Infant Bacterial Therapeutics

November 27, 2018

Staffan Strömberg

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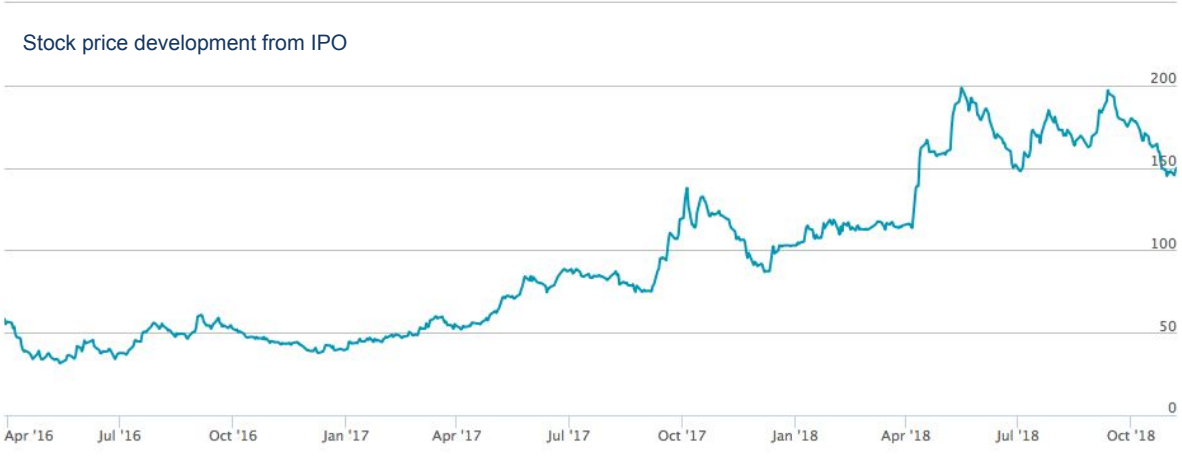
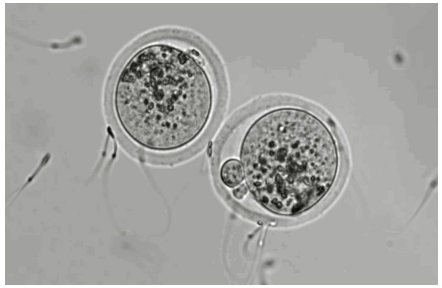
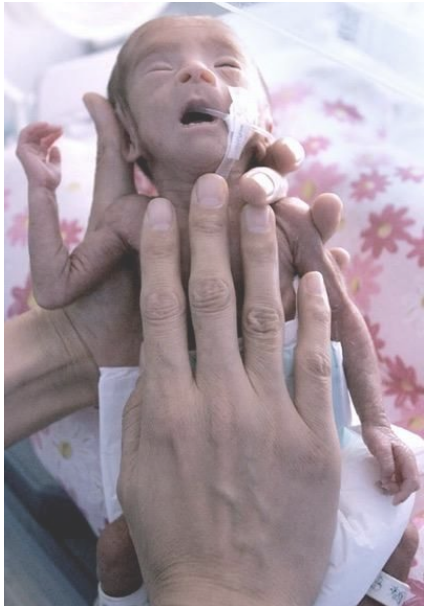
Infant Bacterial Therapeutics AB

Corporate Overview

- Founded in 2013 in Stockholm, Sweden as a subsidiary of BioGaia
- IPO in 2016 on Nasdaq First North, listing on Nasdaq Stockholm Mid-Cap from September 10, 2018
- Among top 10 institutional shareholders and specialist investors: AP4, AP3, AMF, Swedbank Robur, Sectoral
- Total capital raised: 75 MUSD
- Cash end of Q3 2018: 62 MUSD, sufficient to fund IBP-9414 development
- Initiation of Phase III clinical trial during H1 2019
- Market cap: 165 MUSD







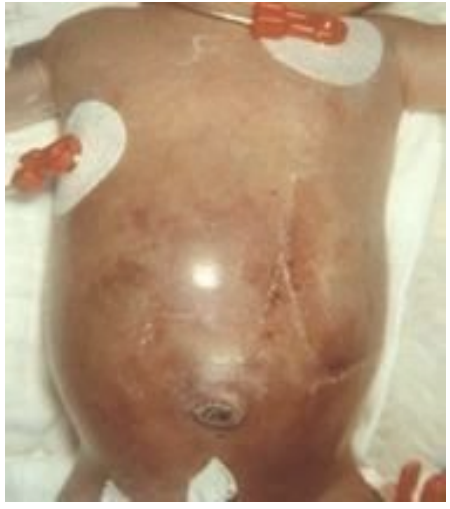

Last menstruation
Fertilisation
Antepartum or Perinatal Period
Periods
Prenatal development
First trimester
Second trimester
Third trimester
Embryogenesis
Fetal development
Week nr.
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 45 46
50% Survival chance
Viability
Childbirth on average
Birth Classication
Preterm
Term
Postmature

