Press release February 4, 2022

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

Message from the CEO

IBT's ongoing pivotal phase lll clinical trial aims to generate data to improve survival possibilities of premature infants. This is accomplished by documenting the effects of IBP-9414 regarding two specific goals: prevention of NEC and reduction of time to Sustained Feeding Tolerance (SFT). The goal in SFT is dual. We know that proper digestion enables normal development in infants, however, we have also shown that reducing the period until the infants have achieved SFT reduces the risk of severe complications, e.g. Sepsis.

Therefore, our study measures how IBP-9414 affects the period from birth until SFT is reached and how the incidence of NEC is affected. SFT is thus the second primary "endpoint", which was validated in 2021 by an agreed procedure with the FDA in which SFT correlates with fewer serious complications. This enables the study to evaluate two primary endpoints instead of one.

In this CEO commentary covering the fourth quarter 2021, I'm expanding on how Covid has affected us recently.

IBT included its initial patient in the comprehensive phase lll trial ("The Connection Study") in July 2019. The study was well received and patient recruitment initiated right away at the hospitals which were open for participation in the study. The first 15 hospitals were quickly integrated as the infrastructure was in place as the majority of these had participated in our successfully concluded phase ll clinical trial during 2016 and 2017.

Following this promising start, we encountered recruitment challenges which we took action on. We learned that our CRO (Clinical Research Organization, i.e. the company assisting IBT to conduct the study) required assistance to increase the recruitment of infants. Furthermore, we improved and simplified procedures while simultaneously deciding to expand the study to five more countries. One of the decisions taken in early 2020 was for the IBT staff to visit and assist hospitals to initiate patient recruitment. We soon concluded that our efforts generated results and we were again happily recruiting as expected.

We had resumed control over recruitment in our study as we received news of a virus spreading in China. Shortly thereafter, Covid was a fact, and visiting hospitals, which we knew would expedite recruitment, became impossible. Additional challenges needed to be addressed, such as ensuring GCP (Good Clinical Practice). Practical issues such as fathers not being allowed to visit hospitals hampered recruitment as the written consent by both parents is required for inclusion in our clinical trial. To effectively resolve this IBT integrated "e-consenting", or electronic consent. This was no trivial matter, as the hospital staff needed to conduct several process amendments during a period when they were stretched due to the increased burden at hospitals as a consequence of Covid. In particular, staff responsible for managing respirators took a heavy load which are the very same staff required to conduct our study. In addition, all non-critical staff, like IT-technicians not involved in direct care were sent home, increasing the difficulties in amending procedures. These are examples of the several challenges we encountered and solutions deployed by IBT, and I hereby wish to express my sincere gratitude to the staff for all they have accomplished since the spring of 2020, which has allowed us to continue our study during the pandemic.

The pace of recruitment during late fall in 2021 was progressing well, until Omicron struck. As of today, February 4, 2022 a total of 788 patients have been recruited in our study. The average pace of recruitment during Omicron amounts to approximately 50 patients per month. The decisive factor is how Omicron develops going forward, which nobody knows. The health authority is therefore assuming several scenarios. Given that approach, I provide three possible scenarios: Low; Omicron remains at current levels and consequently we continue to recruit 50 infants per month, which would result in recruitment concluding in 2024. Medium; the effects of Covid diminishes during the spring and the pace of recruitment increases, however, a new virus strain strikes during the fall, negatively affecting recruitment. I then expect us to conclude recruitment during 2023. High; Covid diminishes rapidly with the effects on society returning to a normal, pre-Covid situation, increasing our level of recruitment to above 100 infants per month in which case we conclude recruitment during the current year.

IBT continuously ”monitors” the hospitals’ work and reporting of patient data. Assessment of our work to ensure quality in the study is ongoing, and our evaluation of noted deviations is that they are not of any decisive consequence for the outcome of results in the study. In addition, we have passed several important milestones in the clinical development program:

- Capital analysis: As Omicron struck IBT conducted a cash-review. The outcome of the analysis is that IBT’s liquidity is sufficient to conclude the study even if the pace of recruitment remains low (50 patients per month).
- Safety analysis: Another analysis of patient data has been conducted. The Data Monitor Committee (DMC) has reviewed unblinded data (thus the DMC can observe the clinical effects of our drug candidate in comparison to observations from placebo), from 600 patients. We have already presented the good news in a press release that there are no objections to continue recruitment of infants in the study. This is not surprising considering the outcome of previously conducted safety studies. Summarizing all conducted safety studies, we may conclude that IBP-9414 is a well-studied drug candidate which has not presented any safety issues to date. These studies include IBT’s phase ll study, the DMC analysis of 300 recruited patients, an extra study by the DMC conducted in September 2021, and also the most recently concluded 600 patient analysis.

