Infant Bacterial Therapeutics

Corporate Presentation
June 2017

INFANT BACTERIAL THERAPEUTICS

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Infant Bacterial Therapeutics

Overview

History

- Pharmaceutical microbiome company focused on areas of unmet medical need
- Founded 2013 by Staffan Strömberg and Eamonn Connolly as subsidiary of BioGaia
- Lead drug candidate IBP-9414, to prophylactically prevent necrotizing enterocolitis (“NEC”), a fatal, rare disease that afflicts premature infants and carries an economic burden of USD 300,000 per complicated NEC
- Pursuing a second rare disease program IBP-1016 for the treatment of an unmet medical need in gastroschisis, a severe disease in infants

Current

- Main drug candidate IBP-9414 in Phase II finalized recruitment of all 120 patients January 2017
- Orphan Drug Designation from FDA and EMA
- Rare Pediatric Disease Designation granted, Priority Review Voucher
- Current financial resources, SEK85m cash
- Current worldwide, royalty free patent

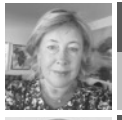
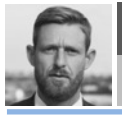
Future

- Phase II results for IBP-9414 expected Q3-Q4 2017
- Future financial requirement SEK 300-600m to conduct Phase III study for IBP-9414
- Label Patient Population 56,000 children in US and 108,000 in EU with Third - party assessed opportunity USD200m – USD350m in US market for IBP-9414
- Expected ease of market introduction and distribution of IBP-9414 in USA
- Market Approval for IBP-9414 target 2020 / 2021

Key IBT people and collaborators

Extensive experience and collaboration with tier 1 institutions

Key IBT decision makers

	**Peter Rothschild, MBA** **Chairman**	▪ Group President and founder of BioGaia ▪ Managing Director of BioGaia for 19 years ▪ Became Chairman of IBT in 2016
	**Staffan Strömberg, Ph.D.** **CEO and co-founder**	▪ Vice President of Nicox France, management positions at AstraZeneca, Head of R&D of Swedish Orphan, Head of Medical Devices at the Swedish Medical Products Agency
	**Eamonn Connolly, Ph.D.** **Head of R&D and co-founder**	▪ Senior VP Research of BioGaia from 2002 to 2013 and extensive experience in the pharmaceutical industry (Kabi Vitrum, Pharmacia & Upjohn)
	**Sanjiv Sharma, M.B.A.** **Chief Commercial Officer**	▪ A blend of successful experience in large, mid-size and start-up companies in the US and Asia, with national and global responsibility for companies like Sanofi and Valeant
	**Anders Kronström, M.Sc.** **Chief Technical Officer**	▪ Extensive experience in the pharmaceutical industry with specialisation on pharmaceutical development, project leadership and business development
	**Agneta Heierson, Ph.D.** **Vice President, Clinical Development**	▪ Over 25 years experience in the pharma industry ▪ Formerly Global VP, R&D Supply Chain at AstraZeneca
	**Daniel Mackey** **Chief Financial Officer**	▪ 20 years experience from diverse U.S. and international management positions in finance and accounting with Investors Bank & Trust Co., Nordea Investment Management AB

IBT's extensive collaboration network

Key Opinion Leader Meetings

- Feb-13: Atlanta, US
- Apr-13: New York, US
- May-14: Vancouver, Canada
- Sep-14: Boston, US
- May-15: San Diego, US
- Sept-15: Budapest, Hungary
- May-16: Baltimore, US
- Nov-16: Stockholm, Sweden
- Mar-17: San Diego, CA

Financial

- IBT B listed on Nasdaq First North Premier
- Cash March 2017 ca SEK85m
- Strong investor base and over 5,000 Shareholders
- Application to Nasdaq Main Market planned 2017
- Market Cap ca SEK500m (€50m)
- YTD Stock performance ca100%

