INFANT BACTERIAL THERAPEUTICS

Pareto Securities

Staffan Strömberg - CEO

September 2022

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IBT Corporate Milestones

Founded 2013
Sweden - in licensed technology platform from Biogaia.

Orphan Designation
Lactobacillus reuteri – a GI bacteria improving gut function and Sustained Feeding Tolerance.

IPO 2016
First North followed by NASDAQ main markets in 2018.

Phase II Completed
Safety and tolerability demonstrated.

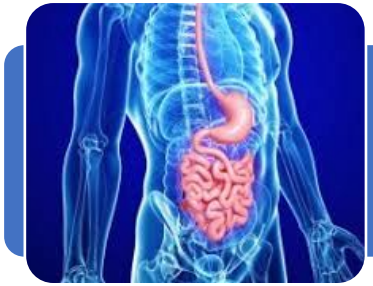
Phase III Underway
Progressing in 10 countries.

Raised eq. $100M
Well funded with cash on hand sufficient for development through approval (Q2/22 SEK 374M).

Priority Review Voucher
Enables expedited FDA review.

Pre-Commercialization Plan Initiated
Breakthrough potential as first and only pharma grade probiotic to prevent life threatening infant diseases including NEC and sepsis by promoting Sustained Feeding Tolerance.

IBT has established strong core competences



Gastroenterology

- Enabling a healthy microbiome extends to multiple treatment options especially in combination with advanced gene modification possibilities

Preterm Babies

- The need for preterm treatment solutions is enormous, where IBT has established comprehensive global network of KOLs and institutions

Pharma Grade Probiotics

- IBT is a global leader in developing LBPs with Phase III in 10 countries, including regulatory, clinical, CMC and commercial pathways to market

Introducing IBP-9414: First Pharmaceutical Grade Probiotic

IBP-9414 on a mission (since 2013) to

become the *first pharma grade probiotic*

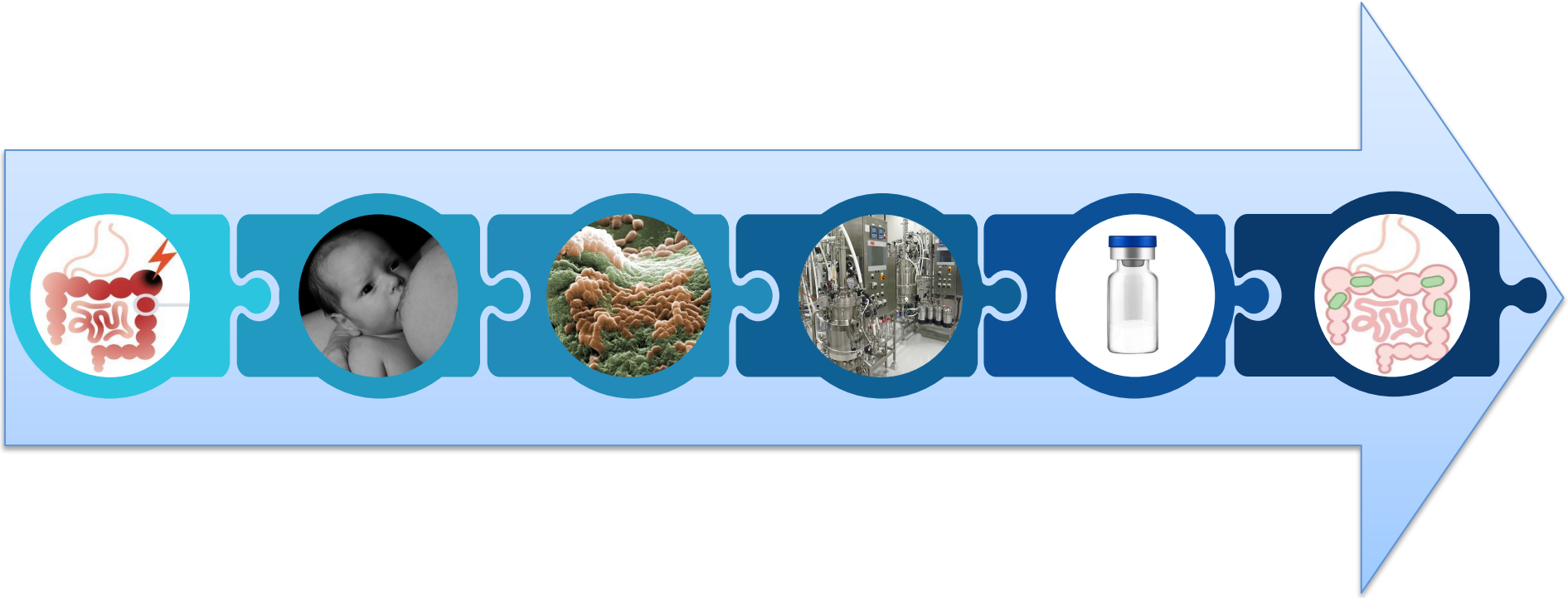
to *prevent* life threatening infant diseases

