

# Infant Bacterial Therapeutics AB

Annual Report 2022



# We aim to satisfy unmet medical needs in the premature infant

## SIGNIFICANT EVENTS 2022

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The company negotiated during 2022 the acquisition of a drug platform that can prevent antibiotic-resistant hospital infections.



**Infant Bacterial Therapeutics AB (publ)**  
**Annual Report** January 1 – December 31, 2022

**Table of Contents**

<b>IBT IN BRIEF</b>	<b>3</b>
<b>IBT'S HISTORY</b>	<b>5</b>
<b>MESSAGE FROM THE CEO</b>	<b>8</b>
<b>IBT'S PIPELINE</b>	<b>10</b>
<b>DIRECTORS REPORT</b>	<b>19</b>
<b>OPERATIONS</b>	<b>19</b>
<b>SIGNIFICANT EVENTS DURING 2022</b>	<b>19</b>
<b>SIGNIFICANT EVENTS AFTER THE FISCAL YEAR</b>	<b>20</b>
<b>SELECTED FINANCIAL DATA</b>	<b>21</b>
<b>FINANCIAL DEVELOPMENT</b>	<b>21</b>
<b>RISKS AND UNCERTAINTIES</b>	<b>23</b>
<b>ENVIRONMENTAL RESPONSIBILITIES</b>	<b>26</b>
<b>SUSTAINABILITY</b>	<b>26</b>
<b>LEGAL PROCEEDINGS</b>	<b>26</b>
<b>CORPORATE GOVERNANCE</b>	<b>26</b>
<b>PUBLICATION</b>	<b>26</b>
<b>CALENDAR</b>	<b>26</b>
<b>ANNUAL GENERAL MEETING</b>	<b>27</b>
<b>BOARD OF DIRECTORS RECOMMENDATION OF APPROPRIATION OF PROFITS</b>	<b>27</b>
<b>INCOME STATEMENT</b>	<b>28</b>
<b>BALANCE SHEET</b>	<b>29</b>
<b>STATEMENT OF CHANGES IN EQUITY</b>	<b>30</b>
<b>STATEMENT OF CASH FLOWS</b>	<b>31</b>
<b>NOTES</b>	<b>32</b>
<b>AUDITOR´R REPORT</b>	<b>52</b>
<b>CORPORATES GOVERNANCE REPORT IBT AB</b>	<b>56</b>
<b>DEDUCTION OF CERTAIN KEY FIGURES</b>	<b>67</b>
<b>SHARES</b>	<b>67</b>
<b>MANAGEMENT</b>	<b>69</b>
<b>BOARD OF DIRECTORS</b>	<b>70</b>

The annual report is published on the company's homepage, [www.ibtherapeutics.com](http://www.ibtherapeutics.com) and is distributed in printed form when ordered. Orders may be placed via [info@ibtherapeutics.com](mailto:info@ibtherapeutics.com). The annual report is also published in Swedish.

## 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 Necrotizing Enterocolitis (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, IBP-1118 to prevent ROP (retinopathy of prematurity), a growing and serious condition that often leads to blindness among prematurely born babies and IBP-1122 for the prevention of antibiotic resistant hospital acquired infections. By developing these drugs, IBT has the potential to fulfill unmet needs for diseases where there are currently no prevention or treatment therapies available.*

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## Vision

Premature infants are the most vulnerable beings on the planet and for them to survive, grow and thrive they need intensive and specialized care. Although advances in medical care and handling over the last 30 years have improved survival and well-being of these sensitive infants, both in the immediate post-natal period and in their subsequent lives, current drugs and therapies are mostly designed for adults and are not adapted to this specific and vulnerable patient population. Specific treatment and prophylactic therapy are thus underdeveloped and there is an urgent demand for drugs designed for the unique needs of the premature baby. IBT:s vision is to become an internationally recognized and leading company in the development of pharmaceuticals in the areas of premature babies, gastrointestinal diseases and probiotics.

## Mission

IBT develops, and intends to market and sell, effective, safe and effective medicines that can prevent or treat rare diseases. The company is focused around three areas of developed competence:

- Gastroenterology - Enabling a healthy gut microbiome extends to multiple treatment options, especially in combination with advanced gene modification possibilities.
- Premature babies - The need for premature treatment solutions is substantial, where IBT has established a comprehensive global network of KOLs and institutions.

- Pharma Grade Probiotics - IBT is a global leader in the development of pharma grade probiotics, meeting the rigorous quality standards required by authorities such as the FDA and EMA

## **Partners**

Clinical trials are conducted through collaborations with CRO's or leading academic research groups chosen based on their experience and specialist knowledge in conducting clinical trials. Suitable sites are selected in cooperation with IBT to conduct clinical trials and to initiate the recruiting process for patients.

## IBT'S HISTORY

### 2013

- IBT is founded as a subsidiary to BioGaia and commences the development of a preventive therapy (IBP-9414) against NEC using *Lactobacillus reuteri*
- IBT is granted Orphan Drug Designation by the FDA for *Lactobacillus reuteri* for the prevention of NEC in premature infants
- FDA provides scientific input to IBT development plans

### 2014

- Pharmaceutical development defining the manufacturing process of IBP-9414
- EMA provides scientific input to IBT development plans

### 2015

- IBT is granted Orphan Drug Designation by the European Commission for IBP-9414 including *Lactobacillus reuteri* for the prevention of NEC in premature infants
- Production of drug candidate IBP-9414 according to all applicable pharmaceutical chemistry-manufacture-control regulations for the safety and tolerability study
- Active IND obtained from FDA for start of Safety and Tolerability clinical trial in 2016
- IBT received approval from the MPA to conduct a clinical trial in Sweden

### 2016

- Separation of IBT from BioGaia
- Listing on Nasdaq First North
- IBT receives Rare Pediatric Disease Designation from FDA for IBP-9414
- IBT adds new indication for Gastroschisis IBP-1016

### 2017

- IBT's share of series B is traded on First North Premier
- IBT completes IBP-9414 safety and tolerability trial and announces that top line data demonstrate similar safety and tolerability profile in the active and placebo groups
- EMA adopts a positive opinion on the Pediatric Investigational Plan proposed by IBT for the development of IBP-9414 for the prevention of NEC

### 2018

- The EGM on January 8 decided on a new share issue amounting to SEK 439.1m and as of January 31 the share issue was fully subscribed. The share issue in combination with

the directed share issue in November of 2017 generated approximately SEK 543.6m prior to transaction costs

- In June 2018, IBT contracted Premier Research International LLC, the company's CRO during the Phase II clinical trial, to also conduct the company's Phase III clinical trial
- IBT series B shares are from September 10 traded on Nasdaq Stockholm, Mid Cap (IBT B)
- At IBT's FDA meeting following the conclusion of the phase II study, the FDA recommended that sustained feeding tolerance (SFT) should be measured as a second primary endpoint in the upcoming phase III study.

## 2019

- IBT signed its first distribution agreement on March 5, 2019, for its product IBP-9414, with MegaPharm Ltd. for the Israeli market and the Palestinian Authority's territories
- On May 19, IBT communicated that an agreement with the FDA had been reached for how to measure sustained feeding tolerance (SFT) in the phase III study. This definition was added into the study design.
- During 2019 IBT's application for clinical trial was also approved in the UK, France, Hungary and Spain
- IBT announced on July 4, 2019 that the first patient had been recruited in the company's pivotal clinical Phase III study, The Connection Study

## 2020

- The COVID-19 pandemic affects the company's development work, for example, activation of hospitals, which has not occurred at the desired rate. As of the date of the 2020 annual report, more than 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 currently does not take place at the desired rate
- IBT's clinical study application was approved in Israel in January, in Poland in October and in Bulgaria in November

## 2021

- IBT validated sustained feeding tolerance (SFT), according to previous agreement with the FDA. This implies that the phase III study has two validated primary endpoints.
- Recruitment of patients in IBT's phase III-study is strongly affected by the pandemic. A likely scenario, assuming that the current recruitment level can be maintained, is that the study can be concluded at the end of 2023. Should the pandemic situation once again get worse, recruitment may require additional time. However, the pandemic does not affect the quality in our data or the possibility to conclude the study. Costs are primarily related to the number of patients in the trial, which means that IBT's liquidity is continuously deemed sufficient to conclude the study.

## 2022

- 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.
- On September 23, the FDA approved IBT's request for a new orphan drug designation for ROP (retinopathy of prematurity).
- IBT published in the British Journal of Gastroenterology in October an article based on IBT's "Connection Study" which demonstrates that sustained feeding tolerance (SFT) is linked to serious disease progression including sepsis and bronchopulmonary dysplasia, validating the study design. It also highlights the potential to reduce healthcare costs with fewer treatment days in the hospital.
- IBT negotiated during 2022 the exclusive access to a probiotic drug platform that can prevent antibiotic-resistant hospital acquired infections.



## MESSAGE FROM THE CEO

IBT is working to develop the world's first probiotic medicine for premature babies. Drug development began in 2013 within the framework of a project that we today call IBP-9414. We have successfully anchored the development program with the regulatory authorities. IBP-9414 was the first drug project to obtain Orphan Drug status in the United States for a preventive treatment against NEC. In addition, IBT is the only company that has succeeded in obtaining the authorities' permission to administer live bacteria to premature babies. Today, we have not only succeeded in obtaining clinical trial authorization in the USA, but also eight more European countries and Israel.

Our clinical development program consists of two studies, a phase II study that we successfully completed in 2017 which highlights the safety of administering our product to premature infants. The second study in the program is a phase III study which is now underway at nearly 1,000 hospitals across 10 countries. The recruitment rate in the phase III study has increased during 2022 with an average intake of around 50 children per month. When the 1,400th child has been recruited, per our study protocol, the study will open up to also include children with a birth weight from 1,001 grams to 1500 grams to participate. It is therefore reasonable that the last patient of the planned 2,158 prematurely born children is recruited into the study during the latter part of 2023.

During 2022 we succeeded in validating our second primary endpoint in the study, Sustained Feeding Tolerance (SFT), in accordance with the manner discussed with the FDA. The validation demonstrates two things, first that SFT correlates to several serious disease progressions among those born prematurely and secondly a reduction in healthcare costs as children reach SFT earlier in life. The results are published in "The British Journal of Gastroenterology". The validation confirms that we have chosen an appropriate design for our clinical development program in which we have two independent primary endpoints, SFT and the prevention of NEC.

Our work continues to be noticed. "The American Association of Pediatrics" has expressed that premature children should not receive products that are not approved by the FDA and mentions our development program as the only development program that intends to seek a marketing authorization from the FDA. IBT's intention is to give European and other children the same level of access to medicine as American children.

We have also prepared for the launch of IBP-9414, and in the latter part of 2022 work began to secure an increased production capacity to be able to carry out a launch. Work on commercial preparations is progressing in parallel and planned to accelerate in 2023.

While we maintain focus on IBP-9414, it is our intention to broaden our company's development portfolio. As you know, we are working on a related project in gastroschisis, IBP-1116, for the treatment of gastroschisis, a serious and rare disease that affects infants. During the fourth quarter, IBT received Orphan Drug Designation from the FDA for our ROP

(retinopathy of prematurity IBP-1118) project. We are developing IBP-1118 together with the University of Florida. ROP can lead to blindness among premature babies. In addition, IBT has signed a license agreement for a treatment against antibiotic-resistant bacteria including hospital-acquired infections caused by vancomycin-resistant enterococci (VRE IBP-1122). VRE infections have become a serious public health challenge linked to antibiotic resistance, which in the United States annually results in 54,000 cases of VRE infections, leading to an estimated 5,000 deaths among hospitalized patients and healthcare costs of \$539 million.

In conclusion, I would like to take the opportunity to thank all colleagues who, with great commitment, drive the work forward with a product that may play a major role for premature babies in the near future.

Stockholm March 22, 2023

Staffan Strömberg

CEO

## IBT'S PIPELINE

TARGET	PRECLINICAL	PHASE I	PHASE II	PHASE III	REGISTRATION	MARKET
NEC & SFT	IBP-9414					
Gastroschisis*	IBP-1016					
Retinopathy of Prematurity	IBP-1118					
Vancomycin-Resistant Enterococcus	IBP-1122					

\* Line extension of IBP-9414 *Lactobacillus reuteri* (L. reuteri)

### IBP-9414

IBP-9414 contains the active substance *Lactobacillus reuteri*, which is a co-evolved human bacterial strain naturally present in breast milk. *Lactobacillus reuteri* is a live bacteria known to be anti-inflammatory, anti-pathogenic and beneficial to gut motility. IBP-9414 is specifically formulated with the consideration of the extremely sensitive target population of premature infants.

IBT was granted Orphan Drug Designation by the FDA for *Lactobacillus reuteri* for the prevention of NEC in premature infants in 2013 and by the European Commission in 2015. IBT also received Rare Pediatric Disease Designation from the FDA for IBP-9414 in 2016.

In June 2016, IBT commenced a Safety and Tolerability study. At the end of 2017 the completed study results demonstrated a similar safety and tolerability profile both in the active group and placebo group.

IBT has, resulting from discussions with the FDA on November 20, 2018, chosen to modify its Phase III study in premature infants for the prevention of necrotizing enterocolitis (NEC). Following the guidance from the FDA, IBT amended the protocol to allow additional areas of treatment such as reduced time to good digestion, called "Sustained Feeding Tolerance" (SFT).

The pivotal Phase III study, The Connection study, commenced in 2019 and the first patient was recruited on July 4, 2019. A blinded evaluation presented in December 2021 showed that a reduction of time to SFT correlates with fewer complications such as blood poisoning and bronchopulmonary dysplasia, a chronic lung disease affecting premature infants.

This means that "The Connection Study" has the opportunity to evaluate two primary endpoints instead of one.

## NEC

NEC is a leading cause of death among premature infants in neonatal intensive care units (NICU). NEC annually kills approximately 3,700 and 1,500 infants in Europe and in the US, respectively. NEC has an unpredictable, spontaneous, and acute onset and major surgery is today the only available treatment. NEC is a serious inflammatory disease of the newborn bowel in which portions of the bowel undergo tissue death (necrosis).

NEC primarily affects premature infants and the risk to contrive NEC increases the lower the birth weight and lower gestational age. Gestational age is defined as the duration from the first day of the last menstruation cycle until birth.

Occurrence of NEC by estimated gestational age is as set forth in Figure 1.

