



# INFANT BACTERIAL THERAPEUTICS



## Company description for listing on Nasdaq First North

### **IMPORTANT INFORMATION ABOUT NASDAQ FIRST NORTH.**

Nasdaq First North is an alternative marketplace operated by an exchange within the Nasdaq group. Companies on Nasdaq First North are not subject to the same rules as companies on the regulated main market. Instead they are subject to a less extensive set of rules and regulations adjusted to small growth companies. The risk in investing in a Company on Nasdaq First North may therefore be higher than investing in a company on the main market. All Companies with shares traded on Nasdaq First North have a Certified Adviser who monitors that the rules are followed. The Exchange approves the application for admission to trading.



### **IMPORTANT INFORMATION**

This company description (the "Company description") is not a prospectus and has been prepared in connection with the listing of series B shares in Infant Bacterial Therapeutics AB (publ) (the "Company" or "IBT") on Nasdaq First North (the "Listing"). In this Company description the "Financial Adviser" refers to Carnegie Investment Bank AB (publ) ("Carnegie"). Refer to the section "Definitions" for the definitions of these and other terms in the Company description. Also refer to the section "Glossary" for certain company specific terms.

Carnegie has assisted IBT with the drafting of the Company description. Carnegie has relied on information provided by the Company and, since all of the information contained in the Company description is derived from IBT, Carnegie disclaims any and all liability regarding direct or indirect economic consequences of investment decisions or other decisions which are based, in whole or in part, on information contained in the Company description.

Some of the figures contained in this Company description have been rounded off. Consequently, certain tables do not appear to add up correctly. No information contained in the Company description has been audited or reviewed by the Company's auditors other than as expressly stated.

Any disputes regarding, or arising as a consequence of, the Listing, the content of this Company description, or legal circumstances related thereto shall be exclusively determined under the laws of Sweden and by a Swedish court of law whereupon the Stockholm District Court shall constitute the court of first instance.

### **FORWARD-LOOKING STATEMENTS**

The Company description contains certain forward-looking statements and opinions. Forward-looking statements are statements that do not relate to historical facts and events and such statements and opinions pertaining to the future that, by example, contain wording such as "believes", "estimates", "anticipates", "expects", "assumes", "forecasts", "intends", "could", "will", "should", "would", "according to estimates", "is of the opinion", "may", "plans", "potential", "predicts", "projects", "to the knowledge of" or similar expressions, which are intended to identify a statement as forward-looking.

Forward-looking statements are based on current estimates and assumptions made according to the best of the Company's knowledge. Such forward-looking statements are subject to risks, uncertainties, and other factors that could cause the actual results, including the Company's cash flow, financial condition and results of operations, to differ materially from the results, or fail to meet expectations expressly or implicitly assumed or described in those statements or to turn out to be less favourable than the results expressly or implicitly assumed or described in those statements. None of the Company or the Financial adviser can give any assurance regarding the future accuracy of the opinions set forth herein or as to the actual occurrence of any predicted developments.

In light of the risks, uncertainties and assumptions associated with forward-looking statements, it is possible that the future events mentioned in the Company description may not occur. Moreover, the forward-looking estimates and forecasts derived from third-party studies referred to in the Company description may prove to be inaccurate. Actual results, performance or events may differ materially from those in such statements due to, without limitation: changes in general economic conditions, in particular economic conditions in the markets on which the Company operates, changes affecting interest rate levels, changes affecting currency exchange rates, changes in competition levels, changes in laws and regulations, and occurrence of accidents or environmental damages.

After the date of the Company description, none of the Company or Carnegie assumes any obligation, except as required by law or First North's Rule Book for Issuers, to update any forward-looking statements or to conform these forward-looking statements to actual events or developments.

### **BUSINESS AND MARKET DATA**

The Company description includes industry and market data pertaining to IBT's business and markets. Such information is based on the Company's analysis of multiple sources, stated in the Company description. For example, IBT has obtained certain market data from a report produced by APEX Healthcare Consulting.

Industry publications or reports generally state that the information they contain has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. The Company has not independently verified and cannot give any assurances as to the accuracy of industry and market data contained in the Company description that were extracted or derived from such industry publications or reports. Business and market data are inherently predictive and subject to uncertainty and not necessarily reflective of actual market conditions. Such data is based on market research, which itself is based on sampling and subjective judgements by both the researchers and the respondents, including judgements about what types of products and transactions should be included in the relevant market.

None of the Company or Carnegie assumes responsibility for the correctness of any business or market data included in the Company description. Information provided by third parties has been accurately reproduced and, as far as the Company is aware and has been able to ascertain from information published by such third parties, no facts have been omitted which would render the reproduced information inaccurate or misleading.

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#### FINANCIAL CALENDAR AND SHARE INFORMATION

Interim report for the period 1 January – 30 June 2016	<b>19 August 2016</b>
Year-end report 2016	<b>February 2017</b>
Annual General Meeting	<b>May 2017</b>
First day of trading on Nasdaq First North	<b>29 March 2016</b>
ISIN code series A share	<b>SE0008015242</b>
ISIN code series B share	<b>SE0008015259</b>
Short name series B share (ticker)	<b>IBT B</b>

# Message from the CEO

**NEARLY THREE YEARS HAVE PASSED** since I, together with BioGaia and Chief Research Officer, Eamonn Connolly, commenced the operations of IBT as a subsidiary to BioGaia. We are pursuing a demanding yet exciting development and growth plan in the company, aiming at developing a drug for premature infants. Our current focus is to prevent one of the leading causes of death among premature infants, the intestinal illness necrotizing enterocolitis (NEC). The technological platform of our operations is based on the bacterial strain that BioGaia has successfully worked with throughout several decades.

Thanks to the outstanding effort of all colleagues, we received, at the end of last year, notification from the American Food and Drug Administration (FDA) that our Investigational New Drug (IND) application had become effective and that we could proceed, in full, with clinical trials in the US. Concurrently, the Swedish Medical Products Agency (Sw. Läkemedelsverket) gave us permission to proceed with clinical trials in Sweden. This confirms that our drug development meets the requirements of both the FDA and Läkemedelsverket to begin clinical studies on premature infants, the most vulnerable individuals imaginable, which are a major milestone for IBT.

Our strong belief and hope is that we can successfully complete the forthcoming clinical trials in a number of clinics and hospitals in, primarily, the US and thereafter receive all necessary market approvals for the drug. All drug development requires significant capital, and our project is no exception. For this reason, we will shortly be asking our shareholders for the capital necessary to fund our first clinical trial. A future commercialization of our product can be completed in several different ways: by licensing our product, by selling the rights of the project or by us bringing the product to the market.

We have a great deal of work ahead of us, but I am confident that we have the capacity and competence necessary to complete our task successfully. I am proud and happy that IBT will now become an independent and listed company and my hope is that all BioGaia shareholders, who now become direct owners of IBT, want to join us on our exciting journey. Of course, I also hope that we can attract new owners who see the potential in our project. It is of the utmost importance that we have our shareholders' confidence, not least in order to secure future capital needs, which may be necessary to complete our ambitions of providing the market with a drug that saves the lives of premature infants.

Staffan Strömberg, Chief Executive Officer

# Risk factors

An investment in IBT's shares involves various risks. A number of factors affect, or could affect, IBT's business, both directly and indirectly. Described below, in no particular order and without claim to be exhaustive, are the risk factors and significant circumstances considered to be material to IBT's business and future development. The risks described below are not the only risks to which IBT and its shareholders may be exposed. Additional risks that are not currently known to IBT, or that IBT currently believes are immaterial, may also adversely affect IBT's business, results of operations or financial condition. Such risks could also cause the price of IBT's shares to fall significantly, and investors could potentially lose all or part of their investment.

In addition to this section, investors should also take into consideration the other information contained in the Company description in its entirety. The Company description also contains forward-looking statements that are subject to future events, risks and uncertainties. IBT's actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors, including the risks described below and elsewhere in the Company description.

## RISKS RELATED TO IBT

### Dependencies on the 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 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. The market value of the Company, and thus the Company's share price, would be prejudiced by setbacks for this development and the clinical trials.

### Clinical trials and regulatory approvals

Drugs are strictly regulated products. Regulatory agencies could proceed to put on hold or stop any drug development, either withdraw temporarily or definitely a drug from the market after market approval at any time if they consider that public health safety is endangered. These risks are intrinsic to all drug development and commercialization. In order to be marketed, all pharmaceuticals which are developed must undergo an extensive registration procedure and be approved by the relevant regulatory authorities on a particular market, for example the Swedish Medical Products Agency, the FDA or the EMA. For example, the registration procedure includes, where applicable, requirements with respect to the development, clinical trials, registration, approval, labeling, manufacturing and distribution of pharmaceuticals products. If such requirements, either current or future, are not fulfilled this may result in the retraction of products, import freezes, denial of registration, the withdrawal of previously approved applications, or the filing of criminal charges. Even if a pharmaceutical manufactured by IBT, or by another party pursuant to agreement with the Company, were to be registered for commercialization, there is a risk that IBT will not be able to fulfill the regulations or be able to maintain the registration or obtain equivalent authorization for additional pharmaceuticals.

There is also a risk that the rules which currently apply to registration, or the interpretation of these rules, will be amended in a way which is disadvantageous to the Company.

Before IBT's products can be launched in the US, IBT must seek and be granted authorization by the FDA. IBT also intends to 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 the necessary authorization. Further, there is also a risk that the ideal clinical trials are designed in a way which limits the number of trial centers available for carrying out such trials. There may also be requirements of additional studies for trials in order to obtain approval which may delay and increase the cost for developing a new product. Even after approval has been obtained, the Company and the products it markets will be under the supervision of national regulatory authorities in the countries where these products are marketed. In the event previously unknown problems are discovered, this can lead to restrictions on the use of a particular product or the withdrawal of the product from the market. Difficulties associated with obtaining and maintaining approval may materially impact IBT's business operations, earnings and financial position.

#### **IBT is dependent on recruiting patients to participate in the clinical trials and is also dependent on co-operations for recruiting patients**

Finding patients for the clinical trial could be a challenge as the patients in this particular case are premature infants. Furthermore, the profile of the clinical trial inclusion criteria can also result in greater difficulties in recruiting patients. The number of patients will have a significant impact on the time plan for the clinical trials. If it becomes very challenging to find patients the project risks delay or closure. In addition, if one or several of the Company's co-operation partners, which the Company relies on for finding patients, were to terminate the agreements and if these cannot be replaced with other agreements, the clinical trials could be delayed which would also affect the timing of the development and ultimately the approval of the pharmaceutical. Such a delay could lead to additional costs and that expected revenues are not generated as planned. This could have a negative effect on the Company's results of operations and financial position.

#### **Patients and others who get in contact with the Company's products could suffer from unknown side effects**

As the Company's business is the development of pharmaceuticals, there is a risk that patients who participate in clinical trials or others who get in contact with the Company's products could suffer from serious unexpected side effects. The consequence of such side effects could be that additional clinical trials are required in respect of the safety and tolerability of the drug, that the project is cancelled completely or that claims for damages are made against the Company. Serious side effects could have a negative effect on IBT's reputation, delay or make it impossible to launch the product which could have a negative effect on the Company's sales and costs.

#### **IBT is dependent on upholding protection for its intellectual property**

IBT may become dependent on BioGaia AB's (publ) ("BioGaia") ability to defend the patent under which IBT has a license. 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 legal systems, 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 inventions, competitors may be afforded 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 into important co-operation 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.

#### **Dependency on licensing agreement with BioGaia**

One of the most important intellectual property rights of IBT is the licensing agreement with BioGaia. Under the agreement, IBT has received an exclusive right to use the patent for the bacterial strain (for IBT called IBP-9414) for developing pharmaceutical treatment in premature infants. Since IBT's research and development to a large extent is based on this licensing agreement, IBT is dependent on the licensing agreement being maintained. Should the licensing agreement for whatever reason be terminated or if BioGaia does not fulfill its obligations under the licensing agreement, the Company's future development, growth and financial position could be negatively affected.

#### **The Company's business is capital intense and the Company may seek to fulfil such needs with different financing options**

The development of pharmaceuticals of the types being developed by IBT is extremely costly. As set out in this Company description, IBT aims to finance its first clinical trial, the safety and tolerability trial, through an upcoming rights issue of SEK 100 million to the Company's shareholders, which is expected to be completed during the second quarter of 2016. In addition thereto, there will be a significant capital need for further clinical trials. The Company has thus far not generated any revenue, which means that IBT will require access to capital in the future before its cash flow turns positive. Access to capital may be limited at times when it is needed by the Company, which may prejudice the Company's financial position and its possibility to commercialize its innovations. Furthermore, even though BioGaia's major shareholder Annwall & Rothschild Investments AB, who holds shares corresponding to approximately nine percent of the share capital and approximately 34 percent of the votes in BioGaia, and who will hold shares in IBT following the distribution of all BioGaia's shares in IBT, has declared its intention to subscribe for its pro rata share in IBT in the upcoming rights issue, there is a risk that the rights issue will not generate the SEK 100 million proceeds required for conducting the first clinical trial. Both the size and timing of the Company's future capital need is dependent on a number of factors, for example the ability to succeed in research and development projects and the ability to enter into co-operation or licensing agreements with external parties. In addition to the already announced capital need of SEK 100 million, the Company believes, based on its current development plan, that additional capital of SEK 300 to 600 million will be required for the development of IBP-9414 and submission for regulatory approval.

Wholly owned projects, such as IBP-9414, are financed either by way of equity financing or through partner financing (e.g. with pharmaceutical companies). The Company could also receive certain governmental contributions, such as research grants. There is however a risk that IBT will not be able to find financing options or be able to finance projects with existing equity. Thus, IBT may in the future turn to the capital market to raise additional capital, which could entail an issue of new shares in the Company. Through an issue of new shares current



shareholders could be diluted. This is especially the case for shareholders in other jurisdictions than Sweden where additional registration measures are required and where the Company, on reasonable grounds, may choose not to complete such registrations.

IBT will also explore other financing options, such as bank loans or other debt financing. There is a risk that such loans cannot be acquired as the need arises, that loans cannot be acquired on favorable terms and conditions and that such loans are not sufficient to cover the financing needs of the operation according to plan. This could have a negative effect on the Company's ability to grow and invest when the opportunity is given.

#### **IBT is dependent on the ability to commercialize the product**

It is of utmost importance for IBT's future profitability and financial position that projects become commercialized in a successful way. Commercialization of the Company's development project could for example take place through co-operations or licensing of the products to a third party, through a sale of all the rights associated with the project or by selling the final products to the market.

If the Company is not successful in commercialization of the project, it may be impossible to realize the entire value of the product. Thus, IBT is throughout all phases of the project dependent on co-operations as well as the forms and organizations of such co-operations. There is a risk that IBT cannot attract the right co-operation partners through the necessary phases of the project or be able to find the proper forms for organizing the co-operations or be able to enter into favorable agreements with such partners. There is also a risk that the Company is not able to retain already existing co-operations partners or that such partners do not fulfill their obligations under the existing agreements. All of the above could have a negative impact on the Company's future development, growth and financial position.

