



Infant Bacterial Therapeutics

Pareto Securities Health Care Conference
September 2017



INFANT BACTERIAL THERAPEUTICS

Disclaimer

This presentation (the “Presentation”) has been prepared by Infant Bacterial Therapeutics AB (publ) (the “Company”) and is furnished to you solely for your information and may not be reproduced or redistributed, in whole or in part, to any other person. By attending the meeting where the Presentation is made, or by reading the presentation slides, you agree to be bound by the following limitations.

The Presentation and any materials distributed in connection with the Presentation are not directed to, or intended for distribution to or use by, any person or entity that is a citizen or resident or located in any locality, state, country or other jurisdiction where such distribution, publication, availability or use would be contrary to law or regulation or which would require any registration or licensing within such jurisdiction. The Company’s securities mentioned herein have not been, and will not be, registered under the US Securities Act of 1933, as amended (the “Securities Act”). The distribution of the Presentation in certain jurisdictions may be restricted by law and persons into whose possession the Presentation comes should inform themselves about, and observe, any such restrictions.

The Presentation does not constitute an offer or invitation to subscribe for, or purchase, any shares of the Company and neither the Presentation nor anything contained herein shall form the basis of, or be relied upon in connection with, any contract or commitment whatsoever.

The Presentation contains various forward-looking statements that reflect management’s current views with respect to future events and financial and operational performance. The words “believe,” “expect,” “anticipate,” “intend,” “may,” “plan,” “estimate,” “should,” “could,” “aim,” “target,” “might,” or, in each case, their negative, or similar expressions identify certain of these forward-looking statements. Others can be identified from the context in which the statements are made. These forward-looking statements involve known and unknown risks, uncertainties and other factors, which are in some cases beyond the Company’s control and may cause actual results or performance to differ materially from those expressed or implied from such forward-looking statements. These risks include, but are not limited to, the Company’s ability to operate, maintain its competitive position, the Company’s ability to promote and improve its reputation and the awareness of its product, the Company’s ability to successfully operate its growth strategy, the impact of changes in pricing policies, political and regulatory developments in the markets in which the Company operates, and other risks.

The information and opinions contained in this document are provided as at the date of the Presentation and are subject to change without notice. No representation or warranty (expressed or implied) is made as to, and no reliance should be placed on, the fairness, accuracy or completeness of the information contained herein. Accordingly, none of the Company, or any of its principal shareholders or subsidiary undertakings or any of such person’s executives or employees accept any liability whatsoever arising directly or indirectly from the use of the Presentation.

Except as explicitly stated herein, no information in the Presentation has been audited or reviewed by the Company’s auditor. Certain financial and other numerical information presented in the Presentation have been subject to rounding adjustments. As a result, the figures in tables may not always sum up to the stated totals.



Infant Bacterial Therapeutics

Overview

History	Current	Future
<ul style="list-style-type: none">■ 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	<ul style="list-style-type: none">■ 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, SEK76m cash■ Current worldwide, royalty free patent	<ul style="list-style-type: none">■ Phase II results for IBP-9414 expected during the autumn 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

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



Not from



etc.

- Clinical proof-of-concept signal published to engage IBT in development

Key IBT people and collaborators

Extensive experience and collaboration with tier 1 institutions

Key IBT decision makers

	Peter Rothschild, MBA Chairman	<ul style="list-style-type: none">■ 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	<ul style="list-style-type: none">■ 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	<ul style="list-style-type: none">■ 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	<ul style="list-style-type: none">■ 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	<ul style="list-style-type: none">■ Extensive experience in the pharmaceutical industry with specialisation on pharmaceutical development, project leadership and business development
	Agneta Heierson, Ph.D. Vice President, Clinical Development	<ul style="list-style-type: none">■ Over 25 years experience in the pharma industry■ Formerly Global VP, R&D Supply Chain at AstraZeneca
	Daniel Mackey Chief Financial Officer	<ul style="list-style-type: none">■ 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 June 2017 ca SEK76m
- Strong investor base and over 5,000 Shareholders
- Application to Nasdaq Main Market planned 2017
- Market Cap ca SEK480m (€50m)
- YTD Stock performance ca 90%



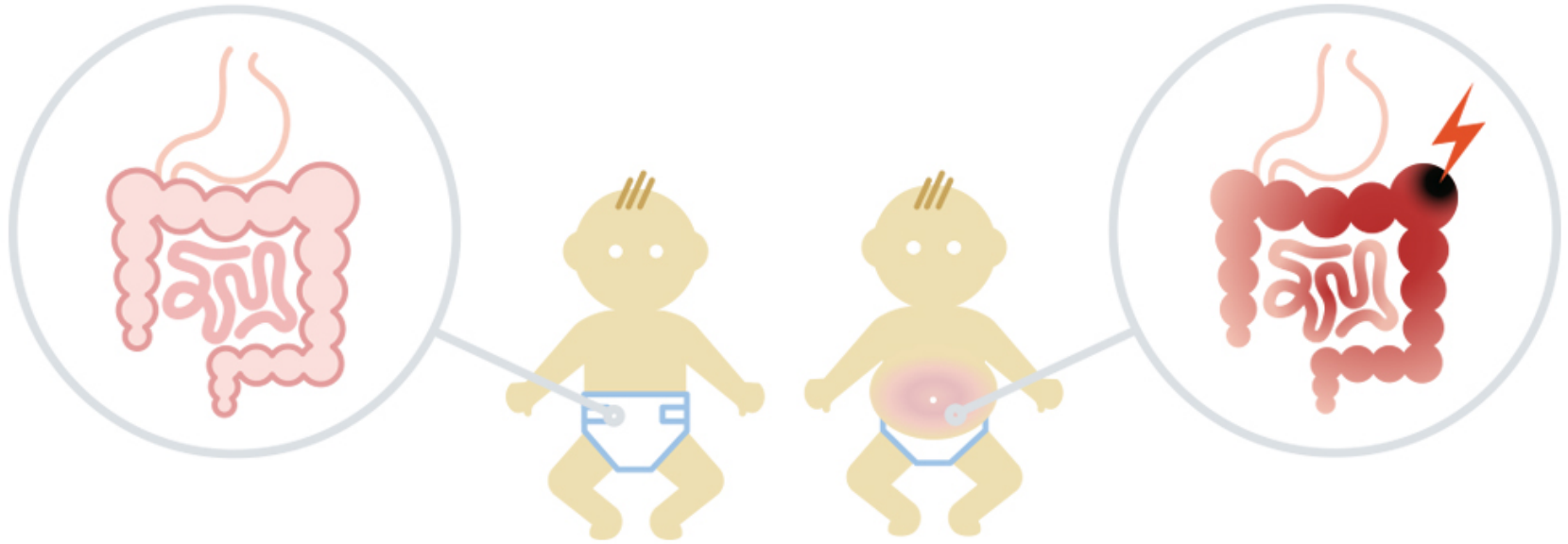
Major Shareholders as of June 30, 2017

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



1. IBP-9414 for the prevention of necrotizing enterocolitis

Necrotizing Enterocolitis (NEC)