including *NEC and sepsis* by promoting

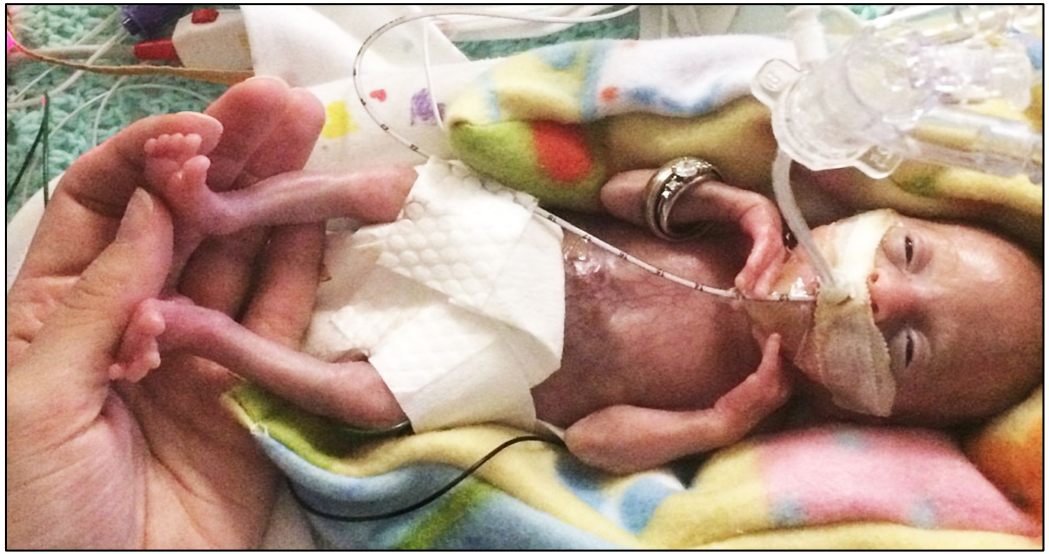
Sustained Feeding Tolerance

IBP-9414 / Lactobacillus Reuteri enables good GI function

First naturally derived pharmaceutical grade probiotic



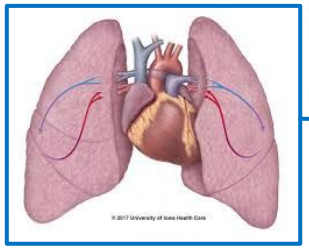
IBP-9414 is addressing a major unresolved medical need

