Infant Bacterial Therapeutics

September 2020

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Corporate and financial information

Founded in 2013 in Stockholm, Sweden

IPO in 2016, listed on Nasdaq Stockholm main market

- Market cap SEK 2 100 M ($240 M)

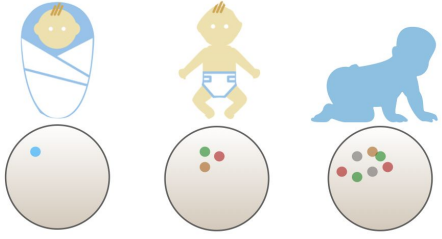
Financial results for the period April - June 2020

- Operational costs amounted to SEK 14.5 M (7.9)
  - IBP-9414 clinical trial costs amounted to SEK 9.2 M (3.1)
- Cash position as of June 30, 2020 SEK 473 M sufficient to fund IBP-9414 development to market

The IBT concept

- Establish the human microbiome to treat diseases related to poor gut function

- Newborn infant microbiome is dynamic



- Human bacterial strains derived from human breast milk

- Published clinical proof-of-concept signal

PEDIATRICS
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

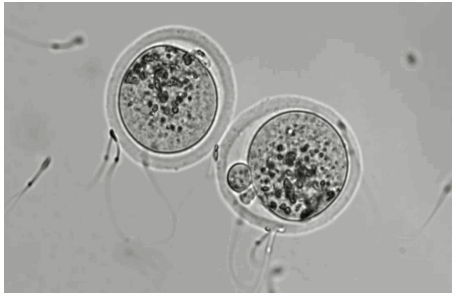
Prophylactic Probiotics to Prevent Death and Nosocomial Infection in Preterm Infants

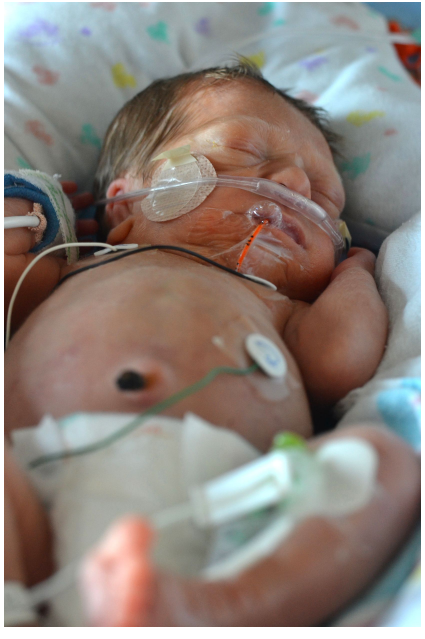
Mario A. Rojas, Juan M. Lozano, Maria X. Rojas, Viviana A. Rodriguez, Martin A. Rondon, Jaime A. Bastidas, Luis A. Perez, Catherine Rojas, Oscar Ovalle, Jorge E. Garcia-Harker, Maria E. Tamayo, Gloria C. Ruiz, Adriana Ballesteros, Maria M. Archila and Mauricio Arevalo

Pediatrics 2012;130;e1113; originally published online October 15, 2012; DOI: 10.1542/peds.2011-3584