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

A devastating gastrointestinal emergency



NEC kills 1500 US och 3700 EU infants every year

Who gets NEC?

Premature infants

High incidence and mortality	Infants birth weight	NEC incidence rate (%)	NEC mortality rate (%)	Mortality (% of weight cohort)
	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

Target population

A preventive therapy for all preterm infants at risk of NEC

Current clinical NEC progression

100 premature infants (751-1,000g)



9 medical NEC cases

*Treated by
antibiotics*



5 survivors



4 surgical cases



1 survivor after
surgery



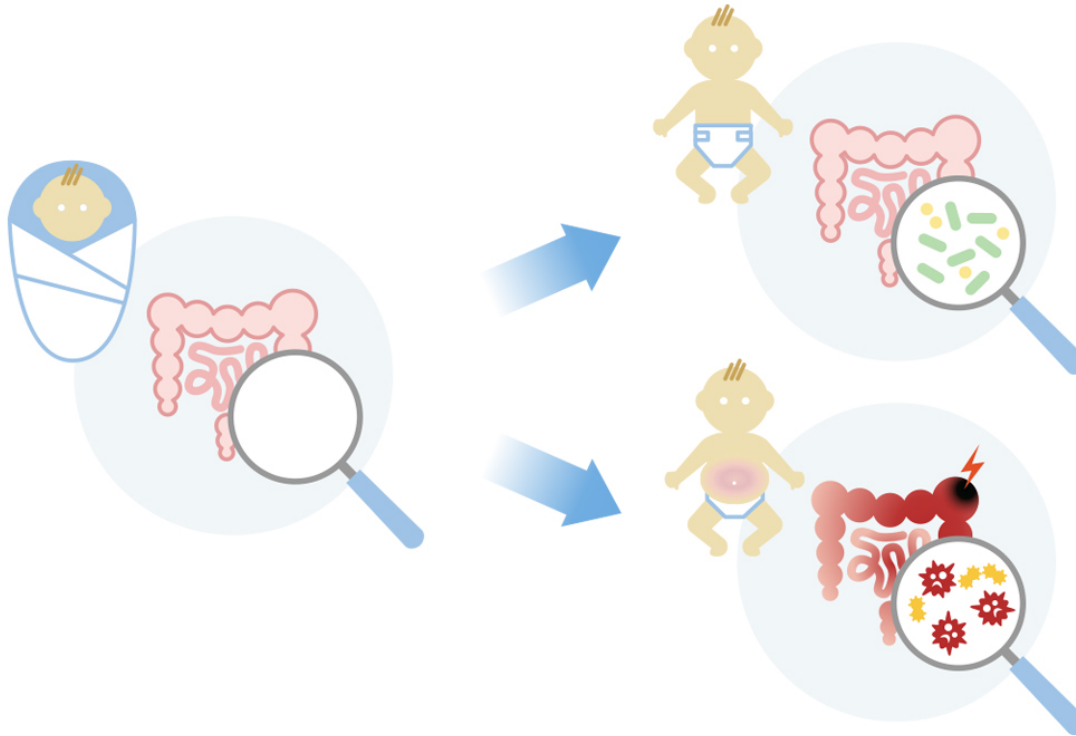
3 deaths

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

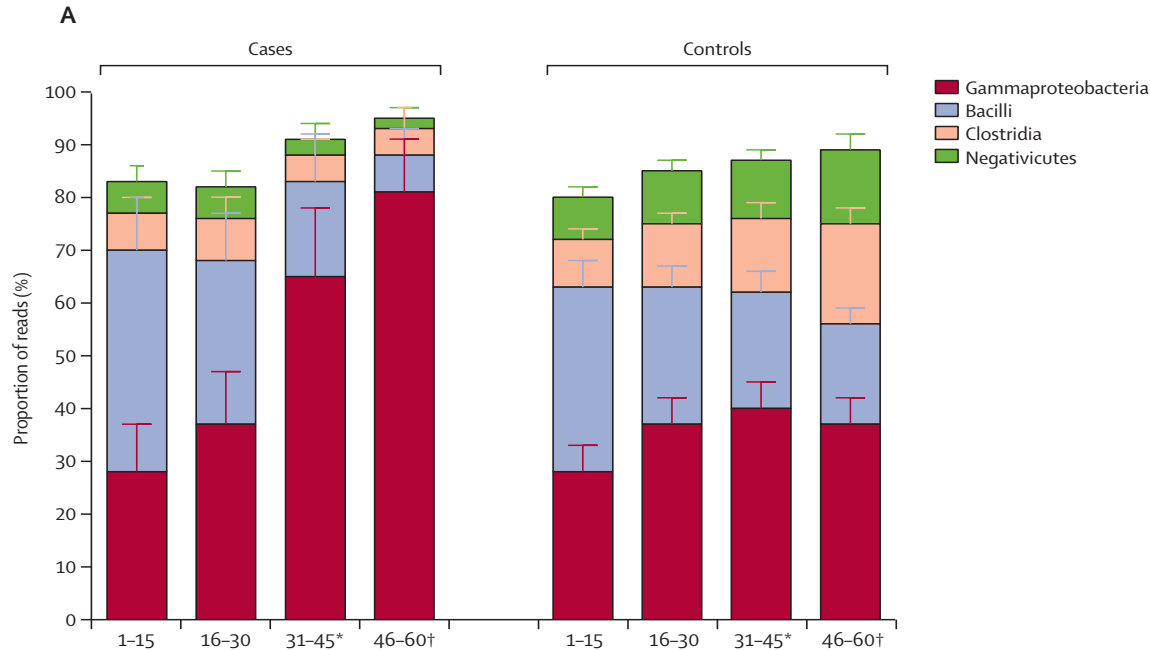
+ Dysbiosis
+ Impaired gut motility
+ Unregulated inflammation
⇒ **NEC**