Major Shareholders as of March 31, 2017

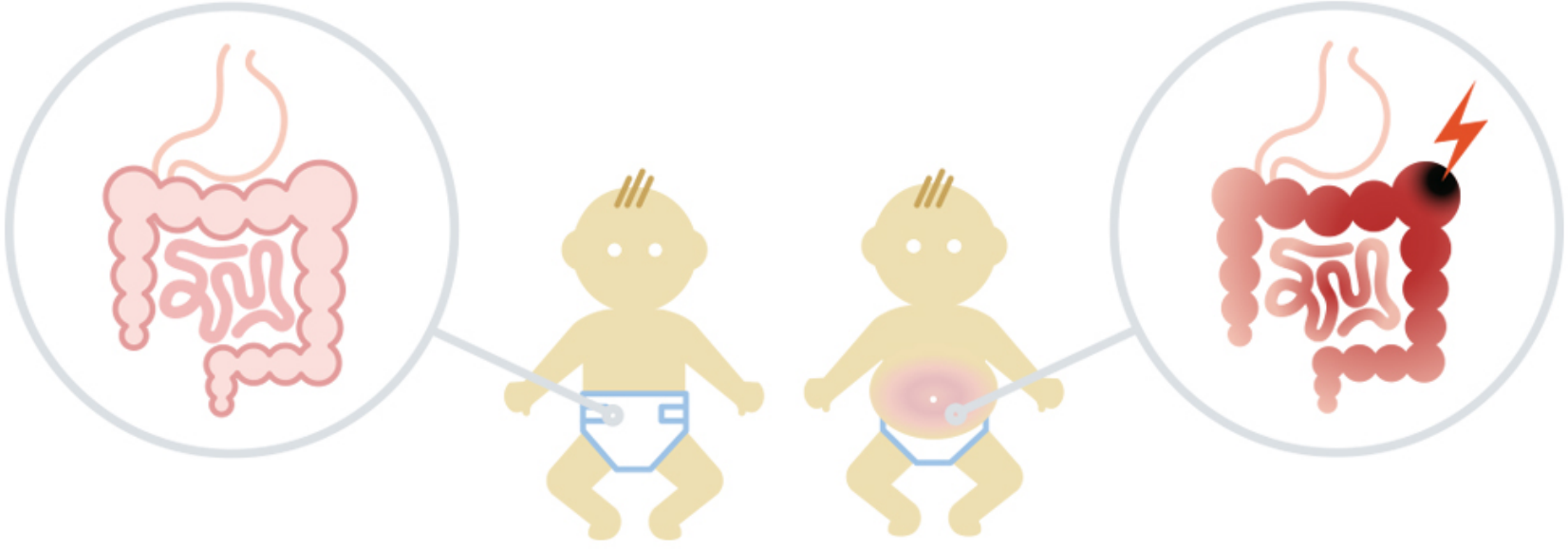
- Annwall & Rothschild Investments AB
- The Fourth Swedish National Pension Fund (AP4)
- AMF Aktiefond Småbolag
- Nordea Småbolagsfond, Norden
- CF Ruffer Investment Funds
- Mingdale Company Ltd
- Swedbank Robur Ny Teknik
- Handelsbanken Svenska Småbolagsfond
- M2 Capital Management





1. IBP-9414 for the prevention of necrotizing enterocolitis

Necrotizing Enterocolitis



NEC is severe inflammation of the bowel in preterm infant bowel which can lead to death of the baby

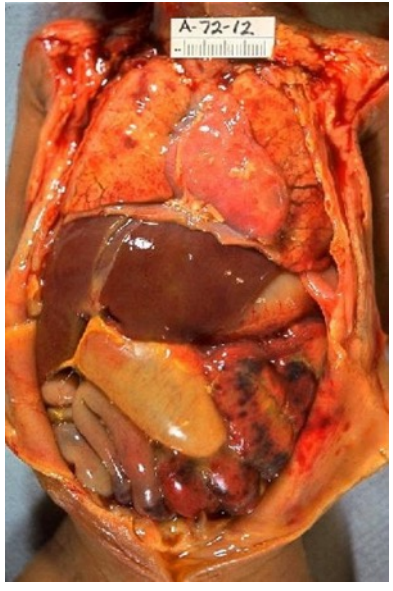
Major surgery required in 20-40% of NEC cases at cost of 300 kUSD or more

