Infant Bacterial Therapeutics

Annual General Meeting 2023

May 8, 2023

Two "microbiome" drugs recently approved in the US

Ferring/Rebiotics product REBYOTA™ and Seres/Nestlé Health Science product VOWST™.

VALIDATES PHARMA GRADE POTENTIAL OF BACTERIA

IBP-9414 in Phase 3, a fully funded development program	• **IBP-9414: 307 MSEK in cash, 70% of Phase 3 completed, Blockbuster**
Experienced industry experts in board and management	• **IBT prepares for application and commercialization of IBP-9414**
IBT will pass milestones in the near future	• **Phase III study recruiting 70-90 patients per month, Phase 3 results for IBP-9414 expected Q1 2024**
Pipeline of IBT owned programs	• **Product portfolio includes four development programs**

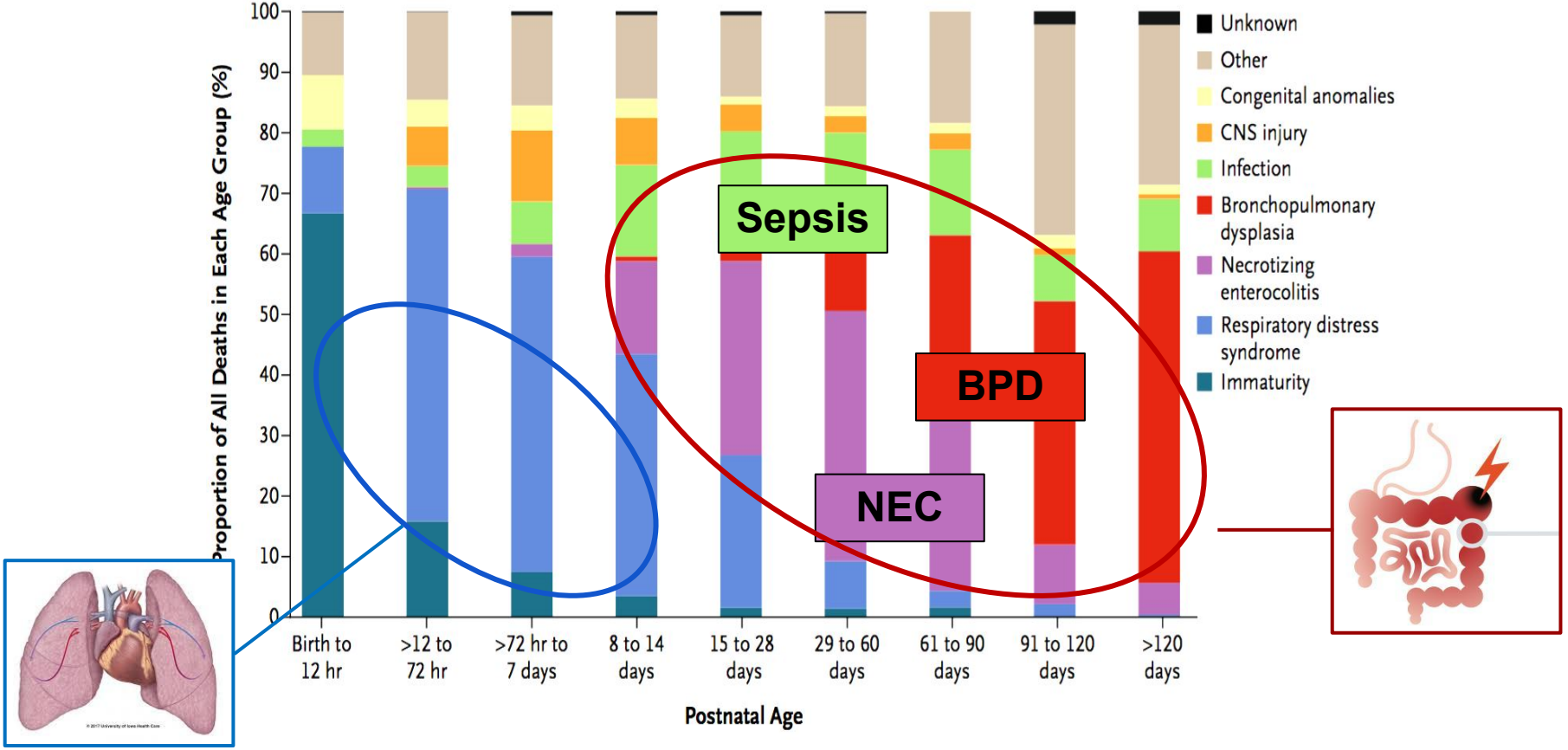
Market-focused IBT

Premature infants require significant access to quality care and treatments - IBT has established an extensive global network.