Our objective is to prophylactically treat against NEC

What causes NEC? – Dysbiosis in the gut

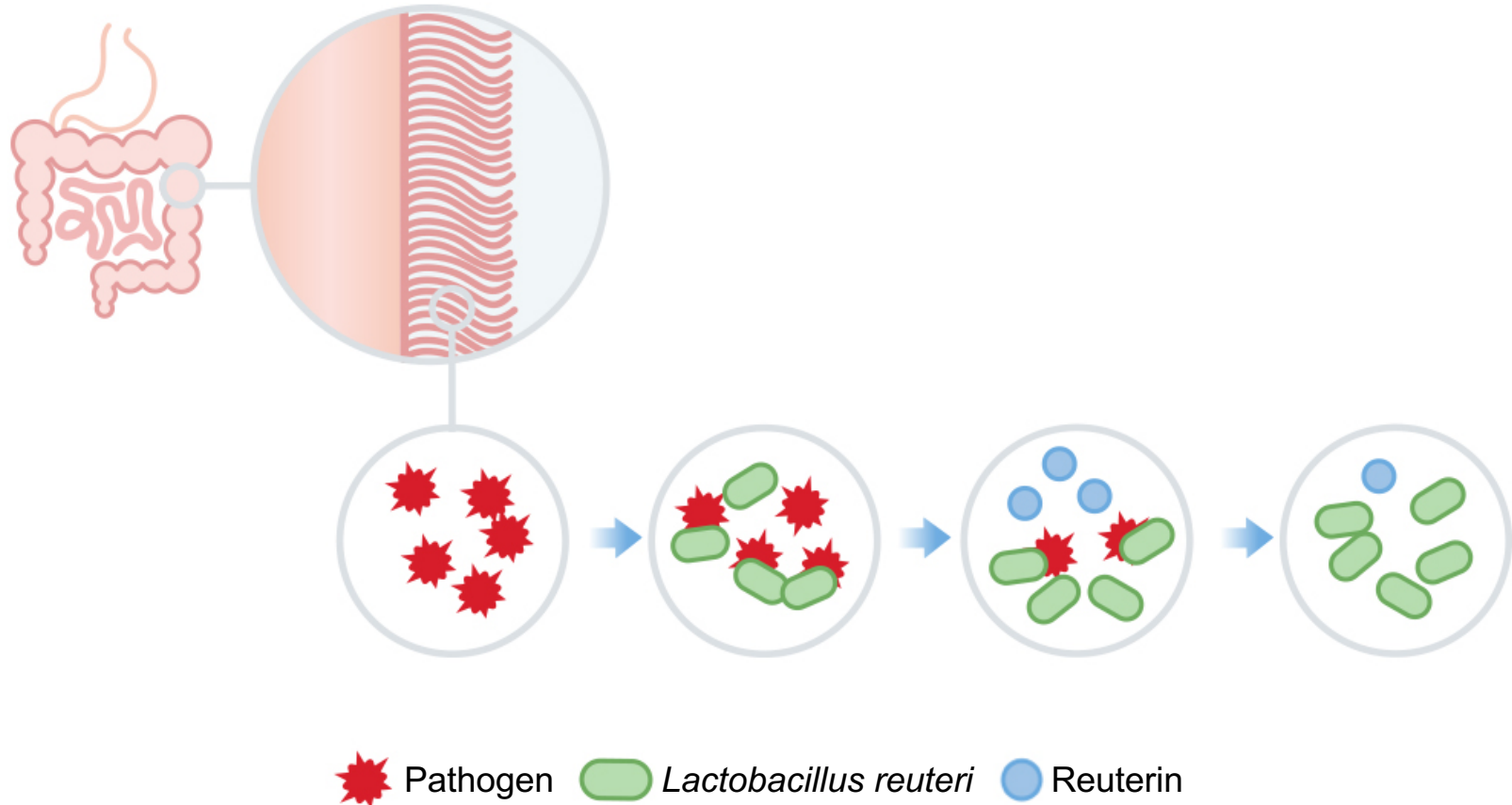
Dysbiosis with inappropriate colonization and pathogen blooms in the microbiota can contribute to necrotizing enterocolitis in preterm infants



Bloom of the pathogen-rich gamma proteobacteria prior to onset of NEC has been shown in 7 different studies to date (Neu, Versalovic in press)