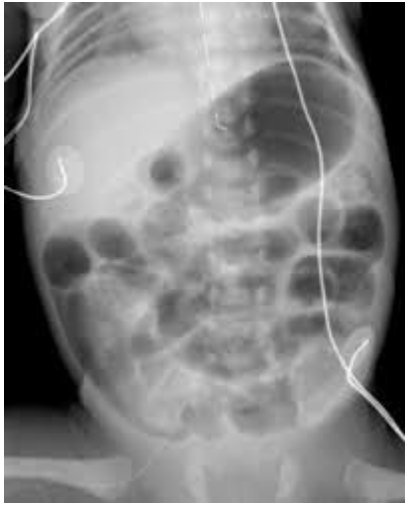
The IBT concept

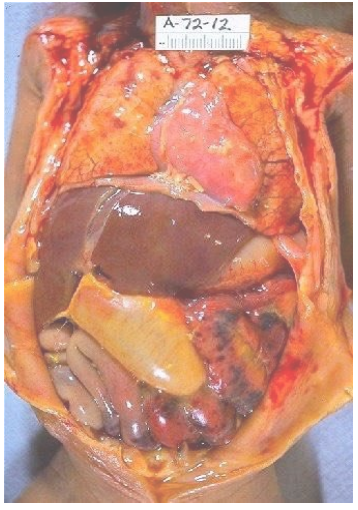
- IBT focuses on concepts of altering the human microbiome to prevent or treat diseases
- Microbiome of the newborn infant is more dynamic than that of the mature human
- Utilize co-evolved human bacterial strains derived from human breast milk
- Published proof-of-concept clinical signal engaged IBT in development

Necrotizing Enterocolitis

NEC is a deadly disease impacting the preterm infant







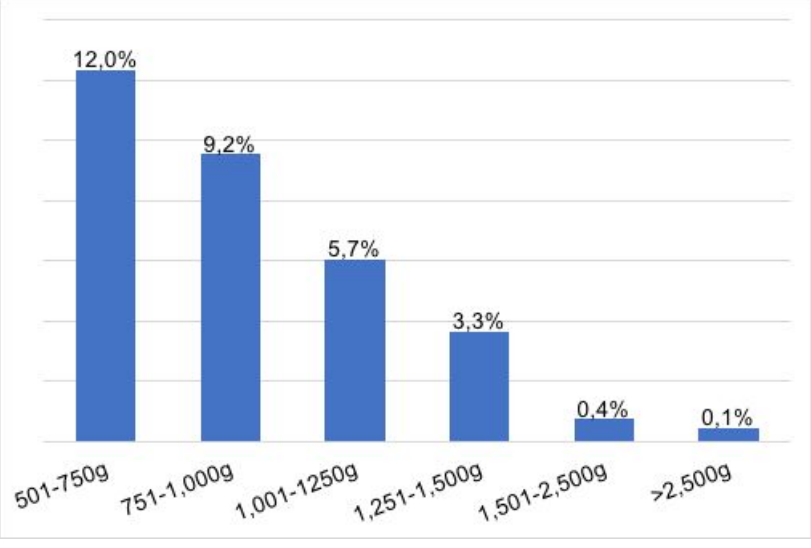
True unmet medical need

- There is no therapy available today
- 20-40% need complicated and costly surgery
- One of the leading causes of death in the NICU (neonatal intensive care unit)
- Up to 40% death rate, 1500 US and 3700 EU infants lost every year

NEC – a devastating disease

The smaller the premature infant is at birth, the more likely he/she will die

NEC incidence rate



NEC mortality rate

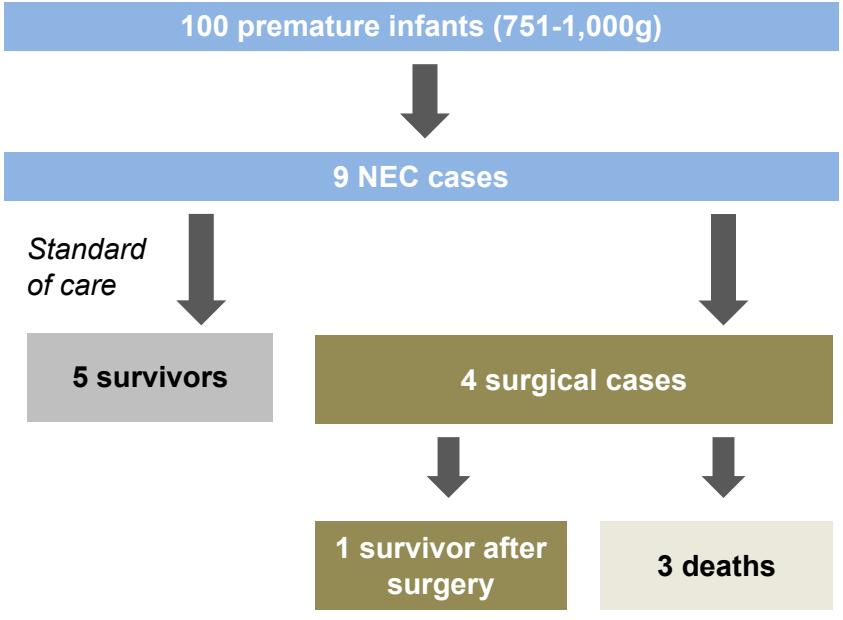
501-750g	42.0%
751-1,000g	29.4%
1,001-1250g	21.3%
1,251-1,500g	15.9%
1,501-2,500g	12,7%