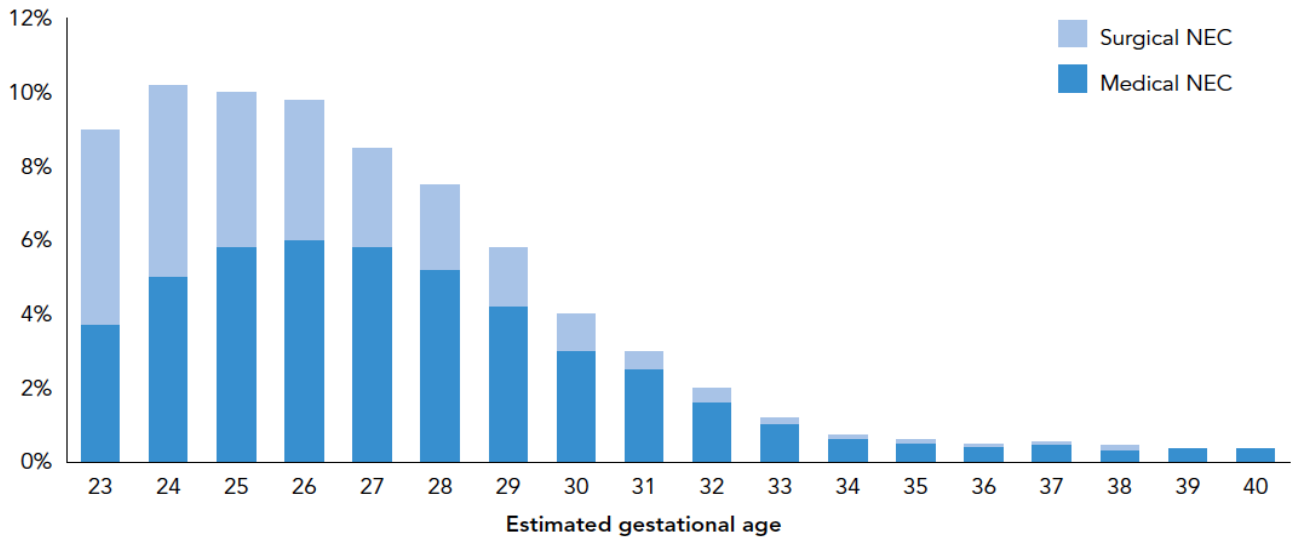


Figure 1. Occurrence of NEC by gestational age (Clark et al, 2012)

The disease has a higher rate of mortality in the younger and less mature infants. Mortality in infants who had a diagnosis of NEC by estimated gestational age is as set forth in Figure 2.

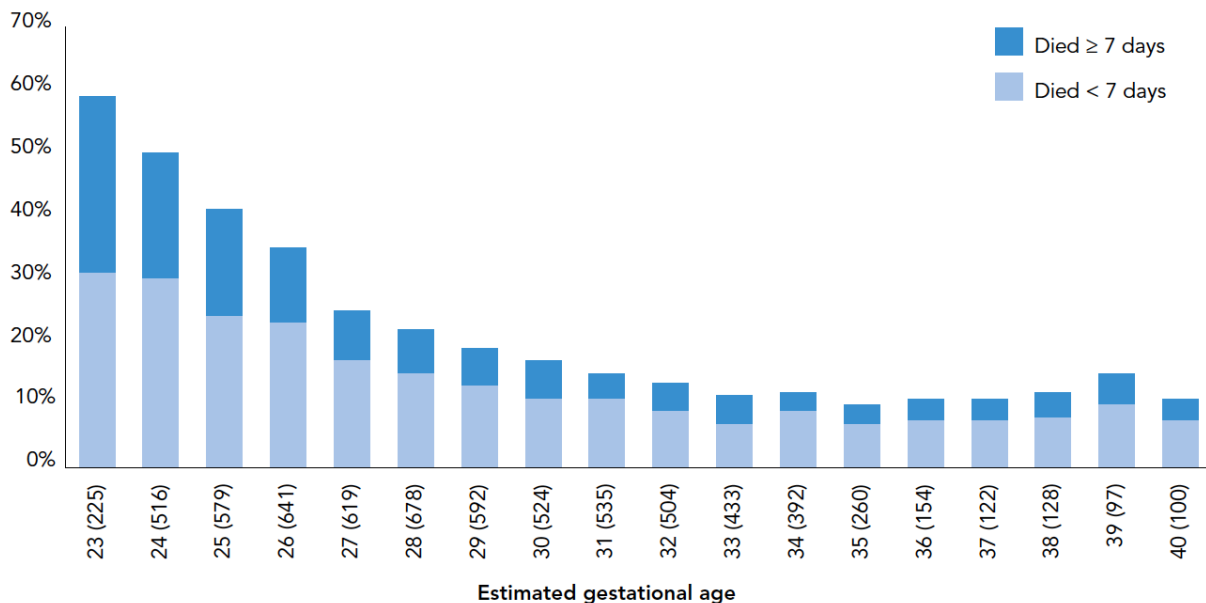


Figure 2. Mortality in infants who had a diagnosis of NEC by estimated gestational age (Clark et al, 2012). The number listed outside parentheses in the table above is estimated gestational age in weeks. The number listed within parentheses represents the number of patients with NEC within each gestational age group.

The long-term clinical consequences for infants who survive NEC are variable and include short bowel syndrome, parenteral nutrition-associated cholestasis, abnormal growth, and adverse neurodevelopmental outcomes, including cerebral palsy, cognitive impairment, visual impairment, and hearing impairment.

### Sustained Feeding Tolerance

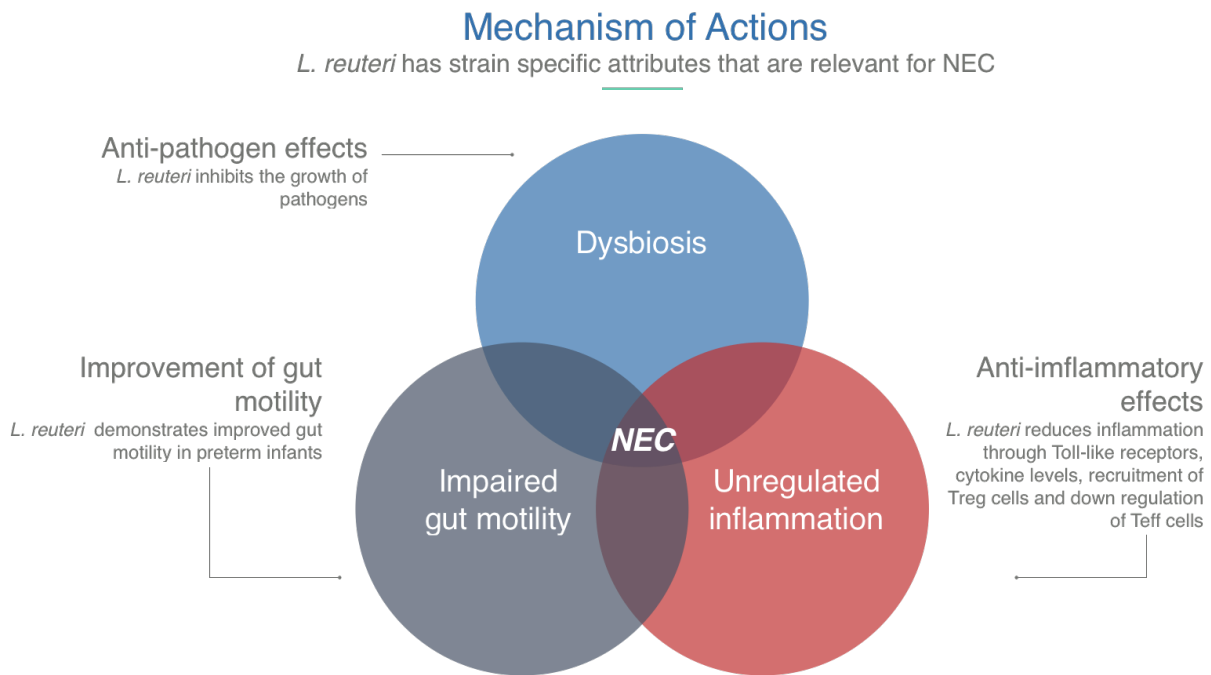
The first weeks of nutrition have important implications for the development of preterm infants. The goal of achieving early and adequate enteral nutrition (tube feeding) in these infants is to facilitate recovery or catch up growth, to achieve normal body composition, whilst minimizing undesirable effects of nutritional imbalances (e.g. hyperglycemia, insulin resistance, etc.). Evidence-based guidelines for nutrition of VLBW-infants (infants with a birthweight of under 1,500 grams) recommend supplementing nutrition (intravenous) within the first hours. When nutrition cannot be given enterally, the children are given nutrition parenterally. However, prolonged parenteral nutrition is associated with complications (intrahepatic cholestasis, increased risk of bronchopulmonary dysplasia, worsening of pulmonary vascular resistance, IV line-mediated infections and sepsis).

The enteral route of nutrition is the most physiological and natural way of administering nutrients to the neonate. The introduction of enteral feeding is therefore recommended as soon as possible, and ideally on day 1. This eliminates the need for parenteral nutrition and the associated risks of complications. Establishing sustained enteral feeding, associated with the discontinuation of parenteral nutrition is thus an important goal, especially in VLBW and ELBW-infants (extremely low birth weight <1000g). Reducing the number of days to reach complete enteral nutrition is considered to be clinically relevant and important in the treatment of the preterm infant. A blinded evaluation of IBT’s Connection Study data published in the British

Journal of Gastroenterology in October 2022 shows that even a one day reduction in time to SFT correlates to several clinically meaningful outcomes including a 7.65% reduction in confirmed Necrotizing Colitis (NEC) events, 6.71% reduction in late onset sepsis, 2.75% reduction in bronchopulmonary dysplasia (BPD) and a 5.85% reduction in days with antibiotic use.

## L. reuteri

*Lactobacillus reuteri* is a co-evolved human bacterial strain naturally present in breast milk. *L. reuteri* is a live bacteria known to be anti-inflammatory, anti-pathogenic and beneficial to gut motility.



## Clinical Experience

Since 2012, thirteen published clinical trials that have enrolled more than 4,000 infants have indicated proof-of-concept of the clinical potential of *Lactobacillus reuteri* in the prevention of NEC.

Since 2012, nine published clinical studies that have enrolled more than 3,100 infants have indicated proof-of-concept of the clinical potential of *Lactobacillus reuteri* for the reduction in episodes of feeding intolerance or reduction in time to full enteral feeding.

The table below shows a summary of studies using *Lactobacillus reuteri* showing clear clinical signal for the reduction in NEC incidence and clear clinical signal for reduction in episodes of feeding intolerance or reduction in time to full enteral feeding.

NICU Study	Number of Patients	Reduction of NEC incidence	Reduction in episodes of feeding intolerance or reduction in time to full enteral feeding
Rojas et al. 2012	750	37 %	43 %
Oncel et al. 2014	400	20 %	33 %
Oncel et al. 2015	300	22 %	36 %
Shadkam et al. 2015	60	82 %	24 %
Hernandez-Enriquez et al. 2016	44	83 %	17 %
Indrio et al. 2017	60		44 %
Spreckels et al. 2018	104	55 %	
Wejryd et al. 2019	134	17 %	0 %
Hunter et al. 2012/Dimaguila et al. 2013	354	89 %	
Jerkovic-Raguz et al. 2016	100	50 %	
Sanchez-Alvarado 2017	225	64 %	
Kaban et al. 2019	94	100 %	67 %
Rolnitsky et al. 2019	1,357	55 %	52 %
Cui 2019	93	75 %	18 %

## Development Plan

The development plan for IBP-9414 consists of two clinical trials: the completed safety and tolerability study followed by the ongoing pivotal Phase III study, The Connection Study. The safety and tolerability study, was been completed on time in Q4 2017. The Connection Study was initiated in the second half of 2019 and is ongoing.

The first study was a randomized, double blind, parallel-group, dose escalation placebo-controlled multicenter study to investigate the safety and tolerability of IBP-9414 in premature infants (ClinicalTrials.gov identifier: NTC02472769). The study included 120 premature infants, defined as a gestational age  $\leq$  32 weeks and birth-weight ranging from 500 to 2,000 grams, recruited and randomized to receive either IBP-9414 or placebo. The first dose of study drug was administered within 48 hours of birth and continued daily for a period of 14 days. Follow-up assessments were occasionally made up to six months after the last dose of the study drug. The primary outcome in this trial was safety and tolerability. This Safety and Tolerability study has been completed on time in Q4 2017. The safety and tolerability study concluded that IBP-9414 was safe and well-tolerated in premature infants with birth weights between 500–2,000 grams, with high compliance to treatment with the study drug and that there was no evidence of cross-contamination with IBP-9414 in placebo treated infants.

The ongoing pivotal Phase III study is designed to demonstrate and document efficacy of IBP-9414 over placebo in two primary “endpoints”, prevention of NEC and improvement of so called “Sustained Feeding Tolerance” in premature infants with a birth weight  $\leq$  1,500 grams. This study will also include safety evaluation.

Given the urgency to provide an effective preventative therapy to this unmet medical need, IBT plans to utilize the available FDA and EMA expedited programs to reach the market as soon as possible.

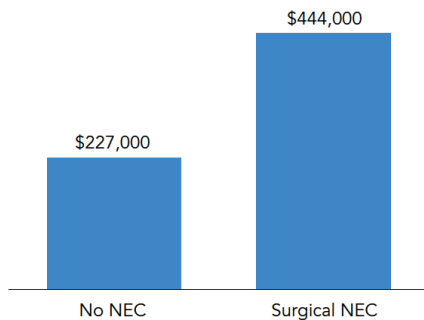
## Medical Need and market

There has been little or no progress in recent years in improving outcomes for infants that are affected by NEC once the disease is underway. Nor is there definitive treatment that modifies the underlying risk factors for the disease. Approximately 20 to 40 percent of patients with NEC will require surgery. Thus, NEC prevention strategies are vital and urgently needed but to date none have been successful or generally adopted as the standard of care. Subsequently, a preventive treatment against NEC remains an unmet medical need.

NEC patients require medical care and in many cases also surgical interventions that increase hospital expenditures and prolong length of stay. The economic burden of NEC has been evaluated to be almost 20 percent of the total cost of the initial care of all newborns in the US, and represents approximately USD 5 billion spent annually on NEC. Moreover, those infants who survive NEC may face serious lifelong sequelae, which eventually decrease their quality of life and generate further costs to the patient and society. In the light of this, a preventive therapy for NEC would therefore be expected to both directly and indirectly reduce these healthcare expenses. IBT intends to demonstrate these benefits to support reimbursement for IBP-9414 in the prevention of NEC from caregivers, insurance companies and pharmaceutical authorities, in order to gain compensation and reimbursement for IBP-9414 for prevention of NEC and SFT.

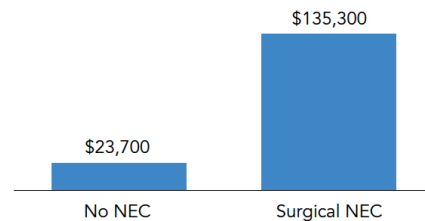
### NICU-cost in the US

Cost at discharge



### Costs continues after NICU discharge

Accumulated cost between 6–36 months



In 2021 an independent consultant company, ClearView Healthcare Partners LLC (“ClearView”), was commissioned by IBT to evaluate the market need for the preventative drug IBP-9414 for NEC (the “ClearView Report”). ClearView completed 30 interviews with neonatologists and hospital Pharmacy and Therapeutics (“P&T”) committee members in the US.