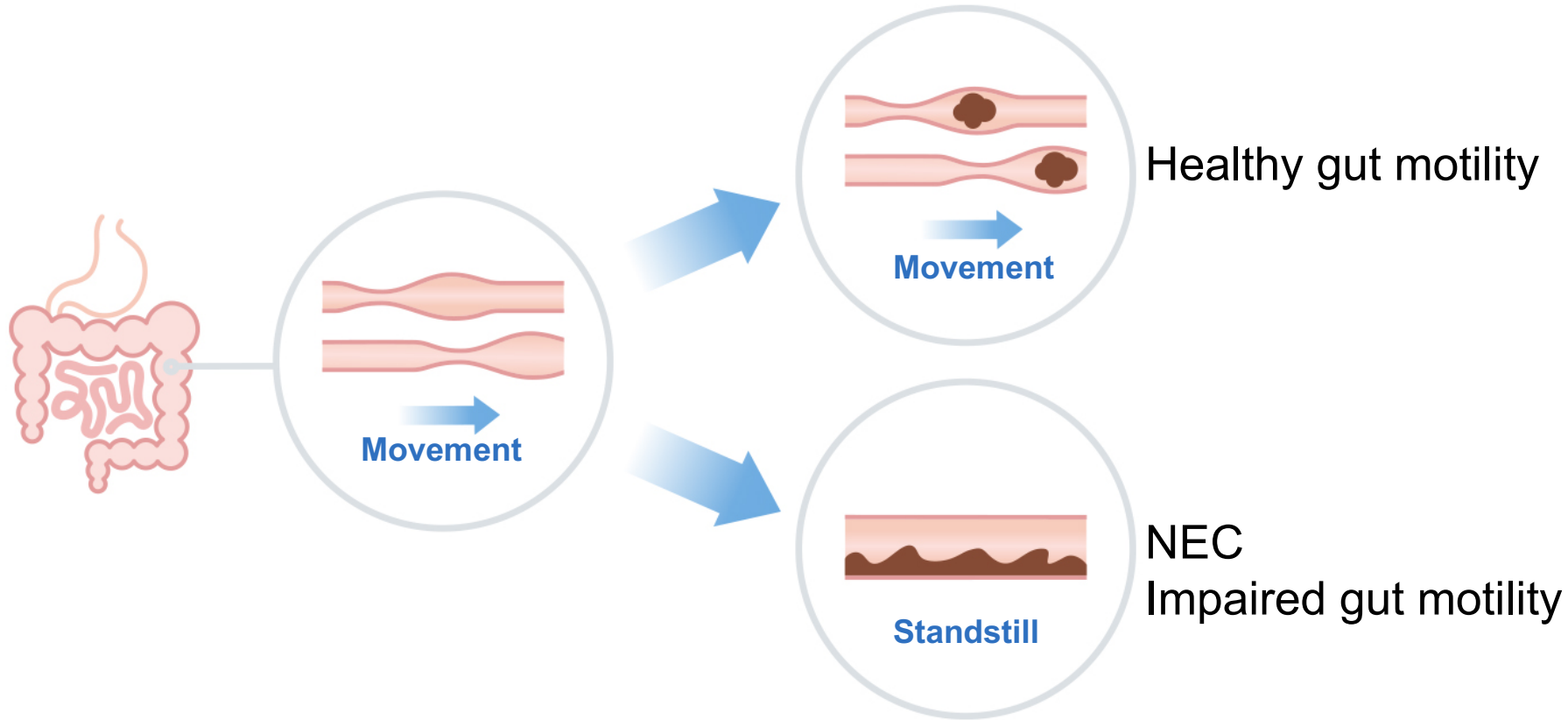
What does *L. reuteri* do to dysbiosis?

Fights pathogen growth in gut



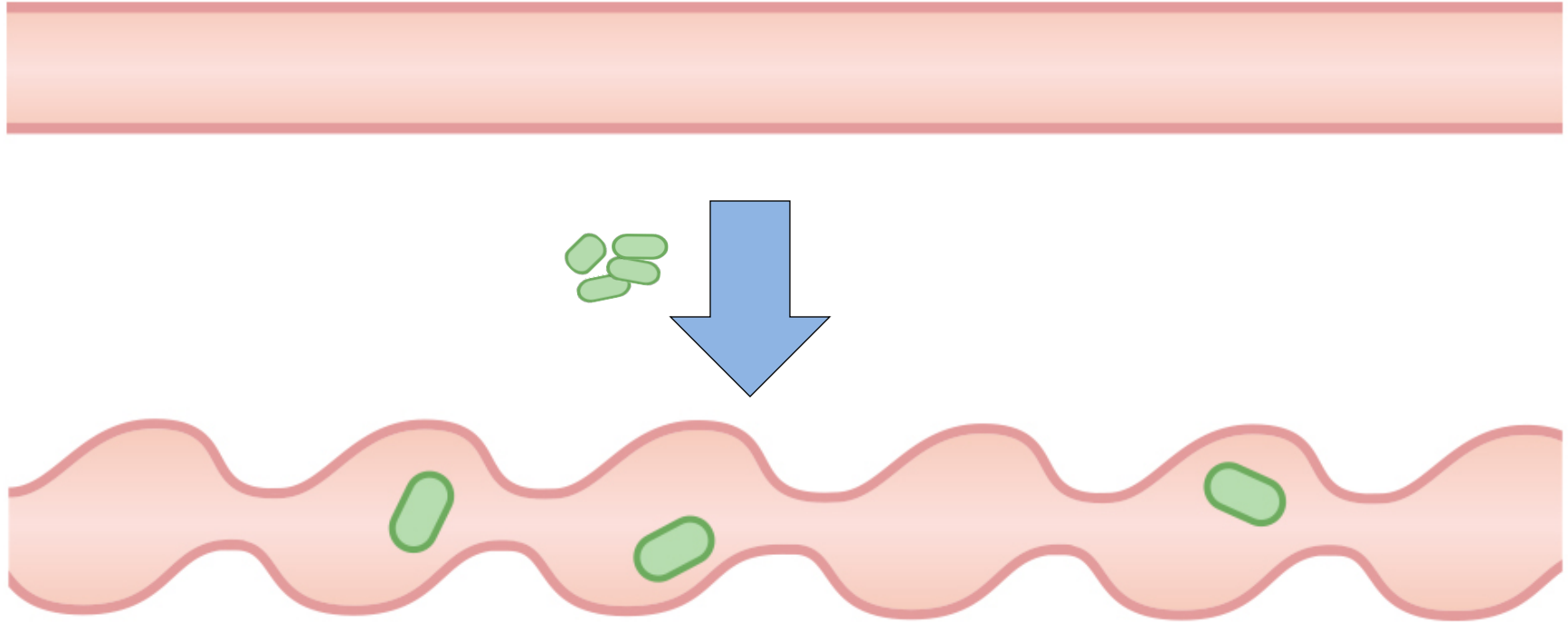
What causes NEC? – impaired gut motility