High unmet medical need

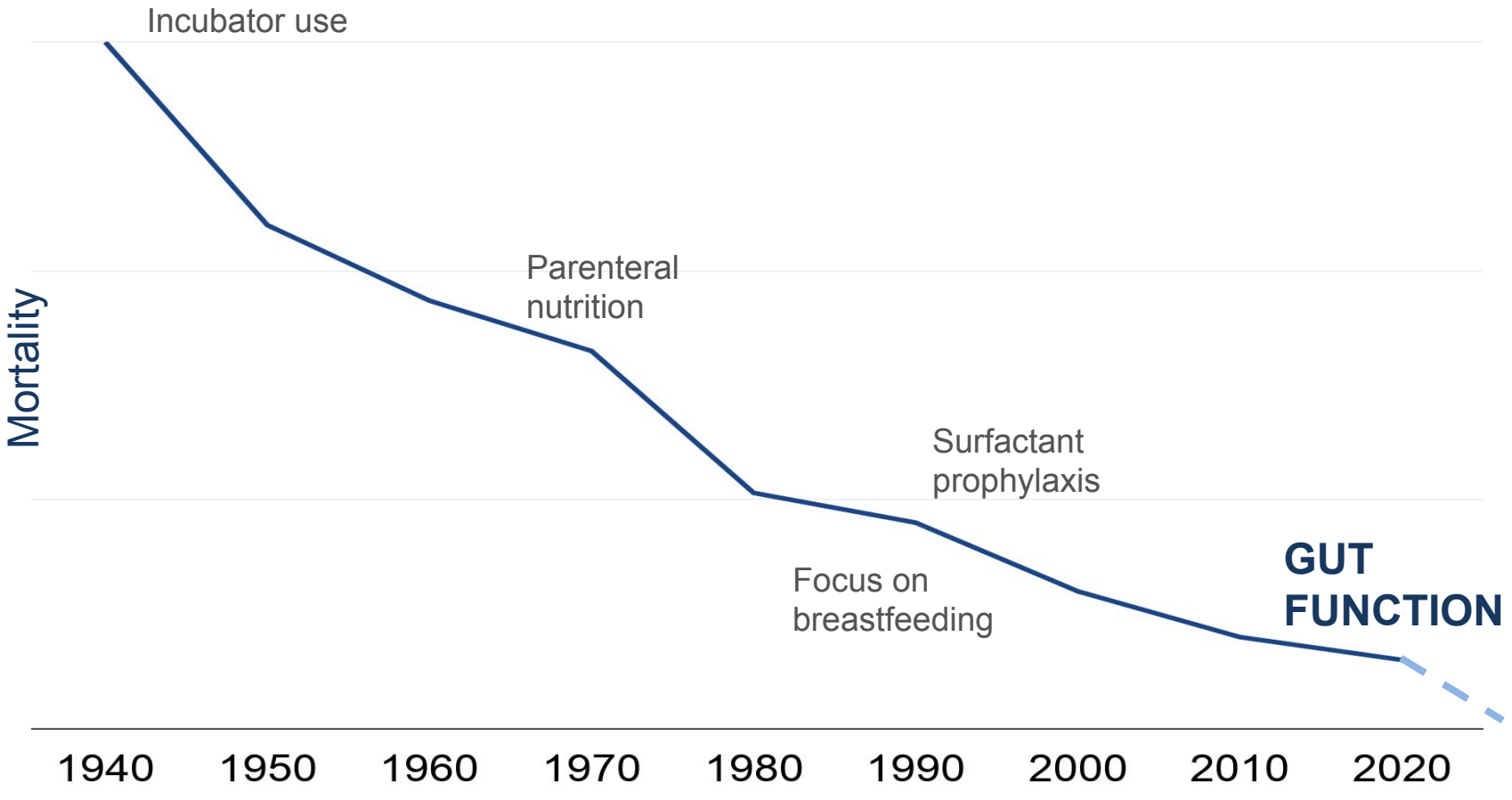
Our patients





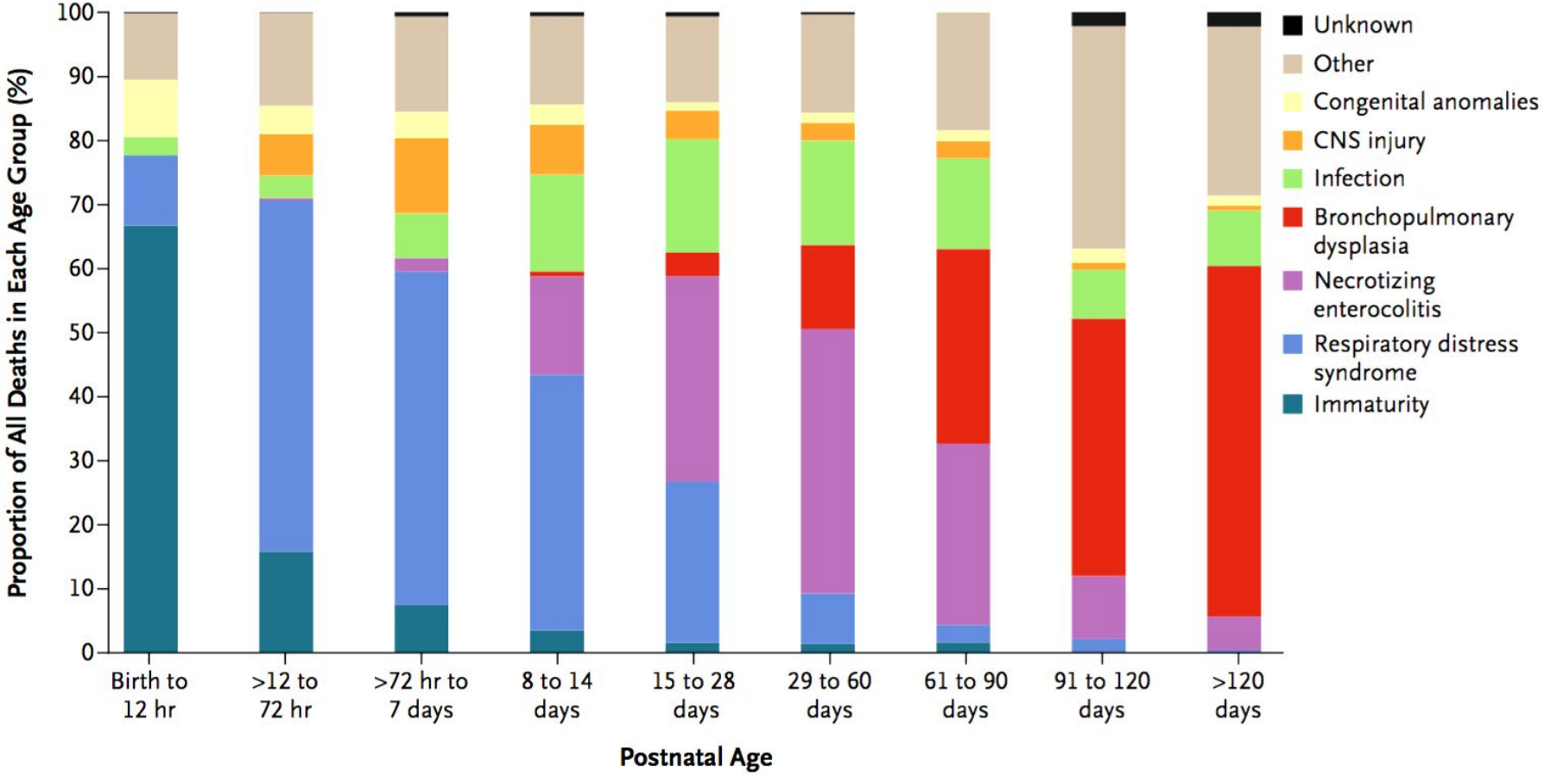
Micah from the U.S.

GI tract left untreated in preterm infants



CDC/NCHS, National Vital Statistics System

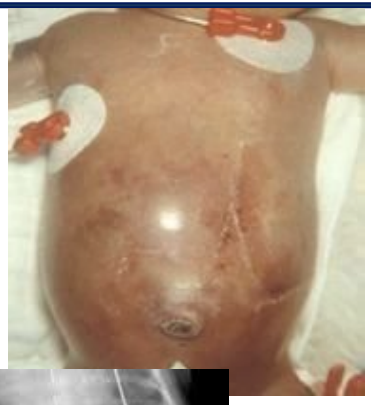
Causes of death

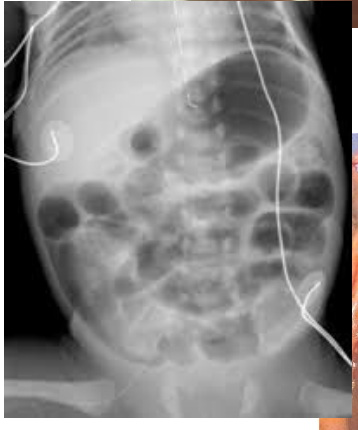


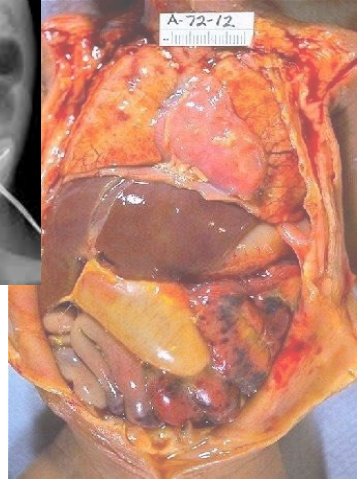
Patel 2015

Necrotizing enterocolitis (NEC)

- NEC is severe inflammation of the bowel in preterm infant where 20-40% need complicated and costly surgery
- Survivors have long-term consequences such as short-bowel syndrome, abnormal growth, cognitive, visual and hearing impairments
- There is no therapy available today
- **NEC is one of the leading causes of death in the Neonatal intensive care unit (NICU) with up to 40% morbidity rate killing 1500 US and 3700 EU infants each year**



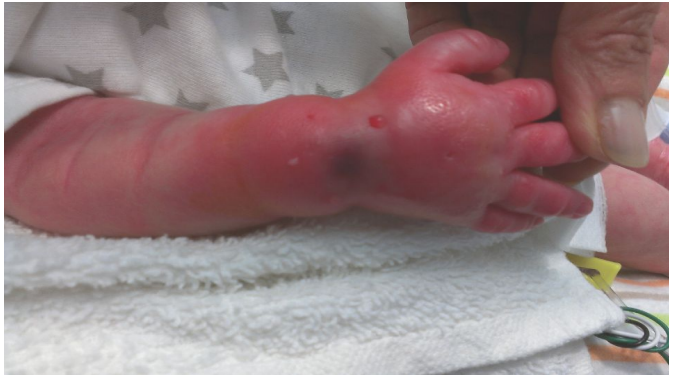




Simpson 2010, Clark 2012

Feeding the preterm infant

- Establishing enteral (mouth) feeding in preterm infants to establish “catch up growth” that is important for e.g. cognitive development.



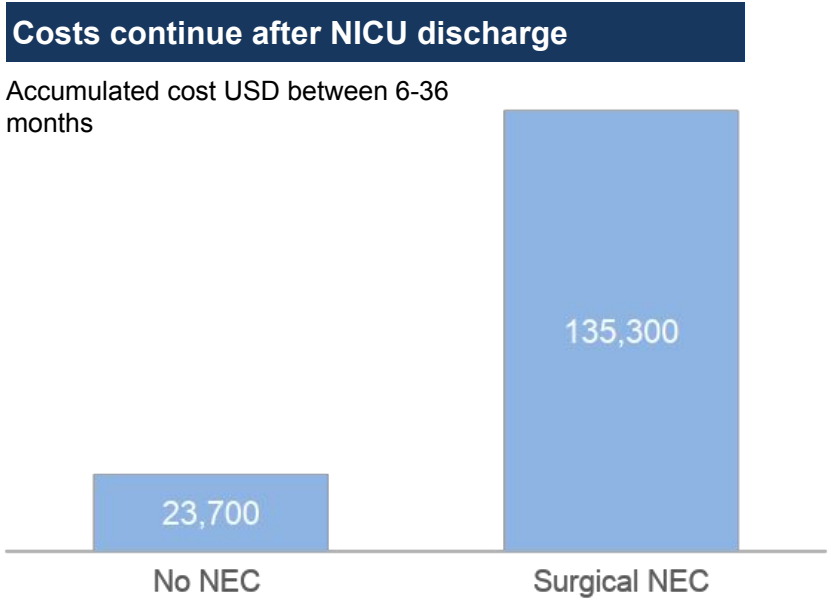
- Prolonged parenteral (needle feeding) nutrition increases cost and causes complications: cholestasis, increased risk of BPD, pulmonary vascular resistance, infections and sepsis.