#### **Orphan drug designation could be revoked**

In August 2013 IBT received an orphan drug designation in the US and in February 2015 IBT received an orphan drug designation in Europe which grant IBT exclusivity on the market for seven and ten years, respectively, as from the grant date of the relevant marketing approval. There is a risk that the orphan drug designations may be revoked if IBT is unable to comply with the laws regulating orphan drugs. If the orphan drug designations were to be revoked this could have a negative effect on the Company's ability to compete on the market which could have a negative effect on the Company's business, results of operations and financial position.

#### **Dependency on co-operation for research and development**

IBT is involved in the research and development of pharmaceuticals and co-operates with well-established researchers. However, some of these co-operation projects are governed by agreements with varying terms. Were key agreements to terminate, it might have negative consequences both for the Company's business operations as well as its earnings and financial position.

#### **Market and competition**

The industry for the development of new pharmaceuticals is heavily exposed to competition. Developing a new pharmaceutical from invention to finished product requires a great deal of time. Not the least for this reason, when development is underway it is uncertain whether there will be any market for the product when it is finally developed and, in such case, how large this market will be, as well as which competing products the Company's products will encounter when they reach the market. This may lead to a negative effect on the Company's earnings.



### **Purchasing and pricing**

On many markets, purchases of pharmaceuticals of the type being developed by the Company are financed, in whole or in part, by a party other than the patient, for example caregivers, insurance companies or governmental authorities subsidizing pharmaceuticals. If the Company does not achieve acceptance for its products and the desired pricing of the products by such financiers, this may make it more difficult for the products to reach the market and may prejudice their commercial potential, which may negatively affect IBT's earnings and financial position. In addition, in case the incidence of NEC is relatively low for certain countries it may be difficult to demonstrate an economic benefit for the approved drug to support reimbursement or formulary acceptance decisions.

### **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 person, this might have a negative effect on the Company's business, financial position and earnings.

### **Trade secrets**

The Company is dependent on ensuring that trade secrets which are not covered by patents or other intellectual property rights can be protected, including among other things information regarding inventions for which patent applications have not yet been filed. The employees of IBT and its co-operating partners are normally subject to confidentiality undertakings but there is always a risk that someone who has access to information of great value to the Company disseminates or uses the information in a way which renders it impossible for the Company to obtain a patent, or otherwise damages IBT from a competition perspective, which may have a negative effect on the Company's business and financial position.

### **Legislation**

The pharmaceuticals industry is to a large degree affected by legislation and other regulations. The regulations include approval processes, quality controls and documentation requirements. Over time new legislation is formed and introduced that can significantly alter the regulatory framework that governs the trial, regulatory approval, production and marketing of the regulated product in question. In addition, regulations from supervisory authorities, and their guiding advices, may be revised or reinterpreted in ways that can significantly affect the Company's operations. Such changes may entail the request for further results or studies, changes in production methods, withdrawal, replacement or termination of authorization for certain products and increased documentation obligations. Changes in legislation and regulations regarding pharmaceuticals, both in the US and in Europe as well as in other parts of the world, may entail increased costs which might have a negative impact on the Company's business, financial position and earnings. In addition, changes in legislation and regulations may affect the conditions for the Company's business operations.

### **Liability claims**

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. Disputes regarding liability may be very costly

and can lead to extensive negative publicity for IBT which may negatively affect the Company's financial position, business and earnings.

#### **Dependence on subcontractors and distributors**

If IBT is unable to secure reliable subcontractors that can deliver at competitive prices, this may negatively affect its business operations and earnings. The same applies where a contracted subcontractor is unable to supply a sufficient quantity at the right quality and at the right time, which could have a negative impact on the Company's business and earnings.

IBT may also be dependent upon distributors to get its products to market. If IBT is unable to establish a distribution organization which can distribute the Company's products to the end customers on terms and conditions advantageous to IBT, this may have a negative effect on IBT's business and earnings.

#### **Financial risks**

There is a risk that IBT will not be able at all, or only at a significantly higher cost, to obtain access to financing in order to meet its contractual obligations. If the Company fails to raise the necessary capital, this might have a negative impact on the Company's business, financial position and earnings.

#### **Tax related risks**

It cannot be ruled out that IBT's interpretation of applicable laws and administrative practice is incorrect, or that applicable laws or administrative practice change, possibly with a retroactive effect. Furthermore, decisions of the tax authorities may deteriorate the IBT's past or current tax positions. In the event that IBT's interpretation of laws or administrative practice is incorrect, if tax laws change or if tax authorities successfully make tax adjustments that deteriorate IBT's past or current tax positions, this could have a negative impact on the Company's business, result of operations, financial condition and future prospects.

#### **Disputes, claims, investigations and proceedings may lead to IBT having to pay damages or cease with certain operations**

Disputes, claims, investigations and proceedings may lead to IBT having to pay damages or cease with certain operations. IBT may become involved in disputes within the framework of their normal business activities and risk being subject to claims in suits concerning agreements. In addition, IBT (or the Company's officers, directors, employees or affiliates) may become subject to criminal investigations and proceedings. Disputes, claims, investigations and proceedings of this kind can be time consuming, disrupt normal operations, involve large claim amounts and result in considerable costs. Moreover, it can be difficult to predict the outcome of complex disputes, claims, investigations and proceedings. Future disputes, claims, investigation and proceedings may have a material adverse effect on IBT's business, prospects, results of operations and financial position.

### **RISKS RELATING TO THE NASDAQ FIRST NORTH LISTING**

#### **An active, liquid and orderly trading market for IBT's shares may not develop, the price of its shares may be volatile, and potential investors could lose a portion or all of their investment**

Trading in securities is always associated with risks and risk-taking. Since an investment in equities can both increase and decrease in value, it is not certain that an investor will recoup all or even a part of the capital invested.

Prior to the planned listing on Nasdaq First North (“**First North**”), there has been no public market for IBT’s shares. There is a risk that an active and liquid market will not develop or, if developed, that it will not be sustained after the listing.

In addition, it should be noted that the pricing of the Company’s shares is dependent on factors beyond the control of IBT including, among other things, the stock market expectations and its development as well as the economy in general. Investments in IBT’s shares should therefore be made following a thorough analysis of the Company, its competitors, and extraneous factors in general as well as general information regarding the industry. An investment in shares should never be viewed as a quick way of generating a return, but rather as a long-term investment which is made with capital one can afford to do without. The price of shares may be subject to fluctuations as a consequence of changes in opinions on the capital market regarding the shares or similar securities, due to various circumstances and events such as changes in applicable legislation and other rules which affect the Company’s business, or changes in the Company’s earnings and business development. Stock markets may experience significant fluctuations from time to time regarding prices and volumes which need not be related to the Company’s business or future prospects. In addition, the Company’s earnings and future prospects may, from time to time, be lower than the expectations of capital markets, analysts or investors. One or more of these factors may result in a drop in the price of the share.

#### **Trading on an unregulated market is usually associated with more risk than trading on a regulated market**

The Company has submitted an application for admission to trading on First North, which according to the Swedish Securities Markets Act, is deemed to be a trading platform, but not a regulated market. A trading platform does not have the same legal restrictions as a regulated market and therefore an investment in shares traded on a trading platform is typically associated with higher risks than an investment in shares on a regulated market.

#### **Influence by major shareholders**

Following the distribution of BioGaia’s shareholding in IBT to the shareholders of BioGaia, a consolidated ownership structure will apply in IBT whereby Annwall & Rothschild Investments AB will hold shares corresponding to approximately eight percent of the share capital and approximately 33 percent of the votes in the Company. Thus, Annwall & Rothschild Investments AB will have a significant influence over the outcome of matters submitted to IBT’s shareholders for approval, including but not limited to resolutions on dividend, capital increases and the election of directors of the board.

#### **IBT’s ability to pay dividends is dependent upon its future earnings, financial condition, cash flows, net working capital requirements, capital expenditures and other factors**

IBT commenced its operations in late 2013 and commercialization of the Company’s current project is still a number of years ahead. Future potential dividends will take into consideration the Company’s cash flow and financing of future expansion. Moreover, the terms and conditions of future loans or credit facilities may prevent IBT from paying a dividend. As a consequence of this, an increase in the price of the Company’s shares will constitute the only possibility for return for a shareholder of the Company within the foreseeable future.

As a result of alterations to the Swedish Annual Accounts Act (Sw. *Årsredovisningslagen*), a limitation of distributing equity is introduced for development costs that are capitalized after 1 January 2016. Equity equal to the capitalized development costs should be allocated to a special

restricted fund within equity called “fund for development costs”. This is only applicable for new/additional capitalized development costs, i.e. capitalization on or after 1 January 2016. The fund for development costs will be reduced with annual depreciation over the expected economic lifetime. The proposed alteration to the Swedish Annual Accounts Act may impact IBT’s ability to pay dividend.

**Differences in currency exchange rates may materially adversely affect the value of shareholdings or dividends paid**

IBT’s shares will be quoted in SEK only, and any dividends will be paid in SEK. As a result, shareholders outside Sweden may experience adverse effects on the value of their shareholding and their dividends, when converted into other currencies if SEK depreciates against the relevant currency.

**New share issues in the Company may not be sufficiently subscribed and such issues, or larger divestments of shares in IBT, may adversely affect the market price of the Company’s shares**

Following the listing of the Company’s series B share on First North, the Company intends to issue new shares with pre-emptive rights for the Company’s shareholders. There is a risk that the issue, and/or future potential share issues, will not be sufficiently subscribed entailing lower issue proceeds than anticipated by the Company. New share issues could also have a negative impact on the market price of the outstanding shares in the Company. The same applies to larger share divestments from major shareholders. Furthermore, new share issues could entail ownership dilutions for current shareholders not being able to or choosing not to participate in the relevant share issue.

# Background and reasons

**IN LATE 2013, BIOGAIA**, together with IBT's current CEO Staffan Strömberg and Head of R&D, Eamonn Connolly, commenced the operations of IBT as a subsidiary to BioGaia. IBT is a pharmaceutical company with a vision to develop drugs to treat rare diseases affecting premature infants. Currently, IBT's current focus is on developing a drug, IBP-9414, using *Lactobacillus reuteri* to prevent necrotizing enterocolitis ("NEC"), a fatal disease that affects premature infants.

IBT aims to develop an orphan drug to prevent NEC, a leading cause of death among all premature newborns, with an average mortality rate of 20-30 percent. According to the current development plan, IBT expects to run two clinical trials 2016–2019. The first clinical trial, the safety and tolerability trial, is expected to be initiated in 2016. The second clinical trial is expected, depending on the first clinical trial, to begin in 2017. The clinical development plan has been designed with input from the FDA, EMA and US/EU key opinion leaders ("KOLs").

IBT has the potential of providing a drug for a disease to which there are currently no prevention drugs available. The time and capital required to complete the clinical trials is by nature uncertain. As is the case with all drug development, the result of the studies to be conducted is uncertain in respect of when and if the drug candidate will reach the market. The Company's goal is to file for market authorization during 2019.

BioGaia has financed the IBT development project since its start in November 2013 due to IBT's interesting application of BioGaia's *Lactobacillus reuteri* bacterial strain. Since the start, BioGaia has invested approximately SEK 82 million to finance mainly pharmaceutical formulation and manufacture work of IBP-9414 and preparation of the clinical trials. To raise the necessary capital required to finance the safety and tolerability trial, the board of directors of BioGaia resolved in June 2015 to evaluate a separate listing of IBT. Further, the extraordinary general meeting in BioGaia, held on 18 mars 2016, resolved upon the distribution of the IBT shares to the BioGaia shareholders. The IBT series B share is expected to begin trading on First North on 29 March 2016. Following completion of the listing on First North, IBT's aim is to apply for admission to trading of the IBT series B share on the main market of Nasdaq Stockholm within 12 to 18 months, subject to market conditions.

Following the listing, and for the purpose of securing the required capital to complete the first planned clinical trial of IBP-9414, which has a budget of approximately SEK 45 million, and to fund the ongoing operations, IBT is planning to resolve on a rights issue in the amount of SEK 100 million during the second quarter of 2016.

*We, the board of directors of IBT, declare that, to the best of our knowledge, the information provided in the Company description is accurate and that, to the best of our knowledge, the Company description is not subject to any omissions that may serve to distort the picture the Company description is to provide, and that all relevant information in the minutes of board meetings, auditors' records and other internal documents is included in the Company description.*

Stockholm, 21 March 2016

**Infant Bacterial Therapeutics AB (publ)**

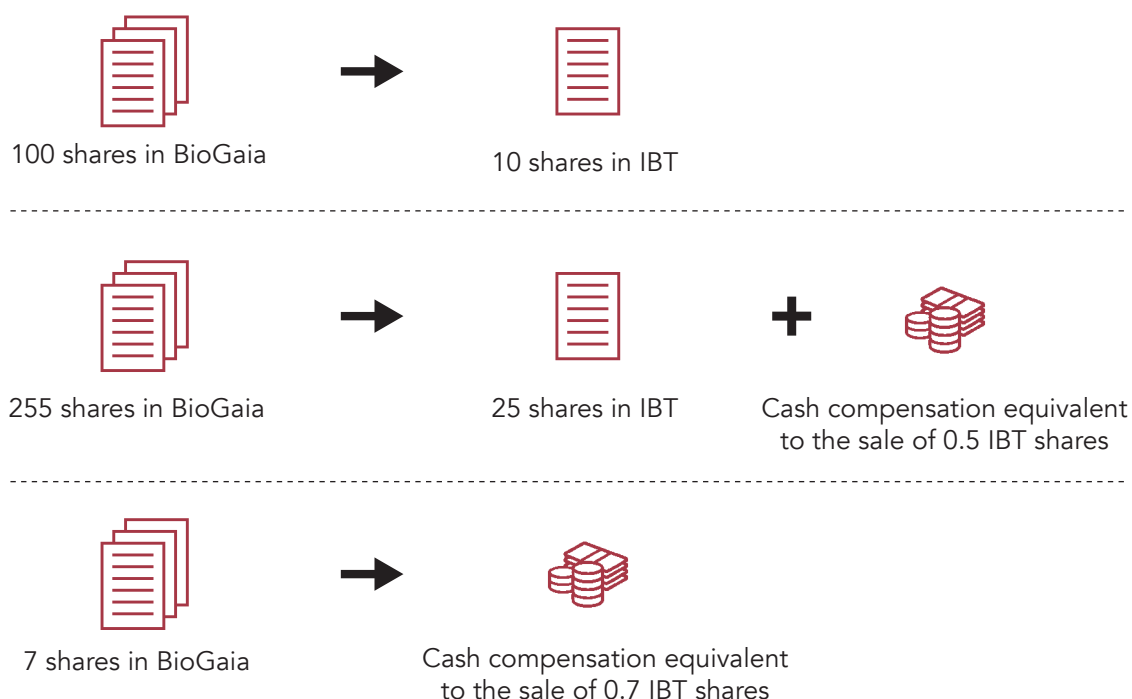
*The board of directors*

# Lex ASEA distribution

## RESOLUTION ON DIVIDEND

On 18 March 2016, the extraordinary general meeting of BioGaia resolved in accordance with the board of directors' of BioGaia proposal to distribute all of BioGaia's shares in IBT, representing approximately 94.5 percent of the shares and 96 percent of votes in IBT,<sup>1</sup> to BioGaia's shareholders. The shares in IBT are distributed in accordance with the so called Lex ASEA rules, meaning that the shares are distributed pro rata to BioGaia's shareholders (the "**Distribution**"). For ten (10) shares in BioGaia one (1) share in IBT will be distributed. If the current shareholding cannot be divided evenly, fractions of shares will be distributed. Such fractions of shares in IBT will be consolidated into whole shares which will be sold by Carnegie once the series B shares of IBT have been listed on First North. No commission will be charged in connection with such sale and the proceeds will be distributed to the shareholders via Euroclear.