Source: Shelley 2012, Bolisetty 2000, Llanos 2002, Fitzgibbons 2009, Abdullah 2010, Christensen 2010

Target population

A preventive therapy for all preterm infants at risk of NEC

Current clinical NEC progression



Target label population

Based on the expected IBP-9414 drug label, the targeted annual label population is:

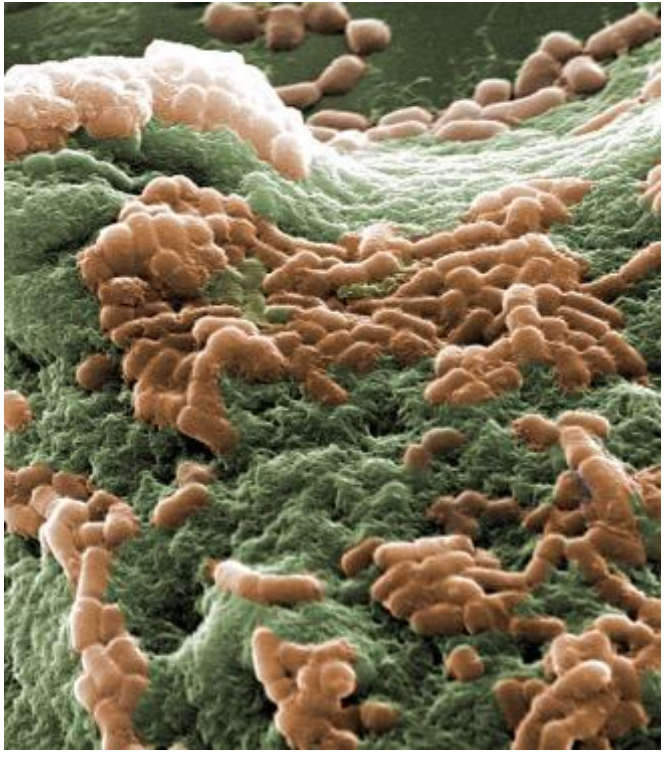
- **US:** 56,000 premature infants (≤1500 gram)
- **EU5:** 108,000 premature infants (≤ 34 weeks)

Approximately 162,000 premature infants at risk of NEC are born each year in US and EU5

Lactobacillus reuteri

Active pharmaceutical ingredient of IBP-9414

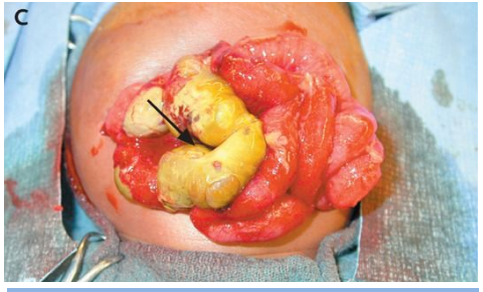
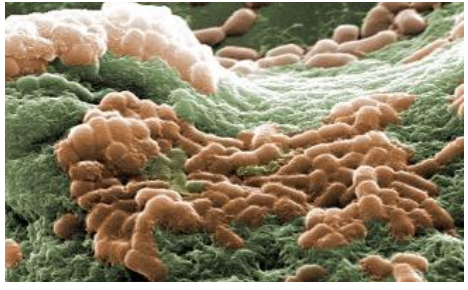
Lactobacillus reuteri present on women's breasts



Lactobacillus reuteri (orange) adhering to intestinal mucus

L. reuteri an ideal candidate for NEC

L.reuteri has strain-specific attributes which affect the NEC pathogenesis

Major processes involved in NEC	L. Reuteri strain specific benefits
	
Dysbiosis	Anti-pathogen effects
Impaired gut motility	Improvement of gut motility
Unregulated Inflammation	Anti-inflammatory effects

