

Infant Bacterial Therapeutics AB (publ)

Interim report January 1-March 31, 2019

First quarter (Jan-Mar) 2019

- Net sales 0 KSEK (0)
- Operating loss -929 KSEK* (-9 144)
- Earnings per share before and after dilution
-0.06 SEK (-3.76)

* Operational costs for the first quarter include exchange rate gains on forward currency contracts and currency deposits amounting to 5 836 (0) KSEK. Operational costs amounted to 6 765 (9 144) KSEK prior to exchange rate gains (Note 2)

Significant events during the first quarter (Jan-Mar) 2019

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

Significant events after the reporting period

- No significant events have occurred after the reporting period

Selected financial data

ooo's	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
Net sales	-	-	-
Operating profit/loss	-929	-9 144	-39 417
Result after tax, SEK	-686	-9 144	-40 607
Total assets	561 035	597 313	563 371
Cash flow for the period (SEK)	-5 647	422 807	381 544
Cash flow per share for the period (SEK)	-0.50	44.61	35.36
Cash	540 514	581 081	542 170
Earnings per share before and after dilution (SEK)	-0.06	-0.96	-3.76
Equity per share (SEK)	49.53	52.48	49.59
Equity ratio (%)	99%	99%	99%

IBT in brief

Infant Bacterial Therapeutics AB (“IBT”) is a public company domiciled in Stockholm. The company’s class B-shares shares are listed on Nasdaq Stockholm, Mid-cap (IBT B).

Infant Bacterial Therapeutics AB (publ) pharmaceutical company with a product is a clinical stage with a vision to develop drugs influencing the infant microbiome, and thereby prevent or treat rare diseases affecting infants.

IBT is currently developing the drug candidate IBP-9414, for the prevention of necrotizing enterocolitis (“NEC”) and improvement of so called *feeding tolerance* in premature infants. IBP-9414 contains the active compound *Lactobacillus reuteri*, which is a human bacterial strain naturally present in breast milk. The product portfolio also includes another project, IBP-1016, for the treatment of gastroschisis, a severe and rare disease affecting infants. By developing these drugs, IBT has the potential to fulfil unmet needs for diseases where there are currently no prevention or treatment therapies available.

Message from the CEO

As previously communicated, IBT had a meeting with the Food and Drug Administration (FDA) on November 20, 2018, to discuss IBT’s clinical development program. The development program is comprised of the clinical phase II safety-and tolerability study, concluded in 2017, and the not yet commenced phase III study, which we have named “The Connection Study”.

IBT has during the first quarter, in conjunction with external experts, amended the clinical development program based on guidance received from the FDA and other authorities in Europe. In general, this is an improvement as we now will also include the primary endpoint in the phase III study of so called *feeding tolerance*. These amendments to the clinical program do not render significant impact on costs or otherwise affect conducting the planned phase III study.

Parallel to the development work, IBT is also continuously evaluating potential marketing and distribution partners. We entered into an agreement in March regarding distribution of IBP-9414 in Israel. The agreement provides IBT with the possibility to long-term receive of the majority of future income from sales of IBP-9414 in Israel. IBT plans to include patients from Israel in the coming phase III study.

We are looking forward to commencing the phase III study as planned in the first half of the current year.

Stockholm May 6, 2019

Staffan Strömberg,
Chief Executive Officer

Description of IBT's development project IBP-9414

The development plan for IBP-9414 is to conduct a clinical program consisting of two clinical trials, the completed safety and tolerability study followed by the planned pivotal phase III study, "The Connection Study". The safety and tolerability study was concluded as planned during the fourth quarter of 2017. The following pivotal phase III study, The Connection Study, is planned to commence during the first half of 2019.

The first study was a multicenter, randomized, double blind, parallel-group, dose escalation placebo-controlled study to investigate the safety and tolerability of IBP-9414 administered in preterm infants. This study included 120 preterm infants (prior to gestation week 32 with birth-weight ranging from 500 to 2 000 grams) randomized for treatment with IBP-9414 or placebo. The initial dose of the product was administered within 48 hours after birth and continued daily for a 14-day period and evaluated at intervals for up to six months post administration. The primary goal of this study was to evaluate safety and tolerability. The study was completed according to plan in the fourth quarter 2017 demonstrated that IBP-9414 was safe and tolerated by premature infants with birth-weight ranging from 500 to 2 000 grams, that they were well exposed to the study medicine, and that there were no indications of cross contamination of IBP-9414 in the preterm infants treated with placebo.