### Example of the number of IBT shares received through the dividend:



## RECORD DATE

The record date for the right to receive the dividend is 23 March 2016. Shareholders who on the record date are registered in the share register of BioGaia maintained by Euroclear on behalf of BioGaia will receive shares in IBT. The last day for trading in the BioGaia share including the right to receive the dividend is 21 March 2016. The shares in BioGaia are traded without the right to receive shares in IBT from and including 22 March 2016.

<sup>1</sup> The remaining shares in IBT are held by members of the board of directors and management of IBT.

## DELIVERY OF SHARES IN IBT

### Directly registered shareholders

Two banking days following the record date for dividend, the IBT shares will be available on the shareholders' securities accounts. Euroclear will distribute VP notices with information regarding the number of shares which are registered on the securities accounts.

### Nominee registered shareholders

Shareholders with its shares in BioGaia nominee registered with a bank or other nominee will not receive an issue account statement from Euroclear. Such shareholders will be informed in accordance with their respective nominee's routines.

### IMPORTANT DATES

Last day for trading in BioGaia's shares with the right to receive shares in IBT	<b>21 March 2016</b>
BioGaia's shares are traded without the right to receive shares in IBT	<b>22 March 2016</b>
Record date to receive shares in IBT	<b>23 March 2016</b>
First day of trading in IBT's series B shares on First North	<b>29 March 2016</b>



# Market overview

The Company description includes information concerning IBT's future markets and other information related to the business. Unless otherwise indicated, the information in the Company description is based on IBT's evaluation of multiple sources stated in the Company description. As IBT does not have access to the facts and assumptions underlying such market data, or statistical information and economic indicators contained in these third party sources, IBT is unable to verify such information and, while IBT believes it to be reliable, IBT cannot guarantee its accuracy or completeness. As far as IBT is aware and able to ascertain through comparison with other information published by such sources, no information has been omitted which could render the reproduced information inaccurate or misleading. For information on the medical terms used in this section, please refer to the section "Glossary".

## NEC

### What is NEC?

NEC is a leading cause of death among all premature infants. The average mortality rate of afflicted infants is 20-30 percent where a lower birth weight entails a higher risk of mortality. NEC is an acquired inflammatory disease of the newborn bowel in which portions of the bowel undergo tissue death with associated high morbidity and mortality.

NEC kills approximately 3,700<sup>2</sup> European and 1,500<sup>3</sup> US infants per year. NEC has an unpredictable, spontaneous, and acute onset and is untreatable, except through major surgery. The long-term clinical consequences for infants who survive NEC are variable and include short bowel syndrome, parenteral nutrition-associated cholestasis, prolonged neonatal hospitalization, abnormal growth, and adverse neurodevelopmental outcomes, including cerebral palsy, cognitive impairment, visual impairment, and hearing impairment.

There is no definitive treatment for NEC. Approximately 20-40 percent of patients with NEC will require surgery.<sup>4</sup> None of the currently available treatments for NEC modify the underlying risk factors for the disease. Thus, NEC prevention strategies are vital and urgently needed but to date none have been successful or generally adopted as the standard of care, and prophylaxis for NEC remains a true unmet medical need.

<sup>2</sup> Approximation calculated with risk-population under 34 weeks gestational age in EU (Euro-Peristat, *The European Perinatal Health Report 2010, Health and Care of Pregnant Women and Babies in Europe in 2010; 2013* and Moser K, Hilder L. Assessing quality of NHS numbers for babies data and providing gestational age statistics. *Health Stat Q* 2008;37:15-23), incidence of NEC of 7 percent (Guillet R, Stoll BJ, Cotton CM, et al. Association of H2-blocker therapy and higher incidence of necrotizing enterocolitis in very low birth weight infants. *Pediatrics*. 2006;117:e137-e142) and mortality of 20-30 percent (Mustafi D, Shiou SR, Fan X, et al. MRI of neonatal necrotizing enterocolitis in a rodent model. *NMR Biomed*. 2013;27:272-279 and Fitzgibbons SC, Ching Y, Yu D, et al. Mortality of necrotizing enterocolitis expressed by birth weight categories. *J Pediatr Surg* 2009;44:1072-75).

<sup>3</sup> Approximation calculated with risk-population  $\leq 1,500$  grams in the US (Martin JA, Hamilton BE, Ventura SJ, et al. *Births: final data for 2010. National Vital Statistics Reports*. 2012; 61:1-100), incidence of NEC of 7 percent (Guillet R, Stoll BJ, Cotton CM, et al. Association of H2-blocker therapy and higher incidence of necrotizing enterocolitis in very low birth weight infants. *Pediatrics*. 2006;117:e137-e142) and mortality of 20-30 percent (Mustafi D, Shiou SR, Fan X, et al. MRI of neonatal necrotizing enterocolitis in a rodent model. *NMR Biomed*. 2013;27:272-279 and Fitzgibbons SC, Ching Y, Yu D, et al. Mortality of necrotizing enterocolitis expressed by birth weight categories. *J Pediatr Surg* 2009;44:1072-75).

<sup>4</sup> Maheshwari A, Corbin LL, Schelonka. Neonatal necrotizing enterocolitis. *Res Rep Neonatol*. 2011;1:39-53.

## MEDICAL NEEDS, MARKET AND COMPETITION

### Medical needs

NEC is a leading cause of death among premature infants in the neonatal intensive care unit (the “NICU”). 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. Additionally, none of the standards of care or currently available treatments for NEC modify the underlying risk factors for the disease.

The independent healthcare consulting firm, Apex Healthcare Consulting Ltd. (“**Apex**”), was commissioned by IBT in November 2014 to evaluate the market potential of the preventative drug IBP-9414 for NEC (the “**Apex Report**”).

Apex interviewed 30 neonatologist KOLs in the US, France, Germany and the UK; five US hospital pharmacists and five EU payers.

The study focused on;

1. The level of unmet medical need for prevention and treatment of NEC;
2. The degree of interest in the IBP-9414 product profile and whether the asset addressed the medical unmet need; and
3. A logical price range for IBP-9414 to support reimbursement.

The report established that there is a clear unmet medical need to reduce the incidence of NEC in vulnerable, premature infants. The expressed need referred to effective but also safe prevention therapies. Respondents pointed the lack of pharmaceutical grade quality, supporting evidence of probiotics in the use in premature infants.

Based on the IBP-9414 product profile, the majority of respondents were in favor of the usage of IBP-9414 for the prevention of NEC and, if successful, the profile would address this unmet medical need.

### Market

There are a number of general factors related to the dynamics of the pharmaceutical industry which could influence the future commercialization of IBP-9414. These factors are to a large extent outside the Company’s control and may differ materially from what the Company anticipates. In an initial stage, the Company is dependent on the completion of clinical development and market approval. Following drug approval, the Company shall request reimbursement status to health insurance national agencies and private carriers. They will determine the degree of reimbursement based on criteria such as medical benefits to patient and benefits over current standard of care.

Apex has in the Apex Report estimated that the number of premature infants eligible to receive prophylaxis for NEC is over 50,000 infants in the US, based on the number of infants born weighing 1,500 grams or less, and over 100,000 infants in EU5 (France, Germany, Italy, Spain, and the UK), based on the number of infants born after less than 34 weeks of gestation.

On the basis of certain assumptions, such as a price of USD 10,000 per six-week treatment course and an average 16 percent market penetration for the US and EU5 markets, Apex estimates peak annual sales of USD 175 million in the US and USD 70 million in EU5. The ana-

lysis considered the early mortality, proportion of infants currently managed prophylactically for NEC, prescribers' price sensitivity, and physician statement.

NEC patients require medical and in many cases also surgical interventions that prolong hospital expenditures and length of stay. The economic burden 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.<sup>5</sup> Moreover, those infants who survive NEC may face serious life-long sequelae, which eventually decrease their quality of life and generate further cost to the patient and society. A preventive therapy for NEC such as IBP-9414 could therefore be expected to indirectly reduce these healthcare expenses and should therefore be attractive for health insurances. IBT intends to demonstrate these benefits to support reimbursement for IBP-9414 in the prevention of NEC.

### Competitors

Competitors are identified in this section as companies developing a drug to prevent NEC in premature infants.

Apart from IBT there are, to the best of the Company's knowledge, two other companies which are in the process of developing a drug candidate for prevention of NEC.

According to [clinicaltrials.gov](http://clinicaltrials.gov), Sigma Tau Pharmaceuticals is developing STP-206 for the prevention of NEC in premature infants. Sigma Tau Pharmaceuticals have completed a phase I study in healthy adults and is currently conducting a phase I/II study to assess safety and tolerability of STP-206 in premature infants. According to information from [clinicaltrials.gov](http://clinicaltrials.gov), Sigma Tau Pharmaceuticals expects to complete their phase I/II study in December 2019. They received orphan drug designation from FDA in March 2015 (IBT received its orphan drug designation from FDA in August 2013 and from the European Commission in February 2015).

Societa Laboratorio Farmaceutico S.I.T. Srl received orphan drug designation for a combination of bacterial strains for the prevention of NEC in premature infants from the European Commission in December 2013. According to [clinicaltrials.gov](http://clinicaltrials.gov), Societa Laboratorio Farmaceutico has not published any clinical data for the prevention of NEC.

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<sup>5</sup> Bisquera JA, Cooper TR, and Berseth CL. Impact of necrotizing enterocolitis on length of stay and hospital charges in very low birth weight infants. *Pediatrics*. 2002;109:423-428.

# Business description

## IBT AND IBT'S AIM

### Introduction and background

IBT is a pharmaceutical company with a vision to develop drugs to treat rare diseases affecting premature infants. Currently, IBT's current focus is on developing a drug, IBP-9414, using *Lactobacillus reuteri* to prevent NEC, a fatal disease that affects premature infants.

Prior to his current assignment, Eamonn Connolly extensively developed the research around *L. reuteri* at BioGaia for 15 years. Over the years, he noted increasing demands and interests of clinicians around the world in the use of *L. reuteri* in premature infants and namely for the prevention of NEC, a fatal and serious disease affecting premature infants which remains an important unmet medical need. BioGaia's products are not intended for premature infants nor are they drugs indicated for a specific disease. When Staffan Strömberg joined BioGaia, he and Eamonn Connolly saw the opportunity with their extensive pharmaceutical experience to answer this particular unmet medical need with a pharmaceutical approach and more specifically an orphan drug strategy. Together with Staffan Strömberg and Eamonn Connolly, BioGaia commenced the operations of a BioGaia subsidiary, namely IBT, in 2013 which would focus exclusively on the development of drugs for premature infants, thereby differentiating from its parent company BioGaia. In December 2015, the Investigational New Drug ("IND") became effective, allowing IBT to conduct clinical trials in the US. Furthermore, IBT received approval from the Swedish Medical Products Agency to conduct a clinical trial in Sweden.

IBT is based in Stockholm and the Company's series B shares are intended to be listed for trading on First North in Stockholm as from 29 March 2016 with Erik Penser Bankaktiebolag as its certified adviser.

## The IBT story

### 1990

- ▶ *Lactobacillus reuteri* is isolated by Dr. Ivan Casas from human breast milk

### BioGaia

### 1990-2007

- ▶ Increasing requests from clinicians for the use of *Lactobacillus reuteri* and conduct studies in premature infants
- ▶ Extensive use of *Lactobacillus reuteri* in humans (including adults, children and premature infants) leads to published safety track records

### 2007-2013

- ▶ First investigator approaches BioGaia to use *Lactobacillus reuteri* in a prophylactic study in premature infants
  - Primary outcome is to evaluate the prevention of death and nosocomial infections
  - Incidence of NEC is measured as a secondary outcome
  - Clear clinical signal that *Lactobacillus reuteri* could decrease the incidence of NEC
  - Study is published in 2012 (Rojas et al, 2012)
- ▶ Further investigator uses *Lactobacillus reuteri* in a retrospective cohort study in premature infants
  - The study compares the incidence of NEC before and after the introduction of *Lactobacillus reuteri* as routine prophylaxis
  - The study shows statistically significant benefit of *Lactobacillus reuteri* in the prophylaxis of NEC
  - Study is published in 2012 and additional data is published in 2013 (Hunter et al, 2012; Dimaguila et al, 2013)



### 2013

- ▶ Infant Bacterial Therapeutics AB (IBT) commence its activities and start 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 to IBT development plans

### 2014

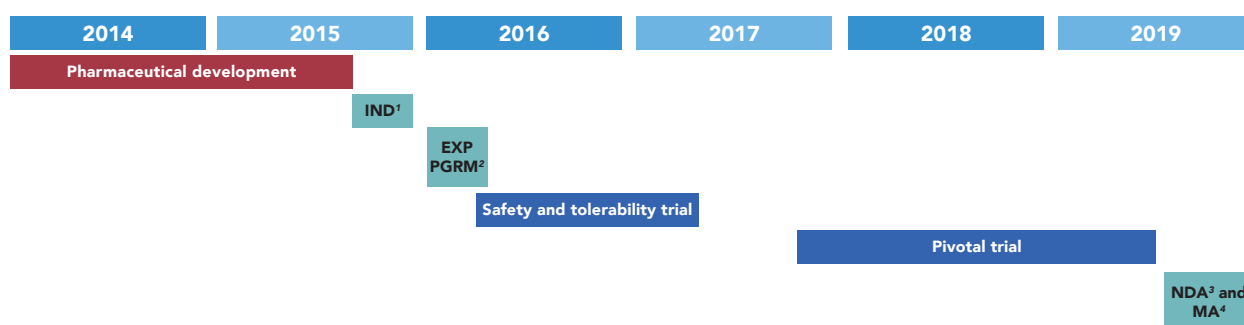
- ▶ Pharmaceutical development defining IBP-9414 formulation and manufacturing process
- ▶ The European Medicines Agency provides scientific input to IBT development plans

### 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 trial phase II
- ▶ Active IND obtained from FDA for start of clinical trial phase II in 2016

In June 2015, BioGaia announced that the management team of BioGaia will evaluate the possibility of a separate listing of IBT. On 18 March 2016, BioGaia resolved on the separation to take place through a dividend of all BioGaia's shares in IBT to the shareholders of BioGaia, applying the so called Lex ASEA rules. Following the dividend it is intended that IBT's series B shares will become listed on First North on 29 March 2016. Through the separation from BioGaia, IBT will be able to continue focusing on development, research and marketing as a stand-alone company.