Antibiotic resistance has become a significant global health problem - IBT is a leader in pharma-grade probiotics.

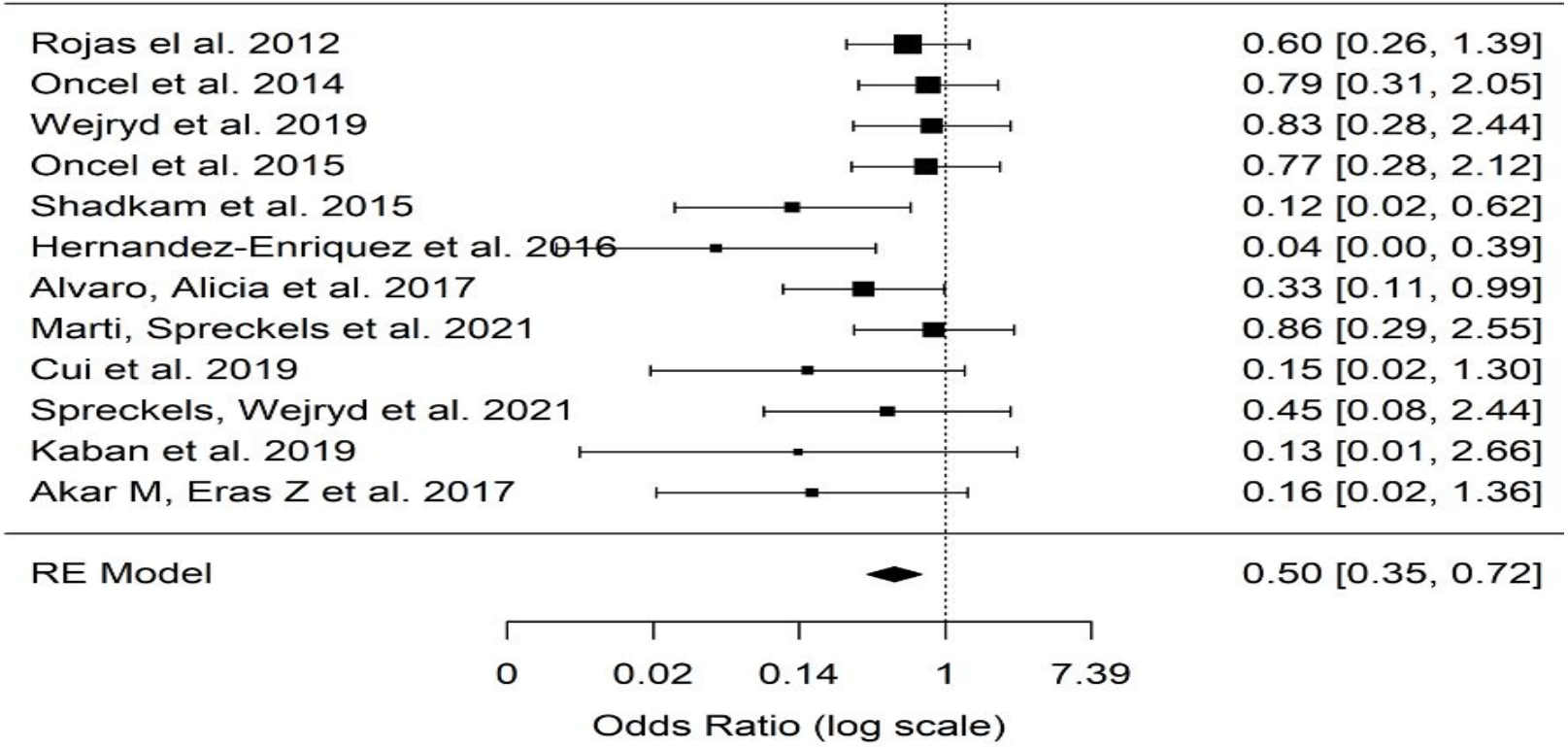
** Gastroschisis "line extension" on IBP-9414*