The Clearview report established that neonatologists perceive NEC to represent a key priority despite its low incidence. In addition, the need to improve digestion (SFT) in premature infants is of decisive importance. The neonatologists nearly unanimously stated a need for improved prevention of NEC and SFT to relieve both the clinical and economic burdens.

Clearview also reported an increasing interest by neonatologists to prescribe food supplements to prevent NEC and SFT but that the majority of neonatologists do not recommend food supplements to any great extent due to their opinion that FDA-regulation is key to guarantee the required quality control. The ClearView Report estimated that the number of premature

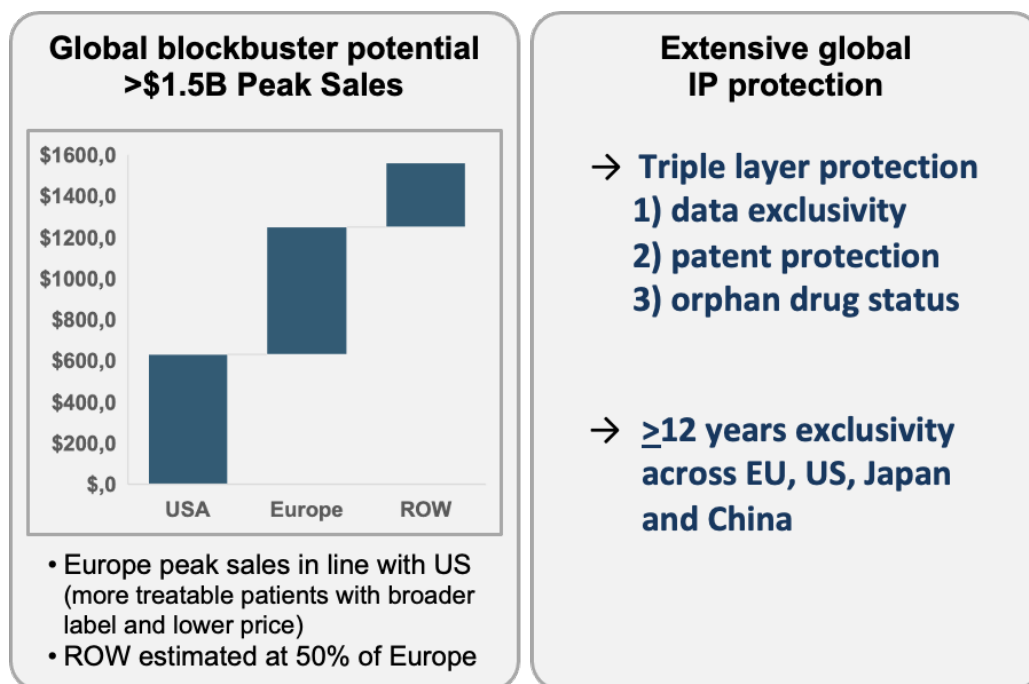


infants eligible to receive prophylaxis for NEC and SFT is over 56,000 infants per annum in the US.

A target product profile (“TPP”) was presented to interviewees in the interviews conducted by Clearview. The TPP defined among other things the safety profile, method of administration, and expected efficacy in the prevention of NEC of 33% and a statistically significant reduction in time to SFT.

The ClearView Report has shown that when presented with the TPP of IBP-9414, neonatologists reacted positively and expressed a strong willingness to use IBP-9414 in their clinical practice (90 percent of Physician Preference Share), and according to a hospital template a majority of P&T (Pharmacy and therapeutics) members expressed willingness to adopt the product. An adapted price range was tested in the ClearView report, depending on gestation age. At a price of USD 5,000 per week until the infant reaches 34 weeks as a baseline, ClearView estimates sales amounting to USD 630m per annum in the USA. The analysis considered the number of addressable patients, physician preference scores, formulary inclusion and protocol access.

With the results from the analysis for the USA with IBP-9414:s two primary endpoints, ClearView made an assessment of what the corresponding results would be for the European market and the rest of the world (ROW), illustrated as follows in the table below. This shows that the potential for Europe corresponds to what we see for the USA, and ROW is estimated at approximately half of the USA, resulting in a “megabrand” potential of USD 1.5bn.



Clearview market research assessment 2021.

## Intellectual property

IBP-9414 is protected by already approved patents on *Lactobacillus reuteri*, held by BioGaia. IBT has been granted from BioGaia an exclusive royalty-free license to use *Lactobacillus reuteri* in IBT's areas of interest. The license is valid for the duration of the patent term.

IBT has and intends to apply for patent protection for innovations for the purpose of securing a sufficient and efficient protection of IBT's current and future commercial position and interests. Patent applications regularly cover the US, the EU, Japan and China, but also other markets where it is commercially justified.

The patent protection granted in the US is valid until 2026 and in Europe, China and Japan until 2027. Thereafter patent term extensions are possible in certain areas of the world which could provide additional patent protection of the innovation via patent term extensions.

IBT has filed for further patent protection for IBP-9414 which aims to protect patents until 2036. On February 9 IBT announced that the Japan Patent Office has 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, and the same was also announced January 10th for Australia. The Japanese patent is valid until 2036. The same was announced in 2021 from the patent authorities of China, Mexico, Brazil and Hong Kong.

## IBP-1016

Gastroschisis is a rare, life-threatening and debilitating birth abnormality in infants where the infant is born with externalized intestines.

After the initial surgical repair, gastroschisis represents an area of significant unmet medical need with no definitive treatment available. Post-operative management of gastroschisis is largely aimed at overcoming the significant morbidity related to the reduction in gut motility and consequent feeding intolerance necessitating the prolonged requirement for parenteral nutrition. Infants suffering from gastroschisis have a greatly increased risk of sepsis and liver cholestasis. It is common for neonates born with gastroschisis to have typically an extended hospital stay of 1-5 months thereby causing significant burden to the healthcare system.

The active bacteria used in IBP-1016 is known to enhance gut motility and function in infants with feeding intolerance.

## IBP-1118

Retinopathy of prematurity (ROP) affects 50-70% of preterm infants weighing less than 1,500 grams at birth, which in several cases leads to blindness. Current treatments do not sufficiently address the medical need as serious cases have increased significantly from 1,7 to 14,8 per 1,000 premature infants between 1990 and 2021.

IBT is at an early stage of investigating the possibilities of developing a drug to prevent ROP, a growing and serious condition that often leads to blindness among prematurely born babies. The FDA granted orphan drug designation for IBT's product on Sep 20th, 2022.

The drug candidate, IBP-1118, is a dipeptide developed under the direction of Dr. Josef Neu, professor at the University of Florida Health, Department of Pediatrics, Division of Neonatology, and Dr. Maria Grant, professor at the University of Florida Health, Department of Endocrinology, Diabetes, and Metabolism.

## **IBP-1122**

Antibiotic resistance is rising to dangerous levels across the world. Hospital acquired infections caused by vancomycin-resistant enterococci (VRE) have become a serious public health challenge linked with the complexities of antibiotic resistance, resulting in 54,000 cases and 5,000 deaths among hospitalized patients in the United States every year. VRE infections are estimated to cause direct annual U.S. healthcare costs of \$539M.

IBP-1122 is a bacterial strain engineered to eliminate VRE developed by Drs. Nita Salzman, Chris Kristich, and Sushma Kommineni in the departments of Pediatrics and Microbiology & Immunology at the Medical College of Wisconsin (MCW).

IBT has secured an exclusive global license from MCW for the platform consisting of genetically modified bacteria. Leveraging MCW's commitment to innovative patient care and IBT's expertise in developing pharma grade probiotics is a crucial step toward alleviating the pressure placed on hospitals by vancomycin-resistant enterococci.

## DIRECTORS REPORT

The Board of Directors and CEO of Infant Bacterial Therapeutics AB (publ) ("IBT"), reg. no. 556873-8586 hereby presents the Annual Report for the financial year January 1, 2020 to December 31, 2021.

This financial report is prepared in accordance with RFR 2, Reporting for legal entities and "Årsredovisningslagen".

## OPERATIONS

IBT is a clinical stage pharmaceutical company with a vision to develop drugs influencing the infant microbiome, and thereby prevent or treat rare diseases affecting premature infants. IBT is currently developing its drug candidate IBP-9414 to prevent necrotizing enterocolitis (NEC), and improve so called "feeding tolerance" affecting premature infants. IBP-9414 contains the active ingredient *Lactobacillus reuteri*, which is a human strain of bacteria found in breast milk.

The portfolio also contains a IBP-1016, for the treatment of gastroschisis, a rare and severe disease in infants, IBP-1118 for the prevention of ROP (retinopathy of prematurity), a growing and serious condition that can lead to blindness among prematurely born children, and IBP-1122 to prevent antibiotic resistant hospital acquired infections. By developing these drugs, IBT has the potential to fulfill medical needs where there are currently no treatment therapies available.

The FDA and the European Commission have granted IBT Orphan Drug Designation, and the FDA has granted "Rare Pediatric Disease" Designation for IBP-9414 for the prevention of NEC.

## SIGNIFICANT EVENTS DURING 2022

- It was announced on January 10 that the patent office in Australia had issued an approval for the patent: "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.
- Maria Ekdahl assumed the role of CFO on September 19.
- On September 23, the FDA approved IBT's request for a new orphan drug designation for ROP (retinopathy of prematurity).
- The British Journal of Gastroenterology published in October an article based on IBT's "Connection Study" demonstrating that SFT is linked to serious disease progression including sepsis and bronchopulmonary dysplasia.

## SIGNIFICANT EVENTS AFTER THE FISCAL YEAR

- On January 12, 2023 IBT announced it secured a probiotic drug platform that can prevent antibiotic-resistant hospital acquired infections.
- The British Journal of Gastroenterology published in January new results that validate "Sustained Feeding Tolerance" (SFT) as a relevant primary endpoint in "The Connection Study".

## SELECTED FINANCIAL DATA

ooo's	2022 Jan-Dec	2021 Jan-Dec
Net sales	-	-
Other income	12	94
Operating profit/loss	-65 808	-44 578
Result after tax	-65 451	-44 991
Total assets	349 619	408 478
Cash flow for the period	-83 911	-55 532
Cash flow per share for the period (SEK)	-7.47	-4.95
Cash	335 840	386 752
Earnings per share before and after dilution (SEK)	-5.83	-4.01
Equity per share (SEK)	29.55	35.21
Equity ratio (%)	95%	97%

## FINANCIAL DEVELOPMENT

Amounts are reported in KSEK (SEK in thousands). Amounts in parenthesis refer to the same period in the previous year unless stated otherwise.

### Result

Operational result amounted to KSEK -65,808 (-44,578) and result after financial items amounted to KSEK -65,451 (-44,991).

Result after tax amounted to KSEK -65,451 (-44,991).

Result per share prior and after dilution amounted to SEK -5.83 (-4.01).

### Costs

Costs for the ongoing IBP-9414 clinical trial are reported net of exchange rate effects on foreign currency deposits. Exchange rate effects during the reporting period amounted to KSEK 33,000 (18,846), (Note 1, 2).

Operational costs amounted to KSEK 98,819 (63,518) prior to exchange rate effects on foreign currency deposits, and after exchange rate gains to KSEK 65,818 (44,672).

Costs for the ongoing IBP-9414 clinical trial amounted to KSEK 74,218 (42,196) prior to exchange rate gains.

Personnel costs amounted to KSEK 18,933 (15,789).

Other external costs amounted to KSEK 5,668 (5,533).

Operational costs in total prior to exchange rate gains increased during the reporting period compared to the previous year.

Costs for the ongoing clinical study increased regarding production of clinical trial material, trial insurance coverage, patient recruitment and dosing in the ongoing phase III study which was initiated in 2019.

Personnel costs are higher in the reporting period compared to the corresponding period last year due to a bonus in connection with the introduction of a new share-based incentive program. Bonus salaries amounted to approximately KSEK 4,600.

On a rolling twelve-month period, the company had 7 (8) full time equivalent employees. The company had 8 (8) employees on the balance sheet date.

Other external costs are at the same level as the corresponding period last year.

## **Cash flow**

Cash flow for the period amounted to KSEK -83,911 (-55,532). Cash flow per share amounted to SEK-7.47 (-4.95).

## **Financial position**

Prepaid expenses amounted to approximately KSEK 1,716 (9,140) and refers mainly to rents and insurance.

Accrued expenses amounted to approximately KSEK 8,667 (7,648) and mainly refer to research and development and personnel costs.

The Company's cash balance on December 31, 2022, amounted to KSEK 335,840 compared to KSEK 386,752 on December 31, 2021.

The Company's shareholder's equity on December 31, 2022, amounted to KSEK 331,705 compared to KSEK 395,254 on December 31, 2021. Shareholder's equity per share on December 31, 2022, amounted to SEK 29.55 compared to SEK 35.21 on December 31, 2021.

The Company's equity ratio on December 31, 2022, amounted to 95% compared to 97% on December 31, 2021.

IBT's liquidity and capital is deemed sufficient to conduct the ongoing Phase III clinical study, as well as to fund the company's activities until application for market approval.

## **Prospects for 2023**

The development plan for IBP-9414 is comprised of a clinical program consisting of two clinical trials: the completed safety and tolerability study and the ongoing pivotal Phase III study, "The Connection Study". The Safety and Tolerability Study was completed on schedule during the fourth quarter of 2017. The following pivotal study, "The Connection Study", commenced on July 4, 2019.

The primary goal in the first trial was to evaluate safety and tolerability. This study was completed on time in Q4 2017 and concluded that IBP-9414 was safe and well-tolerated in premature infants with birth weights between 500–2,000 grams, with high compliance to treatment with the study drug and that there was no evidence of cross-contamination with IBP-9414 in placebo treated infants.

The ongoing pivotal Phase III study is designed to demonstrate and document efficacy of IBP-9414 over placebo in the prevention of NEC and the reduced time to Sustained Feeding Tolerance in premature infants with a birth weight  $\leq 1,500$  grams. This study will also include safety evaluation. A blinded analysis of IBT's clinical phase III-study in 2021 showed that reduced time to SFT significantly reduces the risk of serious complications such as blood poisoning. The validation of SFT as an endpoint was based on a procedure agreed with the FDA. The validation conducted in 2021 means that the effect of IBP-9414 is documented for two goals rather than one: to prevent NEC and also to reduce the time until SFT. Thus, the study has two validated endpoints.

As a consequence of the COVID-19 pandemic the study is delayed and is as previously communicated currently expected to be concluded in beginning of 2024.

## **RISKS AND UNCERTAINTIES**

### **Risk management and control**

The Company's Board of Directors work continually and systematically with risk assessment to identify risks and take the necessary actions to cope with them. The internal control environment as described in the Company code of conduct report comprises mainly the following components: control environment, risk assessment, control activities, information and communication, as well as monitoring. For every identified significant risk, risk mitigation actions are formulated.