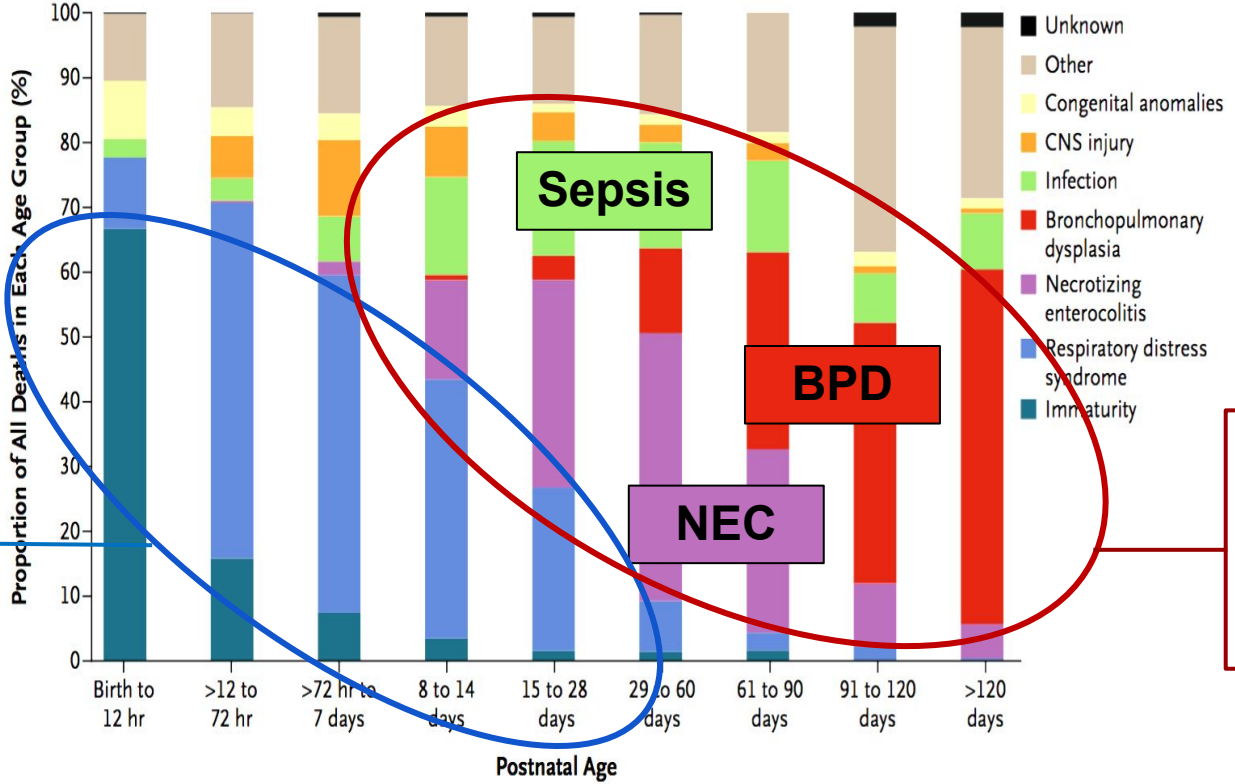


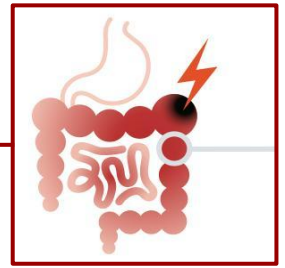
Despite all current efforts with neonatal intensive care - a 24 week GA baby stand a 50% chance of survival…