Source: Neu and Walker 2011
L. reuteri picture copyright: Versalovic

Clear efficacy signal from *L. reuteri*

All studies show clinically significant reduction of NEC

Study	Number of patients	Reduction in NEC incidence
Rojas et al. (2012)	▪ 750 patients	▪ 40% in the total study population ▪ 37% in infants ≤1,500g
Oncel et al. (2014)	▪ 400 patients	▪ 20% in the total study population ▪ 38% in infants ≤1,000g
Spreckels et al. (2018)	▪ 104 patients	▪ 53% in infants ≤1,000g
Hunter et al. (2012) & Dimaguila et al. (2013)	▪ 354 patients	▪ 89% in the total study population
Sanchez Alvarado (2017)	▪ 225 patients	▪ 64% in infants ≤1,500g
Rolnitsky et al. (2017)	▪ 937 patients	▪ 49% in the total study population
Jerkovic Raguz et al. (2016)	▪ 100 patients	▪ 50% in the total study population
Shadkam et al. (2015)	▪ 60 patients	▪ 82% in the total study population
Hernandez-Enriquez et al. (2016)	▪ 44 patients	▪ 92% in the total study population

L. Reuteri demonstrates clear signal on improved feeding tolerance

Premature infants are extremely difficult to feed. In most cases intravenous fluid solutions are used on these infants for nutrition supply. However, intravenous nutrition is inadequate, and IV nutrition (TPN) can also be toxic to the liver.

Improved feeding tolerance in preterm infants

Study	Number of patients	Results
Rojas et al. (2012)	■ 750 patients	■ 34% reduction in episodes of feeding intolerance (p=0.08) ■ 55% in infants ≤1500g (p=0.04)
Oncel, et al. (2014)	■ 400 patients	■ 29% reduction in episodes of feeding intolerance (p=0.015)
Oncel et al. (2015)	■ 300 patients	■ 36% reduction in episodes of feeding intolerance (p=0.004)
Rolnitsky et al. (2018)	■ 937 patients	■ 52% reduction in episodes of feeding intolerance (p<0.01)

Network of KOLs

IBT has developed IBP-9414 program with deep considerations of KOLs experience and clinical practice

Some of the external participants

Aideen Moore, The Hospital for Sick Children, Toronto, Canada.
Alexandre Lapillonne, Necker Hospital for Sick Children, Paris, France
Andreas Repa, Medical University of Vienna, Austria
Hans van Goudoever, VU University Medical Center and Emma Children's Hospital, Amsterdam, the Netherlands
Jae Kim, University of California San Diego, CA
Josef Neu, University of Florida College of Medicine, Gainesville, FL
Kara Calkins, University of California Los Angeles School of Medicine, CA
Lawrence Moss, Nationwide Children's Hospital, Columbus, OH
Mario Rojas, University of Wake Forest University School of Medicine, NC
Mark Underwood, University of California Davis Children's Hospital, CA
Michael Caplan, North Shore Research Institute, Chicago, IL
Miguel Sáenz de Pipaon, University Hospital "La Pa", Madrid, Spain
Robert White, Memorial Hospital, South Bend MI
Teresa del Moral, University of Miami School of Medicine, FL
Thomas Abrahamsson, Linköping University Hospital, Sweden
Walter Mihatsch, Harlaching Hospital, Munich, Germany

Key Opinion Leader Meetings

- Feb 2013: Atlanta, US
- Apr 2013: New York, US
- May 2014: Vancouver, Canada
- Sep 2014: Boston, US
- May 2015: San Diego, US
- Sep 2015: Budapest, Hungary
- May 2016: Baltimore, US
- Nov 2016: Stockholm, Sweden
- Mar 2017: San Diego, US
- Dec 2017: Washington DC, US

Manufacturing Process of IBP-9414

Stringent control of manufacturing environment

Cell Bank

Fermentation

Filling and Freeze-drying

IBP-9414
powder for oral suspension

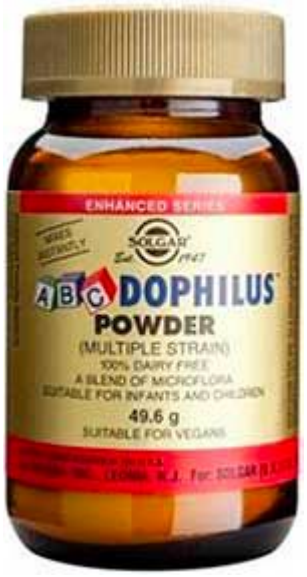
Probiotics and the Prevention of NEC

Concerns

- No FDA approved product or indication
- Limited strain-specific & combination specific testing
- Questions about effective dose
- Questions about method(s) of administration
- Questions about purity
- Risk of bacteremia
- Potential underreporting of risk