The following pivotal phase III study will be designed to show and document the effect of IBP-9414 compared to placebo for the prevention of NEC and improvement of so called *feeding tolerance* in premature infants with birth weights of 1 500g or less. This study will also include safety evaluation.

Risks and uncertainties

The value of the Company is largely dependent on success in the Company's development of IBP-9414, 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 program is in the development stage and there is a risk that IBP-9414 will not demonstrate the required effect. If the development on IBP-9414 is unsuccessful, IBT may try to focus on other projects but there is a risk that such projects will not be successful.

Financial risk management

A predominant share of IBT's development costs are commitments in foreign currencies.

Currency risk is the risk that the value of assets and liabilities fluctuate due to changes in exchange rates. Should the SEK depreciate versus the specific currency, it could have a significant impact on the Company's financial position and results. The currencies against which IBT has the greatest exposure are USD and EUR.

The company has entered into currency hedging (see Note 2).

IBT has during 2017 and 2018 generated approximately SEK 528m less transaction costs by new share issues. The capital generated is deemed sufficient to conduct the planned pivotal phase III clinical study, and operational costs until application for market approval.

For further information on risks and uncertainties please refer to IBT's Annual Report 2018 and IBT's Rights Issue Prospectus dated January 10, 2018 on the Company's homepage www.ibtherapeutics.com

Related party transactions

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

The Chairman of the Board, Mr. Peter Rothschild, receives Board fees amounting to 200 KSEK per annum, and annually 400 KSEK as operational Chairman.

No other significant related party transactions have occurred.

Financial calendar

Interim report January-June 2019

August 21, 2019

Interim report January-September 2019

November 7, 2019

Contact persons

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Publication

The Report was submitted for publication, by the CEO, at 13.00 CET on May 6, 2019.

Financial development – first quarter (Jan-Mar) 2019

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

Costs

Costs for the planned clinical IBP-9414 clinical trial are reported net of exchange rate effects on foreign currency forward contracts and currency deposits. Exchange rate gains during the first quarter amounted to 5 836 (0) KSEK (Note 2).

Operational costs amounted to 6 765 (9 144) KSEK prior to exchange rate gains on currency forward contracts amounting to 5 836 (0) KSEK, and after exchange rate gains to 929 (9 144) KSEK. Costs for the planned IBP-9414 clinical trial amounted to 1 625 (1 914) KSEK prior to exchange rate gains amounted to -4 211 (1 914) KSEK after exchange rate gains.

Personnel costs amounted to 3 783 (2 910) KSEK.

Other external costs amounted to 1 357 (4 320) KSEK.

Result and financial position

Operational result amounted to -929 (-9 144) KSEK and result after financial items amounted to -686 (-9 144) KSEK.

Result after tax amounted to -686 (-9 144) KSEK.

Result per share amounted to -0.06 (-0.96) SEK.

Cash flow for the period amounted to -5 647 (422 807) KSEK. Cash flow per share amounted to -0.50 (44.61) SEK. Cash flow during the comparative period included a new share issue amounting to 430 900 KSEK. Cash flow during the comparative period less the new share issue amounted to -0.85 KSEK.

The Company's cash balance on March 31, 2019, amounted to 540 514 KSEK compared to 542 170 KSEK on December 31, 2018.

The Company's shareholder's equity on March 31, 2019, amounted to 556 030 KSEK compared to 556 717 KSEK on December 31, 2018. Shareholder's equity per share amounted to 49.53 compared to 49.59 SEK on December 31, 2018.

The Company's equity ratio amounted to 99% compared to 99% on December 31, 2018.

Operational costs during the reporting period were lower compared to the previous year as the company's clinical phase II trial was concluded during the first half of 2018, and costs for the planned clinical phase III trial were lower than clinical trial costs during the previous year.

Costs for the planned IBP-9414 clinical trial are reported net including exchange rate gains on currency forward contracts and currency deposits during the reporting period amounting to 5 836 (0) KSEK (Note 2).

