



Infant Bacterial Therapeutics AB

Annual Report 2018

We aim to satisfy unmet medical needs in the premature infant

Significant events 2018

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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 traded on Nasdaq Stockholm, Mid Cap, since September 10, 2018 (IBT B).

IBT has, resulting from discussions with the FDA on November 20, 2018, chosen to modify its phase III study in premature infants. Following the guidance from the FDA, IBT will improve the protocol which may allow additional claims such as improvement of "feeding tolerance", that could increase the chance of success in the Company's phase III study and the market potential of the product.

Infant Bacterial Therapeutics AB (publ)

Annual Report January 1 – December 31, 2018

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The Annual Report is published on IBT's website, ibtherapeutics.com and is distributed in printed form on request. A printed copy can be requested by sending a mail to info@ibtherapeutics.com. This is a translation of IBT's Swedish Annual Report 2018, which is the original.



Company Presentation

IBT is a pharmaceutical company with its registered office in Stockholm with a vision to develop drugs influencing the human infant microbiome, and thereby prevent or treat rare diseases affecting premature infants. IBT is currently developing its lead drug candidate IBP-9414, to prevent NEC and improving feeding tolerance in premature infants. IBP-9414 contains the active compound *Lactobacillus reuteri*, which is a human bacterial strain naturally present in breast milk. IBT is further pursuing a second rare disease program IBP-1016 for the treatment of an unmet medical need in gastroschisis, a severe disease in infants. By developing these drugs, IBT has the potential to fulfil unmet needs for diseases where there are currently no prevention or treatment therapies available.

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 has a vision to become an internationally recognized and leading company in the development of therapies to prevent or treat diseases of the premature infants.

Mission

IBT develops, and intends to market and sell safe and efficacious therapies well adapted to its purpose that affects infants' microbiome and thereby prevent or treat rare diseases that affects premature infants. IBT seeks to remain close to the needs expressed by healthcare providers and parents to provide satisfactory therapeutic solutions and continuously improve its offering.

Partners

IBT does not currently have in-house research or manufacturing sites. Instead, research is conducted through collaborations with external leading academic research groups and organizations, and product development takes place in co-operation with external service providers and CMOs, that carry out small- and largescale quality-assured production for clinical trial supply. The management of clinical studies is carried out by a CRO selected for their experience and expertise in conducting clinical trials.

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 IBP-9414 manufacturing process
- ▶ 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 Paediatric Investigational Plan proposed by IBT for the development of IBP-9414 for the prevention of NEC

2018

- ▶ The EGM decided on a new share issue amounting to SEK 439.1m prior to transaction costs and the share issue was fully subscribed.

- ▶ 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 traded on Nasdaq Stockholm, Mid Cap
- ▶ IBT has, resulting from discussions with the FDA chosen to modify its phase III study for the prevention of necrotizing enterocolitis (NEC) in premature infants. Following the guidance from the FDA, IBT will improve the protocol which may allow additional claims such as improvement of "feeding tolerance", that could increase the chance of success in the Company's phase III study and the market potential of the product.

Message from the CEO

IBT passed several significant milestones in 2018. The capital raise which commenced during 2017 was concluded during the year. The company generated SEK 439m in a preferential new share issue, which together with the directed new share issue we performed in 2017 generated SEK 544m to the company.



With the confidence IBT's shareholders have shown, IBT deems that the remainder of the development program for IBP-9414 is now financed up to the point of market approval, which we are working hard to achieve. As a significant part of the costs for conducting the study will be in USD, we chose to hedge the currency by buying USD in April which has significantly reduced the currency risk for IBT.

As previously communicated, IBT met with the American Food and Drug Administration

(FDA) on November 20, 2018, to discuss IBT's clinical development program. The development program consists of the safety and tolerance clinical phase II trial concluded in 2017 and the pending clinical phase III trial, which we have named "The Connection Study".

The meeting with the FDA was productive and, among other things, IBT received guidance regarding possible improvements in the study. Discussions during the meeting addressed the fact that the primary endpoint of the study solely included observations regarding NEC, in spite of the fact that our pharmaceutical candidate IBP-9414 also may show other clinically relevant effects which may benefit premature infants such as so-called feeding tolerance. To put the need in perspective, a significant number of premature infants with birth weight below 1,500 grams have problems related to feeding. The pharmaceutical candidate is designed for prophylactic use in all premature infants with birth weight below 1,500 grams.

Since the FDA meeting, we have added parameters to our clinical program related to feeding tolerance. This means that the study currently contains a number of endpoints, so called multiple endpoints, covering both NEC and feeding intolerance. Having multiple endpoints enables us to achieve positive results from the study even if one endpoint might fail. In practice, this means that the study has greater chances of success. Hopefully, the results from the study will demonstrate that our product both reduces the risk for infants will get NEC and further that infants also will demonstrate improved use of nutrients.

Modifications of the study result in the addition of 102 infants, thereby recruiting in total 2,158 infants, versus the previously planned total of 2 056 infants. Notably, the modifications to the protocol will not result in significantly increased costs, and thus IBT's development program is financed until a possible market approval. The company's goal is to file for market approval for IBP-9414 in 2021.

IBT has also made other preparations for the commencement of The Connection Study, among other milestones, resulting in agreements with clinics in the USA, Europe, and in Israel where we will conduct the study. We have also developed and enhanced our cooperation with Premier Research, our Contract Research Organization, to conduct the study. Furthermore, we have produced the clinical trial material for the study and strengthened our own organization to meet the requirements of IBT in the coming years.

In 2018, IBT also made a listing change to Nasdaq Stockholm. IBT's class B-shares are now traded on the main list under the "mid-cap" segment.

Finally, it should be mentioned that we continuously evaluate potential marketing and distribution partners. In March 2019, this work resulted in concluding an agreement regarding the distribution of IBP-9414 in Israel. The agreement provides IBT with the long-term opportunity to benefit from the majority of future income from sales of IBP-9414 in Israel.

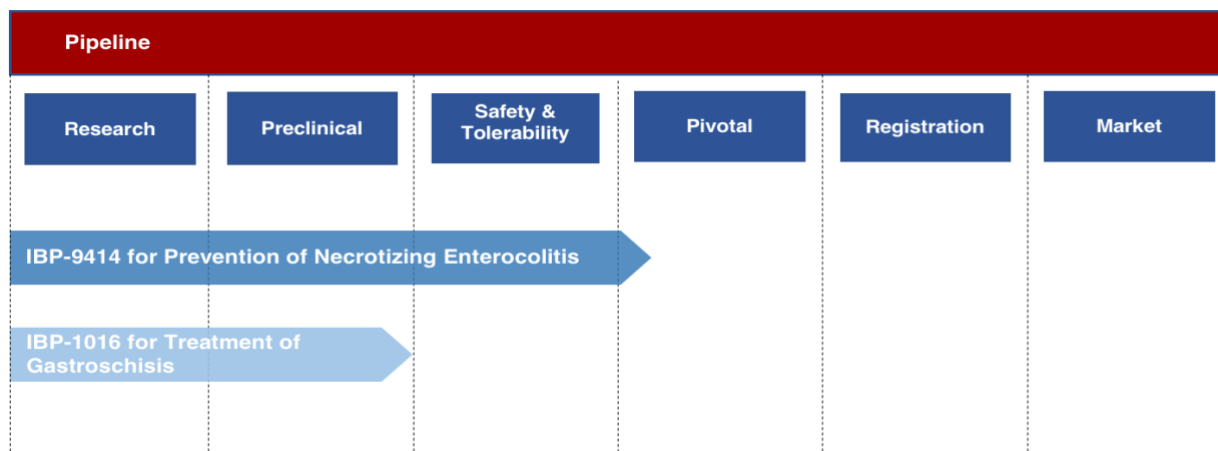
I have great expectations for 2019. We will be able to commence the concluding part of our development program and hopefully be able to offer the medical community a new method to save human lives.

Stockholm April 4, 2019-04-04

Staffan Strömberg

CEO

IBTs Pipeline



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 for the 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, meaning that IBT may be awarded a priority review voucher following market approval.

