



# INFANT BACTERIAL THERAPEUTICS



## Annual Report 2016

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## Infant Bacterial Therapeutics AB (publ) Annual Report January 1 – December 31, 2016

### IBT in Brief

Infant Bacterial Therapeutics AB (“IBT”) is a pharmaceutical Company based in Stockholm. IBT is listed on Nasdaq First North in Stockholm since March 29, 2016 (IBT B) with Erik Penser Bank as Certified Adviser.

Infant Bacterial Therapeutics AB (publ) (“IBT”) is a pharmaceutical Company with a vision to develop drugs influencing the human infant microbiome, and thereby prevent or treat rare diseases affecting premature infants. Using its extensive experience in live bacterial therapeutics and its well-developed knowledge of the action of *Lactobacillus reuteri*, IBT is developing its lead drug candidate IBP-9414, to prevent necrotizing enterocolitis (“NEC”), a rare and often fatal disease that afflicts 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.

## Financial summary

SEK 000's	2016 Jan-Dec	2015 Jan-Dec
Total comprehensive income	162	-
Net profit/loss	-38 090	-20 615
Result after tax	-38 106	-23
Total assets	110 109	82 543
Cash flow for the period	49 375	43 357
Cash	93 786	44 411
Earnings per share, weighted average, before and after dilution (SEK)	-8.4	0.0
Equity per share (SEK)	19.1	831.2
Equity ratio (%)	96%	91%

## Message from the CEO

Almost five years have passed since Eamonn Connolly and I realized that something extraordinary could be done to ensure that premature infants would not be affected by the often-deadly disease NEC. The idea was triggered by two independent American research groups that had performed clinical studies which demonstrated that *Lactobacillus reuteri* could reduce the risk that these infants would develop NEC. Until the end of March 2016, we were a subsidiary of BioGaia, a company which has successfully worked with and developed *Lactobacillus reuteri* for several decades. Supported by knowledge and financing from BioGaia, we developed a completely new product focused on treating these highly vulnerable infants. Together with leading world experts and governmental agencies we have generated a well-grounded development plan for our drug candidate IBP-9414 for the prevention of NEC.

IBT was granted Orphan Drug status by the Food and Drug Administration (FDA) as well as the European Medicines Agency (EMA) for the Orphan Drug candidate IBP-9414 for the prevention of NEC. During the year IBT was also granted "Rare Pediatric Disease" status by the FDA. That implies that IBT can be awarded a Priority Review Voucher by the FDA at market approval of IBP-9414. A Priority Review Voucher stipulates that the FDA will treat a drug application with an expedited timeline. At the turn of the year 2015 / 2016, IBT received approval from the Swedish medical agency (Läkemedelsverket) and the FDA to perform a clinical Phase II study (NCT02472769) within the framework of pharmaceutical development of IBP-9414. During the month of June, the first patients were recruited and dosed in the NEC study in the USA. The last patient was recruited on 23 January 2017 and the results of the study are expected during the autumn of 2017.

With that background, we were able to make 2016 an important year in IBT's history in which we accomplished important milestones in our pharmaceutical development. During the month of December, IBT presented a further development project, IBP-1016, which is aimed to address the medical issues that arise in infants that are affected by gastroschisis, a rare and serious disease in infants.

The company's financial resources are sufficient to complete the ongoing Phase II study as well as prepare for the next step towards a market approval. We will even have the possibility to prepare for the following planned pivotal Phase III study, and create a development plan for IBP-1016. To complete the planned Phase III study for IBP-9414 and further develop our project IBP-1016 we will require additional capital. IBT is currently working actively with several possible financing opportunities.

2017 is going to be an important year for IBT. We will continue to build our organization so that we are well prepared for future challenges. We expect to understand how agencies and experts view our new project IBP-1016 and we also expect to receive our Phase II (NCT02472769) results.

It is our long-term hope and ambition to offer the market pharmaceuticals that can save the lives of premature infants and I am optimistic about the future of IBT and our projects.

Stockholm, March 2017

Staffan Strömberg,  
Chief Executive Officer

## Description of IBT's development project IBP-9414

IBT has developed the production process for drug candidate IBP-9414 which is a complex process involving many steps including fermentation, purification and lyophilization to obtain the final product. The risks for impurities are identified, minimized and controlled.

IBT intends to conduct a clinical program consisting of two clinical trials.

The first study is a phase II safety and tolerability study for two different dose levels of IBP-9414 in 120 premature infants in total with birth-weight ranging from 500 to 2,000 g. The aim is to assess the safety and tolerability of the drug candidate IBP-9414 administered in premature infants. The infants in the study are treated with IBP-9414 or placebo for 14 days, and the study will be completed by a six-month follow up after the last dose has been administered. Results from the ongoing phase II clinical trial are expected during the fourth quarter of 2017.

The budget for the first clinical study is approximately 45 MSEK.

The subsequent phase III pivotal study will be designed to demonstrate and document efficacy of IBP-9414 over placebo in the prevention of NEC in preterm infants with a birth-weight  $\leq 1,500$  g. This study will also include safety evaluation in the larger cohort.

Two independent companies, Apex Healthcare Consulting Ltd. and Clearview Healthcare Partners, have during 2014 and 2016 estimated the market potential for IBP-9414. The market potential was estimated to be in the interval 200 MUSD to 350 MUSD in the USA annually. IBT is also planning on distributing the product in additional markets. As of today, IBT does not know of any approved pharmaceutical product aimed to address the same indication.

