

Press Release May 6, 2019

## Infant Bacterial Therapeutics AB (publ) Interim Management Statement, January 1 – March 31, 2019

### Message from the CEO

As previously communicated, IBT had a meeting with the Food and Drug Administration (FDA) on November 20, 2018, to discuss IBT's clinical development program. The development program is comprised of the clinical phase II safety-and tolerability study, concluded in 2017, and the not yet commenced phase III study, which we have named "The Connection Study".

IBT has during the first quarter, in conjunction with external experts, amended the clinical development program based on guidance received from the FDA and other authorities in Europe. In general, this is an improvement as we now will also include the primary endpoint in the phase III study of so called *feeding tolerance*. These amendments to the clinical program do not render significant impact on costs or otherwise affect conducting the planned phase III study.

Parallel to the development work, 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. IBT plans to include patients from Israel in the coming phase III study.

We are looking forward to commencing the phase III study as planned in the first half of the current year.

Stockholm May 6, 2019

Staffan Strömberg,  
Chief Executive Officer

### Selected financial data

ooo's	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
Net sales	-	-	-
Operating profit/loss	-929	-9 144	-39 417
Result after tax, SEK	-686	-9 144	-40 607
Total assets	561 035	597 313	563 371
Cash flow for the period (SEK)	-5 647	422 807	381 544
Cash flow per share for the period (SEK)	-0.50	44.61	35.36
Cash	540 514	581 081	542 170
Earnings per share before and after dilution (SEK)	-0.06	-0.96	-3.76
Equity per share (SEK)	49.53	52.48	49.59
Equity ratio (%)	99%	99%	99%

\* Operational costs for the first quarter include exchange rate gains on forward currency contracts and currency deposits amounting to 5 836 (0) KSEK. Operational costs amounted to 6 765 (9 144) KSEK prior to exchange rate gains (Note 2)

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### Significant events during the first quarter (Jan-Mar) 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

- No significant events have occurred after the reporting period

#### **About Infant Bacterial Therapeutics AB**

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).

Infant Bacterial Therapeutics AB (publ) pharmaceutical company with a product is a 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.

#### **For additional information please contact**

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