Preventive treatments are needed

IBP-9414 is targeting leading causes of mortality among preterm babies

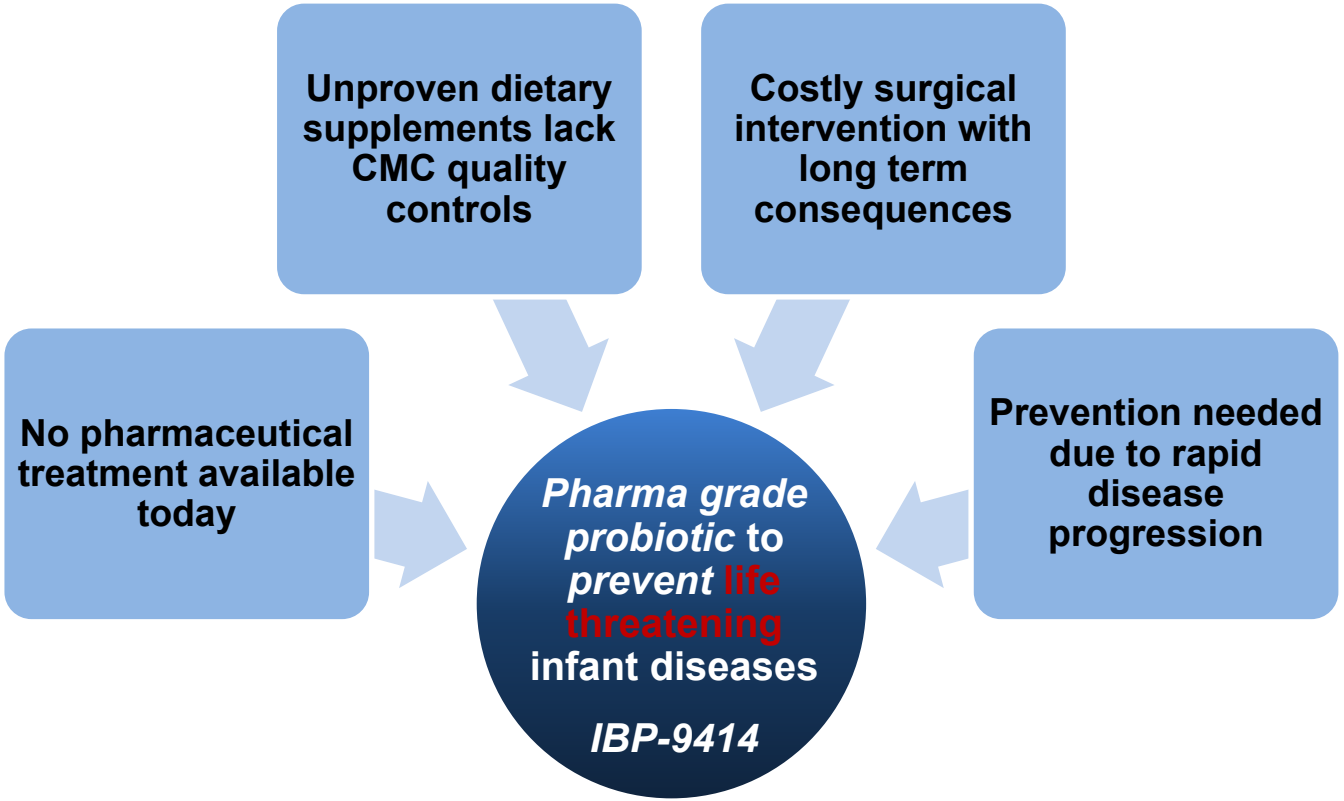




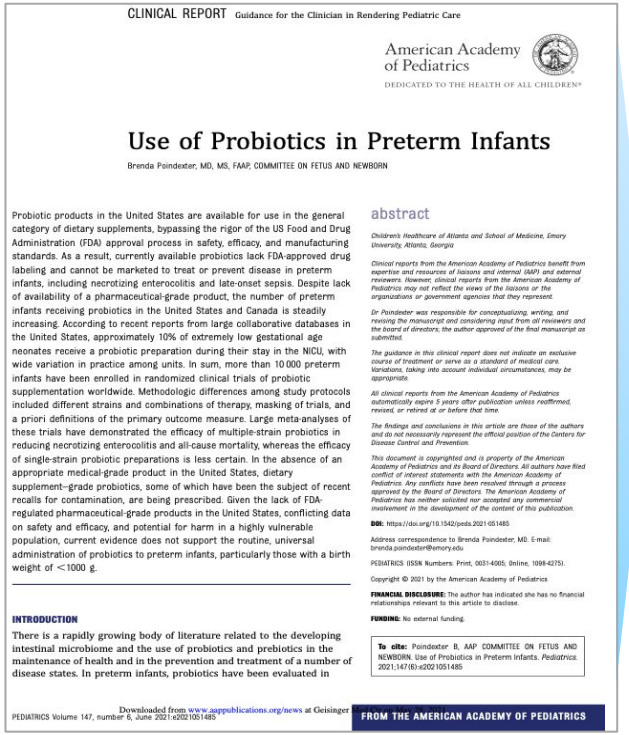


Patel 2015

IBP-9414 will resolve the clinical practice void that is a reality today



IBP-9414 is anticipated as the first and much needed regulated pharma grade probiotic for preterm infants



CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Use of Probiotics in Preterm Infants

Brenda Poindexter, MD, MS, FAAP, COMMITTEE ON FETUS AND NEWBORN

Probiotic products in the United States are available for use in the general category of dietary supplements, bypassing the rigor of the US Food and Drug Administration (FDA) approval process in safety, efficacy, and manufacturing standards. As a result, currently available probiotics lack FDA-approved drug labeling and cannot be marketed to treat or prevent disease in preterm infants, including necrotizing enterocolitis and late-onset sepsis. Despite lack of availability of a pharmaceutical-grade product, the number of preterm infants receiving probiotics in the United States and Canada is steadily increasing. According to recent reports from large collaborative databases in the United States, approximately 10% of extremely low gestational age neonates receive a probiotic preparation during their stay in the NICU, with wide variation in practice among units. In sum, more than 10 000 preterm infants have been enrolled in randomized clinical trials of probiotic supplementation worldwide. Methodologic differences among study protocols included different strains and combinations of therapy, masking of trials, and a priori definitions of the primary outcome measure. Large meta-analyses of these trials have demonstrated the efficacy of multiple-strain probiotics in reducing necrotizing enterocolitis and all-cause mortality, whereas the efficacy of single-strain probiotic preparations is less certain. In the absence of an appropriate medical-grade product in the United States, dietary supplement–grade probiotics, some of which have been the subject of recent recalls for contamination, are being prescribed. Given the lack of FDA-regulated pharmaceutical-grade products in the United States, conflicting data on safety and efficacy, and potential for harm in a highly vulnerable population, current evidence does not support the routine, universal administration of probiotics to preterm infants, particularly those with a birth weight of <1000 g.

INTRODUCTION

There is a rapidly growing body of literature related to the developing intestinal microbiome and the use of probiotics and prebiotics in the maintenance of health and in the prevention and treatment of a number of disease states. In preterm infants, probiotics have been evaluated in

abstract

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Clinical reports from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, clinical reports from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

Dr Poindexter was responsible for conceptualizing, writing, and revising the manuscript and considering input from all reviewers and the board of directors; the author approved of the final manuscript as submitted.

The guidance in this clinical report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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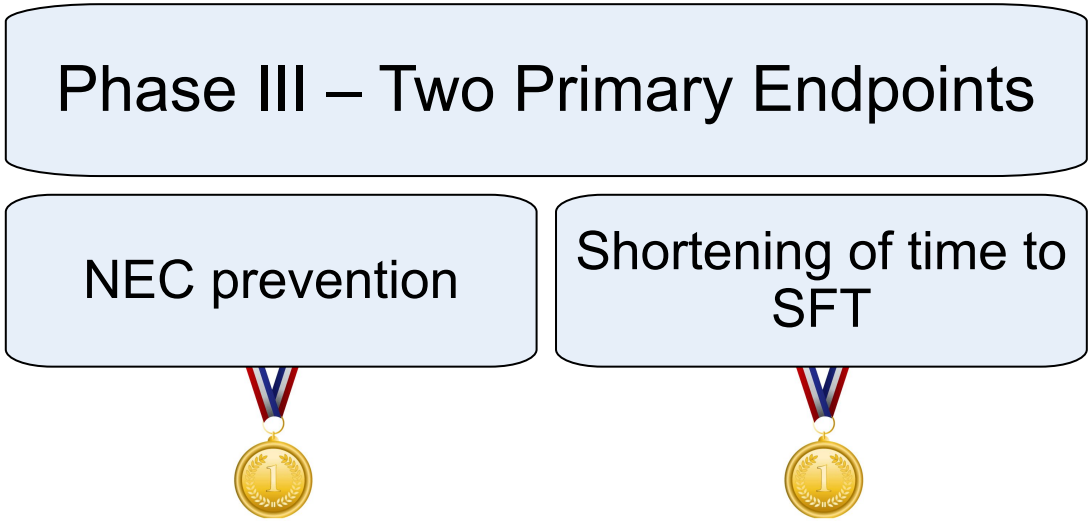
FROM THE AMERICAN ACADEMY OF PEDIATRICS