Further, in March 2016, IBT was awarded Rare Pediatric Disease designation for IBP-9414 by FDA, meaning that IBT may be awarded a priority review voucher following market approval. Such a voucher may be used for another product candidate or be divested.

## History

### 2013

- Infant Bacterial Therapeutics AB (IBT) commenced its activities and started 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
- U.S. Food and Drug Administration (FDA) provides scientific input for IBT's development plans

### 2014

- Pharmaceutical development defining the formulation and manufacturing process for IBP-9414
- The European Medicines Agency provides scientific input for IBT's development plans

### 2015

- IBP-9414 is granted Orphan Drug Designation by the European Commission for *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 clinical phase II trial
- IBT received approval from the Swedish Medical Products Agency to conduct a clinical trial in Sweden

### 2016

- BioGaia distributes its shares in IBT to BioGaia's shareholders
- The Company's shares are listed on Nasdaq First North
- IBT receives Rare Pediatric Disease Designation from FDA for IBP-9414
- IBT completed a share issue which generated approximately 89 MSEK
- All Board members, the CEO and Head of Research and Development subscribed to shares in the Company in the Rights Issue completed in May 2016

- IBT announced that the first premature infant has been enrolled and dosed in the Company's phase II clinical trial (NCT0242769) in the USA
- This financial report is IBT's first financial report prepared in accordance with RFR 2

## Directors Report

The Board of Infant Bacterial Therapeutics AB (publ) ("IBT"), org.nr. 556873-8586 presents the Annual Report for the financial year January 1, 2016 to December 31, 2016.

This financial report is IBT's first financial report prepared in accordance with RFR 2, Reporting for legal entities and Årsredovisningslagen. Adoption of RFR 2 means that IBT complies with all IFRS recommendations accepted by the EU possibly allowed within the frameworks of the Annual Accounts Act (Årsredovisningslagen) and Tryggandelagen and in consideration of the association between reporting and taxation.

IBT will begin providing quarterly financial reports from and including the first quarter of 2017.

## The Company

Infant Bacterial Therapeutics AB (publ) ("IBT") is a pharmaceutical company with a vision to develop drugs influencing the human infant microbiome, and thereby prevent or treat rare diseases affecting premature infants. Using its extensive experience in live bacterial therapeutics and its well-developed knowledge of the action of *Lactobacillus reuteri*, IBT is developing its lead drug candidate IBP-9414, to prevent necrotizing enterocolitis ("NEC"), a rare and often fatal disease that afflicts 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 2016

- The Annual General Meeting decided on repayment of conditional shareholder contributions by offsetting previously received group contributions by 20.6 MSEK
- BioGaia AB (publ) distributed its entire holding (94.5 % of shares and 96 % of votes) in IBT to BioGaia's shareholders
- IBT's shares were listed on Nasdaq First North
- IBT completed a guaranteed share issue which generated approximately 89 MSEK after deduction of issuance costs
- In June, the first premature infants were enrolled and dosed in the Company's phase II clinical trial in IBP-9414 (NCT02472769)
- During the month of November, the independent safety committee (DSMB) reviewed the ongoing clinical phase II study of IBP-9414 (NCT02472769). After the review by the DSMB, the study could proceed with a higher dose in the last patient cohort.
- During December, IBT presents an additional development project, IBP-1016, which aims to address the medical issues that arise in infants that are impacted by gastroschisis, a rare and serious disease in infants.

## Significant events after the reporting period

- In January 2017, all 120 patients were included in the Company's phase II clinical trial in IBP-9414 (NCT02472769)
- During March 2017, IBT transferred trading listing from Nasdaq First North to Nasdaq First North Premier
- This financial report is IBT's first Annual Report prepared in accordance with RFR 2, and Årsredovisningslagen. IBT will as of the first quarter 2017 prepare financial statements on a quarterly basis
- No other significant events have occurred after the reporting period

## Results and Financial Position

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

### Result Development

Operational result amounted to -38 090 (-20 615) kSEK and result after financial items amounted to -38 106 (-20 624) kSEK.

Result after appropriations and tax amounted to -38 106 (-23) kSEK.

Result per share amounted to -8.42 (0.01) SEK.

Cash flow for the period amounted to 49 375 (43 357) kSEK. Cash flows included share issues amounting to 89 123 (52 800) kSEK.

Operational costs amounted to 40 795 (20 615) kSEK of which costs for the ongoing IBP-9414 clinical trial amounted to 26 658 (11 843) kSEK. Balanced development costs amounted to 0.0 (10 150) kSEK.

Personnel costs amounted to 7 130 (6 315) kSEK.

Other external costs amounted to 7 007 (2 457) kSEK.

Share issue costs amounted to 11.0 (0.0) MSEK which was charged to shareholder's equity.

### Financial Position

Cash flow for the period amounted to 49 375 (43 357) kSEK. Cash flows included share issues amounting to 89 123 (52 800) kSEK.

The Company's cash balance on December 31, 2016, amounted to 93 786 compared to 44 411 kSEK on December 31, 2015.

The Company's shareholder's equity on December 31, 2016, amounted to 105 226 compared to 74 809 kSEK on December 31, 2015. Shareholders' equity per share amounted to 19.12 compared to 831.21 SEK on December 31, 2015.

The Company's equity ratio amounted to 96% compared to 91% on December 31, 2015.

Results are in line with expected costs according to Budget. The Company's financial resources are sufficient to complete the ongoing clinical phase II-trial and to prepare the next stage for regulatory approval.