The baby's gut movements stop

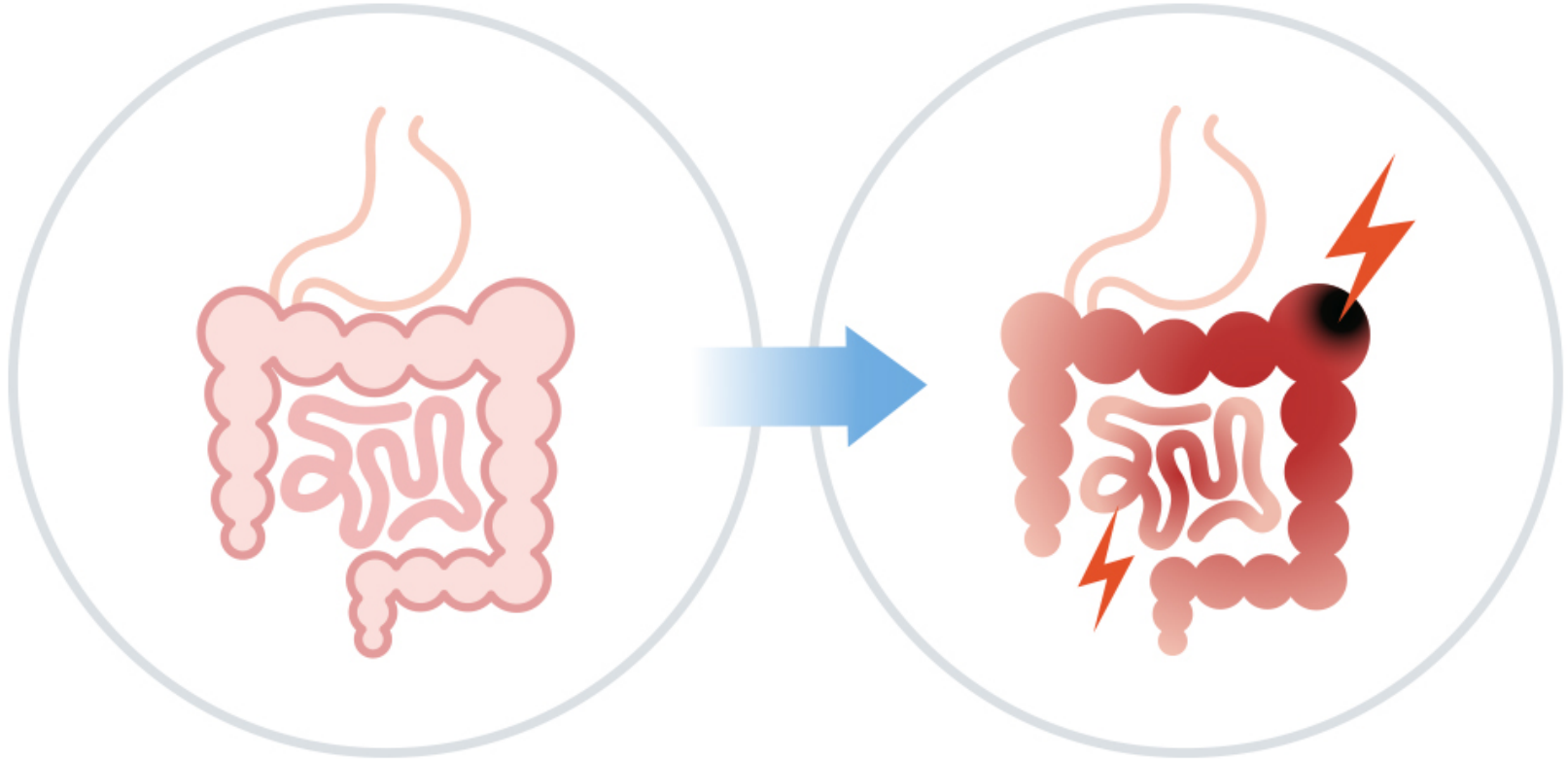


What does *L. reuteri* do to gut motility?

