

Press Release February 8, 2019

Infant Bacterial Therapeutics AB (publ) Interim Management Statement, January 1 – December 31, 2018

Message from the CEO

IBT reached several significant milestones during 2018. IBT reached agreement with a CRO (Contract Research Organization) to conduct the pivotal Phase III clinical trial, The Connection Study, and the listing change of IBT's class B shares to Nasdaq Stockholm was completed.

As previously communicated, IBT had a meeting with the Food and Drug Administration (FDA) on November 20, 2018, to discuss IBT's protocol, which in detail describes IBT's clinical development program. The meeting was fruitful and, among other things, IBT received guidance from the FDA regarding possible improvements to the protocol. During the meeting there was discussion of the fact that the primary endpoint of the study solely included observations regarding NEC, in spite of the fact that our pharmaceutical candidate IBP-9414 also has the possibility to show other clinical effects which may help premature infants, for example so-called "feeding intolerance". Since the meeting with the FDA we have been working to include parameters related to feeding intolerance in our clinical program. Consequently, we plan a combined primary endpoint in which both NEC and feeding intolerance are included, which in practice means that we give the study a further chance for success.

In parallel with revision of the protocol, IBT has made other preparations for the start of The Connection Study, including progress in contracting hospitals, manufacturing of clinical trial material and strengthening the organization. Finally, it is worth mentioning that we continue our contacts with potential marketing and distribution partners.

We maintain our plan to dose the first patient in The Connection Study during the first half of this year.

Stockholm February 8, 2019

Staffan Strömberg,
Chief Executive Officer

Selected financial data

000's	2018 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
Net sales	-	-	-	238
Operating profit/loss	-23 837	-9 060	-39 417	-36 141
Result after tax, SEK	-24 143	-9 060	-40 607	-36 156
Total assets	563 371	175 024	563 371	175 024
Cash flow for the period (SEK)	-27 322	91 098	381 544	64 488
Cash flow per share for the period (SEK)	-2.43	15.52	35.36	11.53
Cash	542 170	158 274	542 170	158 274
Earnings per share before and after dilution (SEK)	-2.15	-1.44	-3.76	-6.05
Equity per share (SEK)	49.59	11.97	49.59	25.50
Equity ratio (%)	99%	96%	99%	96%

* Operational costs for the fourth quarter include exchange rate gains on forward currency contracts and currency deposits amounting to 1 442 (0) KSEK. Operational costs amounted to 25 279 (9 060) KSEK prior to exchange rate gains. Operational costs for the nine-month period include exchange rate gains on forward currency contracts and forward currency deposits amounting to 12 009 (0) KSEK. Operational costs amounted to 51 426 (36 379) KSEK prior to exchange rate gains (Note 2)

Press Release February 8, 2019

Significant events during the fourth quarter (Oct-Dec) 2018

- IBT has, resulting from discussions with the FDA on November 20, 2018, chosen to modify its Phase III study for the prevention of necrotizing enterocolitis (NEC) in premature infants. Following the guidance from the FDA, IBT will improve the protocol which may allow additional claims such as reduction in “feeding intolerance”, that could increase the chance of success in the Company’s Phase III study and the market potential of the product.

Significant events during the reporting period (Jan-Dec) 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
- 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 (Contract Research Organization) during the Phase II clinical trial, to also conduct the Company’s phase III clinical trial
- IBT series B shares are traded on Nasdaq Stockholm, Mid Cap, since September 10, 2018 (IBT B)

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 developing drug candidate IBP-9414 to prevent necrotizing enterocolitis (NEC), a devastating and often fatal disease 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.

Infant Bacterial Therapeutics (IBT B) shares are listed on Nasdaq Stockholm.

For additional information please contact

Staffan Strömberg, CEO
Infant Bacterial Therapeutics AB
Bryggargatan 10
111 21 Stockholm
Phone: +46 8 410 145 55
info@ibtherapeutics.com
www.ibtherapeutics.com