Infant Bacterial Therapeutics AB (publ)

Interim report January 1-March 31, 2020

First quarter (Jan-Mar) 2019

- Net sales 0 KSEK (0)
- Operating income 1 206 KSEK* (-929)
- Earnings per share before and after dilution 0.10 SEK (-0.06)

* Operational income includes exchange rate gain on foreign currency deposits for the purpose of securing future outflows amounting to 13 857 (3 991) KSEK.

Significant events during the first quarter (Jan-Mar) 2020

- IBT's clinical study application was approved in Israel at the end of January 2020
- The COVID-19 pandemic affects our development work, for example, activation of hospitals, which has not occured at the desired rate. As of the date of this interim report, approximately half of the planned hospitals have been activated. IBT's cash position is sufficient to carry out the ongoing Phase III study, even if recruitment in the study currently does not take place at the desired rate.

Significant events after the reporting period

- IBT's Board of Directors decided to postpone the Annual General Meeting until June 16, 2020, instead of the originally planned date of May 11, 2020

Selected financial data

ooo's	2020 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
Net sales	-	-	-
Other income	75	-	-
Operating profit/loss	1 206	-929	-47 200
Result after tax, SEK	1 178	-686	-46 320
Total assets	523 168	561 035	518 273
Cash flow for the period (SEK)	-8 050	-5 647	-51 301
Cash flow per share for the period (SEK)	-0.72	-0.50	-4.57
Cash	500 995	540 514	495 188
Earnings per share before and after dilution (SEK)	0.10	-0.06	-4.13
Equity per share (SEK)	45.57	49.53	45.46
Equity ratio (%)	98%	99%	98%

IBT in brief

Infant Bacterial Therapeutics AB ("IBT") is a public company domiciled in Stockholm. The company's Class B shares are listed on Nasdaq Stockholm, Mid-cap (IBT B).

Infant Bacterial Therapeutics AB (publ) is a pharmaceutical company with a product in 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 fulfill unmet needs for diseases where there are currently no prevention or treatment therapies available.

Message from the CEO

IBT is currently developing its lead drug candidate IBP-9414 to prevent necrotizing enterocolitis (NEC), and to improve so called “feeding intolerance” affecting premature infants. Including an additional indication means having multiple independent endpoints for IBP-9414 and may increase the chances of success in the ongoing Phase III study, “The Connection Study” and the product's future market potential. IBP-9414 contains Lactobacillus reuteri as an active substance, which is a human bacterial strain found naturally in breast milk.

This message from the CEO is written in early May 2020 during an ongoing COVID-19 pandemic.

It has become more difficult to maintain full activity with our suppliers and a greater number of hospitals are affected to a greater extent as the pandemic continues.

Our study is not dependent on "normal" hospital or doctor visits, since the infants we recruit are already in the intensive care units irrespective of our study. This is essential for the completion of our study as many hospitals have now introduced a ban on non-essential visitors. This is very different from the vast majority of clinical trials conducted globally, which usually require that patients come to clinics to receive the medication as well as for measurements to be performed. As announced in the Annual Report, we have not achieved the expected recruitment rate in the study and it is clear that the pandemic and the "lock-down" that took place in the USA, France and Spain, for example, make it difficult to increase the pace of the study. At the time of writing, we have contracted 62 hospitals of which 45 are activated and can include patients however contracting additional hospitals is currently difficult due to the COVID-19 pandemic.

The pandemic has changed our way of working, we cannot travel and have face to face meetings, which means that these activities occur at a distance. For example, hospitals are now activated through virtual meetings.

Our goal to complete the ongoing Phase III study in 2021 remains. We are still recruiting infants in the study, however due to the Corona crisis, there is a risk that we cannot achieve this goal. Thus, there is a not insignificant risk that the study results may be delayed.

IBT's qualified team continues to work in a dedicated and focused manner with the aim of delivering study results which, in turn, hopefully means that a product that really plays a vital role for the premature infants can reach the market as soon as possible.

