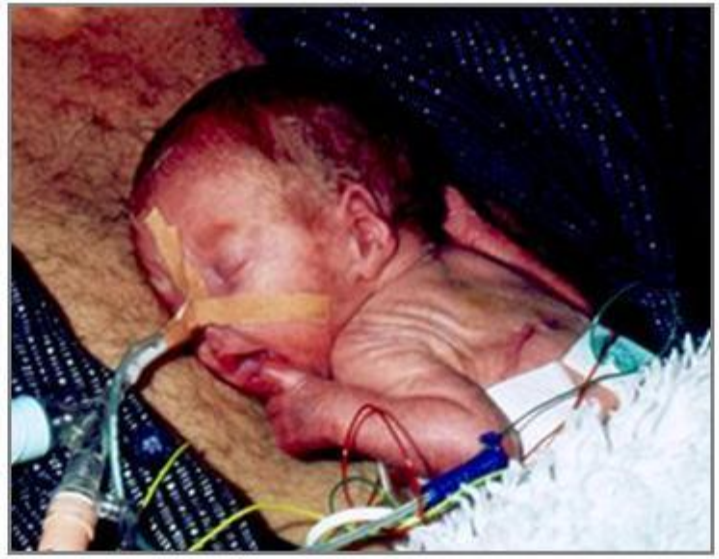
Agenda

- Kiobrina –Enzyme Replacement Therapy in preterm infants
  -Introduction and Clinical Program
  An van Es- Johansson , M.D,
  Head of Clinical Development , Sobi

-Improving Growth of premature Babies: How and Why
Berthold Koletzko, M.D, PhD, Professor Pediatrics
Dr. von Hauner Children's Hospital
University of Munchen, Germany

- Understanding the Value of Kiobrina
Anders Edvell, M.D., Ph.D., MBA
Vice President and Head of Marketing & Sales , Sobi

- Q&A
An van Es-Johansson
Berhold Koletzko
Anders Edvell



Improving growth of premature babies: why and how?

Berthold Koletzko, MD PhD

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Dr. von Haunersches Kinderspital

LMU KLINIKUM DER UNIVERSITÄT MÜNCHEN

Outline of presentation

1. Preterm infants: current challenges and role of substrate supply
2. Poor growth: implications
3. Benefits of improved fat absorption through human breast milk lipase (BSSL)

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Premature birth

- Premature birth:

  <37 weeks (≈12.5 % of infants)

- Low birth weight (LBW):

  birthweight ≤2500 g (≈6.5 %)

- Very low birth weight (VLBW):

  birthweight ≤1500 g (≈0.7 %)

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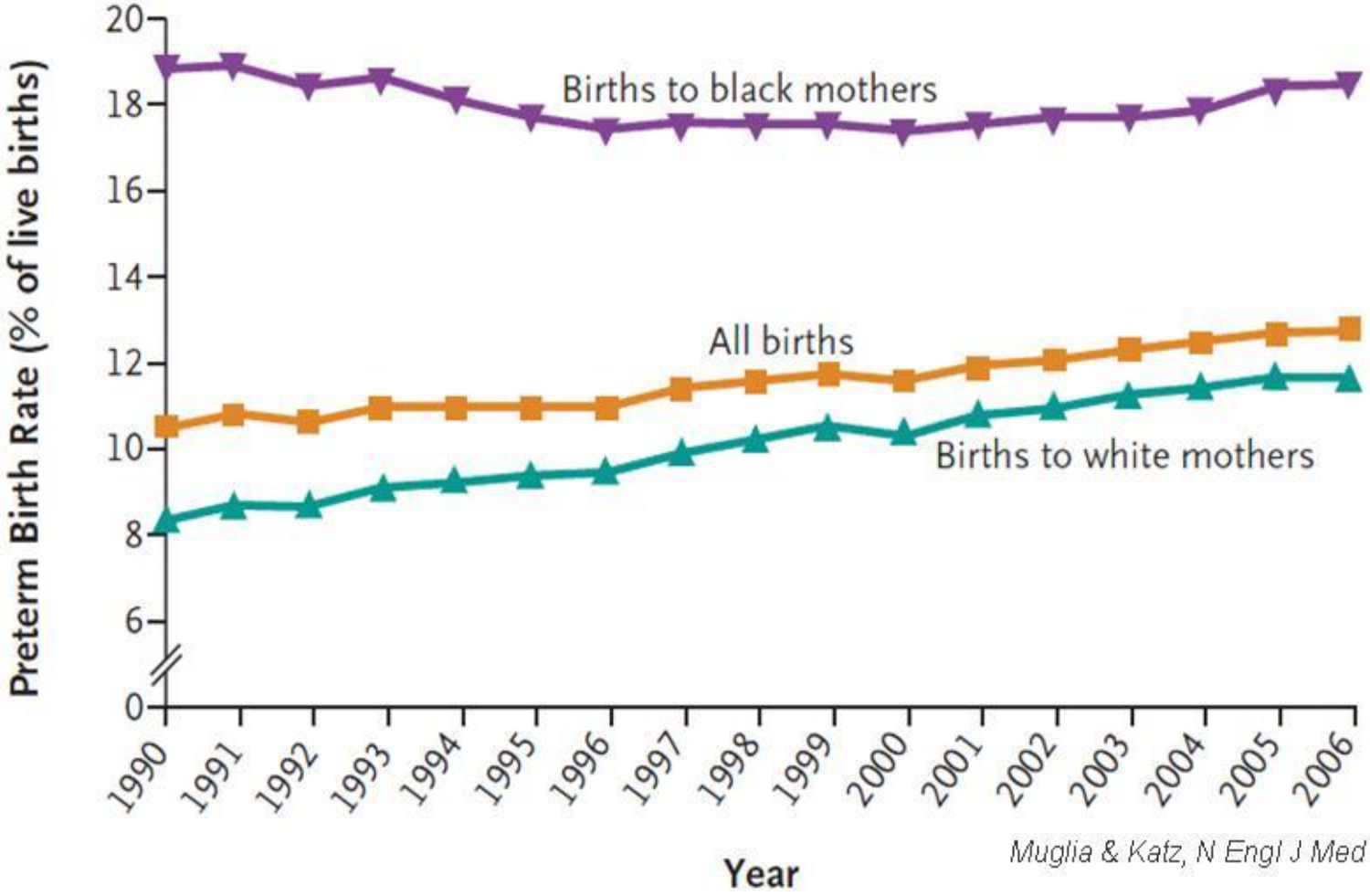
Preterm birth rates, USA



Muglia & Katz, N Engl J Med 2010;362:529-35.

Trends in most other high-income countries similar to those in the USA, accurate data from low-income countries not yet available.

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Raju, Clin Perinatol 2006;33:751-63.

High and increasing survival rates even in the most immature preterm infants

North American tertiary perinatal centers

Gestational age	Since 1990	2010
24 weeks	52 %	61 %
25 weeks	70 %	79 %
26 weeks	83 %	87 %

Lorenz, Saudi Med J 2011;32:885-94.

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The smaller the baby, the more important is nutrient supply

- Fetal weight doubles in only 6 weeks *(30⇨36 wks)*
- Preterm care aims at matching fetal growth

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Weight doubles in only 6 weeks

Preterm infant,
now 1000 g

- Jan. 10: 2000 g
- 120 kcal/day
- 6 g fat/day
- 150 mL milk/day

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Weight doubles in only 6 weeks

Preterm infant, now 1000 g

- Jan. 10: 2000 g
- 120 kcal/day
- 6 g fat/day
- 150 mL milk/day

Extrapolated to an adult, now 70 kg

- Jan. 10: 140 kg
- 8400 kcal/day
- 420 g fat/day
- 10,5 L milk/day

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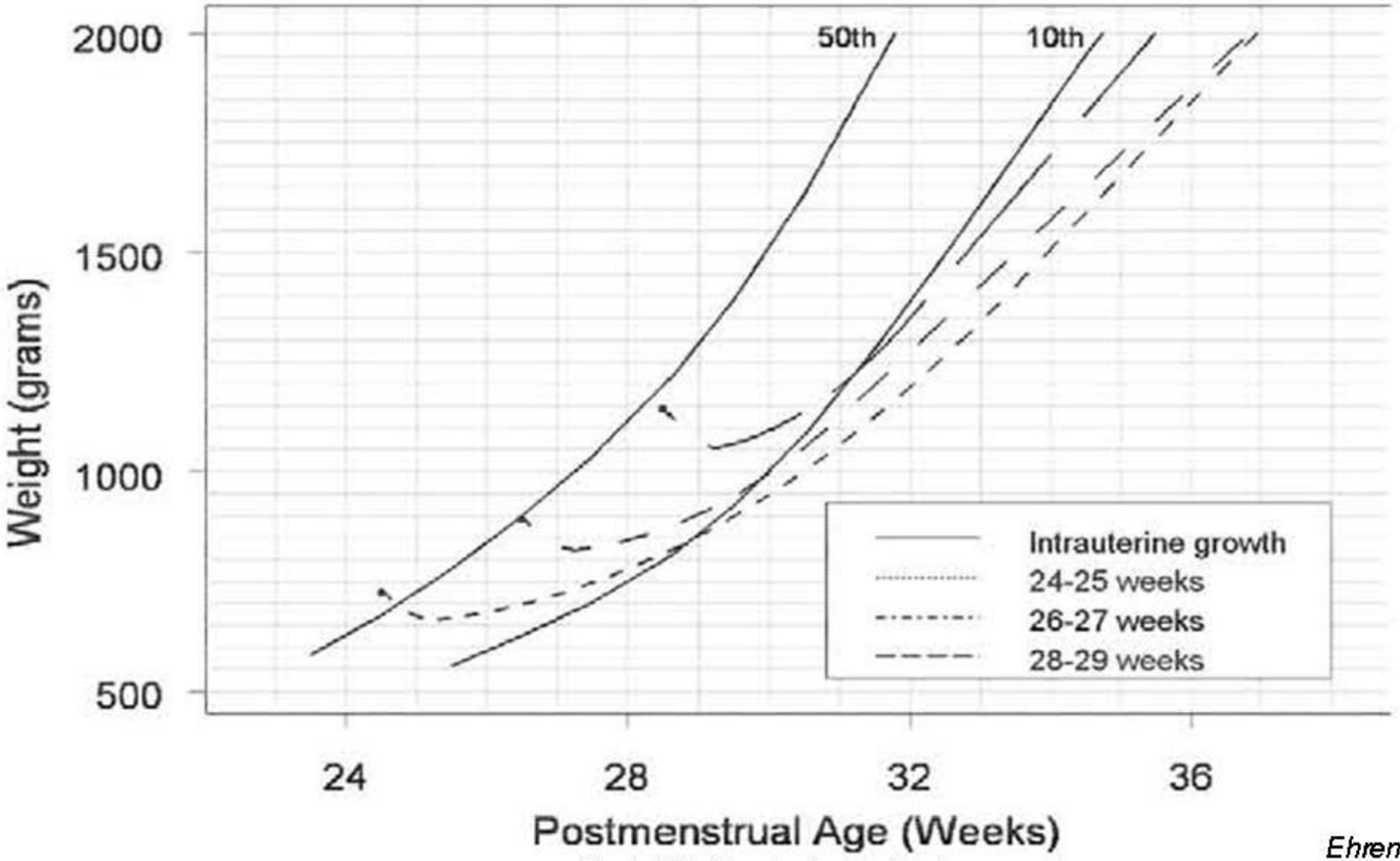
Preterm babies develop malnutrition on a regular basis



Ehrenkranz 2007

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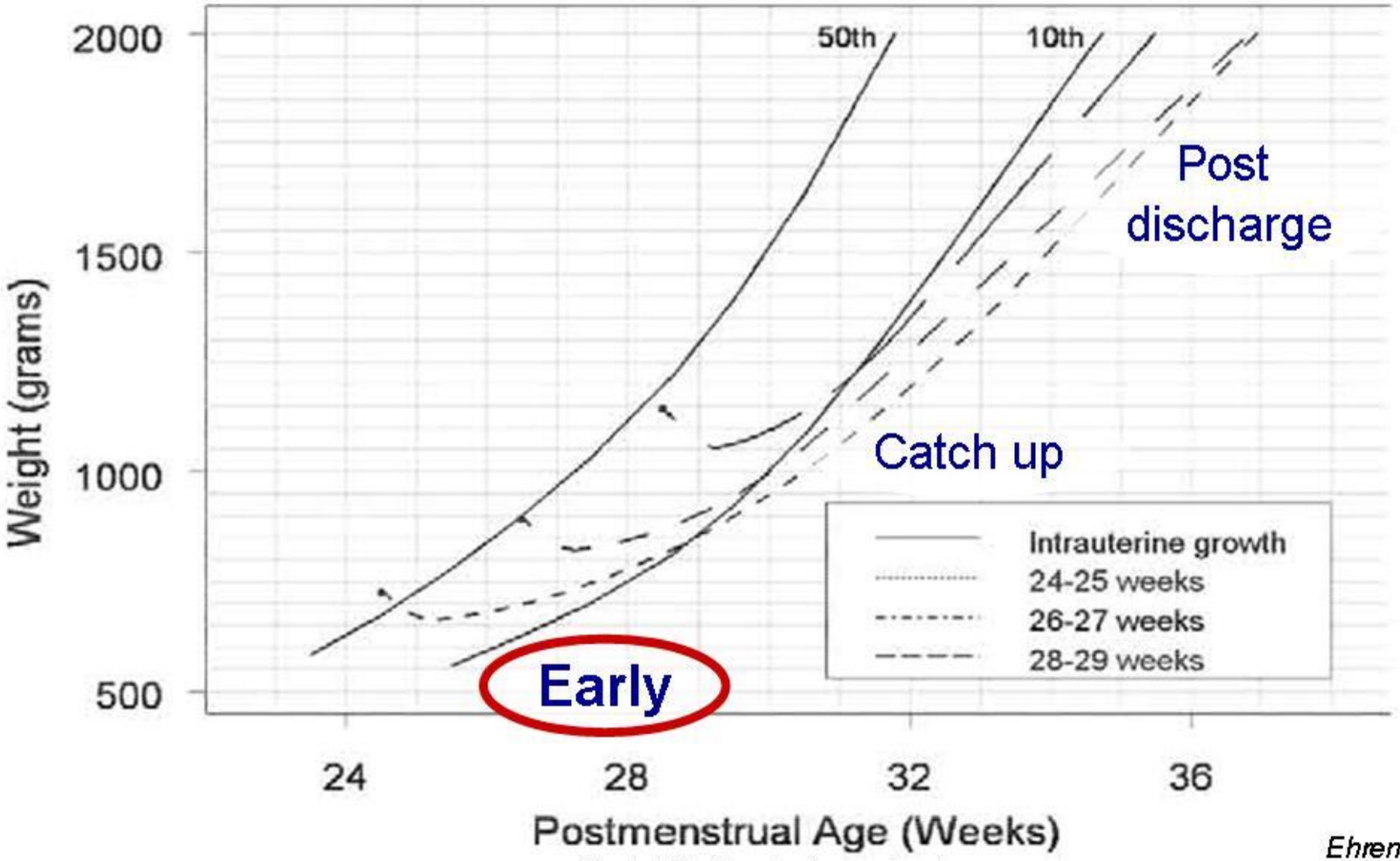
Preterm babies develop malnutrition on a regular basis



Ehrenkranz 2007

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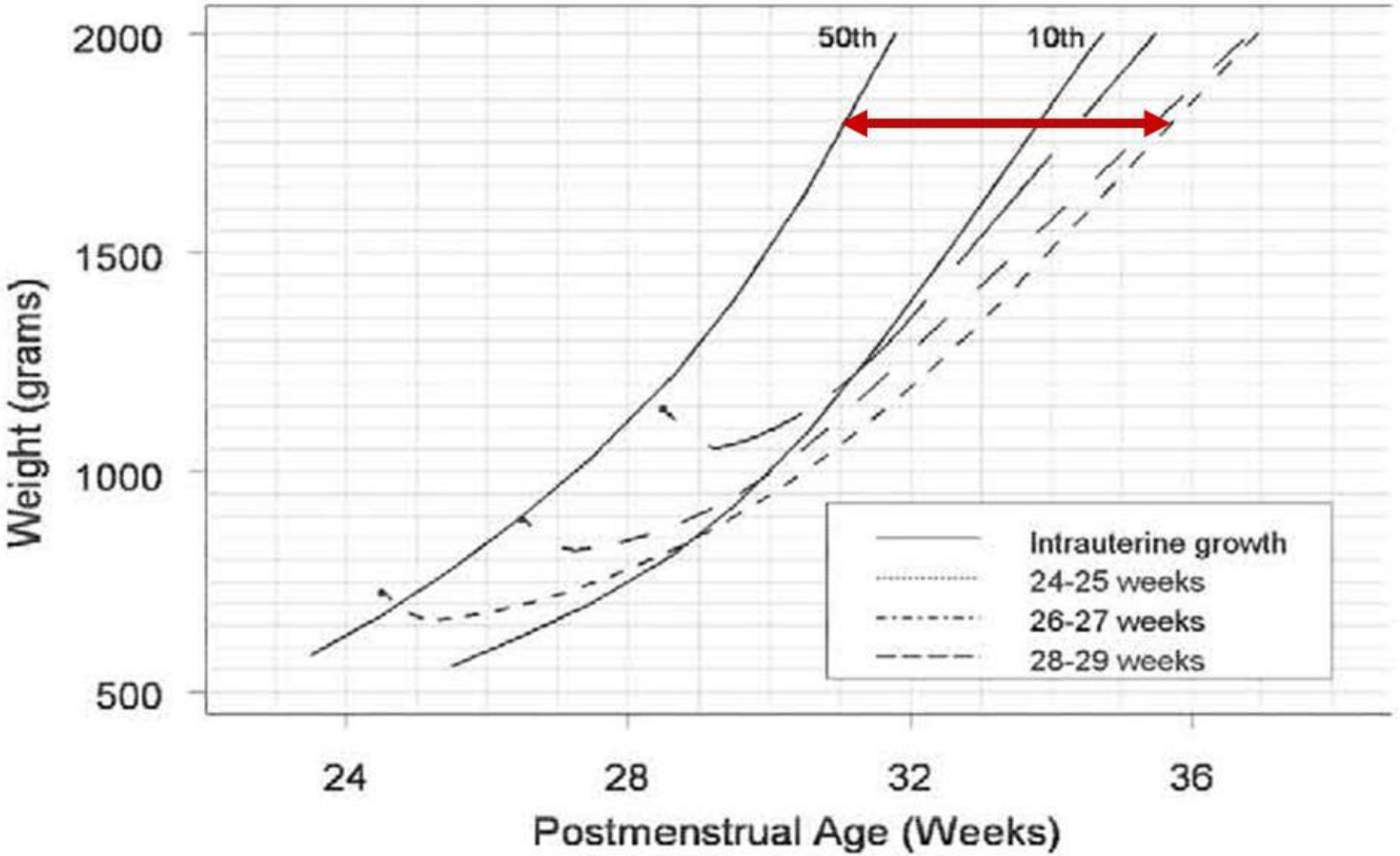
Poor growth may delay hospital discharge by up to ≈4-5 weeks



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Slow weight gain in preterms

- Later discharge from hospital
- ↑ Complications
  (e.g. hospital acquired infections)
- Disturbed parent child interaction, may affect bonding and development
- High resulting costs