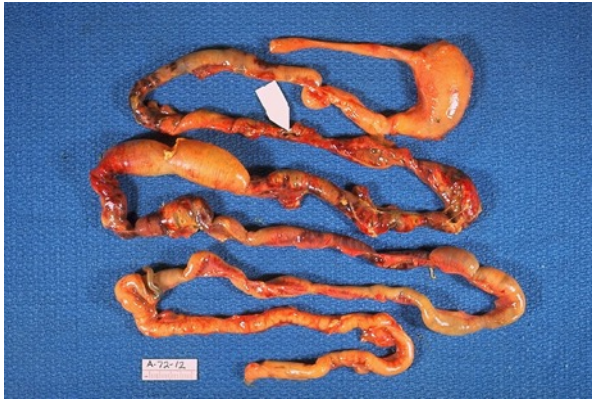
Survivors have long-term consequences: short-bowel syndrome, abnormal growth, cognitive, visual and hearing impairments

There is no preventive treatment for NEC

Necrotizing Enterocolitis (NEC)

A devastating gastrointestinal emergency





NEC kills 1500 US och 3700 EU infants every year

Pictures from Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities

Who gets NEC?

Premature infants

	Infants birth weight	NEC incidence rate (%)	NEC mortality rate (%)	Mortality (% of weight cohort)
High incidence and mortality	501-750g	12.0%	42.0%	5.0%
	751-1,000g	9.2%	29.4%	2.7%
	1,001-1250g	5.7%	21.3%	1.2%
	1,251-1,500g	3.3%	15.9%	0.5%
	1,501-2,500g	0.4%	8.2-17%	0.03-0.06%
	>2,500g	0.1%	0-20%	0-0.02%

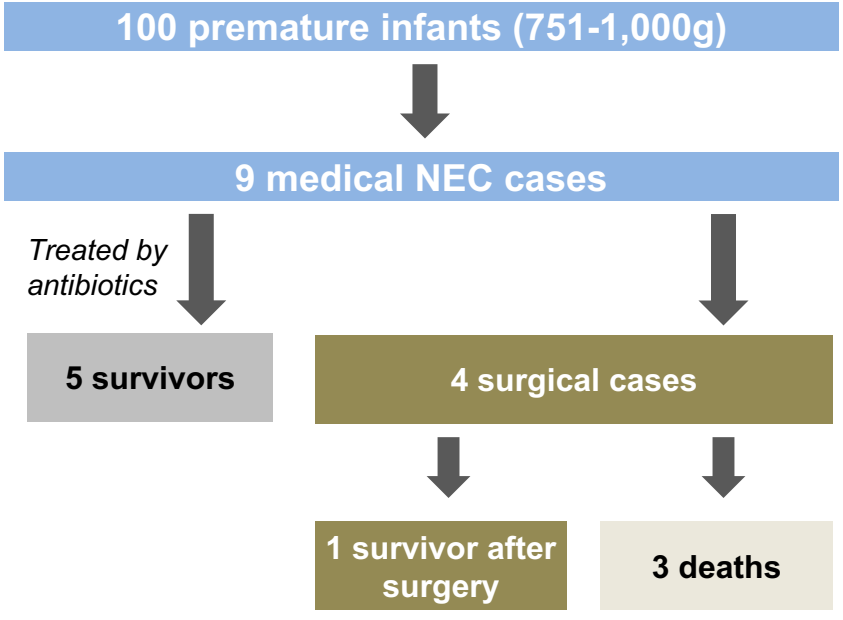
The smaller the premature infant is at birth, the more likely he/she will get NEC and die