### **Dependent on development of one product**

The value of the Company is largely dependent on success in the Company's development of IBP-9414 and the successful completion of clinical trials and the grant of a marketing authorization by the US Food and Drug Administration ("FDA") and/or the European Medicines Agency ("EMA"). IBT's clinical development is at development stage and there is a risk that IBP-9414 will not demonstrate the required effect. If the development on IBP-9414 is unsuccessful, IBT may try to focus on other projects but there is a risk that such projects will not be successful.

### **Patents and trademarks**

BioGaia has a patent on *Lactobacillus reuteri* DSM 17938. BioGaia has granted IBT an exclusive license to use *Lactobacillus reuteri* DSM 17938 for the development of a medical treatment for premature infants. No royalties will be paid to BioGaia upon commercialization of IBT's drug candidates.

The main patent protection for IBP-9414 is the product claim for the use of *Lactobacillus reuteri* DSM 17938. This form of protection is often referred to as "full product protection", similar to that used by the pharmaceutical industry for new chemical substances in the small molecule product segment. Patents that include a product claim for the bacterial strain have been issued in most major markets. The patent protection granted in the United States is valid until June 2026 and in Europe, China and Japan until May 2027. Thereafter, the patent term



may be extended in certain areas of the world, which may give the innovation additional patent protection.

- IBT has also applied for additional patent protection for IBP-9414 aimed at providing extended protection for IBP-9414 until 2036.
- On February 12, 2021, the Japanese Patent Office issued the patent: "A method of activating lactic acid bacteria", which covers formulations of IBP-9414. The Japanese patent runs until 2036.
- On April 13, 2021, the Chinese Patent Office issued the patent: "A method of activating lactic acid bacteria", which covers formulations of IBP-9414. The Chinese patent extends to 2036 and IBP-9414 is intended to be marketed in China once market approval is obtained.
- On September 7, 2021, the Mexican Patent Office issued the patent: "A method of activating lactic acid bacteria", which covers formulations of *Lactobacillus reuteri* including IBP-9414.
- On December 23, 2021, Australia issued the patent: "A method of activating lactic acid bacteria", which covers formulations of *Lactobacillus reuteri* including IBP-9414.
- On February 1, 2022, the Brazilian Patent Office issued a patent for *Lactobacillus reuteri* covering IBP-9414. The patent expires in 2036.
- On January 14, 2022, the Hong Kong Patent Office issued a patent covering formulations of *Lactobacillus reuteri* DSM 17938. The patent runs until 2036.

In addition to its patent protection, IBP-9414 will also be protected as a biologic product and be provided exclusivity as an orphan drug. Presently, the protection for orphan drugs and biologics in the US is 7 and 12 years respectively from time of market approval. Similar frameworks exist in Europe.

In the type of business conducted by IBT, there is always the risk that the company's licenses, patents, trademarks or other intellectual property rights do not provide sufficient protection or that the company's rights cannot be maintained. Furthermore, patents may be infringed, which may lead to costly litigation. The outcome of such disputes cannot be guaranteed in advance. Negative outcomes of intellectual property disputes may result in the losing party losing protection, being prohibited from continuing to use the relevant right or being required to pay damages.

## **Regulatory risk**

IBT develops medicinal products and is dependent on assessments and decisions by applicable authorities. Such assessments are preceded by decisions, among other, regarding permission to conduct clinical studies, permission to market and sell pharmaceuticals, prerequisites for prescribing pharmaceuticals, pricing of pharmaceuticals subject to reimbursement systems,

and discounts on pharmaceuticals. It cannot be guaranteed that IBT will obtain the authoritative decisions necessary to conduct clinical studies and receive market approval.

It cannot be excluded that national authorities may take a contrary view or act to stop the product being sold in the applicable country, which could lead to delays or withdrawal of market approval.

To mitigate the regulatory risks IBT involves world-leading external expertise in relation to, for example, regulatory matters or the design of clinical studies.

## **Production**

IBT utilizes contract manufacturers for production of IBP-9414 which makes the Company dependent on external deliveries meeting agreed requirements for example for quality, quantity and time of delivery. There is no guarantee that IBT will not be impacted by delayed or failed deliveries, which could impact the progress of the clinical studies. To minimize this risk, IBT has evaluated a number of contract manufacturers that are able to produce IBP-9414.

## **Product liability and insurance**

IBT conducts development of pharmaceutical products and conducts clinical studies which causes risks related to product liability. To mitigate such risk, IBT carries insurance coverage for products under development. There is however no guarantee that the insurance coverage provides sufficient protection against claims for damages for eventual damages caused by the company's products or product candidates.

The Company's insurance policies include coverage for patients who participate in clinical trials and product liability insurance for products under development and in the market. The insurance coverage is subject to continuous review. The Company deems that the Company's insurance coverage is appropriate for the current scope of the business.

## **Dependence on key persons**

IBT is, to a high degree, dependent on a few key persons, both employees as well as directors. The Company's future earnings are affected by its ability to attract and retain qualified key persons. In cases where one or more key persons leave the Company and the Company is not successful in replacing such persons, this might have a negative effect on the Company's business, financial position and earnings.

## **Financial Risks**

A predominant share of IBT's development costs are commitments in foreign currencies. Should the SEK depreciate versus the specific currency, it could have a significant impact on the Company's financial position and results. The currency against which IBT has the greatest exposure is USD.

IBT's balance sheet item "cash and cash equivalents" in the balance sheet represents cash deposits at Danske Bank and SEB. The Company's assessment is that the counterparty risk at Danske Bank and SEB is very low. See note 18 for further information about financial risks.

The general macroeconomic situation regarding inflation and cost increases contributes to some uncertainty and it cannot be excluded that IBT will be affected by this in the future. So far, IBT has countered cost increases by purchasing USD and EUR in the past when the exchange rate was more favorable.

Further information on risks and uncertainties is available in IBT's Rights Issue Prospectus dated January 10, 2018 on the Company's homepage [www.ibtherapeutics.com](http://www.ibtherapeutics.com).

## ENVIRONMENTAL RESPONSIBILITIES

The Company's operations do not have any specific environmental risks and is not subject to notification obligations under the Swedish Environmental Code. The Board of Directors of the Company is of the opinion that the Company is in compliance with applicable rules and regulations and offers its employees a sound and safe working environment.

## SUSTAINABILITY

IBT should be perceived as an innovative and creative Company that represents quality, health and provides a function in society. It is important for IBT to work actively with sustainability issues. Respect for human rights, environment and anti-corruption shall reflect the company's operations with regard to business strategies, financing, investments and purchasing processes. The Company is not legally required to publish a sustainability report.

## LEGAL PROCEEDINGS

IBT is not and has never been involved in any legal proceedings.

## CORPORATE GOVERNANCE

The company's Corporate Governance Report for 2022 is included in this annual report and published on the Company's webpage [www.ibtherapeutics.com](http://www.ibtherapeutics.com)

## PUBLICATION

IBT strives to have good communication with the Company's shareholders. The Company's publication of information should be correct, pertinent, and timely. The Company's communication will also be characterized by openness and the Company will publish periodic interim reports and annual reports in Swedish and English. Events which are determined to have potential impact on the share price will be distributed as press release.

## CALENDAR

Interim report January – March 2023  
Interim report January – June 2023  
Interim report January – September 2023

May 8, 2023  
August 25, 2023  
November 10, 2023

## ANNUAL GENERAL MEETING

The Annual General Meeting for IBT will be held on May 8, 2023 in Stockholm.

## BOARD OF DIRECTORS RECOMMENDATION OF APPROPRIATION OF PROFITS

<b>SEK</b>	<b>2022</b>
<b>Recommendation of appropriation of profits or loss</b>	
The Board of directors propose that the following surplus:	
Income carried forward	-276 828 919
Surplus reserve	670 925 576
Result for the period	-65 450 864
<b>Total</b>	<b>328 645 793</b>
<b>Be appropriated as follows:</b>	
Income carried forward	328 645 793
<b>Total</b>	<b>328 645 793</b>

Regarding results and financial position in general please refer to the following income statements and balance sheets with accompanying notes.

## INCOME STATEMENT

SEK 000	Note	2022 Jan-Dec	2021 Jan-Dec
Net sales		-	-
Other income		12	94
Research and development costs	2,3,4	-65 820	-44 672
<b>Operating loss</b>		<b>-65 808</b>	<b>-44 578</b>
<b>Result from financial items</b>			
Interest income and similar profit/loss items		650	-
Interest expense and similar profit/loss items		-293	-413
<b>Result after financial items</b>		<b>-65 451</b>	<b>-44 991</b>
<b>Result for the period*</b>		<b>-65 451</b>	<b>-44 991</b>

### Result per share

SEK			
Result per share, before and after dilution*		-5.83	-4.01
Number of shares, weighted average*		11 226 184	11 226 184
Number of shares at end of period **		11 226 184	11 226 184

\* No dilution effects exist

\*\*On December 31, 2022, allocation of emitted shares amounted to 377,736 A-shares carrying 10 votes per share and 10,848,448 B-shares carrying 1 vote per share

## BALANCE SHEET

SEK 000	Note	2022-12-31	2021-12-31
<b>ASSETS</b>			
<b>Non-current assets</b>			
<i>Intangible non-current assets</i>			
Activated development costs	6	10 518	11 334
Shares in subsidiary	7	70	50
<b>Total non-current assets</b>		<b>10 588</b>	<b>11 384</b>
<b>Current assets</b>			
<i>Current receivables</i>			
Accounts receivable		-	-
Other receivables	8	1 474	1 202
Prepaid expenses and accrued income	9	1 716	9 140
<b>Total current assets</b>		<b>3 191</b>	<b>10 342</b>
Cash and cash equivalents	10	335 840	386 752
<b>Total current assets</b>		<b>339 031</b>	<b>397 094</b>
<b>TOTAL ASSETS</b>		<b>349 619</b>	<b>408 478</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<i>Restricted equity</i>			
Share capital		3 060	3 060
<i>Unrestricted equity</i>			
Share premium reserve		670 926	669 022
Accumulated losses		-276 829	-231 837
Net loss for the year		-65 451	-44 991
<b>Total equity</b>		<b>331 705</b>	<b>395 254</b>
<b>Liabilities</b>			
<i>Current liabilities</i>			
Accounts payable		8 746	4 797
Other current liabilities		500	779
Accrued expenses and prepaid income			
11		8 667	7 648
<b>Total current liabilities</b>		<b>17 913</b>	<b>13 224</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>349 619</b>	<b>408 478</b>

## STATEMENT OF CHANGES IN EQUITY

SEK 000	Restricted equity		Unrestricted equity		
	Share capital		Share premium reserve	Accumulated losses incl. loss for the period	Total equity
<b>Opening equity on Jan 1, 2021</b>	<b>3 060</b>		<b>668 9317</b>	<b>-231 837</b>	<b>440 154</b>
Net loss for the year				-44 991	-44 991
<b>Total comprehensive income</b>				<b>-44 991</b>	<b>-44 991</b>
<b>Shareholder transactions</b>					
Warrants			91		91
<b>Closing equity on Dec 31, 2021</b>	<b>3 060</b>		<b>669 022</b>	<b>-276 828</b>	<b>395 254</b>
<b>Opening equity on Jan 1, 2022</b>	<b>3 060</b>		<b>669 022</b>	<b>-276 828</b>	<b>395 254</b>
Net income for the period				-65 451	-65 451
<b>Total comprehensive income</b>				<b>-65 451</b>	<b>-65 451</b>
<b>Shareholder transactions</b>					
Warrants			1 904		1 904
<b>Closing equity on Dec 31, 2022</b>	<b>3 060</b>		<b>670 926</b>	<b>-342 279</b>	<b>331 705</b>

## STATEMENT OF CASH FLOWS

SEK 000	2022 Jan-Dec	2021 Jan-Dec
<b>Operating activities</b>		
Operating profit/loss	-65 808	-44 578
Interest income received	650	-
Paid interest costs	-293	-413
Adjustment for non - cash flow affecting items:		
Depreciation production process	816	816
Value variance currency accounts	-33 000	-18 846
<b>Cash flow from operating activities before changes in working capital</b>	<b>-97 635</b>	<b>-63 021</b>
<b>Cash flow from changes in working capital</b>		
Increase (-)/Decrease (+) in operating receivables	7 151	4 338
Increase (+)/Decrease (-) in operating liabilities	4 689	3 060
<b>Cash flow from operating activities</b>	<b>-85 795</b>	<b>-55 623</b>
<b>Financing activities</b>		
Sharholder contributions IBT Baby AB	-20	-
Warrants	1 904	91
<b>Cash flow from financing activities</b>	<b>1 884</b>	<b>91</b>
<b>Cash flow for the period</b>	<b>-83 911</b>	<b>-55 532</b>
Unrealized exchange rate difference in cash	33 000	18 846
Cash and cash equivalents at the beginning of the period	386 752	423 438
<b>CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR</b>	<b>335 840</b>	<b>386 752</b>



## NOTES

### Note 1 Accounting principles

This financial report is prepared in accordance with the Annual Accounts Act, "Årsredovisningslagen" and as stipulated by RFR 2 Reporting for legal entities. Adoption of RFR 2 means that IBT applies all IFRS and statements as adopted by the EU to the extent possible subject to the Annual Accounts Act, "Tryggandelagen" and considerations of the relation of reporting and taxation. Preparation of financial reports in agreement with RFR 2 requires application of some significant estimates regarding various evaluations and assessments of principles of items for accounting purposes.

IBT has no transactions to report under total comprehensive income and a statement to that effect is provided under the income statement.

The subsidiary, IBT Baby AB, was established in May 2017. During the second quarter of 2017 and third quarter of 2020 IBT Baby AB received warrants at no cost from the parent company, which during the second quarter have been sold to personnel employed by IBT at market price. Other transactions have not occurred. As the company was established with a share capital amounting to 50 KSEK and only incurred marginal establishment costs, consolidated income statement and balance sheet, in all material aspects, equal those of the parent company and therefore no consolidation has been made, supported by the Annual Accounts act, "Årsredovisningslagen 7 kap. 3a §".

IFRS 16 'Leases'. The standard requires assets and liabilities related to all leases, with some exceptions, to be recognized in the balance sheet. Early adoption is permitted. IBT only prepares financial statements for legal entities and has thus chosen not to apply the rules in IFRS 16. IBT instead applies paragraphs 2-12 of RFR 2 and thus lease payments continue to be recognized as an expense on a straight-line basis over the lease term.

The changes that have entered into force and that apply from January 1, 2022 have not had any significant impact on IBT's financial statements.

For financial years beginning on or after January 1, 2023, the amendment to IAS 1 on disclosure of accounting policies is applied. By applying the amendments, an entity discloses its essential accounting policies, rather than its significant accounting policies. Further amendments to IAS 1 are to explain how an entity can identify a significant accounting policy. To support the amendments, the IASB has also developed guidance and examples to explain and identify a significant accounting policy. Management believes that this amendment may impact disclosures about accounting policies applied but has not yet fully evaluated these impacts. Other amendments within IFRS/RFR 2 that are not yet effective are not expected to have a material impact on IBT's financial statements.

#### *Functional currency and reporting currency*

IBT's functional currency is SEK. The financial statements are presented in SEK rounded to the nearest thousand unless otherwise stated. Rounding to thousands may result in incorrect amounts when summarized.