- "Probiotic products in the United States are available for use in the general category of **dietary supplements, bypassing the rigor of the US Food and Drug Administration (FDA)** approval process in **safety, efficacy, and manufacturing standards."**
- "**Given the lack of FDA- regulated pharmaceutical-grade products in the United States**, conflicting data on safety and efficacy, and potential for harm in a highly vulnerable population, **current evidence does not support the routine, universal administration of probiotics** to preterm infants, particularly those with a birth weight of <1000 g."
- The Connection Study referenced - "…a **phase III randomized clinical trial to evaluate the safety and efficacy of Lactobacillus reuteri (IBP- 9414; NCT03978000**) to prevent NEC in preterm infants is currently ongoing."

* PEDIATRICS Volume 147, number 6, June 2021:e2021051485

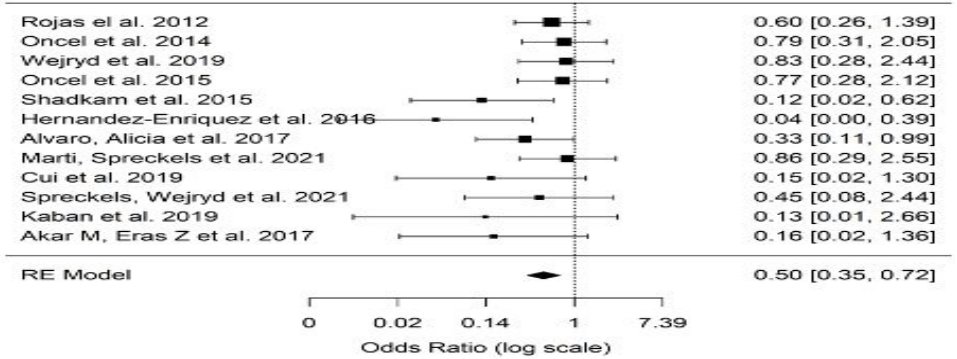
IBP-9414's development is targeting two independent endpoints



SFT = Sustained Feeding Tolerance

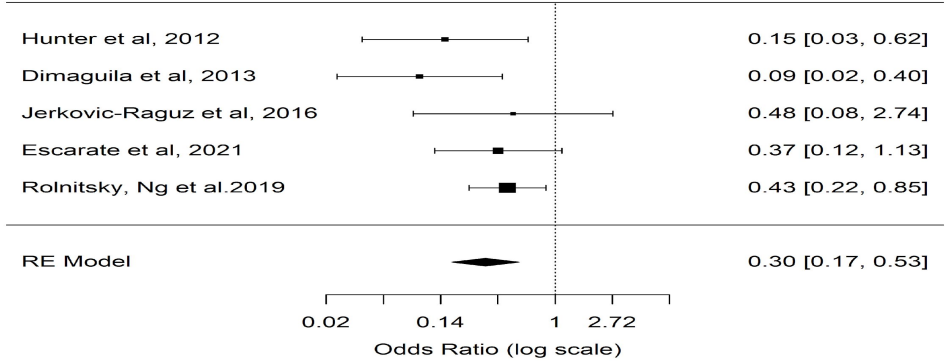
IBP-9414 active ingredient has demonstrated a favorable effect on NEC

Randomized Control Trials



50% reduction in NEC with L.reuteri

Historical Control Trials



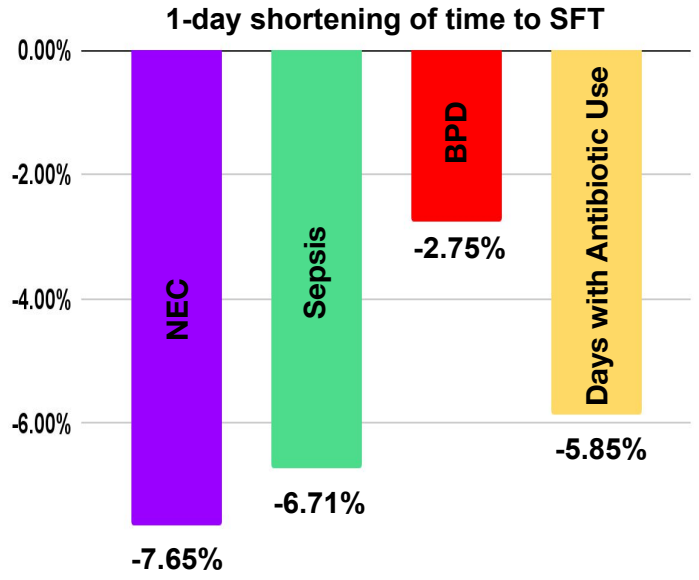
70% reduction in NEC with L.reuteri

Time to Sustained Feeding Tolerance (SFT) correlates to a multitude of important clinical events

A shortening of this time should reflect increased growth and well-being of the VLBW infant.

