Infant Bacterial Therapeutics AB (publ) (IBT), Interim Management Statement, July 1 – September 30, 2022

Message from the CEO

Our IBP-9414 clinical phase III development project is progressing well, and as previously mentioned, we are pursuing several initiatives to accelerate study execution. It is particularly satisfying that the recruitment rate has increased at the European hospitals, after we deployed additional resources. We will continue to add new hospitals while concluding collaborations with hospitals that have not recruited to any significant extent. Today we have recruited 1,215 children. When we reach 1,400 children, in line with our clinical protocol, we may open a third cohort C (birth weight between 1,001 to 1,500 grams) for recruitment. This is anticipated to occur during the first quarter of 2023 based on the current recruitment rate. The recruitment rate should thus increase, and our hope is thus to finish recruiting the 2,158 planned children in 2023. IBT's existing funds are still expected to be sufficient to carry out the entire phase III study as planned.

We are very pleased to see how our study, the Connection Study, is receiving attention. In October, the British Journal of Gastroenterology demonstrated that Sustained Feeding Tolerance (SFT) is linked to serious disease progression including sepsis and bronchopulmonary dysplasia, a chronic lung disease that affects premature babies. The implication is that SFT is validated and that IBP-9414 accordingly has two independent primary endpoints in its study.

I can also report that we continuously review the safety data we obtain from the study and can sum up that the side effect reporting is in line with the expected outcome.

In terms of pre-launch preparations, negotiations are ongoing to ensure large-scale product availability of IBP-9414. Concurrent discussions are progressing with potential distribution partners who have shown interest in the right to distribute our product. We are now considering what is best in the long term.

While we keep our focus on IBP-9414, it is also our intention to build on the unique expertise that IBT has generated. In September, the FDA announced that IBT received Orphan Drug Designation for our ROP (retinopathy of prematurity) project, which aims to investigate the possibilities of developing a drug to prevent ROP. The disease affects 50-70% of premature babies who weigh less than 1,500 grams at birth. Many children can be cured without permanent visual impairment, but unfortunately, ROP too often results in children becoming blind. Current treatments do not meet the medical need as severe cases have increased significantly in recent years. It is important to stress that we continue to explore the ROP project which we have named IBP-1118 prior to initiating costly drug development. We must first confirm the required regulatory pathway to obtain market approval. IBP-1118 has thus not been allocated any significant resources as IBT's funds are earmarked to conclude the drug development of IBP-9414.

We also had the pleasure of welcoming Maria Ekdahl, who was appointed as the new Chief Financial Officer (CFO). In conclusion, I would like to take the opportunity to thank all the employees and experts around the world who with great commitment help us get closer to our vision through the development of probiotic drugs, especially with IBP-9414 which can play a very big role for the premature babies.

Stockholm, November 10, 2022

Staffan Strömberg
CEO

Financial overwiew for the period

Third quarter (Jul-Sep) 2022

- Net sales KSEK 0 (0)
- Operating income KSEK -7 746* (228)
- Earnings per share before and after dilution SEK -0.69 (-0.01)

Reporting period (Jan-Sep) 2022

- Net sales KSEK 0 (0)
- Operating income KSEK -25 051* (-28 485)
- Earnings per share before and after dilution SEK -2.26 (-2.56)

* Operational income includes exchange rate effects on foreign currency deposits for the purpose of securing future outflows during the third quarter amounting to KSEK 17 220 (-7 313) and during the reporting period amounting to KSEK 43 451 (13 550)

Significant events during the third quarter (Jul-Sep)

- On September 19, Maria Ekdahl took office as the new CFO.
- On September 23, the FDA approved IBT's Orphan Drug Designation application for a drug to prevent ROP (retinopathy of prematurity).

Significant events during the reporting period

- 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 British Journal of Gastroenterology published in October an article based on the IBT's “Connection Study” demonstrating SFT is linked to serious disease progression including sepsis and bronchopulmonary dysplasia.

Selected financial data

ooo's	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-dec
Net sales	-	-	-	-	-
Other income	-	-	3	94	94
Operating profit/loss	-7 746	228	-25 051	-28 485	-44 578
Result after tax	-7 782	-58	-25 335	-28 773	-44 991
Total assets	396 361	421 452	396 361	421 452	408 478
Cash flow for the period	-22 864	-26 019	-61 870	-46 628	-55 532
Cash flow per share for the period (SEK)	-2,04	-2,32	-5,51	-4,15	-4,95
Cash	368 331	390 360	368 331	390 360	386 752
Earnings per share before and after dilution (SEK)	-0,69	-0,01	-2,26	-2,56	-4,01
Equity per share (SEK)	33,12	36,65	33,12	36,65	35,21
Equity ratio (%)	94%	98%	94%	98%	97%

IBT in brief

Infant Bacterial Therapeutics AB ("IBT") is a public company domiciled in Stockholm. The company's Class B shares are since September 10, 2018, listed on Nasdaq Stockholm (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 conducting sound 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 and IBP-1118 to prevent ROP (retinopathy of prematurity), a growing and serious condition that often leads to blindness among prematurely born babies. By developing these drugs, IBT has the potential to fulfill unmet needs for diseases where there are currently no prevention or treatment therapies available.

Contact persons

Staffan Strömberg, CEO

Maria Ekdahl, CFO

Contact information

Infant Bacterial Therapeutics AB (Reg. no. 556873-8586)
Bryggargatan 10
111 21 Stockholm, Sweden
Telephone: +46 76 219 37 38
info@ibtherapeutics.com
www.ibtherapeutics.com

Publication

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