INFANT BACTERIAL THERAPEUTICS

Press Release February 5, 2021

Infant Bacterial Therapeutics AB (publ) Interim Management Statement, January 1 – December 31, 2020

Message from the CEO

IBT is currently developing its lead drug candidate IBP-9414 to prevent necrotizing enterocolitis (NEC), and to improve so-called "feeding tolerance" in premature infants. IBP-9414 contains *Lactobacillus reuteri* as an active ingredient, which is a human bacterial strain found naturally in breast milk.

This message from the CEO is written during the continuing COVID-19 pandemic which now has been ongoing for one year. The pandemic appeared to be under control during the fall, however the outbreak of COVID worsened during November and December in many parts of the world. I have in previous quarterly reports described the impact of the pandemic on IBT. Simply put, our recruitment rate is affected, but the quality of data generated in the study is not. The bulk of the costs for conducting the study are incurred at the time of recruitment. This means that IBT's liquidity is expected to be sufficient to complete the study even if the study is concluded at a later point in time.

Scientific articles published during the final quarter of 2020 stated that the birth rates of premature infants were lower than in previous years. The authors mention for example the fact of reduced shift-labor being performed along with improved diets, and also limited social contacts as possible factors affecting observations of reduced numbers of premature births. Regardless of the cause, we have received similar signals from our direct contact with neonatologists in our study that have also indicated reduced numbers in premature births. We expect the number of births to return to normal when the COVID pandemic decreases in intensity.

IBT's study design includes infants with birthweights from 500 to 1 500 grams, however, thus far in the study we only included infants with birthweights from 750 to 1 000 grams, i.e. a range of 250 grams. IBT always applies the rule of caution, which is a regulatory key for us as the sole company worldwide with FDA approval of dosing premature infants with live bacteria. We have in addition to trial permits in the USA been granted approval for our study also in France, Hungary, Israel, Spain, and the UK, and in the fourth quarter also received approvals in Poland and Bulgaria. We currently have 68 active hospitals which are able to include patients compared to 62 in the previous quarterly report. It is against this background that we have chosen to open up for inclusion of patients under 750 grams only after reviewing the data from the initial 300 patients. We expect to have included 300 patients in the study within the month.

The fact that we during the initial phase of the study recruit patients in a narrow range of 250 grams, during an ongoing pandemic, has resulted in relatively few patient inclusions to date. IBT hopes that diminishing effects of the pandemic in combination with opening up the study to include infants born below 750 grams will significantly increase the recruitment rate during 2021.

We have during the fourth quarter aimed for a better understanding of the value of our second primary endpoint in the phase III-study, "sustained feeding tolerance". After consultations with the FDA, an expert group has been established by IBT comprised of neonatologists, nurses, and patient organizations. Our goal with this expert group is to better understand as well as to demonstrate how malnutrition negatively affects premature infants both in the short and long term. These experts have already made clear that poor nutrition reduces growth of infants resulting in severe suffering in combination with high costs for healthcare payers. We seek to quantify the market value of improved "feeding tolerance" by our product IBP-9414 and I shall revisit the issue in due course.

Press Release February 5, 2021

We at IBT look forward to continuing our development work as our efforts can have great impact for all premature infants. Motivation will be even higher after the initial phase of this study, comprised of 300 patients, is concluded.

Stockholm, February 5, 2021

Staffan Strömberg
Chief Executive Officer

Financial overview for the period

Fourth quarter (Oct-Dec) 2020
- Net sales 0 KSEK (0)
- Operating income -26 702 KSEK* (-27 428)
- Earnings per share before and after dilution -2.38 SEK (-2.45)

Reporting period (Jan-Dec) 2020
- Net sales 0 KSEK (0)
- Operating income -71 918** KSEK (-47 200)
- Earnings per share before and after dilution -6.41 SEK (-4.13)

Significant events during the fourth quarter (Oct-Dec) 2020
- The COVID-19 pandemic affects our development work, for example, activation of hospitals, which has not occurred at the desired rate. As of the date of this interim report, more than half of the planned hospitals have been activated. IBT's cash position is sufficient to carry out the ongoing Phase III study, even if recruitment in the study currently does not take place at the desired rate

Significant events during the reporting period (Jan-Dec) 2020
- IBT's clinical study application was approved in Israel in January, in Poland in October and in Bulgaria in November

Significant events after the reporting period
- No significant events have occurred after the reporting period

Selected financial data

ooo's	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
Net sales	-	-	-	-
Operating profit/loss	-26 702	-27 428	-71 918	-47 200
Result after tax, SEK	-26 726	-27 535	-72 007	-46 320
Total assets	450 318	518 273	450 318	518 273
Cash flow for the period (SEK)	-27 864	-8 546	-56 625	-51 301
Cash flow per share for the period (SEK)	-2.48	-0.76	-5.04	-4.57
Cash	423 438	495 188	423 438	495 188
Earnings per share before and after dilution (SEK)	-2.38	-2.45	-6.41	-4.13
Equity per share (SEK)	39.21	45.46	39.21	45.46
Equity ratio (%)	98%	98%	98%	98%

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 feeding tolerance in premature infants. IBP-9414 contains the active

substance *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).

For additional information please contact
Staffan Strömberg, CEO
Daniel Mackey, CFO
Infant Bacterial Therapeutics AB
Bryggargatan 10
111 21 Stockholm
Phone: +46 70 670 1226
info@ibtherapeutics.com
www.ibtherapeutics.com

The information was submitted for publication on February 5, 2021 at 08:00 (CET).