Common OTC Probiotic Products Used for NEC Prevention

The Solgar Case*

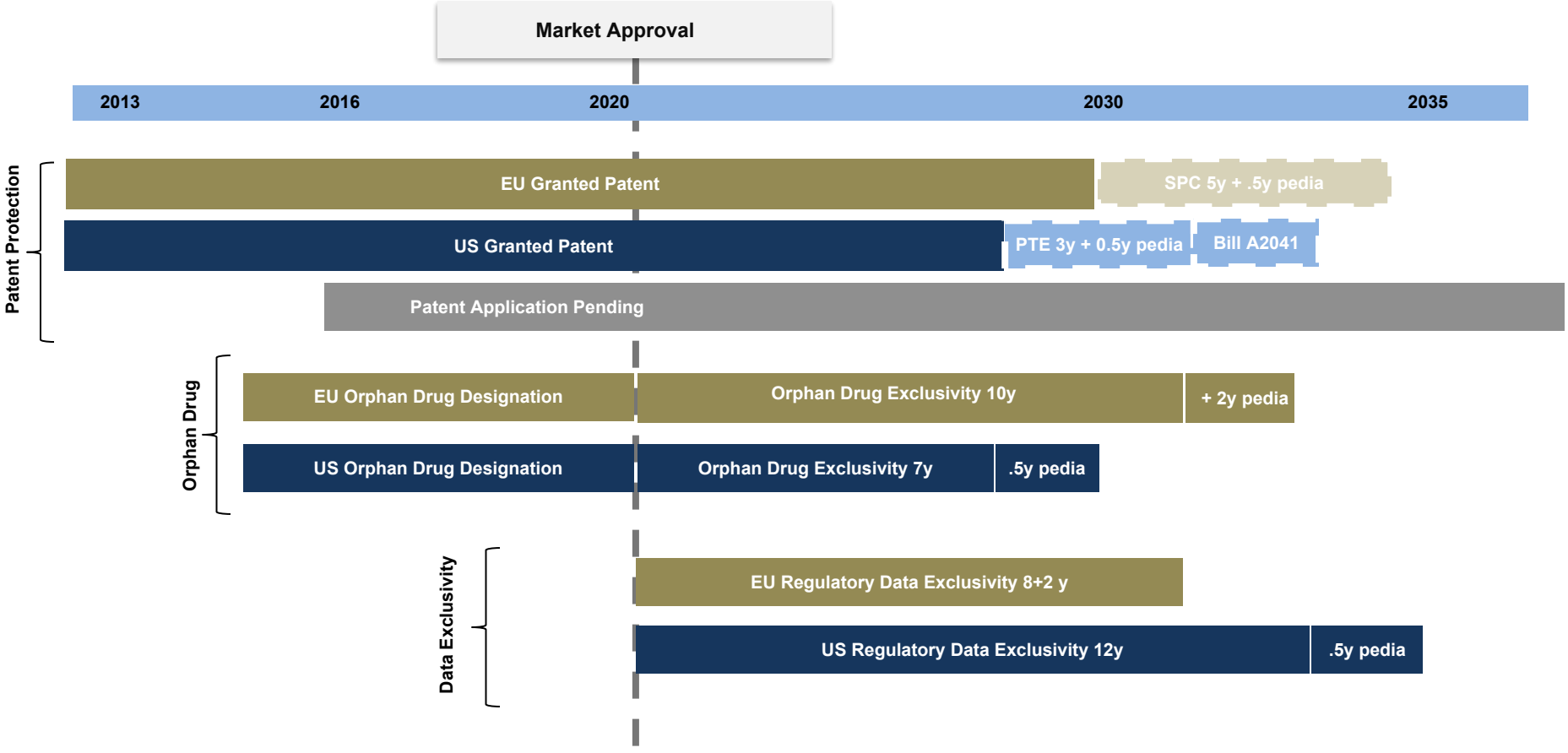


June 2016 FDA issued a guidance document demanding pharmaceutical grade products.

August 2018 FDA Commissioner Scott Gottlieb reiterated the FDAs concern about the use of dietary supplements in this vulnerable population.

IBP-9414 Market Exclusivity

Three layers of IP protection



Timelines are indicative, this slide contains forward looking statements and may be subject to change

IBP-9414's eligibility for a Priority Review Voucher

- FDA granted Rare Pediatric Disease product status to IBT for IBP-9414, which means that IBT should be awarded a priority review voucher at the time of approval
- A voucher is transferable and does not expire. 23 vouchers have been awarded as of November 2018

Known transactions as of August 2018

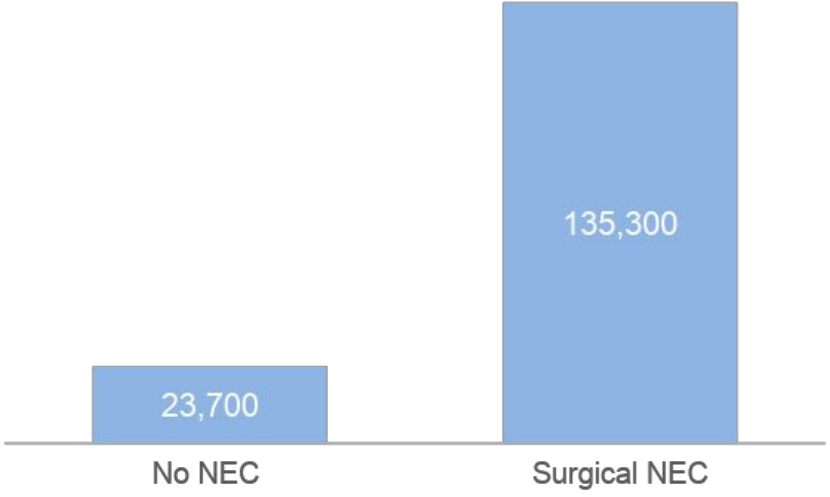
Year	Recipient	Price	Buyer
2018	SIGA	$80M	Lilly
2018	ultragenyx	$80.6M	Undisclosed
2018	Spark Therapeutics	$110M	Jazz Pharmaceuticals
2017	BIOMARIN	$125M	Undisclosed
2017	SAREPTA THERAPEUTICS	$125M	GILEAD
2017	Undisclosed	$130M	gsk ViiV Healthcare
2017	Undisclosed	$150M	TEVA Pharmaceutical Industries Ltd.
2017	ultragenyx	$130M	NOVARTIS
2016	PaxVax	$200M	GILEAD
2015	United Therapeutics Corporation	$350M	abbvie
2015	Asklepion	$245M	SANOFI
2014	BIOMARIN	$67.5M	REGENERON SANOFI
2014	Knight	$125M	GILEAD