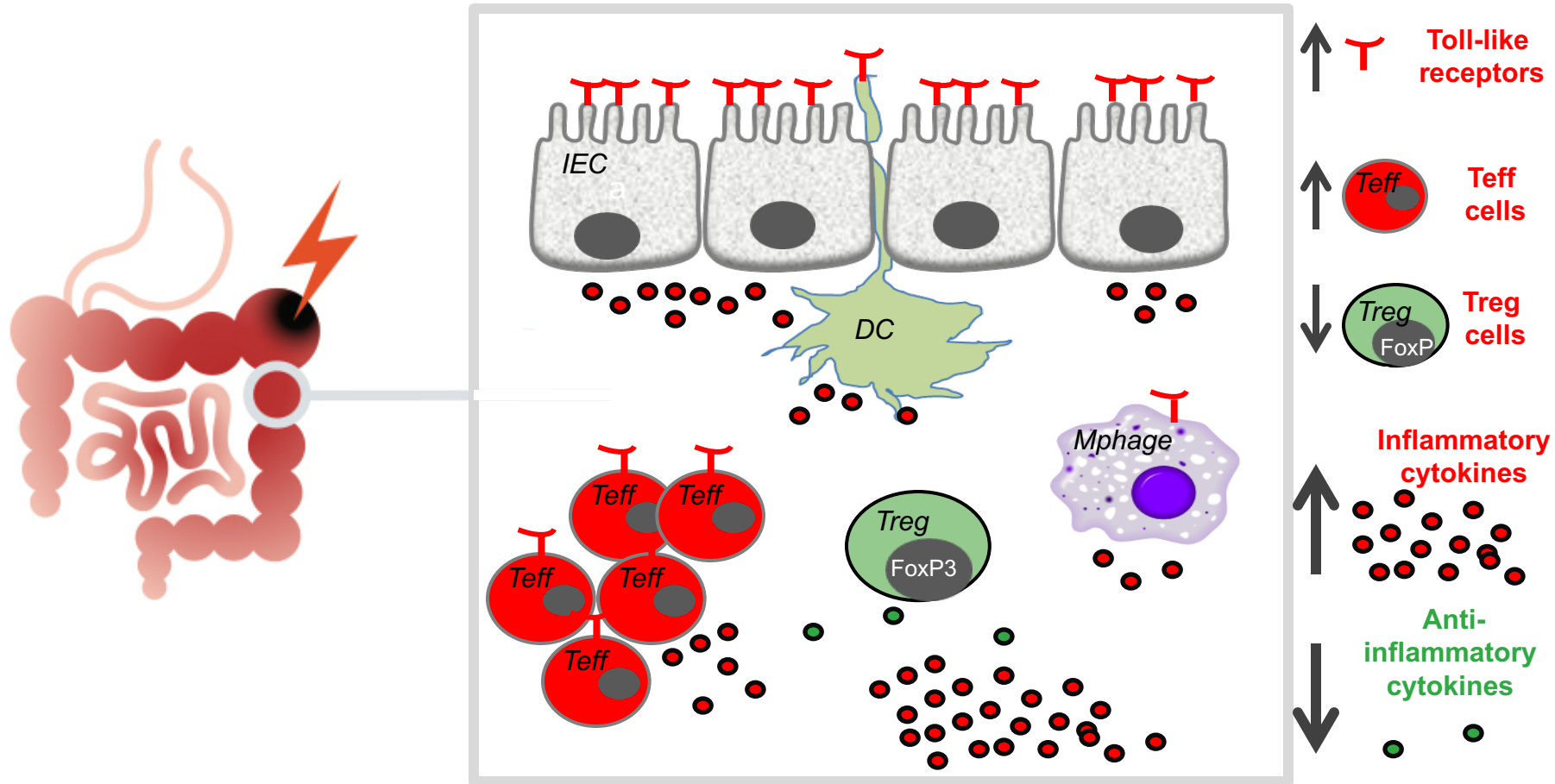
***L. reuteri* improves gut motility**



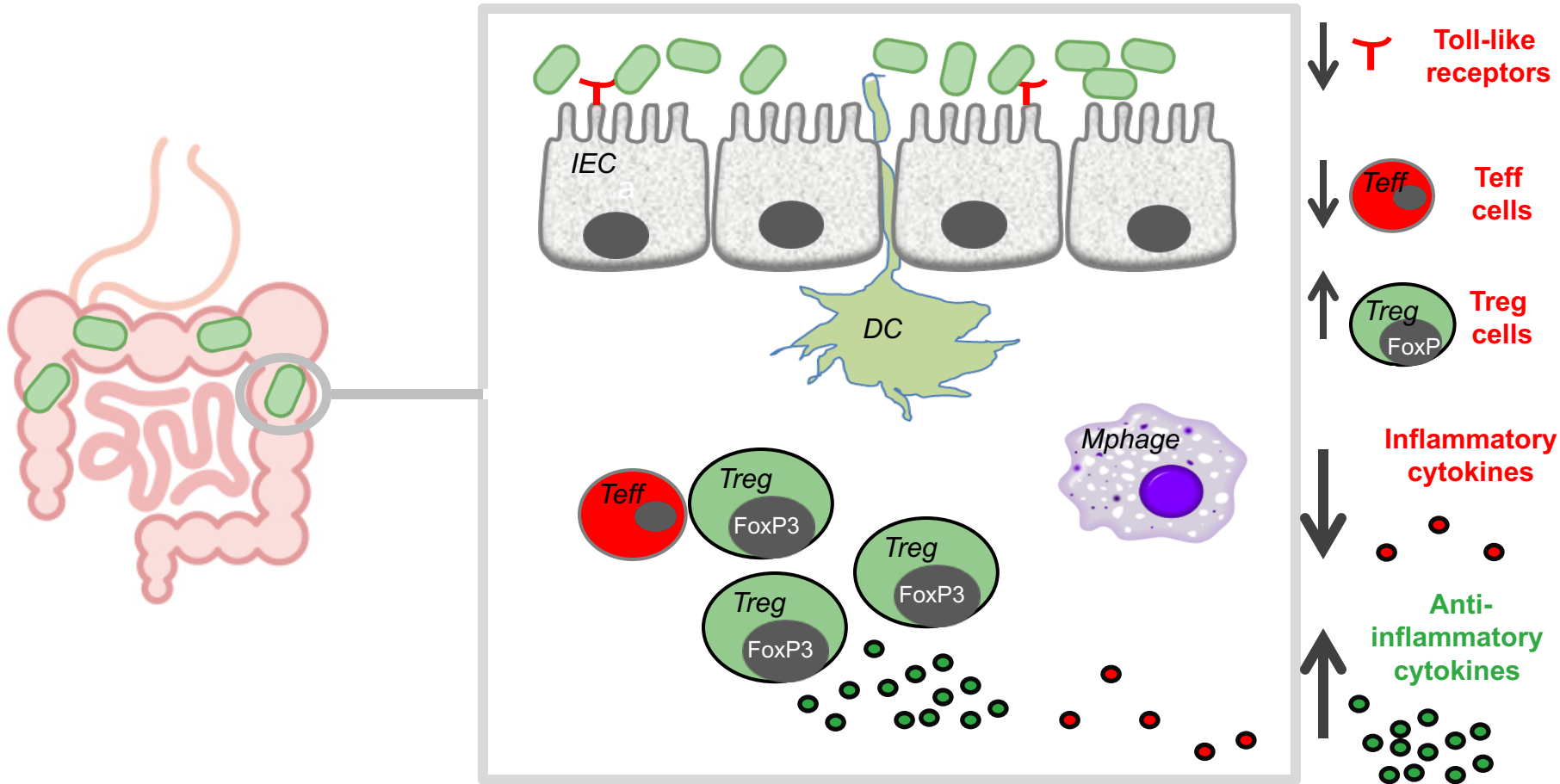
What causes NEC? – Inflammation in the gut



What causes NEC? – Inflammation in the gut



What does *L. reuteri* do to inflammation in the gut?



