Press Release February 11, 2020

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

Message from the CEO

IBT's ongoing clinical phase III study with IBP-9414 has, as of the date of this year-end report, conducted patient recruitment for more than seven months. We have, as previously communicated, the approval to conduct the study in France, Spain, the U.K., Hungary and the U.S. At the end of January 2020 our phase III study with IBP-9414 was also approved in Israel. This means that the regulatory process regarding trial approval may be concluded as we have received approval in every country we plan to conduct the study.

IBT expected the recruitment rate in the phase III study to approximate the rate noted during our concluded phase II study, and as previously communicated in the most recent financial report, we were not satisfied with the rate of recruitment. There have been a number of practical reasons, including misunderstandings regarding interpretation of an exclusion criteria, which precluded doctors from including patients in the study. This was addressed during the autumn.

We have focused our work on improving the recruitment rate in the study and IBT has visited nearly all open centers. We are now able to conclude that we can achieve similar recruitment rate as we achieved during the phase II study at centers which have initiated recruitment.

As of the date of this report 51 of a total of 100 planned centers have been contracted and we are working intensively to initiate more. Since the previous interim report we have further strengthened our clinical department at IBT in order to ensure that the "best practice" is spread from the top recruiting centers to others.

During January 2020, IBT strengthened its organization by recruiting a senior clinical project manager and a senior CMC ("Chemistry, Manufacturing and Controls") specialist in order to satisfy the long-term supply for the market as well as the study material for the ongoing study.

The study is double blinded which means that we are not able to make observations regarding efficacy in our pharmaceutical candidate yet. However, we can observe important factors relevant for conducting the study. Firstly, we note that the relevant infants are recruited to the study which means that the infants meet the specific inclusion criteria. Secondly, we note that systems managing side effects, patient allocation and independent assessment of X-rays of NEC are conducted as planned. This means that the study is operationally progressing as expected.

Our ongoing study is randomized, double blinded and placebo controlled to assess safety and efficacy of IBP-9414 for prevention of of necrotizing enterocolitis ("NEC"), and also includes other important clinical effect parameters in feeding premature infants comprising so called *feeding tolerance*, thus comprising multiple endpoints. Hopefully the results from the study will show that our product will both reduce the risk that infants develop NEC, and additionally, that infants will be able to absorb nutrition better.

I also wish to state that IBT's liquidity is adequate to conduct the ongoing clinical phase III study in spite of the fact that the initial recruitment rate of the study did not meet our expectation. IBT's qualified team is working in a dedicated and focused manner with all vital details which are so important in order to reach our recruitment goals.

Stockholm, February 11, 2020

Staffan Strömberg, Chief Executive Officer

Press Release February 11, 2020

Selected financial data

ooo's	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Net sales	-	-	-	-
Operating profit/loss	-27 428	-23 837	-47 200	-39 417
Result after tax, SEK	-27 535	-24 143	-46 320	-40 607
Total assets	518 273	563 371	518 273	563 371
Cash flow for the period (SEK)	-8 546	-27 322	-51 301	381 544
Cash flow per share for the period (SEK)	-0.76	-2.43	-4.57	35.36
Cash	495 188	542 170	495 188	542 170
Earnings per share before and after dilution (SEK)	-2.45	-2.15	-4.13	-3.76
Equity per share (SEK)	45.46	49.59	45.46	49.59
Equity ratio (%)	98%	99%	98%	99%

Significant events during the fourth quarter (Oct-Dec) 2019

- Lilian Wikström Ph.D. resigned from the Board of Directors of IBT due to the risk of conflict of interest that has arisen in her role as CEO of KI Innovations AB

Significant events during the reporting period (Jan-Dec) 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
- 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
- IBT announced on July 4 that the first patient had been recruited in the company's pivotal clinical phase III study, The Connection Study

Significant events after the reporting period

- IBT's clinical trial application was approved in Israel at the end of January 2020
- No other significant events have occurred after the reporting period

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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 fulfill 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).

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Publication
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