Stockholm,
May 11, 2020

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 ongoing 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, was initiated on July 4, 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 ongoing 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 has not yet concluded any clinical development of any pharmaceutical 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 and 3).

IBT has during 2017 and 2018 generated approximately SEK 528m after 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 400 KSEK annually as operational Chairman.

No other significant related party transactions have occurred.

Financial calendar

Annual general meeting, Stockholm	June 16, 2020
Interim statement January-June 2020	August 14, 2020
Interim statement January-September 2020	November 5, 2020

The annual general meeting for IBT will be held on June 16th 2020 at 15.00 at Svenska Läkaresällskapet, Klara Östra kyrkogata 10, Stockholm. The last date to request that a matter be put before the annual general meeting is May 15, 2020.

Contact persons

Staffan Strömberg, CEO

Daniel Mackey, CFO

Contact information

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Publication

This information is such that IBT AB (publ) is required to publish in accordance with the financial securities law.

The Report was submitted for publication, by the CEO, at 16.00 CET on May 11, 2020.

Financial development – first quarter (Jan-Mar) 2020

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 deposits. Exchange rate gains during the first quarter amounted to 13 857 (5 836) KSEK (Note 2).

Operational costs amounted to 12 726 (6 765) KSEK prior to exchange rate gains on foreign currency deposits, and after exchange rate gains to -1 131 (929) KSEK.

Costs for the ongoing IBP-9414 clinical trial amounted to 7 491 (1 625) KSEK prior to exchange rate gains.

Personnel costs amounted to 4 449 (3 783) KSEK.

Other external costs amounted to 786 (1 357) KSEK.

Result and financial position

Operational result amounted to 1 206 (-929) KSEK and result after financial items amounted to 1 178 (-686) KSEK.
Result after tax amounted to 1 178 (-686) KSEK.
Result per share amounted to 0.10 (-0.06) SEK.

Cash flow for the period amounted to –8 050 (-5 647) KSEK. Cash flow per share amounted to -0.72 (-0.50) SEK.

Prepaid expenses amounted to approximately SEK 7.8m (9.4). The increase refers to contractual milestone payments paid to the company's CRO regarding unfulfilled obligations and are reported as receivable in the balance sheet.

Accrued expenses amounted to approximately SEK 9.7m (6.4). The increase refers to research and development costs.

The Company's cash balance on March 31, 2020, amounted to 500 995 KSEK compared to 495 188 KSEK on December 31, 2019. The Company's cash balance has increased during the reporting period due to foreign currency exchange gains.

The Company's shareholder's equity on March 31, 2020, amounted to 511 575 KSEK compared to 510 397 KSEK on December 31, 2019. Shareholder's equity per share on March 31, 2020 amounted to 45.57 compared to 45.46 SEK on December 31, 2019.

The Company's equity ratio on March 31, 2020 amounted to 98% compared to 98% on December 31, 2019.

Operational costs increased during the reporting period compared to the previous year as recruitment increased in the ongoing clinical phase III study which was initiated in 2019.

Other external costs during the reporting period were lower than during the same period in the previous year primarily as a result of reduced travel-and related costs.

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. The company had 10(9) full time equivalent employees. The company had 11 employees on the balance sheet date.

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 2019 amounting to approximately SEK 188m. 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, 2020, and March 31, 2020, respectively, the total number of shares amounted to 11 226 184 shares of which 377 736 class A-shares carrying ten votes and 10 848448 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 31, 2020 amounted to 82.40 SEK.