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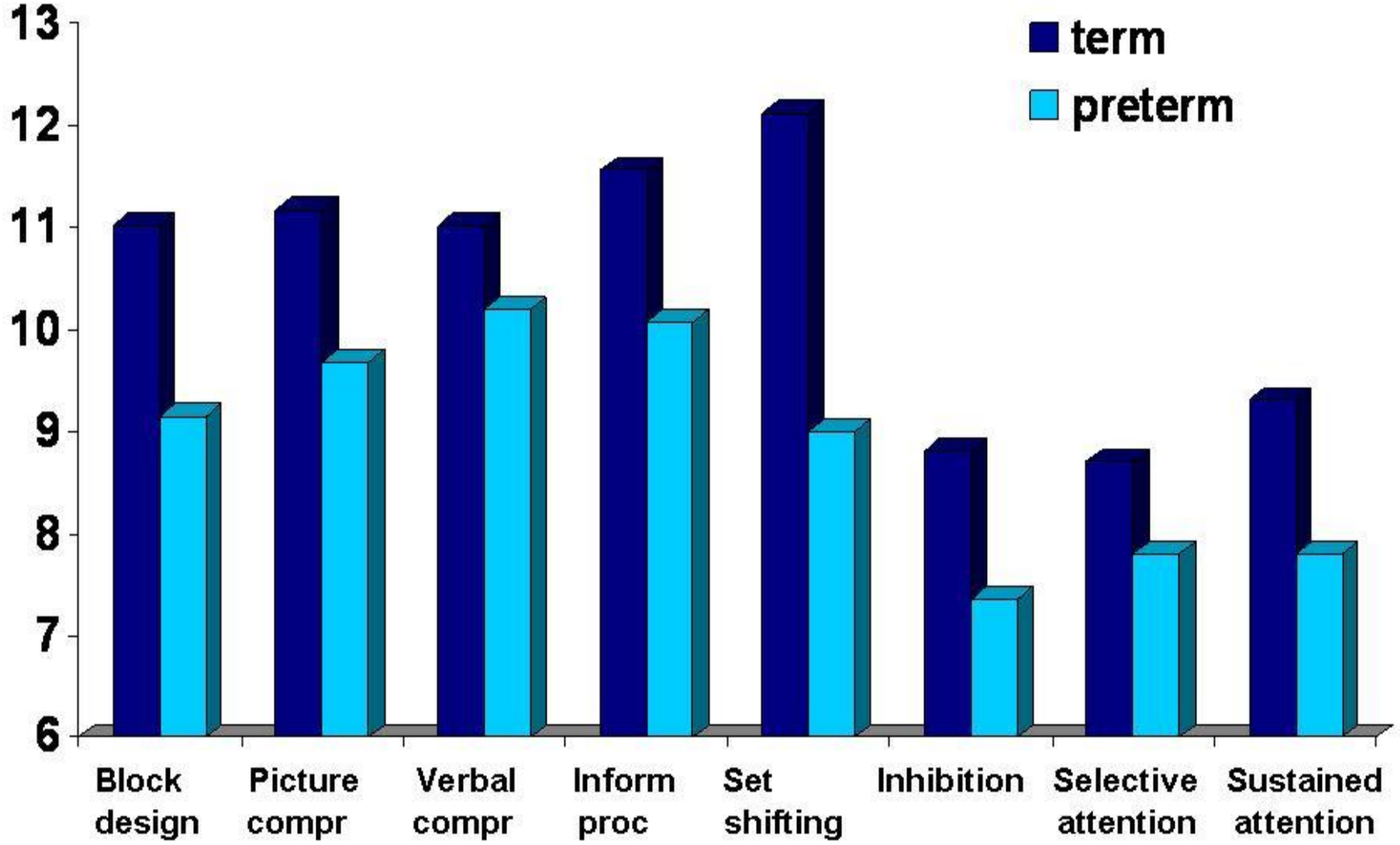
Preterms: ↓ executive function at age 8 yrs



Mean birthweight 1200 g

Bayliss et al Early Hum Dev 2007;83:247

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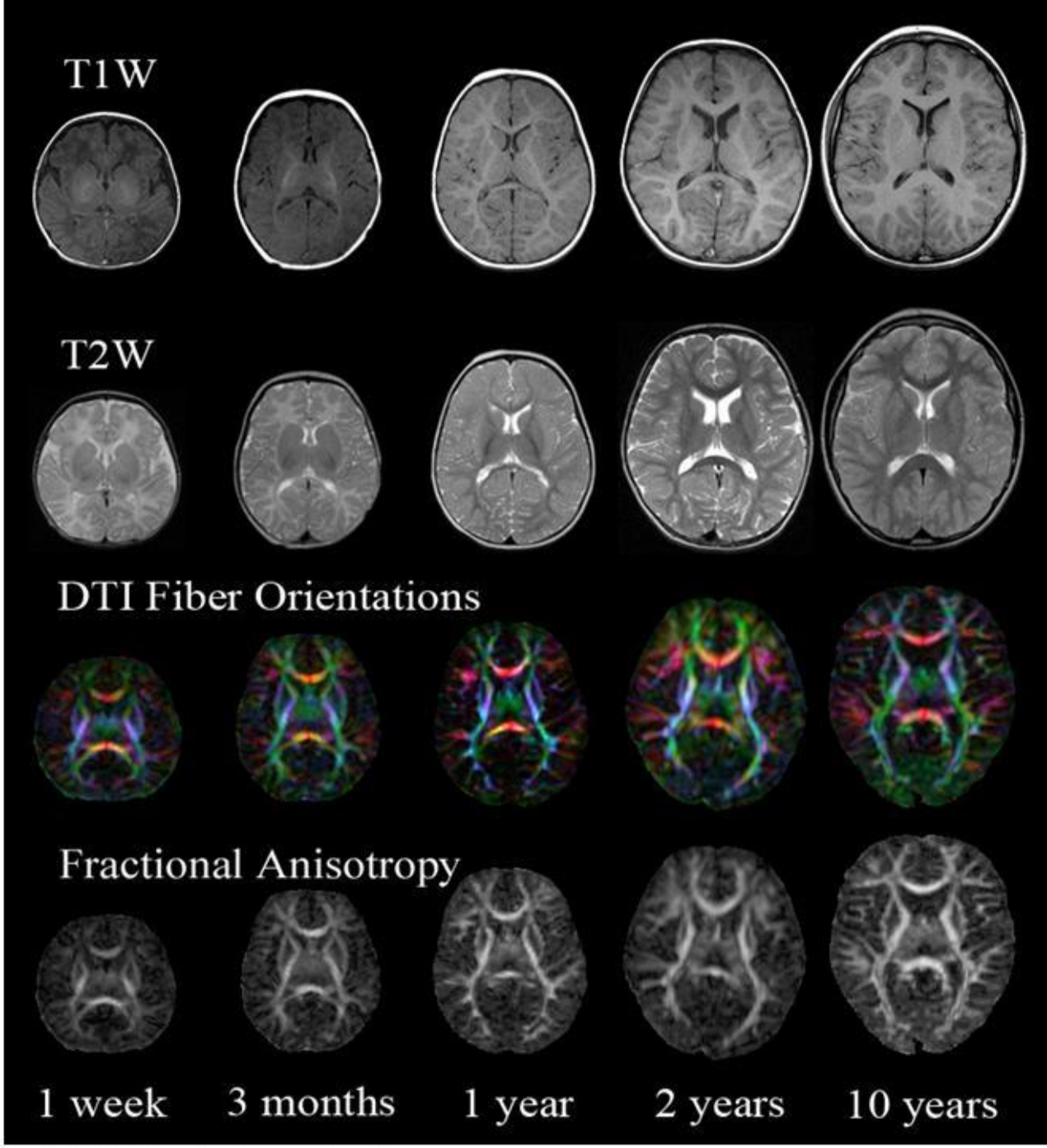
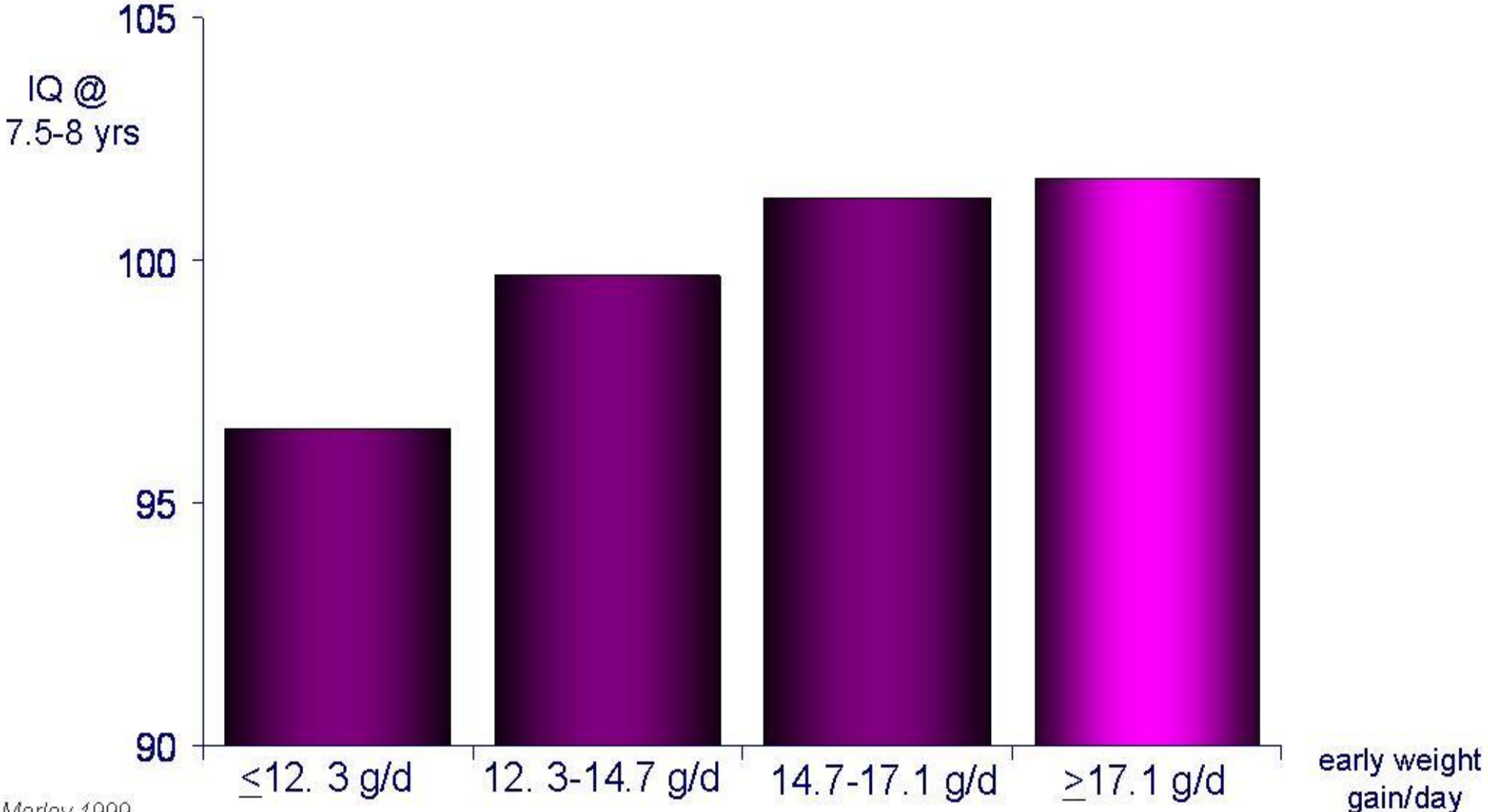
Rapid brain growth and development requires energy and building blocks

Fat >50% of brain structure



H.Preissl
http://www.bic.mni.mcgill.ca/nihpd/info/image_gallery.html#

Nutrition and growth velocity predict IQ @7.5-8 years in 598 preterms



Morley 1999

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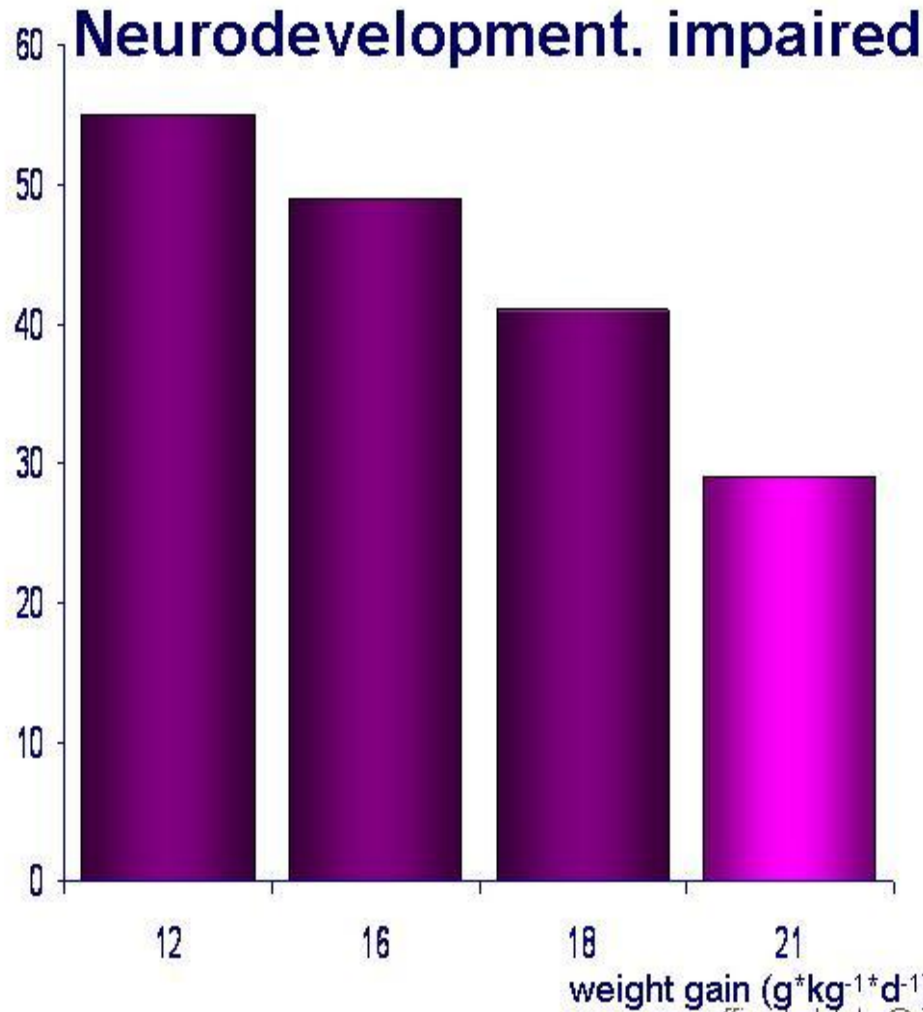
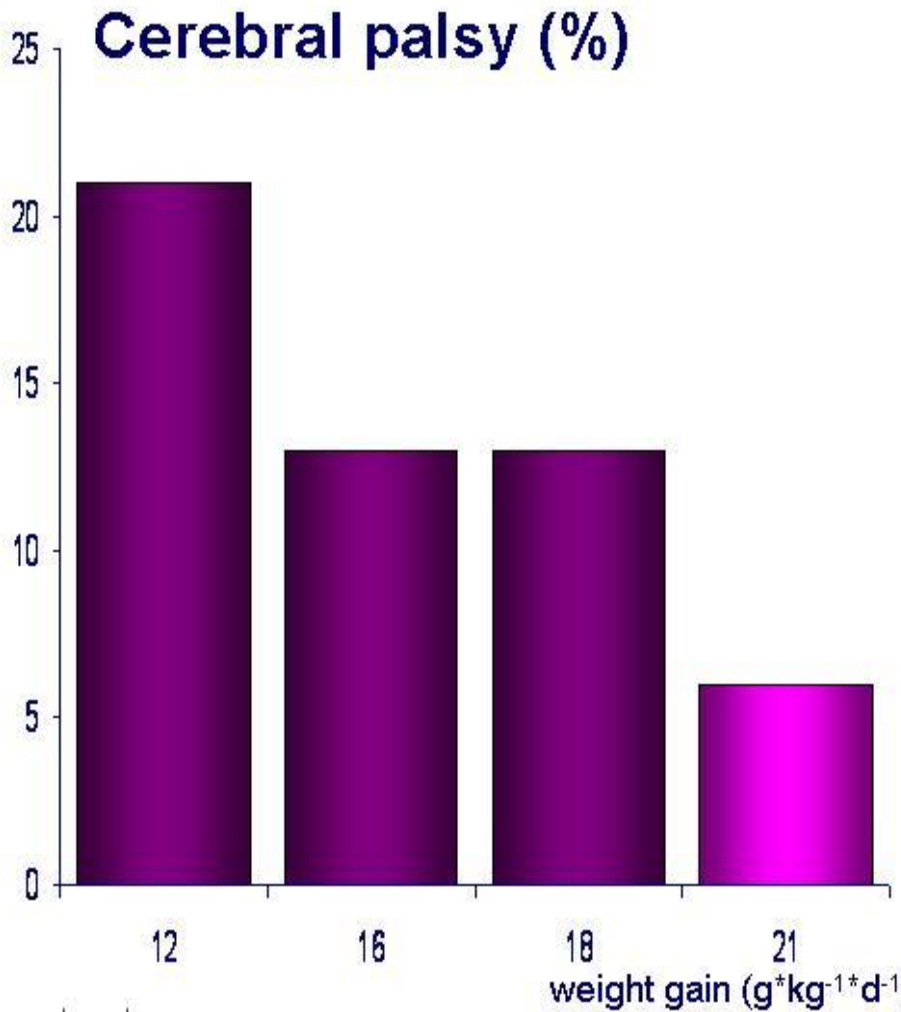
Preterm growth velocity on the neonatal intensive care unit predicts neurological outcome

490 preterms, USA, followed to 18-22 mon corr. age





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Importance of early fat supply

- Main energy source
  (for energy expenditure and growth)
- Building block in all cell membranes, including brain
- Supplies essential fatty acids and lipid soluble vitamins (A,D,E,K)

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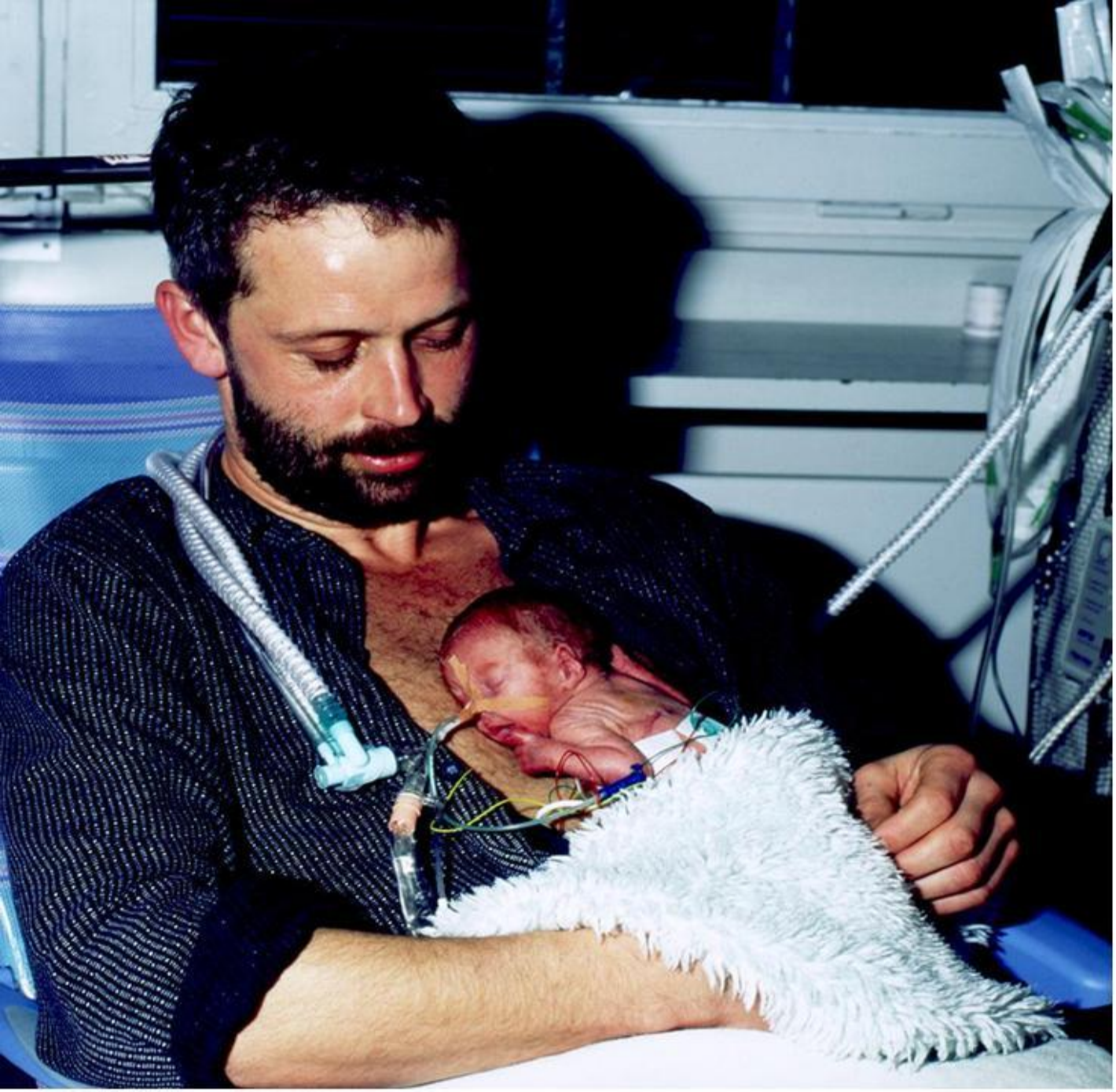