### Prospects for 2017

The development plan with respect to IBP-9414 is to complete a clinical program comprised of two clinical studies. The first, ongoing, study of IBP-9414 is in a phase II safety and tolerability study for two different dosing levels of IBP-9414 to a total of 120 premature infants with a birth weight between 500 and 2000 grams.

The top-line results from the ongoing phase II study are expected during the fourth quarter of 2017.

The subsequent phase III pivotal study in the clinical program for IBP-9414 is a larger study to demonstrate the efficacy of IBP-9414 in relation to prevention of NEC. This study will also include a safety in a larger group of patients.

During December, IBT presents an additional development project, IBP-1016, which aims to address the medical issues that arise in infants that are impacted by gastroschisis, a rare and serious disease in infants.

The Company's financial resources are sufficient to establish a development plan for IBP-1016 and prepare for the pivotal Phase III study for IBP-9414.

## Risks and uncertainties

### Risk management and control

The Company's Board of Directors works continually and systematically with risk assessment to identify risks and take the necessary actions to cope with them. Risk assessment is designed to identify such risks that can have a significant impact on internal control of financial reporting.

The internal control environment at IBT mainly comprises the following components: control environment, risk assessment, control activities, information and communication, as well as monitoring. Every identified significant risk a risk management action plan is 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 an early stage and there is a risk that IBP-9414 will not demonstrate the required e etc. 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.

### Patent and trademarks

BioGaia has patents on *L. reuteri*. IBT has been granted an exclusive license to use *L. reuteri* in IBT's areas of interest from BioGaia.

The main patent protection for IBP-9414 is the product claim for the use of a specific strain of *L. 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 US, 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.

IBT is not aware of any third-party patents or patent applications applicable which would impair the Company's ability to use the IBP-9414 within the Company's area interest.

Protection of intellectual property for pharmaceutical companies may be uncertain and involve complicated legal and technical questions. There is a risk that a patent granted will be circumvented or invalidated. Pursuing litigation for infringement and/or involving the validity of a patent is normally associated with significant costs. By having access to greater economic resources, competitors may be better positioned than IBT to carry such costs. In certain jurisdictions, these costs may be imposed on IBT even where the outcome of the case for the Company is otherwise positive. If the Company or BioGaia does not succeed in obtaining or defending patent protection for its innovations, competitors may have an opportunity to freely develop and use copies of IBT's candidate drugs and pharmaceutical products, which may prejudice the Company's ability to commercialize its business. In addition, this might negatively affect the possibility for the Company to enter important cooperation agreements. Future patents may be granted to other parties than IBT, which may limit IBT's possibility of commercializing its intangible assets. In case such patents are granted it may negatively affect IBT's business, earnings and financial position. There is a risk that the Company may infringe the intellectual property rights of third parties and may be exposed to claims for compensation for

this. In such cases, the Company may also be enjoined from using such rights in the future, which could have an adverse effect on the Company's operations, results and financial position.

### **Regulatory risk**

Before IBT's products can be launched in the US, IBT must seek and be granted authorization by the FDA. IBT may also in the future launch its products in the EU, for which approval from EMA is required. Before a pharmaceutical is approved for marketing, it must undergo clinical testing in patients. There is a risk that IBT will not achieve sufficient results in such clinical trials to obtain necessary authorizations.

IBT develops and commercializes medical products and is dependent on assessments and decisions made by relevant regulatory authorities. Such assessments include authorizations for clinical trials, licenses to market and sell pharmaceuticals, conditions for the prescribing of pharmaceuticals, pricing of pharmaceuticals covered by reimbursement schemes and discounts on pharmaceuticals. It cannot be guaranteed that IBT will obtain the authoritative decisions necessary to generate commercially and financially valuable products in the market.

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

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

### **Production**

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

### **Product liability and insurance**

The clinical trialing and marketing as well as sales of pharmaceuticals products entail a significant risk of liability claims arising out of harm to children and others who are exposed to IBT's trials and products. There is a risk that the Company's liability insurance will not cover any claims regarding liability which may be brought. There is also a risk that in the future IBT may not be able to obtain or maintain insurance coverage at acceptable terms.

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 continually assesses its insurances to ensure that they are adequate for the risks normally associated to IBT's business. However, there is no guarantee that IBT will not suffer losses not covered by insurances.

The Board 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

Listing IBT's class B shares on Nasdaq First North and the following Share Issue in May 2016 generated capital sufficient to complete the ongoing IBP-9414 clinical phase II-trial (NCT02472769). The Company also has the possibility to prepare the following planned clinical phase III-trial and to prepare a development plan for IBP-1016. Additional capital will be required to conduct the planned clinical phase III-trial and to develop IBP-1016.

Access to capital may be limited at the time it is required by the Company. The Company estimates, based on its current development plan, that additional capital will be required for the development of IBP-9414 and submission for regulatory approval. The Company has previously communicated the need for additional capital and the capital needs will be more accurately defined.

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.

IBT's balance sheet item "cash and cash equivalents" in the balance sheet represents cash deposits at Danske Bank. The Company's assessment is that the counterparty risk at Danske Bank is very low. See note 17 for further information about financial risks.

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

## Environmental policy

IBT endeavors to ensure that the impact on the environment is as little as possible. The Company's operation is not subject to notification obligations under the Swedish Environmental Code (*Sw. Miljöbalken*). The Board of Directors of the Company is of the opinion that the Company is in compliance with applicable rules and regulations and possesses the necessary licenses for its operations.

## Sustainability

IBT should be perceived as an innovative and creative Company that represents quality, health and provides an important 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 regards to business strategies, financing, investments and purchasing processes.