Economic burden of NEC

NEC Economic Burden is estimated to be 20% of the total cost of initial care and USD 5 Billion spent annually on NEC in the US.

Costs continue after NICU discharge

Accumulated cost between 6-36 months



And long term costs associated with sequelae such as impaired growth, short bowel syndrome and poor neurodevelopment

Source: Ganapathy 2011, 2013

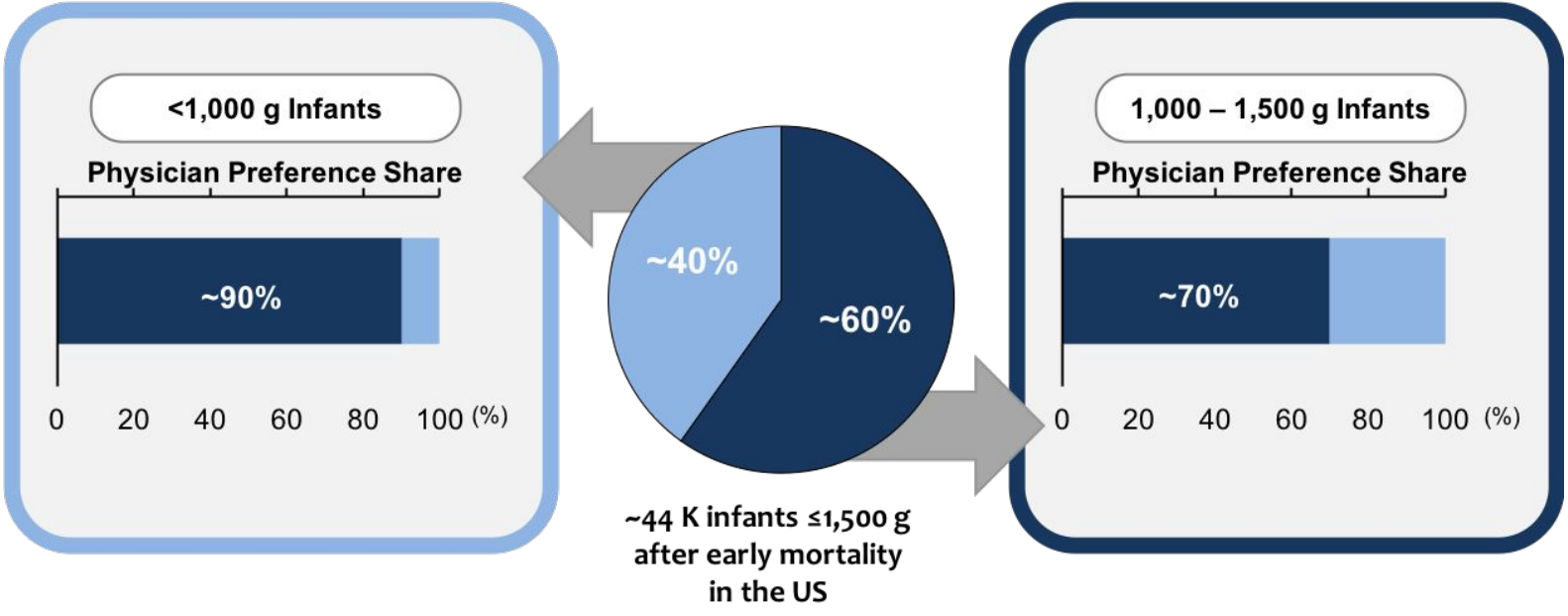
IBP-9414 Target Product Profile

For the prevention of necrotising enterocolitis

Product description	▪ Oral suspension ▪ Supplied as a freeze-dried powder in a prefilled, clear, glass vial ▪ To be reconstituted in sterile water and delivered in enteral syringe
Administration	▪ Once daily until gestational age 34 weeks ▪ Administered enterally through the nasogastric or orogastric tube
Product efficacy	▪ Demonstrates 33% reduction in the incidence of NEC compared to standard of care alone
Safety profile	▪ Well tolerated with no known side effects ▪ No increase in risk of sepsis or multi-resistance to antibiotics ▪ No known contraindications