Preterm infants: ↓↓ body fat stores

1000 g
birth weight
⇒ only 20g
body fat

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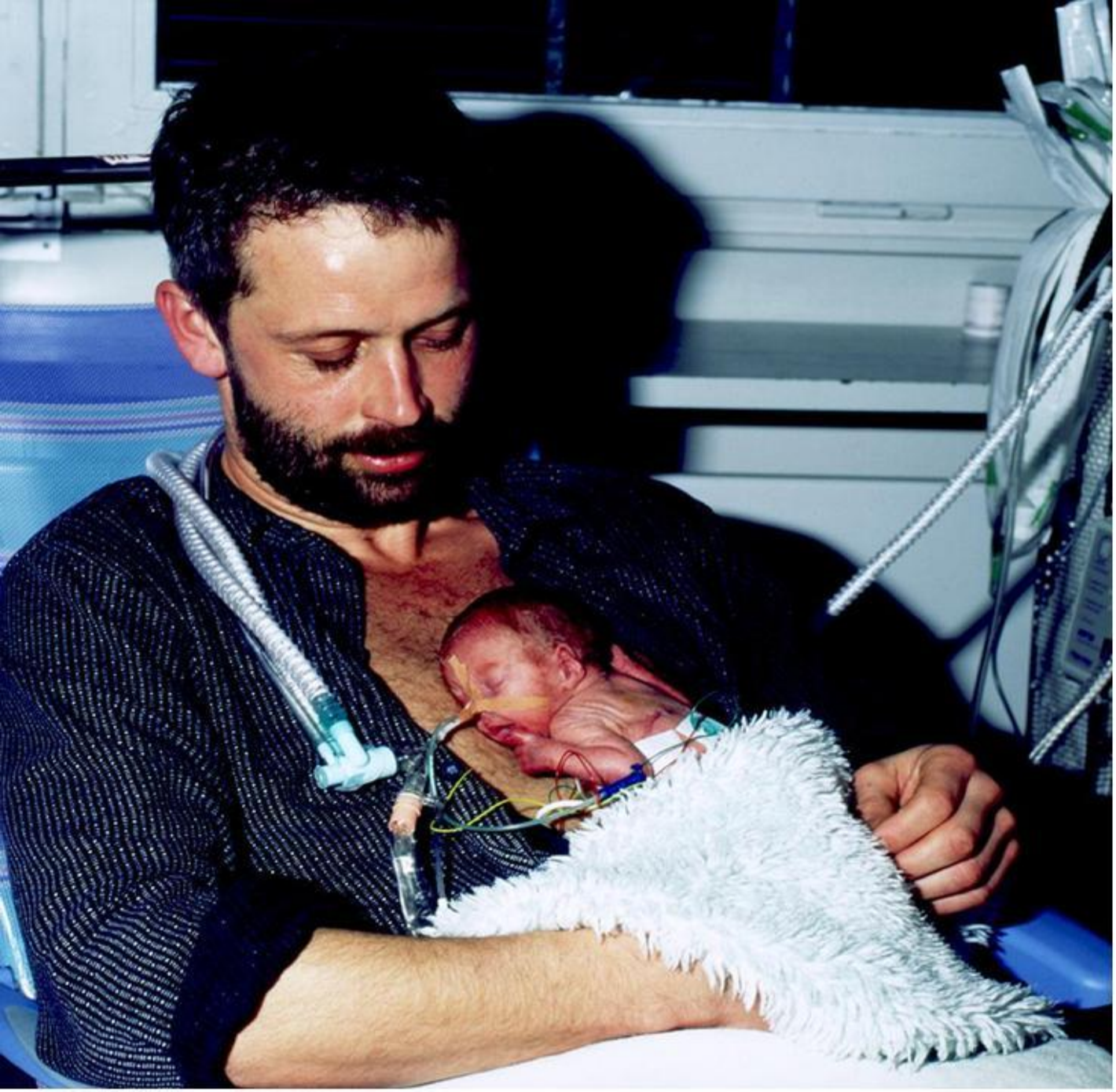

Preterm infants: ↓↓ body fat stores

1000 g
birth weight
⇒ only 20g
body fat

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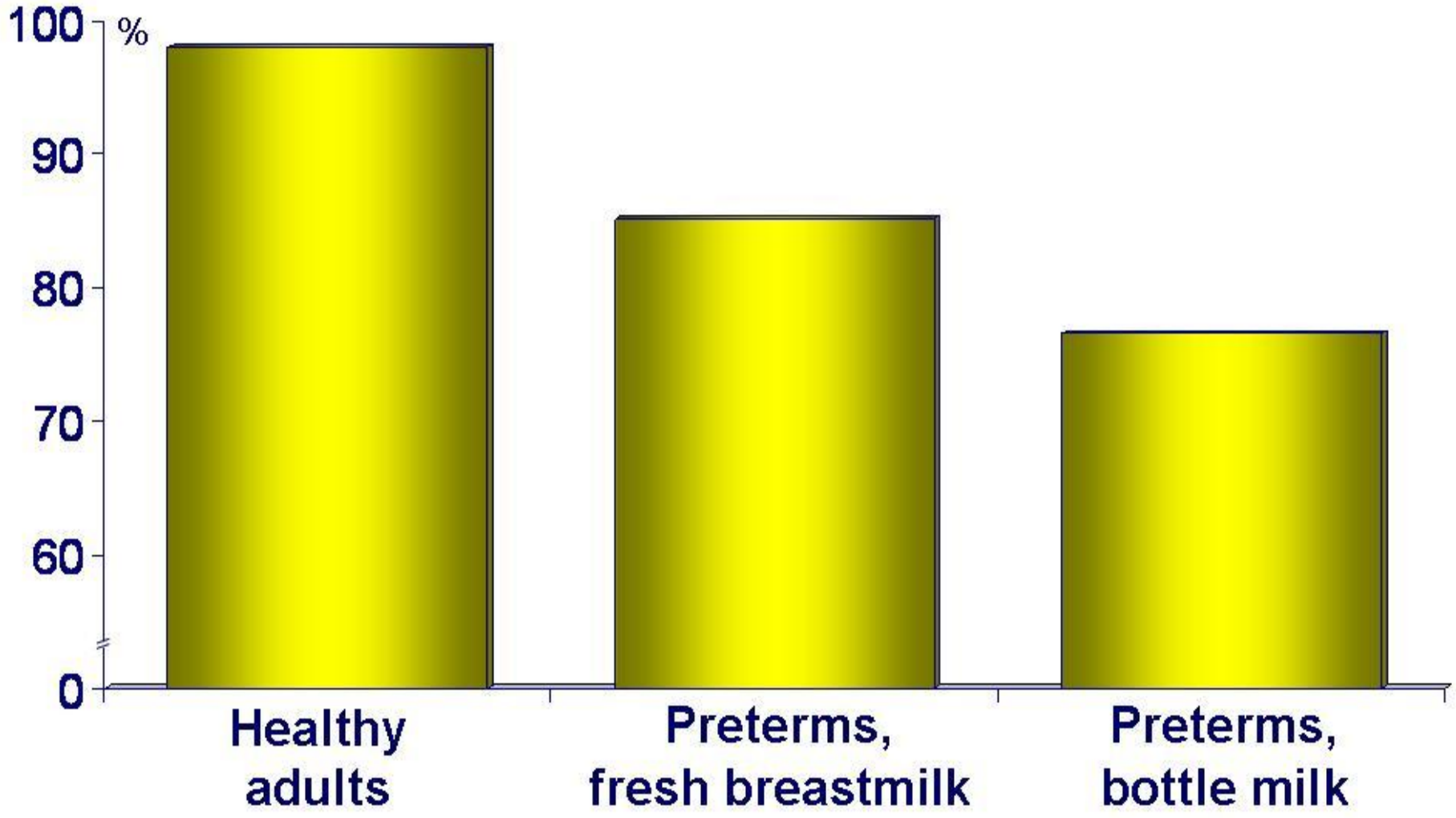
Absorption of dietary fat



Mean of results of Söderhjelm et al 1952, Williamson et al 1978, Atkinson et al 1981, Chappell et al 1986, Carnielli et al 1997, Andersson et al 2007

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Poor lipid digestion and absorption in preterm babies: consequences

Short term

- Loss of energy, essential fatty acids, fat-soluble vitamins and calcium

Long term

- Slow growth ⇨ impaired neurodevelopment
- Poor bone mineralization

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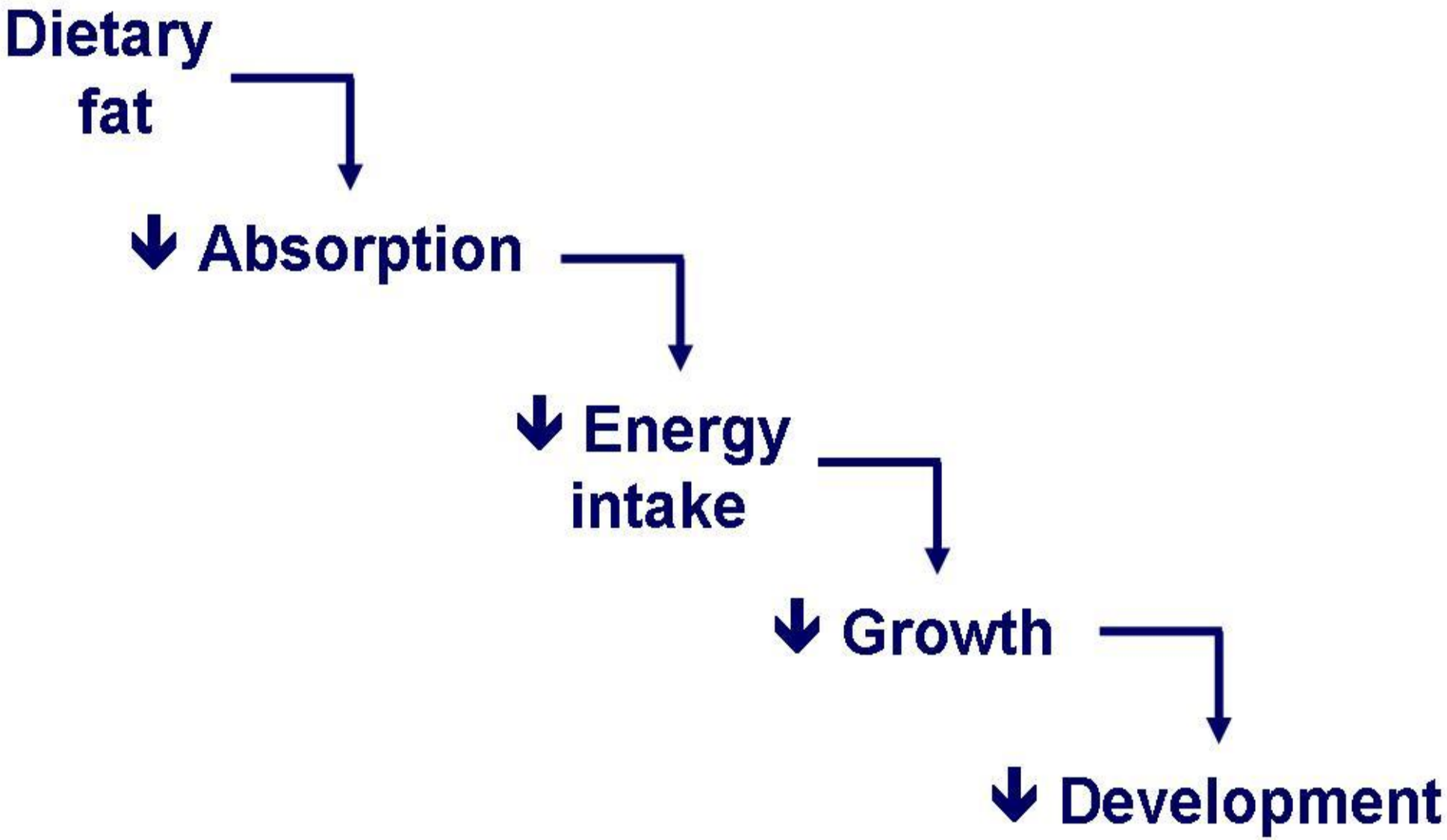
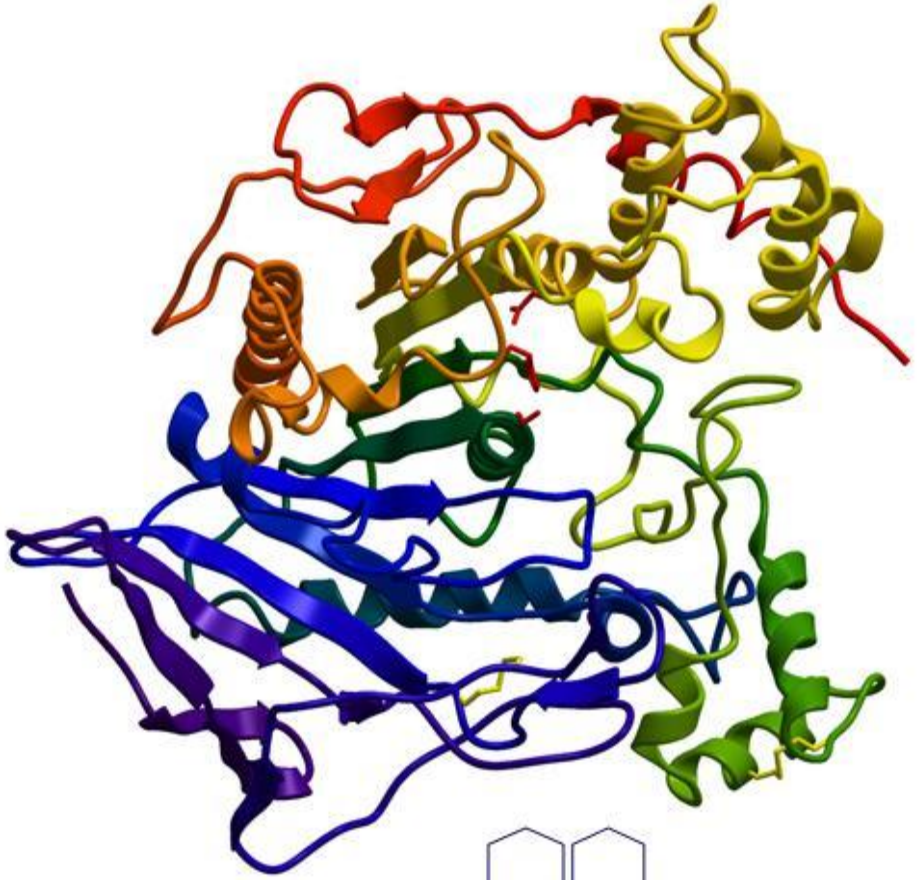
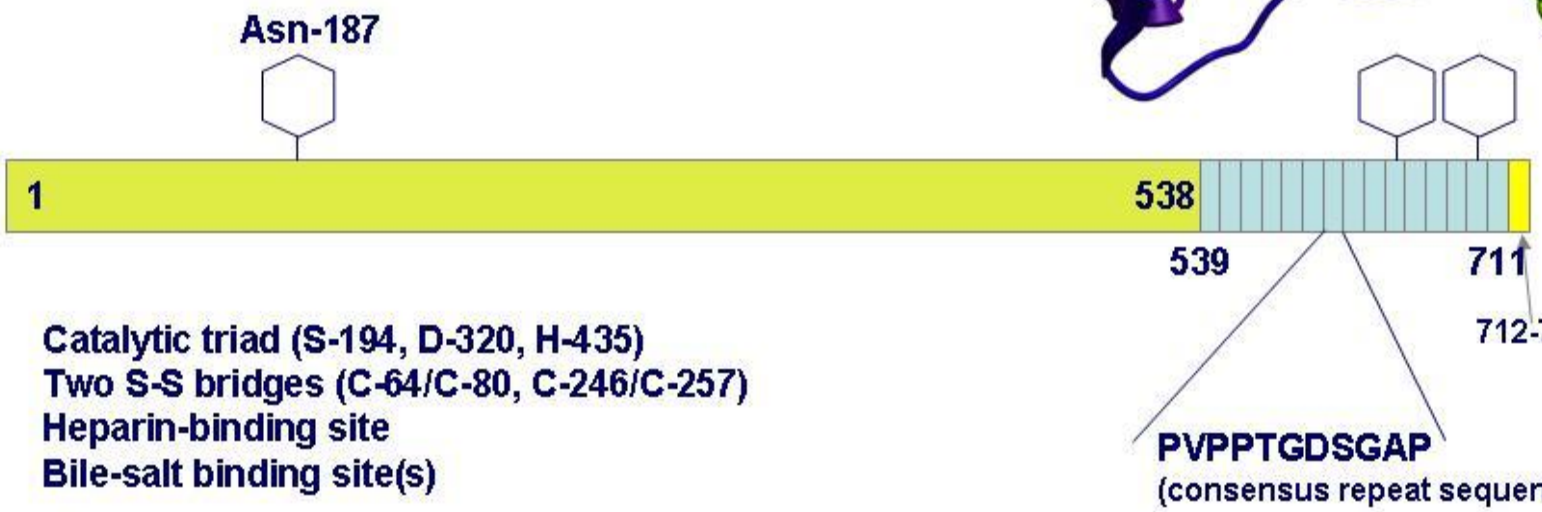

Dietary fat
Absorption
Energy intake
Growth
Development

Human breast milk contains

Bile salt Stimulated Lipase (BSSL)





Catalytic triad (S-194, D-320, H-435)
Two S-S bridges (C-64/C-80, C-246/C-257)
Heparin-binding site
Bile-salt binding site(s)

- Glycosylation sites

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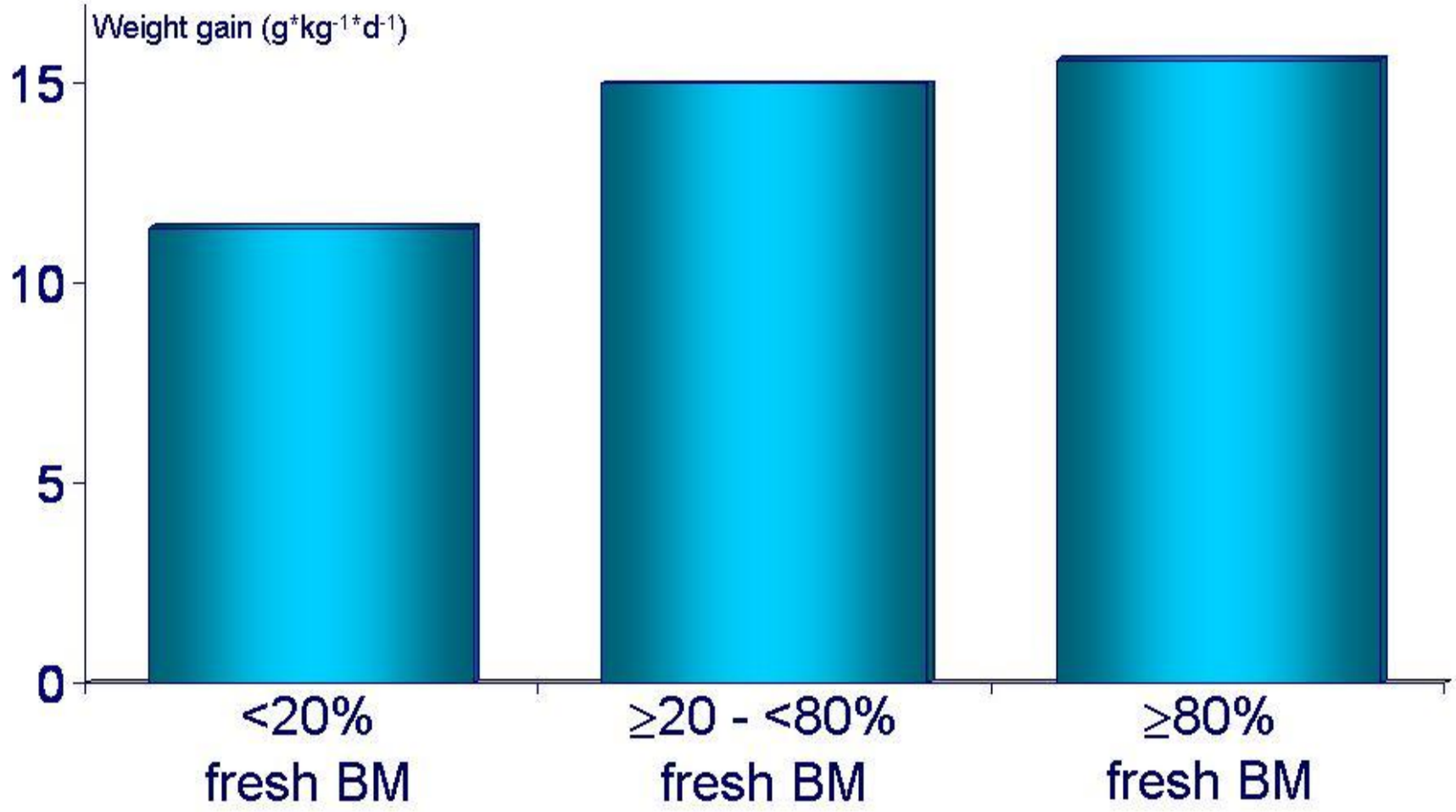
Better preterm growth with more fresh breast milk (lipase +) vs. pasteurized milk (lipase -)



Montjaux-Régis et al, Acta Paediatr. 2011;100(12):1548-54.