Analysts covering IBT:

SEB, Stockholm
Chardan Capital Markets, New York, NY

Ownership March 31, 2020

Name	Series A shares	Series B shares	Share capital %	Voting rights %
ANNWALL & ROTHSCHILD INVESTMENTS AB	377 736	410 478	7,02	28,63
FJÄRDE AP FONDEN	-	1 112 919	9,91	7,61
ÖHMAN BANK S.A.	-	1 106 452	9,86	7,57
SWEDBANK ROBUR NY TEKNIK BTI	-	579 172	5,16	3,96
TREDJE AP-FONDEN	-	507 064	4,52	3,47
AMF AKTIEFOND SMÅBOLAG	-	501 585	4,47	3,43
UNIONEN	-	447 196	3,98	3,06
HANDELSBANKEN SVENSKA, SMABOLAGSFOND	-	360 000	3,21	2,46
CBNY-NORGES BANK	-	338 500	2,79	2,14
DANGOOR, DAVID	-	283 501	2,52	1,94
ANDRA AP-FONDEN	-	263 500	2,35	1,80
SWEDBANK ROBUR MICROCAP	-	250 000	2,23	1,71
ÅLANDSBANKEN I ÄGARES STÄLLE	-	239 357	2,13	1,64
BANQUE PICTET & CIE SA, W8IMY	-	235 380	2,10	1,61
SEB AB, LUXEMBOURG BRANCH, W8IMY	-	231 016	2,06	1,58
RBC INVESTOR SERVICES BANK S.A	-	222 708	1,98	1,52
FÖRSÄKRINGSAKTIEBOLAGET, AVANZA PENSION	-	201 258	1,79	1,38
HANDELSBANKEN MICROCAP SVERIGE	-	170 220	1,52	1,16
NORDNET PENSIONSFÖRSÄKRING AB	-	160 889	1,43	1,10
HANVAD INVEST AKTIEBOLAG	-	136 593	1,22	0,93
Sub-total	377 736	7 757 788	72,25	78,70
Other shareholders	-	3 090 660	27,75	21,30
Total	377 736	10 848 448	100	100

Source: Euroclear Sweden

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

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 11, 2020

Peter Rothschild Chairman	Anthon Jahreskog Director	Margareta Hagman Director
Eva Idén Director	Kristina Sjöblom Nygren Director	Staffan Strömberg CEO

Income statement

SEK 000	Note	2020 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
Net sales		-	-	-
Other income		75	-	-
Research and development costs	2	1 131	-929	-47 200
Operating loss		**1 206**	**-929**	**-47 200**
Result from financial items				
Interest income and similar profit/loss items		58	481	1 605
Interest expense and similar profit/loss items		-86	-238	-725
Result after financial items		**1 178**	**-686**	**-46 320**
Result for the period*		**1 178**	**-686**	**-46 320**

* Result for the period equals total comprehensive income

Result per share

SEK			
Result per share Result per share, before and after dilution*	0.10	-0.06	-4.13
Number of shares, weighted average*	11 226 184	11 226 184	11 226 184
Number of shares at end of period **	11 226 184	11 226 184	11 226 184

* No dilution effects exist
**On March 31, 2020, allocation of emitted shares amounted to 377 736 A-shares carrying 10 votes per share and 10 848 448 B-shares carrying 1 vote per share

Balance sheet

SEK 000	Note	2020-03-31	2019-03-31	2019-12-31
ASSETS				
Non-current assets				
Intangible non-current assets				
Activated development costs		12 762	13 578	12 966
Shares in subsidiary		50	50	50
Total non-current assets		**12 812**	**13 628**	**13 016**
Current assets				
Current receivables				
Other receivables		1 587	6 088	713
Prepaid expenses and accrued income		7 774	805	9 356
Total current assets		9 361	6 893	10 069
Cash and cash equivalents	3	500 995	540 514	495 188
Total current assets		**510 356**	**547 407**	**505 257**
TOTAL ASSETS		**523 168**	**561 035**	**518 273**
EQUITY AND LIABILITIES				
Equity				
Restricted equity				
Share capital		3 060	3 060	3 060
Unrestricted equity				
Share premium reserve		667 167	667 167	667 167
Accumulated losses		-159 830	-113 511	-113 510
Net loss for the year		1 178	-686	-46 320
Total equity		**511 575**	**556 030**	**510 397**
Liabilities				
Current liabilities				
Accounts payable		1 385	910	943
Other current liabilities		493	358	512
Accrued expenses and prepaid income		9 715	3 737	6 421
Total current liabilities		**11 593**	**5 005**	**7 876**
TOTAL EQUITY AND LIABILITIES		**523 168**	**561 035**	**518 273**