## IBT DEVELOPMENT PROJECT: IBP-9414



### Notes

<sup>1</sup> Investigational New Drug Application <sup>2</sup> Expedited Program for Serious Conditions <sup>3</sup> New Drug Application <sup>4</sup> Market Authorisation

### Introduction and background

IBT's current focus is to develop the drug candidate IBP-9414 to reduce the incidence of NEC. IBP-9414 contains *Lactobacillus reuteri* as active substance which is licensed from BioGaia. *L. reuteri* is a co-evolved human bacterial strain derived from human breast milk.

Eamonn Connolly, IBT Head of R&D has worked with *L. reuteri* for 15 years as Senior Vice President Research BioGaia and collected important pre-clinical and clinical knowledge around *L. reuteri* and its possible applications. His most recent interest led to IBT drug candidate IBP-9414 for the prevention of NEC in premature infants. Indeed several recent studies indicated a clear signal that *L. reuteri* has great potential to demonstrate significant effect in preventing NEC if studied in adequately designed pharmaceutical standard clinical trials.<sup>6</sup>

### Development plan for IBP-9414

To bring a new drug to the market, it must be demonstrated to regulatory agencies, such as the FDA and the EMA, that the proposed drug candidate is both safe and effective for use in a specific disease. The drug development program is composed of a drug discovery step, a pre-clinical, a CMC (Chemistry-Manufacture-Control) step and a clinical development phase:

#### ► Drug discovery

A drug discovery phase consists of a screening process to identify lead compounds with high potential to have a desired effect against a specific disease to become drug candidates.

#### ► Pre-clinical development phase

Prior to any use in human, the drug candidate is studied to demonstrate initial proof of safety and efficacy using laboratory studies. Pre-clinical studies can also be carried out to identify the mechanism of actions in disease-specific models. These studies can be *in vitro* or *in vivo* methods. *In vitro* experiments are laboratory experiments performed outside a living organism; whereas *in vivo* experiments are carried in a living organism such as mice.

<sup>6</sup> Rojas MA, Lozano JM, Rojas MX, et al. Prophylactic probiotics to prevent death and nosocomial infection in preterm infants. *Pediatrics*. 2012;130:e1113-20, Hunter C, Dimagulia MA, Gal P, et al. Effect of routine probiotic, *Lactobacillus reuteri* DSM 17938, use on rates of necrotizing enterocolitis in neonates with a birth weight < 1000 grams: a sequential analysis. *BMC Pediatrics*. 2012;12:142-47, Dimagulia MA, Gal P, Wilson T et al. Pharmacoeconomic impact of use of the probiotic *Lactobacillus reuteri* DSM 17938 for prevention of necrotizing enterocolitis in extremely low birth-weight infants. *Res Rep Neonatol*. 2013;3:21-25 and Oncel MY, Sari FN, Arayici S, et al. *Lactobacillus reuteri* for prevention of necrotizing enterocolitis in very low birthweight infants: a randomised controlled trial. *Arch Child Fetal Neonatal Ed*. 2014;99:F110-F115.

### ► Clinical development phase

The clinical development phase of a drug development consists of four clinical trial phases conducted in humans:

**Clinical trial phase I:** usually conducted with healthy volunteers and emphasizes safety. It usually follows a dose-escalation process, starting at a first low dose to reach step-wise a higher targeted dose. The goal is to identify the most frequent and serious adverse events related to the drug exposure. It could also include pharmacodynamics and pharmacokinetics measures (how the drug interacts with the body).

**Clinical trial phase II:** conducted in the target population for which the new therapy is intended to collect preliminary data on efficacy (whether the studied drug show the desired effect on the disease) and evaluate safety on short-term adverse events.

**Clinical trial phase III:** usually pivotal study engaging a larger patient sample than previous phases to collect sufficient safety and efficacy of a studied drug to support a market approval application.

**Clinical trial phase IV:** a surveillance study occurring after regulatory agencies have approved the studied drug for marketing. The aim of this phase is to evaluate the real world effectiveness and safety profile of a drug. It is based on observations from the drug use in the market.

IBT intends to conduct a clinical program consisting of two clinical trials. This clinical development plan, designed with input from US and EU KOLs, has been discussed with both FDA in 2013 and EMA in 2014 and adapted to include and accommodate their respective input. 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.

The first study is a phase II safety and tolerability study for two different dose levels of IBP-9414 in 120 premature infants with birth-weight ranging from 500 to 2,000 g. The study is planned to be initiated in 2016. The aim is to assess the safety and tolerability of the drug candidate IBP-9414 administered in premature infants. The incidence of NEC will also be observed. The budget for the first clinical study is approximately SEK 45 million.

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.

	Safety and tolerability trial	Pivotal trial
Expected duration	2016-2017	2017-2019
Clinical trial details	<ul style="list-style-type: none"><li>► ClinicalTrial.gov identifier: NCT02472769</li><li>► A randomized, double blind, parallel-group, dose escalation placebo-controlled multicenter study to investigate the safety and tolerability of IBP-9414 administered in preterm infants.</li><li>► Requested by FDA prior to the pivotal study to assess safety and tolerability of the new formulated IBP-9414 in a small sample of the target population of premature infants intended to be used in the pivotal trial.</li></ul>	<ul style="list-style-type: none"><li>► A randomized, double blind, parallel-group, placebo controlled study to evaluate the efficacy of IBP-9414 in premature infants, <math>\leq 1,500</math> grams, in the prevention of NEC</li></ul>



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. The Company's goal is to file for market authorization for IBP-9414 during 2019.

### Orphan drug designation

To stimulate the development of therapies for patients affected by rare diseases with unmet medical needs, regulatory authorities worldwide introduced the designation of Orphan Drug.

The Orphan Drug Act of 1983<sup>7</sup> introduces several incentives for drug companies developing drugs to prevent, diagnose or treat so-called rare diseases that affect less than 200,000 individuals in the US.<sup>8</sup> These incentives consist of seven years of market exclusivity from the grant date of marketing approval, assistance in clinical research study designs, tax credits for the costs of clinical research, FDA fee waiver and eligibility for FDA grants.

The European Parliament adopted the Orphan Regulation on 16 December 1999 to lay down the EU procedure for designation of orphan medicines and stimulate the development of orphan medicinal products. An orphan disease is defined as a disease or condition affecting not more than 5 in 10,000 European citizens with no satisfactory method of diagnosis, prevention or treatment. The adopted incentives consist of 10 years of market exclusivity from the grant date of marketing approval in the EU, protocol assistance and scientific advice, fee reductions on EMA procedural activities and eligibility for EU grants.

FDA and the European Commission granted IBT orphan drug status for *L. reuteri* for the prevention of NEC on 1 August 2013 and 12 February 2015, respectively.

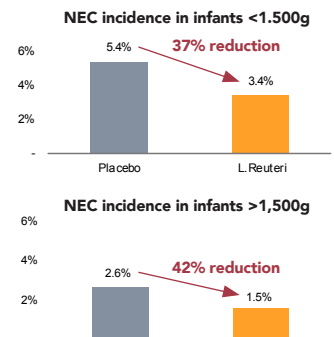
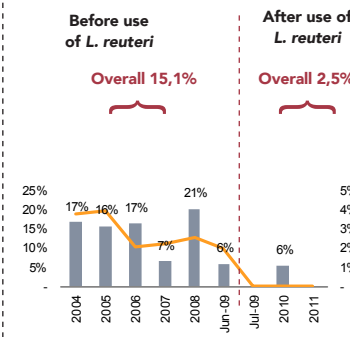
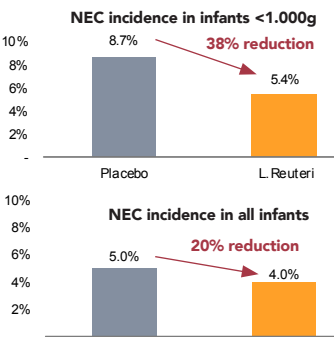
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<sup>7</sup> Reagan R., Statement on signing the Orphan Drug Act, 1983, available at: <http://www.presidency.ucsb.edu/ws/?pid=40583>

<sup>8</sup> U.S. Food and Drug Administration, Orphan Drug Act, Federal Regulation, available at: <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdact/significantamendmentstothefdact/orphandrugact/default.htm>

## Clinical experience

Three published clinical studies examining the use of the *L. reuteri* for prevention of NEC have been conducted (see table below). In addition, a pharmacoeconomic analysis using data from one of these publications, with data from an additional 43 infants, has been published.

	Rojas et al. (2012)	Hunter et. al (2012) / Dimaguila et al. (2013)	Oncel et. al (2014)
<b>Aim of the study</b>	Determine whether prophylactic administration of <i>L. reuteri</i> to pre-term infants reduces the incidence of the composite outcome of death or nosocomial infection	Examine the potential benefit of administering <i>L. reuteri</i> on the rate of NEC in extremely low-birth-weight infants	Evaluate the effect of administration of <i>L. reuteri</i> on the incidence and severity of NEC and sepsis in very low-birth-weight infants
<b>Target population</b>	≤2,000 g birth weightsplit into <1,500 and 1,501g-2,000g	≤1,000g birth weight	≤32 GA weeks and ≤1,500g birth weight
<b>Method</b>	Placebo-controlled trial conducted in 9 NICUs between 2008-2011	Retrospective comparison of the rates of NEC in neonates before and after the introduction of <i>L. reuteri</i> routine use	Placebo-controlled trial conducted between 2012-2013
<b>Number of patients</b>	750 patients (372 <i>L. reuteri</i> and 378 placebo)	354 patients (232 before and 122 after the introduction of <i>L. reuteri</i> )	400 patients (200 <i>L. reuteri</i> and 200 placebo)
<b>Results</b>	<ul style="list-style-type: none"> <li>▶ 37% reduction in NEC incidence in infants ≤1,500g</li> <li>▶ 40% reduction in NEC incidence in the total study population</li> <li>▶ No infections and no adverse effects</li> </ul> 	<ul style="list-style-type: none"> <li>▶ Reduction in NEC incidence in neonates who received <i>L. reuteri</i> (2.5%) vs. others (15.1%)</li> <li>▶ Additional data from Dimaguila et al. (2013) (1.6% vs. 15.1%)</li> <li>▶ No infections and no adverse effects</li> </ul> 	<ul style="list-style-type: none"> <li>▶ 20% reduction in NEC incidence in the total study population</li> <li>▶ 38% reduction in NEC incidence in infants ≤1,000g</li> <li>▶ No infections and no adverse effects</li> </ul> 

These data have been recently reviewed by assessing the existing literature on previously conducted trials with *L. reuteri* in premature infants.<sup>9</sup> The review concluded that *L. reuteri* has the potential to reduce the risk of NEC in premature infants and that larger adequate trials are needed to confirm these findings.

*L. reuteri* has been shown in clinical research to be well-tolerated in humans, with no evidence of any adverse effects on the cardiovascular, central nervous, or respiratory systems. The extensive published clinical literature of studies of *L. reuteri* in over 4,600 humans indicates the safe use of *L. reuteri* in humans at doses ranging from 10<sup>6</sup> to 10<sup>11</sup> CFU/day, including preterm infants at risk for NEC. In addition, there is a large body of published clinical literature in which *L. reuteri* was administered to over 2,400 infants, including preterm (<37 weeks GA) and full-term infants at risk for NEC, which provides substantial safety experience to support the proposed clinical development plan.

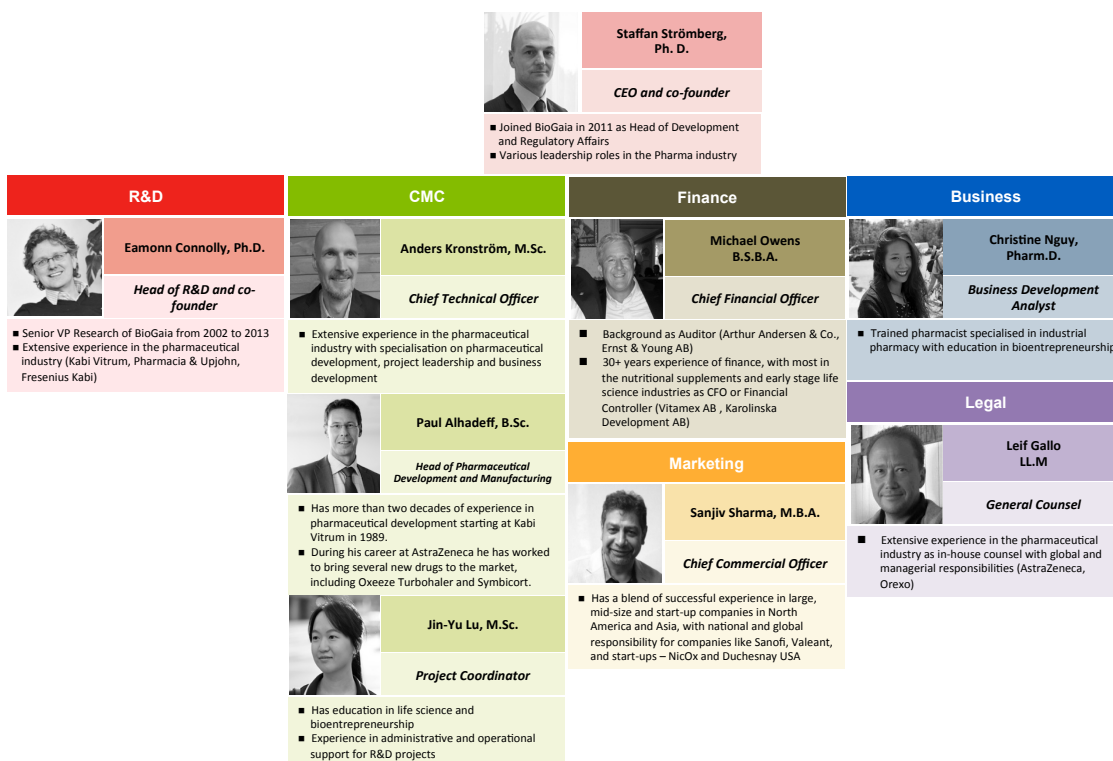
<sup>9</sup> Athalye-Jape G, Rao S, and Patole S. *Lactobacillus reuteri* DSM 17938 as a probiotic for preterm neonates: A strain-specific systematic review. *JPEN J Parenter Enteral Nutr.* 2015.

## ORGANIZATION

The board of directors of IBT consists of the chairman Peter Rothschild and directors Jan Annwall, Anders Ekblom and Margareta Hagman. For more information on the members of the board of directors, please refer to the section “Board of directors, executive management and auditors”.

The management consists of CEO Staffan Strömberg, CFO Michael Owens and Head of R&D Eamonn Connolly.