### *Recalculation from foreign currency*

Transactions in foreign currencies are converted into the functional currency at the exchange rates on the transaction date. Monetary assets and liabilities in foreign currencies are converted into the functional currency at the exchange rates on the balance sheet date. Exchange rate differences resulting from the conversion are reported in the financial items section in the income statement. Non-monetary assets and liabilities are normally reported at historical cost and converted to exchange rate at date of transaction.

### *Financial instruments, IFRS 9*

Financial instruments are reported at cost. Financial assets are deleted from the balance sheet when the right to receive cash flows from the instrument has ceased or been transferred and the Company has transferred in principle all risks and benefits associated with possession. Financial liabilities are deleted from the balance sheet when the liability in the agreement has been fulfilled or otherwise revoked.

### *Classification and valuation*

Financial assets are classified based on the business model in which the asset is placed and the cash flow character of the asset. If the financial asset is held within the framework of a business model with the objective to collect contractual cash flows (hold to collect) and the contractual terms relating to the financial asset at predetermined periods generates cash flows solely comprised of capital and interest on the capital amount outstanding the asset will be reported at accumulated cost.

If on the other hand the business model goal is met by both collecting contractual cash flows and selling financial assets (hold to collect and sell), and the contractual terms of the financial asset at determined periods generates cash flows solely comprised of payments of capital and interest on the capital amount outstanding the asset will be reported at fair value under other comprehensive income.

All other business models (other) where the purpose is speculation, carry for sale or where the cash flow character eliminates other business models are consequently reported at fair value in the income statement.

Financial assets are comprised of cash. Cash is comprised of immediately available cash held by Swedish banks. The company applies the business model hold to collect regarding cash.

Financial liabilities are valued at fair value in the income statement provided they have a determined price upon which IFRS 3 applies, carry for trade or if initially identified as liabilities at fair value in the income statement. Other financial liabilities are valued at accumulated cost.

### *Write downs*

The company reports loss reserves for expected credit losses on financial assets valued at accumulated cost. On each balance sheet date the company reports changes in expected credit losses since initial reporting in the result.

The company values the credit losses for all financial assets amounting to 12 months expected losses. For financial assets with significant increase in risk since the initial reporting a reserve is reported based on credit losses over the entire duration of the asset (the general model).

The company reports expected credit losses for the remaining duration of all financial instruments with significant increase in risk since the initial reporting, either estimated individually or collectively, considering all reasonable and verifiable information, including forward looking. The company evaluates expected credit losses from financial instruments in such manner that reflects objectively and by likelihood amounts ascertained by assessing an interval of possible outcomes, discounted value of money and reasonable and verifiable information regarding present conditions and forecasts regarding future economic conditions.

Cash is subject to the general model for write downs. The exemption for limited credit risk on the balance sheet date applies to cash.

The company defines default as if it is deemed unlikely that the counterparty will meet its obligations due to indications of financial difficulty and passed due payments. Default is regardless deemed to be the case when payment is 90 days past due. The company will delete a receivable when no further possible cash flows are deemed to exist.

### *Accounts payable*

Accounts payable are commitments to pay for goods or services acquired in operations from suppliers. Amounts are unhedged and normally payable within 30 days. Accounts payable are classified as current liabilities when due within one year or sooner (or a normal cycle of operation if longer). If not, they are reported as long-term debt. Liabilities are initially disclosed at Fair value and thereafter at accrued cost applying the effective interest method.

### *Other liabilities*

Expected duration for other liabilities is short, and therefore the liability is disclosed at nominal amount without using the discounting method for accrued cost.

### *Accounts receivable and other receivables*

Accounts receivable are reported at nominal value. Other receivables are reported at nominal value. Fair value of accounts receivable and other receivables equals reported value as the discounting effect is not material.

### *Non-current fixed assets*

IBT's development of internally generated non-current fixed assets are separated in a research phase and a development phase. All costs related to the research phase are reported as costs as they are incurred. All costs related to development are reported as assets according to IAS 38 if all the following criteria are met:

- the technical and commercial feasibility of the product or process has been established so it may be used or sold
- the Company intends and is able to complete the intangible asset and either use it or sell it
- there are prevailing conditions to use or sell the intangible asset
- It should be probable that the future economic benefits attributable to the asset will flow to the Company
- There are necessary and adequate technical, financial and other resources to complete the development and to use or sell the intangible asset.
- The expenditure attributable to the intangible asset during its development can be reliably estimated.

Costs related to the project are charged to income in the development phase should the above criteria not be met.

IBT's assessment is that development of the production process for the pharmaceutical candidate IBP-9414 meets the above criteria. Costs generated by the project have been activated as of the point in time the criteria were met. The production process has been assessed as completed for accounting purposes. The intangible asset "production process" is therefore depreciated over its estimated time of use and has caused depreciation costs in 2016. Estimated useful life is 20 years. Depreciation is reported in the R&D function in the income statement.

The currently ongoing development project, IBP-9414, is not deemed to meet the above criteria in IAS 38 to be activated as development in the balance sheet. The development costs are therefore charged to income as incurred.

### *Impairment of non-financial assets*

Non-financial assets with uncertain periods of use or non-financial assets not ready for use, are not depreciated but tested annually, or upon indication of impairment, for possible impairment. Assets which are depreciated are evaluated regarding impairment any time events or changes in circumstances indicate that the reported value may not be recovered. Write downs are made by such amounts that reported value exceeds recoverable value. Recoverable value is the higher of the assets Fair value reduced by sales costs and its useful value. Estimated impairment requirements are grouped for assets at lowest possible levels where most significant independent cash flow exists (cash generating groups). For assets (other than goodwill) previously impaired a test is made at each balance sheet date if recovery should be made.

### *Liquid assets*

Liquid assets in the balance sheet are comprised of cash and bank deposits.

### *Employee compensation*

Employee compensation in the form of salaries, bonuses, paid vacation, paid sick leave, and pension benefits are reported as earned. No pension commitments exist in the Company in addition to pension premiums paid annually. All pension plans are fee based.

### *Cash flow statement*

The cash flow is prepared according to the so called indirect method.

### *Income*

Income is reported at Fair value received or to be received. The company had no income as of the balance sheet date.

### *Leasing*

Leasing where a significant part of risk and benefits with ownership are retained by the seller are classified as operational leasing. Payments made during the term of lease are charged to income in the income statement on a linear basis over the term of lease.

### *Segment reporting*

Operational segments are reported in a method consistent with internal reporting provided to the highest executive decision maker. The Board of Directors are the Company's highest executive decision maker. The Company's operations are comprised of only one branch of operation – to develop pharmaceutical products. The Company's report of total comprehensive income and financial position is solely one operating segment.

### *Taxes*

The Company's reported tax costs or tax income refers to current tax and changes in deferred taxes. Current tax is calculated based on taxable income for the period in accordance with prevailing tax laws. Current tax also includes adjustments from prior years.

IBT's taxable losses amount to approximately 371 (305) MSEK. Deferred taxes are reported for all temporary differences generated between the taxable value of assets and liabilities and their reported values. Deferred tax receivables are reported to the extent that it is likely that future taxable profits will be available, against which temporary differences may be offset. Deferred tax receivables in the company's financial statements will be activated only when it is certain

that taxable income will occur. No deferred tax receivable is reported in the company's financial statements.

### *Significant assessments and estimates*

Assessments and estimates are appraised continuously and are based on historical experience and other factors, including expectations of future events considered to be reasonable under current circumstances. The Company makes assessments and estimates regarding the future. The resulting estimates for accounting purposes will, by definition, seldom equal the actual results. Assessments are also made regarding the Company's accounting principles.

The currently ongoing development project, IBP-9414, is not deemed to meet the above criteria in IAS 38 to be activated as development in the balance sheet. The development costs are therefore charged to income as incurred.

Amounts are reported in KSEK (SEK in thousands). Amounts in parenthesis refer to the same period in the previous year unless stated otherwise.

## **Note 2      Financial instruments**

Fair value of other receivables, cash, accounts payable and other liabilities are estimated to equal book value (accumulated cost) due to the short duration.

The effects on earnings are reported in the income statement against research and development costs.

## **Note 3      Leasing**

IBT carries no financial leasing agreements. Leasing costs related to operational leasing are charged at cost over the leasing period. No non-terminable leases exist after a duration of five years.

Total future leasing costs regarding leasing agreements on the balance sheet date are as follows:

<b>Operational leasing</b>	<b>2022-12-31</b>	<b>2021-12-31</b>
<b>000's</b>		
Due for payment within one year	971	986
Due for payment within one and five years	876	1 763
<b>Total</b>	<b>1 847</b>	<b>2 749</b>
<b>Operational leasing costs during the year</b>	<b>2022</b>	<b>2021</b>
<b>000's</b>		
Rent	666	816
Parking	51	62
Automobiles	300	237
<b>Total</b>	<b>1 017</b>	<b>1 115</b>

#### **Note 4 Personnel**

	<b>Average number of employees</b>			<b>Average number of employees</b>		
	<b>2022</b>			<b>2021</b>		
	<b>Female</b>	<b>Male</b>	<b>Total</b>	<b>Female</b>	<b>Male</b>	<b>Total</b>
Sweden	3	4	7	3	5	8
<b>Total</b>	<b>3</b>	<b>4</b>	<b>7</b>	<b>3</b>	<b>5</b>	<b>8</b>
	<b>2022 Actual on Dec, 31</b>			<b>Actual on 2021 Dec, 31</b>		
	<b>Female</b>	<b>Male</b>	<b>Total</b>	<b>Female</b>	<b>Male</b>	<b>Total</b>
Board of Directors	3	2	5	3	3	6
Other management	1	4*	5	0	4	4
<b>Total</b>	<b>4</b>	<b>6</b>	<b>10</b>	<b>3</b>	<b>7</b>	<b>10</b>

\*One other management does not receive salary but invoices fees

<b>Total salaries, pension- and social costs, 000's</b>	<b>2022</b>	<b>2021</b>
Salaries and other compensation	13 643	11 491
Invoice fees other management	2 304	-
Pensions	1 509	1 720
Social costs	2 280	2 201
Other costs	409	283
<b>Total</b>	<b>20 145</b>	<b>15 695</b>

Variable compensation to management amounted to SEK 3 810 (953) k.

### *Board of Directors and committees*

Fees are paid in accordance with the decision taken at the annual general meeting.

### *Chief executive officer*

Base salary for the CEO, Mr. Staffan Strömberg, during 2022 amounted to SEK 2 815k plus SEK 2 402k in variable compensation.

The CEO has fee based pension compensation and the company has therefore no other pension commitments other than stated here. Pension premiums in 2022 amounted to SEK 894k.

The CEO and the company have a mutual notice period of six months. In addition, the company has a commitment of severance pay equal to nine months salary upon termination by the company.

### *Other management*

Compensation to other management is comprised of base salary, performance compensation, other compensation and pension premiums. Other management in the company refers to four persons who along with the CEO comprise the management group (Note 7).

The management group was in 2022 comprised of CEO Mr. Staffan Strömberg, COO Mr. Anders Kronström, CSO, CMO Mr. Jonas Rastad and CFO, Mr. Michael Owens until June, CFO Mrs Maria Ekdahl from September, CCO Mr Robert Molander from May.



<b>Management compensation 2022 000's</b>	<b>Base salaries/ fees</b>	<b>Variable compensation</b>	<b>Other benefits</b>	<b>Pension costs</b>	<b>Total</b>
Peter Rothschild, Chairman of the Board	670*	-	-	-	670
Margareta Hagman, Board member	138**	-	-	-	138
Eva Idén, Board member	138	-	-	-	138
Anthon Jahreskog, Board member	178	-	-	-	178
Robert Molander, Board member	63	-	-	-	63
Kristina Sjöblom Nygren, Board member	138	-	-	-	138
Staffan Strömberg, CEO	2 815	2 402	173	894	6 285
Other management (4)	5 235	1 408	80	435	7 661
<b>Total</b>	<b>9 373</b>	<b>3 810</b>	<b>253</b>	<b>1 329</b>	<b>14 765</b>

\*Of which 400k as working Chairman, of which 25k is paid out 2023

\*\* Of which 63k is paid out 2023

In order to meet IBT's long-term interests and ensure that the CEO has a market-based and competitive remuneration package, the Board of Directors has decided to deviate from the guidelines for remuneration to senior executives regarding variable remuneration for 2022. The variable remuneration for the CEO for 2022 mainly consists of long-term share-based remuneration

The management group was in 2021 comprised of CEO Mr. Staffan Strömberg, COO Mr. Anders Kronström, CMO Mr. Jonas Rastad and CFO, Mr. Michael Owens.

<b>Management compensation 2021 000's</b>	<b>Base salaries/fees</b>	<b>Performance compensation</b>	<b>Other benefits</b>	<b>Pension costs</b>	<b>Total</b>
Peter Rothschild, Chairman of the Board	670*	-	-	-	670
Margareta Hagman, Board member	125	-	-	-	125
Anthon Jahreskog, Board member	165	-	-	-	165
Eva Idén, Board member	125	-	-	-	125
Robert Molander, Board member	125	-	-	-	125
Kristina Sjöblom Nygren, Board member	125	-	-	-	125
Staffan Strömberg, CEO	2 739	878	166	823	4 606
Other management (3)	3 415	75	35	672	4 197
<b>Total</b>	<b>7 489</b>	<b>953</b>	<b>202</b>	<b>1 495</b>	<b>10 139</b>

\*Of which 400k as working Chairman

## Note 5 Audit fees

<b>Deloitte AB, 000's</b>	<b>2022</b>	<b>2021</b>
Auditing	270	353
<b>Totalt</b>	<b>270</b>	<b>353</b>

Auditing refers to compensation for review of the company's internal controls, accounting, annual report and administration by the Board of Directors and CEO.

## Note 6 Intangible non-current assets

<b>Activated development costs, 000's</b>	<b>2022</b>	<b>2021</b>
Opening accumulated costs	16 225	16 225
Activated costs	-	-
<b>Total cost</b>	<b>16 225</b>	<b>16 225</b>
Opening accumulated depreciation	-4 891	-4 075
Depreciation	-816	-816
<b>Total accumulated depreciation</b>	<b>-5 707</b>	<b>-4 891</b>
<b>Carrying amount at end of the period</b>	<b>10 518</b>	<b>11 334</b>

Activated development costs refer to the production process of the pharmaceutical candidate IBP-9414. Period of use is based on the underlying useful life of the patent of 20 years.

Depreciation is linear from 2016 and is reported in the R&D-function in the income statement

### *Impairment test*

The criteria according to IAS 38 and IAS 36, respectively, require testing the immaterial fixed assets for impairment whenever events or changed circumstances indicate that the reported value may not be recovered.

Activated costs referring to the production process have been assessed. The company has at the time of disclosure of this financial report utilized the pharmaceutical candidate produced by the production process in a clinical Phase II study in which 120 patients were dosed.