Despite intensive nutritional strategies for premature infants, growth failure remains a major problem

Murgas-Torrazza, 2013; Agostoni, 2010

Economic burden of NEC

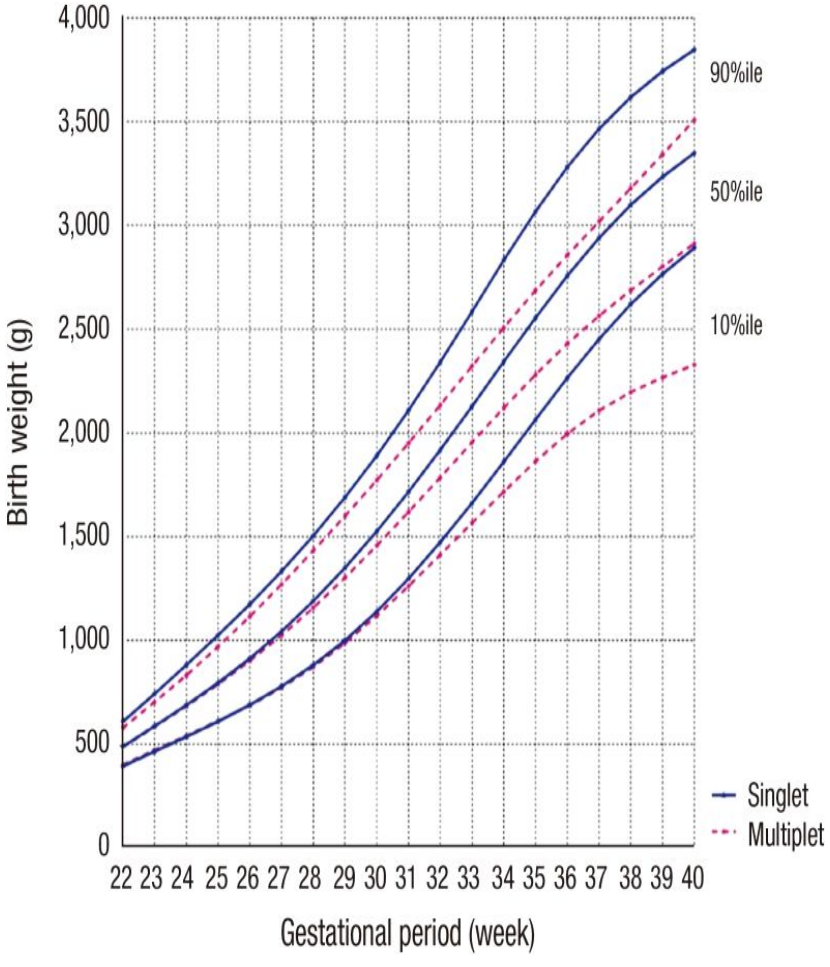
NEC Economic Burden is estimated to be 20% of the total cost of initial care and USD 5 Billion spent annually on NEC in the US.



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

Ganapathy 2011, 2013

Growth around week 30 is critical



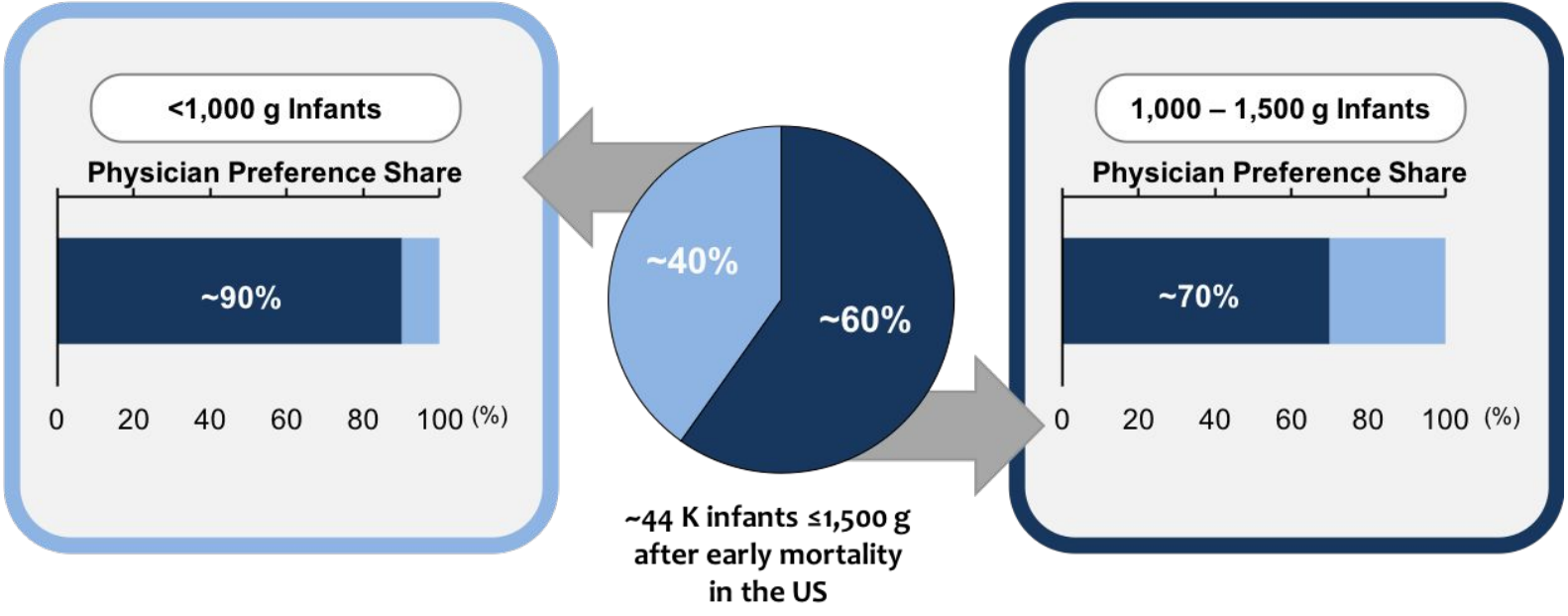
Lee 2016

- Prolonged hospital stay of the preterm infant is associated with a high direct cost burden
- Improved growth velocity improves neurodevelopmental outcomes in extremely low birth weight infants

Strong interest from the market

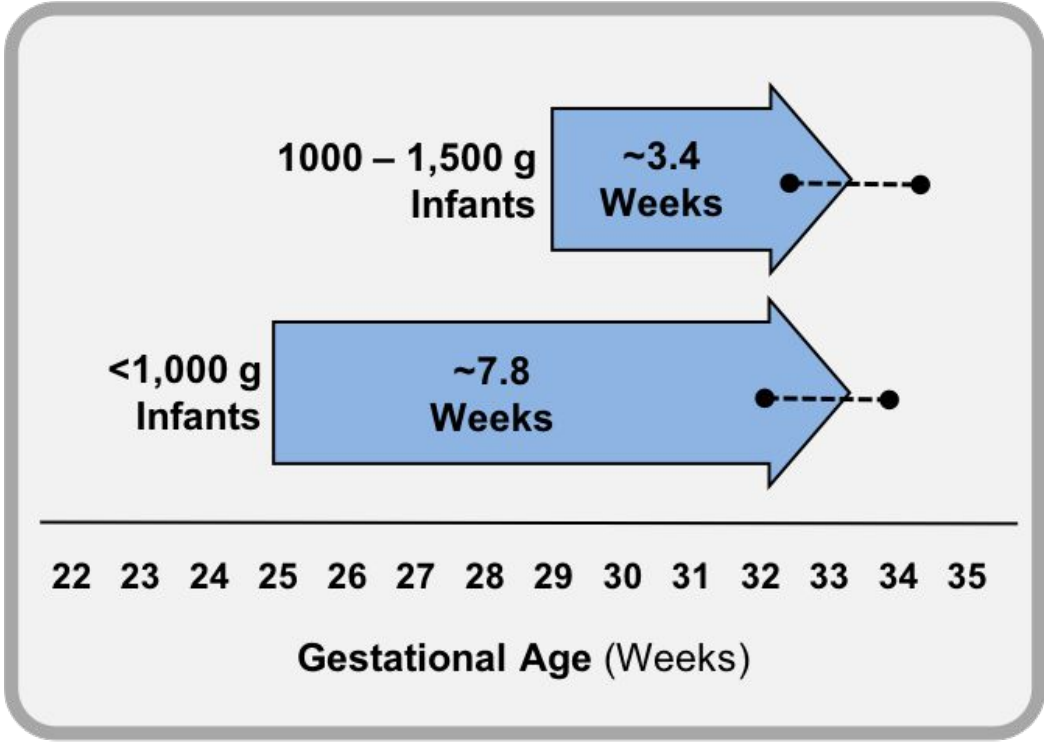
Neonatologists show high willingness to prescribe IBP-9414