IBP-9414 prevents several deadly diseases linked to the gut

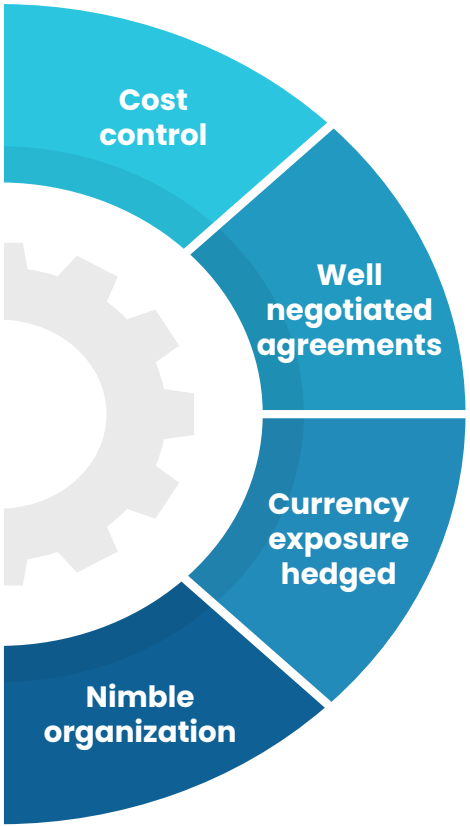


Source: Patel 2015

Lactobacillus Reuteri reduces the risk of infants getting NEC



Well organized and financed according to plan



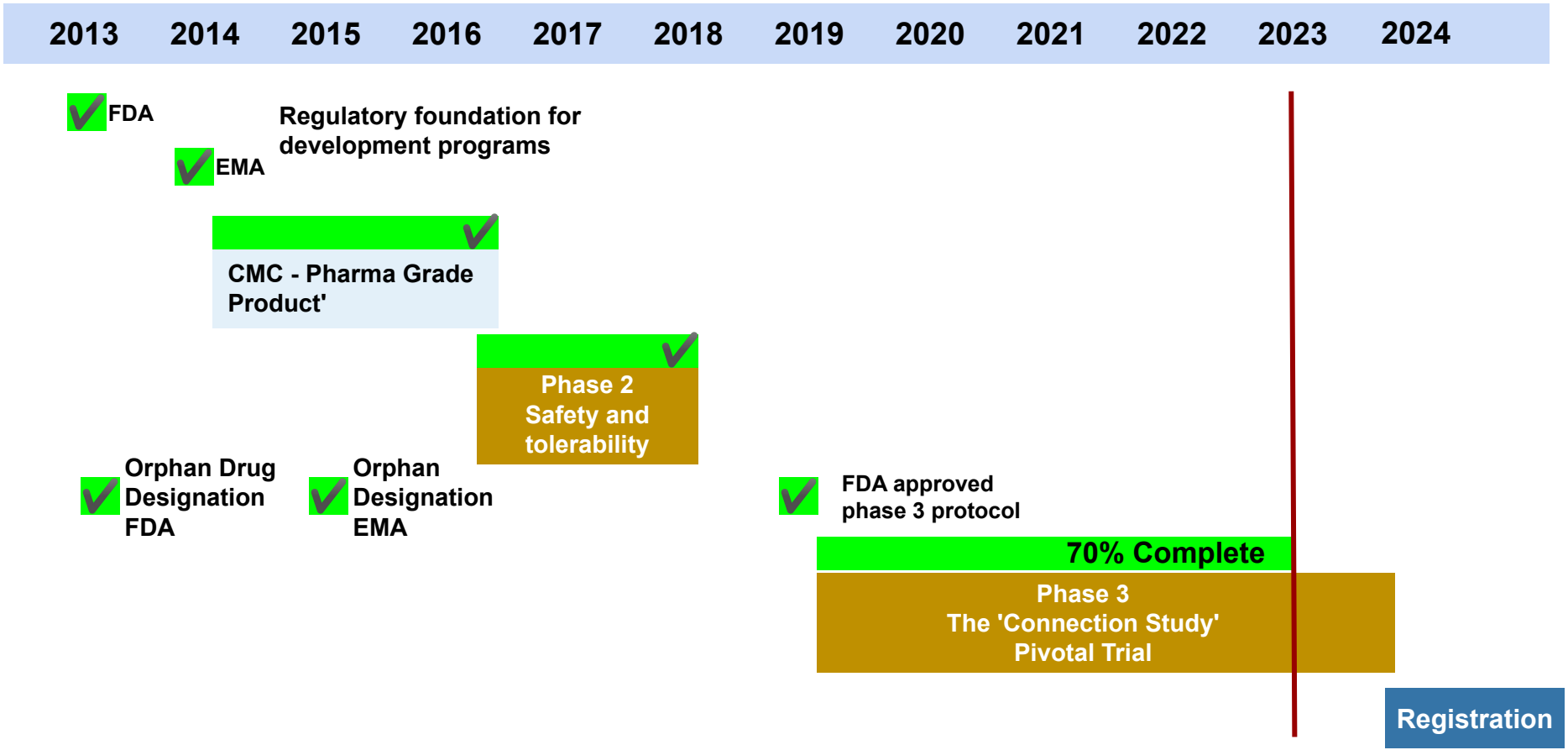
Funding to complete the study till market application