Source Clark et al, 2012

Target population

A preventive therapy for all preterm infants at risk of NEC

Current clinical NEC progression

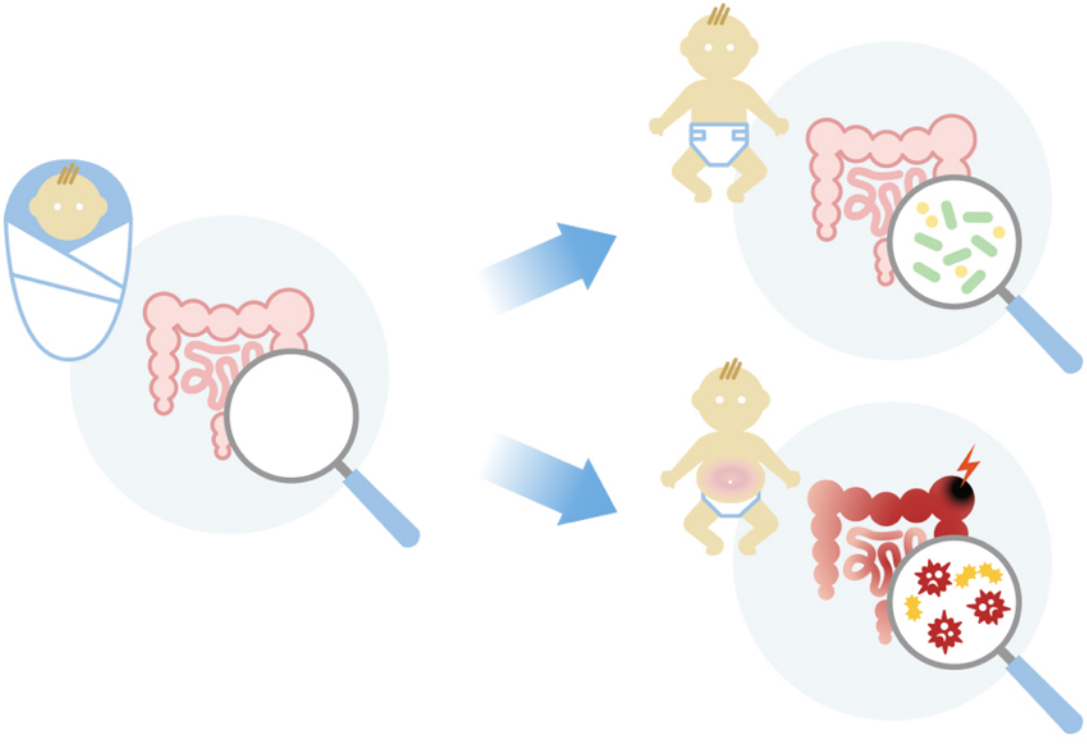


Target label population

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)

What causes NEC?



