

Press Release November 23, 2017

## Infant Bacterial Therapeutics AB (publ) Interim Management Statement, January 1 – September 29, 2017

### Message from the CEO

IBT announced results from the safety and tolerability study of IBP-9414 on September 11<sup>th</sup>. The data demonstrate a similar safety and tolerability profile in the active and placebo groups. The study included 120 preterm infants, dosed during two weeks and evaluated at time points up to 6 months after administration of the study drug at 15 neonatal centers in the United States. We can conclude that the recruitment rate was higher than expected without any variance between large or small infants and that the demographics of the study population was representative of the target population. IBT was able to complete the study according to plan in terms of recruitment, timelines and budget. We are continuing our preparations for the next and final part of the IBP-9414 development program, the planned pivotal efficacy study for the prevention of NEC.

In September, The Paediatric Committee (PDCO) at the European Medicines Agency (EMA) adopted a positive opinion on the “Paediatric Investigation Plan” proposed by IBT for the development of IBP-9414 for the prevention of necrotizing enterocolitis (NEC). Adoption of the “Paediatric Investigation Plan” is a prerequisite for continuing our clinical development program. I am very happy that the IBT team again has shown its capability to reach a significant milestone in the global development program.

IBT has the financial resources to prepare the following pivotal study of IBP-9414 which is planned to be initiated in the beginning of 2018. The ongoing planning and preparations for the pivotal study include CMC (Chemical, manufacturing and control) activities for the production of clinical trial material.

As previously announced, the pivotal study will require additional capital. IBT is working very actively on several different financing possibilities. In addition, IBT is progressing in its preparation for the application to admittance for trading on the main marketplace, Nasdaq Stockholm as previously communicated.

Staffan Strömberg  
CEO

### Financial summary

SEK 000's	2017 Jul-Sep	2016 Jul-Sep	2017 Jan-Sep	2016 Jan-Sep	2016 Jan-Dec
Total comprehensive income	-	49	238	49	162
Operating profit/loss	-4 571	-7 900	-27 082	-23 978	-38 090
Result financial net	-4 586	-7 717	-27 097	-24 001	-38 106
Total assets	83 006	125 682	83 006	125 682	110 109
Cash flow for the period	-9 147	-8 338	-26 610	63 635	49 375
Cash flow per share for the period (SEK)	-1,66	-1,51	-4,83	17,74	10,91
Cash	67 176	108 046	67 176	108 046	93 786
Earnings per share, weighted average, before and after dilution (SEK)	-0,83	-1,40	-4,92	-6,69	-8,42
Equity per share (SEK)	14,36	21,68	14,36	21,68	19,12
Equity ratio (%)	95%	95%	95%	95%	96%

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### **Significant events during the third quarter 2017**

- Infant Bacterial Therapeutics ("IBT") reported results from the safety and tolerability study for IBP-9414 on September 11. The results show a similar safety and tolerability profile in the active group as in the placebo group in IBT's clinical safety and tolerability study on IBP-9414 (NCT02472769)
- IBT reported on September 28 that The European Medicines Agency's (EMA) paediatric committee (PDCO) approved IBT's proposed "paediatric investigation plan (PIP) for IBP-9414 in prevention of necrotizing enterocolitis (NEC)"

### **Significant events during the reporting period January – September 2017**

- In January 2017, all 120 patients were included in the Company's clinical safety and tolerability study in IBP-9414 (NCT02472769)
- IBT's series B shares were listed on Nasdaq First North Premier on March 14
- Eva Idén and Anthon Jahreskog were elected new board members at the AGM on May 4
- The subsidiary IBT Baby AB was established in May for administration of a new share based incentive program
- All personnel subscribed for their respective allotments in a new share based incentive program

### **Significant events after the reporting period**

- No significant events have occurred after the reporting period

Infant Bacterial Therapeutics AB (publ) Interim Report is now available on the company's website [www.ibtherapeutics.com](http://www.ibtherapeutics.com).

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

Infant Bacterial Therapeutics AB (publ) ("IBT") is a pharmaceutical company with a vision to develop drugs influencing the human infant microbiome, and thereby prevent or treat rare diseases affecting premature infants. Using its extensive experience in live bacterial therapeutics and its well-developed knowledge of the action of *Lactobacillus reuteri*, IBT is developing its lead drug candidate IBP-9414, to prevent necrotizing enterocolitis ("NEC"), a fatal, rare disease that can afflict premature infants. The FDA and the European Commission have granted IBT Orphan Drug Designation, and the FDA have granted Rare Pediatric Disease Designation for IBP-9414 for the prevention of NEC.

IBT is further pursuing a second rare disease programme IBP-1016 for the treatment of an unmet medical need in gastroschisis, a severe disease in 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.

IBT is listed on Nasdaq First North Premier with Erik Penser Bank as Certified Adviser. [www.ibtherapeutics.com](http://www.ibtherapeutics.com)

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

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**Publication**

This information is information that Infant Bacterial Therapeutics AB is obliged to make public pursuant to the Securities Markets Act. The information was submitted for publication at 08.30 CET on November 23, 2017.