### IBT organization chart



## BUSINESS MODEL AND STRATEGY

### Business model

IBT carries out pharmaceutical innovation for the unmet medical needs of premature infants in accordance with all applicable pharmaceutical regulations. Such innovative therapies, production processes or medical uses, when possible, are patented in order to secure fundamental commercial rights as and when they become available.

The Company's current business focus is the development of drug candidate IBP-9414 for the prevention of NEC in premature infants. However, IBT plans to broaden in the future its research and development activities towards other unmet medical needs of premature infants.

IBT does not currently have in-house research sites. IBT collaborates with external research groups and organizations, including leading academic research groups, to explore new drug candidates and therapeutic strategies.

Evaluations of market potential and unmet medical needs are carried out by IBT personnel or external consultants.

Product development including pharmaceutical formulation and manufacture process takes place in cooperation with external service providers and contract manufacturing organizations ("CMOs"). IBT does not currently own any manufacturing site. Production is outsourced to contract manufacturing organizations to carry out small- and large-scale quality-assured production for clinical trial supply.

Evaluations of the regulatory conditions for IBT activities are carried out on a need basis by IBT personnel or by external consultants with specific expertise.

Commercialization is intended to take place through market introduction by the Company itself or through appropriate marketing and distribution partners through out-licensing in exchange for different types of compensation in the form of advance payments, milestone compensation and royalties.

### Strategy

#### Vision

Premature infants are the most vulnerable humans 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 the vision to become an internationally recognized and leading company in the development of therapies for the needs of premature infants.

#### Mission

IBT develops, and intends to market and sell therapies in accordance with all applicable pharmaceutical regulations to satisfy the unmet medical needs of the premature infants. IBT strives to conduct effective drug development to launch on the market suitable, safe and effective drugs for 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.

### **Research strategy**

Even though IBT's current focus is on developing the drug candidate IBP-9414 for prevention of NEC, additional projects may be developed in the future which can be based on the same active substance *L. reuteri* or new active substances in other therapeutic applications. IBT will seek collaborations with leading research groups and organizations in relevant fields for future therapeutic exploratory research.

IBT intends to keep close relationships with leading research institutes and clinics in the academic fields of interest to the Company's business. Key experts and KOLs in both the US and Europe are approached for their expertise and knowledge necessary for optimal product development. Sanjiv Sharma, IBT Chief Commercial Officer based in the US, is in close contact with these scientists in order to establish high awareness of IBT's activities and if suitable develop close collaborations with IBT.

### **Development and production strategy**

IBT drug development consists of pre-clinical and clinical development phases, consistent to standard pharmaceutical development, with the purpose to demonstrate that IBT drug candidates are safe and effective in order to obtain market approval.

Pre-clinical development primarily involves experiments in various cell and animal models which are carried out in order to study the mechanisms of action, desired effects and initial safety of the drug candidate. Experiments could be carried out in-house (which is currently not the case for IBT) or by external research groups or organizations.

The management of clinical studies will be carried out by a contract research organization ("CRO") or academic groups selected for their experience and expertise in conducting clinical trials. Under the supervision of IBT, they select the suitable clinical sites to engage in the clinical trials and establish the process for patient recruitment. IBT can supervise clinical operations and drug safety management in-house or delegate to the CRO.

Regulatory interactions regarding the drug candidate and development plans are managed by IBT personnel with the help of external consultants as necessary. Sofus Regulatory Affairs AB, headquartered in Stockholm, Sweden has assisted IBT in regulatory interactions with EMA and Cardinal Health, Inc., headquartered in Dublin, Ohio, US, assists in interactions with FDA.

To guarantee an effective and safe drug, both quality of the manufacturing process and supply chain must follow pharmaceutical regulations. The production of a drug candidate takes place by different means depending on the stage of the development of the drug candidate. The production of a drug candidate for use in clinical trials currently involves contract manufacturing organizations with required manufacturing technology and expertise, adequate production capacity and quality-assured facilities and processes. Production for subsequent commercialization may take place either in a CMO or if it is cost effective, the Company may acquire its own manufacturing facilities.

### **Commercialization**

In order to achieve good distribution channels for specific geographic regions or to leverage marketing, specific distribution partnerships could be required. Appropriate distribution partners may be a pharmaceutical company focusing on orphan drugs or specific therapeutic areas with experience in reimbursement and marketing in the various markets. Terms for such distribution partnerships will be defined when needed.

### Financing strategy

The Company's capital requirements have historically been satisfied through capital contributions from the current parent company BioGaia. As per the date hereof, IBT has received SEK 82 million from BioGaia. As the Company's drug candidate IBP-9414 achieves important milestones in drug development, additional possibilities are opened up for financing. As a Swedish stock exchange listed company, one possibility for the Company is issuing new shares subject to preemptive rights for its shareholders. Other possibilities include sublicensing specific rights of the drug candidate to pharmaceutical partners and a new issue of shares to new investors, provided this can take place on terms and conditions favorable to the current shareholders. Debt financing is not considered an appropriate form of financing, other than on a temporary basis, before the Company has achieved profitability and positive cash flow.

Following the listing on First North and for the purpose of securing the required capital to complete the first planned clinical trial of IBP-9414 and to fund the ongoing operations, IBT is planning to carry out a rights issue of SEK 100 million during the second quarter of 2016. In addition, the Company believes, based on its current development plan, that additional capital of SEK 300 to 600 million will be required for the development of IBP-9414 and submission for regulatory approval.

## PATENTS, INTELLECTUAL PROPERTY RIGHTS AND ORPHAN DRUG DESIGNATIONS

### Strategies for intellectual property rights

IBT has and intends to apply for patent protection for innovations for the purpose of securing fundamental commercial opportunities. Patents are obtained for entirely new innovations, and for innovations which support or strengthen an earlier innovation or patent. Patent applications may relate to the substances per se, production processes, or medical uses. Patent applications regularly cover the United States, the European Union, Japan and China, but also other international markets where it is justified for the interest of the Company. The documentation of the patent applications is prepared by the Company and, if applicable, in cooperation with academic research groups and other inventors or rights holders. The formalization and registration of patent applications is carried out through international patent agents. IBT currently uses the services of Synergon AB, a patent strategy agency headquartered in Göteborg, Sweden. After a patent is granted, regular monitoring of the validity of the patent is carried out as well as any possible infringement of the patent protection and monitoring of possible competing patent applications from other parties. In addition to its own patent applications, IBT will analyze the possibilities to license or acquire rights to other parties' patents. Other parties may hold patents which either limit the possibilities for the Company to utilize the rights within the scope of its own patent protection or which entail a new use of rights for the Company. Licensing and acquisition will only be carried out when it is believed to be of sufficient commercial value.

In addition to patent protection, IBT applies for other types of rights protection such as orphan drug designations, trademarks and domains.

### Patents

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 filed 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.

#### **Other intellectual property and orphan drug designations**

Granted patents and patent applications, together with orphan drug protection other legal protective possibilities, including license agreements will, according to the Company's assessment, provide a strong protection for the development, use and marketing of the final drug. The granted orphan drug designations provide market exclusivity from the grant date of marketing approval for seven and ten years in the United States and the EU, respectively.

Once the drug candidate has been commercialized, the Company intends to seek protection for trademarks to be used for marketing the drug.

Further to the above, IBT is the registered owner of the domain name [ibtherapeutics.com](http://ibtherapeutics.com).



# Selected financial information

**THE SELECTED FINANCIAL INFORMATION** presented below has been derived from IBT's audited financial statements for the years ended 31 December 2014 and 2015 and have been prepared in accordance with the Swedish Annual Reports Act (Sw. *Årsredovisningslagen (1995:1554)*) and BFNAR 2012:1 (K3), unless otherwise stated. The cash flow analyses below have not been derived from the audited financial statements and have not been audited or reviewed but have been derived from the Company's internal accounting and reporting systems.

The following information should be read in conjunction with the section "*Comments on financial development*", including the sub-section "*Significant events following 31 December 2015*", and IBT's audited financial statements for the financial years 2014 and 2015, including the related notes, as incorporated by reference.

## INCOME STATEMENT

SEK thousand	2015	2014
Net sales	-	-
Cost of goods sold	-	-
<b>Gross profit</b>	-	-
Selling expenses	-2,600	-
Research and development expenses	-17,974	-6,592
Other operating expenses	-41	-
<b>Operating loss</b>	<b>-20,615</b>	<b>-6,592</b>
<i>Results from financial investments</i>		
Interest income and similar profit/loss items	-	1
Interest expense and similar profit/loss items	-9	-156
<b>Result after financial items</b>	<b>-20,624</b>	<b>-6,747</b>
<i>Appropriations</i>		
Group contribution	20,601	6,730
<b>Result for the year</b>	<b>-22</b>	<b>-17</b>

## BALANCE SHEET

SEK thousand	Dec 31, 2015	Dec 31, 2014
<b>Non-current assets</b>		
Intangible assets	16,225	6,075
<b>Total non-current assets</b>	<b>16,225</b>	<b>6,075</b>
<b>Current assets</b>		
<i>Current receivables</i>		
Receivables parent company	20,420	6,956
Other receivables	535	346
Prepaid expenses and accrued income	952	106
Cash and cash equivalents	44,411	1,054
<b>Total current assets</b>	<b>66,318</b>	<b>8,462</b>
<b>Total assets</b>	<b>82,543</b>	<b>14,537</b>
<b>Equity</b>		
<i>Restricted equity</i>		
Share capital (90,000 shares)	500	50
<i>Non-restricted equity</i>		
Profit/loss brought forward	21,981	10,998
Premium fund	52,350	-
Result for the year	-22	-17
<b>Total equity</b>	<b>74,809</b>	<b>11,031</b>
<b>Liabilities</b>		
<i>Current liabilities</i>		
Trade payables	518	492
Other liabilities	137	131
Accrued expenses	7,079	2,883
<b>Total current liabilities</b>	<b>7,734</b>	<b>3,506</b>
<b>Total equity and liabilities</b>	<b>82,543</b>	<b>14,537</b>
Pledged assets	None	None
Contingent liabilities	22,000	11,000

## CASH FLOW

SEK thousand	2015	2014
<i>Operating activities</i>		
Profit/loss before financial items	-20,615	-6,592
Financial items, net	-9	-155
<b>Cash flow from operating activities before changes in working capital</b>	<b>-20,624</b>	<b>-6,747</b>
Change in working capital	3,600	2,975
<b>Cash flow from operating activities</b>	<b>-17,024</b>	<b>-3,772</b>
Cash flow from investing activities	-10,150	-6,075
Cash flow from financing activities	70,531	10,000
<b>Cash flow for the period</b>	<b>43,357</b>	<b>153</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>1,054</b>	<b>901</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>44,411</b>	<b>1,054</b>

## KEY INFORMATION AND DATA

SEK thousand	2015	2014
Revenue	-	-
Result after financial items	-20,624	-6,747
Total assets	82,543	14,537
Total equity	74,809	11,031
Equity ratio (%)	91	76
Number of employees (FTE)	4	3
Number of shares, thousand	90	50

## FINANCIAL DEFINITIONS

**Equity ratio:** Total equity as a percent of total assets

**Net sales:** Net sales for the period

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

**Number of employees:** Average number of employees during the period

**Result after financial items:** Profit after financial income and expenses for the period

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

**Total equity:** Total equity at the end of the period

# Comments on financial development

The comments on financial development set forth below are based on the 2015 and 2014 financial years. The information presented below should be read in conjunction with the section *"Selected financial information"* and the Company's audited financial statements for the financial years 2015 and 2014, which are incorporated by reference. The information below contains forward-looking statements that are subject to various risks and uncertainties. The Company's actual results may differ materially from those anticipated in these forward-looking statements as a result of many different factors, including, but not limited to, those described in the section *"Important information to investors – Forward-looking statements"* and elsewhere in this Company description, including those in the section *"Risk factors"*. The audited financial statements have been prepared in accordance with the Swedish Annual Reports Act (Sw. *Årsredovisningslagen* (1995:1554)) and BFNAR 2012:1 (K3).

## OVERVIEW

IBT is a newly started pharmaceutical company which commenced its operations in late 2013. Currently, IBT's focus is on developing its drug candidate IBP-9414 to prevent NEC, a fatal disease that affects premature newborns. In accordance with the development plan for IBP-9414, IBT expects to run two clinical trials within the next four years. The Company's goal is to have an approved drug ready to be launched on the market during 2019. The Company is not expected to have any sales before its drug candidate has been approved and launched.

The Company's primary expenses are research and development expenses related to the development of its drug candidate IBP-9414. The research and development expenses primarily consist of expenses for personnel and consultants (responsible for the preparation of protocols, clinical studies, regulatory, legal etc.). Development expenses that are expected to result in future revenue are capitalized as development expenses in the balance sheet. The expenses are presented in the income statement net of capitalization and amortization.

## COMPARISON BETWEEN THE PERIOD JANUARY TO DECEMBER 2015 AND JANUARY TO DECEMBER 2014

Net sales for the period 1 January to 31 December 2015 amounted to SEK 0 and for the same period 2014, SEK 0. IBT continues to focus on developing its NEC formulation and has yet to reach commercialization.

IBT's operating result amounted to SEK -20.6 million during 2015 compared to SEK -6.6 million during 2014, a decrease of SEK 14 million. The decrease is mainly explained by increased research and development expenses to develop the Company's NEC formulation.

The company has received group contribution of SEK 20.6 million (6.7) and the result for 2015 decreased to SEK -22,488 compared to SEK -17,036 for 2014.

Cash flow from operating activities gave rise to an outflow of SEK 17 million during 2015 compared to an outflow of SEK 3.8 million during 2014. This increase is primarily a result of increased operating costs (see above). Cash flow from investing activities gave rise to an outflow of SEK 10.2 million during 2015, compared to an outflow of SEK 6.1 million during 2014. This increase is explained by capitalized development expenditures. Cash flow from financing

activities gave rise to an inflow of SEK 70.5 million during 2015, compared to an inflow of SEK 10 million during 2014. The increase is explained by contributions, in the form of a conditional shareholders contribution of SEK 11 million and a group contribution of SEK 6.7 million from the parent company, including a share issue of SEK 52.8 million to finance IBT's operations and development of its NEC formulation.

#### **SIGNIFICANT EVENTS DURING THE PERIOD 1 JANUARY 2014 – 31 DECEMBER 2015**

On 23 February 2015, the EMA approved IBT's request for orphan drug designation. On 26 March 2015 and 7 September 2015 BioGaia decided to invest an additional USD 520,000 and SEK 35 million, respectively, in the IBT-project.

In August 2015, the extraordinary general meeting of IBT resolved on a rights issue and a bonus issue of SEK 52.8 million and SEK 410,000, respectively. In December 2015, FDA informed IBT that the IND became effective, allowing IBT to conduct a clinical trial in the US. Furthermore, IBT received approval from the Swedish Medical Products Agency to conduct a clinical trial in Sweden.

#### **SIGNIFICANT EVENTS FOLLOWING 31 DECEMBER 2015**

Shareholder contributions (Sw. *aktieägartillskott*) corresponding to SEK 20.6 million have been repaid to BioGaia by way of set-off against group contributions (Sw. *koncernbidrag*) received during 2015, following a resolution at the annual general meeting of IBT on 8 February 2016 which approved of such repayment.