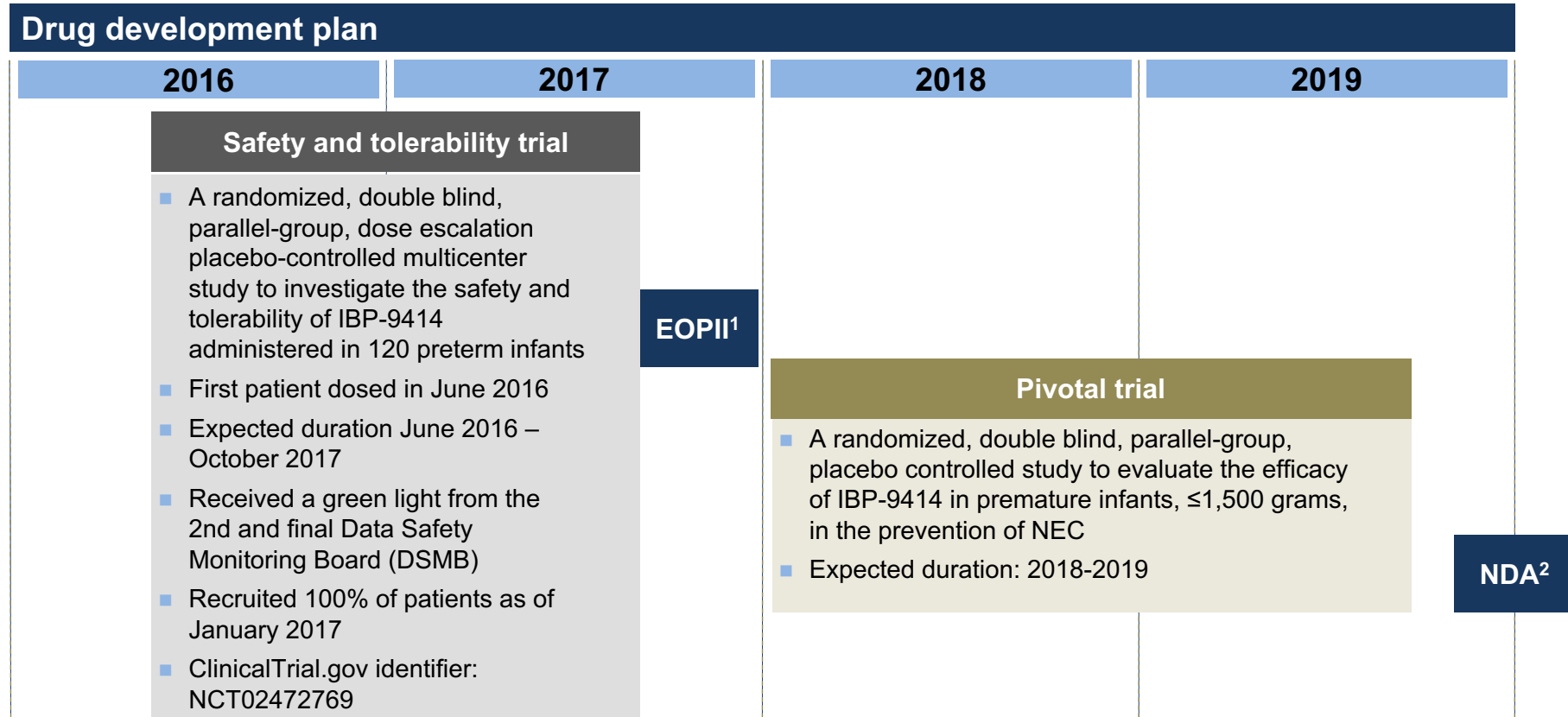
Clear clinical signal from *L. reuteri*

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 $\leq 1,500\text{g}$
Oncel et al. (2014)	■ 400 patients	■ 20% in the total study population ■ 38% in infants $\leq 1,000\text{g}$
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

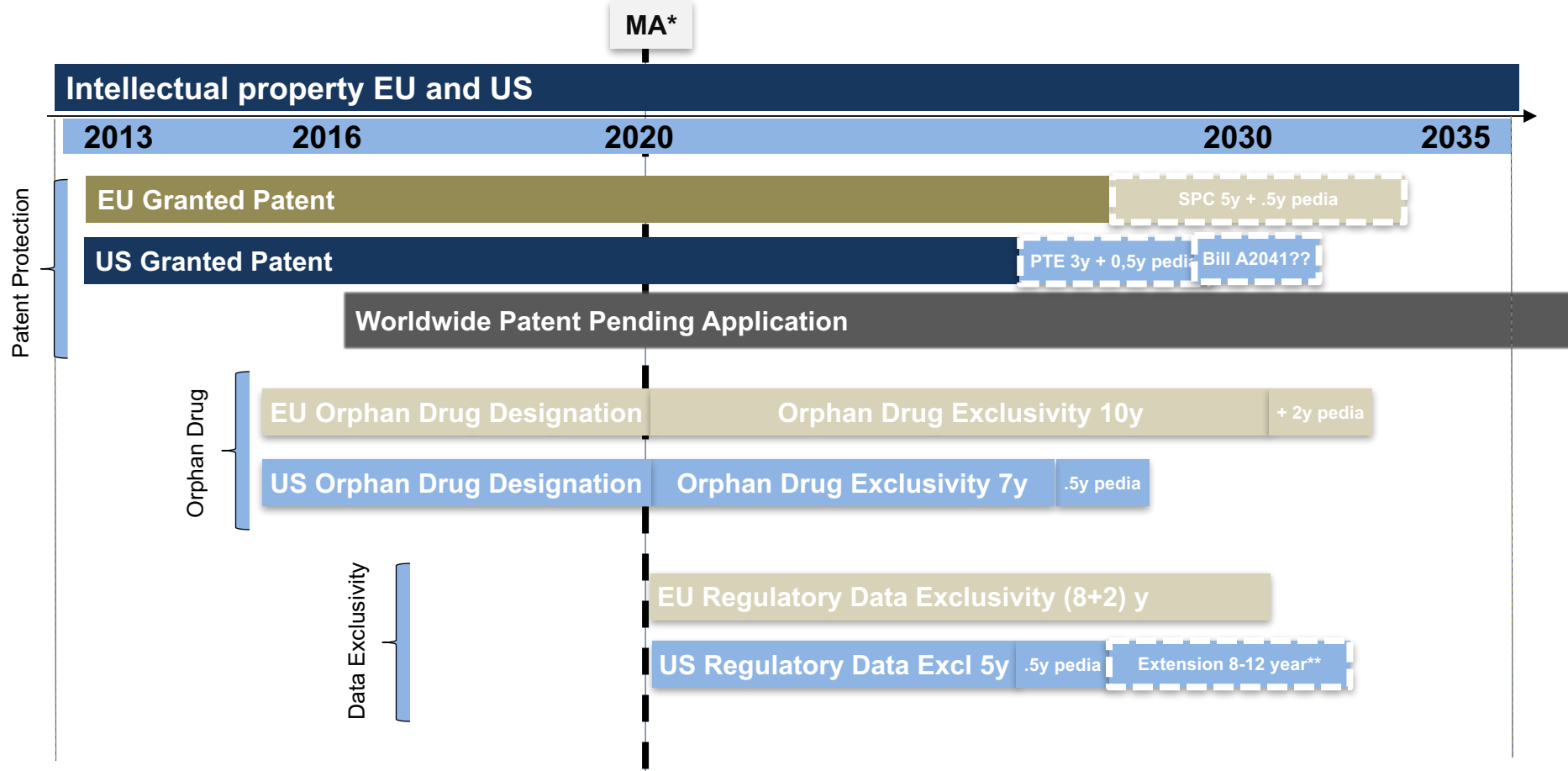


Notes

- 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, ** Possible extension of Data Exclusivity, 8-12 years