The Company does not 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 is published on the Company's webpage [www.ibtherapeutics.com](http://www.ibtherapeutics.com)

## Publication

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

## Agenda

Interim report January – March 2017	May 4, 2017
Interim report January – June 2017	August 28, 2017
Interim report January - September 2017	November 23, 2017

## Annual General Meeting

The Annual General Meeting for IBT will be held on May 4, 2017 at Citykonferens Ingentörhuset Malmskillnadsgatan 46 in Stockholm, Sweden. Shareholders who wish to have a matter addressed at the AGM must submit a request by sending an email to the Company's Secretary of the Board, Per-Erik Andersson at [pererik.andersson@ibtherapeutics.com](mailto:pererik.andersson@ibtherapeutics.com), see also [www.ibtherapeutics.com](http://www.ibtherapeutics.com).

The Annual Report for 2016 will be published and available by April 3, 2017 on the Company's website [www.ibtherapeutics.com](http://www.ibtherapeutics.com).

**Board of Directors recommendation of appropriation of profits**

<b>SEK</b>	<b>2016</b>
<b>Recommendation of appropriation of profits</b>	
The Board of Directors recommend that disposable funds:	
Income carried forward	1 358 630
Surplus reserve	140 473 432
Result for the period	-38 105 979
<b>Total</b>	<b>103 726 083</b>
<b>be appropriated as follows:</b>	
carried forward	103 726 083
<b>Total</b>	<b>103 726 083</b>

The Board of Directors and CEO propose that no dividend shall be paid for fiscal year 2016.

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

## Income statement

SEK 000	Not	2016 Jan-Dec	2015 Jan-Dec
Net sales		162	-
Selling expenses *		2 543	-2 600
Research and development expenses	2-6	-40 795	-17 974
Other operating expenses			-41
<b>Operating loss</b>		<b>-38 090</b>	<b>-20 615</b>
<b>Result from financial items</b>			
Interest income and similar profit/loss items		-	-
Interest expense and similar profit/loss items		-16	-9
<b>Result after financial items</b>		<b>-38 106</b>	<b>-20 624</b>
<b>Appropriations</b>			
Group contribution		0	20 601
<b>Result for the period **</b>		<b>-38 106</b>	<b>-23</b>

\* Reversal from 2015

\*\* Result for the period equals total comprehensive income

## Result per share

SEK			
Result per share, before and after dilution*	7	-8.42	-0.01
Number of shares, weighted average*		4 525 213	1 806 382
Number of shares at end of period **		5 503 638	90 000

\* Weighted average 2015 restated due to split 2016. No dilution effects exist

\*\*On December 31, 2016, allocation of emitted shares amounted to 222 198 A-shares carrying 10 votes per share and 5 281 440 B-shares carrying 1 vote per share

**Balance sheet**

SEK 000	Not	Dec 31, 2016	Dec 31, 2015	Jan 1, 2015
<b>ASSETS</b>				
<b>Non-current assets</b>				
<i>Intangible non-current assets</i>				
Activated development expenses	6	15 414	16 225	6 075
<b>Total non-current assets</b>		<b>15 414</b>	<b>16 225</b>	<b>6 075</b>
<b>Current assets</b>				
<i>Current receivables</i>				
Accounts receivable	8	53	-	-
Receivable from parent company		-	20 420	6 956
Other receivables	9	708	535	346
Prepaid expenses and accrued income		148	952	106
<b>Total current assets</b>		<b>909</b>	<b>21 907</b>	<b>7 408</b>
Cash and cash equivalents	16	93 786	44 411	1 054
<b>Total current assets</b>		<b>94 695</b>	<b>66 318</b>	<b>8 462</b>
<b>TOTAL ASSETS</b>		<b>110 109</b>	<b>82 543</b>	<b>14 537</b>
<b>EQUITY AND LIABILITIES</b>				
<b>Equity</b>				
<i>Restricted equity</i>				
Share capital	10	1 500	500	50
<i>Unrestricted equity</i>				
Share premium reserve		140 473	52 350	-
Accumulated losses		1 359	21 981	10 981
Net loss for the period		-38 106	-22	-
<b>Total equity</b>		<b>105 226</b>	<b>74 809</b>	<b>11 031</b>
<b>Liabilities</b>				
<i>Current liabilities</i>				
Accounts payable		1 116	518	492
Other current liabilities		167	137	131
Accrued expenses and prepaid income	11	3 600	7 079	2 883
<b>Total current liabilities</b>		<b>4 883</b>	<b>7 734</b>	<b>3 506</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>110 109</b>	<b>82 543</b>	<b>14 537</b>

### Statement of changes in equity

SEK 000	Restricted equity		Unrestricted equity	
	Share capital	Share premium reserve	Accumulated losses incl. loss for the period	Total equity
<b>Opening equity at Jan 1, 2015</b>	<b>50</b>	<b>0</b>	<b>10 981</b>	<b>11 031</b>
Net loss for the period			-23	-23
<b>Total comprehensive income</b>			<b>-23</b>	<b>-23</b>
<b>Shareholder transactions</b>				
Shareholder contribution			11 000	11 000
Share issue	40	52 760		52 800
Bonus issue	410	-410		0
<b>Closing equity at Dec 31, 2015</b>	<b>500</b>	<b>52 350</b>	<b>21 958</b>	<b>74 808</b>
<b>Opening equity at Jan 1, 2016</b>	<b>500</b>	<b>52 350</b>	<b>21 958</b>	<b>74 808</b>
Net loss for the period			-38 106	-38 106
<b>Total comprehensive income</b>			<b>-38 106</b>	<b>-38 106</b>
<b>Shareholder transactions</b>				
Repayment of shareholder contribution			-20 600	-20 600
Share issue	1000	99 166		100 166
Share issue costs		-11 043		-11 043
<b>Closing equity at Dec 1, 2016</b>	<b>1500</b>	<b>140 473</b>	<b>-36 748</b>	<b>105 225</b>