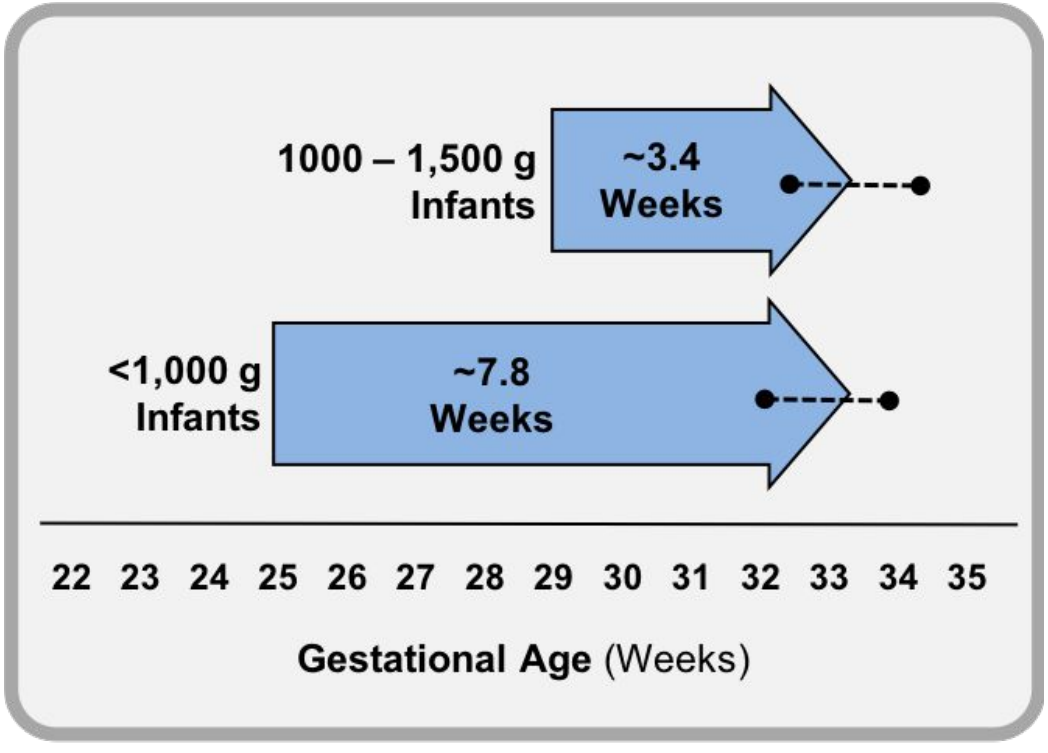
Neonatologists show high willingness to prescribe IBP-9414

Clearview US market research indicates an overall 78% physician preference share reflecting a high unmet medical need



ClearView Healthcare Partners

Treatment up to 34 weeks



●------● ***Physicians expected to halt IBP-9414 treatment once infants had reached 32 to 34 weeks postmenstrual age***

ClearView Healthcare Partners

Expected Formulary Inclusion by Institution Type

In the United States, high adoption in hospitals is anticipated in institutions which have the biggest share of premature infants