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, 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**
Opening equity on Jan 1, 2019	**3 060**	**667 167**	**-113 510**	**556 717**
Net loss for the year			-46 320	-46 320
Total comprehensive income			**-46 320**	**-46 320**
Closing equity on Dec 31, 2019	**3 060**	**667 167**	**-159 830**	**510 397**
Opening equity on Jan 1, 2020	**3 060**	**667 167**	**-159 830**	**510 397**
Net income for the period			1 178	1 178
Total comprehensive income			**1 178**	**1 178**
Closing equity on Mar 31, 2020	**3 060**	**667 167**	**-158 652**	**511 575**

Statement of cash flows

SEK 000	2020 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
Operating activities			
Operating profit/loss	1 206	-929	-47 200
Interest income received	58	395	1 605
Paid interest costs	-86	-238	-725
Adjustment for non - cash flow affecting items:			
Depreciation production process	204	204	816
Value variance currency forward contracts	-13 857	-1 739	-4 319
Cash flow from operating activities before changes in working capital	**-12 475**	**-2 307**	**-49 823**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in operating receivables	708	-1 691	-2 700
Increase (+)/Decrease (-) in operating liabilities	3 717	-1 649	1 222
Cash flow from operating activities	**-8 050**	**-5 647**	**-51 301**
Cash flow for the period	**-8 050**	**-5 647**	**-51 301**
Unrealized exchange rate difference in cash	13 857	3 991	4 319
Cash and cash equivalents at the beginning of the period	495 188	542 170	542 170
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	**500 995**	**540 514**	**495 188**

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 2019 annual report.

IBT has no transactions to report under other comprehensive income and thus presents information thereon under the income statement.
IBT entered into foreign exchange forward contracts during the second quarter 2018. Effects of these hedges are reported in the company's financial statements at market value in the income statements item research-and development costs (Note 2).
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. Income effects are reported in the income statement item research-and development costs.

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 March 31, 2020, amounted to SEK 501.0m (540.5m) of which USD amounted to SEK 131.3m (110.3m) and EUR amounted to SEK 66.0m (0m).
Liquidity in SEK has been charged with Deposit Fees. Deposits of USD and SEK on fixed term time deposits generate interest income reported under other financial income and expenses.

Note 4 Alternative key figures

The company presents some financial measures in the interim report that are not defined in accordance with IFRS. The company believes that these measures provide valuable supplementary information to investors and the company's management as they enable evaluation of the company's presentation. Since not all companies calculate financial measures in the same way, these are not always comparable to measures used by other companies. These financial measures should therefore not be seen as a substitute for measures defined in accordance with IFRS. The key ratios below are not defined in accordance with IFRS unless otherwise stated.
For definitions and other reasons, refer to the Annual Report 2019.

Deduction of certain key figures

	2020 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
Cash flow per share			
Cash flow for the period, 000's	-8 050	-5 647	-51 301
Average number of shares	11 226 184	11 226 184	11 226 184
Cash flow per share (SEK)	**-0.72**	**-0.50**	**-4.57**
Equity per share			
Equity, 000's	511 575	556 030	510 397
Number of shares at end of period	11 226 184	11 226 184	11 226 184
Equity per share (SEK)	**45.57**	**49.53**	**45.46**
Equity ratio			
Equity, 000's	511 575	556 030	510 397
Total equity and liabilities, 000's	523 168	561 035	518 273
Equity ratio %	**98%**	**99%**	**98%**