### Statement of cash flows

SEK 000	2016 Jan-Dec	2015 Jan-Dec
<b>Operating activities</b>		
Operating profit/loss	-38 090	-20 615
Financial items, net	-16	-9
Adjustment for non - cash flow affecting items (depreciation production process)	811	
<b>Cash flow from operating activities before changes in working capital</b>	<b>-37 295</b>	<b>-20 624</b>
<b>Cash flow from changes in working capital</b>		
Increase (-)/Decrease (+) in operating receivables	578	-628
Increase (+)/Decrease (-) in operating liabilities	-3 031	4 228
<b>Cash flow from operating activities</b>	<b>-39 748</b>	<b>-17 024</b>
<b>Investment activities</b>		
Acquisition of immaterial assets		-10 150
<b>Financing activities</b>		
Conditional shareholder contributions		11 000
Group contribution		6 731
Share issue	89 123	52 800
<b>Cash flow from financing activities</b>	<b>89 123</b>	<b>70 531</b>
<b>Cash flow for the period</b>	<b>49 375</b>	<b>43 357</b>
Cash and cash equivalents at the beginning of the year	44 411	1 054
<b>CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD</b>	<b>93 786</b>	<b>44 411</b>

## Note 1 Accounting principles

This financial report is IBT's first annual report prepared in accordance with RFR 2, accounting for legal entities and the annual accounts act, Årsredovisningslagen. Application of RFR 2 means that IBT applies all IFRS and statements adopted by the EU to the extent possible within the framework of årsredovisningslagen, tryggandelagen in consideration of the relation between accounting and taxation. Preparation of financial reports in accordance with RFR 2 requires application of certain important assessments of various item valuations and estimates of principles for accounting purposes.

Amendments in IFRS effective in 2016 have not had any significant impact on the financial reports.

IBT applied Årsredovisningslagen and Bokföringsnämndens allmänna råd BFNAR 2012:1 Årsredovisning och koncernredovisning (K3) in its latest annual report. The conversion to RFR 2 has not caused any numerical adjustments in the balance sheet or income statement. Accounting principles applied in the latest annual report have not been affected by the conversion.

According to RFR 2 other total comprehensive income shall be presented below the income statement. IBT has no other transactions to report in other total comprehensive income which is stated below the income statement. Due to the conversion to RFR 2 a balance sheet as of the beginning of the comparative year, January 1, 2015, is also presented.

### Standards, amendments and interpretations effective from 2017:

Numerous new and amended IFRS have been published but not yet adopted. None of these have been early adopted by IBT. IFRS which may have impact on the Company's financial statements are described below.

#### *IFRS 9, Financial Instruments:*

IFRS 9, Financial Instruments, effective from January 1, 2018, replacing IAS 39 Financial Instruments: Accounting and valuation. The new standard has been revised in various sections and some apply to accounting for and valuation of financial assets and financial liabilities. The Company has not yet evaluated the effects of the new standard.

#### *IFRS 15, Revenue from Contracts with Customers:*

IFRS 15 is effective from January 1, 2018. The standard replaces previous published standards and interpretations applicable to income. IFRS 15 contains a comprehensive model for accounting for income and customer contracts. The Company has not yet evaluated the effects of the new standard.

#### *IFRS 16, Leases:*

IFRS 16 replaces IAS 17 from January 1, 2019. There is no information available to date regarding when the EU may approve the standard. No evaluation of the effects of the standard has begun.

### Recalculation from foreign currency 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.

#### *Transactions and balance sheet items*

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 does not present any Fair value hierarchy as all financial instruments are valued at cost and there are no items valued at Fair value.

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 receivable:**

Accounts receivable are reported at nominal value.

### **Other receivables:**

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 (see Note 2).

### **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 reduced by rebates and value added tax and is reported as follows:

- Services are invoiced on delivery and is reported in the income statement when significant risks and benefits have been transferred to the buyer
- Milestone payments are reported when all prerequisites for the right to receive milestone payments in accordance with the agreement have been met
- Government grants and research subsidies are reported as other income in the income statement during the same period that the costs which the grants are meant to compensate

**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. 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.

**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.

IBT will as of the first quarter 2017 prepare financial reports on a quarterly basis.

Amounts are stated in thousands (000's). Figures in parenthesis refer to the equivalent period during the previous year unless otherwise stated.

**Note 2 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.

**Deferred taxes**

IBT's taxable losses amount to approximately 49 (0.0) MSEK. Deferred tax receivable is reported for deductible temporary differences and for taxable loss deductions when taxable temporary differences or when convincing factors exist indicating that it is probable that the Company will generate taxable profits in the future. Future results are

difficult to estimate and therefore no deferred tax receivable is activated.

### 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 resources 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, at present in a phase II clinical trial safety and tolerability study for two different doses of IBP-9414 to 120 premature babies in total, is not deemed to meet the above criteria in IAS 38 to be activated as development in the balance sheet.

The development costs for the phase II clinical trial are therefore charged to income as incurred.

