

Press Release 19 August 2016

## Infant Bacterial Therapeutics AB (publ), (IBT) Interim report January 1 – June 30 2016

### Message from the CEO

“In June we announced that the first premature infant had been enrolled and dosed in the Company’s Phase II clinical trial. This Phase II trial is 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. The multicenter trial is being conducted in a number of neonatal intensive care units in the US and will enroll 120 premature infants in total. The first planned independent Data Safety Monitoring Board (DSMB) evaluation of safety data was performed on August 12th. The DSMB concluded that there were no objections to dose escalation based on the information provided to the DSMB. We are very pleased that the trial has begun and is progressing according to plan. This is another major milestone in the development of a new pharmaceutical for this very sensitive group of patients.”

Staffan Strömberg,  
Chief Executive Officer

### Financial summary

SEK 000's	2016 Jan-Jun	2015 Jan-Jun
Net sales	-	-
Net profit/loss	-16 078	-9 673
Result after tax	-16 284	-9 680
Total assets	133 127	15 917
Cash flow for the period	71 973	463
Cash	116 384	1 517
Earnings per share, weighted average, before and after dilution (SEK)	-6,4	-5,4
Equity per share (SEK)	23,1	207,0
Equity ratio (%)	95%	65%

Infant Bacterial Therapeutics AB (“IBT”) is a pharmaceutical company based in Stockholm that develops drugs that meet the needs of the premature infant. IBT’s current focus is on clinical development of IBP-9414, a drug candidate containing *Lactobacillus reuteri*, in the prevention of necrotizing enterocolitis (“NEC”), a fatal disease that affects premature infants. IBT is listed on Nasdaq First North with Erik Penser Bank as Certified Adviser.

[www.ibtherapeutics.com](http://www.ibtherapeutics.com)

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### Significant events during the first six months

- The Annual General Meeting decided on 8 February on repayment of conditional shareholder contributions by offsetting previously received group contributions by SEK 20.6m
- BioGaia AB (publ) distributed its entire holding (94.5 % of shares and 96 % of votes) in IBT to BioGaia's shareholders
- IBT's shares were listed on Nasdaq First North
- IBT completed a guaranteed share issue which generated approximately SEK 89m after deduction of issue costs
- The first premature infant has been enrolled and dosed in the Company's Phase II clinical trial

### Significant events after the reporting period

- There were no significant events after the reporting period prior to the date of publication of this interim report

### For additional information please contact

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### Publication

The information in this Interim Report is such which IBT is obliged to make public pursuant to the EU Market Abuse Regulation and which is to be made public according to the Nasdaq regulations for companies listed on Nasdaq First North.

The information was submitted for publication, by the CEO stated above, at 08.00 a.m. CET on 19 August, 2016.

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## Interim Report

January 1 – June 30, 2016

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SEK 000's	2016 Jan-Jun	2015 Jan-Jun	2015 Jan-Dec
Net sales	-	-	-
Net profit/loss	-16 078	-9 673	-20 615
Result after tax	-16 284	-9 680	-23
Total assets	133 127	15 917	82 543
Cash flow for the period	71 973	463	43 357
Cash	116 384	1 517	44 411
Earnings per share, weighted average, before and after dilution (SEK)	-6,4	-5,4	0,0
Equity per share (SEK)	23,1	207,0	831,2
Equity ratio (%)	95%	65%	91%

### IBT in brief

Infant Bacterial Therapeutics AB (IBT) is a public Company domiciled in Stockholm. The Company's B-shares are traded on Nasdaq First North in Stockholm (IBT B) since 29 March, 2016.

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

## Message from the CEO

Three years have passed since I, together with BioGaia and Head of Research and Development, 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 species that BioGaia has successfully worked with throughout several decades.

Thanks to the fantastic 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 with clinical trials in the US. Concurrently, the Swedish Medical Products Agency (Sw. Läkemedelsverket) gave us permission to proceed with clinical trials in Sweden on premature infants, the most vulnerable individuals imaginable. This was a major milestone for IBT.