In June 2016, IBT commenced the Safety and Tolerability study. The completed study results demonstrate a similar safety and tolerability profile 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. Following the guidance from the FDA, IBT will improve the protocol which may allow additional claims such as improvement of “feeding tolerance”, that could increase the chance of success in the Company’s phase III study and the market potential of the product.

The pivotal phase III study, The Connection study, is planned to commence in the first half of 2019.

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 single most significant risk factor for the development of NEC is the degree of prematurity of the infant, with lower birth weight and lower gestational age increasing the risk for the disease. Occurrence of NEC by estimated gestational age is as set forth in Figure 1.

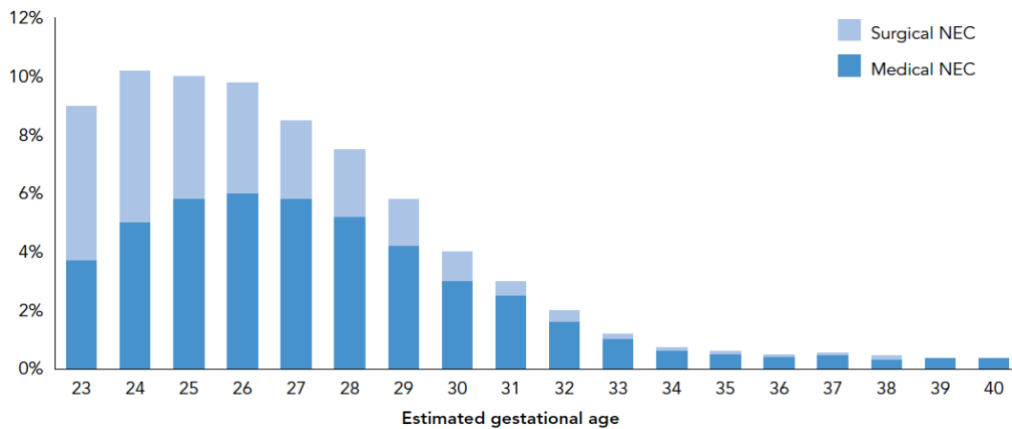


Figure 1. Occurrence of NEC by gestational age (Clark et al, 2012)

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.

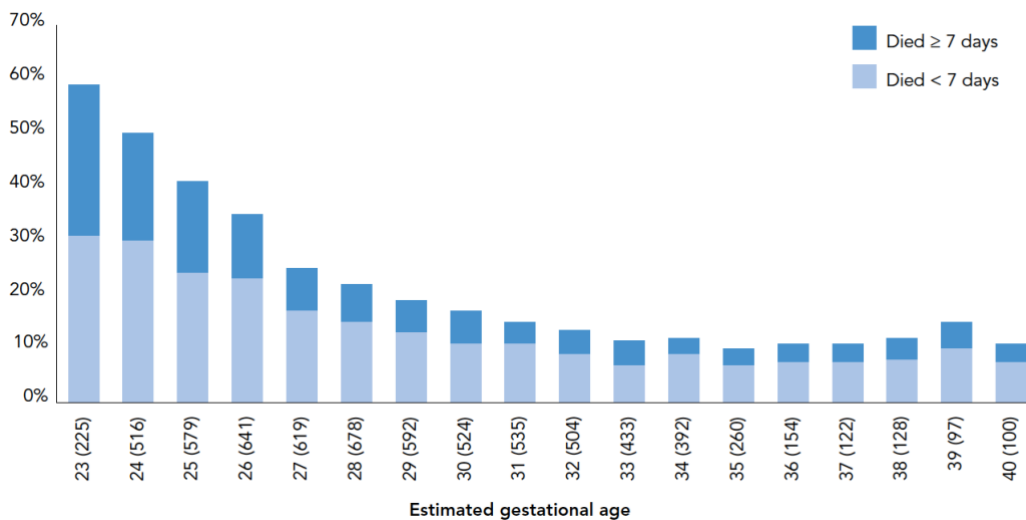


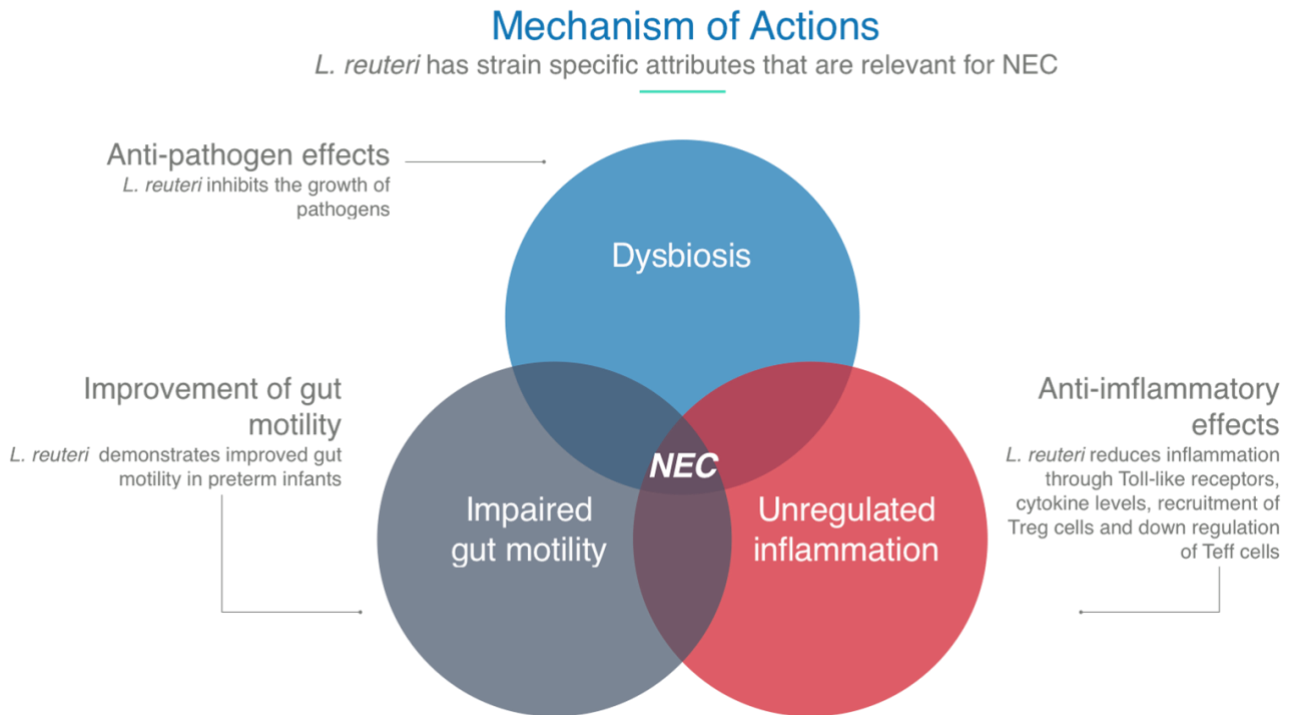
Figure 2. Mortality in infants who had a diagnosis of NEC by estimated gestational age (Clark et al, 2012)

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.

L. reuteri

L. reuteri 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.



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 infants with a birthweight of under 1,500 grams recommend starting parenteral nutrition (intravenous) within the first hours postnatally as the immature gastrointestinal tract is not ready to accept full enteral feedings in these infants directly after birth. 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 with the goal of reaching full volume feedings to support growth as quickly as clinically feasible in combination with the termination of parenteral nutrition. This not only eliminates the need for parenteral nutrition and the associated risks of complications, but also the administration of enteral feed in the developing gut has long been known to combat intestinal atrophy. Establishing sustained enteral feeding, associated with the discontinuation of parenteral nutrition is thus one of the most important goals, especially in infants with a birthweight under 1,500 grams. Reducing the number of days to reach this goal is considered to be clinically important in the development of the preterm infant.

Clinical Experience

Since 2012, ten published clinical trials that enrolled more than 2,800 infants has indicated proof-of-concept of the clinical potential of *Lactobacillus reuteri* to prevent NEC.