# Capitalization, indebtedness and other financial information

**THE TABLES IN THIS SECTION DESCRIBE** the Company's capitalization and indebtedness as of, 31 December 2015. See the section "*Share capital and ownership*" for further information about the Company's share capital and shares. The tables in this section should be read in conjunction with the section "*Comments on financial development*" and the Company's financial information, including the related notes, which are incorporated by reference.

## CAPITALIZATION

SEK Thousand	Per 31 December 2015
<b>Current debt</b>	
Guaranteed	-
Secured	-
Unguaranteed/unsecured	-
<b>Total current interest-bearing debt</b>	-
<b>Non-current debt</b>	
Guaranteed	-
Secured	-
Unguaranteed/unsecured	-
<b>Total non-current interest-bearing debt</b>	-
<b>Shareholders' equity</b>	
Share capital	500
Legal reserve	-
Other reserves	74,309
<b>Total equity</b>	<b>74,809</b>

## NET INDEBTEDNESS

SEK Thousand	Per 31 December 2015
(A) Cash	-
(B) Cash equivalents	44,411
(C) Trading securities	-
<b>(D) Liquidity (A)+(B)+(C)</b>	<b>44,411</b>
<b>(E) Current financial receivables</b>	-
(F) Current bank debt	-
(G) Current portion of non-current debt	-
(H) Other current debt (non-interest bearing)	7,734
<b>(I) Current financial debt (F)+(G)+(H)</b>	<b>7,734</b>
<b>(J) Net current financial indebtedness (I)-(E)-(D)</b>	<b>-36,677</b>
(K) Non-current bank loans	-
(L) Bonds issued	-
(M) Other non-current financial debt	-
<b>(N) Non-current financial indebtedness (K)+(L)+(M)</b>	-
<b>(O) Net financial indebtedness (J)+(N)</b>	<b>-36,677</b>

IBT has historically financed its operations through shareholder equity and Group contributions from BioGaia. IBT has no interest-bearing liabilities.

## INVESTMENTS

IBT's investments relate to investments in capitalized development expenditures. Development expenses which are expected to result in future revenue and meet the criteria for capitalization according to IAS38 are capitalized as development expenses in the balance sheet. The expenses are presented in the income statement net of capitalization of intangible assets.

During 2015, investment in capitalized development expenses amounted to SEK 10.2 million. The investments relate to the development of the manufacturing process of the drug candidate IBP-9414. IBT believes that the developed manufacturing process will be useful even if the drug candidate is not successful. Capitalized expenses include internally generated and externally acquired assets. Amortization is started when the project has been completed and the product begins generating revenue. No amortization of intangible assets has been made during the period.

Investments in capitalized development expenses amounted to SEK 6.1 million in 2014. The investments primarily relate to the development of the manufacturing process of the drug candidate. IBT believes that the developed manufacturing process will be useful even if the drug candidate is not successful. Capitalized expenses include internally generated and externally acquired assets. No amortization of intangible assets has been made during the year.

## WORKING CAPITAL

As per 31 December 2015, IBT had financing available corresponding to approximately SEK 44 million. IBT's assessment is that the existing working capital is sufficient to meet the needs of the on-going operations over the next twelve months. IBT does however plan to initiate a first clinical trial, the safety and tolerability study, for the Company's drug candidate IBP-9414. The trial, which will be conducted in 2016, has a budget of approximately SEK 45 million.

To fund the clinical trial and continued development of the Company, IBT plans to conduct a rights issue of SEK 100 million in the second quarter of 2016. BioGaia's largest shareholder Annwall & Rothschild Investments AB, who holds shares corresponding to approximately nine percent of the share capital and approximately 34 percent of the votes in BioGaia, and who will hold shares in IBT following the Distribution, has declared its intention to subscribe for its pro rata share in IBT in the upcoming rights issue.

In the event that the rights issue is not fully completed, the Company may have to postpone or amend the planned clinical study. If sufficient funding for the clinical study is not raised, IBT might seek a licensing deal involving the IBP-9414 project or a collaborative partnership.



# Board of directors, executive management and auditor

## 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

*Born 1950. Chairman of the board since 2011. Independent in relation to the Company and the executive management but not independent in relation the Company's major shareholder following the Distribution.*

#### Education

Master of Business Administration from Stockholm School of Economics.

#### Other current assignments

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 and Department of Biology and Biological Engineering at Chalmers and founder and President of the BioGaia group.

#### Previous assignments (last five years)

CEO of BioGaia. Member of the board of directors of Moberg Pharma AB.

#### Shareholding in the Company

None. Based on shareholding in BioGaia (indirect through Annwall & Rothschild Investments AB, a company co-owned with Jan Annwall) as per the date hereof, the expected indirect shareholding in the Company following the Distribution is 74,066 series A shares and 75,933 series B shares.

## **JAN ANNWALL**

*Born 1950. Board member since 2014. Independent in relation to the Company and the executive management but not independent in relation the Company's major shareholder following the Distribution.*

<b>Education</b>	Business Administration degree from Stockholm University.
<b>Other current assignments</b>	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.
<b>Previous assignments (last five years)</b>	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.
<b>Shareholding in the Company</b>	None. Based on shareholding in BioGaia (indirect through Annwall & Rothschild Investments AB, a company co-owned with Peter Rothschild) as per the date hereof, the expected indirect shareholding in the Company following the Distribution is 74,066 series A shares and 75,933 series B shares.

## **ANDERS EKBLOM**

*Born 1954. Board member since 2014. Independent in relation to the Company, the executive management and the Company's major shareholder following the Distribution.*

<b>Education</b>	M.D., Ph.D, D.D.S and Associate Professor at Karolinska Institutet.
<b>Other current assignments</b>	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, SwedenBIO Service AB, RSPR Pharma AB, Viscogel AB and NxtScience AB.
<b>Previous assignments (last five years)</b>	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.
<b>Shareholding in the Company</b>	9,173 series B shares through the wholly-owned company NxtScience AB.

## **MARGARETA HAGMAN**

*Born 1966. Board member since 2015. Independent in relation to the Company, the executive management and the Company's major shareholder following the Distribution.*

<b>Education</b>	Master of Business Administration, Örebro University.
<b>Other current assignments</b>	Member of the board of directors of TwoPac Machine AB, TwoPac Laboratories AB and CapAble AB, deputy member of the board of directors of TwoPac Aktiebolag, TriPac AB and Annwall & Rothschild Investments AB and deputy CEO of BioGaia.
<b>Previous assignments (last five years)</b>	None.
<b>Shareholding in the Company</b>	None. Based on shareholding in BioGaia as per the date hereof, the expected shareholding in the Company following the Distribution is 700 series B shares.

## **EXECUTIVE MANAGEMENT**

### **STAFFAN STRÖMBERG**

*Born 1967. CEO since 2013.*

<b>Education</b>	M.Sc. in chemical engineering and Ph.D. in organic chemistry from the Royal Institute of Technology in Stockholm. M.Sc. thesis at Università Degli Studi Di Napoli Fredrico II, Dipartimento di Chimica Neaples.
<b>Other current assignments</b>	Member of the board of directors of Cycle Pharmaceuticals AB.
<b>Previous assignments (last five years)</b>	CEO of Billerud Tenova Bioplastics AB and Head of Medical Devices at the Swedish Medical Products Agency.
<b>Other relevant experience</b>	Staffan Strömberg has more than 17 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.
<b>Shareholding in the Company</b>	45,864 series B shares.

**MICHAEL OWENS**

*Born 1956. CFO since 2015.*

<b>Education</b>	M.Sc., Linköping University.
<b>Other current assignments</b>	Member of the board of directors and owner of M Owens Management Consulting AB and CFO of Lecra Sustian AB.
<b>Previous assignments (last five years)</b>	Member of the board of directors of KD Incentive AB and Dilaforette Holding AB. CEO of KCIF Fund Management AB. Deputy member of the board of directors of Cial AB, Kment Förvaltning AB, Avaris AB, HBV Theranostica AB, KDev Oncology AB, Limone AB, Aprea Personal AB and GliGene AB.
<b>Shareholding in the Company</b>	None.

**EAMONN CONNOLLY**

*Born 1957. Head of R&D since 2013.*

<b>Education</b>	Doctor of Philosophy (Ph.D.), University of Manchester Institute of Science and Technology and B.Sc. (Hons) Biochemistry, First class, University of Manchester.
<b>Other current assignments</b>	Chief Scientific Officer, BioGaia.
<b>Previous assignments (last five years)</b>	Member of the board of directors of IBT. Senior Vice President Research, BioGaia.
<b>Other relevant experience</b>	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.
<b>Shareholding in the Company</b>	45,864 series B shares.

## OTHER INFORMATION ABOUT THE BOARD OF DIRECTORS AND EXECUTIVE MANAGEMENT

There are no family ties between any of the members of the board of directors or executive management.

There are no conflicts of interest or potential conflicts of interest between the obligations of members of the board of directors and executive management of the Company and their private interests and/or other undertakings.

During the last five years, none of the members of the board of directors or the members of the executive management have (i) been sentenced for fraud-related offences, (ii) represented a company which has been declared bankrupt or filed for liquidation with the exception of Michael Owens who was a deputy member of the board of directors of Cial AB when the company was declared bankrupt in 2013, (iii) been the subject of sanctions or accused by authorities or bodies acting for particular professional groups under public law or (iv) been subject to injunctions against carrying on business.

All members of the board of directors and the members of the executive management are available at the Company's main office at Bryggargatan 10, SE-111 21 Stockholm, Sweden.

## AUDITOR

Grant Thornton Sweden AB was the Company's auditor from 2011 until the annual shareholders' meeting on 5 May 2015, at which time Deloitte AB was elected as the Company's auditor with Birgitta Lööf (born 1960) as the auditor in charge until the end of the annual shareholders' meeting 2017. Birgitta Lööf is an authorized public accountant and a member of FAR (professional institute for authorized public accountants). Deloitte AB's office address is Rehnsgatan 11, SE-113 57 Stockholm, Sweden. Deloitte AB replaced Grant Thornton Sweden AB as the Company's auditor due to BioGaia, having had the same auditor since 1990.

# Corporate governance

## CORPORATE GOVERNANCE

IBT is a Swedish public limited liability company. Corporate governance in the Company is based on Swedish law and internal rules and instructions. Since the Company will be listed on First North, the Company also complies with First North's Rule Book for Issuers. The Swedish Corporate Governance Code (the **"Code"**) (Sw. *Svensk kod för bolagsstyrning*) are to be applied by companies with the shares listed on a regulated market in Sweden. First North is not a regulated market and the Company is thus not required to apply the Code.

## SHAREHOLDERS' MEETING

According to the Swedish Companies Act (2005:551) (Sw. *aktiebolagslagen*), the shareholders' meeting is the Company's ultimate decision-making body. At the shareholders' meeting, the shareholders exercise their voting rights in key issues, such as the adoption of income statements and balance sheets, appropriation of the Company's results, discharge from liability of members of the board of directors and the CEO, election of members of the board of directors and auditors and remuneration to the board of directors and the auditors.

The annual shareholders' meeting must be held within six months from the end of the financial year. In addition to the annual shareholders' meeting, extraordinary shareholders' meetings may be convened. According to the articles of association, shareholders' meetings are convened by publication of the convening notice in the Swedish National Gazette (Sw. *Post- och Inrikes Tidningar*) and on the Company's website. At the time of the notice convening the meeting, information regarding the notice shall be published in Svenska Dagbladet.

### Right to participate in shareholders' meetings

Shareholders who wish to participate in a shareholders' meeting must be included in the shareholders' register maintained by Euroclear Sweden on the day falling five workdays prior to the meeting, and notify the Company of their participation no later than on the date stipulated in the notice convening the meeting. Shareholders may attend the shareholders' meetings in person or by proxy and may be accompanied by a maximum of two assistants. Typically, it is possible for a shareholder to register for the shareholders' meeting in several different ways as indicated in the notice of the meeting. A shareholder may vote for all Company shares owned or represented by the shareholder.

### Shareholder initiatives

Shareholders who wish to have a matter brought before the shareholders' meeting must submit a written request to the board of directors. Such request must normally be received by the board of directors no later than seven weeks prior to the shareholders' meeting.

## BOARD OF DIRECTORS

The board of directors is the second-highest decision-making body of the Company after the shareholders' meeting. According to the Swedish Companies Act, the board of directors is responsible for the organization of the company and the management of the company's affairs, which means that the board of directors is responsible for, among other things, setting targets and strategies, securing routines and systems for evaluation of set targets, continuously assessing the financial condition and profits as well as evaluating the operating management. The board of directors is also responsible for ensuring that annual reports and interim reports are prepared in a timely manner. Moreover, the board of directors appoints the CEO.

Members of the board of directors are normally appointed by the annual shareholders' meeting for the period until the end of the next annual shareholders' meeting. According to the Company's articles of association, the members of the board of directors elected by the shareholders' meeting shall be not less than three (3) and not more than ten (10) members with no deputy members.

The board of directors applies written rules of procedure, which are revised annually and adopted by the inaugural board meeting every year. Among other things, the rules of procedure govern the practice of the board of directors, functions and the division of work between the members of the board of directors and the CEO. At the inaugural board meeting, the board of directors also adopts instructions for the CEO, including instructions for financial reporting.

The board of directors meets according to an annual predetermined schedule. In addition to these meetings, additional board meetings can be convened to handle issues which cannot be postponed until the next ordinary board meeting. In addition to the board meetings, the chairman of the board of directors and the CEO continuously discuss the management of the Company.

Currently, the Company's board of directors consists of four (4) ordinary members elected by the shareholders' meeting, who are presented in the section "Board of directors, executive management and auditor".

## THE CEO AND OTHER EXECUTIVE MANAGEMENT

The CEO is subordinated to the board of directors and is responsible for the everyday management and operations of the Company. The division of work between the board of directors and the CEO is set out in the rules of procedure for the board of directors and the CEO's instructions. The CEO is also responsible for the preparation of reports and compiling information for the board meetings and for presenting such materials at the board meetings.

According to the instructions for the financial reporting, the CFO is responsible for the financial reporting in the Company and consequently must ensure that the board of directors receives adequate information for the board of directors to be able to evaluate the Company's financial condition.

The CEO must continuously keep the board of directors informed of developments in the Company's operations, the development of sales, the Company's result and financial condition, liquidity and credit status, important business events and all other events, circumstances or conditions which can be assumed to be of significance to the Company's shareholders.

The CEO and executive management are presented in the section "Board of directors, executive management and auditor".



## REMUNERATION TO THE MEMBERS OF THE BOARD OF DIRECTORS, CEO AND EXECUTIVE MANAGEMENT

### Remuneration to the members of the board of directors

Fees and other remuneration to the members of the board of directors, including the chairman, are resolved by the shareholders' meeting. No remuneration was paid to the board of directors during the financial year 2015. At the annual shareholders' meeting held on 8 February 2016, it was resolved that the fee to the chairman of the board of directors should be SEK 200,000 per year and that the chairman shall receive an additional SEK 400,000 per year in the capacity of working chairman of the board of directors, and that the fee to the other members of the board of directors not employed by the Company should be SEK 100,000 per member and year. The members of the board of directors are not entitled to any benefits following termination of their assignments as directors of the board.