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 largest share of premature infants

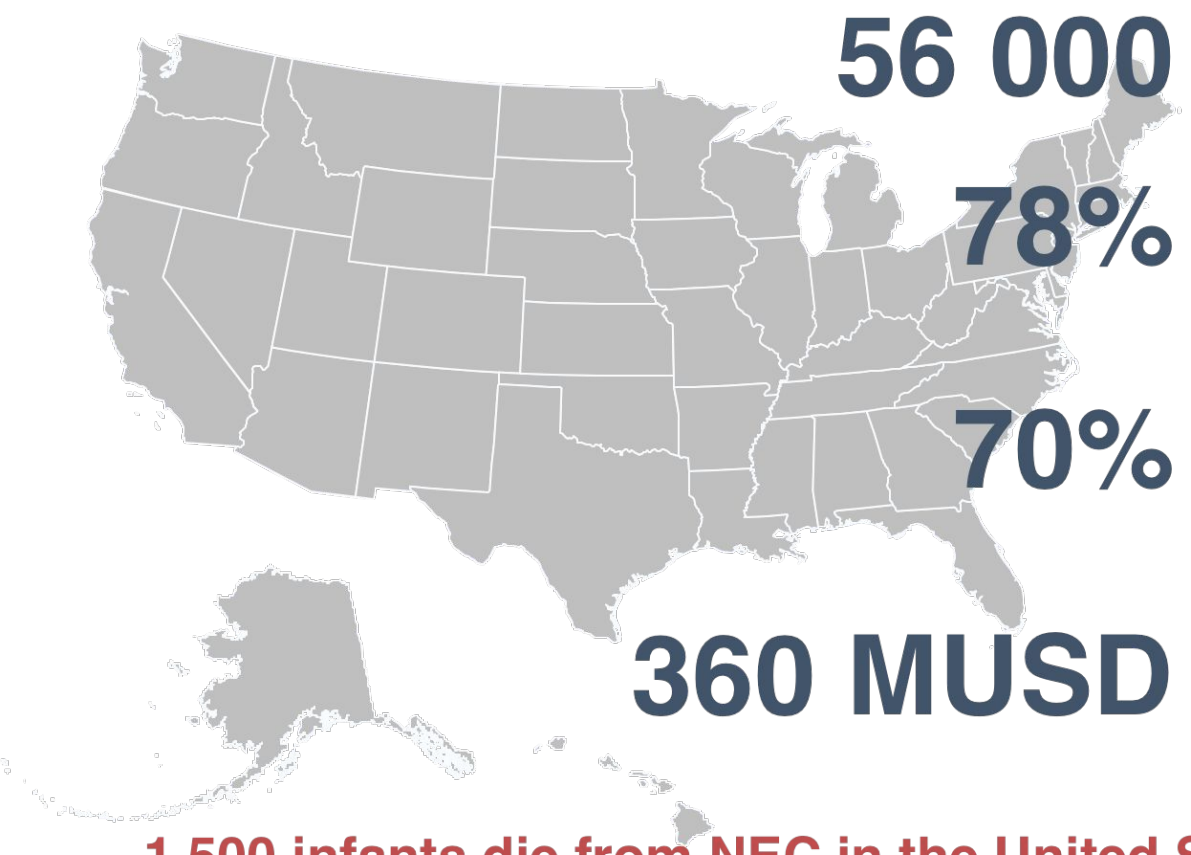


Institution Type	Major Medical Centers	Medium Hospitals	Small Community Hospitals
Share of Premature Infants	~60%	~30%	~10%
Estimated Formulary Adoption	~85%	~60%	~0%
Overall Formulary Inclusion	Approximately 70% of addressable patients are anticipated to receive care at an institution that includes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

ClearView Healthcare Partners

A valuable pharmaceutical

Results of market analysis by ClearView Healthcare Partners



56 000

Number of infants born under 1,500 grams in the United States annually

78%

Physician preference share demonstrates neonatologists show high willingness to prescribe IBP-9414

70%

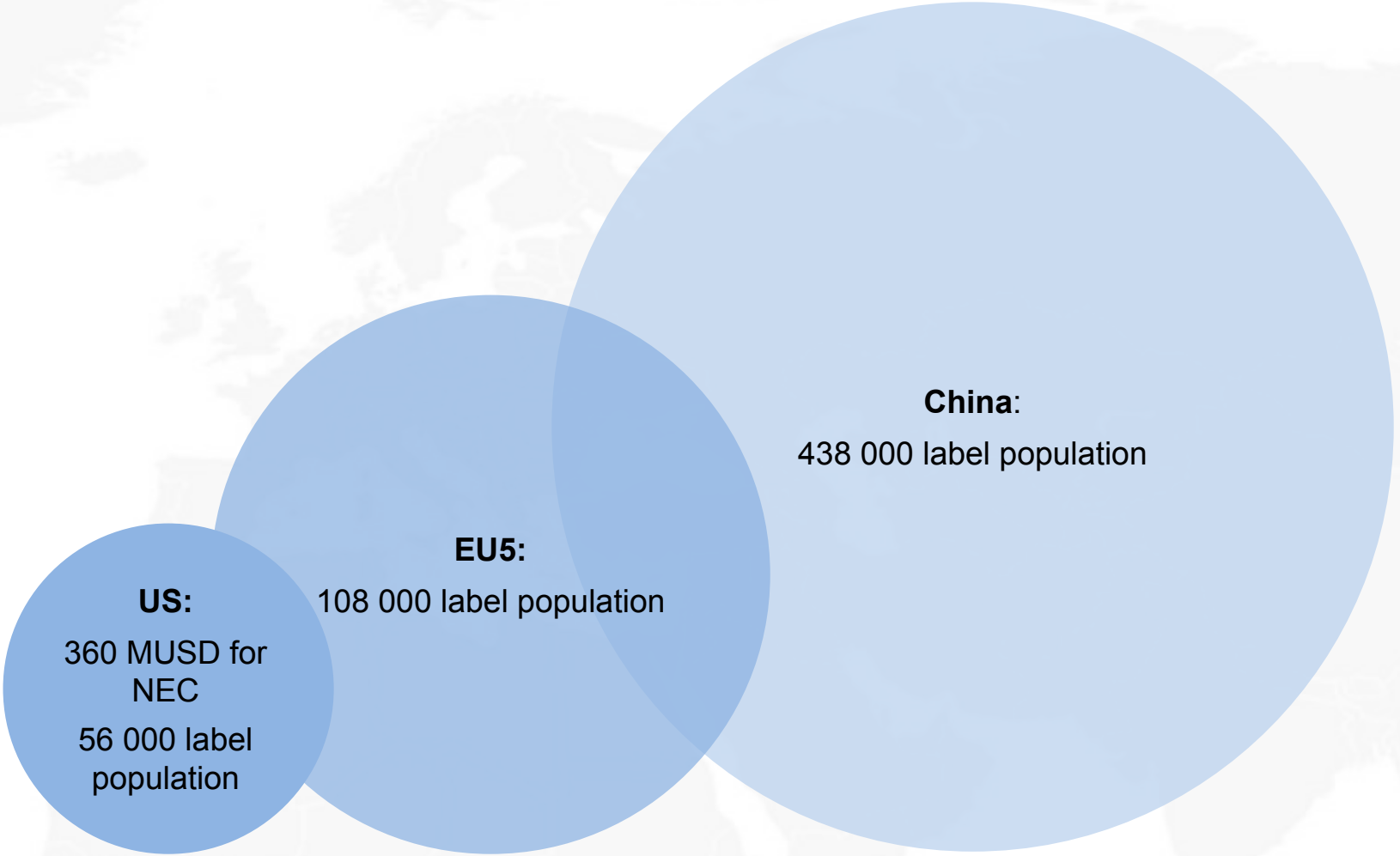
Of addressable patients are anticipated to receive care at an institution that includes IBP-9414 on formulary