The table below shows a summary of studies using *Lactobacillus reuteri* showing clear clinical signal for the reduction in NEC incidence.

NICU Study	Number of Patients	Control	With L. reuteri	Reduction of NEC incidence
Rojas et al. 2012	750	5,4 % ↘	3,4 %	40 %
Oncel et al. 2014	400	5,0 % ↘	4,0 %	20 %
Oncel et al. 2015	300	6,0 % ↘	4,7 %	22 %
Speckels et al. 2018	104	9,0 % ↘	4,0 %	53 %
Hunter et al. 2012/Dimaguila et al. 2013	354	15,1 % ↘	1,6 %	89 %
Sanchez-Alvarado 2017	225	14,6 % ↘	5,3 %	64 %
Rolnitsky et al. 2017	937	6,0 % ↘	2,9 %	49 %
Jerkovic-Raguz et al. 2016	100	8,0 % ↘	4,0 %	50 %
Shadkam et al. 2015	60	36,7 % ↘	6,7 %	82 %
Hernandez-Enriquez et al. 2016	44	25,0 % ↘	4,2 %	92 %

Since 2012, four published clinical trials that enrolled more than 2,000 infants has indicated proof-of-concept of the clinical potential of *Lactobacillus reuteri* to improve feeding tolerance.

The table below shows a summary of studies using *Lactobacillus reuteri* showing clear clinical signal for the reduction in feeding intolerance episodes.

NICU Study	Number of patients	Results
Rojas et al. 2012	750	34% reduction in episodes of feeding intolerance (p=0.08)
Oncel et al. 2014	400	29% reduction in episodes of feeding intolerance (p=0.015)
Oncel et al. 2015	300	36% reduction in episodes of feeding intolerance (p=0.004)
Rolnitsky et al. 2018	937	52% reduction in episodes of feeding intolerance (p<0.01)

Development Plan

The development plan for IBP-9414 consists of two clinical trials: the completed safety and tolerability study followed by the planned pivotal phase III study, The Connection Study. The safety and tolerability study, has been completed on time in Q4 2017. The Connection Study is expected to be initiated in the first half of 2019.

The first study was a randomized, double blind, parallel-group, dose escalation placebo-controlled multicentre study to investigate the safety and tolerability of IBP-9414 administered 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 study demonstrated that treatment with IBP-9414 leads to presence of *Lactobacillus reuteri* in the feces on the day of the last dose and that 30 days after the last dose, the bacteria have been washed out. 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. With these results in hand, the IBP-9414 clinical development program is now moving forward into The Connection Study.

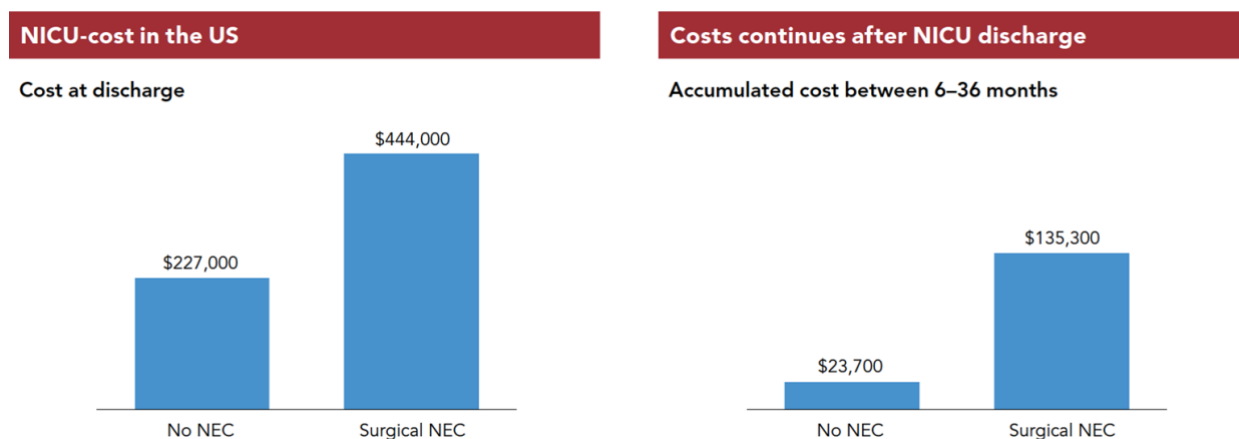
The Connection Study is designed to demonstrate and document efficacy of IBP-9414 over placebo in the prevention of NEC and improvement of feeding tolerance in premature infants with a birth weight \leq 1,500 grams. This study will also include safety evaluation.

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. Submission for market approval for IBP-9414 is targeted to be in 2021.

Medical Needs and Expenditures

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 such as IBP-9414 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 September 2016 an independent consultant company, ClearView Healthcare Partners LLC ("ClearView"), were commissioned by IBT to evaluate the market need for the preventative drug IBP-9414 for NEC (the "ClearView Report"). ClearView completed 31 interviews with neonatologists and hospital Pharmacy and Therapeutics ("P&T") committee members in the US.

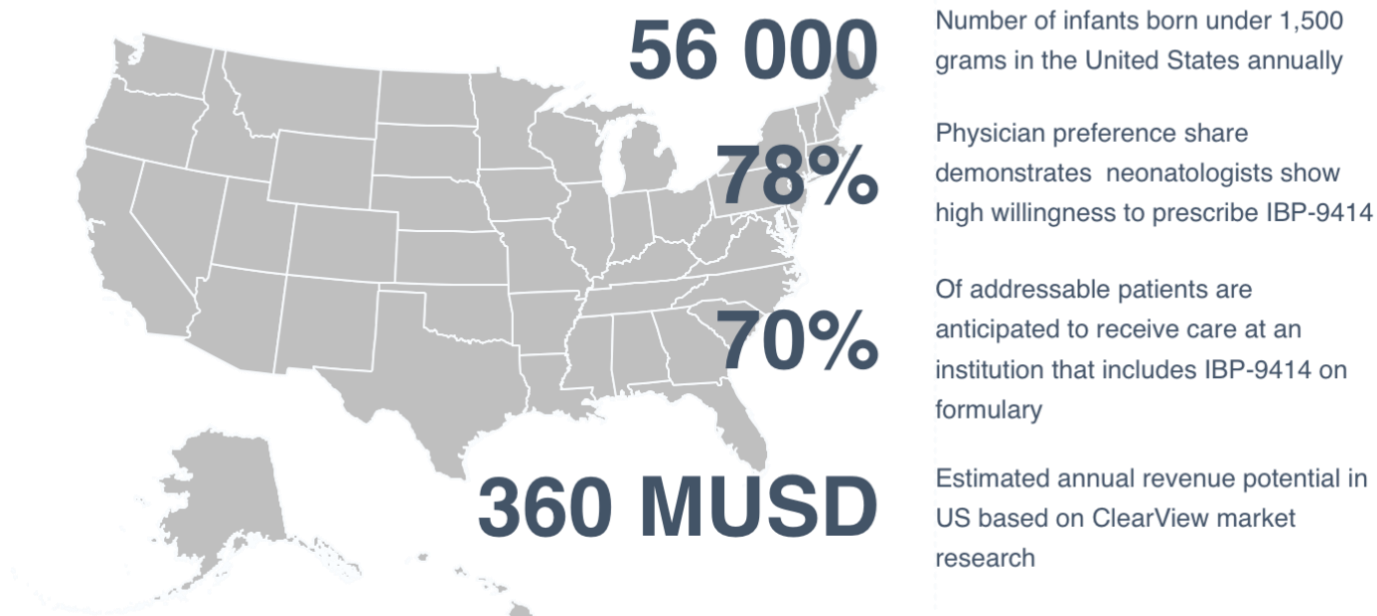
The Clearview report established that neonatologists perceive NEC to represent a key priority despite its low incidence. The neonatologists nearly unanimously stated a need for improved prevention of NEC to relieve both the clinical and economic burdens.