Other external costs during the reporting period were lower than during the same period in the previous year which then incurred costs relating to the listing change to Nasdaq Stockholm in the amount of approximately SEK 2.0m.

Personnel costs have increased during the reporting period in comparison to the equivalent period during the prior year due to staff recruitment required for conducting the clinical Phase III trial.

IBT has during November 2017 and 2018 generated approximately SEK 528m after transaction costs in new share issues. Capital thus generated is deemed sufficient to conduct the planned phase III clinical study, as well as to fund the company's activities until application for market approval.

Tax position

IBT has accumulated operational losses since the company was established in 2012 and until year-end of 2018 amounting to approximately SEK 142m. Deferred tax receivables are reported when it is likely that future taxable income will be available against which the temporary differences may be utilized. The company has not reported any temporary tax receivables in its statement of financial position.

Shares

On January 1, 2019, and March 31, 2019, respectively, the total number of shares amounted to 11 226 184 shares of which 377 736 class A-shares carrying ten votes and 10 848 448 class B-shares carrying one vote.

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

IBT's closing share price on March 29, 2019 amounted to SEK 195.00.

Analysts covering IBT:

SEB: Carl Mellerby, Mattias Vadsten, Carsten Lønborg Madsen

Chardan Capital Markets, New York, NY: Taylor Feehley, PhD. info@chardan.com

Ownership March 31, 2019

Name	Series A shares	Series B shares	Share capital %	Voting rights %
ANNWALL & ROTHSCHILD INVESTMENTS AB	377 736	410 478	7.02	28.63
ÖHMAN BANK S.A.	-	1 063 481	9.47	7.27
FJÄRDE AP FONDEN	-	1 052 716	9.38	7.20
SKANDINAVISKA ENSKILDA BANKEN S.A., W8IMY	-	563 194	5.02	3.85
AMF AKTIEFOND SMABOLAG	-	501 585	4.47	3.43
TREDJE AP-FONDEN	-	489 160	4.36	3.34
UNIONEN-SVENSKA	-	447 196	3.98	3.06
SWEDBANK ROBUR MICROCAP	-	340 694	3.03	2.33
SWEDBANK ROBUR NY TEKNIK BTI	-	320 000	2.85	2.19
DANGOOR, DAVID	-	290 144	2.58	1.98
ANDRA AP-FONDEN	-	263 500	2.35	1.80
BANQUE PICTET & CIE SA, W8IMY (WITHOUT P.R.)	-	252 582	2.25	1.73
ÅLANDSBANKEN I ÄGARES STÄLLE	-	246 699	2.20	1.69
NORDNET PENSIONS FÖRSÄKRING AB	-	236 418	2.11	1.62
FÖRSÄKRINGS AKTIEBOLAGET, AVANZA PENSION	-	228 443	2.03	1.56
RBC INVESTOR SERVICES BANK S.A	-	225 733	2.01	1.54
CBNY-NORGES BANK	-	203 293	1.81	1.39
CATELLA SMÅBOLAGSFOND	-	150 654	1.34	1.03
HANVAD INVEST AKTIEBOLAG	-	136 593	1.22	0.93
STRÖMBERG, STAFFAN	-	122 592	1.09	0.84
Sub-total	377 736	7 545 155	70.58	77.41
Other shareholders	-	3 303 293	29.42	22.59
Total	377 736	10 848 448	100	100

This report has not been subject to review by the company's auditors.

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

Board's assurance

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

Stockholm, May 6, 2019

Peter Rothschild
Chairman

Anders Ekblom
Director

Margareta Hagman
Director

Eva Idén
Director

Anthon Jahreskog
Director

Kristina Sjöblom Nygren
Director

Lilian Wikström
Director

Staffan Strömberg
CEO

Income statement

SEK 000	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
Net sales	-	-	-
Research and development costs	-929	-9 144	-39 417
Operating loss	-929	-9 144	-39 417
Result from financial items			
Interest income and similar profit/loss items	481	-	327
Interest expense and similar profit/loss items	-238	-	-1 517
Result after financial items	-686	-9 144	-40 607
Result for the period *	-686	-9 144	-40 607