- **45% of funding spent**
- **70% of patients recruited**

- Validation of the production process
- All regulatory documentation for market authorization

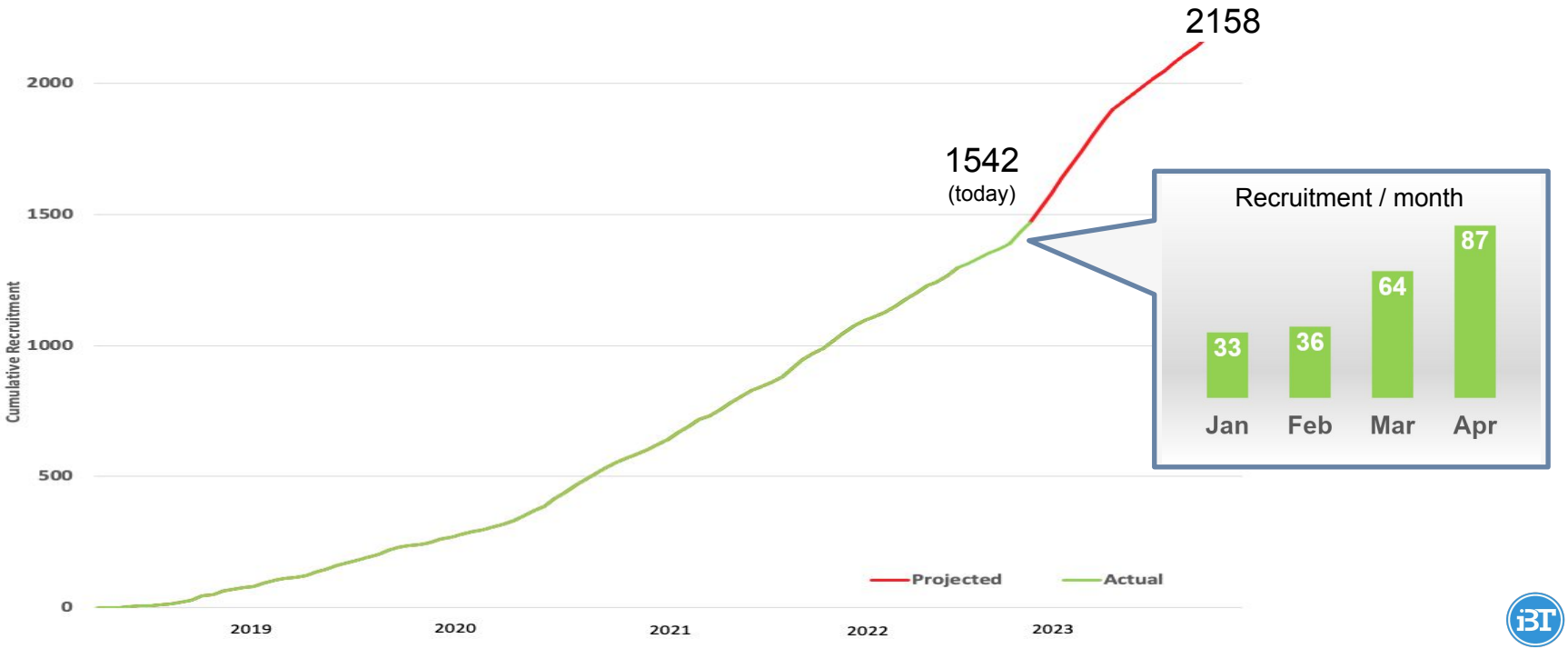
Structure and control

IBP-9414 Development program in final phase



Successful recruitment in world-first study

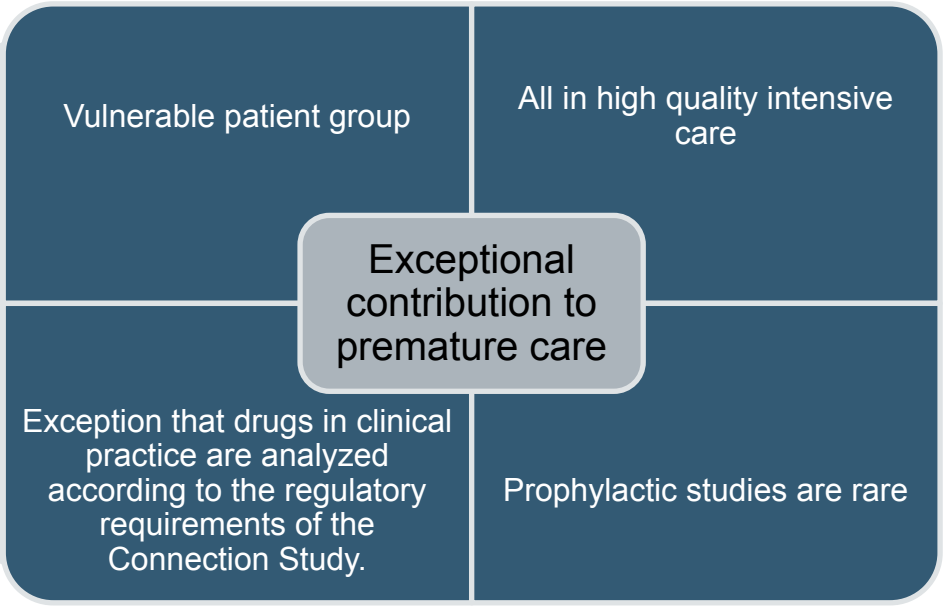
World's largest study among the smallest patients → Global study in 10 countries at 87 specialist hospitals → Great pace of recruitment → Recruitment projected to complete in 2023



Connection Study - Medical update

Main tasks medical management responsibility

1. Infant safety
2. Medical investigator questions
3. Scientific analysis



Connection Study - Infant safety

Continuous reporting 'Adverse Events' (AE)

- 500+ categories, doctor's discretion
- 1/4 of children have at least one life-threatening event (Serious AE)
- The type and frequency of events as per expectations
- 140,000+ care days

Data Monitoring Committee (DMC)

- Unblinded analysis by neonatologists and stat experts
- 2 briefings with no concerns, 3rd in progress
- Details of results not disclosed outside of DMC

