

## Press Release May 11, 2020

# Infant Bacterial Therapeutics AB (publ) Interim Management Statement, January 1-March 31, 2020

#### Message from the CEO

IBT is currently developing its lead drug candidate IBP-9414 to prevent necrotizing enterocolitis (NEC), and to improve so called "feeding intolerance" affecting premature infants. Including an additional indication means having multiple independent endpoints for IBP-9414 and may increase the chances of success in the ongoing Phase III study, "The Connection Study" and the product's future market potential. IBP-9414 contains Lactobacillus reuteri as an active substance, which is a human bacterial strain found naturally in breast milk.

This message from the CEO is written in early May 2020 during an ongoing COVID-19 pandemic.

It has become more difficult to maintain full activity with our suppliers and a greater number of hospitals are affected to a greater extent as the pandemic continues.

Our study is not dependent on "normal" hospital or doctor visits, since the infants we recruit are already in the intensive care units irrespective of our study. This is essential for the completion of our study as many hospitals have now introduced a ban on non-essential visitors. This is very different from the vast majority of clinical trials conducted globally, which usually require that patients come to clinics to receive the medication as well as for measurements to be performed. As announced in the Annual Report, we have not achieved the expected recruitment rate in the study and it is clear that the pandemic and the "lock-down" that took place in the USA, France and Spain, for example, make it difficult to increase the pace of the study. At the time of writing, we have contracted 62 hospitals of which 45 are activated and can include patients however contracting additional hospitals is currently difficult due to the COVID-19 pandemic.

The pandemic has changed our way of working, we cannot travel and have face to face meetings, which means that these activities occur at a distance. For example, hospitals are now activated through virtual meetings.

Our goal to complete the ongoing Phase III study in 2021 remains. We are still recruiting infants in the study, however due to the Corona crisis, there is a risk that we cannot achieve this goal. Thus, there is a not insignificant risk that the study results may be delayed.

IBT's qualified team continues to work in a dedicated and focused manner with the aim of delivering study results which, in turn, hopefully means that a product that really plays a vital role for the premature infants can reach the market as soon as possible.

Stockholm, May 11, 2020

Staffan Strömberg, Chief Executive Officer



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#### Selected financial data

000's	2020	2019	2019
	Jan-Mar	Jan-Mar	Jan-Dec
Net sales	-	-	-
Other income	75	-	-
Operating profit/loss	1 206	-929	-47 200
Result after tax, SEK	1 178	-686	-46 320
Total assets	523 168	561 035	518 273
Cash flow for the period (SEK)	-8 050	-5 647	-51 301
Cash flow per share for the period (SEK)	-0.72	-0.50	-4.57
Cash	500 995	540 514	495 188
Earnings per share before and after dilution (SEK)	0.10	-0.06	-4.13
Equity per share (SEK)	45.57	49.53	45.46
Equity ratio (%)	98%	99%	98%

## Significant events during the first quarter (Jan-Mar) 2020

- IBT's clinical study application was approved in Israel at the end of January 2020
- The COVID-19 pandemic affects our development work, for example, activation of hospitals, which has not occured at the desired rate. As of the date of this interim report, approximately half of the planned hospitals have been activated. IBT's cash position is sufficient to carry out the ongoing Phase III study, even if recruitment in the study does not take place at the desired rate.

## Significant events after the reporting period

IBT's Board of Directors decided to postpone the Annual General Meeting until June 16, 2020, instead
of the originally planned date of May 11, 2020

#### About Infant Bacterial Therapeutics AB

Infant Bacterial Therapeutics ÅB (publ) is a pharmaceutical company with a product in clinical stage 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).

#### For additional information please contact

Staffan Strömberg, CEO
Daniel Mackey, CFO
Infant Bacterial Therapeutics AB
Bryggargatan 10
111 21 Stockholm
Phone: +46 70 670 1226
info@ibtherapeutics.com

www.ibtherapeutics.com



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#### **Publication**

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