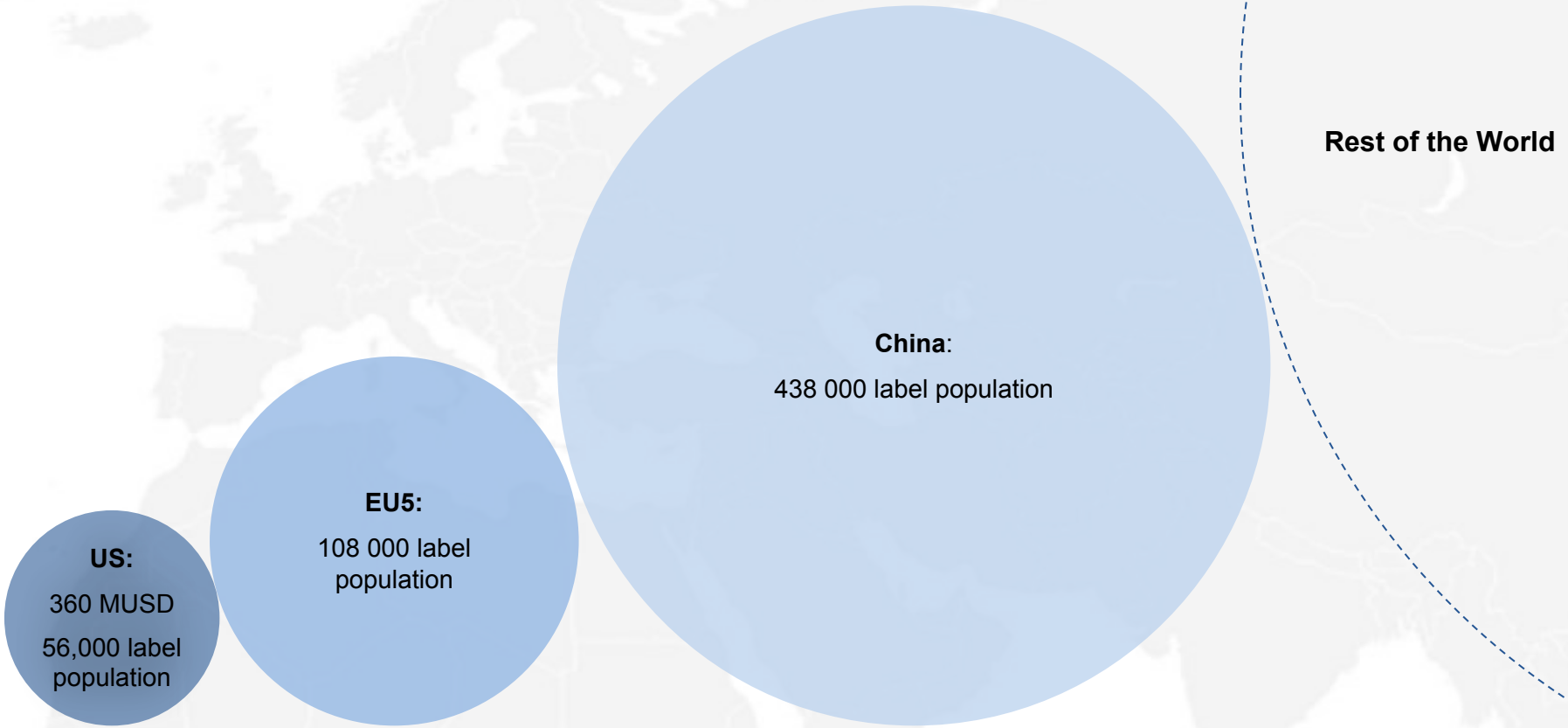
Institution Type	Major Medical Centers	Medium Hospitals	Small Community Hospitals
Share of Premature Infants	~60%	~30%	~10%
Estimated Formulary Adoption	~85%	~60%	~0%
Overall Formulary Inclusion	Approximately 70% of addressable patients are anticipated to receive care at an institution that includes IBP-9414 on formulary		

ClearView Healthcare Partners

Market potential for IBP-9414 assessment

IBT has mandated consultants to assess the market opportunity…	APEX CLEARVIEW Healthcare Partners
…who have interviewed the relevant key stakeholders across US and Europe…	▪ Including 60 Neonatology Key Opinion Leaders interviews ▪ 15 Pharmacy and Therapeutics neonatologists and pharmacists (P&T members) ▪ Payers
…resulting in significant market opportunity	▪ Estimated annual revenue potential of **USD200m – USD360m in US**

A globally valuable pharmaceutical



IBP-9414 Development Plan Phase II

A randomized, double blind, parallel-group, dose escalation placebo-controlled multicenter study to investigate the safety and tolerability of IBP-9414 administered in premature infants ≤2,000 grams birth weight

	Safety and tolerability study
Timeline	2016-2017
Status	Completed
Clinical trial details	▪ 15 sites in the US ▪ Recruitment rate was higher than estimated

Concluded with similar safety and tolerability profile in the active and placebo group

The Phase 3 study protocol is modified after IBT's meeting with the FDA

EU:
Pediatric Investigation plan (PIP) approved September 2017

USA:
Meeting with FDA Nov 20 2018
We do not want delays to our development program, especially with the unmet medical need that necrotizing enterocolitis represents, but we feel that the FDA guidance will have a positive effect on our program by improving our Phase III study, allowing us ultimately to bring significant benefits to premature babies. The company's current financial position is sufficient to finance IBTs continued operations and finalize the development program

IBT has received development input from FDA and EMA

IBP-9414 Development Plan Phase III

Pivotal phase III study – The Connection Study
2019-2020
Planned
• A randomized, double blind, parallel-group, placebo-controlled multicenter study to evaluate the efficacy of IBP-9414 in premature infants ≤1,500 grams birth weight in the prevention of NEC ***and additional indication e.g. feeding intolerance*** • 2056 premature infants • 100 sites in US, France, Germany, the Netherlands, Spain, (Hungary, Czech Republic and Austria) • Interim analysis planned

This means:

- Targeted Launch in 2021
- Financial position is sufficient to finalize the development program
- Risk reduction in the program

IBP-9414 for the prevention of necrotizing enterocolitis

IBP-9414 is based on all relevant pillars for the development of a successful drug

- Market exclusivity
- Medical need
- Aligned payers
- Mechanism of action
- Clinical data
- Safe
- Aligned regulatory agencies
- GMP manufacture
- Priority review voucher eligibility

Thank you!

Infant Bacterial Therapeutics AB

+46 (0) 8 410 145 55

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