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

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 (78 percent of Physician Preference Share), and a majority of P&T members expressed willingness to adopt the product on hospital formulary. In the ClearView Report from 2016 it is estimated that the number of premature infants eligible to receive prophylaxis for NEC is over 56,000 infants in the US. In the Clearview Report, an adapted age dependent price range was tested. Assuming a price of USD 3,000 per week of treatment until the infant reaches 34 weeks PMA, Clearview estimates 48 percent market penetration and sales to be USD 360 million per year in the USA. The analysis considered number of addressable patients, physician preference scores, formulary inclusion and protocol access.

A valuable pharmaceutical

Results of market analysis by ClearView Healthcare Partners



1 500 infants die from NEC in the United States each year

In addition to the expected effects that IBP-9414 will have on NEC, the company expects to see an effect on feeding tolerance in the same patient population.

Improvements in feeding tolerance is an important part of treating premature infants. Considering the psychological and economic benefit to the entire family of allowing the release of the infant to the family at home, together with the reduction in costs for society for each hospital day saved, a reduction in the number of days in hospital for the infant is of major clinical, familial and economic importance.

Expected improvements in feeding tolerance due to IBP-9414 and associated improved growth and development of the preterm infant are expected to lead to a reduced number of days of hospitalization. Evidence from earlier clinical experience in randomized, controlled

clinical trials in the target population show that duration of hospitalization in the target population was significantly reduced with the same strain of *L. reuteri* delivered by IBP-9414.

Length of hospital stay is a strong marker for resource utilization. The costs of hospitalization are significantly higher, and the length of hospital stay are more than 6-fold greater for infants born <1000g birth weight, than for their late preterm counterparts and the costs for an extremely premature (<28 weeks gestational age) infant in a US NICU were estimated to be around \$3200 per day.

The enteral route 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 with the goal of reaching full volume feedings. This eliminates the need for parenteral nutrition and the associated risks of complications. 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 goal of achieving early and adequate enteral nutrition 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.). Establishing sustained enteral feeding, associated with the discontinuation of parenteral nutrition is thus one of the most important goals.

IBT intends to evaluate the market potential of the IBP-9414 within the additional indication area feeding tolerance.

IBP-1016

Gastroschisis is a rare, life-threatening and debilitating birth abnormality in late preterm 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.

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, after those years 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 also filed for further patent protection relating to the improvement of the formulation of IBP-9414. The patent is currently pending and aims to further protect IBP-9414 until 2036.

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, 2018 to December 31, 2018.

This financial report is IBT's third annual report prepared in accordance with RFR 2, Reporting for legal entities and "Årsredovisningslagen".

Operations

Infant Bacterial Therapeutics AB (publ) ("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 infants. Utilizing its extensive experience in treatment with live bacteria and developed knowledge of mechanisms in *Lactobacillus reuteri*, IBT is currently developing its lead drug candidate IBP-9414 to prevent necrotizing enterocolitis (NEC), and improving feeding tolerance affecting premature infants. IBT is further pursuing a second rare disease program IBP-1016 for the treatment of an unmet medical need in gastroschisis, a severe disease in infants. By developing these drugs, IBT has the potential to fulfil unmet needs for diseases where there are currently no prevention or treatment therapies available.

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

Significant Events During the Reporting Period January – December 2018

- On January 8, 2018, the EGM decided on a new share issue amounting to SEK 439.1m prior to transaction costs and on January 31 it was fully subscribed
- On May 15, 2018, the annual general meeting elected Kristina Sjöblom Nygren and Lilian Henningson Wikström as new board members, and Jan Annwall resigned from the board
- In June 2018, IBT contracted Premier Research International LLC, the Company's CRO (Contract Research Organization) during the phase II clinical trial, to also conduct the Company's phase III clinical trial
- IBT series B shares are traded on Nasdaq Stockholm, Mid Cap, since September 10, 2018 (IBT B)
- IBT has, resulting from discussions with the FDA on November 20, 2018, chosen to modify its phase III study for the prevention of necrotizing enterocolitis (NEC) in premature infants. Following the guidance from the FDA, IBT will improve the protocol which may allow additional claims such as improvement of "feeding tolerance", that could increase the chance of success in the Company's phase III study and the market potential of the product.

Significant Events After the Reporting Period

- IBT has on March 5, 2019, signed the first distribution agreement for IBP-9414 with MegaPharm Ltd., for the Israeli market and the Palestinian Authority's territories. The agreement gives MegaPharm exclusive rights to market and sell the product, if and when the product receives market approval. IBT's share will, after an initial shorter period, account for 70% of revenues. IBT plans to open clinical trial centers for the pivotal phase III trial in the country. MegaPharm is already participating in this work as it is essential to engage "key opinion leaders" in the marketing of the product.
- No other significant events have occurred after the reporting period

Selected Financial Data

ooo's	2018	2017
	Jan-Dec	Jan-Dec
Net sales	-	238
Operating profit/loss	-39 417	-36 141
Result after tax, SEK	-40 607	-36 156
Total assets	563 371	175 024
Cash flow for the period (SEK)	381 544	64 488
Cash flow per share for the period (SEK)	35.36	11.53
Cash	542 170	158 274
Earnings per share before and after dilution (SEK)	-3.76	-6.05
Equity per share (SEK)	49.59	25.50
Equity ratio (%)	99%	96%

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.

Financial development

Operational result amounted to -39 417 (-36 141) KSEK and result after financial items amounted to

-40 607 (-36 156) KSEK.

Result after tax amounted to -40 607 (-36 156) KSEK.

Result per share amounted to -3.76 (-6.05) SEK before and after dilution (no dilution effects exist).

Costs

Costs for the planned clinical IBP-9414 clinical trial are reported net of exchange rate gains on foreign currency forward contracts and currency deposits. Exchange rate gains during the reporting period amounted to 12 009 (0) KSEK (Note 2).

Operational costs amounted to 51 426 (36 379) KSEK prior to exchange rate gains on foreign currency forward contracts and currency deposits amounting to 12 009 (0) KSEK, and after exchange rate gains amounted to 39 417 (36 379) KSEK, of which costs for the planned IBP-9414 clinical trial amounted to

28 747 (17 482) KSEK and after exchange rate gains amounted to 16 738 (17 482) KSEK.

Personnel costs amounted to 13 342 (12 595) KSEK. The comparative period included a bonus payment amounting to approximately SEK 2.4m. IBT had 8 (6) full time equivalent employees at the end of the reporting period.

Other external costs amounted to 9 337 (6 317) KSEK. New share issue costs amounted to SEK 10.2m (6.1) charged directly to shareholders equity.

Operational costs during the reporting period are higher than during the same period in the previous year as the company's phase II clinical trial was concluded during the first half of 2018 and costs for the planned phase III clinical trial exceeded clinical costs during the previous year.

Other external operational costs increased during the reporting period compared to the previous year resulting from costs incurred relating to the listing change to Nasdaq Stockholm in the amount of approximately SEK 2.0m and business development costs amounting to approximately SEK 1.6m.

Personnel costs have increased during the reporting period in comparison to the equivalent period during the prior year (disregarding the bonus payment during the comparative period) due to staff recruitment required for conducting the clinical phase III trial.

Result and financial position

Cash flow for the period amounted to 381 544 (64 488) KSEK. Cash flow 2018 included a new share issue in the amount of SEK 429.0m (98.4). Cash flow per share amounted to 35.36 (11.53) SEK. Cash flow per share less the new share issues amounted to -4.40 (-6.06) SEK.

The Company's cash balance on December 31, 2018, amounted to 542 170 KSEK compared to 158 274 KSEK on December 31, 2017.

The Company's shareholder's equity on December 31, 2018, amounted to 556 717 KSEK compared to 168 371 KSEK on December 31, 2017. Shareholder's equity per share amounted to 49.59 compared to 25.50 SEK on December 31, 2017.

The Company's equity ratio amounted to 99% compared to 96% on December 31, 2017.

IBT has during November 2017 generated SEK 104.5m in a directed new share issue to institutional investors. In January 2018, a preferred new share issue generated SEK 439.1m. Capital thus generated amounting to approximately SEK 543.6m prior to transaction costs and approximately SEK 528m less transaction costs is deemed sufficient to conduct the planned phase III clinical study, as well as to fund the company's activities until market approval.