Our intention is to 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. The share issue in May provided the capital necessary to fund the first clinical trial. A future commercialization of the product can be completed in several different ways: by licensing the product, by selling the rights of the project or by us bringing the product to the market.

In June we announced that the first premature infant had been enrolled and dosed in the Company's Phase II clinical trial. This Phase II trial is 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. The multicenter trial is being conducted in a number of neonatal intensive care units in the US and will enroll 120 premature infants in total. The first planned independent Data Safety Monitoring Board (DSMB) evaluation of safety data was performed on August 12th. The DSMB concluded that there were no objections to dose escalation based on the information provided to the DSMB. We are very pleased that the trial has begun and is progressing according to plan. This is another major milestone in the development of a new pharmaceutical for this very sensitive group of patients.

We have a great deal of work ahead of us, but I am confident that we have the capacity and competence necessary to complete the task successfully. I am proud and happy that IBT since March is a listed company, and my hope is that all shareholders want to join us on our exciting journey. I also hope that we can attract new owners and licensing partners who see the potential in the project. It is of the utmost importance that we have our shareholders' confidence in order to secure future capital needs, which will 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

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

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

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

The first study is a phase II safety and tolerability study for two different dose levels of IBP-9414 in 120 premature infants in total with birth-weight ranging from 500 to 2,000 g. The study was initiated in May, 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. Results from the ongoing phase II clinical trial are expected during the fourth quarter of 2017.

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.

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.

## History

### 2013

- Infant Bacterial Therapeutics AB (IBT) commenced its activities and started the development of a preventive therapy (IBP-9414) against NEC using *Lactobacillus reuteri*
- IBT is granted Orphan Drug Designation by the FDA for *Lactobacillus reuteri* for the prevention of NEC in premature infants
- U.S. Food and Drug Administration (FDA) provides scientific input for IBT's development plans

### 2014

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

### 2015

- IBP-9414 is granted Orphan Drug Designation by the European Commission for *Lactobacillus reuteri* for the prevention of NEC in premature infants
- Production of drug candidate IBP-9414 according to all applicable pharmaceutical chemistry-manufacture-control regulations for clinical phase II trial
- IBT received approval from the Swedish Medical Products Agency to conduct a clinical trial in Sweden

### 2016

- BioGaia distributes its shares in IBT to BioGaia's shareholders
- The Company's shares are listed on Nasdaq First North
- IBT receives Rare Pediatric Disease Designation from FDA for IBP-9414
- IBT completed a share issue which generated approximately SEK 89m
- All Board members, the CEO and Head of Research and Development subscribed to shares in the Company in the Rights Issue completed in May, 2016
- IBT announced that the first premature infant has been enrolled and dosed in the Company's phase II clinical trial in the USA

## Risks and uncertainties in summary

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 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.

In addition to the completed Share Issue in May, 2016, there will be significant capital needs for further clinical trials. The Company has 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 needed by the Company. The Company estimates, based on its current development plan, that additional capital of SEK 300m to 600m will be required for the development of IBP-9414 and submission for regulatory approval.

A predominant share of IBT's development costs are commitments in foreign currencies. Should the SEK depreciate in value versus the specific currency, it could have a significant impact on the Company's financial position and results.

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

## Related party transactions

The Company was a subsidiary of BioGaia AB (publ) until 23 March, 2016. There were no significant related party transactions with BioGaia until 23 March, 2016. BioGaia issued a subscription guarantee in the Rights Issue in May, 2016, for which the Company paid a guarantee fee in June 2016 amounting to approximately SEK 1.3m. No related party transactions have occurred.

## Financial calendar

Year – end Report 2016: 14 February 2017

Annual Report 2016: April 2017

## Certified Adviser

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

## Contact persons

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Peter Rothschild, Chairman, telephone: +46 8 410 145 55

## Contact information

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[www.ibtherapeutics.com](http://www.ibtherapeutics.com)

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## Financial development – comments to development during the first half year 2016

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

### Costs

Operational costs amounted to 16 078 (9 673) KSEK of which costs for the ongoing IBP-9414 clinical trial amounted to 10 009 (4 582) KSEK.