Healthy development
of gut microbiota

+ Dysbiosis
+ Impaired gut motility
+ Unregulated inflammation
⇒ **NEC**

Our objective is to prophylactically treat against NEC

Clear clinical signal from *L. reuteri*

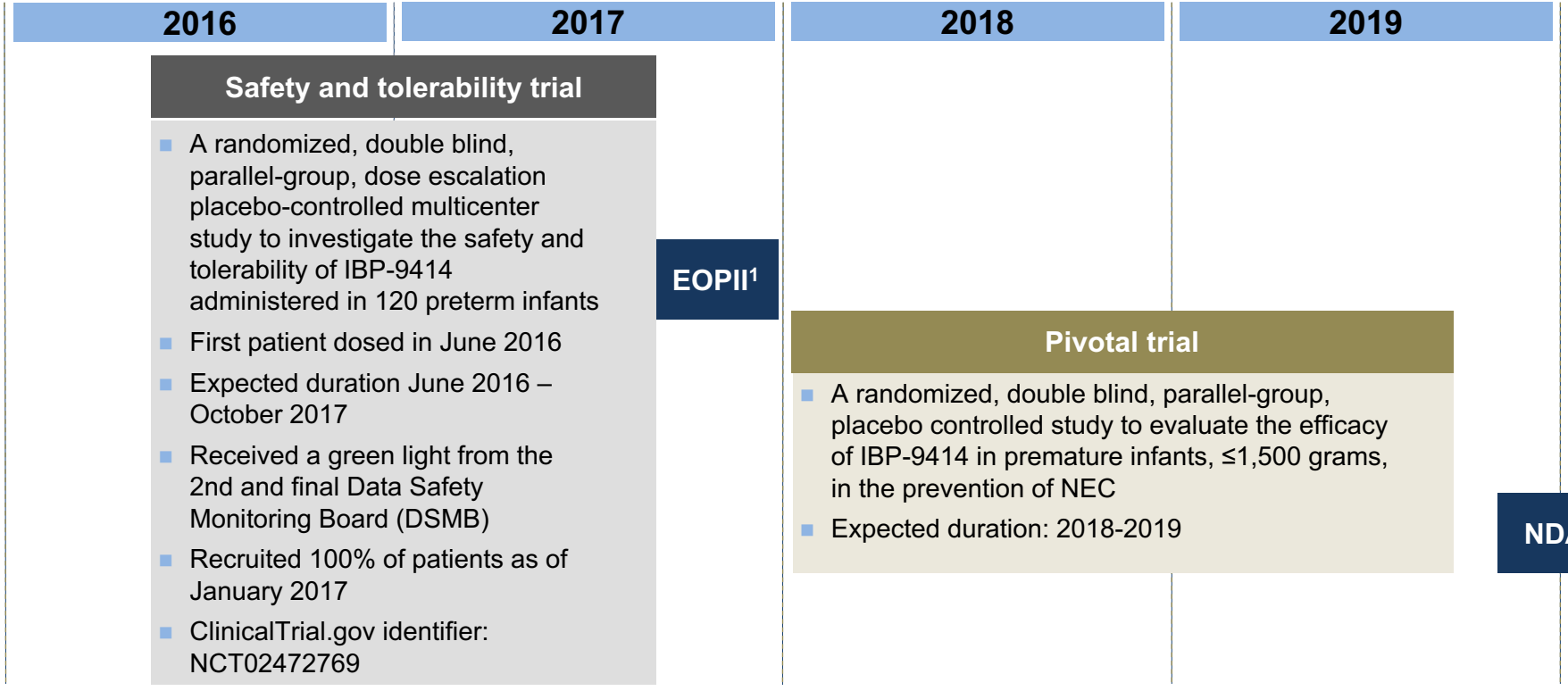
All studies show clinically significant reduction of NEC

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
Hunter et al. (2012) & Dimaguila et al. (2013)	▪ 354 patients	▪ 89% 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

