Press Release August 21, 2019

Infant Bacterial Therapeutics AB (publ) Interim Management Statement, January 1 – June 30, 2019

Message from the CEO

On July 4 we were able to announce that the first patient had been recruited and dosed in the company's clinical phase III-study. Our work is now to focused to ensure that contracted clinics become operational for recruitment of patients and that we may be able to maintain a rapid recruitment rate of premature infants in the study. This work is conducted in part by our CRO, and the IBT staff are deeply involved in the various phases of this work, such as negotiating contracts with hospitals, motivating participating doctors, as well as other health care personnel, to give our study priority and to ensure that clinical trial material is at hand at the right time.

The ongoing pivotal phase III-study, which we have named "The Connection Study" is a randomized, double blind and placebo-controlled study to investigate the safety and efficacy of IBP-9414 for the prevention of necrotizing enterocolitis (NEC), and includes other significant clinical aspects in feeding preterm infants.

Comments on our development program from the FDA and other authorities in Europe improved the clinical program as we now also include the primary endpoint in the phase III-study of so called "*feeding tolerance".* The study will include 2 158 infants with birthweight of 500-1 500 grams and will be conducted at approximately 100 hospitals in the USA, Europe and Israel.

The amendments to the clinical program do not render significant impact on costs or otherwise affect conducting the planned phase III-study.

The ongoing clinical phase III-study is historical as it is the most comprehensive clinical study to ever be conducted regarding necrotizing enterocolitis, and to IBT's knowledge the most comprehensive clinical study ever on premature infants.

In parallel to the development project, IBT is also continuously evaluating potential marketing and distribution partners. We entered into an agreement in March regarding distribution of IBP-9414 in Israel. The agreement provides IBT with the possibility to long-term receive of the majority of future income from sales of IBP-9414 in Israel.

Stockholm
August 21, 2019

Staffan Strömberg,
Chief Executive Officer

Press Release August 21, 2019

Selected financial data

ooo's	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
Net sales	-	-	-	-	-
Operating profit/loss	-7 973	1 286	-8 766	-7 858	-39 417
Result after tax, SEK	-7 561	665	-8 247	-8 479	-40 607
Total assets	554 977	600 420	554 977	600 420	563 371
Cash flow for the period (SEK)	-1 114	-6 788	-8 691	416 019	381 544
Cash flow per share for the period (SEK)	-0.10	-0.60	-0.82	40.19	35.36
Cash	539 453	576 800	539 453	576 800	542 170
Earnings per share before and after dilution (SEK)	-0.67	0.06	-0.73	-0.82	-3.76
Equity per share (SEK)	48.86	52.54	48.86	52.54	49.59
Equity ratio (%)	99%	98%	99%	98%	99%

* Operational costs for the second quarter include exchange rate gains on forward currency contracts and currency deposits amounting to 53 (10 739) KSEK. Operational costs amounted to 7 976 (9 453) KSEK prior to exchange rate gains (Note 2)

Significant events during the second quarter (Apr-Jun) 2019

- On May 19, 2019, we announced that IBT had responded satisfactorily to the comments that the FDA had regarding the study design. As a consequence of the FDA's comments, an evaluation of the effects of IBP-9414 on the digestive system of premature infants in the forthcoming phase III study is now planned, as a serious medical problem for premature infants is that they cannot take up nourishment in an adequate way. The prior focus was solely prevention of NEC (necrotizing enterocolitis) that in itself is a terrible intestinal disease affecting premature infants and too often leads to fatal outcomes. Including another indication means having multiple independent endpoints which may increase the chances of success in the study and thus the market potential
- IBT's IND-Application (Investigational New Drug) was approved in the USA and the clinical study has also been approved in the UK, France, Hungary and Spain

Significant events during the reporting period (Jan-Jun) 2019

- IBT signed its first distribution agreement on March 5, 2019, for its product IBP-9414, with Megapharm Ltd. for the Israeli market and the Palestinian Authority's territories. The agreement gives MegaPharm exclusive rights to market and sell the product, if and when the product receives market approval. IBT's share will, after an initial shorter period, account for 70% of revenues. IBT plans to open clinical trial centers for the pivotal phase III trial in the country. Megapharm is already participating in this work as it is essential to engage "key opinion leaders" in the marketing of the product

Significant events after the reporting period

- IBT announced on July 4 that the first patient had been recruited in the company's pivotal clinical phase III-study, The Connection Study
- No other significant events have occurred after the reporting period

About Infant Bacterial Therapeutics AB

Infant Bacterial Therapeutics AB (publ) is a pharmaceutical company with a product in clinical stage with a vision to develop drugs influencing the infant microbiome, and thereby prevent or treat rare diseases affecting infants.

IBT is currently developing the drug candidate IBP-9414, for the prevention of necrotizing enterocolitis ("NEC") and improvement of so called *feeding tolerance* in premature infants. IBP-9414 contains the active compound *Lactobacillus reuteri*, which is a human bacterial strain naturally present in breast

milk. The product portfolio also includes another project, IBP-1016, for the treatment of gastroschisis, a severe and rare disease affecting infants. By developing these drugs, IBT has the potential to fulfil unmet needs for diseases where there are currently no prevention or treatment therapies available.

Infant Bacterial Therapeutics AB ("IBT") is a public company domiciled in Stockholm. The company's class B-shares shares are listed on Nasdaq Stockholm, Mid-cap (IBT B).

For additional information please contact
Staffan Strömberg, CEO
Daniel Mackey, CFO
Infant Bacterial Therapeutics AB
Bryggargatan 10
111 21 Stockholm
Phone: +46 70 670 1226
info@ibtherapeutics.com
www.ibtherapeutics.com