Result of regression analysis for the 248 infants reaching the 10-day SFT definition

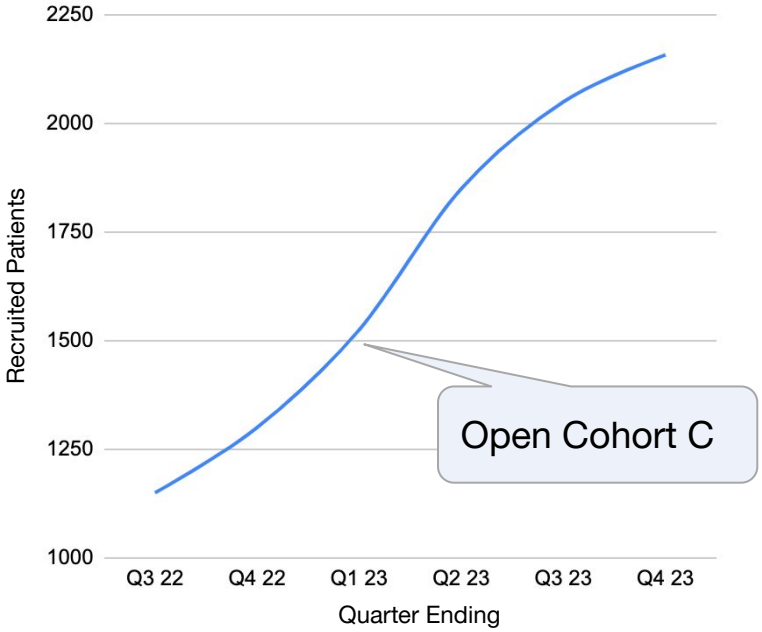
	Mean	N events	Estimate*	95 % CI	p-value
Confirmed NEC Events		20	1.0765	(1.0357-1.1189)	0.0002
Days with Clinical Signs of Feeding Intolerance	5.2	-	1.0029	(0.9791-1.0272)	0.8155
Relevant Gastrointestinal AEs	-	55	1.0586	(1.0293-1.0887)	0.0001
Late Onset Sepsis	-	29	1.0671	(1.0326-1.1028)	0.0001
Weight Gain (g/day)	21.2	-	-0.0831	(-0.1333--0.0328)	0.0014
Clinically Suspected Sepsis	-	18	1.0531	(1.0108-1.0972)	0.0133
Bronchopulmonary Dysplasia	-	85	1.0275	(1.0018-1.0539)	0.0360
Retinopathy of Prematurity	-	65	1.0500	(1.0221-1.0786)	0.0004
Number of Respiratory AEs	1.2	-	1.0331	(1.0214-1.0449)	<0.0001
Number of Days of Hospitalization	75.8	-	0.7710	(0.5086-1.0335)	<0.0001
Number of SAEs	0.4	-	1.0420	(1.0076-1.0776)	0.0162
Days with Antibiotic Use	15.4	-	1.0585	(1.0353-1.0821)	<0.0001
Concurrent Respiratory and Cardiac AEs	-	9	1.0392	(0.9848-1.0967)	0.1611



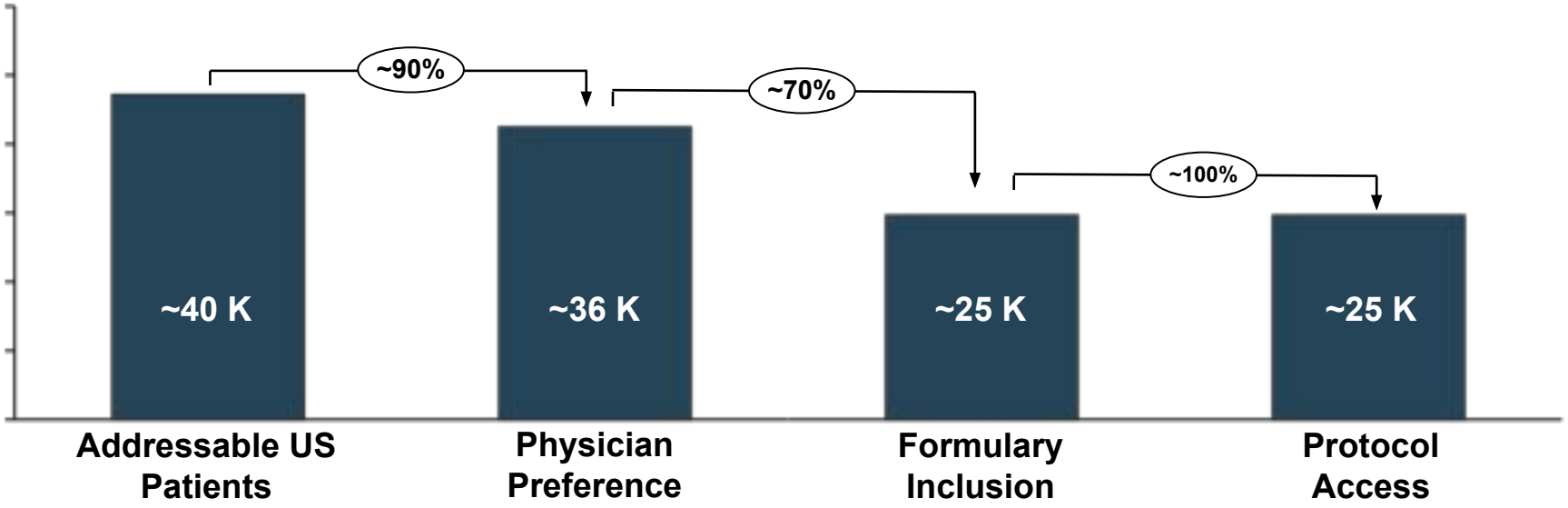
Accepted for publication, in press
British Journal of Gastroenterology