IBP-9414 – development plan

A development program consisting of two clinical trials

Drug development plan



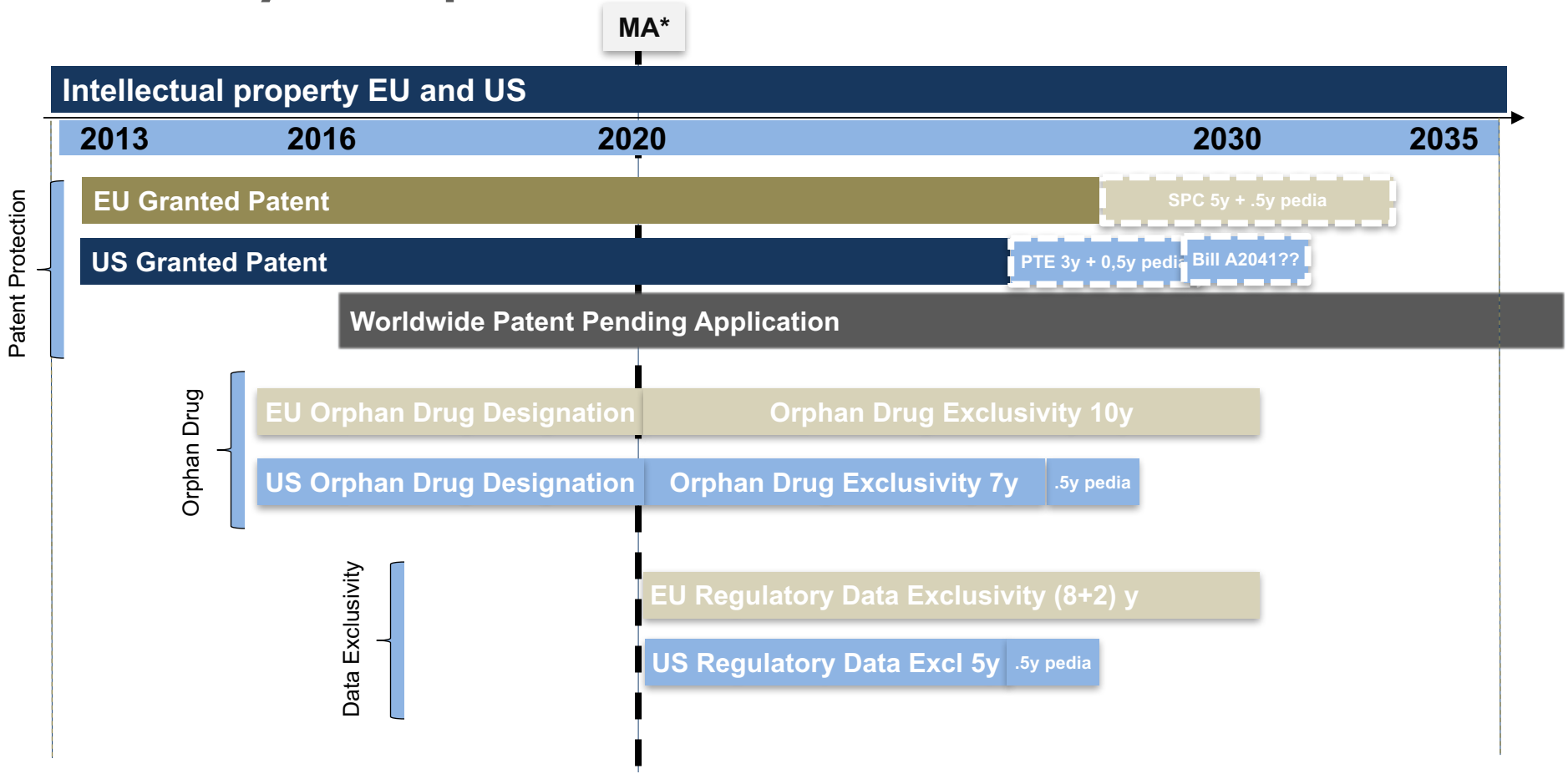
Notes

1 End of Phase II

2 New Drug Application

IBP-9414 – Intellectual Property

Three layers of protection



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

* Market Approval

IBP-9414 Target Product Profile

For the prevention of necrotizing enterocolitis

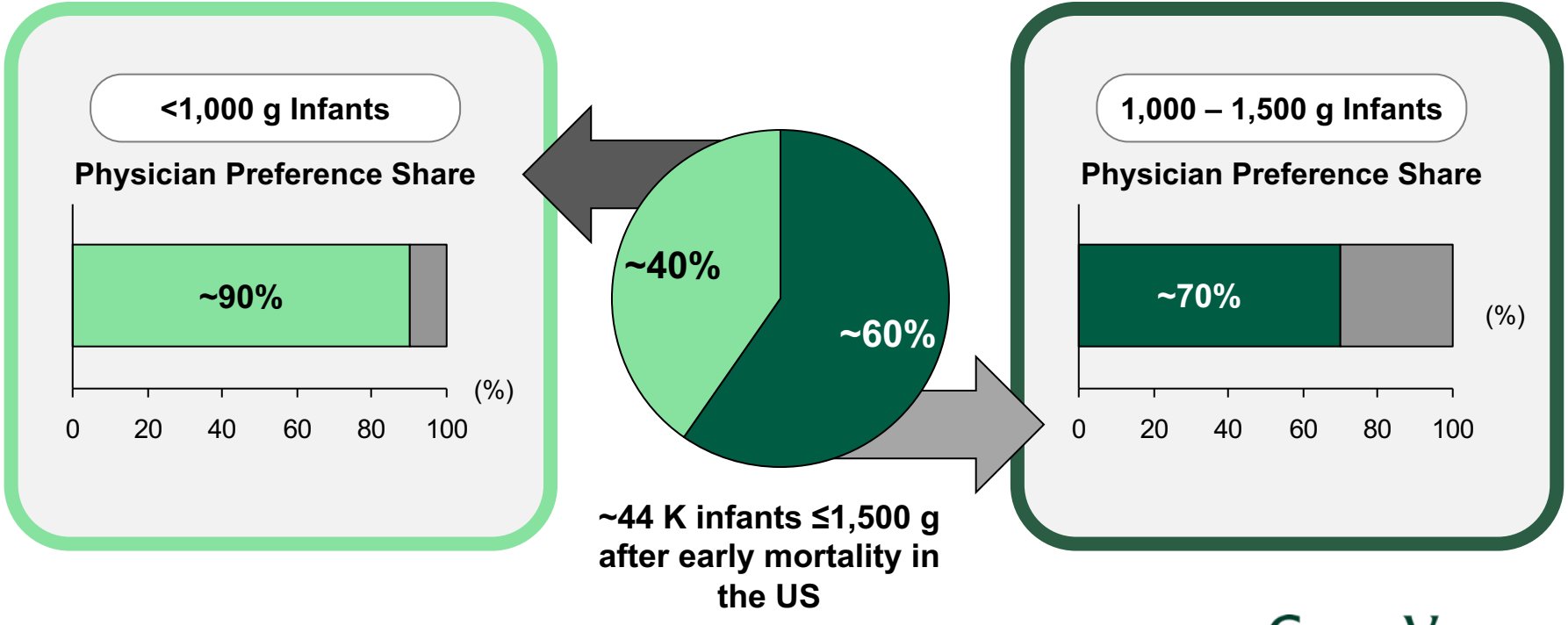
Product description	▪ Pharmaceutical therapy approved as Orphan Drug in EU and US to prevent NEC ▪ The first FDA and EMA-approved drug product to prevent NEC
