INFANT BACTERIAL THERAPEUTICS

Press Release Aug 13, 2021

Infant Bacterial Therapeutics AB (publ) Interim Management Statement, January 1 – June 30, 2021

Message from the CEO

As is well known, IBT is conducting a large phase III study ("The Connection Study"), the final study in our clinical development program with our drug candidate IBP-9414, which contains Lactobacillus reuteri as the active substance. The active substance is a naturally occurring bacterial strain found in women's breast milk. The goal of our development is to offer physicians a unique treatment option which is partly intended to prevent very serious medical complications, such as NEC (necrotizing enterocolitis) and sepsis (blood poisoning), which occur when a child is too born prematurely. In addition, our product is expected to improve the development of the stomach and intestines, which in turn leads to improved intestinal function and nutrient uptake.

During the second quarter of 2021, IBT completed the pilot study which the company agreed with the FDA to conduct after having recruited 300 patients in "The Connection Study". The purpose of the pilot study was to validate the second primary endpoint "sustained feeding tolerance". We evaluated whether our way of measuring "sustained feeding tolerance" in the study could be linked to medically relevant observations. IBT also tested whether these "blinded" medical relationships were statistically significant. The result of the important pilot study was that the protocol's selected endpoint called "sustained feeding tolerance" confirmed statistical significance and demonstrated also medical relevant effects according to a panel of international clinical experts. This is favorable news which confirms that we in the ongoing study can verify the drug candidate's effects on the now validated endpoint.

IBT is currently alone in conducting clinical drug trials in children with drug probiotics after being authorized to conduct the Phase III study by the FDA and eight other countries' authorities after that they have reviewed our protocol and our production of the product. I expect IBT to be "first in class" when we hopefully can deliver the first probiotic product with a drug approval issued by the FDA and other pharmaceutical authorities in markets around the world.

The COVID-19 pandemic has subsided, although the delta variant of the virus still causes uncertainty about the future. In February 2021, we announced that we had completed the first phase of our Phase III study when we had recruited 300 patients, so more children can be included in the study. The improved Covid situation in combination with the expanded inclusion criteria hassled to a significant increase in the recruitment rate in the study. During Q2, the rate more than tripled vs. the prior quarter. We take note that the US recruitment rate significantly exceeds Europe and Israel. To date approximately 80% of the children in the study were born in America. We are investigating the cause of this and will focus on accelerating recruitment in Europe to try to match the pace we see in the United States. So far, we have just exceeded 500 recruited patients. We are thus quickly approaching the next, pre-planned, safety evaluation at 600 patients. We expect to reach 600 children in Q3 this year.

During the summer, IBT received an additional national clinical trial permit for implementation of the study in Serbia. We are accordingly engaging hospitals across the US, the UK, France, Spain, Poland, Hungary, Israel, Serbia and Bulgaria.

We have today 77 activated hospitals ready to include patients. But more importantly, it is critical to track how many of those actually recruit patients. By the end of March 2021, 51 hospitals had admitted at least one patient and today the corresponding figure is 61. This is a positive trend which we will further develop. We expect to be able to complete the study in 2022 and IBT's funding is expected to be sufficient for the implementation of the study.

IBT has recruited a new experienced CFO named Marie-Louise Alamaa and we look forward to welcoming Marie-Louise August 16th when she assumes her responsibilities. She replaces Daniel Mackey who left the company during the summer.

In conclusion, I would like to take this opportunity to thank all employees and experts who with great commitment drive the work forward with our unique product which may play a major role for prematurely born children.

Stockholm, August 13th, 2021

Staffan Strömberg
CEO

Interim report January 1-June 30, 2021

Second quarter (Apr-Jun) 2021

- Net sales 0 KSEK (0)
- Operating income -29 164 KSEK* (-27 915)
- Earnings per share before and after dilution -2.60 SEK (-2.49)

Reporting period (Jan-Jun) 2021

- Net sales 0 KSEK (0)
- Operating income -28 712 KSEK* (-26 708)
- Earnings per share before and after dilution -2.56 SEK (-2.38)

* Operational income includes exchange rate effects on foreign currency deposits for the purpose of securing future outflows during the second quarter amounting to -5 876 (-13 369) KSEK and during the reporting period to 6 237 (488) KSEK.

Significant events during the second quarter (Apr-Jun) 2021

- On April 15, we announced that the Chinese Patent Office has issued a decision to grant a patent entitled: "A method of activating lactic acid bacteria", which protects the formulation of Lactobacillus reuteri. The Chinese patent is valid until 2036 and IBP-9414 is intended for marketing in China upon market approval.
- On April 29, we announced that inclusion criteria of "The Connection Study" has been expanded to include 500 - 1000 gram birth weight in premature infants (from earlier 750 -1000 grams) after the Data Monitoring Committees' planned review of safety data and performing futility-analysis regarding NEC.

Significant events during the reporting period (Jan-Jun) 2021

- On February 9, we announced that the Japan Patent Office has issued a decision to grant a patent entitled: "A method of activating lactic acid bacteria", which protects the formulation of Lactobacillus reuteri including IBP-9414. The Japanese patent is valid until 2036 and IBP-9414 is intended for marketing in Japan upon market approval.
- On February 10, we announced that the company has reached an important milestone after recruiting 300 premature infants to the ongoing clinical Phase III study of IBP-9414. A safety assessment of the data has been conducted and infants with very low birthweights may now be recruited to the study, significantly increasing the rate of recruitment.
- The ongoing clinical Phase III study's second primary endpoint called "sustained feeding tolerance" has been validated.
- In response to the pandemic, IBT is closely monitoring developments and is actively taking measures to minimize or limit affects thereof on the company's operations. IBT adheres to guidelines from Folkhälsomyndigheten, WHO och ECDC (European center for prevention and control of disease). The recruitment level in IBT's pivotal study, "The Connection study" is affected by COVID-19. The bulk of the costs for conducting the study are generated in connection with recruitment of patients, and thus the assessment is that IBT has sufficient funds to conclude the study even if this occurs at a later point in time than originally planned.

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Significant events after the reporting period
IBT has recruited Marie-Louise Alamaa as new CFO.

Selected financial data

ooo's	2021 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
Net sales	-	-	-	-	-
Other income, KSEK	31	79	94	154	-
Operating profit/loss, KSEK	-29 164	-27 915	-28 712	-26 708	-71 918
Result after tax, KSEK	-29 165	-27 937	-28 714	-26 759	-72 007
Total assets, KSEK	429 414	473 608	429 414	492 620	450 318
Cash flow for the period, KSEK	-10 816	-14 018	-20 609	-22 068	-56 625
Cash flow per share for the period (SEK)	-0.96	-1.25	-1.84	-1.97	-5.04
Cash, KSEK	409 066	473 608	409 066	473 608	423 438
Earnings per share before and after dilution (SEK)	-2.60	-2.49	-2.56	-2.38	-6.41
Equity per share (SEK)	36.66	43.08	36.66	43.08	39.21
Equity ratio (%)	96%	98%	96%	98%	98%

About Infant Bacterial Therapeutics AB
Infant Bacterial Therapeutics AB ("IBT") is a public company domiciled in Stockholm. The company's Class B shares are listed on Nasdaq Stockholm, Mid-cap (IBT B).

Infant Bacterial Therapeutics AB (publ) ("IBT") is a pharmaceutical company with a product in clinical phase III 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. The ambition for IBP-9414 is to become the world's first approved probiotical drug with the goal to prevent life threatening diseases in premature infants including NEC and sepsis by promoting healthy stomach-and bowel development 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

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