### Remuneration paid during the 2015 financial year

The table below presents an overview of remuneration to the CEO and other employees during the 2015 financial year.

Title	Salary and other remuneration, SEK	Pension costs, SEK	Other social security costs, SEK
CEO	1,726,539	307,997	617,199
Other employees	2,624,275	441,974	534,899

### Current employment agreements for the CEO and other executive management

Decisions as to the current remuneration levels and other conditions for employment for the CEO and the other members of the executive management have been resolved by the board of directors.

Members of the executive management domiciled in Sweden and their employers are entitled to a mutual period of notice of three months, unless a longer notice period is provided by applicable Swedish law.<sup>10</sup> The CEO is entitled to severance pay in the amount of nine months' salary in addition to the salary set out above during the period of notice when notice is given by the Company. Further, the CEO and the Head of R&D will receive a bonus from the Company of SEK 100,000 and 75,000, respectively, following recruitment of the first patient in the first clinical trial (i.e. the safety and tolerability study), SEK 200,000 and SEK 150,000, respectively, following recruitment of the first patient after the end of phase II meeting with FDA, SEK 500,000 and 300,000, respectively, following market authorization in the US for an IBT drug relating to NEC and SEK 300,000 and SEK 200,000, respectively, following market authorization in Europe for an IBT drug relating to NEC.

<sup>10</sup> The Company's CFO is not employed by IBT but is working on the basis of a consultancy agreement. The agreement has a mutual period of notice of three months.



## AUDITING

The auditor shall review the Company's annual reports and accounting, as well as administration of the management of the board of directors and the CEO. Following each financial year, the auditor shall submit an audit report to the annual shareholders' meeting.

Pursuant to the Company's articles of association, the Company shall have one auditor and no deputy auditors. The Company's auditor is Deloitte AB, with Birgitta Lööf as auditor in charge. The Company's auditor is presented in more detail in the section "Board of directors, executive management and auditor".

# Share capital and ownership structure

## GENERAL INFORMATION

Pursuant to the Company's articles of association, the Company's share capital may not be less than SEK 500,000 and not more than SEK 2,000,000, and the number of shares may not be less than 1,800,000 and not more than 7,200,000. Shares may be issued in two series, series A shares and series B shares. As at the date of this Company description, the Company has issued a total of 1,834,546 shares, of which 74,066 are series A shares and 1,760,480 are series B shares. The shares are denominated in SEK and the quota value of each share is approximately SEK 0.27.

All shares in the Company have been issued pursuant to Swedish law. All issued shares have been fully paid and are freely transferrable.

The shares are not subject to a mandatory offering, redemption rights or sell-out obligation. No public takeover offer has been made for the offered shares during the current or preceding financial year.

As far as the board of directors is aware, there are no shareholder agreements or other agreements between the Company's shareholders with the aim of jointly controlling the Company and there are no agreements or similar arrangements that may lead to a change of the control of the Company.

## CERTAIN RIGHTS ASSOCIATED WITH THE SHARES

Shares may be issued in two series, series A shares and series B shares. The rights associated with the shares issued by the Company, including those pursuant to the articles of association, can only be amended in accordance with the procedures set out in the Swedish Companies Act.

### Voting rights

Each series A share in the Company entitles the holder to ten votes at shareholders' meetings and each series B share in the Company entitles the holder to one vote at shareholders' meetings. Each shareholder is entitled to cast votes equal in number to the number of shares held by the shareholder in the Company.

### Preferential rights to new shares, etc.

If the Company issues new shares, warrants or convertibles in a cash issue or a set-off issue, shareholders shall, as a general rule, have preferential rights to subscribe for new shares of the same series of shares pro rata to the number of shares previously owned (primary preferential right). Shares which are not subscribed for by those shareholders entitled to subscribe pursuant to primary preferential rights will be offered to all shareholders (subsidiary preferential rights).

### Rights to dividends and balances in case of liquidation

All shares give equal rights to dividends, if any, and the Company's assets and possible surpluses in the event of liquidation.

Resolutions regarding dividend are passed by shareholders' meetings. All shareholders registered as shareholders in the share register maintained by Euroclear Sweden on the record date adopted by the shareholders' meeting shall be entitled to receive dividends, if any. Dividends,

if any, are normally distributed to shareholders as a cash payment per share through Euroclear Sweden, but may also be paid out in a manner other than cash (in-kind dividend). If shareholders cannot be reached through Euroclear Sweden, such shareholder still retains its claim on the Company to the dividend amount, subject to a statutory limitation of ten years. Upon the expiry of the period of limitations, the dividend amount shall pass to the company.

There are no restrictions on the right to dividends for shareholders domiciled outside Sweden. Shareholders not resident in Sweden for tax purposes must normally pay Swedish withholding tax, see also the section “Tax issues in Sweden”.

## ISSUE AUTHORIZATION

On 12 February 2016, the extraordinary general meeting of IBT resolved to authorize the board of directors for the period up to the next annual shareholders’ meeting to adopt decisions, whether on one or several occasions and whether with or without pre-emption rights for the shareholders, to issue new shares, warrants and/or convertibles.

## CENTRAL SECURITIES REGISTER

The Company’s shares are registered in a CSD register in accordance with the Swedish Financial Instruments Accounts Act (1998:1479) (Sw. lagen (1998:1479) om kontoföring av finansiella instrument). This register is managed by Euroclear Sweden AB. No share certificates have been issued for the Company’s shares. The account operator is Carnegie Investment Bank AB (publ). The ISIN number for the Company’s series A shares is SE0008015242 and the ISIN-code for the Company’s series B shares is SE0008015259.

## SHARE CAPITAL DEVELOPMENT

The below table shows historic changes in the Company’s share capital since 2011, and the changes in the number of shares and the share capital which will be made in connection with the Distribution.

Time	Event	Change in number of shares			No. of shares after transaction			Share capital	
		Ordinary one series shares	Ordinary series A shares	Ordinary series B shares	Ordinary one series shares	Ordinary series A shares	Ordinary series B shares	Change	Total
2011-11-22	Formation	50,000	-	-	50,000	-	-	50,000	50,000
2015-09-15	New share issue	40,000	-	-	90,000	-	-	40,000	90,000
2015-09-15	Bonus issue	-	-	-	90,000	-	-	410,000	500,000
2016-02-12	Split and re-classification	-	74,066	1,760,480	-	74,066	1,760,480	-	500,000

## CONVERTIBLES, WARRANTS, ETC.

At the date of this Company description, there are no outstanding warrants, convertibles or other share-related instruments or incentive programs in the Company.

## OWNERSHIP STRUCTURE

The table below sets forth IBT's ownership structure immediately before and after the Distribution.

	Shareholding before the Distribution				Shareholding after the Distribution			
	Number		Percent		Number		Percent	
Shareholder	Series A shares	Series B shares	Share capital	Voting rights	Series A shares	Series B shares	Share capital	Voting rights
BioGaia	74,066	1,659,579	94.5	96	-	-	-	-
Staffan Strömberg	-	45,864	2,5	1,8	-	45,864	2,5	1,8
Eamonn Connolly	-	45,864	2,5	1,8	-	45,864	2,5	1,8
NxtScience AB <sup>11</sup>	-	9,173	0,5	0,4	-	9,173	0,5	0,4
Annwall & Rothschild Investments AB	-	-	-	-	74,066	75,933	8,2	32,7
<b>Total</b>	<b>74,066</b>	<b>1,760,480</b>	<b>100</b>	<b>100</b>	<b>74,066</b>	<b>176,834</b>	<b>13,7</b>	<b>36,7</b>
Other shareholders	-	-	-	-	-	1,583,646	86,3	63,3
<b>Total</b>	<b>74,066</b>	<b>1,760,480</b>	<b>100</b>	<b>100</b>	<b>74,066</b>	<b>1,760,480</b>	<b>100</b>	<b>100</b>

<sup>11</sup> A company wholly-owned by the board member Anders Eklom.

# Articles of association

Articles of association for Infant Bacterial Therapeutics AB (publ), registration number 556873-8586, adopted by the extraordinary shareholders' meeting on 12 February 2016.

## **1 § NAME**

The company's name is Infant Bacterial Therapeutics AB. The company is a public limited liability company (publ).

## **2 § REGISTERED OFFICE**

The board of directors' has its registered office in the Stockholm Municipality, Stockholm County.

## **3 § BUSINESS**

The company shall directly or through subsidiaries or other forms of partnerships or co-operations develop, produce, market and sell pharmaceuticals, medical devices and conduct business compatible therewith.

## **4 § SHARE CAPITAL**

The share capital shall be not less than SEK 500,000 and not more than SEK 2,000,000.

## **5 § SERIES OF SHARES**

Shares may be issued in two series: series A carrying ten votes per share and series B carrying one vote per share. Shares of each series may be issued in a number corresponding to the total number of shares in the Company.

If the company resolves to issue new series A and series B shares through a cash issue or an issue with payment by way of set-off of claim, owners of series A and series B shares shall enjoy pre-emption rights to subscribe for new shares of the same series pro rata to the number of shares previously held by them (primary pre-emption right). Shares that have not been subscribed for pursuant to the primary pre-emption rights shall be offered to all shareholders (secondary pre-emption right). If the shares thus offered are not sufficient for the subscription pursuant to the secondary pre-emption rights, the shares shall be allocated between the subscribers pro rata to the number of shares previously held and, to the extent such allocation cannot be effected, by the drawing of lots.

If the company resolves to issue only series A or series B shares through a cash issue or an issue with payment by way of set-off of claim, where payment is not to be made in kind, all shareholders shall, irrespective of whether their shares are series A or series B shares, have pre-emption rights to subscribe for new shares pro rata to the number of shares previously held by them.

If the company resolves to issue warrants or convertibles through a cash issue or an issue with payment by way of set-off of claim, the shareholders shall have pre-emption rights to subscribe for warrants as if the issue applied to the shares that may be subscribed for pursuant to the right of option and pre-emption rights to subscribe for convertibles as if the issue applied to the shares that the convertibles may be converted to, respectively.

The above shall not limit the right to resolve upon a cash issue or an issue with payment by way of set-off of claim with deviation from the shareholders' pre-emption rights.

If the share capital is increased by a bonus issue, new shares shall be issued in relation to the number of shares of the same series already issued. In such cases, old shares of a specific series shall entitle to new shares of the same series. Following a requisite amendment in the Articles of Association, the aforementioned stipulation shall not infringe on the possibility to issue shares of a new series by a bonus issue.

## **6 § NUMBER OF SHARES**

The number of shares shall be not less than 1,800,000 and not more than 7,200,000.

## **7 § BOARD OF DIRECTORS**

The board of directors shall consist of not less than 3 and not more than 10 members.

## **8 § AUDITOR**

The company shall have one auditor. As auditor an authorized public accountant or a registered public accounting firm shall be elected.

## **9 § NOTICE OF SHAREHOLDERS' MEETING**

Notice of shareholders' meetings shall be published in the Swedish Official Gazette and on the company's website. An announcement that the notice has been issued shall be published in Svenska Dagbladet. Shareholders must notify the company if the shareholder and any counsels are to participate in the shareholders' meeting not later than on the day specified in the notice convening the meeting.

## **10 § ANNUAL SHAREHOLDERS' MEETING**

At annual shareholders' meetings, the following business shall be addressed:

1. Election of a chairman of the meeting;
2. Preparation and approval of the voting list;
3. Election of one or two persons who shall approve the minutes of the meeting;



4. Approval of the agenda;
5. Determination of whether the meeting was duly convened;
6. Presentation of the annual report and the auditors' report and, where applicable, the consolidated financial statements and the auditors' report for the group;
7. Resolutions regarding:
  - a) adoption of the income statement and the balance sheet and, when applicable, the consolidated income statement and the consolidated balance sheet;
  - b) allocation of the company's profits or losses in accordance with the adopted balance sheet;
  - c) discharge of the members of the board of directors and the managing director from liability;
8. Determination of fees for members of the board of directors and auditor;
9. Election of the members of the board of directors and auditor;
10. Other matters, which should be resolved by the meeting according to the Swedish Companies Act.

## **11 § FINANCIAL YEAR**

The company's financial year shall be the calendar year.

## **12 § CSD-PROVISION**

The company's shares shall be registered in a securities register in accordance with the Swedish Financial Instruments Accounts Act (1998:1479).

# Legal considerations and supplementary information

## LEGAL GROUP STRUCTURE

The Company's business is conducted in accordance with the Swedish Companies Act. Infant Bacterial Therapeutics AB (registration number 556873-8586) is a Swedish public limited liability company which was founded on 22 November 2011 and registered with the Swedish Companies Registration Office on 30 November 2011. The Company's registered office is situated in Stockholm. The Company does not have any subsidiaries.

## MATERIAL AGREEMENTS

### Licensing agreement with BioGaia

IBT has entered into a licensing agreement with BioGaia according to which IBT, for the duration of the underlying patents, is granted an exclusive right to IBP-9414 for the purpose of developing a drug candidate and to use the active substance in IBP-9414 in a potentially approved drug for the pharmaceutical prevention and treatment of NEC and other gastrointestinal disorders. According to the agreement, BioGaia is entitled to use IBP-9414 outside the area licensed to IBT and IBT has also granted BioGaia a cross license according to which BioGaia is entitled to use IBT's intellectual property rights related to the license granted by BioGaia to IBT. All licenses under the agreement are royalty free.

### Clinical research organization agreements

In the US, IBT has engaged Premier Research International LLC, an international CRO to conduct and provide the services required to complete IBT's phase II study of IBP-9414. The agreement is valid until August 2017. Furthermore, agreements have been entered into with regulatory consultants Cardinal Health Regulatory Sciences in the US and Sofus Regulatory Affairs in Europe for the assistance with regulatory interaction with FDA, EMA and other European authorities, respectively. The agreement with Cardinal Health Sciences Regulatory runs under one-year periods as from 12 March 2014 and is automatically extended, provided that notice is not given within 30 days prior to the expiry of the current one-year period. The agreement with Sofus Regulatory Affairs runs until further notice with a notice period of three months.

## INTELLECTUAL PROPERTY

IBT has the intellectual property rights described in the section *"Business and market overview – Intellectual property rights"*. IBT assesses that its protection for intellectual property rights is adequate for the Company's business.

## RELATED PARTY TRANSACTIONS

All transactions between companies within the Group are carried out on commercial terms. As per the date of this Company description, BioGaia has invested approximately SEK 82 million

in IBT. In addition hereto BioGaia provided SEK 20.6 million in form of group contributions (Sw. *koncernbidrag*) during 2015. At the annual general meeting of IBT on 8 February 2016, it was resolved on repayment of SEK 20.6 million conditional shareholder contributions (Sw. *villkorat aktieägartillskott*) to BioGaia by way of set off against the received group contributions. In addition hereto, IBT has during 2015 acquired certain services from BioGaia, including economy and payroll functions, for which IBT has paid approximately SEK 700,000 to BioGaia. Also, the Company's CFO is not employed by IBT but is working on the basis of a consultancy agreement under which IBT has been invoiced approximately SEK 100,000 during the financial year 2015.