* Result for the period equals total comprehensive income

Result per share

SEK			
Result per share, before and after dilution*	-0.06	-0.96	-3.76
Number of shares, weighted average*	11 226 184	9 477 103	10 788 914
Number of shares at end of period **	11 226 184	11 226 184	11 226 184

* No dilution effects exist

**On March 31, 2019, allocation of emitted shares amounted to 377 736 class A-shares carrying 10 votes per share and 10 848 448 class B-shares carrying 1 vote per share

Balance sheet

SEK 000	Note	2019-03-31	2018-03-31	2018-12-31
ASSETS				
Non-current assets				
<i>Intangible non-current assets</i>				
Activated development costs		13 578	14 394	13 782
Shares in subsidiary		50	50	50
Total non-current assets		13 628	14 444	13 832
Current assets				
<i>Current receivables</i>				
Other receivables	2	6 088	1 552	7 114
Prepaid expenses and accrued income		805	236	255
Total current assets		6 893	1 788	7 369
Cash and cash equivalents	3	540 514	581 081	542 170
Total current assets		547 407	582 869	549 539
TOTAL ASSETS		561 035	597 313	563 371
EQUITY AND LIABILITIES				
Equity				
<i>Restricted equity</i>				
Share capital		3 060	3 060	3 060
<i>Unrestricted equity</i>				
Share premium reserve		667 167	668 139	667 167
Accumulated losses		-113 511	-72 903	-72 903
Net loss for the period		-686	-9 144	-40 607
Total equity		556 030	589 152	556 717
Liabilities				
<i>Current liabilities</i>				
Accounts payable		910	1 326	3 507
Other current liabilities		358	470	752
Accrued expenses and prepaid income		3737	6 365	2 395
Total current liabilities		5 005	8 161	6 654
TOTAL EQUITY AND LIABILITIES		561 035	597 313	563 371

Statement of changes in equity

SEK 000	Restricted equity		Unrestricted equity	
	Share capital	Share premium reserve	Accumulated losses incl. loss for the period	Total equity
Opening equity on Jan 1, 2018	1 800	239 474	-72 903	168 371
Net loss for the period			-9 144	-9 144
Total comprehensive income			-9 144	-9 144
Shareholder transactions				
Share issue	1 260	437 882		437 882
Share issue costs		-9 217		-9 217
Closing equity on Mar 31, 2018	3 060	668 139	-82 047	589 152
Opening equity on Jan 1, 2018	1 800	239 474	-72 903	168 371
Net loss for the period			-40 607	-40 607
Total comprehensive income			-40 607	-40 607
Shareholder transactions				
Share issue	1 260	437 882		439 142
Share issue costs		-10 189		-10 189
Closing equity on Dec 31, 2018	3 060	667 167	-113 510	556 717
Opening equity on Jan 1, 2019	3 060	667 167	-113 510	556 717
Net loss for the period			-686	-686
Total comprehensive income			-686	-686
Closing equity on Mar 31, 2019	3 060	667 167	-114 196	556 030

Statement of cash flows

SEK 000	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
Operating activities			
Operating profit/loss	-929	-9 144	-39 417
Interest income received	395		327
Paid interest costs	-238	-	-1 517
Adjustment for non - cash flow affecting items:			
Depreciation production process	204	204	816
Value variance currency forward contracts	-1 739	-	-8 752
Cash flow from operating activities before changes in working capital	-2 307	-8 940	-48 543
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in operating receivables	-1 691	314	1 133
Increase (+)/Decrease (-) in operating liabilities	-1 649	533	1
Cash flow from operating activities	-5 647	-8 093	-47 409
Financing activities			
Share issue	-	439 142	439 142
Share issue costs	-	-8 242	-10 189
Cash flow from financing activities	0	430 900	428 953
Cash flow for the period	-5 647	422 807	381 544
Unrealized exchange rate difference in cash	3 991	-	2 352
Cash and cash equivalents at the beginning of the year	542 170	158 274	158 274
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	540 514	581 081	542 170

Note 1 Accounting principles

The interim report has been prepared in accordance with IAS 34 Interim reporting, and the Annual Accounts act, Årsredovisningslagen. The Company's reporting has been prepared in accordance with the Annual Accounts act, Årsredovisningslagen and as stipulated by RFR 2 Reporting for legal entities. Disclosures in accordance with IAS 34 are presented in Notes as well as in other sections in the interim report.