Prospects for 2019

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 planned 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" is planned to commence during the first half of 2019.

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 been granted IBT an exclusive license to the BioGaia patent for use *Lactobacillus reuteri*, DSM17938, in developing of a medicinal remedy for treatment of premature infants. There are no royalties payable by IBT to BioGaia when commercializing IBT's pharmaceutical candidates.

The main patent protection for IBP-9414 is the product claim for the use of a specific strain of *Lactobacillus reuteri*. This is a claim-type which is often referred to as "unlimited product protection" similar to that used for new chemical entities in the relation to small-molecules based products in the pharmaceutical industry. Patents including a product claim for the strain are issued in most important markets. The patent protection granted in the USA, China and Japan are valid until 2026 and in Europe until 2027. After those years patent term extensions are possible in certain areas of the world which could provide additional patent protection of the innovation.

IBT has also applied for further patent protection relating to IBP-9414 which is currently pending and aim to further protect IBP-9414 until 2036.

There is an inherent risk within the type of business that IBT conducts that the company's licenses, patents, trademarks or other non-tangible assets do not provide sufficient protection for the company, or the company's rights may not be upheld. Furthermore, patent infringement may occur which may involve costly litigation. Results from infringement cannot be guaranteed. Negative outcome from litigation regarding non-tangible assets may cause the losing party to lose protection, future use of said rights being prohibited, or the obligation to pay for damages. The company has filed patent applications for products under development, which have not yet been granted. There is no guarantee that such applications will be granted.

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 identified a number of contract manufacturers 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

IBT's operations are capital intensive.

IBT has during November 2017 generated SEK 104.5m in a directed share issue to institutional investors and SEK 439.1m in a preferred share issue in January 2018. Capital generated amounted to approximately SEK 544m before share issue costs and approximately SEK 528m after share issue costs, and is deemed sufficient to conduct the planned phase III study, and operational costs for one year after conclusion of the study.

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. During April 2018, IBT purchased 4.5 MUSD for placement on account, and 13.5 MUSD in foreign exchange forward contracts for the duration up to 12 months hedging such expenses (Notes 2 and 10).

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.

IBT has declared taxable losses which may be nullified should the company be subject to new ownership controlling in excess of 50% of the votes of the company, or new owners who each control in excess of 5 % of the votes and collectively control in excess of 50% of the votes of the company. Nullification of these taxable losses would result in economic loss for IBT which may have a negative impact on the company's results and financial position.

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

Environmental Responsibilities

The Company's operations do not cause 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 should be a part of our daily work 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 2018 is published on the Company's webpage 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.

Agenda

Interim report January – March 2019	May 6, 2019
Interim report January – June 2019	August 21, 2019
Interim report January - September 2019	November 7, 2019

Annual General Meeting

The Annual General Meeting for IBT will be held on May 6, 2019 at 15.00 CET at Svenska Läkaresällskapet on Klara Östra kyrkogata 10, 111 52 Stockholm.

The Annual Report for 2018 will be available on April 4 on the Company's homepage www.ibtherapeutics.com

Board of Directors Recommendation of Appropriation of Profits

SEK	2018
Recommendation of appropriation of profits or loss	
The Board of directors propose that the following surplus:	
Income carried forward	-72 903 621
Surplus reserve	667 166 892
Result for the period	-40 607 018
Total	553 656 253
be appropriated as follows:	
Income carried forward	553 656 253
Total	553 656 253

The board of directors recommend that no dividend be paid for fiscal year 2018.

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	2018 Jan-Dec	2017 Jan-Dec
Net sales		-	238
Research and development costs	2,3,4	-39 417	-36 379
Operating loss		-39 417	-36 141
Result from financial items			
Interest income and similar profit/loss items		327	-
Interest expense and similar profit/loss items		-1 517	-15
Result after financial items		-40 607	-36 156
Result for the period *		-40 607	-36 156

* Result for the period equals total comprehensive income

Result Per Share

SEK	2018 Jan-Dec	2017 Jan-Dec
Result per share		
Result per share, before and after dilution*	-3,76	-6,05
Number of shares, weighted average*	10 788 914	5 595 305
Number of shares at end of period **	11 226 184	6 603 638

*Issue price at the share issue in February 2018 amounted to SEK 95 per share which corresponded to approximately 84 percent of the fair value of the share at time of issue. Bonus share element was considered when calculating result per share before and after dilution, resulting in restatement of comparative figure (positive effect amounting to SEK 0.41 in 2017). There are no other dilution effects

**On December 31, 2018, 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	2018-12-31	2017-12-31
ASSETS			
Non-current assets			
<i>Intangible non-current assets</i>			
Activated development costs	6	13 782	14 598
Shares in subsidiary	7	50	50
Total non-current assets		13 832	14 648
Current assets			
<i>Current receivables</i>			
Other receivables	8	7 114	994
Prepaid expenses and accrued income	9	255	1 108
Total current assets		7 369	2 102
Cash and cash equivalents	10	542 170	158 274
Total current assets		549 539	160 376
TOTAL ASSETS		563 371	175 024
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital		3 060	1 800
<i>Unrestricted equity</i>			
Share premium reserve		667 167	239 474
Accumulated losses		-72 903	-36 747
Net loss for the period		-40 607	-36 156
Total equity		556 717	168 371
Liabilities			
<i>Current liabilities</i>			
Accounts payable		3 507	506
Other current liabilities		752	166
Accrued expenses and prepaid income	11	2 395	5 981
Total current liabilities		6 654	6 653
TOTAL EQUITY AND LIABILITIES		563 371	175 024

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
Opening equity on Jan 1, 2017	1 500	140 473	-36 747	105 226
Net loss for the period			-36 156	-36 156
Total comprehensive income			-36 156	-36 156
Shareholder transactions				
Share issue	300	104 200		104 500
Share issue costs		-6 083		-6 083
Warrants		884		884
Closing equity on Dec 31, 2017	1 800	239 474	-72 903	168 371
Opening equity on Jan 1, 2018	1 800	239 474	-72 903	168 371
Net loss for the period			-40 607	-40 607
Total comprehensive income			-40 607	-40 607
Shareholder transactions				
Share issue	1 260	437 882		439 142
Share issue costs		-10 189		-10 189
Closing equity on December 31, 2018	3 060	667 167	-113 510	556 717

Statement of Cash Flows

SEK 000	2018 Jan-Dec	2017 Jan-Dec
Operating activities		
Operating profit/loss	-39 417	-36 141
Interest income received	327	-
Paid interest costs	-1 517	-15
Adjustment for non - cash flow affecting items:		
Depreciation production process	816	816
Value variance currency forward contracts	-8 752	-
Cash flow from operating activities before changes in working capital	-48 543	-35 340
Cash flow from changes in working capital		
Increase (-)/Decrease (+) in operating receivables	1 133	-1 193
Increase (+)/Decrease (-) in operating liabilities	1	1 770
Cash flow from operating activities	-47 409	-34 763
Investment activities		
Acquisition of non-current assets	-	-50
Financing activities		
Share issue	439 142	104 500
Share issue costs	-10 189	-6 083
Warrants	-	884
Cash flow from financing activities	428 953	99 301
Cash flow for the period	381 544	64 488
Unrealized exchange rate difference in cash	2 352	-
Cash and cash equivalents at the beginning of the year	158 274	93 786
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	542 170	158 274

Notes

Note 1 Accounting principles

This financial report is the third annual report by IBT 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 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 §".

A number of new or revised standards, interpretations and improvements have been adopted by the EU and from January 1, 2018, IFRS 9 Financial instruments and IFRS 15 Revenue from Contracts with Customers apply.

IFRS 9 Financial Instruments deals with the classification, measurement and recognition of financial assets and liabilities. It replaces IAS 39 which relate to the classification and measurement of financial instruments and recognition of financial assets and liabilities. The significant amendments are among classification and valuation, impairment and hedging accounting. The company has not adopted hedging accounting.