Personnel costs amounted to 3 326 (3 334) KSEK.

Other external costs amounted to 2 743 (1 757) KSEK.

Share issue costs amounted to SEK 11,0 (0,0)m which was charged to shareholders equity.

## Result and financial position

Operational result amounted to -16 078 (-9 673) KSEK and result after financial items amounted to -16 284 (-9 680) KSEK.

Result after tax amounted to -16 284 (-9 680) KSEK.

Result per share amounted to -6,35 (-5,39) SEK.

Cash flow for the period amounted to 71 973 (463) KSEK. The cash flow included a share issue amounting to 89 123 (0,0) KSEK.

The Company's cash balance on 30 June, 2016, amounted to 116 384 compared to 44 411 KSEK on 31 December, 2015.

The Company's shareholders equity on 30 June, 2016, amounted to 127 048 compared to 74 809 KSEK on 31 December, 2015. Shareholders equity per share amounted to 23,08 compared to 831,21 SEK on 31 December, 2015.

The Company's equity ratio amounted to 95 compared to 91% on 31 December, 2015.

### Personnel

The average number of employees during the first half year amounted to four (four) persons.

### Shares

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

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

IBT's class B – share was listed on Nasdaq First North on 29 March, 2016.

## Board's assurance

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

Stockholm, 19 August, 2016

Peter Rothschild  
Chairman

Jan Annwall  
Director

Anders Ekblom  
Director

Margareta Hagman  
Director

Staffan Strömberg  
CEO

*This interim report has not been subject to review by the Company's auditors.*

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

### Condensed income statement

SEK 000	2016 Jan-Jun	2015 Jan-Jun	2015 jan-dec
Net sales	-	-	-
<b>Revenue</b>	<b>0</b>	<b>0</b>	<b>0</b>
Selling expenses	0	0	-2 600
Research and development expenses	-16 078	-9 673	-17 974
Other operating expenses			-41
<b>Operating loss</b>	<b>-16 078</b>	<b>-9 673</b>	<b>-20 615</b>
<b>Result from financial items</b>			
Interest income and similar profit/loss items	0	0	0
Interest expense and similar profit/loss items	-206	-7	-9
<b>Result after financial items</b>	<b>-16 284</b>	<b>-9 680</b>	<b>-20 624</b>
<b>Appropriations</b>			
Group contribution	0	0	20 601
<b>Result before taxes</b>	<b>-16 284</b>	<b>-9 680</b>	<b>-23</b>
Tax	0	0	0
<b>Result for the period</b>	<b>-16 284</b>	<b>-9 680</b>	<b>-23</b>

### Result per share

SEK			
Result per share, before and after dilution*	-6,35	-5,39	-0,01
Number of shares, weighted average*	2 564 310	1 794 546	1 806 382
Number of shares at end of period **	5 503 638	50 000	90 000

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

\*\*On June 30, 2016, allocation of emitted shares amounted to 222 198 A-shares carrying 10 votes per share and 5 281 440 B-shares carrying 1 vote per share



**Condensed balance sheet**

SEK 000	30 Jun 2016	30 jun 2015	31 Dec 2015
<b>ASSETS</b>			
<b>Non-current assets</b>			
<i>Intangible non-current assets</i>			
Activated development expenses	16 225	13 775	16 225
<b>Total non-current assets</b>	<b>16 225</b>	<b>13 775</b>	<b>16 225</b>
<b>Current assets</b>			
<i>Current receivables</i>			
Receivable from parent company	0	0	20 420
Other receivables	464	519	535
Prepaid expenses and accrued income	54	106	952
<b>Total current assets</b>	<b>518</b>	<b>625</b>	<b>21 907</b>
Cash and cash equivalents	116 384	1 517	44 411
<b>Total current assets</b>	<b>116 902</b>	<b>2 142</b>	<b>66 318</b>
<b>TOTAL ASSETS</b>	<b>133 127</b>	<b>15 917</b>	<b>82 543</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<i>Restricted equity</i>			
Share capital	1 500	50	500
<i>Unrestricted equity</i>			
Share premium reserve	140 473	0	52 350
Accumulated losses	1 359	19 981	21 981
Net loss for the period	-16 284	-9 680	-22
<b>Total equity</b>	<b>127 048</b>	<b>10 351</b>	<b>74 809</b>
<b>Liabilities</b>			
<i>Current liabilities</i>			
Accounts payable	269	1 356	518
Other current liabilities	187	193	137
Accrued expenses and prepaid income	5 623	4 017	7 079
<b>Total current liabilities</b>	<b>6 079</b>	<b>5 566</b>	<b>7 734</b>
<b>Total liabilities</b>	<b>6 079</b>	<b>5 566</b>	<b>7 734</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>133 127</b>	<b>15 917</b>	<b>82 543</b>