IBT has adopted the same accounting principles and calculation methods as those described in the 2018 annual report.

IFRS 16 Leases. In January 2016, the IASB published a new leasing standard that will replace IAS 17 Leases and the related interpretations, IFRIC 4, SIC-15 and SIC-27. The standard requires that assets and liabilities attributable to all leases, with a few exceptions, be recognized in the balance sheet. This accounting treatment is based on the view that the lessee has a right to use an asset during a specific period of time as well as an obligation to pay for this right. For the lessor, the financial reporting will remain essentially unchanged. The standard is applicable for financial years beginning on January 1, 2019 or later. Early application is permitted. IBT presents financial reports for the corporate entity and has thus chosen not to adopt the leasing standards according to IFRS 16. IBT presents in accordance with items 2-12 in RFR 2 and leasing costs are reported as in the past, linear over the term of the lease.

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

Note 2 Financial instruments

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

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

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

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

Foreign exchange forward contracts - income effect*, SEK 000's	2019-01-01- 2019-03-31	2018-01-01- 2018-03-31	2018-04-18- 2018-12-31
Purchases of USD forward contracts and deposit on currency account on 2018-04-18			
Forward contracts, opening balance/time of purchase	-40 021	-	-73 743
Forward contracts on balance sheet date	41 760	-	80 143
Unrealized exchange rate gains/losses	3 991	-	2 352
Realized exchange rate gains/losses	106	-	3 257
Result	5 836	0	12 009

* Purchased forward contracts and currency refer to mitigate risk related to the planned phase III clinical trial in the pharmaceutical drug candidate IBP-9414. The income effect is reported in the income statement item R&D. Results during the reporting period refer to unrealized exchange rate gains on forward contracts amounting to approximately SEK 1.7m and on cash held on interest bearing time deposits amounting to approximately SEK 4.1m (in total approximately SEK 5.8m reported in the balance sheet item other receivables). Of purchased forward contracts amounting to USD 13.5m on April 18, 2018, USD 4.5m expired during the first quarter

Note 3 Liquidity

The Company's liquidity consists solely of cash deposits held at Danske Bank and SEB. Total liquidity on the balance sheet date amounted to SEK 540.5 of which USD amounted to SEK 110.3m. Liquidity in SEK is charged with Deposit Fees. Deposits of USD on fixed term time deposits generate interest income.

Deduction of certain key figures

	2018 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec
Cash flow per share			
Cash flow for the period, 000's	-5 647	422 807	381 544
Average number of shares	11 226 184	9 477 103	10 788 914
Cash flow per share (SEK)	-0.50	44.61	35.36
Equity per share			
Equity, 000's	556 030	589 152	556 717
Number of shares at end of period	11 226 184	11 226 184	11 226 184
Equity per share (SEK)	49.53	52.48	49.59
Equity ratio			
Equity, 000's	556 030	589 152	556 717
Total equity and liabilities, 000's	561 035	597 313	563 371
Equity ratio %	99%	99%	99%

Financial definitions

Alternate key ratios are presented as they in their context support measures defined by relevant rules for financial reporting. Basis for presented alternate key ratios is that they are used by management to assess the financial development and therefore deemed to provide valuable information for analysts and other interested parties. Definitions are provided below for all alternate key ratios used.

Key ratios	Definition	Motive
Average number of shares	Average number of shares during the reporting period	Relevant in calculating income and cash flow per share
Net sales	Sales for the period	Sales of services
Reporting period	January 1 – March 31, 2019	Explanation of period comprised by this financial report
Result per share	Result for the period divided by average number of shares	Result allocated per share
Cash flow per share*	Cash flow for the period divided by average number of shares	Measure to describe cash flow allocated to one share during the period
Number of shares*	Number of shares at the end of the period	Relevant for calculating shareholders' equity allocated to one share
Total assets*	Total assets at the end of the period	Relevant for calculating shareholders' equity
Shareholders equity / share*	Total shareholders' equity divided by the number of shares at the end of the period	Measure to describe shareholders' equity per share
Equity ratio*	Total shareholders' equity as a percentage of total assets	Measure to evaluate the company's ability to meet its financial obligations

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