IBP-9414 Target Product Profile

For the prevention of necrotizing enterocolitis

Product description	<ul style="list-style-type: none">■ 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	<ul style="list-style-type: none">■ Premature infants $\leq 1,500\text{g}$ (US) ca 56,000■ Premature infants ≤ 34 weeks gestational age (EU) ca 108,000
Route of Administration	<ul style="list-style-type: none">■ Oral / enteral
Product efficacy	<ul style="list-style-type: none">■ Demonstrates 33% reduction in the incidence of NEC compared to standard of care alone
Safety profile	<ul style="list-style-type: none">■ 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...



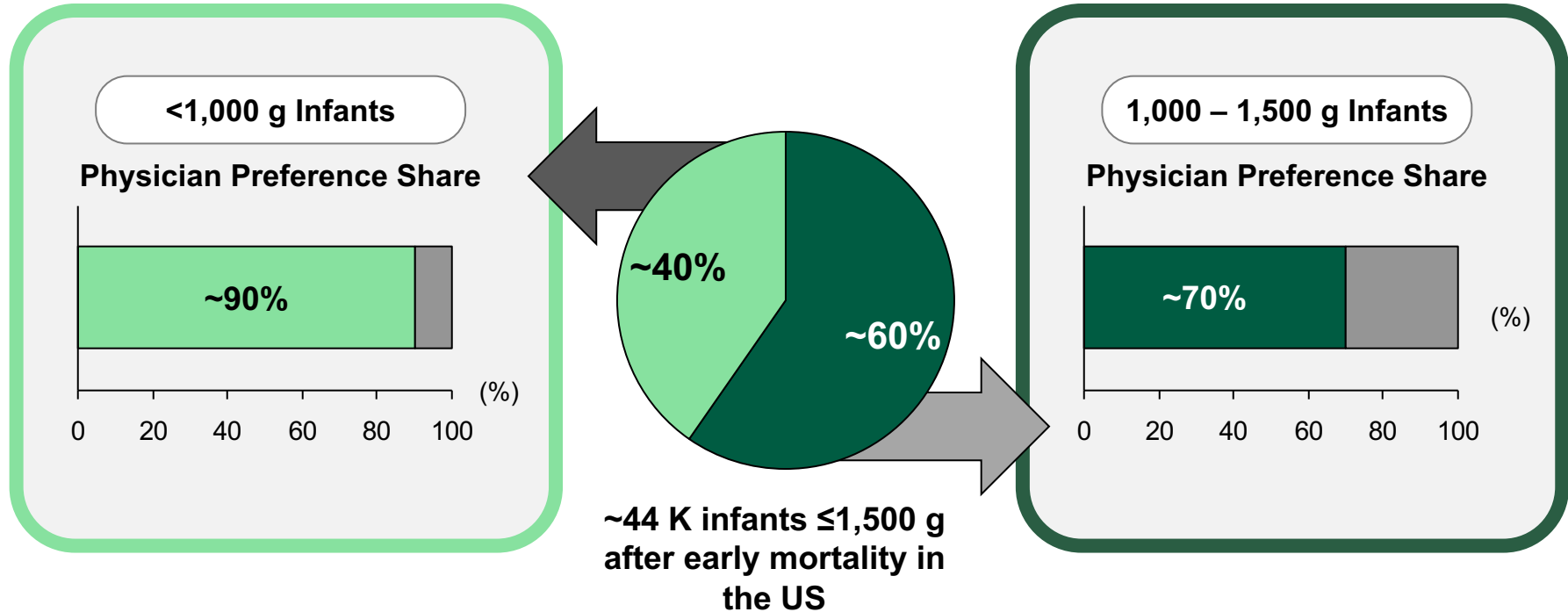
CLEARVIEW
Healthcare Partners

...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

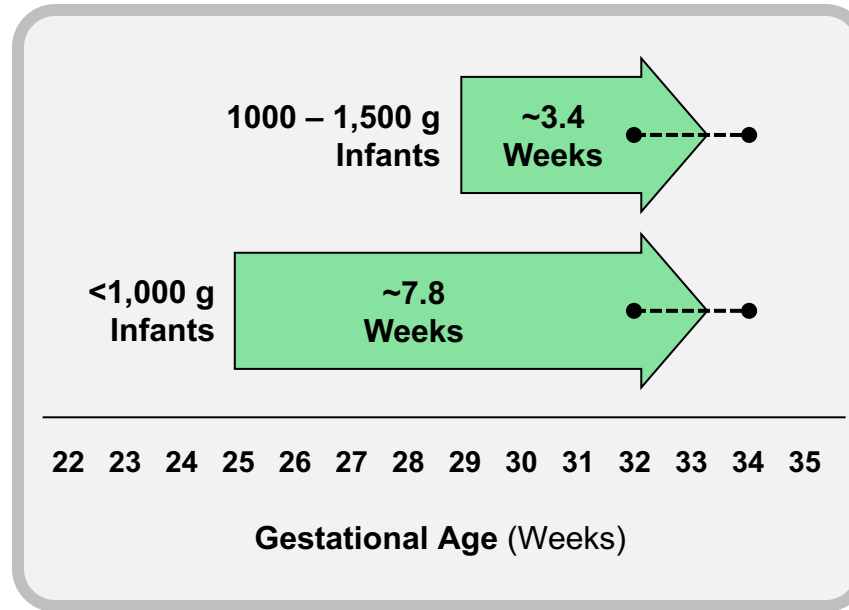
Neonatologists show high willingness to prescribe IBP-9414

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*

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		

Significant market potential for IBP-9414

IBT has mandated consultants to assess the market opportunity...



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

Why IBP-1016 for 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

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

Visit us in Stockholm, Sweden
Infant Bacterial Therapeutics AB Bryggargatan 10

www.ibtherapeutics.com

☎: +46 (0) 8 410 145 55

info@ibtherapeutics.com