IFRS 9 retains a mixed approach to measurement but simplifies the approach in some respects. There are three measurement categories for financial assets, accumulated cost, fair value through other comprehensive income and fair value through profit and loss. How an instrument should be classified depends on the company's business model for reporting the financial asset and cash flow character.

Assets measured at accumulated cost or fair value through other comprehensive income are subject to the regulations regarding write downs. IFRS 9 applies a model for expected credit losses contrary to IAS 39 which applies to actual loss events.

The transition to IFRS 9 did not have significant monetary impact on IBT's financial position or result.

Adoption of IFRS 15 has not had any impact on the financial statements of IBT as the company has not yet concluded any customer contracts that would be subject to IFRS 1. Effects may however impact future financial reports.

IFRS 16 Leases. In January 2016, the IASB published a new leasing standard that will replace IAS 17 Leases and the related interpretations, IFRIC 4, SIC-15 and SIC-27. The standard requires that assets and liabilities attributable to all leases, with a few exceptions, be recognized in the balance sheet. This accounting treatment is based on the view that the

lessee has a right to use an asset during a specific period of time as well as an obligation to pay for this right. For the lessor, the financial reporting will remain essentially unchanged. The standard is applicable for financial years beginning on January 1, 2019 or later. Early application is permitted. IBT presents financial reports for the corporate entity and has thus chosen not to adopt the leasing standards according to IFRS 16. IBT presents in accordance with items 2-12 in RFR 2 and leasing costs are reported as in the past, linear over the term of the lease.

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

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.

Loans receivable and accounts receivable and other financial liabilities are reported after the time of acquisition to accrued cost applying the effective interest method.

Financial assets and liabilities are offset and reported at net value in the balance sheet, only when the legal right exists to offset the reported amounts, and the objective exists to settle the amounts with a net value, or to simultaneously realize the asset and settle the liability.

The Company evaluates at the end of each reporting period if there is any objective evidence existing for impairment of a financial asset or group of financial assets. A financial asset or group of financial assets are subject to impairment when, and are impaired only if objective evidence exists for impairment resulting from one or several incidents taking place after the initial reporting of the asset, and that the incident has impact on the estimated future cash flows for the financial asset or group of financial assets which may be estimated reliably.

Impairment is calculated as the difference between the reported value of the asset and current value of future estimated cash flows discounted at the financial assets original effective interest.

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
- the Company has adequate recourses in accordance with its current finance plan to complete development
- the cost of the asset can be reliably measured

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.

IBTs taxable losses amount to approximately 142 (91) 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.

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.

Financial assets and liabilities valued at fair value in the income statement:

Financial instruments in this category are comprised of foreign exchange forward contracts and are valued at fair value with changes in value reported in the income statement for the period. Valuations are performed by discounting cash flows and is based on the forward exchange rate on the balance sheet date compared to the contractual forward exchange rate. All derivatives are valued at hierarchy level 2.

Value variance in purchased forward contracts and currency deposits are presented in the following table:

Foreign exchange forward contracts - income effect*, SEK 000's	2018-04- 18-2018- 12-31	2017-12- 31
Purchases of USD forward contracts and deposit on currency account on 2018-04-18		
Forward contracts USD 9.0m, as of Dec 31, 2018	-73 743	-
Forward contracts USD 9.0m, on balance sheet date	80 143	-
Unrealized exchange rate gains/losses	2 352	
Realized exchange rate gains/losses	3 257	-
Result	12 009	0

* Purchased forward contracts and currency refer to mitigate risk related to the planned phase III clinical trial in the pharmaceutical drug candidate IBP-9414. The income effect is reported in the income statement item R&D. Result during the reporting period refer to unrealized exchange rate gains on Forward contracts amounting to approximately SEK 6.4m (Other current receivables approximately SEK 7.1m) and exchange rate gains in USD held on deposit amounting to approximately SEK 5.6m. Foreign exchange forward contracts entered into on April 18, 2018 amounted to USD 13.5m of which USD 4.5m expired during the fourth quarter.

Note 3 Leasing

IBT carries no financial leasing agreements. Leasing costs related to operational leasing are charged at cost over the leasing period.

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

Operational leasing	2018-12-31	2017-12-31
000's		
Due for payment within one year	965	918
Due for payment within one and five years	1 132	2 376
Total	2 097	3 294

Operational leasing costs during the year	2018-12-31	2017-12-31
000's		
Rent	718	590
Parking	119	122
Automobiles	249	245
Total	1 086	957

Note 4 Personnel

	Average number of employees			Average number of employees		
	2018	Actual on Dec. 31		2017	Actual on Dec. 31	
	Female	Male	Total	Female	Male	Total
Sweden	3	5	8	3	3	6
Total	3	5	8	3	3	6

Gender	2018			2017		
	Female	Male	Total	Female	Male	Total
Board of Directors	4	3	7	2	4	6
Other management	-	4	4	-	3	3
Totalt	4	7	11	2	7	9

Total salaries, pension- and social costs, 000's	2018	2017
Salaries and other compensation	8 808	8 412
Pension	1 637	1 394
Social costs	2 513	2 446

Other costs	384	343
Total	13 342	12 595

Variable compensation to management amounted to SEK 340 (1 790)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 2018 amounted to SEK 2 083k plus SEK 340k in variable compensation. The company has a commitment regarding performance compensation upon completion of certain individual goals up to a maximum of SEK 0.45m.

The CEO has fee based pension compensation and the company has therefore no other pension commitments other than stated here. Pension premiums in 2018 amounted to 38.9 % of base salary.

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 two persons who along with the CEO comprise the management group (Note 7).

The management group was in 2018 comprised of CEO Mr. Staffan Strömberg, CSO, COO Mr. Anders Kronström, Mr. Eamonn Connolly, and CFO, Mr. Daniel Mackey.

Management and Director compensation 2018 000's	Base salaries/fees*	Performance compensation	Other benefits	Pension costs	Total
Peter Rothschild, Chairman of the Board	600	-	-	-	600
Margareta Hagman, Board member	100	-	-	-	100
Anders Ekblom, Board member	100	-	-	-	100
Eva Idén, Board member	100	-	-	-	100
Anthon Jahreskog, Board member	100	-	-	-	100
Jan Annwall, Board member	50	-	-	-	50
Lilian Wikström, Board member	50	-	-	-	50
Kristina Sjöblom Nygren, Board member	50	-	-	-	50
Staffan Strömberg, CEO	2 083	340	71	837	3 331
Other management (3)	3 581	-	104	682	4 367
Totalt	6 814	340	175	1 519	8 848

The management group was in 2017 comprised of CEO Mr. Staffan Strömberg, CSO, Mr. Eamonn Connolly, and CFO, Mr. Daniel Mackey.

Management and Director compensation 2017 000's	Base salaries/fees*	Performance compensation	Other benefits	Pension costs	Total
Peter Rothschild, Chairman of the Board	600	-	-	-	600
Jan Annwall, Board member	100	-	-	-	100
Margareta Hagman, Board member	100	-	-	-	100
Anders Ekblom, Board member	100	-	-	-	100
Eva Idén, Board member	50	-	-	-	50
Anthon Jahreskog, Board member	50	-	-	-	50
Staffan Strömberg, CEO	1 465	738	71	807	3 081
Other members of management (2)	2 450	1 052	26	482	4 010
Total	4 915	1 790	98	1 290	8 092

Note 5 Audit fees

Deloitte AB, 000's	2018	2017
Auditing	186	173
Prospectus review, pre-IPO	-	680
Other services	46	49
Totalt	232	902

Auditing refers to compensation for review of the company's internal controls, accounting, annual report and administration by the Board of Directors and CEO. Other audit related services refers to review of one interim report and advisory services relating to listing of IBT's class B shares on Nasdaq Stockholm

Note 6 Intangible non-current assets

Activated development costs, 000's	2018	2017
Opening accumulated costs	16 225	16 225
Activated costs	-	-
Total cost	16 225	16 225
Opening accumulated depreciation	-1 627	-811
Depreciation	-816	-816
Total accumulated depreciation	-2 443	-1 627
Carrying amount at end of the period	13 782	14 598

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 FoU-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.