Patient population	▪ Premature infants ≤1,500g (US) ca 56,000 ▪ Premature infants ≤ 34 weeks gestational age (EU) ca 108,000
Route of Administration	▪ Oral / enteral
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

Market potential for IBP-9414 assessment

IBT has mandated consultants to assess the market opportunity…	APEX HEALTHCARE CONSULTING 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

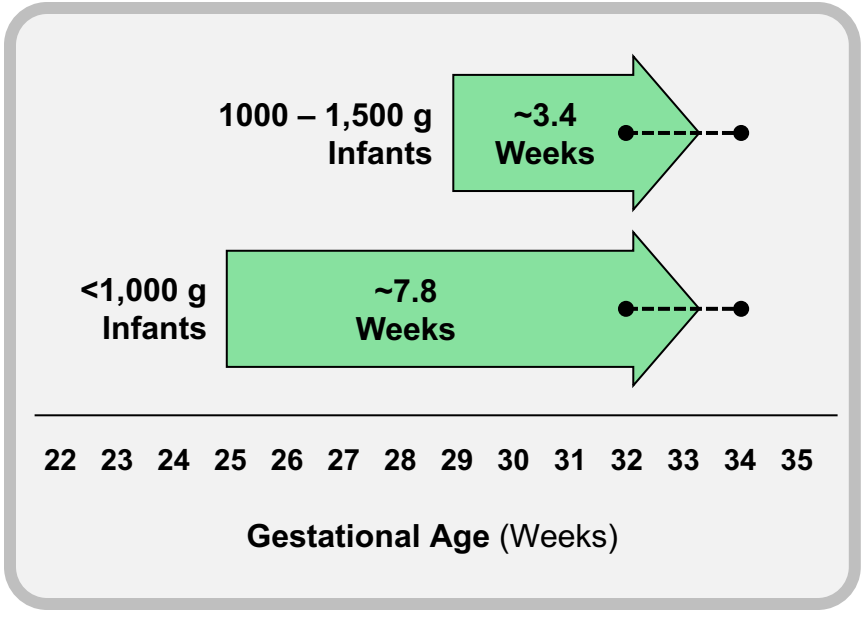
Neonatologists show high willingness to prescribe IBP-9414