360 MUSD

Estimated annual revenue potential in US based on ClearView market research

1 500 infants die from NEC in the United States each year

A globally valuable pharmaceutical

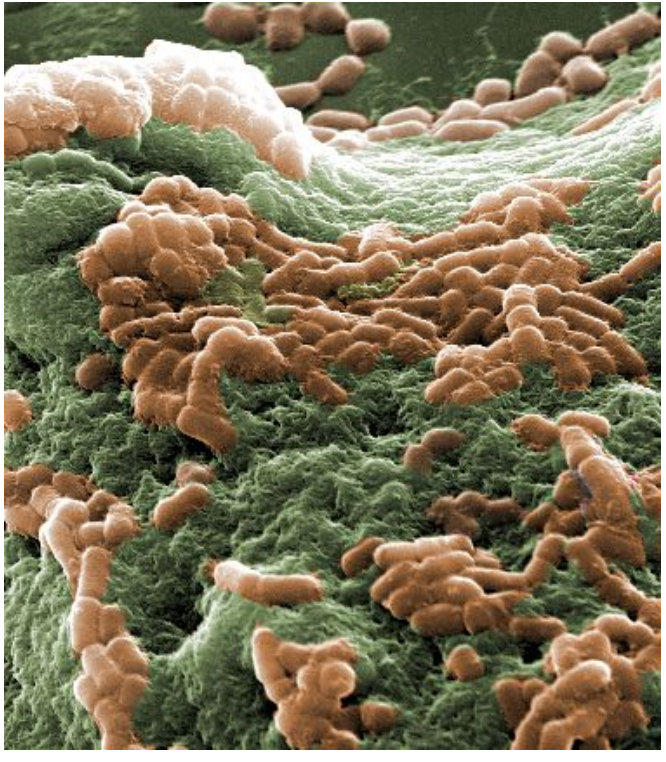


The product

Lactobacillus reuteri

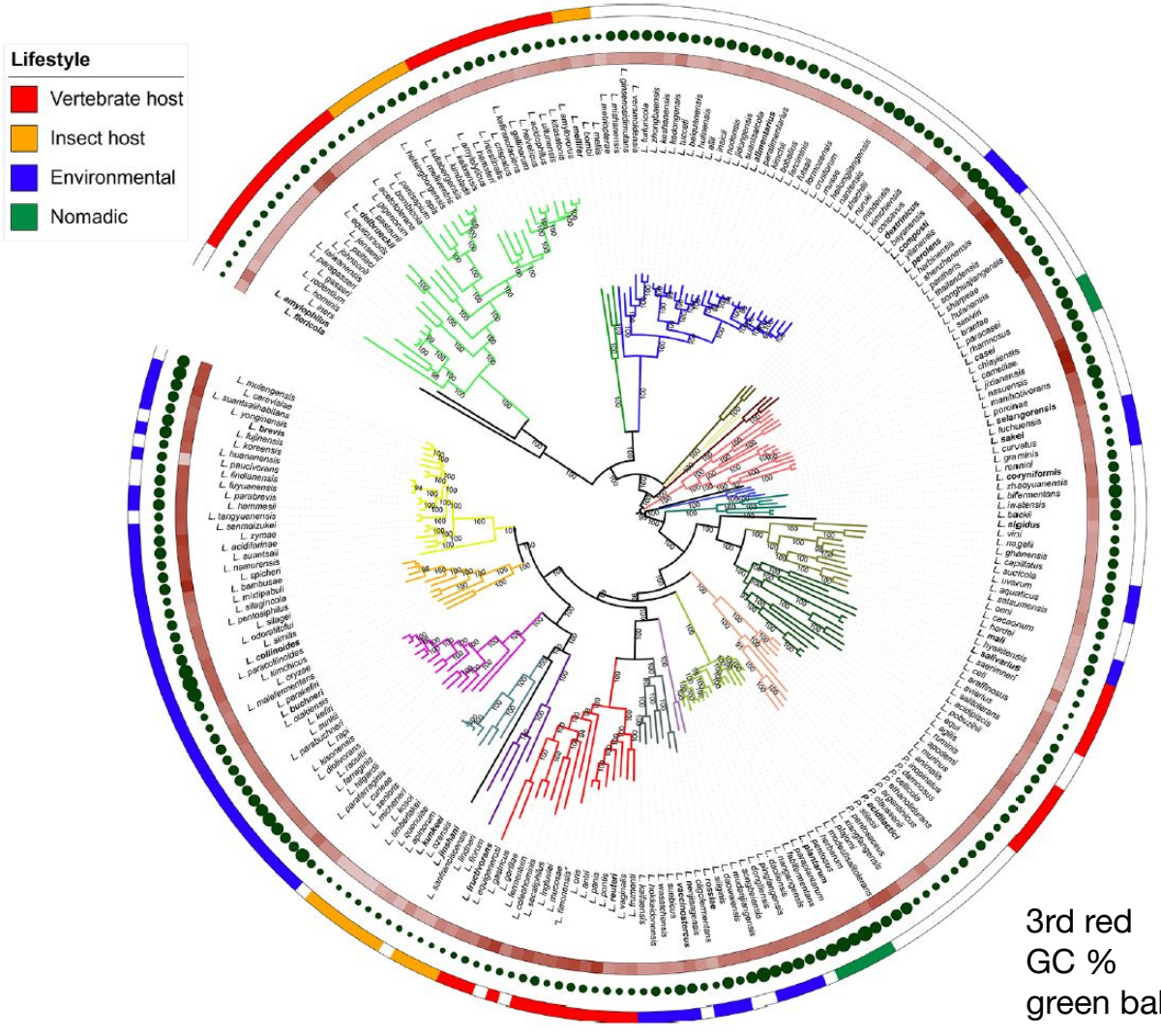
Active substance of IBP-9414

Lactobacillus reuteri present on women's breasts



Lactobacillus reuteri (orange) adhering to intestinal mucus

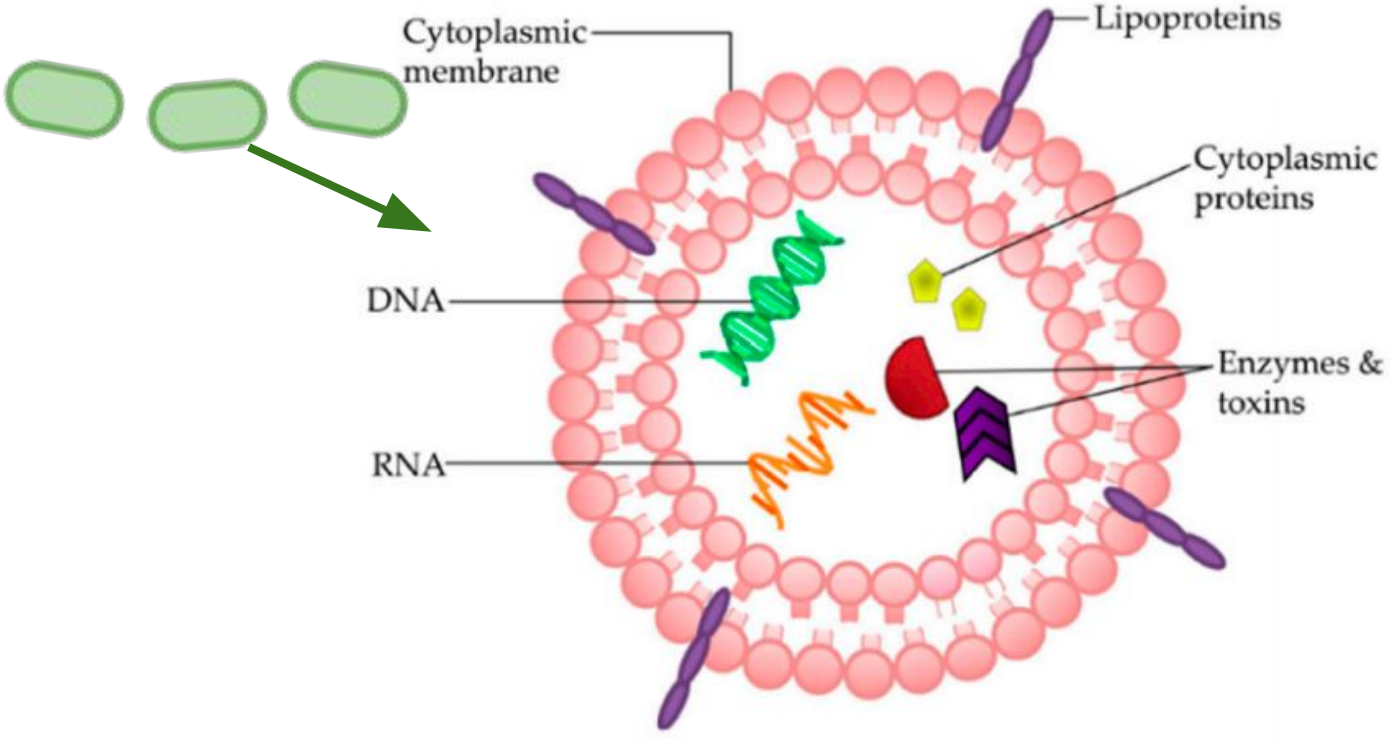
Limosilactobacillus reuteri



3rd red
GC %
green balls genome size

Source Zheng 2020

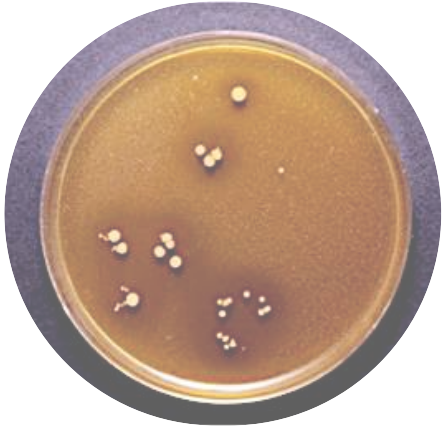
Microvesicles from L. reuteri

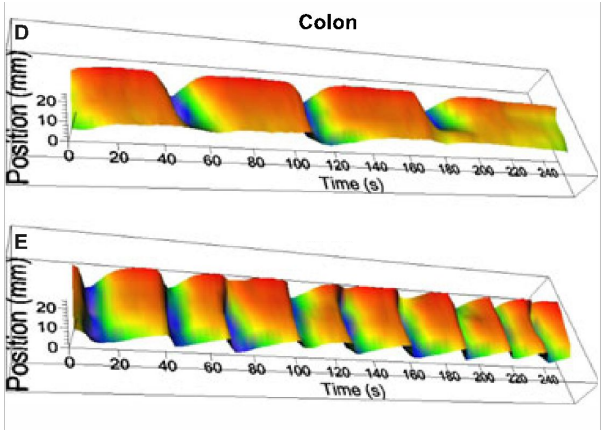


Bacterial membrane vesicles produced by *L. reuteri*