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Conclusions

- Small preterm infants now achieve good survival but less than satisfactory long-term development
- Poor growth is very common and predicts delayed hospital discharge and poor development
- One key reason is poor absorption of fat (& calories)
- Adding breast milk lipase (BSSL) to pasteurized breast milk or formula may improve fat absorption, growth and long term outcome

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Thank you for your kind attention!

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Preterm infants lack BSSL

- Natural component of breast milk
- Naturally occurs in mother's milk
  - Inactivated by heating hence lacking in pasteurized milk
  - Not present in formulas
- Important for growth
- Important for absorption of Omega 3- and 6

Lindqvist Curr Opin Clin Nutr Metab Care 13:314–320 2010
Kleinman Pediatric Nutrition Handbook 6th ed.

Kiobrina is a homologue to the natural BSSL enzyme

- Recombinant human BSSL
- Animal derived product free
- Given orally with formula or pasteurized milk
- Prevents growth restriction in preterm infants not receiving fresh mother's milk

Target indication: Enzyme replacement therapy to restore BSSL activity and prevent growth restriction in preterm infants receiving formula or pasteurized mother's milk

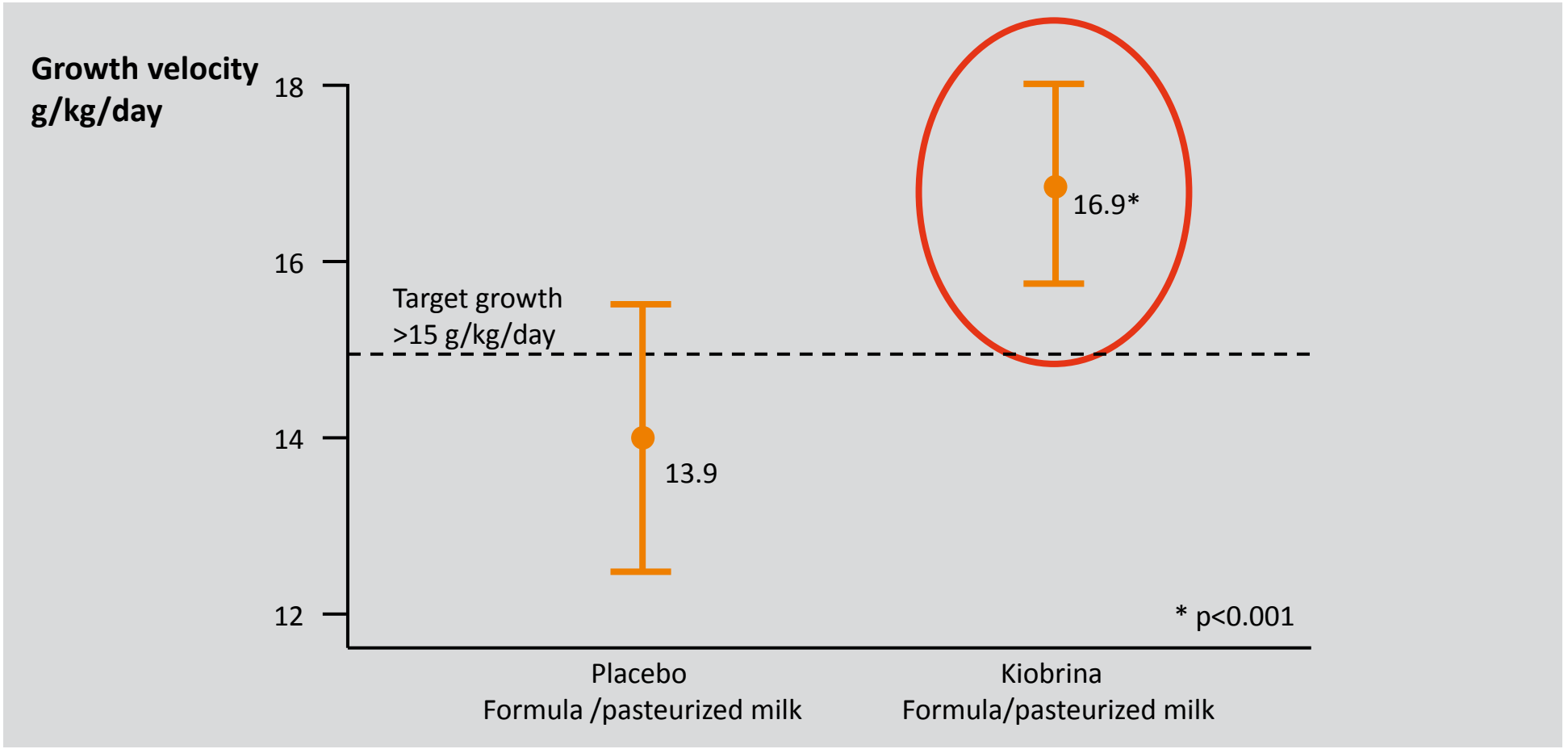
Sobi Competencies well suited to delivering Kiobrina

Development and manufacturing progressing according to plan

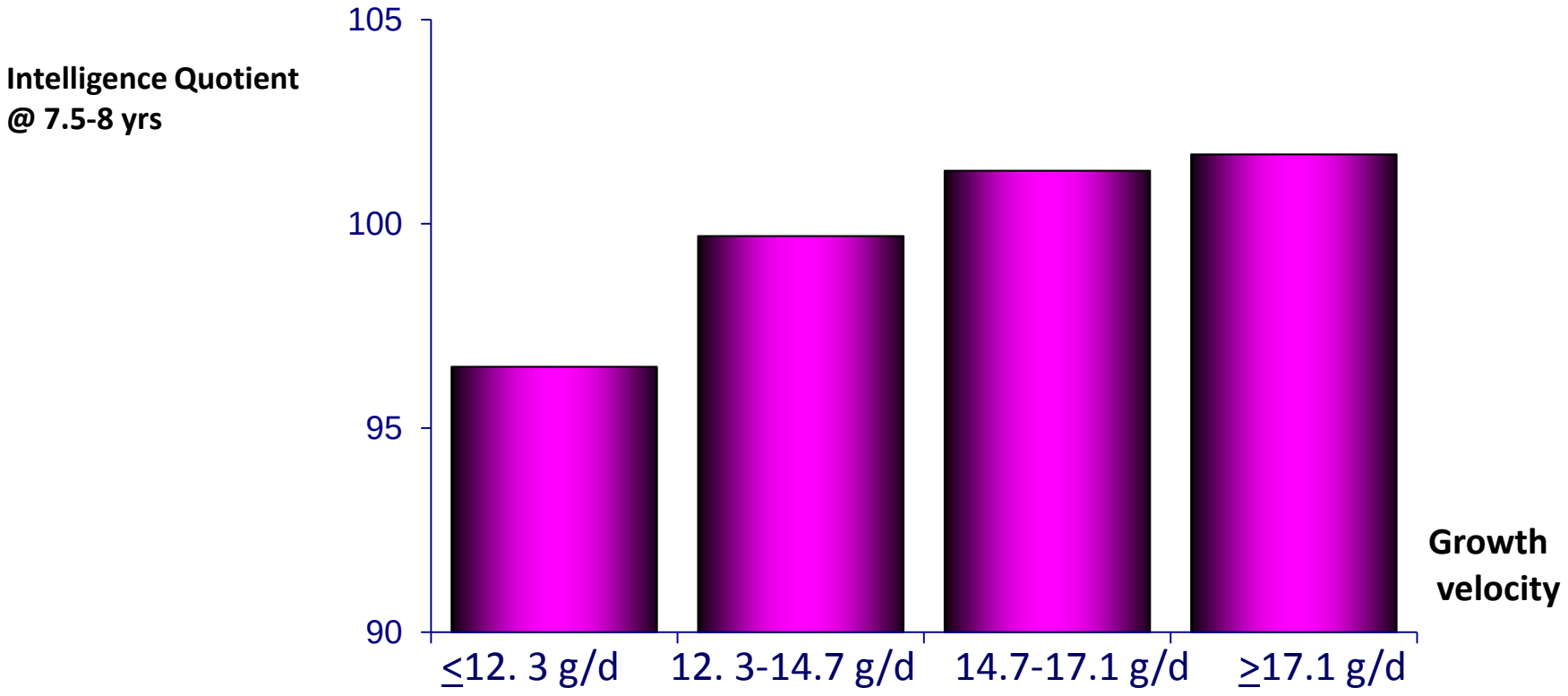
- Pediatric Investigational Plan approved
- EMA approved endpoints and clinical program
- FDA discussions ongoing

- Inhouse protein development capabilities
- Clinical development organisation
- Manufacturing on schedule
- Market access planning underway

Phase II data show Kiobrina significantly accelerated growth after only one week of treatment



Nutrition and growth velocity predict Intelligence Quotient at 7.5-8 years in 598 preterms



75*Morley 1999*

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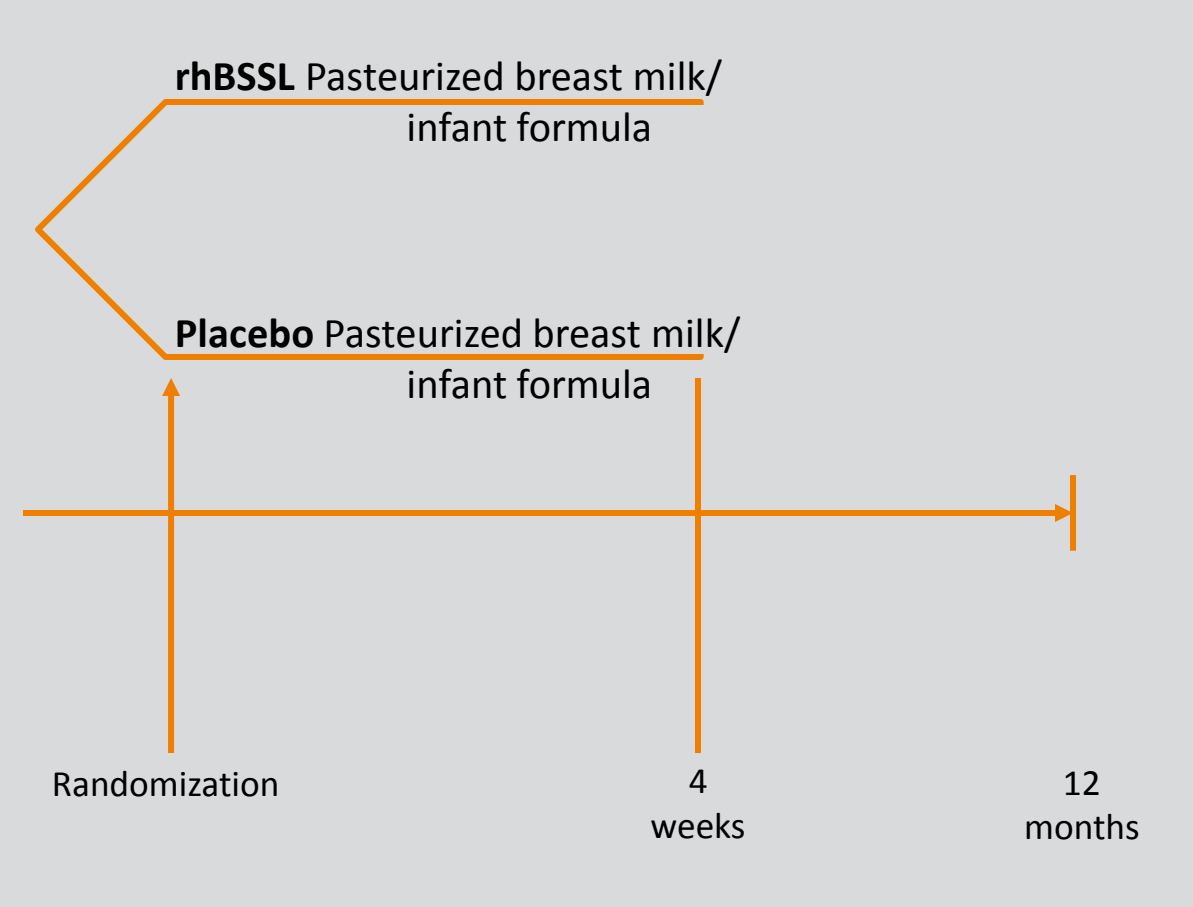
Phase III Study in Broad EU Geography

- Placebo controlled double blind study
- 4 weeks treatment
- ~430 patients, <32 weeks
- 11 Countries, 70 sites

Endpoints Relevant to Physicians and Payers



- Primary efficacy:
  - Growth velocity (g/kg/day)
- Secondary endpoints:
  - NICU stay
  - Early Development
    - Suckle feed
    - Temperature control
  - Tolerability
    - Less infections (sepsis)
    - GI tolerability (NEC)
    - Concomitant medication
- Post approval :
  Development long term follow up

Understanding the Value of Kiobrina

- Earlier discharge from NICU
- Lower incidence acute complications
- Concomitant medication
- Improved development
- Fewer complications
- Readmission to hospital
- Longterm health outcomes
  - Cerebral Palsy
  - Learning disabilities

Understanding the Value of Kiobrina

- Reduced Hospital Utilization
- Reduced Illness due to prolonged hospitalization

Cost per week for 1 patient in a **N**eonatal **I**ntensive **C**are **U**nit

EUR 10 500- 17 500

- Developmental delay
- Functional deficits

Benefit – health outcomes and improved developmental and functional status

Every year about 630 000* infants are born < week 32

A preterms' challenging start in life

Many preemies experience a tough start in life. Your baby might have **lung problems, low blood sugar or yellowing of the skin.**

More alarming concerns could be **infections, bleedings into the brain or learning- and behavioral problems.**

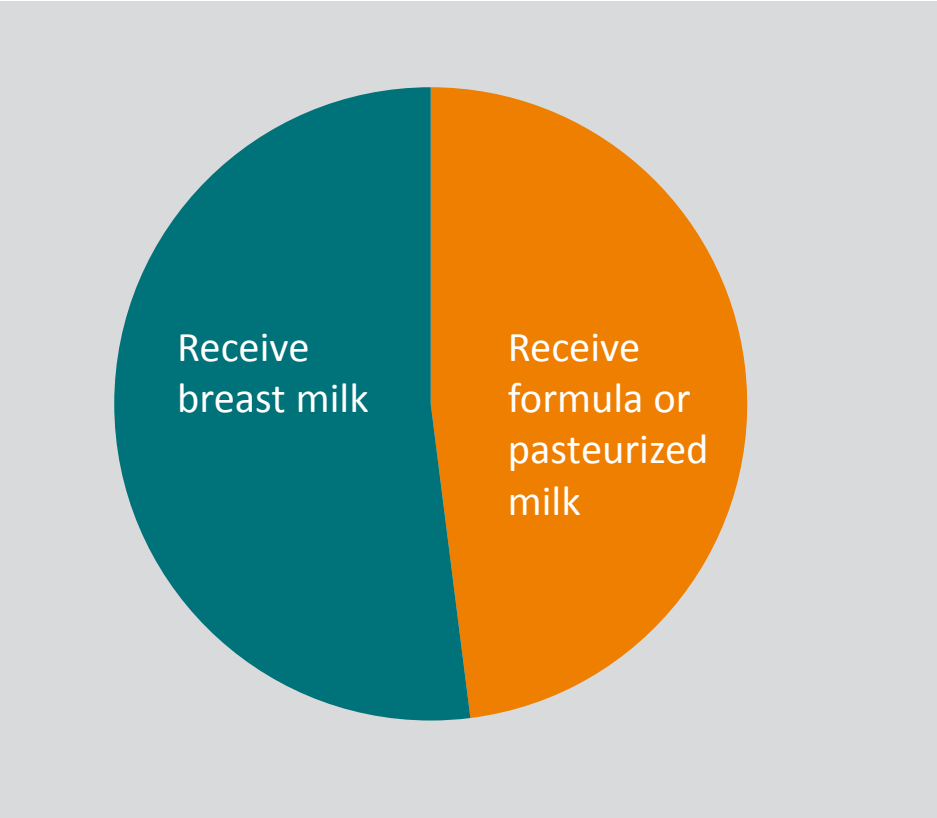
Despite the challenging start in life, many preemies will pick up to an ordinary healthy development.

Letter to parents of preterms

* EU, Russia, Turkey, US, Canada, Brazil, Mexico, Argentina, Venezuela, China, Japan, Korea, Australia, Saudi, Iran, Israel, Egypt

About 300 000 preterms born <week 32 do not receive breast milk

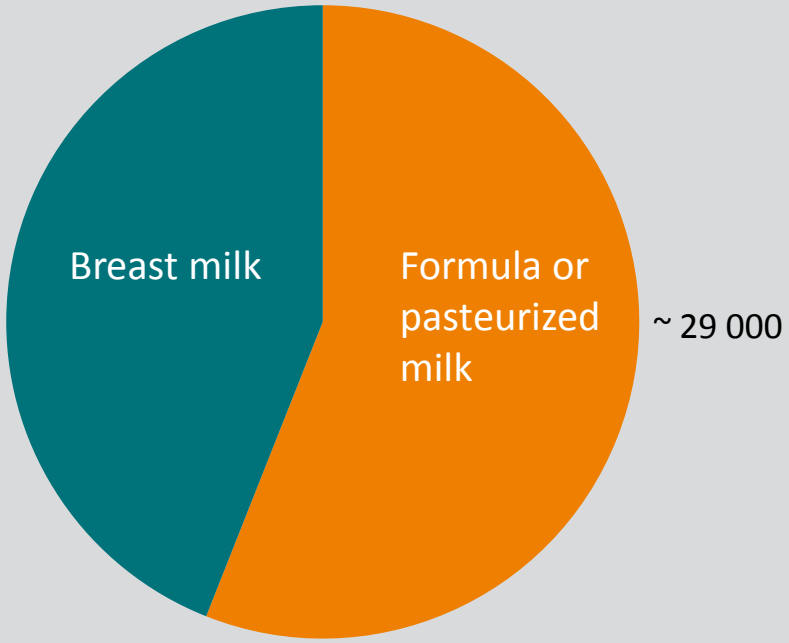
Breast milk contains all nutrition these infants require



- Reasons for not receiving fresh breast milk
  - Medical conditions
  - Different cultural traditions

*Beck et al, Bull World Helth Organ 2010;88:31-38, Key figures on Europe, Statistical pocketbook , 2006

Market in Europe is estimated to about 29 000 patients



Preterm infants born < week 32

56% of preterm infants receive formula or pasteurized milk in EU today

Kiobrina treatment - 4 weeks

1 http://epp.eurostat.ec.europa.eu + Federal State Statistic Service 2010, www.johnstonarchive.net
2 Bonet et al 2010 3 National Vital Statistic report 2007, www.cdc.gov 4 Merewood et al, 2006 * 90% survival