## **INSURANCE**

IBT has insurance against property damage including goods, machinery and equipment, and business interruption losses. In addition, there are insurance policies for liability, personnel, legal protection, crime against property, fire, water damage, business travels as well as for directors and officers. IBT assesses that its insurances 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.

## **PERMITS AND ENVIRONMENTAL ISSUES**

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.

## **LEGAL PROCEEDINGS**

IBT is currently not involved in any legal proceedings, and has not been during the past twelve months. For further information see the section "Risk factors – Disputes, claims, investigations and proceedings may lead to IBT having to pay damages or cease with certain operations".

## **INTERESTS OF ADVISORS**

Carnegie is the financial advisor in conjunction with the Distribution. Carnegie has provided the Company with advice in conjunction with the Distribution and is receiving compensation for this work. Carnegie has performed, and may also perform in the future, various financial advisory and other services on behalf of the Company for which Carnegie has received, and can be expected to receive, compensation.

## **CERTIFIED ADVISER**

All companies whose shares are traded on First North must contract a so called certified adviser who monitors that the company is complying with First North's regulations regarding the provi-

sion of information to the market and investors. Erik Penser Bankaktiebolag is the certified advisor for IBT. Nasdaq Stockholm AB's surveillance function is responsible for checking that both companies and certified advisors comply with First North's regulations. The surveillance also monitors trading on First North. Erik Penser Bankaktiebolag does not own any shares in IBT.

## DOCUMENTS INCORPORATED BY REFERENCE

The documents below are incorporated by reference and constitute a part of the Company description. IBT's annual report for 2014 has been audited by Grant Thornton Sweden AB with authorized auditor Lena Möllerström Nording as auditor in charge and the annual report for 2015 has been audited by Deloitte AB with authorized auditor Birgitta Lööf as auditor in charge. The auditors' reports contain no observations. The documents incorporated by reference are available on the Company's website, [www.ibtherapeutics.com](http://www.ibtherapeutics.com).

- (i) The Company's audited financial statements for the financial year ended 2015 including the income statements (page three), the balance sheet (page four), statement of changes in equity (page five), the notes to the financial statement (pages six to eight) and the auditor's report (page ten); and
- (ii) The Company's audited financial statements for the financial year ended 2014 including the income statements (page two), the balance sheet (page two), the notes to the financial statement (pages three and four) and the auditor's report (page six).

# Tax considerations in Sweden

Below is a summary of certain Swedish tax issues related to the Distribution and the admission to trading at First North of the series B shares in IBT for private individuals and limited liability companies that are residents of Sweden for tax purposes (unless otherwise stated) and that hold series B shares in IBT. The summary is based on current legislation and is intended to provide general information only regarding the Distribution and the series B shares for the period during which the series B shares are traded on First North.

The summary does not cover:

- series A shares;
- situations where securities are held as current assets in business operations;
- situations where securities are held by a limited partnership or a partnership;
- situations where securities are held in an investment savings account (Sw. *investerings-sparkonto*);
- the special rules regarding tax-free capital gains (including non-deductible capital losses) and dividends that may be applicable when the investor holds shares in IBT that are deemed to be held for business purposes (for tax purposes);
- the special rules that in certain cases may be applicable to shares in companies which are or have been so-called close companies or to shares acquired by means of such shares;
- the special rules that may be applicable to private individuals who make or reverse a so called investor deduction (Sw. *investeraravdrag*);
- foreign companies conducting business through a permanent establishment in Sweden; or
- foreign companies that have been Swedish companies.

Further, special tax rules apply to certain categories of companies. The tax consequences for each individual shareholder depend on the shareholder's particular circumstances. Each shareholder is advised to consult an independent tax advisor as to the tax consequences relating to the shareholder's particular circumstances that could arise from the Distribution or admission to trading, including the applicability and effect of foreign tax legislation (including regulations) and provisions in tax treaties. The summary below is based on the assumption that the series B shares are deemed listed for tax purposes in the period while series B shares are admitted to trading on First North (if the series B shares are not deemed listed for tax purposes, partially other tax rules besides the ones summarized below are applicable). However, we do not guarantee that the series B shares will be deemed listed.

## THE DISTRIBUTION OF SHARES IN IBT

The distribution of shares in IBT is intended to be made in accordance with the so-called "Lex ASEA-provisions" and in the opinion of BioGaia all conditions set out under the "Lex ASEA-provisions" are fulfilled, as a result no immediate taxation will arise upon distribution of shares. The tax basis of the shares in BioGaia giving entitlement to the Distribution shall instead be allocated between the shares in BioGaia and the shares in IBT. The allocation of the tax basis is made on the basis of the change in value of the shares in BioGaia due to the Distribution.

BioGaia will request guidelines from the Swedish Tax Agency (Sw. *Skatteverket*) on the allocation of the tax basis. Information regarding the guidelines is expected to be published at the web sites of BioGaia, IBT and [www.skatteverket.se](http://www.skatteverket.se).

## SALE OF OR DIVIDEND ON THE SHARES IN IBT

### Private individuals

For private individuals resident in Sweden for tax purposes, capital income such as interest income, dividends and capital gains is taxed in the capital income category, including capital gains for shareholders, in the event received fractions of shares in IBT are being sold on their behalf. The tax rate in the capital income category is 30 percent.

The capital gain or the capital loss is computed as the difference between the consideration, less selling expenses, and the acquisition value. The tax basis of the shares in IBT is to be determined on the basis of the guidelines that the Swedish Tax Agency is expected to render. The tax basis of each fraction of a share in IBT should be equal to a corresponding portion of the tax basis of a share in IBT, to be determined on the basis of the expected guidelines of the Swedish Tax Agency. The acquisition value for all shares of the same series and type shall be added together and computed collectively in accordance with the so-called average method (Sw. *genomsnittsmetoden*). As an alternative, the so-called standard method (Sw. *schablonmetoden*) may be used at the disposal of listed shares. This method means that the acquisition value may be determined as 20 percent of the consideration less selling expenses.

Capital losses on listed shares and other listed securities taxed as shares may be fully offset against taxable capital gains the same year on shares, as well as on listed securities taxed as shares (however not mutual funds, Sw. *värdepappersfonder*, or hedge funds, Sw. *specialfonder*, containing Swedish receivables only, Sw. *räntefonder*). Capital losses not absorbed by these set-off rules are deductible at 70 percent in the capital income category.

Should a net loss arise in the capital income category, a reduction is granted of the tax on income from employment and business operations, as well as national and municipal property tax. This tax reduction is 30 percent of the net loss that does not exceed SEK 100,000 and 21 percent of any remaining net loss. A net loss cannot be carried forward to future tax years.

For private individuals resident in Sweden for tax purposes, a preliminary tax of 30 percent is withheld on dividends. The preliminary tax is normally withheld by Euroclear or, in respect of nominee-registered shares, by the nominee.

### Limited liability companies

For limited liability companies (Sw. *aktiebolag*) all income, including taxable capital gains and dividends, is taxed as income from business operations at a rate of 22 percent. Capital gains and capital losses are calculated in the same way as described for private individuals above.

Deductible capital losses on shares and other securities taxed as shares may only be offset against taxable capital gains on shares and other securities taxed as shares. A net capital loss on shares and other securities taxed as shares that cannot be utilized during the year of the loss, may be carried forward (by the limited liability company that has suffered the loss) and offset taxable capital gains on shares and other securities taxed as shares in future years, without any limitation in time. If a capital loss cannot be deducted by the company that has suffered the loss, it may be deducted from another legal entity's taxable capital gains on shares and other securities taxed as shares, provided that the companies are entitled to tax consolidation (through so-called group contributions) and both companies request this for a tax year having the same filing date

for each company (or, if one of the companies' accounting liability ceases, would have had the same filing date). Special tax rules may apply to certain categories of companies or certain legal persons, e.g. investment companies.

## **SHAREHOLDERS NOT RESIDENT IN SWEDEN FOR TAX PURPOSES**

For shareholders not resident in Sweden for tax purposes that receive dividends on shares in a Swedish limited liability company, Swedish withholding tax is normally withheld. In accordance with the so-called "Lex ASEA-provisions" dividends in the form of shares in IBT is exempt from Swedish withholding tax. However, dividends in the form of shares in IBT could result in tax consequences in other jurisdictions. The same withholding tax applies to certain other payments made by a Swedish limited liability company for example payments as a result of redemption of shares and repurchase of shares through an offer directed to all shareholders or all holders of shares of a certain series and liquidation of the company. The tax rate is 30 percent. The tax rate is, however, generally reduced through tax treaties. In Sweden, withholding tax deductions are normally carried out by Euroclear or, in respect of nominee-registered shares, by the nominee. Shareholders not resident in Sweden for tax purposes which are not conducting business through a permanent establishment in Sweden are normally not liable for capital gains taxation in Sweden upon disposals of shares. Shareholders may however be subject to taxation in their state of residence.

According to a special rule, private individuals not resident in Sweden for tax purposes are, however, subject to Swedish capital gains taxation upon disposals of shares, including fractions of shares, in IBT, if they have been residents of Sweden due to a habitual abode or stay for more than six consecutive months in Sweden at any time during the calendar year of disposal or the ten calendar years preceding the year of disposal. In a number of cases though, the applicability of this rule is limited by the applicable tax treaty.

# Glossary

<b>American Academy of Pediatrics or AAP</b>	An American organization of 64,000 pediatricians committed to the optimal physical, mental and social health and well-being for all infants, children, adolescents and young adults. The AAP issues policy statements, clinical reports, technical reports and practice guidelines to support the professional needs of its members ( <a href="http://www.aap.org">www.aap.org</a> )
<b>Cerebral palsy</b>	A disability resulting from damage to the brain before, during, or shortly after birth and outwardly manifested by muscular incoordination and speech disturbances
<b>CFU</b>	Colony-forming unit' a measure of the number of bacteria (colonies of viable cells) present in a product, the environment, or on the surface of an aseptic processing room
<b>Chemistry-Manufacture-Control or CMC</b>	Part of the pharmaceutical development that considers identity, potency, quality, purity of drugs. It includes requirements on the manufacturing processes and quality control of drugs
<b>Contract manufacturing organization or CMO</b>	A company contracted to provide drug development and/or manufacturing services. Services may include synthesis, formulation development, or stability studies
<b>Contract research organizations or CRO</b>	A company providing research and development services and support to pharmaceutical, biotechnology and medical device companies
<b>Drug</b>	A drug includes, but is not limited to, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals
<b>Dosage regimen</b>	Modality of administration chosen to reach the therapeutic objective, including formulation, route of administration, drug dose, dosing interval and treatment duration
<b>Effectiveness</b>	How well a treatment works in real practice situation
<b>Efficacy</b>	Health benefit over placebo or other intervention when tested in ideal situation such as tightly controlled clinical trials
<b>Enteral feeding/nutrition</b>	Feeding method delivering a nutritionally complete feed directly into the stomach or intestine using a tube placed in the nose, the stomach or the small intestine
<b>Gestational age or GA</b>	Gestation is the period of time between conception and birth. Gestational age is the common term used during pregnancy to describe how far along the pregnancy is. It is measured in weeks, from the first day of the woman's last menstrual cycle to the current date. A normal pregnancy can range from 38 to 42 weeks
<b>Gastrointestinal or GI</b>	Relating to, or affecting both stomach and intestine
<b>IBP-9414</b>	IBT drug candidate containing <i>Lactobacillus reuteri</i>
<b>Investigational New Drug or IND</b>	A request for authorization from the FDA to administer an investigational drug or biological product to humans



<b>Key opinion leaders or KOL</b>	Experts in their field recognized by their peers for their original research leading to disease understanding and new therapies
<b><i>Lactobacillus reuteri</i> or <i>L. reuteri</i></b>	<i>L. reuteri</i> bacteria are classified within the class Bacilli, order Lactobacillales, and family Lactobacillaceae. <i>L. reuteri</i> is a live bacteria which naturally exists in human breast milk and the stomach and intestine
<b>Live Biotherapeutic Product</b>	A biological product that: 1) contains live organisms, such as bacteria; 2) is applicable to the prevention, treatment, or cure of a disease or conditions of human beings; and 3) is not a vaccine
<b>Morbidity</b>	It is another term for illness. A person can have several co-morbidities
<b>Mortality</b>	Number of deaths in a defined total population
<b>Necrotizing enterocolitis or NEC</b>	NEC is an acquired inflammatory often fatal disease of the newborn bowel in which portions of the bowel undergo tissue death and is primarily a disease of premature infants
<b>Neonatal intensive care unit or NICU</b>	An intensive care unit specialized in providing medical care to premature neonates
<b>Nosocomial infections</b>	Hospital-acquired infections
<b>Orphan drug</b>	Drug approved for a rare disease
<b>Orphan Drug Designation</b>	Regulatory bodies such as FDA and the European Commission grants Orphan Drug Designation to drug candidate with the potential to prevent, diagnosis, treat, cure, or mitigate of a rare disease in human being
<b>Pathogenic</b>	Capable of causing a disease, an infection
<b>Parenteral nutrition</b>	Nutrition through either central or peripheral venous catheter
<b>Parenteral nutrition-associated cholestasis</b>	Liver complication in which the flow of the bile (fluid made and released by the liver) is slowed or blocked due to prolonged parenteral nutrition
<b>Pharmaceutical therapy</b>	Synonym to 'Drug'
<b>Pivotal trial</b>	A study, usually phase III, which presents the data used by regulatory agencies to decide whether to approve a drug for commercialization
<b>Placebo</b>	A substance that does not contain active ingredients and is made to be physically indistinguishable from the actual drug being studied
<b>Post-natal</b>	Occurring or being after birth
<b>Preterm infant</b>	Neonate born before full gestation of 37 weeks
<b>Prophylactic therapy</b>	A therapy preventing the occurrence or the spread of a disease or infection
<b>Safety and tolerability trial</b>	Clinical trial assessing the toxicity of the studied drug, i.e risk of the occurrence of clinical adverse events after exposure to the active substance and the threshold dose inducing these adverse events

# Definitions

The terms defined below are used in the Company description:

<b>BioGaia</b>	BioGaia AB (publ)
<b>Carnegie</b>	Carnegie Investment Bank AB (publ)
<b>Certified adviser</b>	Erik Penser Bankaktiefbolag
<b>Company description</b>	This company description
<b>EUR</b>	Euro
<b>Euroclear Sweden</b>	Euroclear Sweden AB
<b>Financial adviser</b>	Carnegie
<b>First North</b>	The alternative market place operated by the different stock exchanges comprised in Nasdaq
<b>IBT or the Company</b>	Infant Bacterial Therapeutics AB (publ)
<b>SEK</b>	Swedish krona
<b>USD</b>	US Dollar

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