### 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	16-12-31	15-12-31
<b>000's</b>		
Due for payment within one year	853	644
Due for payment between one and five years	1 234	1 491
Due for payment after five years	-	-
<b>Total</b>	<b>2 087</b>	<b>2 135</b>
<b>Operational leasing costs during the year</b>		
<b>000's</b>		
Rent	537	453
Parking	135	38
Automobile	162	-
<b>Total</b>	<b>834</b>	<b>491</b>

**Note 4 Personnel**

Average number of employees	2016			Actual on Dec. 31	2015			Actual on Dec. 31
	Female	Male	Total	Total	Female	Male	Total	Total
Sweden	2	2	4	5	2	2	4	4
<b>Total</b>	<b>2</b>	<b>2</b>	<b>4</b>	<b>5</b>	<b>2</b>	<b>2</b>	<b>4</b>	<b>4</b>

  

Gender	2016			2015		
	Female	Male	Total	Female	Male	Total
Board of Directors	1	3	4	1	3	4
Other management	-	2	2	-	2	2
<b>Total</b>	<b>1</b>	<b>5</b>	<b>6</b>	<b>1</b>	<b>5</b>	<b>6</b>

Total salaries, pension- and social costs, 000's	2016	2015
Salaries, pensions and other compensation	5 680	5 104
Social costs	1 290	1 152
Other costs	160	59
<b>Total</b>	<b>7 130</b>	<b>6 315</b>

Performance compensation to management fulfilling individual goals amounted to 175 (0.0) kSEK.

## Management compensation

### 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 2016 amounted to 1 575kSEK plus 100kSEK in performance compensation. The Company has a commitment regarding performance compensation upon completion of certain individual goals up to a maximum of 1.0 MSEK. The CEO has fee based pension compensation and the Company has therefore no other pension commitments other than stated here. Pension premiums in 2016 amounted to 29.1 % of base salary.

The CEO and the Company have a mutual notice period of three 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. The management in the Company refers to one person who along with the CEO comprise the management group. The management group was in 2016 comprised of the CEO and the head of research and development, Mr. Eamonn Connolly.

#### Management compensation 2016

000's	Base salaries/fees*	Performance compensation	Other benefits	Pension costs	Other compensation	Total
Peter Rothschild, Chairman of the Board	400	-	-	-	-	400
Jan Annwall, Board member	50	-	-	-	-	50
Margareta Hagman, Board member	50	-	-	-	-	50
Anders Ekblom, Board member	66	-	-	-	-	66
Staffan Strömberg, CEO	1 575	100	54	459	-	2 188
Eamonn Connolly, CSO	1 472	75	-	282	-	1 829
<b>Total</b>	<b>3 613</b>	<b>175</b>	<b>54</b>	<b>741</b>	<b>0</b>	<b>4 583</b>

\* Anders Ekblom has invoiced the Board fee including social costs and VAT via a company. This method is cost neutral for IBT. IBT has no share based incentive programs.

### Note 5 Audit fees

Deloitte AB, 000's	2016	2015
Auditing	190	15
Other audit related services	56	76
<b>Total</b>	<b>246</b>	<b>91</b>

Auditing refers to review of the Company's internal controls, accounting, annual report and administration by the Board of Directors and CEO. Other audit related services refer to review of interim reports and advisory services.

## Note 6 Intangible non-current assets

Activated development costs, 000's	2016	2015
Opening accumulated costs	16 225	6 075
Activated costs	-	10 150
<b>Total cost</b>	<b>16 225</b>	<b>16 225</b>
Opening accumulated depreciation	-	-
Depreciation	-811	-
<b>Total accumulated depreciation</b>	<b>-811</b>	<b>0</b>
<b>Carrying amount at end of the period</b>	<b>15 414</b>	<b>16 225</b>

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 350 MUSD per annum.

To the best of IBT's knowledge, there are no competitors in the same indication.

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

Assets which are depreciated are evaluated regarding impairment any time events or changes in circumstances indicate that the reported value may not be recovered.

## Note 7 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	2016	2015
Result for the period, 000's	-38 106	-23
Weighted average number of shares before and after dilution*	4 525 213	1 806 382
<b>Result per share before and after dilution*</b>	<b>-8.42</b>	<b>-0.01</b>

\* There are no dilution effects

## Note 8 Accounts receivable

Accounts receivable and other receivables, 000's	2016	2015
Accounts receivable	53	-
Reserve for bad debts	-	-
<b>Total cost</b>	<b>53</b>	<b>0</b>

All accounts receivable were paid within 30 days.

Reserve for bad debts is nil

**Note 9 Other receivables**

<b>Other receivables, 000's</b>	<b>2016</b>	<b>2015</b>
Parent company receivable	-	20 420
Other receivables	708	535
<b>Reported value at end of period</b>	<b>708</b>	<b>20 955</b>

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

**Note 10 Share capital development (SEK)**

<b>Period</b>	<b>Transaction</b>	<b>Change</b>	<b>Series A shares</b>	<b>Series B shares</b>	<b>Share capital</b>	<b>Quota value</b>	<b>Subscription price</b>	<b>Total Invested*</b>
11-11-22	Founding	50 000			50 000	1.00	1.00	50 000
15-09-15	Share issue	40 000			90 000	1.00	1 320.00	52 800 000
15-09-15	Bonus issue	90 000			500 000	5.56	-	52 850 000
16-02-12	Split and reclass	-90 000	74 066	1 760 480	500 000	0.27	-	52 850 000
16-05-30	Share issue	-	148 132	3 520 960	1 500 000	-	27.30	153 016 212
<b>Total</b>		<b>0</b>	<b>222 198</b>	<b>5 281 440</b>	<b>1 500 000</b>	<b>0.27</b>	<b>-</b>	<b>153 016 212</b>

