INFANT BACTERIAL THERAPEUTICS

Press Release August 16, 2018

# Infant Bacterial Therapeutics AB (publ) Interim Management Statement, January 1 – June 30, 2018

#### Message from the CEO

The second quarter was dominated by extensive preparatory work relating to the pivotal phase III study, called "The Connection Study". Our experience from the completed phase II study have contributed valuable insight that we utilize when designing The Connection Study. The preparations are considerable, as we plan to recruit more than 2 000 preterm infants, which is likely to be the largest study ever conducted in this particularly vulnerable population.

As previously communicated, IBT has elected Premier Research International LLC, which was also IBT's contract research organization during the finalized phase II-study, as our CRO for the Connection Study. The plan is to initiate the clinical study during the second half of this year. The company's expectation is to file an application for registration of IBP-9414 during year 2020. In addition, we are continuously in contact with several companies to identify the right partners for marketing and distribution of IBP-9414.

IBT has since its inception strived to be internationally recognized as a pioneer in the field of neonatal therapies. To exemplify, IBT is working together with the FDA in the Critical Path Initiative (CPI), which aims to reform pharmaceutical development. This fall, we plan to participate in several investor conferences, among others the Nordic-American Life Science Conference in New York in November to further promote the awareness of IBT.

IBT's organization is continuously developing to comply with the demands relating to the Connection Study. During the spring, the medical competencies of IBT were increased by the hiring of Professor Jonas Rastad MD, Ph.D., Chief Medical Officer, with long experience from Astra Zeneca R&D as well as from academic research. In addition Jonas Häggström Ph.D., an expert statistician, working as expert evaluator to the European Commission, and as expert statistics consultant to the Bill and Melinda Gates Foundation has also started at IBT.

During the spring an Advisory Board was established to evaluate new development projects. IBT will focus on finding projects to bring to the market which satisfy unmet medical needs on par with IBP-9414. More information shall be provided if and when additional such projects are identified.

Two new board members were elected at the AGM in May, who will contribute with their significant experience to the development of the company. The new board members are Lilian Wikström, CEO of Karolinska Institutet Innovations AB, and Kristina Nygren, Chief Medical Officer, Head of Development at Santhera Pharmaceuticals in Basel.

As previously communicated, IBT has applied for listing on Nasdaq's main list. I expect IBT to be approved for listing.

In summary, everything is progressing according to plan and we are looking forward to getting The Connection Study started and listing change approved in the near future.

Stockholm, August 16, 2018

Staffan Strömberg, Chief Executive Officer



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## Selected financial data

000'S	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Net sales		121		238	238
Operating profit/loss*	1 286	-13 826	-7 858	-22 510	-36 141
Result after tax, SEK	665	-13 827	-8 479	-22 511	-36 156
Total assets	600 420	92 224	600 420	92 224	175 024
Cash flow for the period (SEK)	-4 281	-8 350	418 526	-17 463	64 488
Cash flow per share for the period (SEK)	-0.38	-1.52	40.43	-3.17	11.53
Cash	576 800	76 323	576 800	76 323	158 274
Earnings per share before and after dilution (SEK)	0.06	-2.51	-0.82	-4.09	-6.5
Equity per share (SEK)	52.54	15.19	52.54	15.19	25.5
Equity ratio (%)	98%	91%	98%	91%	96%

\* Operational costs for the second quarter include exchange rate gains on forward currency contracts and currency deposits amounting to 10 739 (0) KSEK, operational costs amounted to 9 453 (13 826) KSEK prior to exchange rate gains. Operational costs for the six month period include exchange rate gains on forward currency contracts and forward currency deposits amounting to 10 739 (0) KSEK, operational costs amounted to 18 597 (22 748) KSEK prior to exchange rate gains (Note 2).

### Significant events during the second quarter (Apr-Jun) 2018

- On May 15, 2018, the annual general meeting elected Kristina Sjöblom Nygren and Lilian Henningson Wikström as new board members, and Jan Annwall resigned from the board
- In June 2018, IBT contracted Premier Research International LLC, the company's CRO during the phase II clinical trial, to also conduct the company's phase III clinical trial

### Significant events during the reporting period (Jan-Jun) 2018

• On January 8, 2018, the EGM decided on a new share issue amounting to SEK 439.1m prior to transaction costs and on January 31 the share issue was fully subscribed

### Significant events after the reporting period

· No significant events have occurred after the reporting period

### About Infant Bacterial Therapeutics AB

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

IBT is currently developing its lead drug candidate IBP-9414 to prevent NEC in premature infants. IBP-9414 contains the active substance *Lactobacillus reuteri*, which is a human bacterial strain naturally present in breast milk. IBT has an additional project in its portfolio, a second rare disease program, 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 fulfill 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.

### For additional information please contact

Staffan Strömberg, CEO Infant Bacterial Therapeutics AB





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#### Publication

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