Technology transfer possibility of the manufacturing method has been verified by third parties. The production process will be applied in the production of the drug upon potential market approval.

Two independent companies, Apex Healthcare Consulting Ltd., and Clearview Healthcare Partners have evaluated the market potential in 2014 and 2016, respectively, for IBP-9414 in the USA.

Their assessment of the market potential amounted to an interval of 200 MUSD to 360 MUSD per annum.

The total assessment is that the criteria in IAS 38 are met.

## Note 7 Shares in subsidiary

Name	Reg. No.	Domicile, country	No. Shares	Ownership	Book value 2022	Book value 2021
IBT Baby AB	559110-7353	Stockholm, Sweden	50 000	100%	70 000	50 000
<b>Total, SEK</b>					<b>50 000</b>	<b>50 000</b>

IBT Baby AB manages incentive programs for key personnel employed by IBT AB.

IBT issues warrants which are sold by IBT Baby AB to employees of IBT AB eligible to participate in the parent company's incentive program as follows:

### *Share based incentive programs*

#### **WARRANTS 2020/2024**

On June 16, 2020, the Annual General Meeting decided on an incentive program by designated issue of warrants to the subsidiary IBT Baby AB. The maximum number of warrants to be issued are 375 000.

In September 2020, 185 027 warrants were allotted at market terms at a price determined by calculating market price at the time of issue using the Black & Scholes method of valuation.

During the first quarter of 2021, 49 046 warrants were allotted. Total market price for the allotted 49 046 warrants during the first quarter of 2021 amounted to 88 KSEK.

During the third quarter of 2021, 10 000 warrants were allotted. Total market price for the allotted 10 000 warrants during the third quarter of 2021 amounted to 3 KSEK.

The holder of warrants may during the period from July 1, 2024 through September 20, 2024, for each warrant subscribe for one point one (1) new class B share in the company at a subscription price per share amounting to SEK 400. On the balance sheet date December 31, 2021, a total of 244 073 (185 027) warrants had been allotted. The remaining 130 927 warrants are reserved for future employees.

The warrants are subject to first right of refusal stipulating that the warrants shall be sold back to IBT Baby AB should the employee, from the date of signing, terminate employment within one year by 100%, within two years by 75%, within three years by 50%.

The warrants carry no dividend rights. The warrants are issued at market value and have thus have not resulted in any benefits which require accruals for social costs in the parent company. The subscription price per share exceeds the market price of IBT's share on the balance sheet date which means that the warrants do not cause any dilution when calculating result per share.

Based on the existing number of shares the dilution resulting from the adopted incentive program, provided that all warrants are utilized for subscription of class B-shares, amounts to approximately 2.13 percent of shares, and 1.69 percent of votes.

<b>Ownership of warrants 2020/2024</b>	<b>Number allotted 2022-12-31</b>	<b>Number issued 2022-12-31</b>	<b>Number allotted 2021-12-31</b>	<b>Number issued 2021-12-31</b>
Staffan Strömberg, CEO	50 000	50 000	50 000	50 000
Anders Kronström, COO	40 000	40 000	40 000	40 000
Other	154 073	154 073	154 073	154 073
<b>Total</b>	<b>244 073</b>	<b>244 073</b>	<b>244 073</b>	<b>244 073</b>

## **WARRANTS 2022/2025**

The Annual General Meeting on May 4, 2022 decided to introduce an incentive program, Warrants 2022/2025 through a directed issue of warrants to the subsidiary IBT Baby AB. The number of warrants amounts to a maximum of 304,500.

During the month of June 2022, 272,000 warrants have been transferred on market terms at a price determined based on a calculated market value at the time of the transfer using the Black & Scholes valuation model.

During the period from June 1, 2025 up to and including September 30, 2025, warrant holders are entitled to subscribe for one (1) new Class B share in the company at a subscription price per share corresponding to SEK 129.56. As of December 31, 2022, 272,000 warrants had been issued. The remaining 32,500 warrants have not been allocated.

The warrants are subject to pre-emption, which stipulates that the warrants shall be sold back to IBT Baby AB if the employee from the subscription date terminates his/her employment within one year with 100%, within two years with 75%, and within three years with 50%. After three years, the holder is entitled to keep the warrants.

Based on the existing number of shares in the company, the dilution as a result of the implemented incentive program, assuming that all warrants are exercised for new subscription of B shares, is approximately 2.37 percent of the shares and approximately 1.83 percent of the votes.

The warrants carry no right to dividends. The options have been issued at market value and have therefore not entailed any benefit that gives rise to a provision for social security contributions in the parent company.

The subscription price per share exceeds the market price of the IBT share on the balance sheet date, so the options do not entail any dilution when calculating earnings per share. The total market price for 272,000 warrants issued during the second quarter of 2022 amounted to SEK 1,904 thousand, which was recognized directly against equity in IBT.

<b>Ownership of warrants 2022/2025</b>	<b>Number allotted 2022-12-31</b>	<b>Number issued 2022-12-31</b>	<b>Number allotted 2021-12-31</b>	<b>Number issued 2021-12-31</b>
Staffan Strömberg, CEO	120 000	120 000	0	0
Anders Kronström, COO	75 000	75 000	0	0
Robert Molander, CCO	20 000	20 000		
Other	57 000	57 000	0	0
<b>Total</b>	<b>272 000</b>	<b>272 000</b>	<b>0</b>	<b>0</b>

### **Total number of allotted warrants in existing incentive programs**

<b>Allotted warrants, year</b>	<b>Issued warrants</b>	<b>Strike price*</b>	<b>Value per allotted warrant</b>	<b>Volatility, %*</b>	<b>Risk-free interest, %</b>	<b>Value per share</b>	<b>Expiry, year</b>
2020 (2020/2024)	87 543	400	14.24	40	-0,3	170	2024
2020 (2020/2024)	97 484	400	4.86	40	-0,3	125	2024
2021 (2020/2024)	49 096	400	1.78	40	-0,3	105	2024
2021 (2020/2024)	10 000	400	0.29	40	-0,3	81	2024
2022 (2022/2025)	272 000	129,56	7	40	1,32	66,90	2025
<b>Total</b>	<b>516 073</b>	-	-	-	-	-	-

\*Expected future volatility is ascertained by comparison of historical average and median values for comparable listed companies in the same sector as IBT based on analysis in S&P Capital IQ.

### **Note 8 Other receivables**

<b>000's</b>	<b>2022</b>	<b>2021</b>
Taxes	1 179	831
Other receivables	295	371
<b>Total cost</b>	<b>1 474</b>	<b>1 202</b>

## Note 9 Prepaid expenses and accrued income

000's	2022	2021
Accrued interest income	304	-
Prepaid rent	185	165
Prepaid insurance	612	294
Prepaid CRO costs	610	8 599
Other prepaid expenses	6	82
<b>Total cost</b>	<b>1 716</b>	<b>9 140</b>

The maximum credit risk exposure on the balance sheet date equals reported value.

## Note 10 Cash and bank deposits

000's	2022	2021
Bank deposits at Danske Bank and SEB	335 840	386 752
<b>Total cost</b>	<b>335 840</b>	<b>386 752</b>

The Company's liquidity consists solely of cash deposits held at Danske Bank and SEB. Total liquidity on the balance sheet date December 31, 2022, amounted to SEK 335.8 (386.8m) of which USD amounted to SEK 180.9m (200.4m) and EUR amounted to SEK 35.8m (45.2m).

## Note 11 Accrued expenses and prepaid income

000's	2022	2021
R&D costs	6 159	4 700
Social costs and special salary taxes	709	1 153
Vacation pay	1 473	1 427
Salaries	-1	81
Board fees	63	78
Other accrued expenses	263	209
<b>Total</b>	<b>8 667</b>	<b>7 648</b>

All accrued expenses are due for payment within twelve months.

## Note 12 Significant events after the reporting period

- On January 12, IBT announced it secured a probiotic drug platform that can prevent antibiotic-resistant hospital acquired infections.
- The British Journal of Gastroenterology published in January new results that validate "Sustained Feeding Tolerance" (SFT) as a relevant primary endpoint in "The Connection Study".

## Note 13 Board of Directors recommendation of appropriation of profits

SEK	2022
<b>Recommendation of appropriation of profits or loss</b>	
The Board of directors propose that the following surplus:	
Income carried forward	-276 828 919
Surplus reserve	670 925 576
Result for the period	-65 450 864
<b>Total</b>	<b>328 645 793</b>
<b>Be appropriated as follows:</b>	
Income carried forward	328 645 793
<b>Total</b>	<b>392 645 793</b>

## Note 14 Related party transactions

Compensations to the Board of directors are paid in accordance with the annual general meeting.

The Chairman of the Board, Mr. Peter Rothschild, receives Board fees amounting to KSEK 300 per annum, and KSEK 400 annually as operational Chairman.

Bonuses were paid during the second quarter to Staffan Strömberg amounting to KSEK 1 953 and to Anders Kronström KSEK 1 221, and to Robert Molander KSEK 187.

Bonus was paid during the fourth quarter to Staffan Strömberg amounting to KSEK 449 as variable bonus as a percentage of gross salary.

Mr. Robert Molander invoiced consulting fees January to April amounting to KSEK 832, mainly relating to commercialization of IBP-9414. From May Mr. Robert Molander invoiced KSEK 1 472 for his position as CCO at IBT. During 2022 Mrs [Eva Idén](#) invoiced KSEK 15, consultancy fees related to assistance with various policies.

KSEK 1 904 has been transferred from IBT Baby to IBT AB:s equity for warrants. IBT AB has made a shareholder contribution to IBT Baby of KSEK 20.

No other significant related party transactions have occurred.

## Note 15 Pledged assets and contingent liabilities

	2021	2020
Pledged assets and contingent liabilities	None	None



## Note 16 Result per share

Calculations are in accordance with IAS 33 Earnings per share. Earnings per share are calculated by dividing result for the period with the weighted average number of outstanding shares during the period.

<b>Result per share, SEK</b>	<b>2022</b>	<b>2022</b>
Result for the period, 000's	-65 451	-44 991
Weighted average number of shares before and after dilution*	11 226 184	11 226 184
<b>Result per share before and after dilution</b>	<b>-5.83</b>	<b>-4.01</b>

## Note 17 Share capital development (SEK)

<b>Period</b>	<b>Transaction</b>	<b>Change</b>	<b>Series A shares</b>	<b>Series B shares</b>	<b>Share capital</b>	<b>Quota value</b>	<b>Subscription price</b>	<b>Total Invested</b>
2011-11-22	Founding	50 000			50 000	1,00	1,00	50 000
2015-09-15	Share issue	40 000			90 000	1,00	1 320,00	52 800 000
2015-09-15	Bonus issue	90 000			500 000	5,56	-	52 850 000
2016-02-12	Split/reclass	-90 000	74 066	1 760 480	500 000	0,27	-	52 850 000
2016-05-30	Share issue	-	148 132	3 520 960	1 500 000	0,27	27,30	153 016 212
2017-11-30	Share issue	-	-	1 100 000	1 799 802	0,27	95,00	257 516 212
2018-02-05	Share issue	-	155 538	4 435 663	3 051 120	0,27	95	693 680 307
2018-02-13	Share issue	-	-	31 345	3 059 663	0,27	95	696 658 082
<b>Totalt</b>		<b>0</b>	<b>377 736</b>	<b>10 848 448</b>	<b>3 059 663</b>	<b>0,27</b>	<b>-</b>	<b>696 658 082</b>

## Note 18 Financial risk management

### General

The financial risks related to the Company's operations are mainly liquidity, currency, and counterparty risks.

### Liquidity risks

Liquidity risks are such risks as not having access to liquidity to meet the Company's operational requirements. The Company has no financial liabilities with agreed duration. Other liabilities are commitments to pay for goods or services obtained during operations from suppliers. The amounts are unhedged and normally payable within 30 days. Capital needs are monitored by budget review.

## *Financing strategy*

The Company's capital requirements have previously been met by capital injections from its former parent company, BioGaia and share issue in connection with listing the Company on Nasdaq First North in March 2016. To date, IBT has received 82 MSEK from BioGaia and 100 MSEK from other shareholders in connection with the May 2016 share issue.

IBT has during November 2017 generated SEK 104.5m in a directed share issue to institutional investors and in January 2018, a preferred share issue generated SEK 439.1m. Capital generated amounting to approximately SEK 543.6m prior to transaction costs and approximately SEK 528m post transaction costs is deemed sufficient to conduct the planned pivotal Phase III clinical study.

As the Company's pharmaceutical candidate IBP-9414 reaches important milestones in its pharmaceutical development, additional financing possibilities are available. As a listed company in Sweden the Company can issue new shares with preemptive rights for its shareholders. Other possible financing methods are licensing specific rights to the pharmaceutical to pharmaceutical company partners and a share issue to new investors, conditional upon being possible on terms acceptable to current shareholders.

Obtaining loans for financing is not deemed suitable other than as a temporary solution before the Company reaches profitability and has positive cash flow. The company has only financial liabilities with short duration which are due for payment within 12 months.

Access to capital may be limited at times when needed by the Company.

## *Counterparty risks*

Only investments in instruments with low credit risk and high liquidity are allowed. The company works with established and creditworthy counterparties and continuously evaluates receivables to ensure a low exposure to bad debts. To reduce this risk, IBT places its excess liquidity in accounts with Danske Bank and SEB. On the balance sheet date, the company had approximately SEK 255 million invested in 3 (SEK 96 million) and 6 (SEK 159 million) month fixed rate accounts.

Currency risk is the risk that the value of assets and liabilities will vary due to changes in exchange rates. The majority of IBT's development costs consist of commitments in other currencies. If the SEK decreases in value against the currency in question, it can have a significant impact on the company's position and results. The currencies to which IBT has the greatest exposure are USD and EUR.

## FINANCIAL DEFINITIONS

Key ratios	Definition	Motive
<b>Average number of shares</b>	Average number of shares during the year	Relevant in calculating income and cash flow per share
<b>Net sales</b>	Sales for the year	Sales of services
<b>Reporting period</b>	January 1 - December 31, 2022	Defines time period comprised by this financial report
<b>Result per share</b>	Result for the year divided by average number of shares	Result allocated per share
<b>Cash flow per share*</b>	Cash flow for the year divided by average number of shares	Measure to describe cash flow allocated to one share during the year
<b>Number of shares*</b>	Number of shares at the end of the year	Relevant for calculating shareholders' equity allocated to one share
<b>Shareholders equity/share*</b>	Total shareholders' equity divided by the number of shares at the end of the year	Measure to describe shareholder's equity per share
<b>Equity ratio*</b>	Total shareholders' equity as a percentage of total assets	Measure to evaluate the company's ability to meet its financial obligations

\*The Company presents certain financial measures in the Year-end report not defined by IFRS. The Company deems that these measures provide valuable additional information for investors and management of the Company as they enable evaluation and benchmarking of the Company's performance. As all companies do not calculate financial measures the same way, these measures are not always comparable to those used by other companies. These financial measures shall therefore not be viewed as replacements for those defined by IFRS. The financial definitions are not defined by IFRS unless otherwise stated.