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 2018	Book value 2017
IBT Baby AB	559110-7353	Stockholm, Sweden	50 000	100%	50 000	50 000
Total, SEK					50 000	50 000

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 program

WARRANTS 2017/2022

On May 4, 2017, the Annual General Meeting decided on an incentive program by designated issue of warrants to a subsidiary established for this purpose.

The maximum number of warrants to be issued are 280 000.

The warrants were issued in June 2017 at market terms at a price determined by calculating market price at the time of issue using the Black & Scholes method of valuation.

The holder of warrants may during the period from April 3, 2022 through May 3, 2022, for each warrant subscribe for one point one (1.1) new share in the company at a subscription price per share amounting to SEK 272.41 (300.00).

During 2017 a total of 200 000 warrants were issued and allotted. Allotted warrants were reduced by 10 000 during the reporting period due to staff reduction. As of the balance sheet date on December 31, 2018, 190 000 (200 000) warrants have been issued. The remaining 90 000 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%, and within 4 years by 25%.

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 1.66 percent of shares, and 1.28 percent of votes.

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.

Total market value for the 200 000 issued warrants during the second quarter amounted to 884 KSEK.

Allotted warrants, year	Issued warrants	Strike price	Value per allotted warrant	Volatility, %*	Risk-free interest, %	Value per share, weighted average**	Expiry, year
2018	190 000	272	4.42	40	-0.2	85	2022
Total	190 000	272	4.42	40	-0.2	85	2022

*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.

** Volume weighted average share price for IBT's class B share during the period June 12, 2017 through June 16, 2017

Ownership of warrants	Number allotted 2018-12-31	Number outstanding 2018-12-31	umber allotted 2017-12-31	Number outstanding 2017-12-31
Staffan Strömberg, CEO	70 000	70 000	70 000	70 000
Eamonn Connolly, CSO	50 000	50 000	50 000	50 000
Daniel Mackey, CFO	50 000	50 000	50 000	50 000
Other employees*	20 000	20 000	30 000	30 000
Total	190 000	190 000	200 000	200 000

*Alloted warrants were reduced by 10 000 during the reporting period due to staff reduction

Note 8 Other receivables

000's	2018	2017
Exchange rate gains - unrealized	6 407	-
Other receivables	707	994
Total cost	7 114	994

Note 9 Prepaid expenses and accrued income

000's	2018	2017
Prepaid issue-and listing costs	-	1 108
Prepaid rent	153	-
Other prepaid expenses	102	-
Total cost	255	1 108

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

Note 10 Cash and bank

000's	2018	2017
Bank deposits at Danske Bank and SEB	542 170	158 274
Total cost	542 170	158 274

The Company's liquidity consists solely of cash deposits held at Danske Bank and SEB. Total liquidity on the balance sheet date amounted to SEK 542.2m of which USD amounted to SEK 64.5m. Liquidity in SEK is charged with Deposit Fees. Deposits of USD on fixed term time deposits generate interest income.

Note 11 Accrued expenses and prepaid income

000's	2018	2017
R&D costs	298	1 294
Financial advisor fees	-	2 208
Social costs and special salary taxes	613	1 128
Vacation pay	1 139	966
Salaries	70	-
Board fees	67	117
Audit fees	46	-
Other accrued expenses	162	268
Total	2 395	5 981

All accrued expenses are due for payment within twelve months.

Note 12 Significant events after the reporting period

IBT has on March 5, 2019, signed the first distribution agreement for IBP-9414 with MegaPharm Ltd., for the Israeli market and the Palestinian Authority's territories. The agreement gives MegaPharm exclusive rights to market and sell the product, if and when the product receives market approval. IBT's share will, after an initial shorter period, account for 70% of revenues. IBT plans to open clinical trial centers for the pivotal phase III trial in the country. MegaPharm is already participating in this work as it is essential to engage "key opinion leaders" in the marketing of the product.

No other significant events have occurred after the reporting period.

Note 13 Board of Directors recommendation of appropriation of profits

SEK	2018
Recommendation of appropriation of profits or loss	
The Board of directors propose that the following surplus:	
Income carried forward	-72 903 621
Surplus reserve	667 166 892
Result for the period	-40 607 018
Total	553 656 253
be appropriated as follows:	
Income carried forward	553 656 253
Total	553 656 253

The board of directors recommend that no dividend be paid for fiscal year 2017.

Note 14 Related party transactions

Annwall & Rothschild Investments AB, who is the Company's largest shareholder by voting rights with 28.63% of votes and a shareholding of 7.02% of capital, participated in the preferred new share issue by the company during the first quarter 2018 by subscribing to 155 538 class A-shares and 169 020 B-shares in the amount of approximately SEK 30.9m (Note 4).

No other significant related party transactions have occurred.

Note 15 Pledged assets and contingent liabilities

	2018	2017
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.

Result per share, SEK	2018	2017
Result for the period, 000's	-40 607	-36 156
Weighted average number of shares before and after dilution*	10 788 914	5 595 305
Result per share before and after dilution*	-3,76	-6,05

*Issue price at the share issue in February 2018 amounted to SEK 95 per share which corresponded to approximately 84 percent of the fair value of the share at time of issue. Bonus share element was considered when calculating result per share before and after dilution, resulting in restatement of comparative figure (positive effect amounting to SEK 0.41 in 2017). There are no other dilution effects.

Note 17 Share capital development (SEK)

Period	Transaction	Change	Series A shares	Series B shares	Share capital	Quota value	Subscription price	Total Invested*
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	300 000	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
Total		0	377 736	10 848 448	3 059 663	0,27	-	696 658 082

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 including operational costs during one year after concluding the 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.

Counter party risks

The Company allows only investments in interest bearing instruments which carry low risk and high liquidity. The Company cooperates with established and credit worthy counterparties and evaluates receivables on an ongoing basis in order to achieve low exposure to bad debts. To mitigate this risk, IBT deposits its surplus liquidity in liquid

accounts at Danske Bank and SEB. The Company had no short-term deposits on the balance sheet date.

Currency risk

Currency risk is the risk of fluctuating values in assets or liabilities resulting from variations in exchange rates. The majority of IBT's development costs are commitments in foreign currencies. Should the SEK be reduced in value versus foreign currencies, it may have considerable impact on the Company's financial position and results. As of the balance sheet date, the Company has no currency hedges. The currencies against which IBT has the greatest exposure are USD and EUR.

A variance in the SEK versus USD and EUR of 1 percent, based on total research-and-developments cost, all else being equal, would have affected 2018 results by approximately SEK 2.0m.

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.

Deduction of Certain Key Figures

	2018 Jan-Dec	2017 Jan-Dec
Cash flow per share		
Cash flow for the period, 000's	381 544	64 488
Average number of shares	10 788 914	5 595 305
Cash flow per share (SEK)	35.36	11.53
Equity per share		
Equity, 000's	556 717	168 371
Number of shares at end of period	11 226 184	6 603 638
Equity per share (SEK)	49.59	25.50
Equity ratio		
Equity, 000's	556 717	168 371
Total equity and liabilities, 000's	563 371	175 024
Equity ratio %	99%	96%

Financial Definitions

Key ratios	Definition	Motive
Average number of shares	Average number of shares during the reporting period (split in 2016 restated for comparative figures)	Relevant in calculating income and cash flow per share
Net sales	Sales for the period	Sales of services
Reporting period	January 1 - December 31, 2018	Defines time period comprised by this financial report
Result per share	Result for the period divided by average number of shares	Result allocated per share
Cash flow per share*	Cash flow for the period divided by average number of shares	Measure to describe cash flow allocated to one share during the period
Number of shares*	Number of shares at the end of the period	Relevant for calculating shareholders' equity allocated to one share
Total assets	Total assets at the end of the period	Relevant for calculating shareholder's equity
Shareholders equity/share*	Total shareholders' equity divided by the number of shares at the end of the period	Measure to describe shareholder's equity per share
Equity ratio*	Total shareholders' equity as a percentage of total assets	Measure to evaluate the company's ability to meet its financial obligations

*Non-IFRS

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 April 4, 2019 and will be subject to approval at the annual general meeting on May 6, 2019.

