Infant Bacterial Therapeutics AB (publ)

Interim report January 1-March 31, 2022

First quarter (Jan-Mar) 2022

- Net sales KSEK 0 (0)
- Operating income KSEK -19 063* (452)
- Earnings per share before and after dilution SEK -1.71 (0.04)

* Operational income includes exchange rate effects on foreign currency deposits for the purpose of securing future outflows during the first quarter amounting to KSEK 6,252 (12,114).

Significant events during the first quarter (Jan-Mar)

- On January 10, IBT announced that the Australian Patent Office has granted a patent entitled: "A method of activating lactic acid bacteria".
- On January 19, IBT announced that The Connection Study continues after the Data Monitoring Committee (DMC) had completed its pre-scheduled safety analysis without any concerns. At the same time a futility analysis was performed. Based on DMC recommendations and futility outcome, IBT is continuing the recruitment to the study as planned.

Significant events after the reporting period

- The company's CFO, Michael Owens, has decided to retire during the year. A recruitment process has begun.
- At the Annual General Meeting on May 4th 2022, Robert Molander resigned from the Board at his own request. At the same time, Robert is transferring to an operational role as Chief Commercial Officer within the management team for the company.

Selected financial data

ooo's	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Net sales	-	-	-
Other income	3	64	94
Operating profit/loss	-19 063	452	-44 578
Result after tax	-19 201	451	-44 991
Total assets	409 967	451 138	408 478
Cash flow for the period	-10 825	-9 794	-55 532
Cash flow per share for the period (SEK)	-0.96	-0.87	-4.95
Cash	382 179	425 758	386 752
Earnings per share before and after dilution (SEK)	-1.71	0.04	-4.01
Equity per share (SEK)	33.50	39.26	35.21
Equity ratio (%)	92%	98%	97%

Message from the CEO

IBT's vision is to become an internationally leading company in the development of pharmaceuticals in the areas of premature infants, gastrointestinal diseases and probiotics.

We have now successfully driven the development of IBP-9414, the world's first phase III pharmaceutical grade probiotic for children, for almost a decade. The key milestone initiating the development of pharmaceutical grade probiotics occurred when IBT became the first company in the world in 2014 to receive Orphan Drug Designation in the US, where others had previously tried but failed. IBT subsequently became the first to be authorized by the FDA to administer live bacteria to children in a clinical trial in the US. The fact that we have also received permission to carry out pediatric studies in another 10 countries (9 EU + Israel) is further validation of IBT's unique ability to develop pharmaceutical grade probiotics.

Our work is attracting more and more attention. For example, The American Association of Pediatrics recently published that premature infants need pharmaceutically developed probiotics, mentioning our Phase III study in particular. The reason why IBT's work is specifically noticed is that probiotics should be of the highest safety, efficacy, and manufacturing standards when administered to premature babies. Today we know that premature babies can suffer injury and even death from the contaminants that can accompany a product that is not manufactured to the highest drug standards. IBT's production is well scrutinized by the FDA and corresponding authorities across 10 other countries. We have made ongoing investments since 2014 to ensure that our production yields a probiotic product intended to become the first to be approved as a drug.

We maintained good recruitment momentum in our NEC study through the fall of 2021, while omicron affected recruitment during the winter. As of today, May 4th, 2022, we have recruited 915 patients. It is difficult to assess what future recruitment rates will look like, but our focus on our phase III study remains and we expect to be able to complete recruitment in 2023 with existing capital.

During the first quarter of 2022, we initiated preparations for our commercialization phase of IBP-9414, where we are identifying and securing the resources and networks required to be prepared from day one in terms of product, market and organization prior to our launch.

We have concurrently taken the first steps towards expanding IBT's product portfolio, which is based on the unique competence created by IBT. We are also in discussions with several American universities regarding rights for additional medically important treatments. I can also mention that we started our own gastroschisis project (IBP-1016) with, including a key opinion leader meeting in April.

In conclusion, I would like to take this opportunity to thank all the staff and experts around the world who with great commitment help us get closer to our vision through the development of pharmaceutical grade probiotics, especially with IBP-9414 which may play a very significant role for premature babies.

Stockholm, May 4, 2022

Staffan Strömberg
CEO

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 (IBT B).

Infant Bacterial Therapeutics AB (publ) ("IBT") is a pharmaceutical company with a product in clinical phase III 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. The ambition for IBP-9414 is to become the world's first approved probiotical drug with the goal to prevent life threatening diseases in premature infants including NEC and sepsis by conducing sound stomach-and bowel development 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.

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.

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. The currencies against which IBT has the greatest exposure are USD and EUR.

Currency risk is the risk that the value of assets and liabilities fluctuate due to changes in exchange rates. Should the SEK increase or depreciate versus the specific currency, it could have a significant impact on the Company's financial position and results. The company has deposits in foreign currencies and an increase in the SEK generates a negative currency effect (see Notes 1, 2 and 3).

Capital 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 2021 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 KSEK 250 per annum, KSEK 400 annually as operational Chairman, and KSEK 20 for working on the remuneration committee.

Board member Mr. Robert Molander invoiced consulting fees amounting to KSEK 469. Consulting fees refer mainly to commercialization of IBP-9414.

No other significant related party transactions have occurred.

Financial calendar

Interim report January-June 2022	Aug 25, 2022
Interim report January-September 2022	Nov 10, 2022

Contact persons

Staffan Strömberg, CEO

Michael Owens, CFO

Contact information

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Publication

The Report was submitted for publication, by the CEO, at 18.00 on May 4, 2022.