Source Wu 2013, West 2020

L. reuteri - mechanisms of action



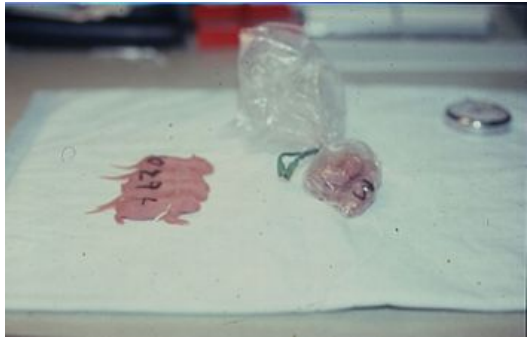


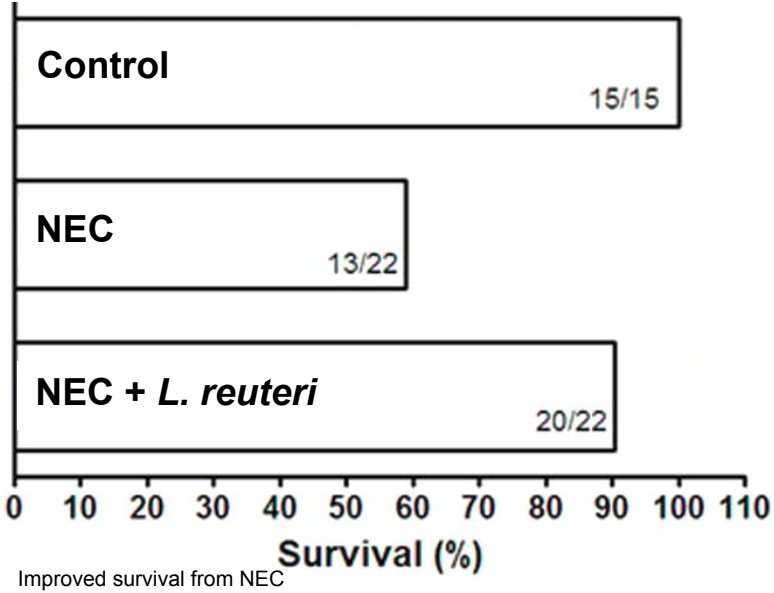
Combats dysbiosis **Reduces inflammation** **Improves gut motility**

Improved gut function including prevention of NEC

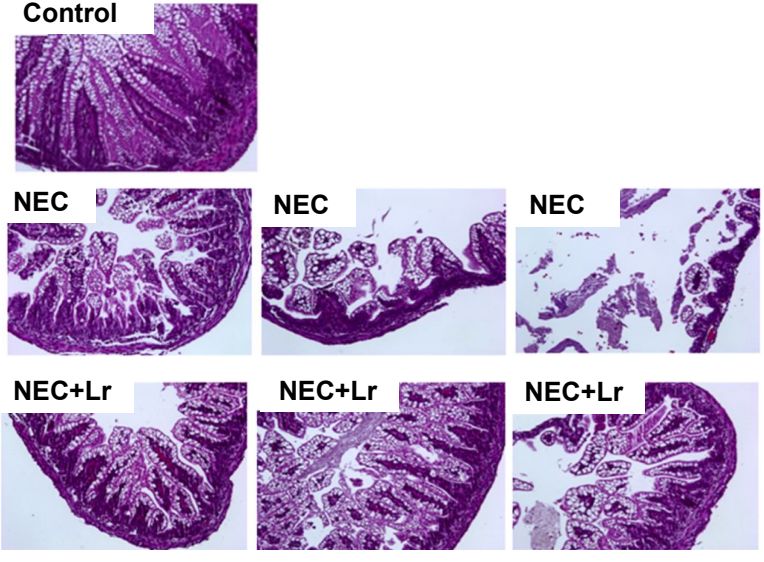
Schaefer 2010, Walter 2011, Wu 2013, West 2020

L. reuteri protects from NEC in animal models





Improved survival from NEC



Reduced intestinal damage

Liu, 2012, 2013, 2014

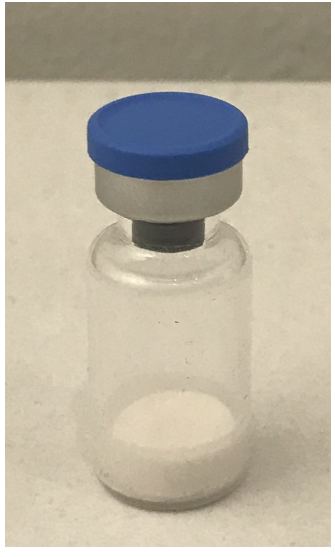
Pharmaceutical drug candidate IBP-9414

Developed under IND and CTX in contrast to food supplements

- Rigorous pharmaceutical Chemistry-Manufacturing-Control standards in all steps with GMP according to 21 CFR Part 210