\* In addition to invested capital the previous parent company of IBT, BioGaia AB, has remitted Group contributions and conditional shareholder contributions amounting to SEK 28.7m

**Note 11 Accrued expenses and prepaid income**

<b>000's</b>	<b>2016</b>	<b>2015</b>
R&D costs	2 049	3 615
Accrued sales costs	-	2 479
Social costs and special salary taxes	687	250
Vacation pay	641	715
Audit fees	140	20
Board fees	83	-
<b>Total</b>	<b>3 600</b>	<b>7 079</b>

**Note 12 Significant events after the reporting period**

In January 2017, all 120 patients were included in the Company's phase II clinical trial in IBP-9414 (NCT02472769)

During March 2017, IBT transferred trading listing from Nasdaq First North to Nasdaq First North Premier. This financial report is IBT's first Annual Report prepared in accordance with RFR 2, and Årsredovisningslagen. IBT will as of the first quarter 2017 prepare financial statements on a quarterly basis. No other significant events have occurred after the reporting period.

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

SEK	2016
<b>Recommendation of appropriation of profits</b>	
The Board of Directors recommend that disposable funds:	
Income carried forward	1 358 630
Surplus reserve	140 473 432
Result for the period	-38 105 979
<b>Total</b>	<b>103 726 083</b>
<b>be appropriated as follows:</b>	
carried forward	103 726 083
<b>Total</b>	<b>103 726 083</b>

The Board of Directors propose that no dividend shall be paid for fiscal year 2016.

### Note 14 Related party transactions

The Company was a subsidiary of BioGaia AB (publ) until March 23, 2016. In accordance with the decision at the 2016 annual general meeting, conditional shareholder contributions were offset against previously received Group contributions in the amount of 20.6 MSEK. The repayment had no liquidity effect on the Company. No other significant related party transactions were made with BioGaia up to and including March 23, 2016.

BioGaia issued a subscription guarantee in the Rights Issue in May 2016, for which the Company paid a guarantee fee in June 2016 amounting to approximately 1.3 MSEK.

BioGaia has patents on *Lactobacillus reuteri* and BioGaia has provided IBT with an exclusive license free of charge to use *Lactobacillus reuteri* within IBT's field of operations.

No significant related party transactions have occurred other than described above.

### Note 15 Pledged assets and contingent liabilities

	2016	2015
<b>Pledged assets and contingent liabilities</b>	<b>None</b>	<b>None</b>

### Note 16 Cash and bank deposits

000's	2016	2015
Cash on account at Danske bank	93 786	44 411
<b>Total</b>	<b>93 786</b>	<b>44 411</b>

### Note 17 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 above-mentioned share issue.

In order to conduct the planned phase III clinical trial for IBP-9414 and to develop IBP-1016, additional capital is required.

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.

Access to capital may be limited at times when needed by the Company. The Company's assessment based on its current development plans is that additional capital will be required for development of IBP-9414 and application for regulatory approval. The Company has previously communicated the need for additional capital and the capital requirements will be determined.

The Company's assessment is that existing liquidity is sufficient to cover the Company's capital requirements during the following twelve months.

### **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 a liquid account at Danske Bank. The Company has no short-term deposits.

### **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 these 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. A variance in the SEK versus these currencies of 1 percent, all else being equal, would affect results by approximately 0.5 MSEK. The Company's exposure in 2016 to costs in foreign currencies amounted to less than 3 MEUR.

### **Financial definitions**

**\*Number of shares:** Number of shares at the end of the period

**\*Total Assets:** Total assets at the end of the period

**\*Shareholders equity/share:** Total shareholders equity divided by the number of shares at the end of the period

**Average number of shares:** Average number of shares during the reporting period (split in 2016 restated for comparative figures)

**Net sales:** Sales for the period

**Reporting period:** Full year 2016

**Result per share:** Result for the period divided by average number of shares

**\*Equity ratio:** Total shareholders equity as a percentage of total assets

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

## Board's assurance

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

The Annual Report was approved for publication by the Board of Directors and CEO on March 24, 2017, and will be subject for approval at the annual general meeting on May 4, 2017.

Stockholm, March 24, 2017

Peter Rothschild	Jan Annwall	Anders Ekblom	Margareta Hagman	Staffan Strömberg
Chairman	Director	Director	Director	CEO

*Note: This is a translation of the Swedish interim half-year report. If any discrepancies exist, the Swedish version shall prevail.*

Our Audit report was submitted on March 27, 2017

Deloitte AB

Birgitta Lööf  
Authorized public accountant

## **AUDITOR'S REPORT**

**To the general meeting of the shareholders of Infant Bacterial Therapeutics AB : corporate identity number 556873-8586**

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

#### ***Opinions***

We have audited the annual accounts of Infant Bacterial Therapeutics AB for the financial year 2016-01-01--2016-12-31. The annual accounts of the company are included on pages 5-24 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of Infant Bacterial Therapeutics AB as of 31 December 2016 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts.

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

#### ***Basis for Opinions***

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of Infant Bacterial Therapeutics AB 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.

#### ***Other Information than the annual accounts***

The Board of Directors and the Managing Director are responsible for the other information. The other information comprises pages 1-4 and 28-30 but does not include the annual accounts and our auditor's report thereon.

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

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

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

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

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

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

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.

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 for the financial year 2016-01-01--2016-12-31 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.

A separate list of loans and collateral has been prepared in accordance with the provisions of the Companies Act.

### ***Basis for Opinions***

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

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

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

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

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

### ***Auditor's responsibility***

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

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

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

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.