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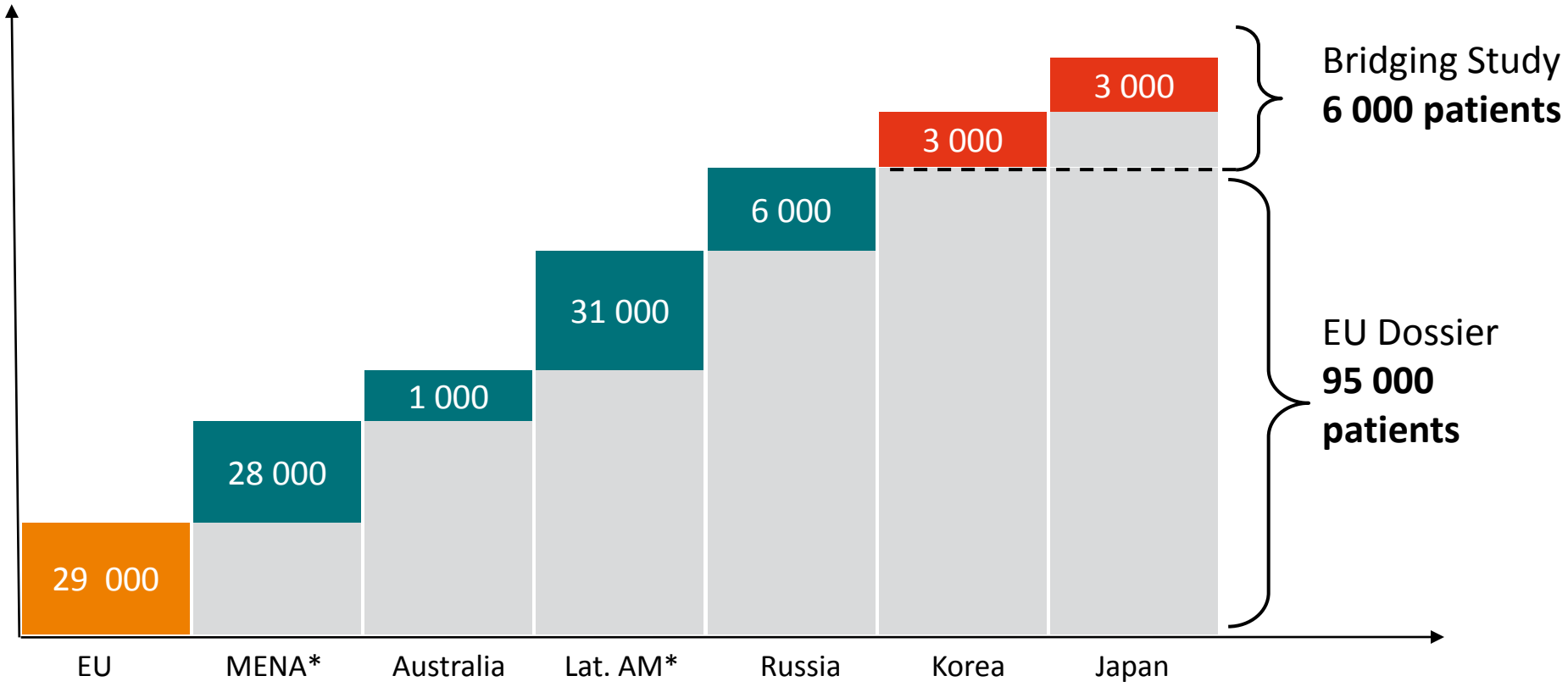
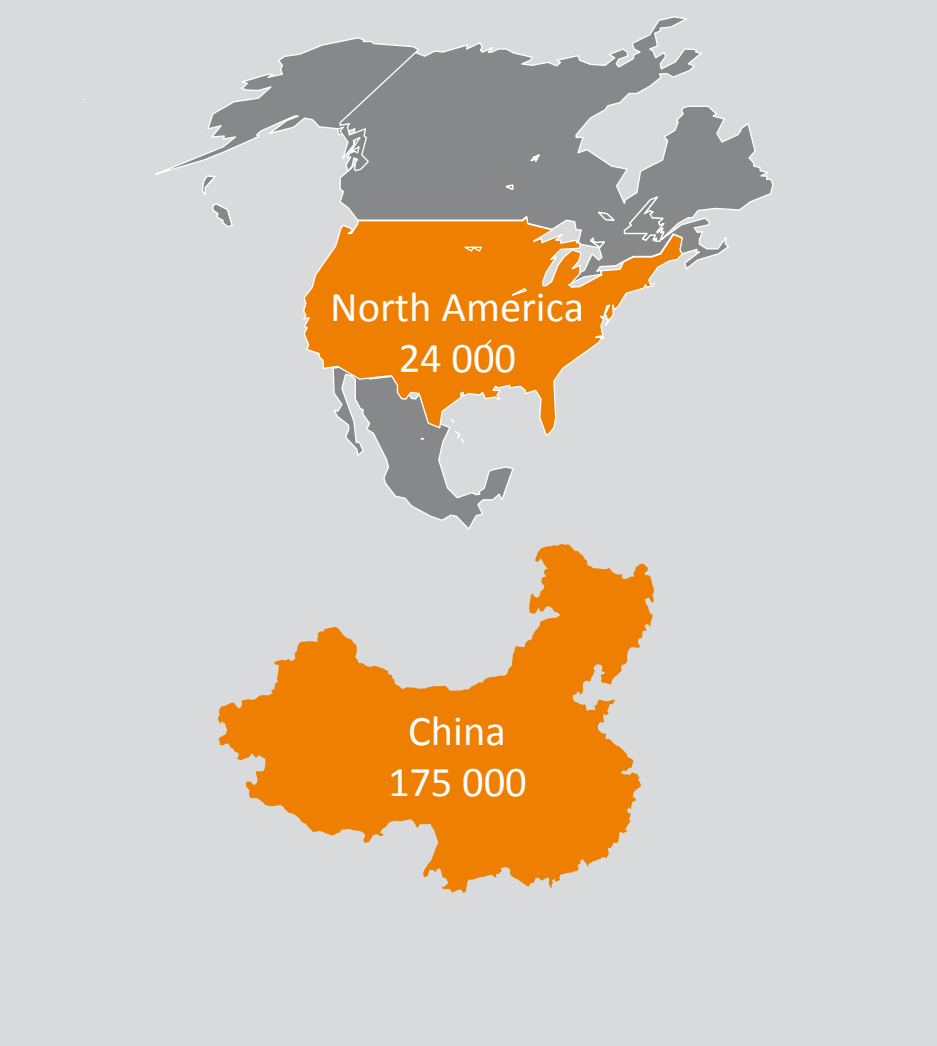
The approval of the EU PIII program will allow us to reach out to additional markets

101 000 target preterms/year



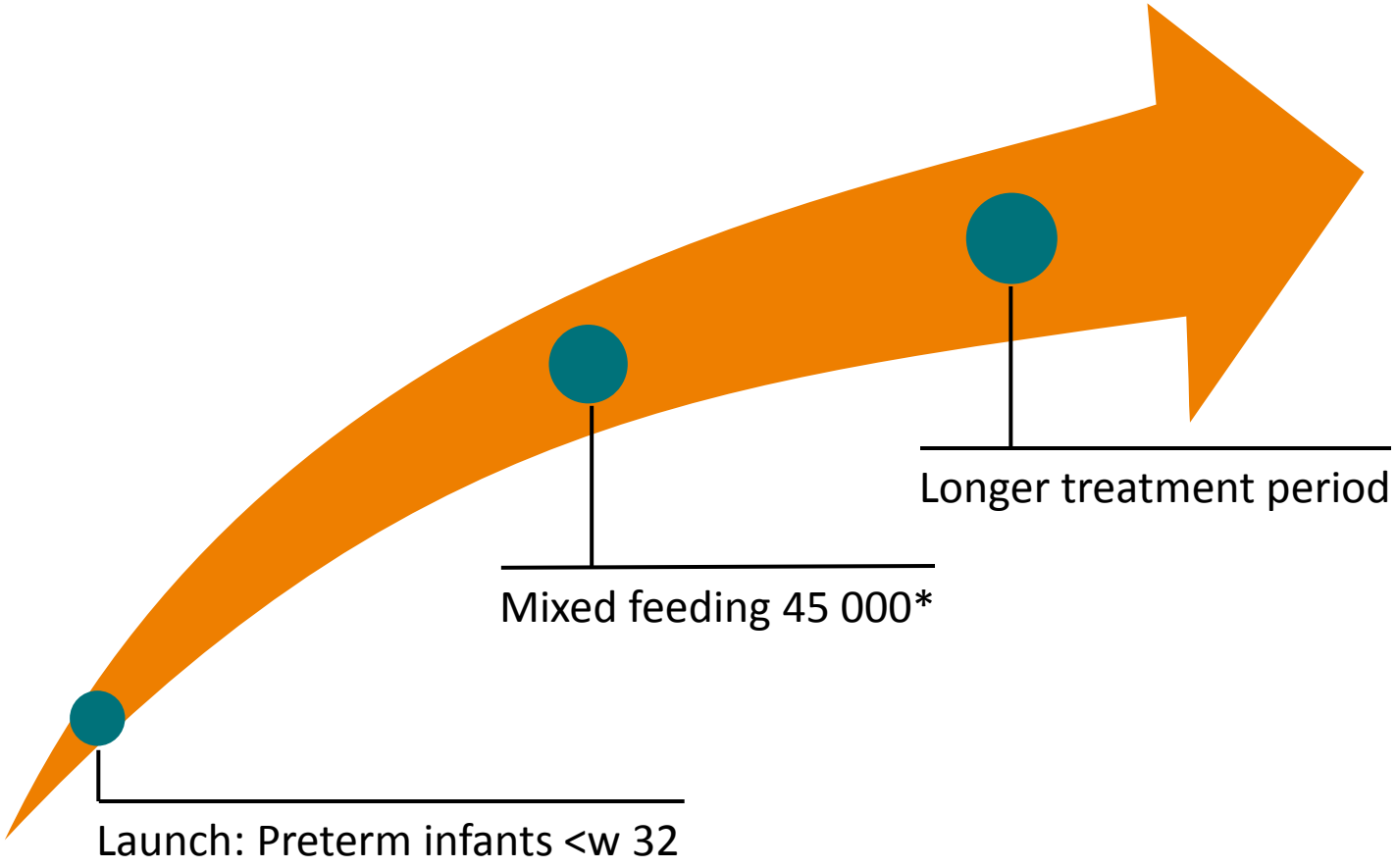
*Lat AM: Brazil, Mexico, Argentina, Venezuela
*MENA: Saudi, Iran, Israel, Egypt, Turkey

We are planning to have Kiobrina into our growing infrastructure in US



- North America
  - Meeting with FDA in H1 2012
  - To seek a partner for development in the US
- China
  - Out-license development and marketing rights and receive milestones and royalties

The Life Cycle Program - a growth opportunity



* EU, Russia, Turkey, US, Canada, Brazil, Mexico, Argentina, Venezuela, Japan, Korea, Australia, Saudi, Iran, Israel, Egypt

Summary on Kiobrina

- Kiobrina addresses significant medical need in preterm infants
- Kiobrina has potential to generate both short term and long term health care value
- Global incidence >300 000 patients of <week 32 preterm infants annually
- Market access supported by EU filing >100 000 patients
- LCM opportunities interesting and significant

Long-Lasting Coagulation Factors for Prolonged Protection in Hemophilia

Sobi Capital Markets Seminar, 2011

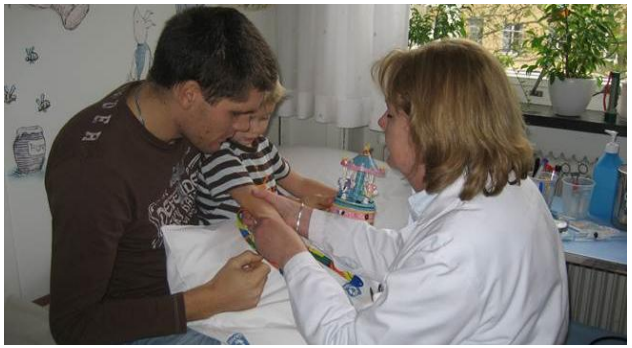


We provide valuable medicines to patients with rare diseases

sobi

Agenda

- Unmet Medical Needs in Hemophilia
  - The role of long lasting products
  Erik Berntorp, Prof. MD, PhD Malmö
- Recombinant Long Lasting Coagulation Factors
  -The Fc Fusion projects
  Glenn Pierce MD, PhD, Biogen Idec
- The Hemophilia Market and its Dynamics
  Helena Rudberg, M. Pharm. Sci. Sobi
- Q&A
  Helena Rudberg
  Glenn Pierce
  Erik Berntorp



We provide valuable medicines to patients with rare diseases

Unmet Medical Needs in Hemophilia

-The role of long lasting products

Prof. Erik Berntorp, Prof. Erik Berntorp, MD, PhD, Professor, Lund University
Research group leader Lund University. Clinical coagulation research, Clinical Sciences, Malmö
Head physician Malmö Centre for Thrombosis and Haemostasis, SUS, Malmö

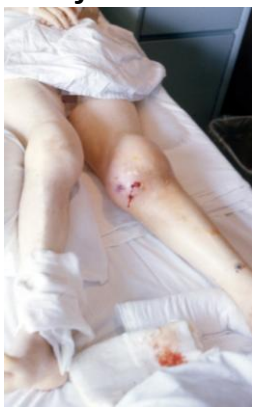
-

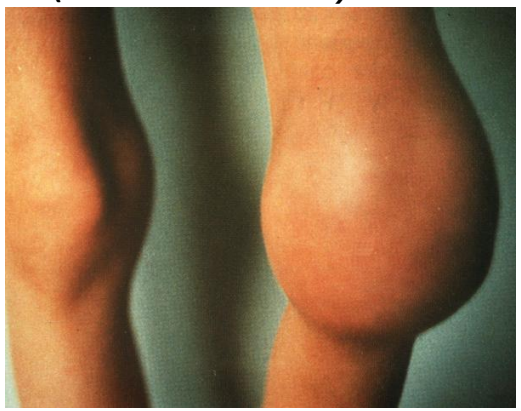


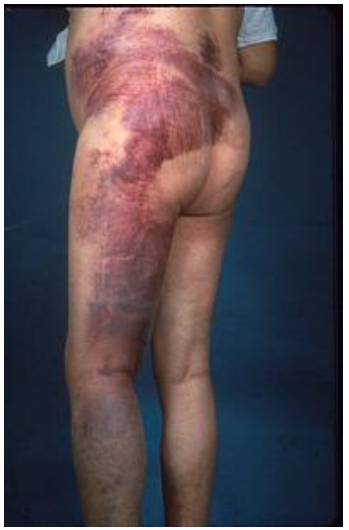
Hemophilia A and Hemophilia B: Two Separate Diseases With the Same Clinical Manifestations

Acute trauma or spontaneous hemorrhage

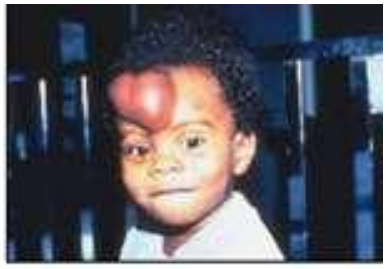
joint bleeds (hemarthroses)

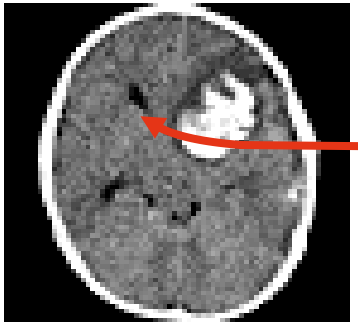






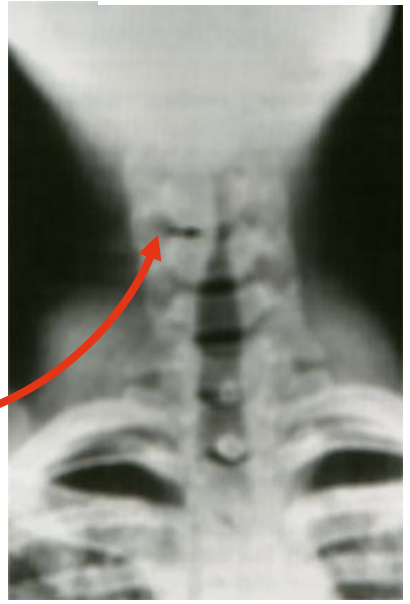
soft tissue bleeds





closed space bleeds- major mortality

- intracranial
- retroperitoneal
- retropharyngeal



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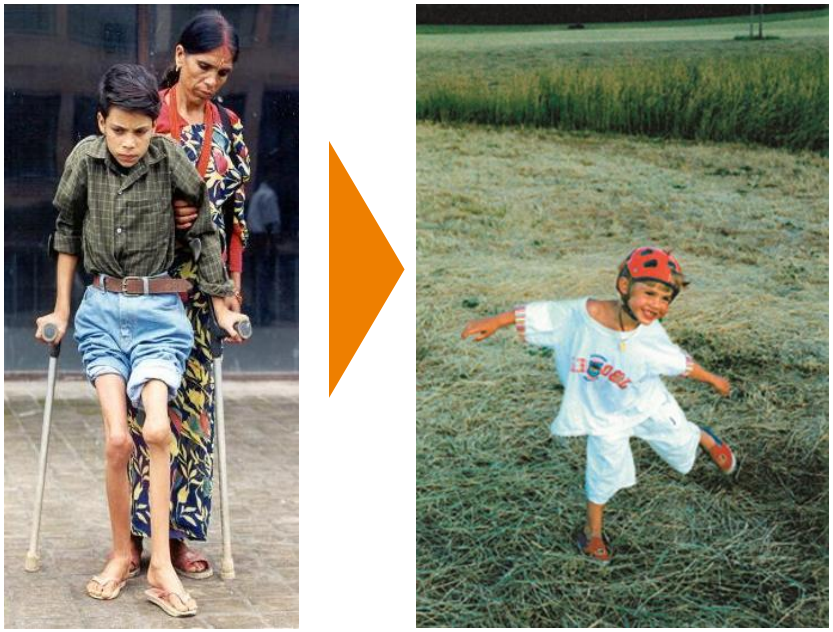
Hemophilia Therapies:

- Intravenous administration
- On-demand
  - FVIII or FIX infusions to stop bleeding episodes
- Regular prophylaxis
  - Regular infusions to maintain a minimum FVIII or FIX level to avoid bleeds
  - 2-4 infusions per week due to short half-life
- Treatment by
  - Family, health-care providers or self administration
  - Treatment at home starting at the age > 2

Benefits of Prophylaxis

- Reduction in bleeding frequency
- Preservation of joint structure in young patients
- May reduce;
  - other morbidities (e.g. ICH)
  - risk of inhibitor formation when started early
- May improve quality of life and productivity and reduce healthcare utilization



Prophylaxis with Short-Acting Factors has Significant Hurdles

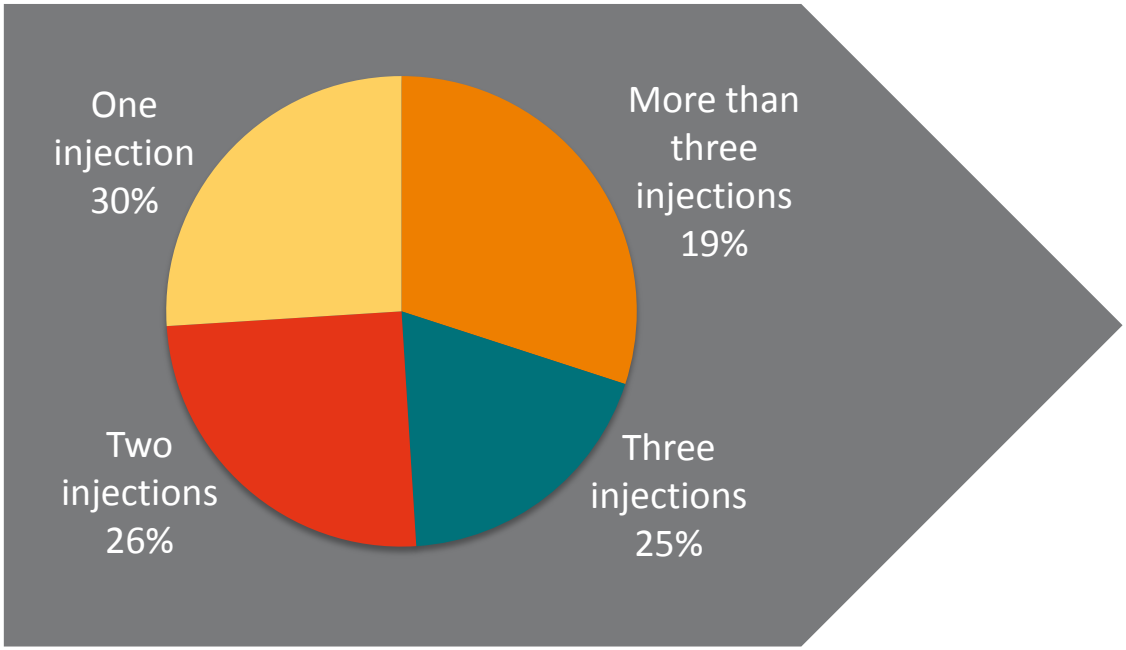
- Clotting factors have short half-lives in circulation
  - rFVIII has a biological half-life of ~12 h
  - rFIX has a biological half-life of ~18h
- Prophylaxis requires intravenous injections as often as every other day
  - ~150-180 (or more) i.v. infusions FVIII per year
  - ~110 i.v. injections FIX per year

