INFANT BACTERIAL THERAPEUTICS

Press Release May 4, 2022

Infant Bacterial Therapeutics AB (publ) Interim Management Statement, January 1 – March 31, 2022

Message from the CEO

IBT's vision is to become an internationally leading company in the development of pharmaceuticals in the areas of premature infants, gastrointestinal diseases and probiotics.

We have now successfully driven the development of IBP-9414, the world's first phase III pharmaceutical grade probiotic for children, for almost a decade. The key milestone initiating the development of pharmaceutical grade probiotics occurred when IBT became the first company in the world in 2014 to receive Orphan Drug Designation in the US, where others had previously tried but failed. IBT subsequently became the first to be authorized by the FDA to administer live bacteria to children in a clinical trial in the US. The fact that we have also received permission to carry out pediatric studies in another 10 countries (9 EU + Israel) is further validation of IBT's unique ability to develop pharmaceutical grade probiotics.

Our work is attracting more and more attention. For example, The American Association of Pediatrics recently published that premature infants need pharmaceutically developed probiotics, mentioning our Phase III study in particular. The reason why IBT's work is specifically noticed is that probiotics should be of the highest safety, efficacy, and manufacturing standards when administered to premature babies. Today we know that premature babies can suffer injury and even death from the contaminants that can accompany a product that is not manufactured to the highest drug standards. IBT's production is well scrutinized by the FDA and corresponding authorities across 10 other countries. We have made ongoing investments since 2014 to ensure that our production yields a probiotic product intended to become the first to be approved as a drug.

We maintained good recruitment momentum in our NEC study through the fall of 2021, while omicron affected recruitment during the winter. As of today, May 4th, 2022, we have recruited 915 patients. It is difficult to assess what future recruitment rates will look like, but our focus on our phase III study remains and we expect to be able to complete recruitment in 2023 with existing capital.

During the first quarter of 2022, we initiated preparations for our commercialization phase of IBP-9414, where we are identifying and securing the resources and networks required to be prepared from day one in terms of product, market and organization prior to our launch.

In parallel, we have taken the first steps towards expanding IBT's product portfolio, which is based on the unique knowhow created by IBT. During the first quarter of 2022, we signed an agreement with a leading American university regarding the development of a potential new drug, separate from IBP-9414, in the treatment of a disease that can also affect those born prematurely. We are also in discussions with another American university regarding the rights to yet another medically meaningful treatment. I can also mention that we started our own gastroschisis project (IBP-1016) with, including a key opinion leader meeting in April.

In conclusion, I would like to take this opportunity to thank all the staff and experts around the world who with great commitment help us get closer to our vision through the development of pharmaceutical grade probiotics, especially with IBP-9414 which may play a very significant role for premature babies.

Stockholm, May 4, 2022

Staffan Strömberg
CEO

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Financial overview for the period

First quarter (Jan-Mar) 2022

- Net sales KSEK 0 (0)
- Operating income KSEK -19 063* (452)
- Earnings per share before and after dilution SEK -1.71 (0.04)

* Operational income includes exchange rate effects on foreign currency deposits for the purpose of securing future outflows during the first quarter amounting to KSEK 6,252 (12,114).

Significant events during the first quarter (Jan-Mar) 2022

- On January 10, IBT announced that the Australian Patent Office has granted a patent entitled: “A method of activating lactic acid bacteria”.
- On January 19, IBT announced that The Connection Study continues after the Data Monitoring Committee (DMC) had completed its pre-scheduled safety analysis without any concerns. At the same time a futility analysis was performed. Based on DMC recommendations and futility outcome, IBT is continuing the recruitment to the study as planned.

Significant events after the reporting period

- The company's CFO, Michael Owens, has decided to retire during the year. A recruitment process has begun.
- At the Annual General Meeting on May 4th 2022, Robert Molander resigned from the Board at his own request. At the same time, Robert is transferring to an operational role as Chief Commercial Officer within the management team for the company.

Selected financial data

ooo's	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Net sales	-	-	-
Other income	3	64	94
Operating profit/loss	-19 063	452	-44 578
Result after tax	-19 201	451	-44 991
Total assets	409 967	451 138	408 478
Cash flow for the period	-10 825	-9 794	-55 532
Cash flow per share for the period (SEK)	-0.96	-0.87	-4.95
Cash	382 179	425 758	386 752
Earnings per share before and after dilution (SEK)	-1.71	0.04	-4.01
Equity per share (SEK)	33.50	39.26	35.21
Equity ratio (%)	92%	98%	97%

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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, Small 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.

For additional information please contact

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