

Press Release November 5, 2020

Infant Bacterial Therapeutics AB (publ) Interim Management Statement, January 1 – September 30, 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 has been ongoing for almost nine months. The pandemic not only affects our work at IBT but of course also the staff at the hospitals where our study is ongoing. Right now, in November 2020, it seems as if the hospitals now again have to care for more COVID-19 patients compared to just a couple of months ago. As the development of the pandemic is difficult to assess, it is equally difficult to predict how it will affect IBT's timelines. I would like to mention again that our study is not dependent on "normal" hospital or doctor visits, as the infants we recruit are already in the intensive care units independent of our study. This is important as many hospitals have now introduced restrictions for non-essential visitors.

As I mentioned earlier, we have managed to change our way of working in order to ensure the quality of our study by, amongst other things, carrying out so-called virtual monitoring and providing the study drug to all recruiting hospitals despite the ongoing COVID pandemic. We have previously communicated that in order to increase the recruitment rate, we have applied to start our clinical study in four more European countries, Poland, Serbia, Bulgaria and Romania. During the third quarter, we have received trial permits in Poland while we are still working on Serbia, Bulgaria and Romania. At the time of writing, we have 101 contracted hospitals, of which 62 are activated and may include patients. During the third quarter, we have managed to open more hospitals compared to the previous quarter when we had 76 contracted and 55 activated. Our goal of completing the ongoing Phase III study in 2021 will most likely not be achieved in the face of the continuing pandemic and its effects on patient recruitment. However, it is important to emphasize that IBT's cash is sufficient for the completion of the ongoing phase III study, even if it takes longer than we would like.

We monitor our study on a regular basis and we can today confirm that the study generates data in the way we predicted. Specifically, we see, among other things, good compliance with the protocol, e.g. administration of the study drug and that the reporting system for clinical observations works well and as expected. We have also carried out two pre-planned safety-oriented interim analyses. The outcome of these analyses is that we continue the study as planned. We also have a planned pilot sub-study regarding "feeding tolerance" which includes data from 300 infants in the current study. Preparations for the analysis in this sub-study are ongoing.

IBT has strengthened its organization by hiring a clinical project manager and a CMC (Chemistry, Manufacturing and Controls) manager. Both of these recruits add significant competence to the organization, which ensures that we can better meet future challenges.

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 could play a vital role for the well-being of premature infants, can reach the market as soon as possible. Today, no drug against NEC exists on the market, and as far as is known to IBT, no other company has any ongoing clinical study for a potential pharmaceutical to prevent, alleviate or cure NEC. IBT thus has a substantial edge over other possible future players in the market.

Stockholm, November 5, 2020

Staffan Strömberg

Chief Executive Officer

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Significant events during the third quarter (Jul-Sep) 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-Sep) 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 Jul-Sep	2019 Jul-Sep	2020 Jan-Sep	2019 Jan-Sep	2019 Jan-Dec
Net sales	-	-	-	-	-
Operating profit/loss	-18 586	-11 007	-45 294	-19 774	-47 200
Result after tax, SEK	-18 600	-10 538	-45 359	-18 786	-46 320
Total assets	480 304	545 348	480 304	545 348	518 273
Cash flow for the period (SEK)	-6 693	-34 064	-28 761	-42 755	-51 301
Cash flow per share for the period (SEK)	-0.60	-3.03	-2.56	-3.81	-4.57
Cash	463 043	511 888	463 043	511 888	495 188
Earnings per share before and after dilution (SEK)	-1.66	-0.94	-4.04	-1.67	-4.13
Equity per share (SEK)	41.43	47.92	41.43	47.92	45.46
Equity ratio (%)	97%	99%	97%	99%	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).

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