INFANT BACTERIAL THERAPEUTICS

Press Release May 4, 2021

Infant Bacterial Therapeutics AB (publ) Interim Management Statement, January 1 – March 31, 2021

Message from the CEO
IBT is conducting a phase III-study ("The Connection Study") which is the last phase of the clinical development program with the pharmaceutical candidate IBP-9414 containing *Lactobacillus reuteri* as active substance. The active substance is a human bacterial strain found naturally in breast milk. The objective of the study is to show that the active substance can prevent necrotizing enterocolitis (NEC) and improve sustained feeding tolerance.

The medical need of a well-functioning digestion system is very high in premature infants and it is our expectation that IBT's pharmaceutical candidate IBP-9414 may improve gut motility in nutritional uptake, and simultaneously also reduce the risk for several complications such as NEC.

The COVID-19 pandemic has now lasted more than one year. I have in previous quarterly statements described how IBT is affected by the pandemic. The pandemic has affected the recruitment level in the phase III-study, and at the same time the quality in the generated data is high, in spite of COVID-19. We have noted a lower recruitment level than we observed in our phase II-study conducted at 15 hospitals in the USA during 2016 through to 2017. During the latter part of the first quarter in 2021 we have, however, in the recruiting hospitals, achieved the recruitment levels expected prior to the initiation of the phase III-study in July of 2019. The recruitment level of infants in the USA has increased, and it is a fair assumption that the increased levels result from the fact that USA has begun to "open up" following a comprehensive vaccination program in the country. We now hope to see a similar effect during the latter part of 2021 in other parts of the world where our study is being conducted. Considerable efforts by our staff have led to increased recruitment since the USA "opened up". However, the pandemic is not over, and we can ascertain that currently we have many hospitals where the administrative preparation is completed, i.e. study approval and study medicine are in place, but that recruitment has not commenced due to resources having been diverted elsewhere within the hospitals. Considering the fact that the pandemic is ongoing, it is naturally difficult to estimate with any certainty when we may be able complete the study. We do however still expect to be able to complete the study in 2022.

In February 2021 we announced that we have concluded the initial phase in our phase III-trial upon recruitment of 300 patients. During the first quarter, the data from these 300 patients have been reviewed by the independent group of experts called the Data Monitoring Committee (DMC). The DMC has reported its conclusions to IBT, and just days ago, IBT was able to increase the inclusion criteria in the study as planned, based on the recommendations by the DMC. This means that we now are able to recruit infants with birthweights from 500 grams to 1000 grams instead of previously only recruiting infants with birthweights from 750 grams to 1000 grams. As this amendment nearly doubles the theoretically possible number of infants eligible for recruitment in our study, our expectation is that the new recruitment criteria will further increase our recruitment levels. It is satisfying to report that within just a few days after opening the new weight group, we have already recruited infants in this weight group.

During the first quarter of 2021 we also recruited our first patient in Bulgaria, and we currently have 75 active hospitals able to recruit patients versus 68 during the previous quarter.
It is worth reiterating that the bulk of the costs for conducting the study are incurred at the time of recruitment. IBT's liquidity is expected to be sufficient to complete the study.
During the first quarter, our own first patents were approved both in China and Japan. This may provide considerably improved protection for potentially exclusive sales of our product. IBT has Orphan Drug status for the IBP-9414 project in both the US and the EU, but lacks the corresponding possibilities in both China and Japan. It is therefore positive that the patents have been granted in particular in China and Japan as they are expected to provide protection until 2036 in these two important markets.

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Finally, I wish to extend my gratitude to all our staff and consultants who with great dedication drive the work forward with a product which can have an important role for the premature infants.

Stockholm May 4, 2021

Staffan Strömberg
Chief executive officer

Interim report January 1-March 31, 2021

First quarter (Jan-Mar) 2021

- Net sales 0 KSEK (0
- Operating income 452 KSEK* (1 206)
- Earnings per share before and after dilution
  0.04 (SEK) 0.10

* Operational income includes exchange rate gains on foreign currency deposits for the purpose of securing future outflows amounting to 12 114 (13 857) KSEK.

Significant events during the first quarter (Jan-Mar) 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. This also means that a safety analysis of these infants will take place in order to also recruit infants with a very low birth weight, which in turn is expected to significantly increase the recruitment rate. Furthermore it means that IBT has an opportunity to validate the study’s second primary endpoint, “feeding tolerance”, and redefine this if necessary.
- In response to the COVID-19 pandemic and the coronavirus, IBT is closely monitoring developments and is actively taking measures to minimize or limit affects thereof on the company’s operations. IBT adheres to directives issued by Folkhälsomyndigheten, the WHO and ECDC (European center for prevention and control of disease). The pandemic affects the recruitment level in IBT’s pivotal study, “The Connection study”. 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

- 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 Aprll 29, we announced that inclusion criteria of The Connection Study has been expanded to include 500 - 1000 gram birth weight premature infants (from earlier 750 -1000 grams) after the Data Monitoring Committees’ planned review of study data. Since April 29, infants in this weight group have been recruited.

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Selected financial data

ooo's	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
Net sales	-	-	-
Other income, KSEK	64	75	-
Operating profit/loss, KSEK	452	1 206	-71 918
Result after tax, KSEK	451	1 178	-72 007
Total assets, KSEK	451 138	523 168	450 318
Cash flow for the period, KSEK	-9 794	-8 050	-56 625
Cash flow per share for the period (SEK)	-0.87	-0.72	-5.04
Cash, KSEK	425 758	500 995	423 438
Earnings per share before and after dilution (SEK)	0.04	-0.10	-6.41
Equity per share (SEK)	39.26	45.57	39.21
Equity ratio (%)	98%	98%	98%

About Infant Bacterial Therapeutics AB
Infant Bacterial Therapeutics AB (publ) is a pharmaceutical company with a product in 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, 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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