- Single dose vial with dose accuracy following ICH Guidelines for Pharmaceuticals

- Stringent control of bioburden and microbial purity on final product analysis according to USA and Eur Pharmacopeia



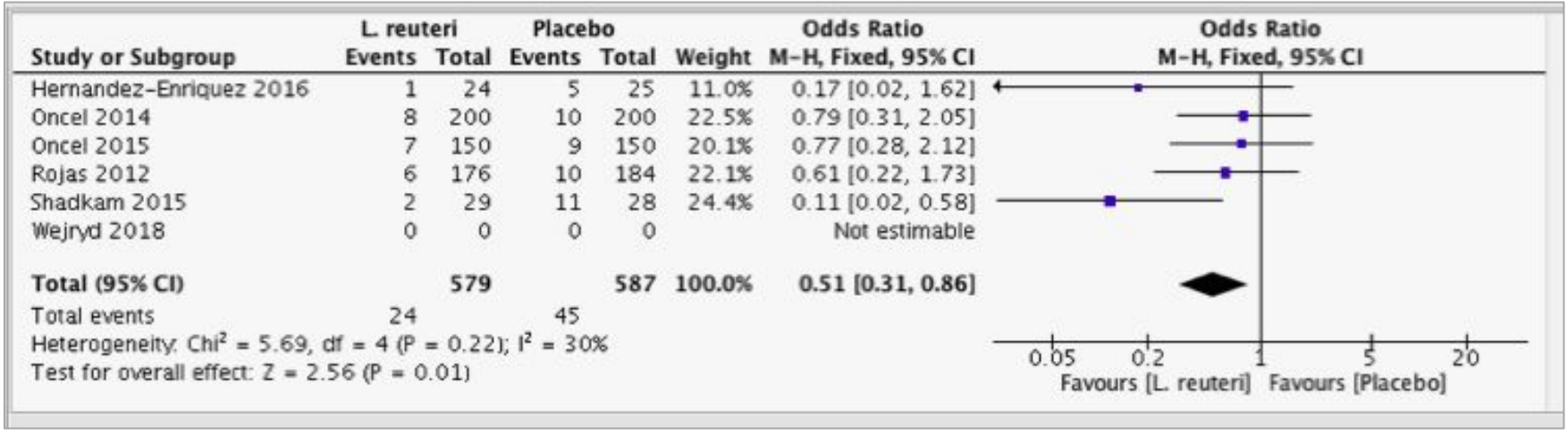
Clinical efficacy signal – *L. reuteri*

Clinical signal

NICU Study	Number of Patients	Reduction of NEC incidence	Reduction in episodes of feeding intolerance *or* reduction in time to full enteral feeding
Rojas et al. 2012	750	**37 %**	**43 %**
Oncel et al. 2014	400	**20 %**	**33 %**
Oncel et al. 2015	300	**22 %**	**36 %**
Shadkam et al. 2015	60	**82 %**	**24 %**
Hernandez-Enriquez et al. 2016	44	**83 %**	**17 %**
Indrio et al. 2017	60		**44 %**
Spreckels et al. 2018	104	**55 %**	
Wejryd et al. 2019	134	**17 %**	**0 %**
Hunter et al. 2012/Dimaguila et al. 2013	354	**89 %**	
Jerkovic-Raguz et al. 2016	100	**50 %**	
Sanchez-Alvarado 2017	225	**64 %**	
Kaban et al. 2019	94	**100 %**	**67 %**
Rolnitsky et al. 2019	1,357	**55 %**	**52 %**
Cui 2019	93	**75 %**	**18 %**

NEC clinical signals

Incidence of NEC



Study or Subgroup	L. reuteri Events	L. reuteri Total	Placebo Events	Placebo Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Hernandez-Enriquez 2016	1	24	5	25	11.0%	0.17 [0.02, 1.62]
Oncel 2014	8	200	10	200	22.5%	0.79 [0.31, 2.05]
Oncel 2015	7	150	9	150	20.1%	0.77 [0.28, 2.12]
Rojas 2012	6	176	10	184	22.1%	0.61 [0.22, 1.73]
Shadkam 2015	2	29	11	28	24.4%	0.11 [0.02, 0.58]
Wejryd 2018	0	0	0	0		Not estimable
Total (95% CI)		**579**		**587**	**100.0%**	**0.51 [0.31, 0.86]**
Total events	24		45			

Heterogeneity: $Chi^2 = 5.69$, $df = 4$ ($P = 0.22$); $I^2 = 30\%$

Test for overall effect: $Z = 2.56$ ($P = 0.01$)

Odds Ratio M-H, Fixed, 95% CI

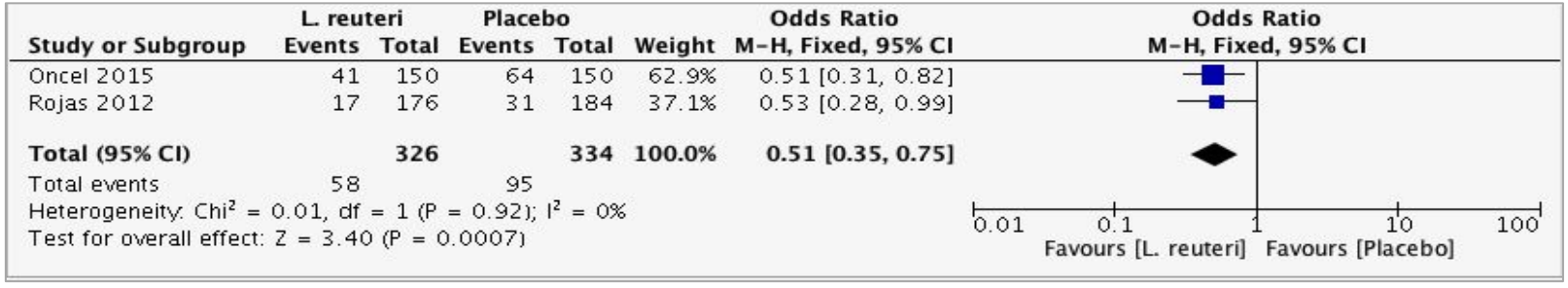
0.05 0.2 1 5 20

Favours [L. reuteri] Favours [Placebo]

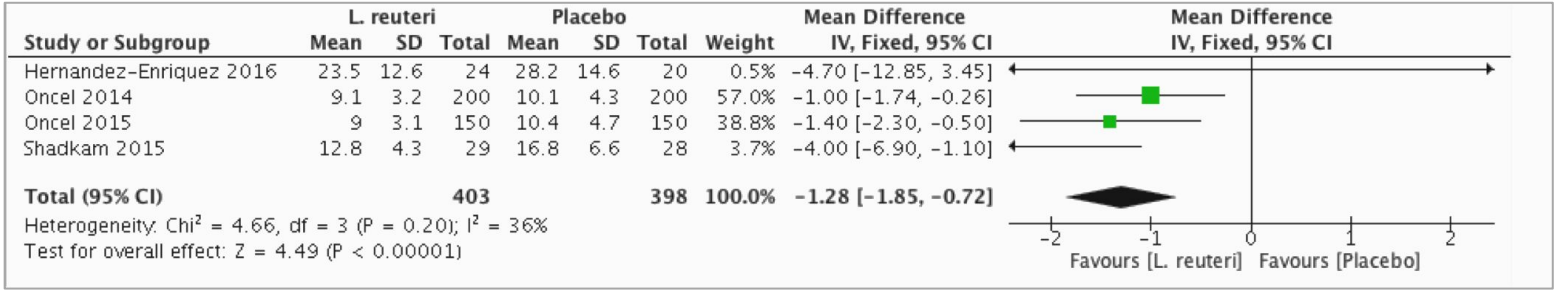
Meta-analysis: NEC <1500g all randomized controlled trials gives an Odds Ratio of 0.51