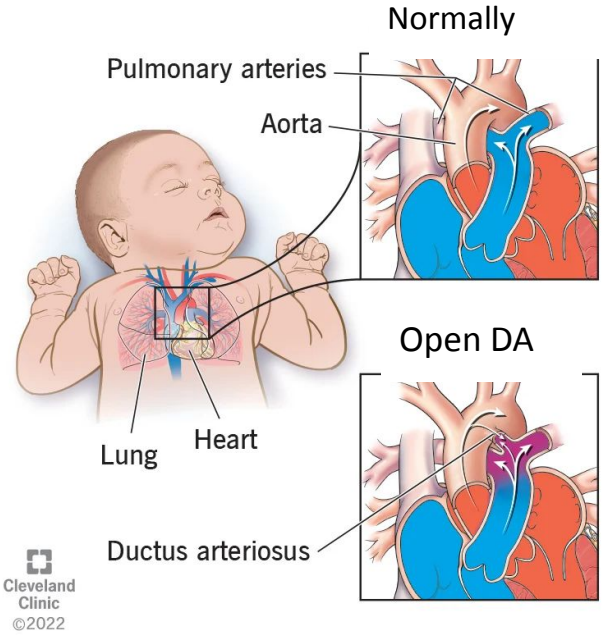
Repeated comparison of GI damage in the treatment groups

- 18 briefings completed

Life-threatening adverse events, some examples

Event	%
Breathing Difficulties (apnea, poor oxygenation, chronic lung injury, etc.)	12.3 / 5.6
Sepsis	12.9 / 5.6
Gastrointestinal disorders including intestinal perforation	11.6 / 5.7
Cerebral haemorrhage	5.0 / 3.1
Patent Ductus Arteriosus (PDA)	3.7 / 1.7
Anemia	2.4 / 0.5

Open ductus arteriosus



(*Aug 2022)

Connection Study - Medical Investigator Questions & Scientific Analysis

Medical investigator questions

- Assessment questions about parallel studies, deviations, adverse events, questions from the responsible physicians, etc.
- Data ’blinded’ on study treatment

Scientific analysis

- The uniqueness of the study allows for new, life-saving treatment and better premature care in general.
- Treatment-blind data published during ongoing study
  - New definition of ”sustained feeding tolerance” and its link to risks of 'adverse events'
  - NEC diagnosis and NEC characteristics reassessed
  - Strong support for market authorization