## BOARD'S ASSURANCE

The Board of Directors and CEO hereby certify that this report gives a true and fair presentation of the Company's operations, financial position and result of operations, and describes material risks and uncertainties facing the Company.

The Annual Report was approved for issuance by the Board of Directors on March 22, 2023 and will be subject to approval at the annual general meeting on May 8, 2023.

Stockholm, March 2, 2023

Peter Rothschild  
Chairman

Eva Idén  
Director

Margareta Hagman  
Director

Kristina Sjöblom Nygren  
Director

Anthon Jahreskog  
Director

Staffan Strömberg  
CEO

Nb: This is a translation of the Swedish annual report. If any discrepancies exist, the Swedish version shall prevail.

Our Auditor's Report was submitted on March 22, 2023

Deloitte AB

Jenny Holmgren  
Authorized public accountant

## Auditor's report

### **To the general meeting of the shareholders of Infant Bacterial Therapeutics AB (publ)**

**corporate identity number 556873-8586**

### **Report on the annual accounts**

#### *Opinions*

We have audited the annual accounts of Infant Bacterial Therapeutics AB (publ) for the financial year 2022-01-01 - 2022-12-31. The annual accounts of the company are included on pages 23-53 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of Infant Bacterial Therapeutics AB (publ) as of 31 December 2022 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet.

#### *Basis for Opinions*

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the *Auditor's Responsibilities* section. We are independent of Infant Bacterial Therapeutics AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

#### *Key Audit Matters*

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and as a whole, but we do not provide a separate opinion on these matters.

#### *Research and development costs*

The company's costs for research and development as of December 31, 2022 amount to TSEK 65 820 after exchange rate gains on foreign currency forward contracts and

currency deposits and is a significant amount in the income statement. It is management's assessment that the entire amount should be expensed instead of being capitalized as intangible assets since the criteria in IAS 38 regarding capitalization are not deemed to be fulfilled. The company describes its positions in the accounting principles on page 36. Our audit procedures included, but were not limited to:

- Examination of a number of transactions to ensure correct classification
- Examination of the company's analysis and assumptions that form the basis of the company's position for the question
- Examination that the required disclosures are provided in the annual accounts

#### *Other information than the annual accounts*

This document also contains other information than the annual accounts and is found on pages 1-22. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard

#### *Responsibilities of the Board of Directors and the Managing Director*

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

#### *Auditor's responsibility*

Our objectives are to obtain reasonable assurance about whether the annual accounts

as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts.

A further description of our responsibilities for the audit of the management's administration is located at the Swedish Inspectorate of Auditors website: [www.revisorsinspektionen.se/revisornsansvar](http://www.revisorsinspektionen.se/revisornsansvar)  
<http://www.revisorsinspektionen.se/ri/showdocument/documents/This> description forms part of the auditor's report.

### *Opinions*

In addition to our audit of the annual accounts, we have also audited the administration of the Board of Directors and the Managing Director of Infant Bacterial Therapeutics AB (publ) for the financial year 2022-01-01 - 2022-12-31 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit to be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

### *Basis for Opinions*

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the *Auditor's Responsibilities* section. We are independent of Infant Bacterial Therapeutics AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### *Responsibilities of the Board of Directors and the Managing Director*

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's type of operations, size and risks place on the size of the company's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's financial situation and ensuring that the company's

organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

*Auditor's responsibility*

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

A further description of our responsibilities for the audit of the management's administration is located at the Swedish Inspectorate of Auditors website:

[www.revisorsinspektionen.se/revisornsansvar](http://www.revisorsinspektionen.se/revisornsansvar)

<http://www.revisorsinspektionen.se/ri/showdocument/documents/This> description forms part of the auditor's report.

Deloitte AB, was appointed auditor of Infant Bacterial Therapeutics AB (publ) by the general meeting of the shareholders on the 2022-05-04 and has been the company's auditor since 2015-03-29.

Stockholm March 22, 2022

Deloitte AB

Jenny Holmgren

Authorized public accountant



## CORPORATE GOVERNANCE REPORT IBT

IBT is a Swedish limited company whose B shares are listed on Nasdaq Stockholm. The company is governed by the AGM, the Board of Directors, the President and the executive management in accordance with the Companies Act, the Articles of Association, rules of procedure for the Board and the CEO's instructions and the Swedish Code of Corporate Governance. The Board is responsible for evaluating established goals and continuously evaluating IBT's financial position and earnings and evaluating the operational management.

The share capital consists of 377,736 Class A shares with 10 voting rights per share and 10,848,448 Class B shares with one voting right per share.

### **Compliance with the Swedish Code of Corporate Governance (Svensk Kod för Bolagsstyrning), common stock market code and applicable stock market rules**

The purpose of the Code is to strengthen confidence in Swedish listed companies by promoting a positive development of the company's corporate governance. The code is based on the principle of "comply or explain" which means that a company can make deviations from the code but these must then be explained.

IBT has not deviated from any of the rules specified in the Code.

IBT has not been subject to a decision by Nasdaq Stockholm's disciplinary committee or a statement by the Swedish Securities Council (Arbetsmarknadsnämnden).

### **Environment and responsibility**

IBT's operations do not pose any specific environmental risks and do not require any specific environmental permits or decisions from authorities. The Board of Directors believes that the company conducts its operations in accordance with applicable health and safety rules and offers its employees a safe and healthy working environment.

### **Diversity and gender equality**

IBT should be a workplace where diversity and gender equality are natural parts of the business. A workplace characterized by diversity and gender equality is necessary for IBT to be an attractive workplace and to achieve set goals. Recruitment shall be based on competence requirements, diversity and gender equality.

### **Sustainability**

IBT is to be perceived as an innovative and creative company, which stands for quality and health and plays a role in society. It is important for IBT to work with sustainability. Respect for human rights, the environment and anti-corruption must characterize our everyday lives through business strategies, financing processes, investments and purchases.

According to the Swedish Annual Accounts Act (Årsredovisningslagen), there is no requirement that the Company prepare a Sustainability Report.

## Articles of Association

In accordance with IBT's articles of association, the Company will develop, manufacture, market and sell pharmaceuticals directly or through subsidiaries or other forms of part-ownership or partnerships and conduct related operations. The seat of the Board is Stockholm.

The Articles of Association do not contain any provisions on the appointment or dismissal of directors or the amendment of the Articles of Association. Nor do the Articles of Association contain any restrictions on the number of votes each shareholder can cast at a general meeting.

The Articles of Association can be found on IBT's website under the heading Investors / Corporate Governance.

## Annual General Meeting

In accordance with the Swedish Companies Act, the Annual General Meeting is IBT's highest decision-making body and at the Annual General Meeting the shareholders exercise their voting rights on key issues, for example establishing a report on comprehensive income and financial position, disposition of IBT's results, granting discharge from the Board of Directors and the Board of Directors, election of the Board of Directors and the CEO and remuneration to the Board of Directors and auditors. In addition to the AGM, an Extraordinary General Meeting can be called. In accordance with the Articles of Association, notice of the Annual General Meeting and Extraordinary General Meeting are published in Post- och Inrikes Tidningar and on IBT's website.

Annwall & Rothschild Investment AB, owns 9.09 percent of the capital and 29.31 percent of the votes in the company.

## Annual General Meeting 2022

At IBT's Annual General Meeting on May 4, 2022, The Annual General Meeting decided, inter alia, the following:

- establishing of the income statement and balance sheet
- granted discharge for Board members and the CEO
- that no dividend is paid
- that the board shall consist of five members without deputies
- re-election of board members Margareta Hagman, Eva Idén, Anthon Jahreskog, Kristina Sjöblom Nygren, Peter Rothschild. Noted that Robert Molander declined re-election.
- re-election of Peter Rothschild as Chairman
- re-election of the registered accounting firm Deloitte AB
- that remuneration to be paid to the Chairman of the Board of SEK 300,000 and an additional remuneration for the work of Chairman of the Board of SEK 400,000 and to other members not employed by the company by SEK 150,000 each
- that audit fees should be paid according to approved invoice
- on the nomination committee in accordance with the nomination committee's proposal
- on approval of the Board's remuneration report

- on authorization for the Board to decide on issue of class B-shares in accordance with the Board's proposal

## **The Annual General Meeting 2023**

The 2023 Annual General Meeting will be held on May 8, 2023 in Stockholm.

## **Notice of Annual General Meeting**

Notice of Annual General Meeting shall be made through advertising in Post- och Inrikes Tidningar and on the company's website. That notice should be announced in Svenska Dagbladet and on the company's website.

## **Nomination Committee**

The Annual General Meeting 2022 resolved that a Nomination Committee should be appointed as follows: "The Chairman of the Board shall convene the three largest shareholders in the company, who each nominate a representative to be a member of the Nomination Committee together with the Chairman of the Board. At the composition of the nomination committee, the ownership conditions as of June 30, 2022 will determine which are the largest shareholders in terms of the number of votes. The representative of the largest shareholder in the nomination committee at this time shall be the chairman of the nomination committee. If one of the three largest shareholders waives their right to appoint a member to the nomination committee, the next shareholder in size shall be given the opportunity to appoint a member to the nomination committee. The names of the three members shall be published when appointed, however, latest six months prior to the 2023 AGM. The period of mandate of the nomination committee lasts until such time a new nomination committee has been appointed."

If the shareholder who appointed the member no longer constitutes one of the three largest shareholders in terms of voting rights, such member may, if the nomination committee deems it appropriate, be dismissed and a member of the shareholder who is next in size in terms of voting rights be given the opportunity to take his or her place. If an appointed member of the nomination committee otherwise resigns from the nomination committee, the shareholder who appointed the member in question shall have the right to appoint a new member of the nomination committee. If the latter refrains from appointing a new member, the nomination committee shall, if it finds it appropriate with regard to the remaining term of office, ask the shareholder who is next in size in terms of voting rights whether he or she wishes to appoint a member of the nomination committee.

The Nomination Committee shall prepare proposals on the following issues to be submitted to the Annual General Meeting 2023 for resolution:

- a) proposal for election of the Chairman of the Meeting
- b) proposals of Board members
- c) proposal for election of the Chairman of the Board
- d) proposal for Board fees
- e) proposals for election of the auditor
- f) proposal for audit fees

- g) proposal on reasonable costs for the nomination committee
- h) proposals regarding nomination committee for the 2023 Annual General Meeting.

## **Mandate**

The 2022 AGM decided on a mandate for the Board to, at one or more instances during the period until the next AGM, decide to issue class B-shares. The Board may decide to issue shares deviating from shareholders pre-emptive rights. Shares may be issued with or without stipulation of contribution in kind, offset, or other conditions in accordance with 13 chapter 5 § first section 6 of aktiebolagslagen.

With regard to the issue of shares with deviation from the shareholders' preferential rights (directed issues), the board of directors shall not be able to make decisions that entail an increase in the share capital by more than twenty percent in relation to the share capital that exists when the authorization to issue shares is first used for a directed issue.

The issue in accordance with the authorization shall be made on market terms. The Board of Directors shall be entitled to determine the other terms and conditions for issues under this authorization and who shall be entitled to subscribe for the shares. The purpose of the authorization is to give the board of directors flexibility in the work to ensure that the company can appropriately raise capital for the financing of the company's continued clinical activities and to enable a broadening of the ownership base in the company.

## **The Board**

According to IBT's Articles of Association, the Board shall consist of a minimum of three and a maximum of ten members and no deputies. The Board is elected annually at the AGM for the period until the end of the next AGM. The Board of Directors has since the Annual General Meeting 2022 consisted of five members elected by the AGM without deputies. Peter Rothschild is indirect shareholder in IBT through Annwall & Rothschild Investment AB. Other members are independent in relation to the company and company management.

The CEO is not a member of the Board but is adjunct to all Board meetings. Other officers in the company participate in Board meetings as rapporteur. The Board of Directors has adopted a rules of procedure, including the division of work between the Board and the CEO and the structure of the Board's work during the year. In addition to the responsibilities of the Swedish Companies Act and the Articles of Association is regulated following the Board's rules:

- Hold at least 4 board meetings, in addition to the statutory meeting
- Determine the overall objectives of the company's operations and decide on the company's strategy and evaluate the operational management and risk assessment in the company.
- Approve budget and corresponding long-term plans including investment budget
- Process matters relating to investments and the like in the amount of five hundred thousand (500,000 SEK) or other commitments for the company, which entails a cost to the company exceeding five hundred thousand (500,000 SEK)
- Decide on the purchase and sale of real estate, shares or acquisitions of another company's operations in excess of five hundred thousand (500,000 SEK)

- Determine the annual report, the directors' report and the interim reports
- Borrowing
- Enter into an agreement with a term of more than three years
- Initial processes of large scope and settlement of disputes of significant importance
- Other issues of significant economic or other importance

The Board of Directors is responsible for monitoring the Company's financial position, for monitoring the efficiency of the Company's internal control, internal audit and risk management, being informed of the audit of the 2021 financial statements and for reviewing and monitoring the auditor's impartiality and independence.

In addition, the Board of Directors has adopted the CEO's instruction, certificate instruction including instructions regarding liquidity management and currency management policy. The work order, CEO instruction and attestation instruction are tested at least once a year.

### The Board of Directors presence in 2022

Name	Position	Member since	Independent in relation to		Attendance 2022
			Company and senior management	Major shareholders	
Peter Rothschild	Chairman of the Board <sup>3</sup>	2011	No <sup>1</sup>	No <sup>2</sup>	8/8
Margareta Hagman	Board member	2015	Yes	Yes	7/8
Eva Idén	Board member	2017	Yes	Yes	8/8
Anthon Jahreskog	Board member <sup>3</sup>	2017	Yes	Yes	8/8
Robert Molander <sup>4</sup>	Board member	2020	Yes	Yes	4/4
Kristina Sjöblom Nygren	Board member	2018	Yes	Yes	8/8

<sup>1</sup>In his role as working chairman, Peter Rothschild is not considered independent in relation to company.

<sup>2</sup>Peter Rothschild is a partner in Annwall & Rothschild Investments AB, the Company's largest shareholder.

<sup>3</sup>Member in Remuneration Committee. The Remuneration Committee has, besides ongoing contact, had three meetings during 2022 with full attendance.

<sup>4</sup> Robert Molander resigned the Board of Directors at AGM May 4, 2022

If a member has not been able to attend a board meeting, this member has had the opportunity to present his / her views to the chairman before the meeting.

Board meeting agenda is as follows where appropriate:

- Business Plans
- Business follow-up
- Investments
- Strategy
- Performance reports
- Significant agreement
- Budget
- Financial statements

The Board continuously evaluates its work through open discussions and annually performs a written evaluation of its work. The Nomination Committee is informed of the results of the evaluation.

## **Remuneration of the Board**

At the 2022 Annual General Meeting, it was decided to pay a fee of SEK 300,000 to the Chairman of the Board, an additional fee of SEK 400,000 to the Chairman in his assignment to be working chairman of the board and SEK 150,000 to the other members, as well as fees for committee work.