  In addition, we have an automatic control system adopting an algorithm performing predetermined calculations, which may trigger a safety analysis by the DMC. The DMC conducted such an analysis which was concluded on September 22, 2021. We have conducted 11 such analyses of which two after September 22, 2021, without any requirement of additional analysis.

- Futility analysis: We also conducted planned ”futility” analyses at the 300 DMC and 600 DMC reviews. These reviews generally aim to stop clinical trials which are not deemed to have a reasonable possibility of statistically showing desired results. More specifically in relation to “The Connection Study”, this translates to our continued good possibility of generating positive results.
- Two validated primary ”endpoints”: IBT concluded its analysis of the pilot study that the company had agreed upon with the FDA to conduct after recruitment of 300 patients during the second quarter 2021. The goal of the pilot study was to validate the second primary “endpoint” “Sustained Feeding Tolerance” (SFT). During the fourth quarter the results from this study were presented during a conference (HotTopics in Neonatology®) on December 6 in Washington, D.C. The results show that a reduction of only one day from birth until SFT is achieved significantly reduces the risk of severe medical complications such as blood poisoning.

We are also pleased that IBTs own patents providing exclusivity for IBP-9414 continuously are approved by more countries. The patent was approved in Brazil and Hong Kong during the fourth quarter, and in Australia during the first quarter of 2022.

IBT has restructured and improved its efficiency in its financial reporting responsibilities, and as part thereof we are pleased that Michael Owens has resumed his role as CFO. Michael has a background as an authorized accountant and has been active since many years as CFO in several life science companies. He has had the role of Controller of IBT since 2015.

We now enter into a stage of commercialization for IBP-9414, and I hereby wish to welcome Mr. Robert Molander as global Chief Commercial Officer. Robert has many years of experience commercializing pharmaceuticals in the US. His office location is in New Jersey, USA.

In closing, I wish to thank all our staff and experts who with great devotion progress our unique product which may be of major significance for the premature infants.

Stockholm, February 4, 2022

Staffan Strömberg

CEO

Financial overview for the period

Fourth quarter (Oct-Dec) 2021

- Net sales KSEK 0 (0)
- Operating income KSEK -16 093* (-26 702)
- Earnings per share before and after dilution SEK -1.44 (-2.38)

Reporting period (Jan-Dec) 2021

- Net sales KSEK 0 (0)
- Operating income KSEK -44 578* (-71 918*)
- Earnings per share before and after dilution SEK -4.01 (-6.41)

* Operational income includes exchange rate effects on foreign currency deposits for the purpose of securing future outflows during the fourth quarter amounting to KSEK 5,296 (-11,741) and during the reporting period (Jan-Dec) to KSEK 18 846 (-15 125).

Significant events during the fourth quarter (Oct-Dec)

- On December 6, an evaluation of IBT's Connection Study presented by Professor Josef Neu, University of Florida, at the 2021 Hot Topics in Neonatology®, that a blinded evaluation of IBT's Connection Study's second primary endpoint, "Sustained Feeding Tolerance" (SFT), correlates with clinical results. The evaluation reveals that even a modest reduction in time to SFT correlates positively to several clinically meaningful outcomes including Sepsis and Bronchopulmonary Dysplasia, a chronic lung disease that affects premature newborns.
- On December 10, Michael Owens assumed the role as CFO.
- On December 27, Infant Bacterial Therapeutics AB announced that the Patent Offices of Brazil and Hong Kong approved a patent of *Lactobacillus reuteri* covering IBP-9414. IBT is currently developing its drug candidate IBP-9414 in Phase III for the prevention of necrotizing colitis and improvement of feeding tolerance in preterm infants.

Significant events previously during the year

- On February 9, IBT announced that the Japan Patent Office 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-749g) was thereafter allowed to be recruited to the study
- The ongoing phase lll study's second primary endpoint called "sustained feeding tolerance" was validated.
- On April 15, we announced that the Chinese Patent Office 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 completed futility-analysis regarding NEC.
- 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 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 another 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 after the reporting period

- On January 10, IBT announced that the Australian Patent Office 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) completed its pre-scheduled safety analysis without any concerns. A futility analysis was concurrently completed. Based on DMC recommendations and futility outcome, IBT is continuing the recruitment to the study as planned.

Selected financial data

ooo's	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Net sales	-	-	61	-
Other income	-	79	33	312
Operating profit/loss	-16 093	-26 702	-44 578	-71 918
Result after tax	-16 218	-26 726	-44 991	-72 007
Total assets	408 478	450 318	408 478	450 318
Cash flow for the period	-8 904	-27 864	-55 532	-56 625
Cash flow per share for the period (SEK)	-0.79	-2.48	-4.95	-5.04
Cash	386 752	423 438	386 752	423 438
Earnings per share before and after dilution (SEK)	-1.44	-2.38	-1.44	-6.41
Equity per share (SEK)	35.21	39.21	35.21	39.21
Equity ratio (%)	97%	98%	97%	98%

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 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. 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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