Manufacturing method established

Cultivation + purification

Filling + lyophilizing

Packing

Cell bank

- Cultivation process established on a commercial scale
- About 90,000 vials have been produced for the Phase 3 study
- The product is stable for at least 4 years

Highest quality for the most vulnerable patients

- ✔ Stringent manufacturing requirements according to highest GMP quality standards
  - FDA CFR 21 (US), Eudralex (EU) and ICH guidelines
- ✔ Meets the quality requirements for <u>pharmaceuticals</u>
  - GMP according to 21 CFR Part 210/211
- ✔ Consistent product quality
  - Assured dose level with 4 year shelf life
- ✔ Guaranteed purity with specific requirements for foreign micro-organisms

IBT has had a close dialog with authorities over the years and is the only company to date that has received FDA permission to administer live bacteria to children in a pivotal drug study.

Now preparing for the launch of IBP-9414

Commercial production

- Establish production capacity for launch volumes in 2024-2025

Regulatory market authorization

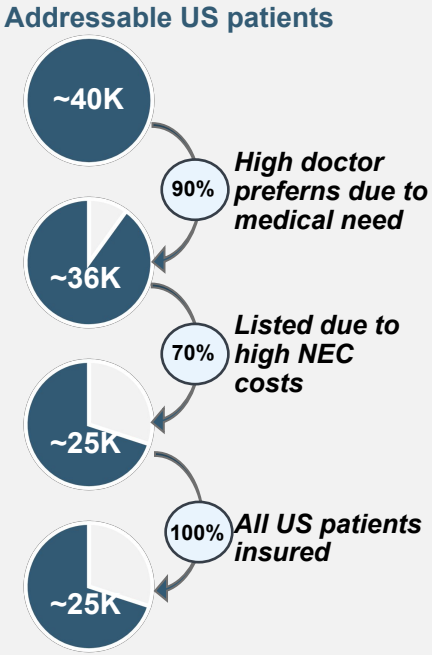
- Results from clinical studies; Efficacy and Safety
- Manufacturing process and product quality

Broad commercial "blockbuster" potential

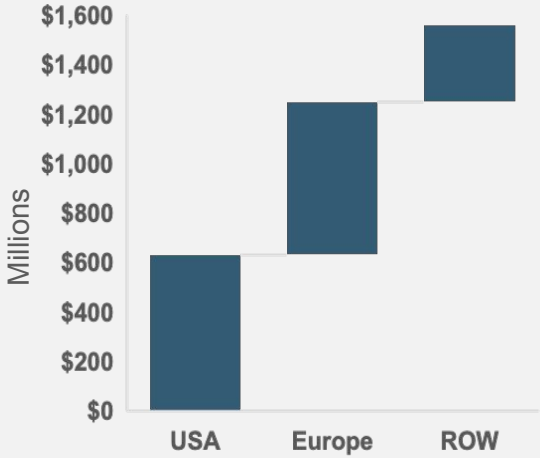
Healthcare providers' interest in probiotics is growing

- Increasing data and clinical experience suggesting benefits of probiotics
- More susceptible given increased use of probiotics in the EU
- Broadening Interest Given Inclusion in Society Guidelines and Conferences
- Desire for FDA regulation and randomized control data

Healthcare providers and insurance companies indicate broad use.



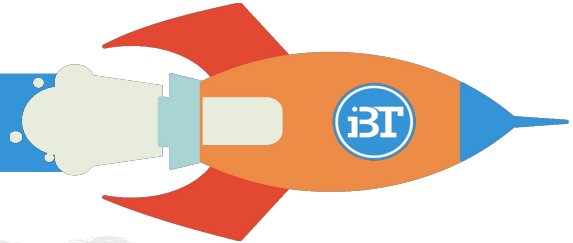
Global "blockbuster" potential of >$1.5 Billion in peak sales



- European sales in line with US (more treatable patients and lower price)

Launch planning well underway

Pre-launch activities



Market access & reimbursement

- Payer coverage policies
- Payer segmentation for access strategy
- Reimbursement approach

Retrospective claims analysis

- Treatment providers, payer and purchase behaviors
- Payer segmentation for value proposition
- Healthcare costs, treatment and patient journey

Health economics & outcomes research

- Identify clinical evidence needed to support coverage
- Scientific publications to address evidence gap

Preparation for **2025 US commercial launch** with a **specialized commercial organization** of approximately 25 employees.

Plan to launch in **Europe and the rest of the world with strategic partners**