Feeding tolerance – clinical signals

Reported feeding intolerance events



Time to full enteral feeding

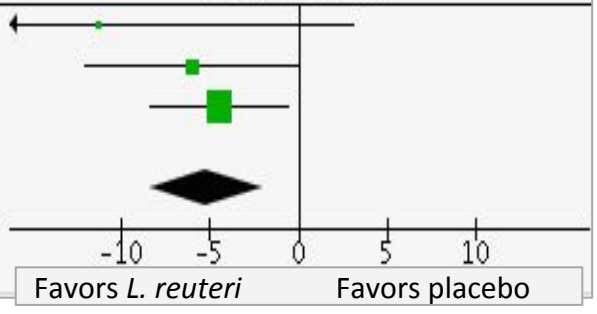


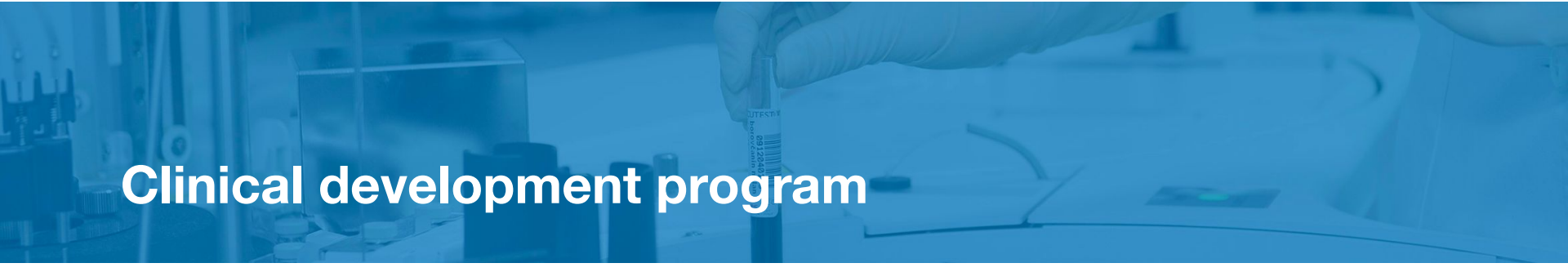
Hospital stay – clinical signal

Study or Subgroup	L. reuteri Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Hernandez-Enriquez 2016	39.3	22.8	24	50.6	25.4	20	4.9%	-11.30 [-25.69, 3.09]
Oncel 2015	42.4	24.1	150	48.4	29.2	150	27.9%	-6.00 [-12.06, 0.06]
Rojas 2012	32.5	17	176	37	20.7	184	67.2%	-4.50 [-8.41, -0.59]
Total (95% CI)			**350**			**354**	**100.0%**	**-5.25 [-8.46, -2.05]**

Heterogeneity: $Chi^2 = 0.88$, $df = 2$ ($P = 0.64$); $I^2 = 0\%$

Test for overall effect: $Z = 3.22$ ($P = 0.001$)





Clinical development program

The Connection Study - COVID-19

- No study-induced hospital visits are required
- Life and death study. Urgent medical need to prevent NEC
- Monitoring is now virtual with no face to face visits needed

NICUs have been able to continue recruiting but since the pandemic continues to affect patient recruitment, there is an increased risk that we will not be able to complete the study during 2021.

Phase III Pivotal Trial - The Connection Study

- Connection Study started July 2019
- Regulatory approvals to start Phase III in Hungary, France, Spain, Israel, UK and USA
- Additional Regulatory filings during summer in Poland, Serbia, Bulgaria and Romania
- 55 (45) sites are activated
- 76 (62) sites that we have signed clinical agreement

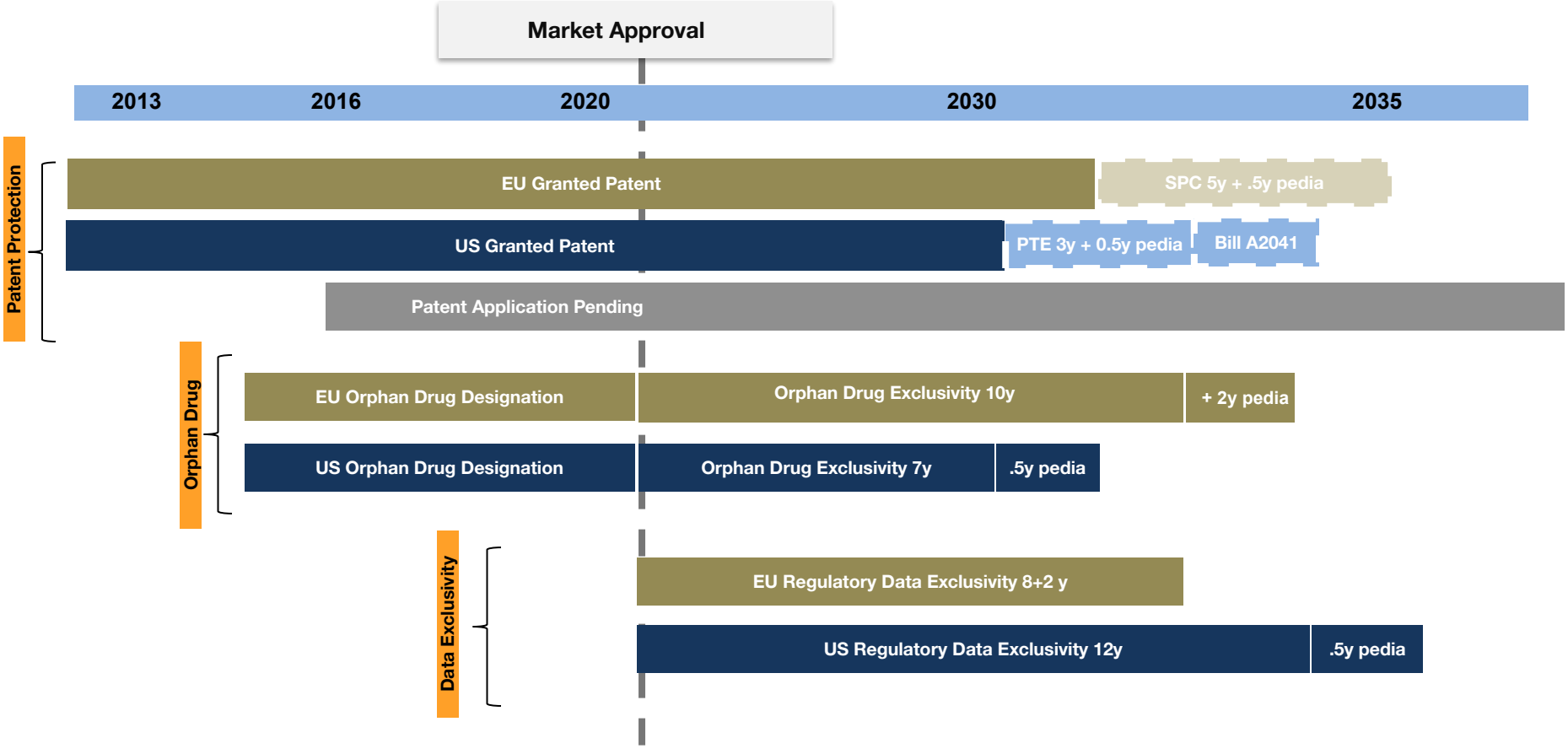
First distribution deal for IBP-9414 in place

With Megapharm for IBP-9414 for the Israeli market and the Palestinian Authority's territories.

- Megapharm responsible for local registration, price negotiation and marketing
- IBT will receive 70% of revenue after an initial period
- Potential to include Israeli medical centers in Phase III trial

IBP-9414 Market Exclusivity

Three layers of IP protection



IBP-9414 our lead Phase III program

Ticks all relevant pillars for the development of a successful drug

Medical need	✓
Mechanism of action	✓
Clinical data	✓
Safe	✓
Aligned regulatory agencies	✓
GMP manufacture	✓
Market exclusivity	✓
Aligned payers	✓
Orphan Drug and Rare Pediatric Disease designations	✓
Cash position sufficient to fund IBP-9414 development	✓


Thank you
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