Stockholm March 27, 2017

**Deloitte AB**

Signature on Swedish original

Birgitta Lööf

Authorized Public Accountant

## Shares and Shareholder information

The total number of shares on January 1, 2016, amounted to 90 000. The shares were split on February 12, 2016, after which the total number of shares amounted to 1 834 546 (calculation of result per share is restated as if average number of shares were split on January 1, 2015).

A total number of 3 669 092 share were issued in a new share issue in May 2016. On June 30, 2016, total number of shares amounted to 5 503 638 of which 222 198 class A - shares carrying ten votes and 5 281 440 class B - shares carrying one vote.

IBT's class B - share was listed on Nasdaq First North on March 29, 2016. The Company's class B-shares are since March 14, 2017 trades on Nasdaq First North Premier in Stockholm (IBT B).

### Ownership December 31, 2016

Name	A-shares	B-shares	Share-capital %	Votes %
ANNWALL & ROTHSCHILD INVESTMENTS AB	222 198	241 458	8.42	32.83
BANQUE ÖHMAN S.A.	-	523 380	9.51	6.98
FJÄRDE AP-FONDEN	-	305 259	5.55	4.07
AMF AKTIEFOND SMÅBOLAG	-	295 050	5.36	3.93
SHAPS CAPITAL AB	-	263 100	4.78	3.51
PLACERINGSFOND SMÅBOLAGSFOND, NORDEN	-	162 070	2.94	2.16
DANGOOR, DAVID	-	155 673	2.83	2.07
HANDELSBANKEN SVENSKA SMABOLAG, SFOND	-	155 052	2.82	2.07
CBNY-NORGES BANK	-	151 000	2.74	2.01
RUFFER INV	-	150 000	2.73	2.00
FÖRSÄKRINGSAKTIEBOLAGET, AVANZA PENSION	-	139 692	2.54	1.86
MINGDALE COMPANY LTD	-	138 459	2.52	1.85
STRÖMBERG, STAFFAN	-	137 592	2.50	1.83
SWEDBANK ROBUR NY TEKNIK BTI	-	118 644	2.16	1.58
RBC INVESTOR SERVICES BANK SA, LUX AIF CLIENTS	-	115 296	2.09	1.54
NORDNET PENSIONS FÖRSÄKRING AB	-	99 747	1.81	1.33
HAMILTON, CAROLINE	-	90 849	1.65	1.21
DANICA PENSION	-	81 255	1.48	1.08
HANVAD INVEST AKTIEBOLAG	-	80 349	1.46	1.07
IRWE, STEN	-	75 130	1.37	1.00
<b>Total 20 largest shareholders</b>	<b>222 198</b>	<b>3 479 055</b>	<b>67.26</b>	<b>75.98</b>
Other shareholders	-	1 802 385	32.74	24.02
<b>Total number of shares</b>	<b>222 198</b>	<b>5 281 440</b>	<b>100.00</b>	<b>100.00</b>

## Board of Directors and 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 Cycle Pharmaceuticals AB.

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

Shareholding in the Company: 91 728 series B shares and 45 864 series B shares through private company.

### 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.

## Board of Directors

IBT's Board of Directors consists of four (4) 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 2017.

### 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 TriPac AB, TwoPac Aktiebolag, TwoPac Machine AB, Looft Industries AB, CapAble AB, TwoPac Laboratories AB, MetaboGen AB, Atina Enterprises AB, Nefor Holding AB and Voranco Holding AB. Member of the Board of Directors of Annwall & Rothschild Investments AB, the Allbright Foundation and Founder and President of the BioGaia group.

Previously CEO of BioGaia, member of the Board of Directors of Moberg Pharma AB and the Institution of Biology and Biochemistry at Chalmers University.

Shareholding in the Company: 222 198 series A shares and 241 458 series B shares through Annwall & Rothschild Investments AB, a company co-owned with Jan Annwall.

### Jan Annwall

Board member since 2014. Born 1950.

Business Administration degree from Stockholm University.

Member of the Board of Directors and CEO of Annwall & Rothschild Investments AB and Konglomeratet AB.

Deputy member of the Board of Directors of Looft Industries AB. Founder and Board Member of BioGaia.

Previously member of the Board of Directors of TwoPac Aktiebolag, TwoPac Machine AB, TwoPac Laboratories AB, TriPac AB and CapAble AB. Executive Vice President and CFO of BioGaia.

Shareholding in the Company: 222 198 series A shares and 241 458 series B shares through Annwall & Rothschild Investments AB, a company co-owned with Peter Rothschild.

**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 Karolinska University Hospital and TFS International AB. Member of the Board of Directors of the Swedish Research Council, Mereo Biopharma Ltd., Medivir Aktiebolag, AnaMar AB, RSPR Pharma AB, and NxtScience AB.

Previously member of the Board of Directors and CEO of AstraZeneca AB, and chairman, member or deputy member of the Board of Directors of a number of subsidiaries of AstraZeneca AB. Member of the Board of Directors of Albireo AB, SwedenBIO Service AB and Viscogel 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 of BioGaia. Member of the Board of Directors of TwoPac Machine AB, TwoPac Laboratories AB and CapAble AB, TwoPac Aktiebolag, TriPac AB and Annwall & Rothschild Investments AB.

Shareholding in the Company: 2 100 series B shares.

**Certified Adviser**

The Company's Certified Adviser is Erik Penser Bank, tel. + 46 8 463 80 00

**Contact person**

Staffan Strömberg, CEO, telephone: +46 8 410 145 55

**Contact information**

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