INFANT BACTERIAL THERAPEUTICS

Press Release October 29, 2021

Infant Bacterial Therapeutics AB (publ), Interim report January 1-September 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 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.

In accordance with the study protocol, patient recruitment was paused on August 25 of infants in stratum A (the smallest infants with birthweights between 500-749g at birth) in anticipation of a safety review conducted by the Data Monitoring Committee (DMC). Recruitment was reinitiated September 22 following DMC's completion of safety review. The DMC concluded that the signal which triggered the temporary recruitment pause did not represent a cause of concern and that there was no prospective medical reason to restrict recruitment of the smallest infants in the study. We reached a milestone of 600 recruited patients in September despite the temporary recruitment pause. During 2021 we also validated the second primary endpoint in "The Connection Study". These two important events representing good momentum in our study and we are committed to continue to move forward with our study with accelerating speed.

The follow-on effects of COVID-19 for our study have started to subside although the virus represent a continued future uncertainty. We take note that the US recruitment pace in the US is significantly ahead of that in Europe and Israel. To date approximately 80% of recruited infants are born in the US. We have identified and mitigated several underlying causes for this trend which will hopefully increase the European pace such that it approaches the US momentum. The next planned DMC review is expected in Q4 2021, based on data from the first 600 randomized infants. This planned review will unlikely yield new conclusions given that the DMC recently completed its analysis on most of the same data in connection to the September recruitment pause.

We are as of today engaged with hospitals across 10 countries: the US, the UK, France, Spain, Poland, Hungary, Israel, Serbia, Romania and Bulgaria. There are currently 83 activated hospitals ready to include patients. An important KPI is track how many hospitals are actively recruiting patients. As of the end of March 2021, 51 hospitals had recruited at least one patient. Today that corresponding figure is 66 hospitals. We dedicate significant priority to further enhance this positive trend and expect to conclude the study during the end of 2022. IBT's funding is expected to be sufficient for the completion of the study.

We received our Mexican patent approval on September 10. Patents were previously secured in China and Japan, strengthening our future IP protection of IBP-9414, which is of particular importance in countries where we do not have orphan drug status designation.

In conclusion, I would like to take this opportunity to express my appreciation to our 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, October 28st, 2021

Staffan Strömberg
CEO

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- **Third quarter (Jul-Sep) 2021**
- Net sales KSEK 0 (0)
- Operating income KSEK 228* (-18,586*)
- Earnings per share before and after dilution SEK -0.01 (-1.66)

Reporting period (Jan-Sep) 2021
- Net sales KSEK 0 (0)
- Operating income KSEK -28,485* (-45,294*)
- Earnings per share before and after dilution SEK -2.56 (-4.04)

* Operational income includes exchange rate effects on foreign currency deposits for the purpose of securing future outflows during the third quarter amounting to KSEK 7,313 (-3,872) and during the reporting period to KSEK 13,550 (3,384).

Significant events during the third quarter (Jul-Sep)

- Marie-Louise Alamaa assumed the position as new CFO on August 16
- On August 25, IBT announced that recruitment of the smallest infants in the Connection Study was paused. IBT started to recruit infants in Stratum A (birth weight of 500g-749g) in The Connection Study on April 29, 2021. At that point in time, 68 infants had been recruited to the group. In accordance with the study protocol and clinical observations, enrolment of infants to Stratum A was paused awaiting a safety review by the Data Monitoring Committee (DMC). Infants that had already been randomized were allowed to continue treatment as per protocol, and infants in Stratum B (750g-1000g) were allowed to continue.
- On September 10, IBT announced that the Mexican Patent Office has granted a patent entitled: “A method of activating lactic acid bacteria”, which protects the formulation of Lactobacillus reuteri including IBP-9414. IBT is currently developing its drug candidate IBP-9414 in Phase III. 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 this population.
- On September 22, IBT announced that the company opened the study recruitment in Stratum A (birthweight of 500 – 749 g) after the independent DMC had completed an additional safety review, in which the DMC had no objections to continue the study.
- On September 30, IBT announced that the company has reached the next important milestone after recruitment of 600 premature infants in the ongoing Clinical Phase III study of IBP-9414. According to the study protocol, a safety and futility analysis will now be performed during which the recruitment will continue.

Significant events during previous periods in 2021

- On February 9, IBT 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, IBT reached the important milestone after recruitment of 300 premature infants to the ongoing clinical Phase III study of IBP-9414. A safety assessment of the data was conducted and infants with very low birthweights (Stratum A, birthweight of 500g-749gwas thereafter allowed to be recruited to the study
- IBT has during Q2, 2021 finished the analysis of the pilot study that IBT had agreed with FDA to perform after recruitment of 300 infants in The Connection Study. The result from the pilot study was that the second primary endpoint called “sustained feeding tolerance” was validated.
- 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 have been expanded to include 500 - 1000 g birthweight in premature infants (from earlier 750g -1000 g) after the Data

Monitoring Committees' planned review of safety data and performing futility-analysis regarding NEC.

- In response to the pandemic, IBT is closely monitoring developments and is actively taking measures to minimize or limit effects thereof on the company's operations. IBT adheres to guidelines from Folkhälsomyndigheten, WHO and ECDC (European center for prevention and control of disease). The recruitment pace 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.

Significant events after the reporting period

No significant events have occurred after the reporting period.

Selected financial data

KSEK	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Net sales	-	-	-	-	-
Other income	-	79	94	233	312
Operating profit/loss	228	-18,586	-28,485	-45,294	-71,918
Result after tax	-58	-18,600	-28,773	-45,359	-72,007
Total assets	421,452	480,304	421,452	480,304	450,318
Cash flow for the period	-26,019	-6,693	-46,628	-28,761	-56,625
Cash flow per share for the period (SEK)	-2.32	-0.60	-4.15	-2.56	-5.04
Cash	390,360	463,043	390,360	463,043	423,438
Earnings per share before and after dilution (SEK)	-0.01	-1.66	-2.56	-4.04	-6.41
Equity per share (SEK)	36.65	41.43	36.65	41.43	39.21
Equity ratio (%)	98%	97%	98%	97%	98%

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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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