Prophylaxis with a Longer-Lasting Factor Products May Provide Several Advantages

- Allow reduced injection frequency;
  - Goal is to achieve substantial reduction (by approximately 50-100/year)
- Improve adherence to prophylaxis
- Avoid need for central catheter implantation
- Reduce total factor consumption
- Increase protection with potential for fewer bleeding episodes
- Increase compliance

Long-Lasting Products Have Potential to Improve Protection in On-Demand Treated Patients

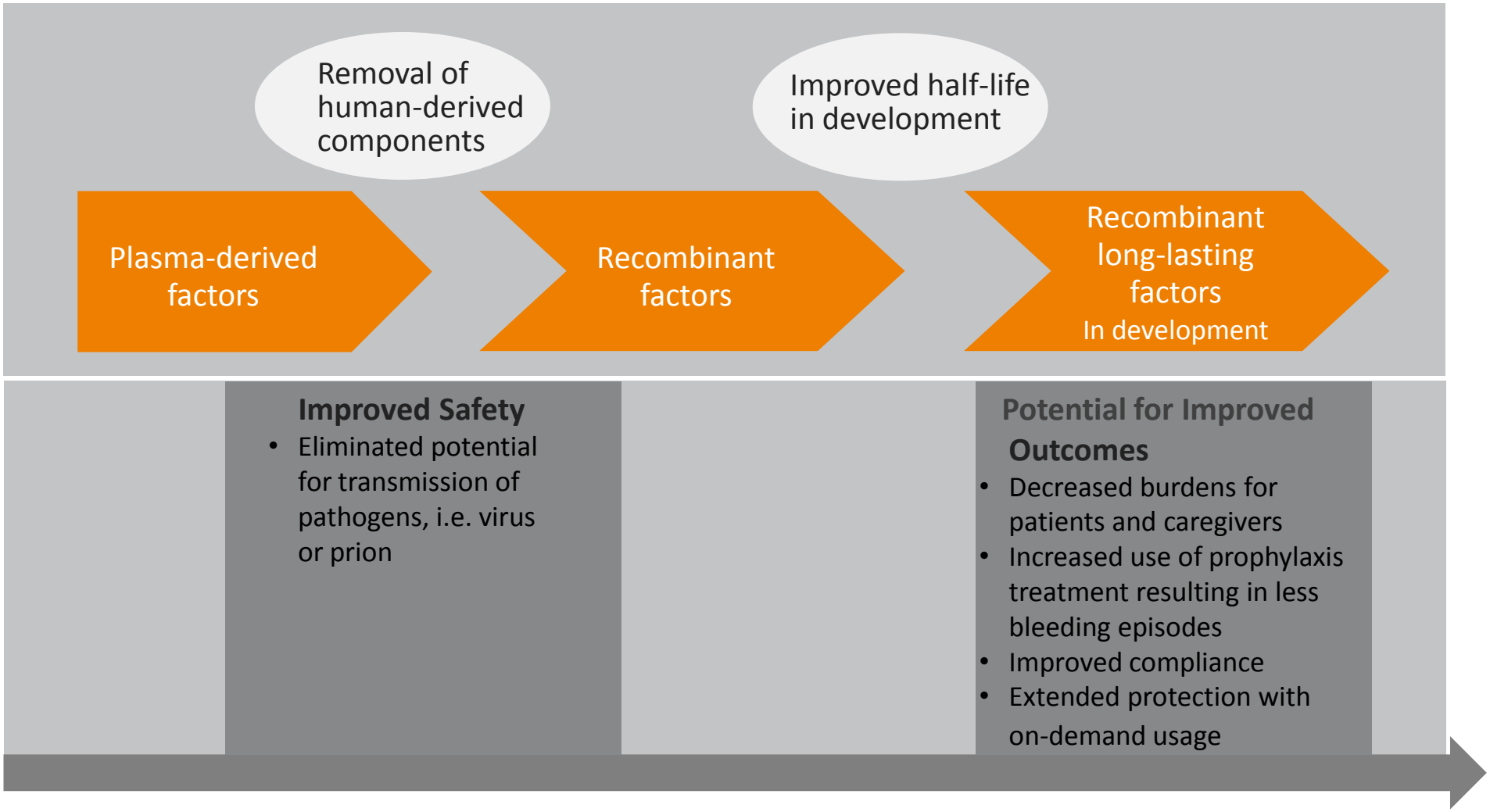
No. of injections given when bleedings occur.



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

Sobi – Factor VIII and vWF market study 2010; UK, Ger, Fr, IT, Sp, Bel, Swe

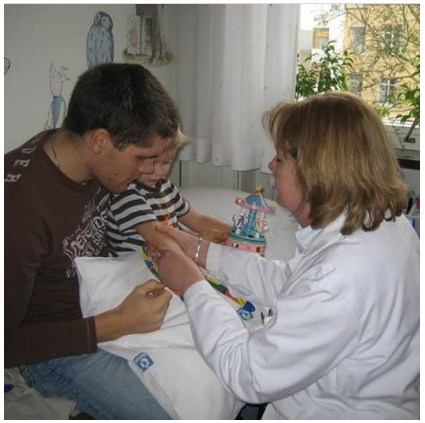
Long-Lasting Products – the Next Treatment Advance for Hemophilia



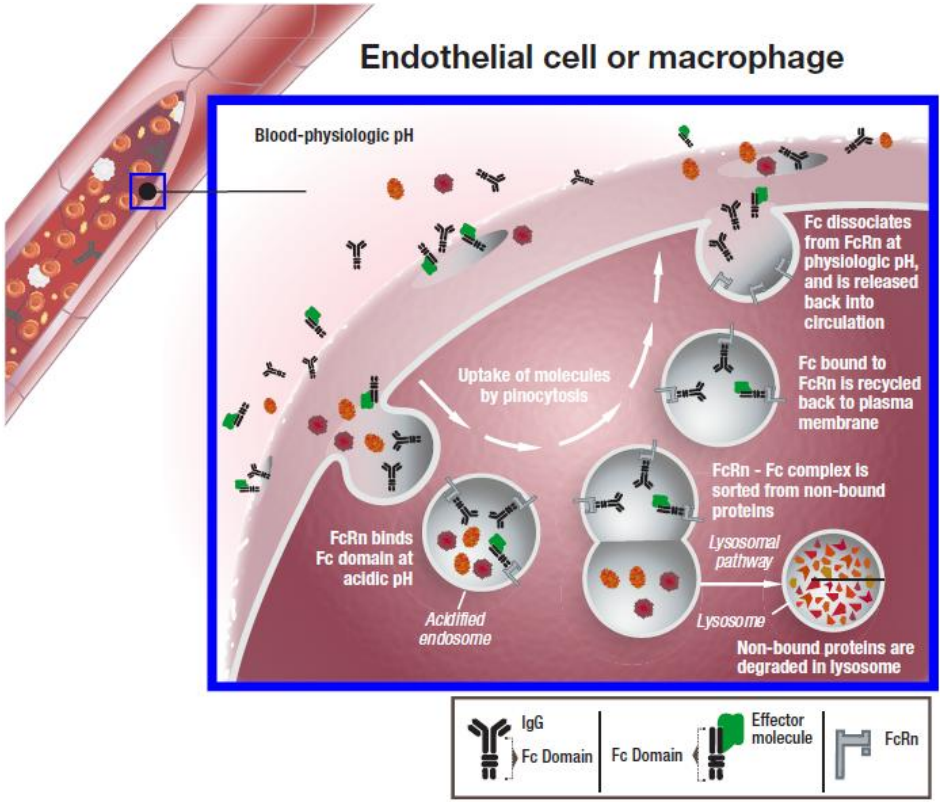
Unmet Medical Needs in Hemophilia

-Two Fc Projects rFVIIIFc and rFIXFc

Glenn Pierce, MD, PhD, SVP and CMO Hemophilia R&D at Biogen Idec



FcRn Recycling – a Natural Pathway for Prolonged $t_{1/2}$



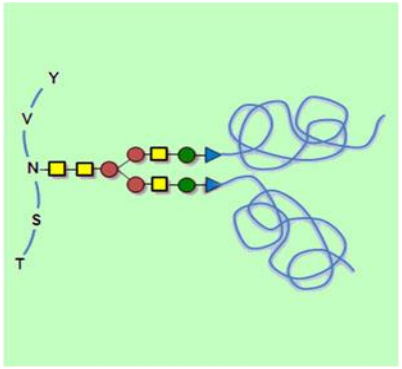
- FcRn is responsible for the long circulating $t_{1/2}$ life of Fc-containing proteins
- FcRn recycles Fc-containing proteins to cell surface, avoiding lysosomal degradation
- Immunoglobulins (antibodies) utilize this pathway to circulate for a prolonged time

99

R&D for Longer Half-life of FVIII and FIX

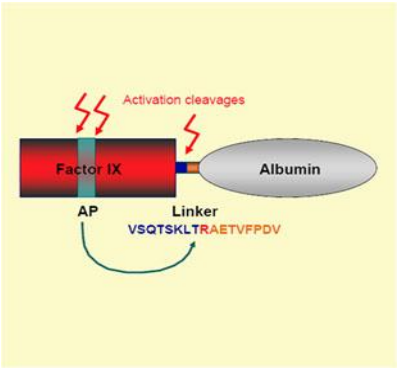
FIX

Glyco-pegylated FIX



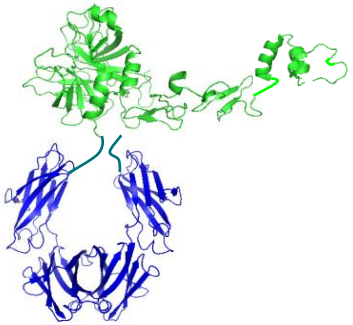
Phase 3 Clinical

FIX albumin fusion



Phase 1 Clinical

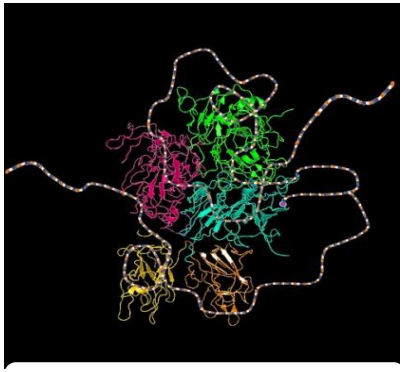
FIX Fc fusion



Phase 3 Clinical

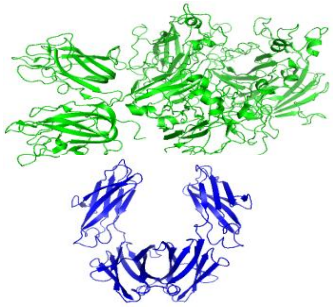
FVIII

(Glyco)Pegylated FVIII



Phase 3 Clinical

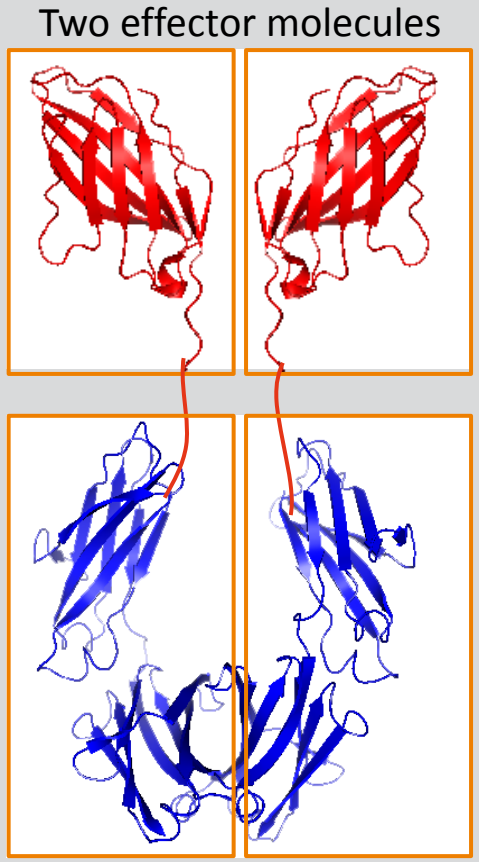
FVIII Fc fusion



Phase 3 Clinical

Traditional Fc Fusion Proteins are Dimeric

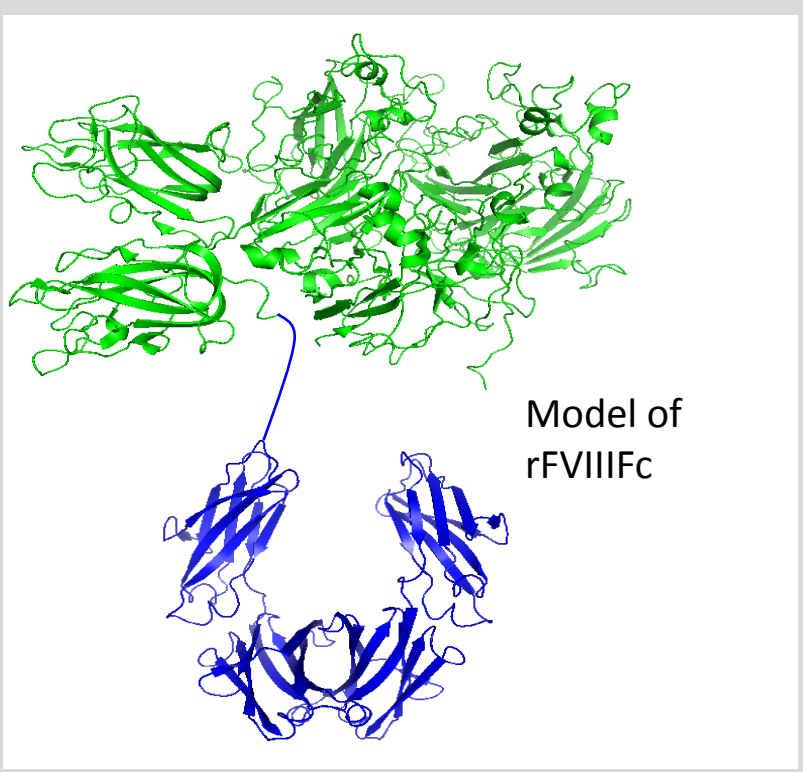
Model of Orencia

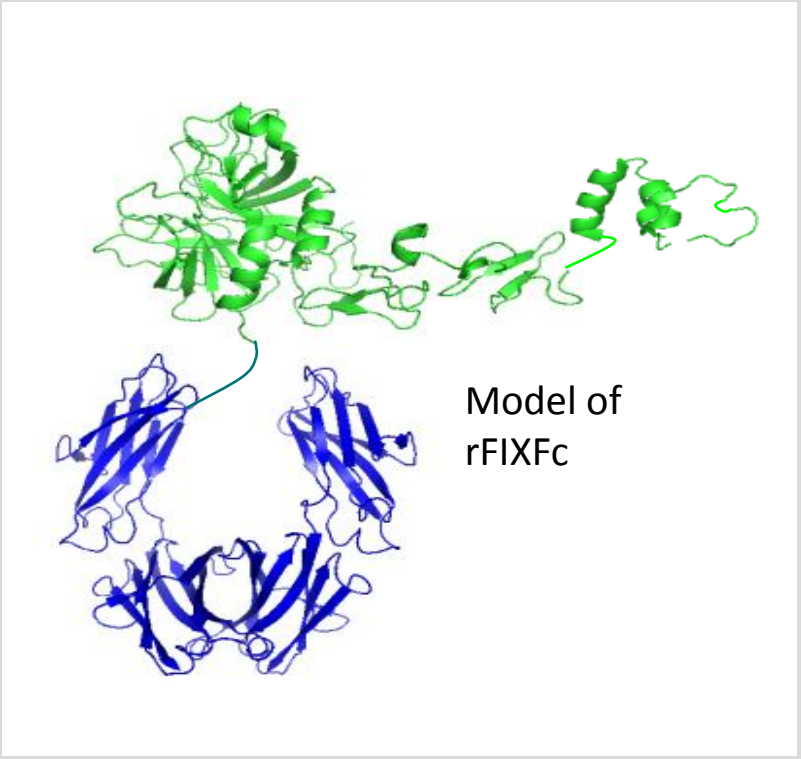


Fc fusion technology has been utilized in approved products for over a decade

- Enbrel® (etanercept)
- Orencia® (abatacept)
- Nplate® (romiplostim)
- Arcalyst® (rilonacept)
- Amevive® (alefacept)

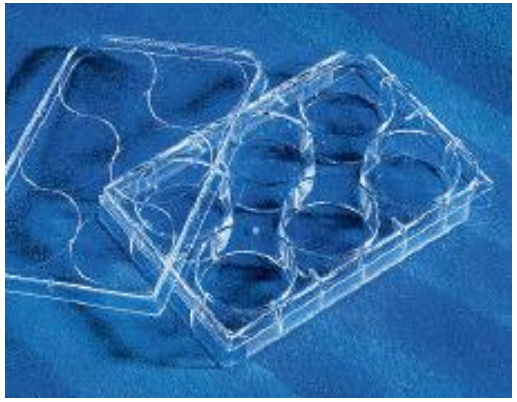
Proprietary **Monomer Technology** Applied to rFVIIIFc & rFIXFc





- **rFVIIIFc:** Single B-domain-deleted rFVIII fused to dimeric Fc region of human IgG1
- **rFIXFc:** Single FIX fused to dimeric Fc region of human IgG1

rFIXFc- Commercial Scale Production in Place Building on Sobi Process Development Work



Cell culture (Human cell line)

Scale-up in Bioreactor

Purification

Formulation and Fill

Pharmaceutical Grade rFIXFc

- Biochemical characterization
- Preclinical efficacy and safety
- Clinical studies

Cell bank

Two Diseases: Two Programs

	rFIXFc	rFVIIIFc
Phase I/II	Completed	Completed
Phase III, Pivotal Studies	B-LONG	A-LONG
No of Patients to be included	105	150
Start Date	December 2009	November 2010
Data Read Out	H2:12	H2:12
Pediatric Studies in Previously Treated Patients Starting	H1:12	H1:12
Orphan Drug Designation	Yes (USA, EU)	Yes (USA, EU)
Fast Track	USA	USA

US and EU Regulatory Requirements

USA

- Specific guidelines have not been published. Development plans have been developed in consultation with the agency
- Pediatric data is not required for registration in the adult population.

