

Infant Bacterial Therapeutics AB (publ) Interim Management Statement, January 1-June 30, 2022

Message from the CEO

Our IBP-9414 clinical phase III development program is progressing well. We have seen an overall acceleration of recruitment rates and, as mentioned previously, have been working on numerous activities to expedite the execution of our study. It is particularly satisfying to note that the recruitment momentum is picking up at the European hospitals. Today, we have recruited 1,102 children, thus slightly more than half of the children that we will include in the study. During the summer months, we have targeted about 50 children a month and I expect that we will recruit 600 children in total during 2022. Today, the study is open to the smallest children in cohort A (birth weight between 500 grams to 749 grams) as well as the slightly larger children in cohort B (birth weight from 750 grams to 1,000 grams). Once we have recruited 1,400 children, the plan is, in accordance with our clinical protocol, to open cohort C (birth weight from 1,001 grams to 1,500 grams), which is expected to increase the recruitment rate further. Our hope is thus to complete the recruitment of the 2,158 planned children in 2023. IBT's existing capital is still expected to be sufficient to carry out the entire phase III study, as planned.

As far as the scientific side is concerned, I can report that we continuously review the safety data that we obtain from the study and can summarize that what is occurring in the study thus far is in line with the expected outcome from a safety point of view. We have also published information documenting how Sustained Feeding Tolerance is linked with clinical observations doctors make when treating premature babies, "Correlating Sustained Feeding Tolerance (SFT) to adverse outcomes during randomized administration of *L. reuteri* for the prevention of necrotizing enterocolitis (NEC) and improved feeding tolerance in preterm infants: The CONNECTION TRIAL", during the month of May at the Pediatrics Academic Society (PAS) meeting in Colorado, USA.

Regarding market launch preparations, negotiations are ongoing to secure large-scale production capacity of IBP-9414 in time for commercialization. Concurrent discussions are progressing with several potential partners who have shown interest in the right to distribute our product. We are now considering what is best for the company from a long-term perspective.

During the first half of 2022, as we prepare the company for the future, we have also focused on the documentation and processes that covers ESG (Environmental, Social and Governance) aspects. Documentation describing processes within the company has been reviewed and supplemented, where necessary. When the internal ESG work was completed, we applied for membership in the UN's (United Nations) Global Compact and on 9 May 2022, IBT obtained membership status. NASDAQ has also reviewed our initiative to become more transparent regarding ESG and during the reporting period IBT officially became classified as a "NASDAQ ESG Transparency Partner".

We look forward to welcoming Maria Ekdahl who has been appointed as the new Chief Financial Officer (CFO), starting September 19, 2022, and express our sincere appreciation towards Michael Owens for his contributions during the past 10 years.

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 pursue our vision through the development of pharmaceutical grade probiotics, especially with IBP-9414 which may play a very significant role for premature babies.

Stockholm, August 25, 2022

Staffan Strömberg

CEO

Financial overview for the period

Second quarter (Apr-Jun) 2022

- Net sales KSEK 0 (0)
- Operating income KSEK 1 758* (-29 164)
- Earnings per share before and after dilution SEK 0.15 (-2.60)

Reporting period (Jan-Jun) 2022

- Net sales KSEK 0 (0)
- Operating income KSEK -17 305* (-28 712)
- Earnings per share before and after dilution SEK -1.56 (-2.56)

* Operational income includes exchange rate effects on foreign currency deposits for the purpose of securing future outflows during the second quarter amounting to KSEK 19 979 (-5 876) and during the reporting period amounting to KSEK 26 231 (6 237)

Significant events during the second quarter (Apr-Jun)

- At the Annual General Meeting on May 4th 2022, Robert Molander resigned from the Board at his own request. At the same time, Robert transferred to an operational role as Chief Commercial Officer within the management team for the company.
- On June 30, IBT announced that Maria Ekdahl has been appointed as new CFO effective on September 19, 2022, pursuant to Michael Owens' retirement.

Significant events during the reporting period (Jan-Jun)

- 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

- No other significant events have occurred after the reporting period.

Selected financial data

ooo's SEK	2022	2021	2022	2021	2021
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Net sales	-	-	-	-	-
Other income	-	31	3	94	94
Operating profit/loss	1 758	-29 164	-17 305	-28 712	-44 578
Result after tax	1 648	-29 165	-17 553	-28 714	-44 991
Total assets	400 007	429 414	400 007	429 414	408 478
Cash flow for the period	-28 182	-10 816	-39 007	-20 609	-55 532
Cash flow per share for the period (SEK)	-2.51	-0.96	-3.47	-1.84	-4.95
Cash	373 976	409 066	373 976	409 066	386 752
Earnings per share before and after dilution (SEK)	0.15	-2.6	-1.56	-2.56	-1.44
Equity per share (SEK)	33.81	36.66	33.81	36.66	35.21
Equity ratio	95%	96%	95%	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 probiotic drug with the goal to prevent life threatening diseases in premature infants including NEC and sepsis by promoting 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 currently also includes an additional 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 preventative or treatment therapies available.

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Publication

The Report was submitted for publication, by the CEO, at 08.00 on August 25, 2022.