INFANT BACTERIAL THERAPEUTICS

Press Release August 14, 2020

Infant Bacterial Therapeutics AB (publ) Interim Management Statement, January 1 – June 30, 2020

Message from the CEO

IBT is currently developing its 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 active substance, which is a naturally-occurring bacterial strain found in breast milk.

This message from the CEO is written during the COVID-19 pandemic that has now been ongoing for nearly six months. The pandemic not only affects our work at IBT but, of course, also affects the staff at the hospitals. The hospitals have to take care of new and additional patients compared to just six months ago. The pandemics development and society's actions are different in different areas of the world. IBT is active in several countries and as circumstances are constantly changing, we have to work more dynamically than usual. I would like to reiterate that our study is not dependent on "normal" hospital or doctor visits because the children we recruit are already in the intensive care units independent of our study. This is essential as many hospitals have introduced a ban on non-essential visitors.

We have succeeded in adjusting our way of working to be able to ensure the quality of our study through, among other things, so-called virtual monitoring as well as providing test material to all recruiting hospitals despite the ongoing COVID-19 pandemic. Furthermore, we have succeeded in continuing to recruit children in all hospitals who had admitted at least one patient to the study before the pandemic began.

In this context, I would like to mention that there is no pharmaceutical to prevent NEC on the market, and as far as is known to IBT, no other company has any ongoing clinical study for a potential drug to prevent, alleviate or cure NEC. IBT thus has a unique edge over other players in the market.

I would also like to inform you that IBT's clinical group has studied and discussed the clinical observations from the ongoing study. We can state that our study generates data in the way we predicted. Specifically, we see, among other things, high compliance of the study protocol, for example that administration of the study medicine and that the reporting system for side effects works well.

As previously communicated, we have not achieved the expected recruitment rate in the study and it is clear that the pandemic and the "lock-down" that has taken place in, for example, the USA, France and Spain make it difficult to increase the recruitment rate in the study. To increase the recruitment rate we are taking further measures to increase this rate and for example we have now applied to start our clinical study in four more European countries, Poland, Serbia, Bulgaria and Romania.

At the time of writing, we have 76 contracted hospitals, of which 55 are activated and can include patients. During the summer months, we have succeeded in opening hospitals in Israel that are actively participating in the study and have begun the opening process with five more hospitals in the United States. Our goal of completing the ongoing phase III study in 2021 remains, but since the pandemic continues to affect patient recruitment, there is an increased risk that we will not be able to complete the study during 2021. There is thus a significant risk that the results of the study may be delayed. In relation to the uncertainty that COVID-19 entails however, it is important to emphasize that IBT's cash is sufficient for the completion of the ongoing phase III study, even with any considerable delay of the study.

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I would also like to state that in our licensing agreement with BioGaia there were previously a clause that could give BioGaia an opportunity to regain the license if IBT did not have the IBP-9414 product on the market before the end of 2022. This option is no longer in the agreement.

This year recommendations from expert groups AGA (American Gastroenterology Association) and ESPHGAN (European Society for Pediatric Gastroenterology, Hepatology and Nutrition) have summarized the research in the field and found that a number of live bacteria show pharmaceutical effects on a number of diseases. Our drug candidate (*Lactobacillus reuteri*) is listed as a suitable candidate for future treatments to prevent NEC. We chose to believe in *Lactobacillus reuteri* several years ago and it feels fantastic at this time to carry out a Phase III program which will hopefully lead to us being able to provide a product that is in demand by the experts and the authorities, but which above all can help the smallest infants in a life-changing way.

IBT's qualified team continues to work in a dedicated and focused manner to deliver study results which in turn hopefully means that a product, which plays a vital role for the premature infants, can reach the market as soon as possible.

Stockholm,
August 14, 2020

Staffan Strömberg,
Chief Executive Officer

Significant events during the second quarter (Apr-Jun) 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, approximately 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-Jun) 2020

- IBT’s clinical study application was approved in Israel at the end of January 2020

Significant events after the reporting period

- No significant events have occurred after the reporting period

Selected financial data

ooo's	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
Net sales	-	-	-	-	-
Operating profit/loss	-27 915	-7 923	-26 708	-8 766	-47 200
Result after tax, SEK	-27 937	-7 561	-26 759	-8 247	-46 320
Total assets	492 620	554 977	492 620	554 977	518 273
Cash flow for the period (SEK)	-14 018	-1 114	-22 608	-8 691	-51 301
Cash flow per share for the period (SEK)	-1.25	-0.10	-1.97	-0.77	-4.57
Cash	473 608	539 453	473 608	539 453	495 188
Earnings per share before and after dilution (SEK)	-2.49	-0.67	-2.38	-0.73	-4.13
Equity per share (SEK)	43.08	48.86	43.08	48.86	45.46
Equity ratio (%)	98%	99%	98%	99%	98%

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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 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).

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