Stockholm, April 4, 2019

Peter Rothschild	Eva Idén	Anders Ekblom	Margareta Hagman
Chairman	Director	Director	Director

Kristina Sjöblom Nygren	Anthon Jahreskog	Lilian Wikström	Staffan Strömberg
Director	Director	Director	CEO

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

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 2018-01-01 - 2018-12-31. The annual accounts and consolidated accounts of the company are included on pages 19-53 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 as of 31 December 2018 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the company as of 31 December 2018 and their 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 for the company.

Our opinions in this report on the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's Board of Directors in accordance with the Audit Regulation (537/2014) Article 11.

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 the company in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

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 as a whole, but we do not provide a separate opinion on these matters.

New share issue

In January 8, 2018 the EGM decided on a new share issue amounting to SEK 439.1 million prior to transactions costs that are reflected in equity. The new share issue is a key audit matter due to extensive requirements for formalities and that it is a significant amount in the balance sheet.

Our audit procedures included, but were not limited to:

- Evaluation of the company's routines and internal control related to new share issue, reconciliation of payment and examination of minutes and other legal formalities
- Examination of a number of transactions costs against invoice to ensure accuracy, classification and cut off
- Examination that the required disclosures are provided in the annual accounts

Research and development costs

The company's costs for research and development as of December 31, 2018 amount to SEK 51.4 million prior to 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 19.

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 written position for the question
- Examination that the required disclosures are provided in the annual accounts

Other information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-18 and 60-65. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated 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 consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated 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 and 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.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.

- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts, including the disclosures, and whether the annual accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the company to express an opinion on the accounts. We are responsible for the direction, supervision and performance of the company audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter.

Report on other legal and regulatory requirements

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 2018-01-01 - 2018-12-31 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 the company 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 and 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.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit.

The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Deloitte AB, was appointed auditor of Infant Bacterial Therapeutics AB by the general meeting of the shareholders on the 2018-05-15 and has been the company's auditor since 2014-03-29.

Stockholm, April 4, 2019

Deloitte AB

Birgitta Lööf

Authorized public accountant

Shares

On January 1, 2018, the total number of shares amounted to 6 603 638 of which 222 198 class A-shares carrying ten votes and 6 381 440 class B-shares carrying one vote.

IBT issued 155 538 class A shares and 4 467 008 class B shares in a new share issue in February 2018 (Note 4).

On December 31, 2018, 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.

IBT's closing share price on December 28, 2018 amounted to SEK 141.50.

The number of shareholders was 5,527 on December 31, 2018 per Euroclear Sweden.

Share price development

IBT's share price increased from 102.93 SEK to 141.51 SEK during 2018. The market value per December 31, 2018 was 1, 535 MSEK.



Analysts covering IBT:

SEB: Carl Mellerby, Mattias Vadsten, Carsten Lønborg Madsen
Chardan Capital Markets, New York, NY: Taylor Feehley, PhD. info@chardan.com

Ownership December 31, 2018

Name	Series A shares	Series B shares	Share capital %	Voting rights %
ANNWALL & ROTHSCHILD INVESTMENTS AB	377 736	410 478	7.02	28.63
ÖHMAN BANK S.A.	-	1 058 481	9.43	7.24
FJÄRDE AP-FONDEN	-	1 052 716	9.38	7.20
SKANDINAVISKA ENSKILDA BANKEN S.A., W8IMY	-	724 093	6.45	4.95
AMF AKTIEFOND SMABOLAG	-	501 585	4.47	3.43
TREDJE AP-FONDEN	-	415 639	3.70	2.84
SWEDBANK ROBUR MICROCAP	-	340 694	3.03	2.33
SWEDBANK ROBUR NY TEKNIK BTI	-	320 000	2.85	2.19
DANGOOR, DAVID	-	290 144	2.59	1.99
RBC INVESTOR SERVICES BANK S.A., W8IMY	-	284 124	2.53	1.94
ANDRA AP-FONDEN	-	263 500	2.35	1.80
ÅLANDSBANKEN I ÄGARES STÄLLE	-	259 916	2.32	1.78
FÖRSÄKRINGSAKTIEBOLAGET, AVANZA PENSION	-	258 424	2.30	1.77
BANQUE PICTET & CIE SA, W8IMY	-	252 582	2.25	1.73
CATELLA SMÅBOLAGSFOND	-	250 663	2.23	1.71
NORDNET PENSIONS FÖRSÄKRING AB	-	241 599	2.15	1.65
UNIONEN-SVENSKA	-	207 196	1.85	1.42
CBNY-NORGES BANK	-	205 035	1.83	1.40
HANVAD INVEST AKTIEBOLAG	-	136 593	1.22	0.93
BNY MELLON SA/NV (FORMER BNY), W8IMY	-	135 180	1.20	0.92
Sub-total 20 largest shareholders	377 736	7 608 642	71.15	77.85
Other shareholders	-	3 239 806	28.85	22.15
Total number of shares	377 736	10 848 448	100	100

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: 76,728 series B shares and 70,000 warrants and 45,864 series B shares through the wholly owned company Eteboxagu AB.

Anders Kronström

COO 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: 170 shares of series B.

Eamonn Connolly

Head of R&D since 2013. Born 1957.

Doctor of Philosophy (Ph.D.), University of Manchester Institute of Science and Technology and B.Sc. (Hons) Biochemistry, First class, University of Manchester.

Eamonn Connolly has more than 25 years of experience of the pharmaceutical and biotechnology industry from his various positions within companies such as: BioGaia, Fresenius Kabi and Pharmacia & Upjohn.

Previously member of the Board of Directors of IBT.

Shareholding in the Company: 56,864 series B shares and 50,000 warrants.

Daniel Mackey

CFO since 2017. Born 1974.

Bachelor of Science in Economics, State University of New York, Plattsburgh, New York.

Daniel has 20 years of experience from management positions in finance from American and international companies such as Investors Bank & Trust Co, Nordea Investment Management AB and Nordea Bank AB.

Shareholding in the Company: 6,312 series B shares and 50,000 warrants.

Board of Directors

IBT's Board of Directors consists of seven (6) 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 2018.

Peter Rothschild

Chairman of the Board since 2011. Born 1950.

Master of Business Administration from Stockholm School of Economics.

Chairman of the Board of Directors of BioGaia Production AB, Looft Industries AB, CapAble AB, MetaboGen AB, Nefor Holding AB, Voranco Holding AB, BioGaia Pharma AB and Annwall & Rothschild Investments AB.

Member of the Board of Directors of TriPac AB samt i Glycom A/S. Founder of and Group Director of BioGaia Group and Partner of Argoinvest Kommanditbolag.

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

Shareholding in the Company: 377,736 series A shares and 410,478 series B shares through Annwall & Rothschild Investments AB, a company co-owned with Jan Annwall.

Anders Ekblom

Board member since 2014. Born 1954.

M.D., Ph.D, D.D.S and Associate Professor at Karolinska Institutet.

Chairman of the Board of Directors of Elypta AB and TFS International AB. Member of the Board of Directors of Alligator Bioscience AB, AnaMar AB, Leo Pharma A/S, Mereo Biopharma Ltd., and NxtScience AB.

Previously Chairman of the Board of Directors and CEO of AstraZeneca AB, member or deputy member of the Board of Directors of a number of subsidiaries of AstraZeneca AB and member of the Board of Directors of SwedenBIO Service AB and Viscogel AB, RSPR Pharma AB, Pharmanest AB, Sällheten Invest AB and Albireo AB.

Shareholding in the Company: 27,519 series B shares through the wholly-owned company NxtScience AB.

Margareta Hagman

Board member since 2015. Born 1966.

Master of Business Administration, Örebro University.

Deputy CEO and CFO of BioGaia AB (publ). Member of the Board of Directors of BioGaia Production AB and CapAble 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 Hamilton Park Consulting Ltd.

Shareholding in the company: None

Contact Persons

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Contact Information

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