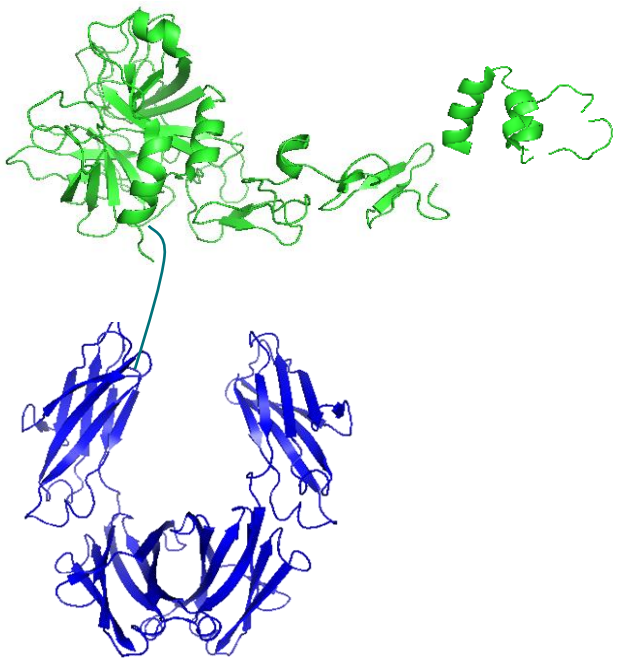
EU

- Guidelines state pediatric trials must be completed before filing

No of Patients required		
	FVIII	FIX
Previously Tx Pts ≥12	50	20
Previously Tx Peds 6-<12*	25	10
Previously Tx Peds <6	25	10
PUPs Post marketing commitment		

*EU Guidelines – FIX Ped < 12 to start after 10 patient & 50EDs
FVIII Ped>12 to start after 20 patients and 50 EDs

Recombinant FIXFc



Phase I/II trial: rFIXFc

Improved PK of rFIXFc Compared to Historical Data for BeneFIX®

14 PTPs
with severe hemophilia B

Dose Escalation study
6 doses 1-100 IU/kg

Global Study
USA, Hong Kong
7 Centers

PK parameter Elimination $T_{½}$ (hours)

rFIXFc n=11 → mean 57 h (42–75 h)

*BeneFIX® n=56 → mean 19 h (11–36 h)

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

*Summary of product characteristics of BeneFIX® (Nov 18, 2009)

Blood 2011 blood-2011-07-367003; published ahead of print November 22, 2011, doi:10.1182/blood-2011-07-367003

Phase I/IIa Study Results

- There were no drug-related serious adverse events
- Dysguesia (abnormal taste in the mouth; n=1) and headache (on the dosing day; n=1) were reported
- No inhibitor or anti-rFIXFc antibody formation after single dose
- No allergic reaction
- Pharmacokinetic results of rFIXFc demonstrated
  - Dose linearity from 25 to 100 IU/kg
  - ~3-fold prolonged half-life compared to historical BeneFIX® data

Phase III Pivotal Study for FIXFc : 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

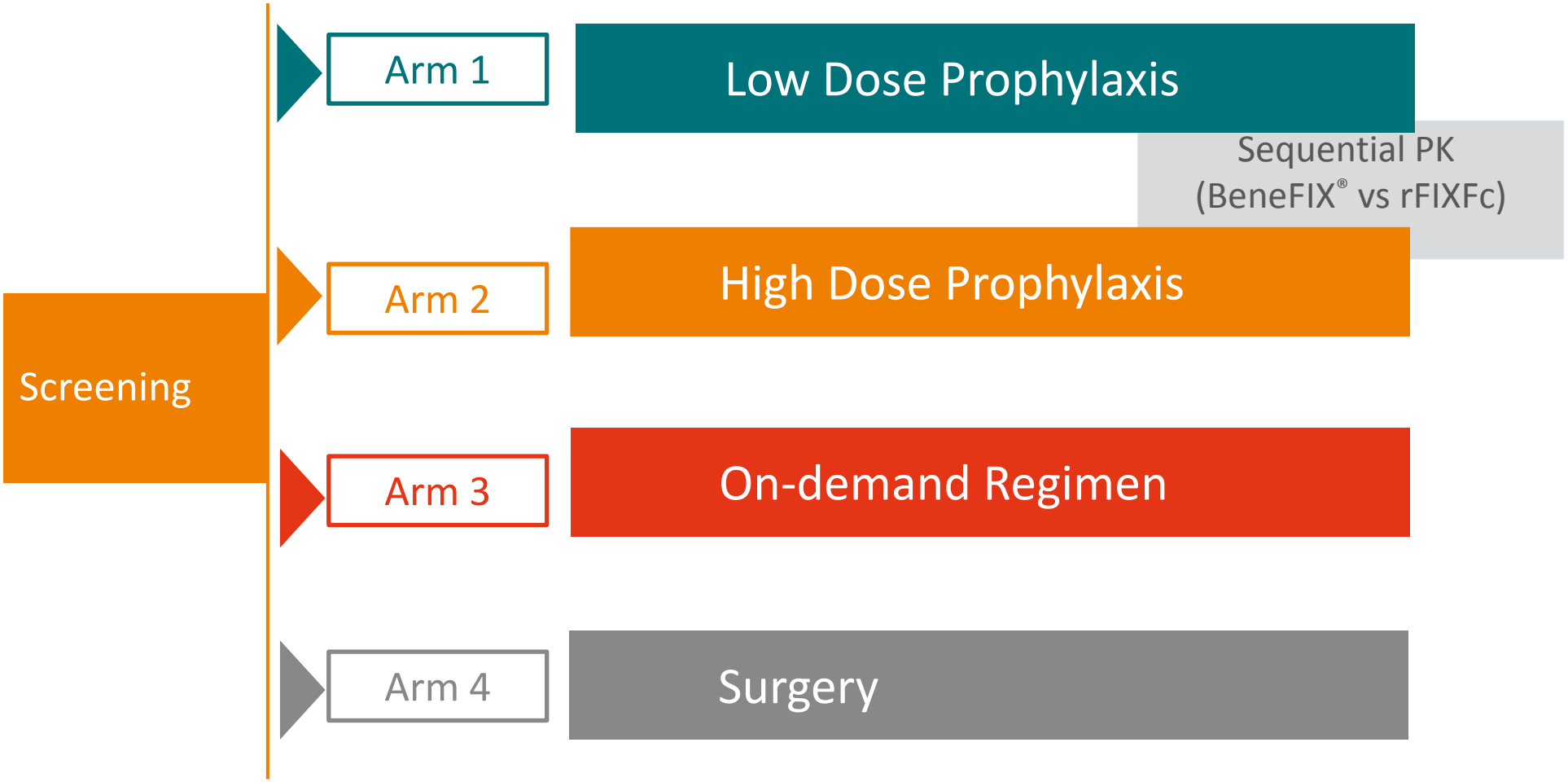
Enrolling sites: ~20 Countries ~75 Centers

Sample Size: ~105 subjects age 12 or older

Sponsor: Biogen Idec Hemophilia

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

B-LONG Addressing both On Demand and Prophylactic Treatment



rFIXFc "Kids B-LONG" Global Pediatric Study in Patients < 12 Years Starting in H1 2012

Primary Outcome Measures:

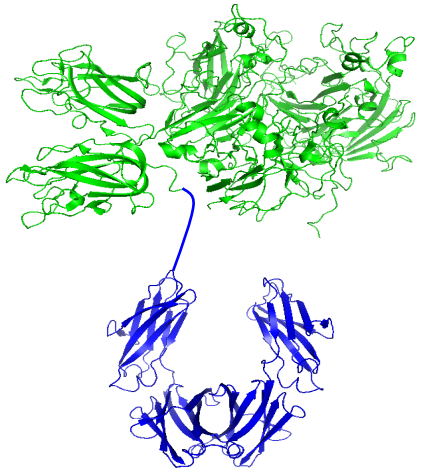
- Frequency of inhibitor development

Secondary Outcome Measures:

- Number of annualized bleeding episodes
- Assessments of response to treatment with rFIXFc for bleeding episodes

Screening → Arm 1 → Prophylaxis regimen n=26

Recombinant FVIIIFc



Phase I/II Trial: rFVIIIFc

Improved PK of rFVIIIFc Compared to Advate®

16 PTPs
with severe hemophilia A

Comparative PK evaluation
In 15 patients vs Advate ®

Global Study
USA, Israel, Hong Kong
6 Centers

PK parameter Elimination $T_{½}$ (hours)

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 subjects had a longer half life with rFVIIIFc than Advate®

15/16 PTPs were included for PK analysis (1 subject did not complete PK profiling)

Submitted, Blood 2011

Phase I/IIa Study Results

- No drug-related serious adverse events
- Most adverse events were unrelated to study drug †
- One drug-related AE: dysgeusia (abnormal taste in the mouth)
- No inhibitor or anti-rFVIIIFc antibody formation after single dose
- Pharmacokinetic results of rFVIIIFc demonstrated
  - Dose linearity from 25 to 65 IU/kg
  - ~1.5-1.75-fold prolonged half-life

* 15/16 PTPs were included for PK analysis (1 subject did not complete PK profiling)
† Adverse events were observed in 11 out of 16 patients
Submitted, Blood 2011

Phase III Pivotal Study: 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

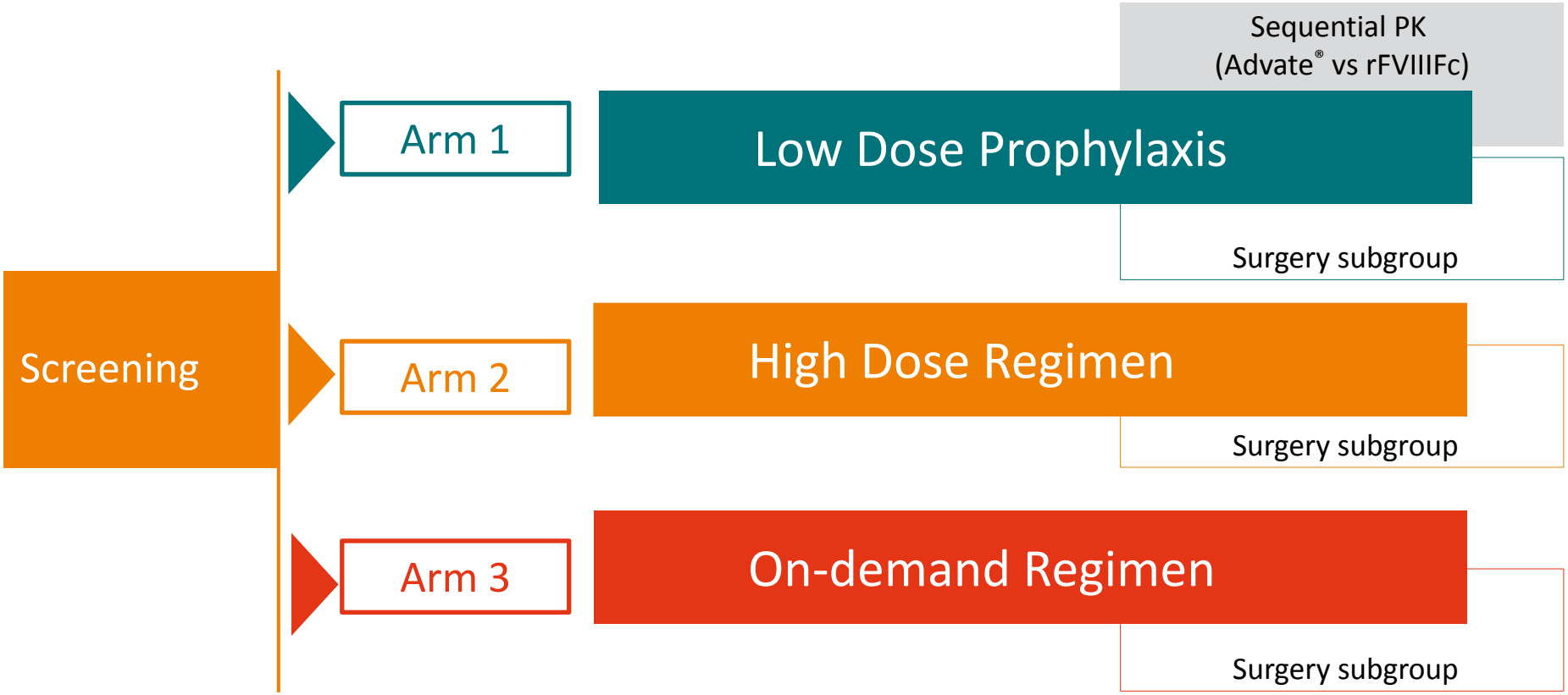
Enrolling Sites: ~25 Countries ~90 Centers

Sample Size: ~150 subjects age 12 or older

Sponsor: Biogen Idec Hemophilia

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

A-LONG Study Addresses Both On Demand and Prophylactic Treatment



rFVIIIFc "Kids A-LONG" Global Pediatric Study in Patients < 12 Years Starting in H1 2012

Primary Outcome Measures:

- Frequency of inhibitor development

Secondary Outcome Measures:

- Number of annualized bleeding episodes
- Assessments of response to treatment with rFVIIIFc for bleeding episodes

Longer Half-Life of FVIII and FIX: Sobi/Biogen Idec Ahead of Competition

		Phase 1 (Clinical trials.gov)	Phase 3 (Clinical trials.gov)
FIX	Sobi/Biogen Idec (rFIXFc)	Completed	Start date: Dec.2009
	Novo Nordisk (NN7999)	Completed	Start date: April 2011 Surgery study not yet recruiting
	CSL Behring (NCT01233440)	Open not recruiting	Not posted
FVIII	Sobi/Biogen Idec (rFVIIIFc)	Completed	Start date: Nov.2010
	Novo Nordisk (NN7088)	Completed	Not posted
	Bayer (94-9027)	Completed	Not posted

Source: clinicaltrials.gov (posting prior to start required for FDA filing and publication)

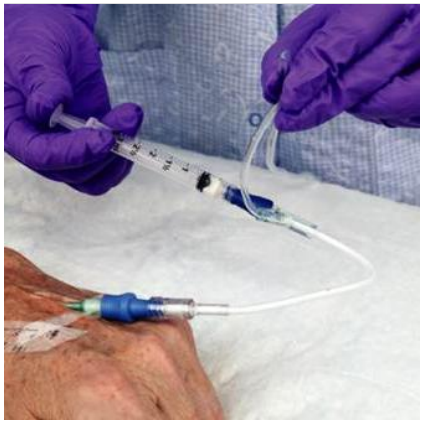
Sobi and Biogen Idec Leading the Development of Long Lasting Coagulation Factors

Summary

- Long-lasting coagulation factors are a highly anticipated development
- rFIXFc and rFVIIIFc are ahead of competition
- The Fc technology takes advantage of a natural pathway in the body to prolong half life
- Robust, proven technology and manufacturing
- Upcoming Milestones
  - Initiation of KIDS B-LONG 1H2012
  - Initiation of KIDS A-LONG 1H2012
  - A-LONG and B-LONG Data Read Out 2H2012

The Hemophilia Market

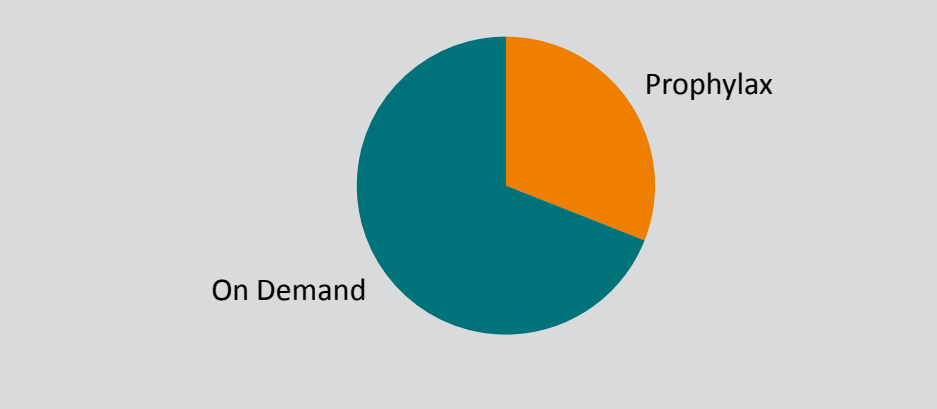
Helena Rudberg M.Pharm.Sci.
Global Director Hemophilia and Hematology, Sobi




Hemophilia is a $3.4B USD Market in Sobi Territory

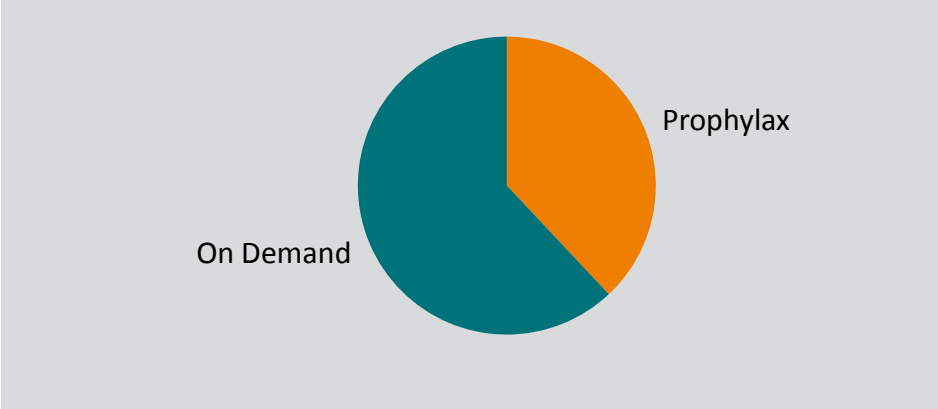
Hemophilia A

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



Hemophilia B

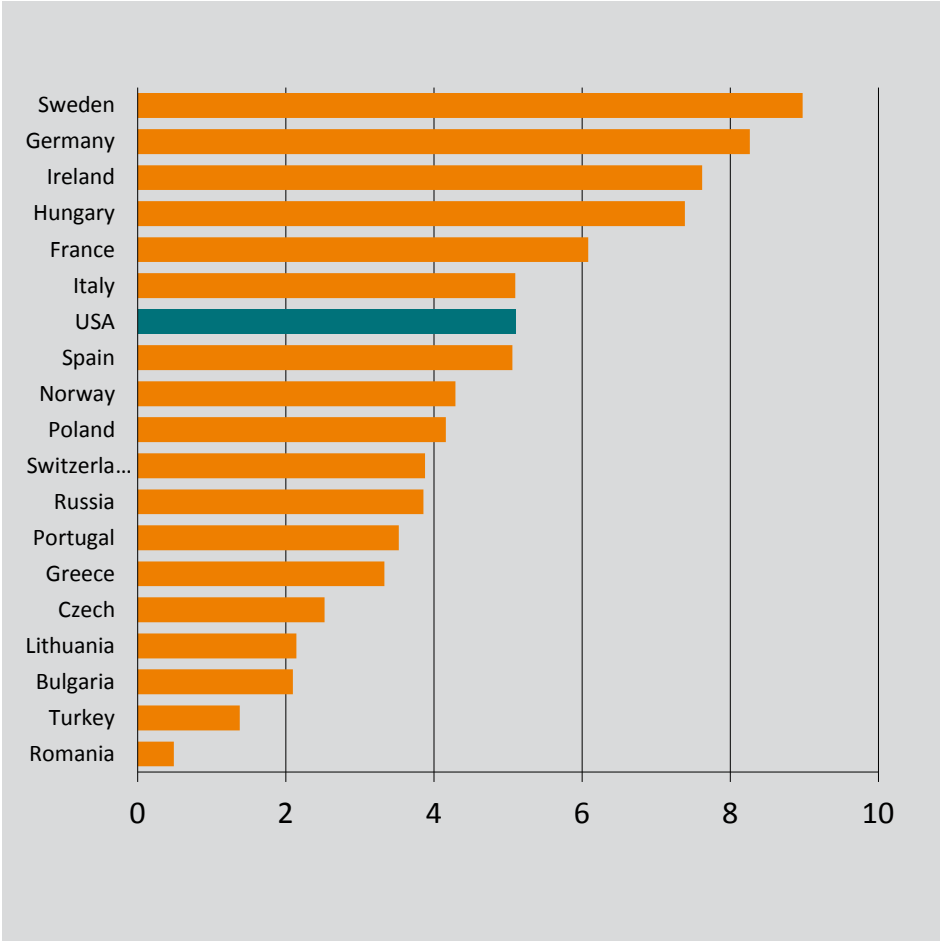
- Europe 380 MUSD
  - 44% of global $ sales
  - >10 Brands
  - ~55 % recombinant
- ~ 4000 patients on regular treatment



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

Factor Utilization is High in Sobi Territories

Per Capita consumption of FVIII (IU/Inhab.)