IBP-9414 Connection Study is progressing

- **Current recruitment to Phase III is on track with >50 patients per month**
- **Projected to accelerate the momentum and also open Cohort C (babies 1000-1500 grams) at 1400 recruited patients**
- **There is sufficient cash on hand, as planned, to complete the study**
- **10,000 patient days of safety data on file**
- **Drug Monitoring Committee (DMC) held at 300 and 600**



HCPs respond that IBP-9414 will receive broad utilization



P&T committee members indicate inclusion across most large institutions and mid-sized institutions

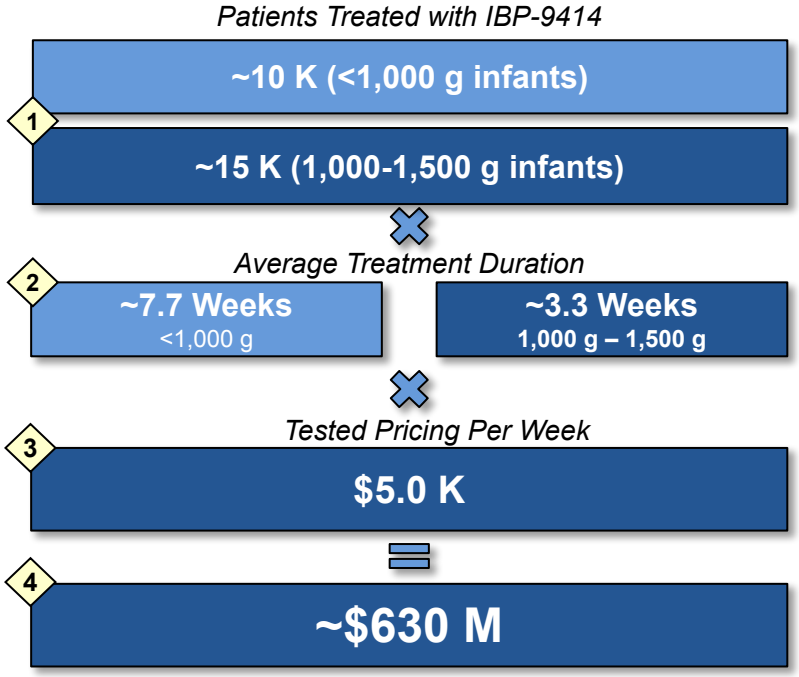
Source: Stakeholder Interviews; ClearView Analysis. AGA: American Gastroenterological Association; RCT: Randomized Controlled Trial.

25K Treated US Patients Expected to Generate $630M Peak Sales

Key Considerations

1. **25K patients treated with full access in two weight cohorts**
2. **Treatment durations of ~7.7 and ~3.3 weeks expected (overall 5.6 weeks average), based on physician preference**
3. **Tested pricing of $5K was thought to be acceptable for NEC alone. Now price sensitivity for a + SFT profile was performed**
4. **US Sales estimated to be ~$630M**

IBP9414 Commercial Opportunity



Source: Stakeholder Interviews; ClearView Analysis.