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



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

Significant market potential for IBP-9414

IBT has mandated consultants to assess the market opportunity…	APEX HEALTHCARE CONSULTING CLEARVIEW Healthcare Partners
…who have strongly engaged and favorably reacted to IBP-9414's targeted profile…	▪ KOLs recognized NEC as a high unmet need with high mortality rates and lack of any medical preventive treatment ▪ 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 ▪ Highly positive reaction towards clinically proven safety and efficacy due to safety concerns ▪ Based on target profile, interviewees would expect IBP-9414 to be included on formulary
…resulting in significant market opportunity	▪ Estimated annual revenue potential of **USD200m – USD350m in US**





2. IBP-1016 for the treatment of Gastroschisis

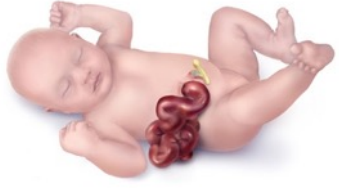
Gastroschisis

What is Gastroschisis?

- Birth defect of the abdominal wall, where the baby's intestines stick outside of the baby's body, through a hole beside the belly button
- Affects late preterm infants with an average gestational age of 36 weeks and average birth weight of 2.4kg

What causes gastroschisis?

- ☑ Dysbiosis and growth of pathogenic bacteria in the gut
- ☑ Sub-optimal gut motility is the main clinical problem



Gastroschisis prevalence

- Approximately 2,000 babies per year are born in the US with this birth defect

What happens when you have gastroschisis?

- After surgery repair, the core complication is due to severe impairment of the gut motility

Gastroschisis is associated with a high economic burden of ca $95,000 per child

Picture sourced from Centers for Disease Control and Prevention

Clear signal on improved gut motility

5 studies with *L. reuteri*

	Study	Number of patients	Results
Improved gut motility in term and preterm infants	Indrio et al. (2008)	■ 30 patients	■ 85% increase in gastric emptying rate (p<0.001)
	Indrio et al. (2011)	■ 34 infants	■ 39% increase in gastric emptying rate (p=0.01)
Improved feeding tolerance in preterm infants	Rojas et al. (2012)	■ 750 patients	■ 34% reduction in episodes of feeding intolerance with interruption of feeding (p=0.08)
	Oncel, Sari et al. (2014)	■ 400 patients	■ 29% reduction in episodes of feeding intolerance with interruption of feeding (p=0.015) ■ 10% reduction in time to full enteral feeding (p=0.006)
	Oncel, Arayici et al. (2014)	■ 300 patients	■ 36% reduction in episodes of feeding intolerance with interruption of feeding (p=0.004)

Infant Bacterial Therapeutics

Summary

- Pharmaceutical microbiome company focused on areas of unmet medical need
- Experienced team supported by a well established network of Key Opinion Leaders
- Clear clinical signal and safety profile of *Lactobacillus Reuteri*
- Strong Intellectual Property protection of *Lactobacillus Reuteri*
- Main project, IBP-9414 for the prevention of NEC, is in Phase 2 in the US and has received:
  - Orphan Drug Designation from the FDA and EU
  - Rare Pediatric Disease designation from the FDA, Priority review voucher may be awarded by the FDA
- Annual revenue potential for IBP-9414 estimated to be USD 200-350m by third-party in the US alone

Thank you!

INFANT BACTERIAL THERAPEUTICS

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