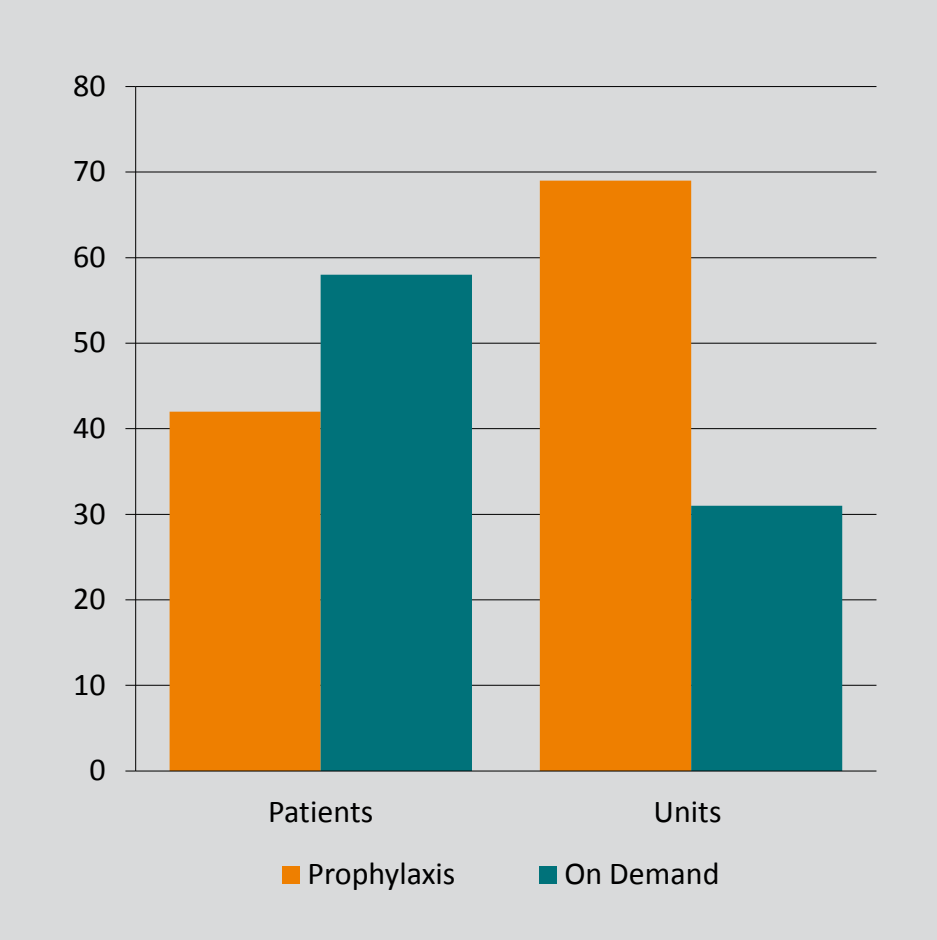


- Highly developed Centers of Excellence
- Early recognition of the value of prophylaxis
  - "Not accepting a bleed"
- Strong Patient Advocacy groups

Source: WFH 2009

Offering Value in the Prophylaxis and On-Demand Segments

Prophylaxis vs On Demand treatment in EU

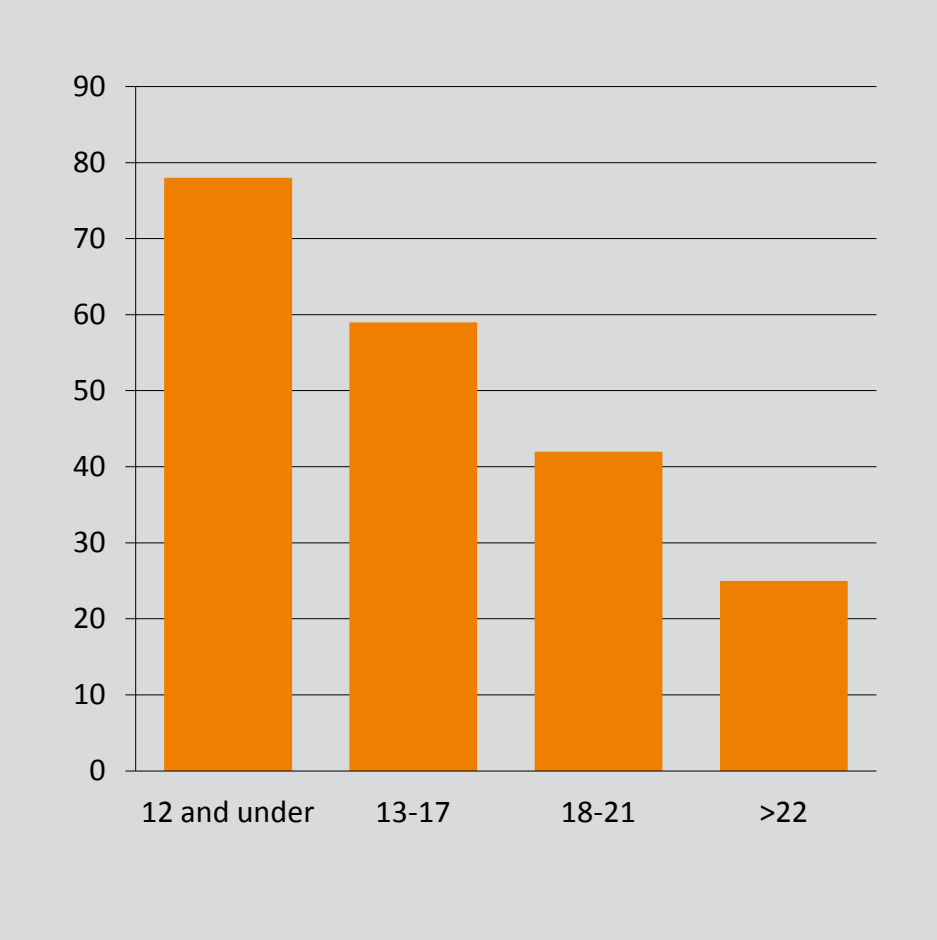


- Long-lasting products in prophylaxis : Potential value
  - Reducing 50-100 injections/year
  - Improved protection
  - Improved Quality of life
- Long-lasting products in on demand treatment: Potential value
  - Improved protection
  - Reduced number of injections
  - Reduced worries
  - Reduced sick-days
- Our development programs address both segments

Source: MRB 2008, WFH 2009, UKHCDO 2011, Internal estimates

Partnering to Address the Needs of Prophylaxis Patients

Prophylactic treatment in different age groups

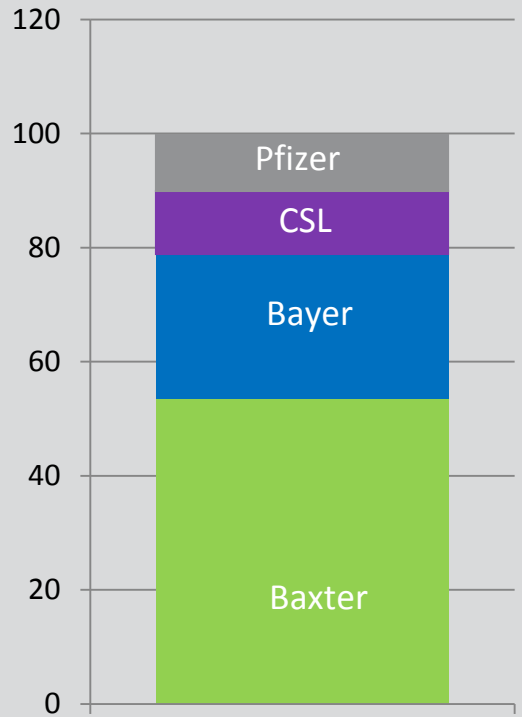


- Prophylaxis growing in EU
  - Well established in young children
- Continuing ahead of USA
- Focus on developing support for prophylaxis also in the Adult and Elderly populations

Source: 2008 Primary Quantitative Research

Differentiated Products Can Overcome Barriers to Entry

rFVIII MS 2010

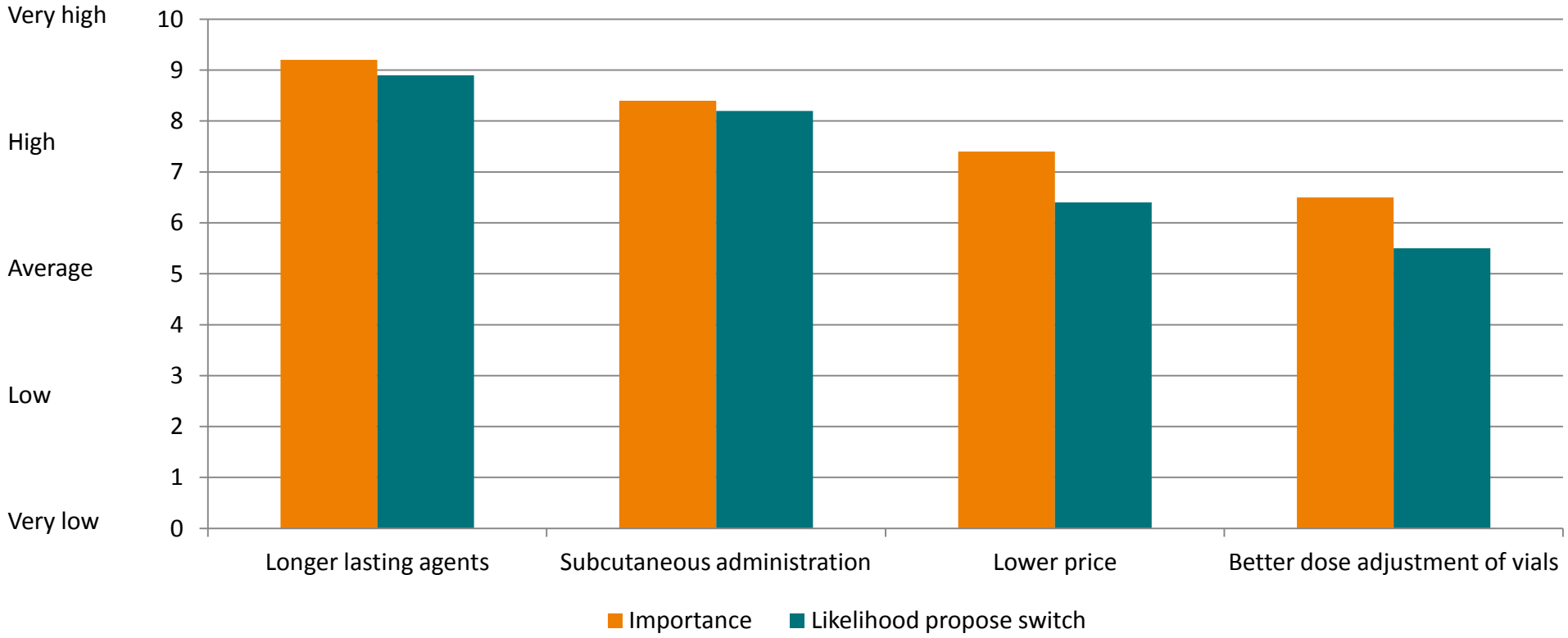


- High barriers for non-differentiated products
  - Low switching rates between comparable products
  - Well-established relationships between healthcare and industry
  - Small patient population and difficult trials to conduct
- But truly differentiated products provide an opportunity:
  - rFIX (BeneFIX®) replacing plasma-derived products
  - rFVIIa (NovoSeven®) replacing alternative treatments

Source: Company Annual Reports,, Internal analysis,

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

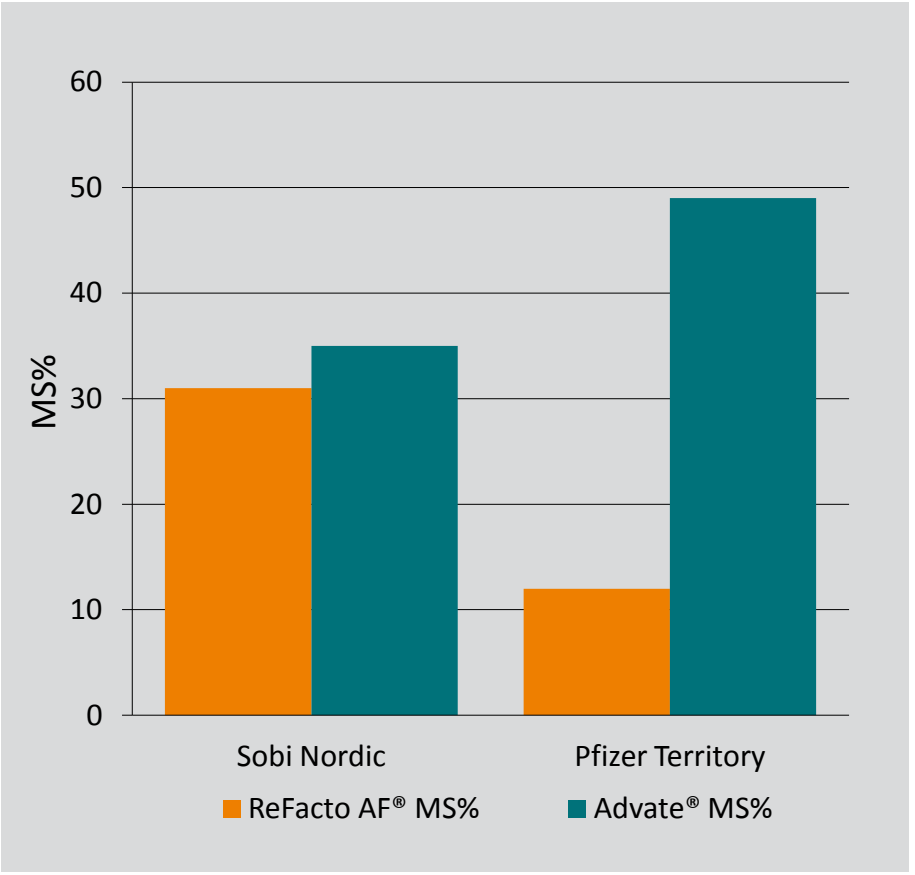
Rank the importance of the following development of coagulation factors and the likelihood to propose a switch (on a scale from 1 to 10)



Sobi has Significant Experience in the Market

ReFacto

Sobi contribution to ReFacto AF®Sales Estimated MS% 2010

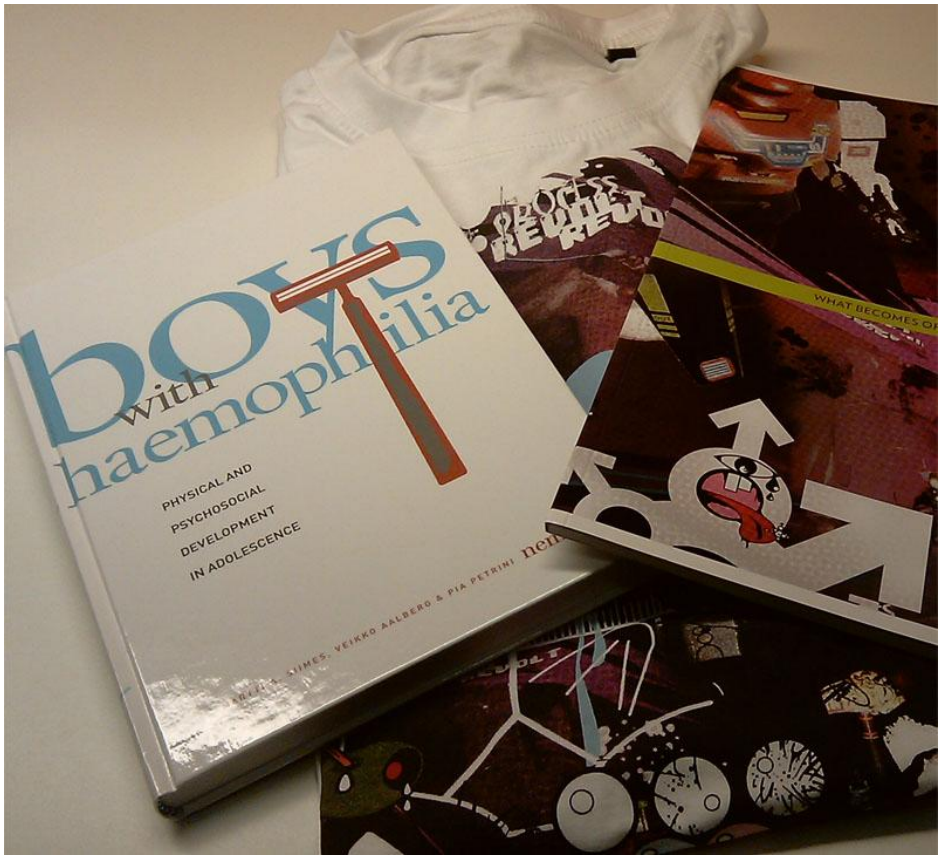


Source: Analyst report internal analysis wholesaler data

sobi

Sobi is Engaging the Hemophilia Community Today

- Supporting education and improved management of hemophilia
  - Improved understanding of the teenagers
  - The Elderly and Co-Morbidities
- Stimulating the scientific dialogue
  - Targeted Symposia and Workshops
- Supporting the Hemophilia Community



Sobi in Hemophilia – Building on our Legacy

- An attractive European market approaching 3.5 Bn USD
- Long-lasting coagulation factors are a highly desired development
- The two Fc programmes address both on-demand and prophylactic therapy
- rFIXFc and rFVIIIFc are ahead of the competition
- Sobi establishing a relation with all customer groups

Capital Markets Day – Wrap Up

29 November 2011



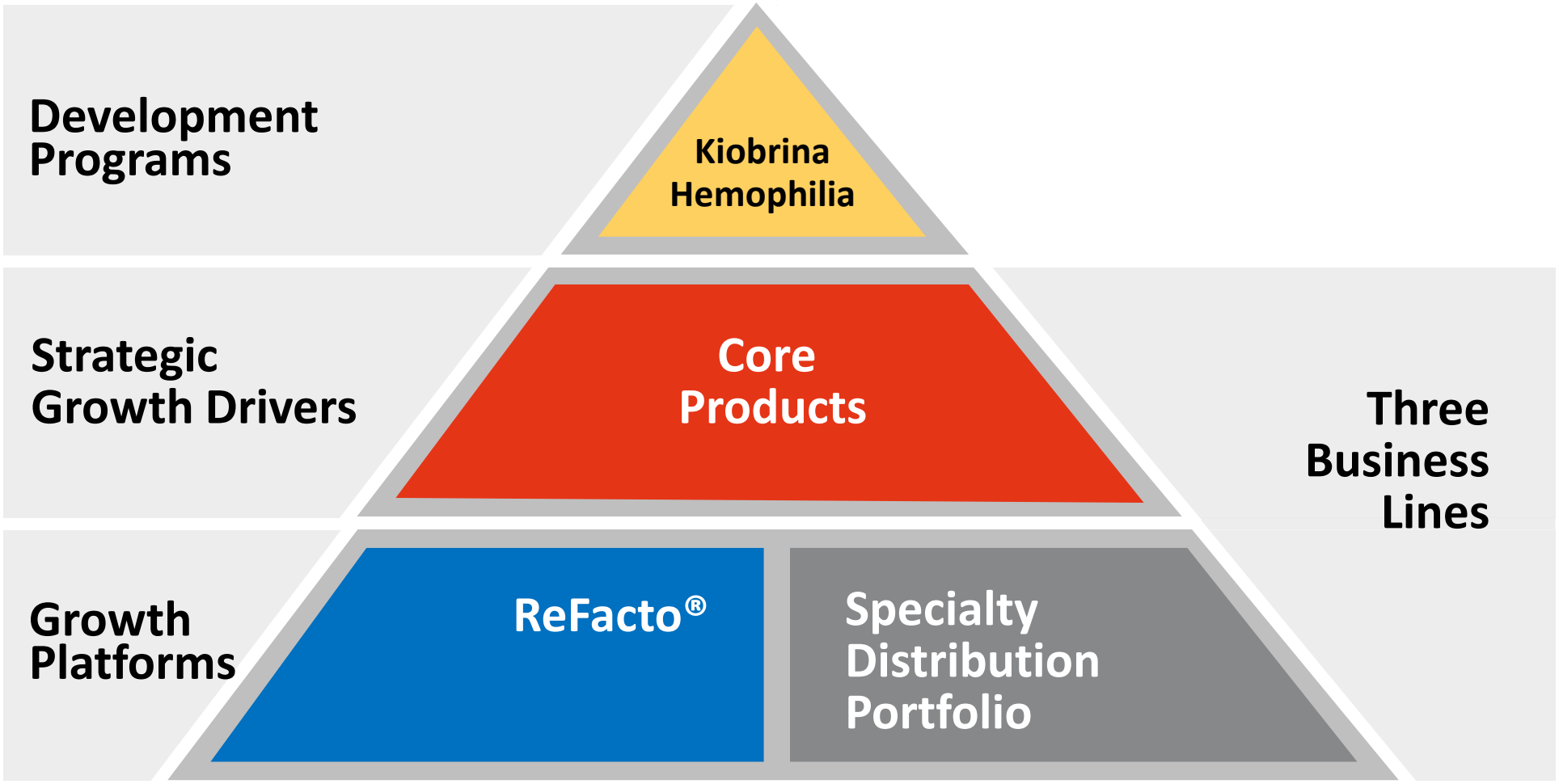
Summary

1. To achieve **positive net cash flow and profitability** in our operations.

2. To efficiently commercialize **our proprietary innovative medicines** for rare disease patients globally.

Pioneer & Partner in Rare Diseases

Focus the Business on Strategic Building Blocks



Upgrading Clarity in Market Communication