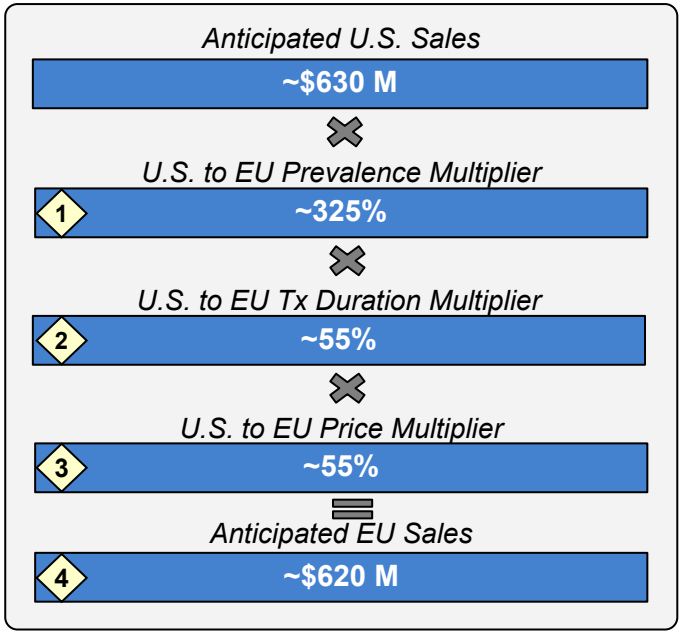
Overall EU Revenue Potential Similar to the US

EU label broader than US; <34Weeks babies in EU vs. ≤1500g in the USA

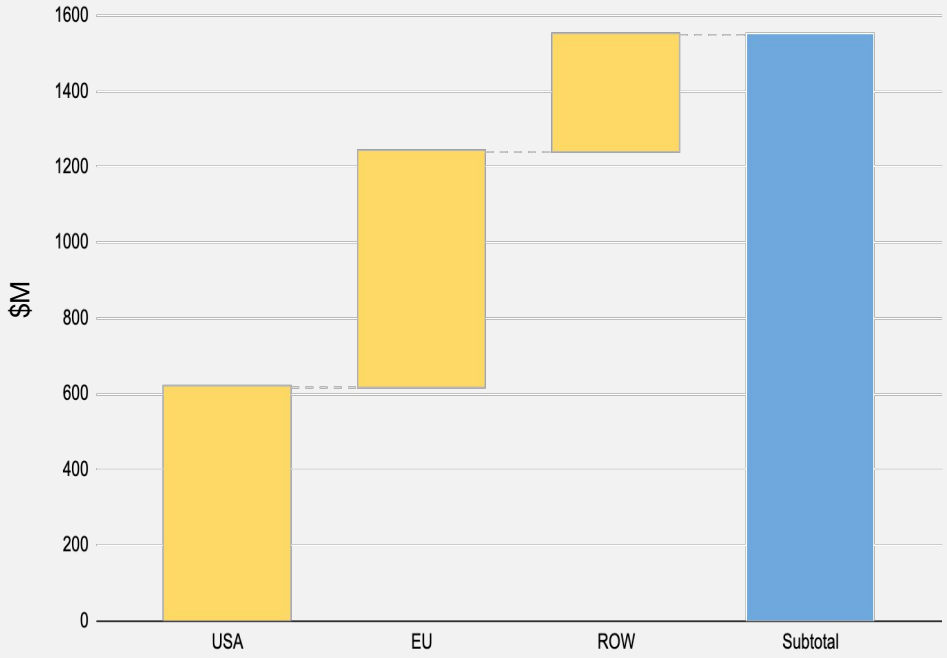
Key Considerations

1. **EU preterm prevalence of 2.8% of 4.7M births = 130K treatable patients, ~325% multiplier vs 40K in the US**
2. **EU average treatment duration is 3.1 weeks compared to US 5.6 weeks, ~55% multiplier**
3. **Evaluation of EU to US pricing analogues (e.g. surfactants) motivates a ~55% multiplier**
4. **EU Sales estimated to be ~$620M**

Projected EU Revenue Potential



IBP-9414 has megabrand potential >$1.5B Peak Sales*



→ **Triple layer IP protection**
1) data exclusivity
2) patent protection
3) orphan drug status

→ **≥12 years exclusivity across EU, US, Japan and China**

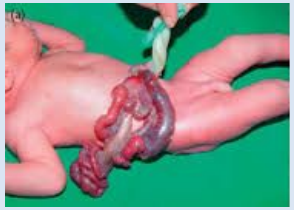
* New market research conducted 2021. ROW estimated at 50% of EU

IBP-9414 our lead Phase III program

New Opportunity: Gastroschisis IBP-1016

Significant unmet need

- 2,000 diagnosed US infants per year
- Post surgery: gut motility is absent, and oral feeding not tolerated for extensive period
- Serious comorbidities including growth retardation, sepsis (31%), NEC (5%) and in hospital mortality (3.6%)
- High economic burden with hospital stay estimated at $200-$300M (20-30 days at $5K per day for 2,000 infants)



Synergies with IBP-9414

- Same API (Lactobacillus reuteri)
- Both conditions in need of gut moving and functioning more quickly
- Adjacent patient target population
  - IBP-9414 targets <1500g Bwt / GA 23-32 weeks
  - IBP-1016 targets ~2500g Bwt / GA ~35 weeks
- Orphan drug potential
- Potential additional IP protection / biologics

Thank you

Infant Bacterial Therapeutics AB

www.ibtherapeutics.com