### Condensed statement of cash flows

SEK 000	2016 Jan-Jun	2016 Jan-Jun	2015 Jan-Dec
<b>Operating activities</b>			
Operating profit/loss	-16 078	-9 673	-20 615
Financial items, net	-206	-7	-9
<b>Cash flow from operating activities before changes in working capital</b>	<b>-16 284</b>	<b>-9 680</b>	<b>-20 624</b>
<b>Cash flow from changes in working capital</b>			
Increase (-)/Decrease (+) in operating receivables	789	6 715	-628
Increase (+)/Decrease (-) in operating liabilities	-1 655	2 128	4 228
<b>Cash flow from operating activities</b>	<b>-17 150</b>	<b>-837</b>	<b>-17 024</b>
<b>Investment activities</b>			
Acquisition of immaterial assets		-7 700	-10 150
<b>Financing activities</b>			
Conditional shareholder contributions		9 000	11 000
Group contribution			6 731
Share issue	89 123	0	52 800
<b>Cash flow from financing activities</b>	<b>89 123</b>	<b>9 000</b>	<b>70 531</b>
<b>Cash flow for the period</b>	<b>71 973</b>	<b>463</b>	<b>43 357</b>
Cash and cash equivalents at the beginning of the year	44 411	1 054	1 054
<b>CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD</b>	<b>116 384</b>	<b>1 517</b>	<b>44 411</b>

### Condensed statement of changes in equity

SEK 000	Restricted equity		Unrestricted equity	
	Share capital	Share premium reserve	Accumulated losses incl. loss for the period	Total equity
<b>Opening equity at 1 Jan 2015</b>	50	0	10 981	11 031
Shareholder contribution			9 000	9 000
Net loss for the period			-9 680	-9 680
<b>Closing equity at 30 Jun 2015</b>	50	0	10 301	10 351
<b>Opening equity at 1 Jul 2015</b>	50	0	10 301	10 351
Shareholder contribution			2 000	2 000
Share issue	40	52 760		52 800
Bonus issue	410	-410		0
Net loss for the period			-10 943	-10 943
Group contribution			20 601	20 601
<b>Closing equity at 31 Dec 2015</b>	500	52 350	21 959	74 809
<b>Opening equity at 1 Jan 2016</b>	500	52 350	21 959	74 809
Repayment of shareholder contribution			-20 600	-20 600
Share issue	1 000	99 166	0	100 166
Share issue costs		-11 043	0	-11 043
Net profit/loss for the year			-16 284	-16 284
<b>Closing equity at 30 Jun 2016</b>	1 500	140 473	-14 925	127 048

## Accounting principles

The interim report has been issued in accordance with the Annual Accounts Act (Årsredovisningslagen) and regulations applicable to companies listed on Nasdaq First North.

IBT applies the Annual Accounts Act and general recommendations BFNAR 2012:1 Årsredovisning och koncernredovisning (K3) by Bokföringsnämnden.

The Company's accounting principles are described in its latest published Annual Report (2015). The same accounting principles and calculation methods used in the Annual Report were applied in the interim report.

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

## Financial definitions

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

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

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

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

**Net sales:** Sales for the period

**Reporting period:** First half year 2016

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

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