## **Chairman of the Board**

The Chairman of the Board is responsible for leading the work of the Board and for the Board to fulfill its obligations in accordance with the Companies Act and the Board's rules of procedure. Through continuous contacts with the CEO, the Chairman of the Board shall monitor the company's development and ensure that the Board receives the information required for the Board to fulfill its commitment. In addition, the Chairman, as a working Chairman of the Board, actively participates in financing issues, licensing issues and presentations to the market and assists company management in business development. Peter Rothschild has been Chairman of the Board since 2011.

## **The CEO**

The CEO is responsible for the company's business development and manages and coordinates day-to-day operations. The CEO has an instruction decided by the Board of Directors, which regulates, among other things, his work with management and development of the company as well as continuous reporting and decision-making to the Board. The Managing Director prepares the necessary information and decision-making documentation such as reports regarding, among other things, the company's finances, order situation, significant business and strategic issues before Board meetings, and is a rapporteur and submits motivated proposals for decisions. In addition, the President keeps the Chairman of the Board regularly informed about the company's operations.

The Managing Director is solely responsible for external communication.

The Board annually evaluates the CEO's work. In this evaluation, no one from the company management is present.

## **Management**

The management of IBT consists of five people.

The management team is led by the CEO and is responsible for planning, directing and monitoring the day-to-day operations. Minuted meetings are held every week. The powers and responsibilities of the CEO, in addition to being regulated by the Companies Act, are defined in the CEO instructions adopted by the Board. The powers and responsibilities of company management are defined in job descriptions and attestation instructions.

## **Remuneration Committee**

The Board has appointed a Remuneration Committee consisting of Chairman of the Board Peter Rothschild and Board member Anthon Jahreskog. Anthon Jahreskog is Chairman of the Remuneration Committee.

The Remuneration Committee shall prepare questions regarding remuneration and other terms of employment for the CEO and other senior executives who together form the company management. The Remuneration Committee has held three meetings. Peter Rothschild and Anthon Jahreskog were present at all three meetings.

Principles for remuneration to senior executives are set at the Annual General Meeting. The remuneration committee's task is to prepare proposals for senior executives in accordance with these principles.

## **Auditors**

IBT's auditors are normally elected for a period of one year at the AGM. At the 2022 Annual General Meeting, re-election of Deloitte AB was resolved for the period up to the end of the Annual General Meeting that will be held in 2023. The Auditing Company has appointed Jenny Holmgren as the designated Auditor. Remuneration to the auditors is paid, in accordance with the decision of the Meeting, on an ongoing basis.

The auditors review the Board of Directors and the CEO's management of the company and the quality of the company's financial reporting. The auditors also carry out, on behalf of the Board, an audit of the financial statements, an audit of the annual report, and a review of a quarterly report.

The auditor's report their audit to the shareholders through the audit report, which is presented at the AGM. In addition, written and oral reports are submitted to the company management and the board. At the board meeting in connection with the review of the third quarter, the auditor participates in the reporting of comments from the ongoing review during the financial year regarding the company's internal control and preparation for the annual accounts.

The auditors also submit an audit opinion on the corporate governance report and a report on the review of remuneration to senior executives.

For information on remuneration to the auditors, see note 5 in the annual report.

The Board of Directors has decided that independent members of the Board possess accounting expertise as well as the Board's ongoing review of the financial reporting and with regard to the company's limited size and scope of transactions, to appoint no Audit Committee. Furthermore, the entire Board meets with the auditor at least once a year without the presence of the company's CEO or another of the company management.

## **The Board's description of internal control regarding the financial reporting for the financial year 2022**

### Introduction

According to the Swedish Companies Act, the Swedish Annual Accounts Act and the Swedish Code of Corporate Governance, the Board is responsible for the internal control. This description has been prepared in accordance with these provisions and thus limited to internal control over the financial reporting.



### Internal control over financial reporting

The Board of Directors is responsible for ensuring that the company's organization is designed so that the accounting, asset management and the company's financial conditions are otherwise controlled in a satisfactory manner.

The Board of Directors adopts annually rules of procedure for the work of the Board and instructions for the division of work between the Board and the CEO. The rules of procedure specify which matters require the approval or confirmation of the board. At the board meetings, the CEO prefers matters that require the board's treatment.

The Managing Director shall ensure that the Board receives a factual, detailed and relevant information base for the Board to be able to make well-informed decisions and that the Board is kept regularly informed of the development of the company's operations and financial position.

Within IBT, internal control of financial reporting is focused, for example, on ensuring efficient and reliable management and accounting of purchases and sales, other income accounting and accounting of the company's financing. The internal control environment mainly comprises the following five components: control environment, risk assessment, control activities, information and communication and follow-up.

### Control environment

In addition to the rules of procedure between the Board and the CEO, IBT's control structure is based on the company's organization and ways of conducting operations where the roles and responsibilities are defined and communicated in the organization. Employee awareness of maintaining good control over financial reporting is satisfactory and analysis and follow-up of financial progress is done monthly. Financial reports and compilations are made by IBT's finance department and reported to the Board on a quarterly basis and to company management on a monthly basis.

### Risk assessment

The company works continuously with risk assessment and risk management to ensure that the risks to which the company is exposed are managed within the framework that is ultimately determined by the Board of Directors. The company management annually analyzes the business processes of the business with regard to efficiency and risks. This work includes identifying significant risks of errors in financial reporting and ensuring that there are appropriate processes and controls within the business to manage these risks. Processes that are considered to be of particular importance to IBT are research and development. A more detailed description of the risk exposure can be found in the annual report.

### Control activities

The risks identified in financial reporting are managed through a number of control measures in the business processes. Processes, policies and controls are reviewed and updated annually. The purpose is to detect, prevent and correct errors and deviations. The control structure also includes, among other things, established powers (eg attestation), division of work, IT risks and

the management's monthly review of financial information. The company controls the subcontractor's fulfillment of current services in accordance with agreements, including quality aspects.

### Information and communication

IBT has information and communication pathways aimed at promoting completeness and accuracy in financial reporting. Certificate arrangements and communication policies are distributed to all employees and kept available on the company's intranet. The entire company's staff meet approx. once a month to increase knowledge of processes and objectives and to exchange information and experience.

### Evaluation

The company management annually evaluates internal control. The company's elected auditors, Deloitte AB, also annually review a selection of IBT's routines and internal controls. The Board then evaluates the information and ensures that measures are taken regarding the deficiencies and proposals that have emerged.

The company has no special internal audit function (internal audit). The Board has made the assessment that, given the company's size and scope of transactions, as well as the expertise in the area that the Board possesses and the Board's meeting with the auditor, there is no reason to establish a formal internal audit department.

### *The auditor's examination of the corporate governance statement*

**To the general meeting of the shareholders in Infant Bacterial Therapeutics AB (publ)  
corporate identity number 556873-8586**

#### **Engagement and responsibility**

It is the board of directors who is responsible for the corporate governance statement for the financial year 2022-01-01 - 2022-12-31 on pages 59-67 and that it has been prepared in accordance with the Annual Accounts Act.

#### **The scope of the audit**

Our examination has been conducted in accordance with FAR's standard RevR 16 *The auditor's examination of the corporate governance statement*. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

#### **Opinions**

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Stockholm 22 March 2023

Deloitte AB

*Signature on Swedish original*

Jenny Holmgren  
Authorized Public Accountant

## DEDUCTION OF CERTAIN KEY FIGURES

	2022 Jan-Dec	2023 Jan-Dec
<b>Cash flow per share</b>		
Cash flow for the period, 000's	-83 911	-55 532
Average number of shares	11 226 184	11 226 184
<b>Cash flow per share (SEK)</b>	<b>-7.47</b>	<b>-4.95</b>
<b>Equity per share</b>		
Equity, 000's	331 705	395 254
Number of shares at end of period	11 226 184	11 226 184
<b>Equity per share (SEK)</b>	<b>29.51</b>	<b>35.21</b>
<b>Equity ratio</b>		
Equity, 000's	331 705	395 254
Total equity and liabilities, 000's	349 619	408 478
<b>Equity ratio %</b>	<b>95%</b>	<b>97%</b>

## SHARES

On January 1, 2022 and December 31, 2022, respectively, the total number of shares amounted to 11 226 184 of which 377 736 class A-shares carrying ten votes and 10 848 448 class B-shares carrying one vote.

IBT's class B share was listed on Nasdaq Stockholm, Mid Cap, on September 10, 2018.

The number of shareholders amounted to 5 485 on December 31, 2022 according to Euroclear Sweden compared to 5 790 on December 31, 2021.

### Share price development

IBT's share price decreased from 66.80 SEK to 50 SEK during 2022. Market value as of December 31, 2022 amounted to 561 MSEK.

### Analysts covering IBT:

SEB: Christopher W. Uhde, PhD, Carl Mellerby, Mattias Vadsten

## Ownership December 31, 2022

Name	Class A-shares	Class B-shares	Share capital %	Votes %
ANNWALL & ROTHSCHILD INVESTMENT AB	377,736	510,478	8.09	29.31
SIX SIS AG, W8IMY	-	1,194,861	10.64	8.17
FJÄRDE AP-FONDEN	-	1,120,000	9.98	7.66
SWEDBANK ROBUR FONDER	-	540,000	4,81	3.69
AMF AKTIEFOND	-	501,585	4.47	3.43
TREDJE AP-FONDEN	-	501,579	4.47	3.43
SKANDINAVISKA ENSKILDA BANKEN	-	347,673	3.10	2.38
ÅLANDSBANKEN	-	331,390	2.95	2.27
UNIONEN	-	322,196	2.87	2.20
DANGOOR, DAVID	-	306,421	2.73	2.10
Total 10 largest shareholders	377,736	5,676,183	54.11	64.64
Other shareholders	-	5,172,265	45.89	35.36
<b>Total</b>	<b>377,736</b>	<b>10,848,448</b>	<b>100.00</b>	<b>100.00</b>

Source: Euroclear Sweden

## MANAGEMENT

### **Staffan Strömberg**

CEO since 2013. Born 1967.

M.Sc. in chemical engineering and Ph.D. in organic chemistry from the Royal Institute of Technology in Stockholm.

Staffan Strömberg has more than 20 years of experience in the pharmaceutical industry. Besides his roles at Billerud Tenova Bioplastics and at the Swedish Medical Products Agency, he has also been Vice President of NIcOx France, had various project management positions in AstraZeneca and been Head of R&D of Swedish Orphan.

Member of the Board of Directors of Eteboxagu AB and BioGaia Pharma AB.

Former CEO of Billerud Tenova Bioplastics AB and Head of Medical Devices at the Swedish Medical Products Agency.

Shareholding in the Company: 43 228 series B shares and 45,864 series B shares through the wholly owned company Eteboxagu AB and 50 000 warrants 2020/2024 and 120 000 warrants 2022/2025.

### **Anders Kronström**

Chief Operating Officer since 2018. Born 1967.

M.Sc., M.B.A.

Anders Kronström has over 20 years of experience working in the pharmaceutical industry. His experience spans across all stages of drug development in different disease segments. During his career at AstraZeneca he has had senior leadership positions within Project Management and Business Development. More recently, he was a CEO of Biosergen AS, a Norwegian biotechnology company.

Shareholding in the Company: 8 170 shares of series B and 40 000 warrants 2020/2024 and 75 000 warrants 2022/2025.

### **Maria Ekdahl**

Chief Financial Officer since 2022. Born 1973.

Master of Business Administration.

Maria has several years of financial background in both accounting and business controlling. She has experience in various organizations such as Coca-Cola, Telenor, Karolinska Hospital and the Swedish Film Institute.

Shareholding in the company: 250 shares of series B.

## **Robert Molander**

Chief Commercial Officer since 2022. Born 1965.

Robert holds an MBA from Washington University and two bachelor's degrees from Miami University in Economics and International Studies.

Robert has over 25 years of experience working in life science organizations launching and commercializing drugs in the US at companies such as Pfizer and Novartis. He has also served as an Executive Council Member at Harvard Medical School.

Shareholding in the company: 10 000 shares of series B and 20 000 warrants 2022/2025.

## **Professor Jonas Rastad, MD, Ph.D.**

Chief Medical Officer since 2019. Born 1950.

Jonas has in excess of 20 years of experience as academic surgeon and has published 250 articles in peer review-magazines. He has held several leading positions at AstraZeneca in Sweden, Japan, The UK and USA. In addition, he has 13 years of experience of public leadership positions, among other head of the Kalmar regional hospital, Västerbottens county council and CEO of Region Skåne.

Shareholding in the Company: None

## **BOARD OF DIRECTORS**

IBT's Board of Directors consists of five ordinary members, including the chairman of the board, with no deputy board members, all of whom are elected for the period up until the end of the annual shareholders' meeting 2022.

## **Peter Rothschild**

Chairman of the Board since 2011. Born 1950.

Master of Business Administration from Stockholm School of Economics.

Founder and Chairman of the Board of Directors of BioGaia AB, BioGaia Pharma AB and Annwall & Rothschild Investments AB. Board member of Allbright.

Previously CEO of BioGaia (publ) and member of the Board of Directors of Moberg Pharma AB (publ).

Shareholding in the Company: 377,736 series A shares and 510,478 series B shares through Annwall & Rothschild Investments AB, a company co-owned with Jan Annwall.

## **Margareta Hagman**

Board member since 2015. Born 1966.

Master of Business Administration, Örebro University.

Advisor and consultant in business, accounting and finance.

Previous positions: Deputy CEO and CFO of BioGaia AB (publ). Member of the Board of Tagmaster AB.

Shareholding in the Company: 3,570 series B shares.

## **Eva Idén**

Board member since 2017. Born 1966.

Civil engineer in chemistry, Chalmers tekniska högskola.

Chairman of the board of Better & Beyond AB.

Previously held management positions at AstraZeneca AB.

Shareholding in the company: 51 series B shares.

## **Anthon Jahreskog**

Board member since 2017. Born 1980.

Candidate degree in Management and systems, City University, London. Bachelor of business administration, Master of science in financial management at University of Cape Town.

Board member of BioGaia AB (publ) and Fast Track Holdings Ltd.

Until July, 2015 Chief Operating Officer, Fund Linked Products, Credit Suisse Investment bank, London. Anthon is a business strategy consultant in several industries.

Shareholding in the company: 3 200 series B shares.

## **Kristina Sjöblom Nygren**

Board member since 2018. Born 1961.

Kristina has received a Doctor of Medical Sciences from Karolinska Institutet and is a licensed physician.

She is Chief Medical Officer, Head of Clinical Development, since May 2021 at Egetis Therapeutics AB (publ) in Stockholm. Kristina Sjöblom Nygren has extensive experience from the pharmaceutical industry, where she has held among other positions Chief Medical Officer, Head Development at Santhera Pharmaceuticals in Basel and Head of Clinical Development at SOBI in Stockholm.

Shareholding in the company: 100 series B shares.



### **Contact Persons**

Staffan Strömberg, CEO  
Maria Ekdahl, CFO

### **Contact Information**

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