Financial development – first quarter (January-March) 2022

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 ongoing IBP-9414 clinical trial are reported net of exchange rate effects on foreign currency deposits. Exchange rate effects during the fourth quarter amounted to KSEK 6,252 (12,114) (Note 1, 2).

Operational costs amounted to KSEK 25,318 (11,726) prior to exchange rate effects on foreign currency deposits, and after exchange rate effects to KSEK 19,066 (-388).

Costs for the ongoing IBP-9414 clinical trial amounted to KSEK 20,496 (7,167) prior to exchange rate effects.

Personnel costs amounted to KSEK 2,997 (3,791). Personnel costs have decreased during the reporting period compared to the equivalent period in the previous year due to reduced staff.

Other external costs amounted to KSEK 1,825 (703).

Result and financial position

Operational result amounted to KSEK -19,063 (452) and result after financial items amounted to KSEK -19,201 (451) KSEK.

Result after tax amounted to -19,201 (451) KSEK.

Result per share prior and after dilution amounted to -1.71 (0.04) SEK.

Cash flow for the period amounted to KSEK -10,825 (-9,794). Cash flow per share amounted to -0.96 (-0.87) SEK.

Prepaid expenses amounted to approximately MSEK 15,454 (10,019) and mainly refer to contractual milestone payments to the company's CRO and CMC producers referring to non-fulfilled commitments which are reported as a receivable in the balance sheet.

Accrued expenses amounted to approximately MSEK 13,780 (6, 709) mainly referring to research-and development and personnel costs.

The Company's cash balance on March 31, 2022, amounted to KSEK 382,179 compared to KSEK 386,752 on December 31, 2021.

The Company's shareholder's equity on March 31, 2022, amounted to KSEK 376,053 compared to KSEK 395,254 on December 31, 2021. Shareholder's equity per share on March 31, 2022, amounted to SEK 33.50 compared to SEK 35.21 on December 31, 2021.

The Company's equity ratio on March 31, 2022, amounted to 92% compared to 97% on December 31, 2021.

Operational costs in total prior to exchange rate gains increased during the reporting period compared to the previous year.

Costs for the ongoing clinical study increased regarding production of clinical trial material, trial insurance coverage, patient recruitment and dosing in the ongoing phase III study which was initiated in 2019.

Personnel costs are lower in the reporting period than during the equivalent period in the previous year due to reduced staff.

On a rolling twelve-month period, the company had 8 (9) full time equivalent employees. The company had 8 (11) employees on the balance sheet date.

Other external costs during the reporting period increased compared to the equivalent period during the previous year primarily as a result of consulting fees regarding market analysis.

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 2021 amounting to approximately MSEK 305 (260). 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, 2022, and March 31, 2022, 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 on September 10, 2018.

IBT's closing share price on March 31, 2022, amounted to 56.10 SEK.

Analysts covering IBT:

SEB, Christopher W. Uhde, PhD, Carl Mellerby, Mattias Vadsten

Ownership March 31, 2022

Name	Class A-shares	Class B-shares	Share capital %	Votes %
ANNWALL & ROTHSCHILD INVESTMENT AB	377,736	410,478	7.02	28.63
SIX SIS AG, W8IMY	-	1,174,087	10.46	8.03
FJÄRDE AP-FONDEN	-	1,120,000	9.98	7.66
SWEDBANK ROBUR FONDER	-	575,000	5.12	3.93
AMF FÖRSÄKRING OCH FONDER	-	501,585	4.47	3.43
TREDJE AP-FONDEN	-	501,579	4.47	3.43
ÅLANDSBANKEN ABP (FINLAND) SWEDISH BRANCH	-	322,439	2.87	2.21
UNIONEN	-	322,196	2.87	2.20
DANGOOR, DAVID	-	306,421	2.73	2.10
SKANDINAVISKA ENSKILDA BANKEN AB, W8IMY	-	257,038	2.29	1.76
Total 10 largest shareholders	377,736	5,490,823	52.28	63.38
Other shareholders	-	5,357,625	47.72	36.62
Total	**377,736**	**10,848,448**	**100.00**	**100.00**

Source: Euroclear Sweden

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 4, 2022

Peter Rothschild Chairman	Anthon Jahreskog Director	Margareta Hagman Director	Robert Molander Director

Eva Idén Director	Kristina Sjöblom Nygren Director	Staffan Strömberg CEO

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

Income statement

SEK 000	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Net sales	-	-	-
Other income	3	64	94
Research and development costs	-19 066	388	-44 672
Operating loss	**-19 063**	**452**	**-44 578**
Result from financial items			
Interest income and similar profit/loss items	-	-	-
Interest expense and similar profit/loss items	-138	-1	-413
Result after financial items	**-19 201**	**451**	**-44 991**
Result for the period*	**-19 201**	**451**	**-44 991**

* Result for the period equals total comprehensive income

Result per share

SEK			
Result per share, before and after dilution*	-1.71	0.04	-4.01
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, 2022, 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	2022-03-31	2021-03-31	2021-12-31
ASSETS				
Non-current assets				
Intangible non-current assets				
Activated development costs		11 130	11 946	11 334
Shares in subsidiary		70	50	50
Total non-current assets		**11 200**	**11 996**	**11 384**
Current assets				
Current receivables				
Accounts receivable		3	77	-
Other receivables		1 131	3 288	1 202
Prepaid expenses and accrued income		15 454	10 019	9 140
Total current assets		16 588	13 384	10 342
Cash and cash equivalents	2, 3	382 179	425 758	386 752
Total current assets		**398 767**	**439 142**	**397 094**
TOTAL ASSETS		**409 967**	**451 138**	**408 478**
EQUITY AND LIABILITIES				
Equity				
Restricted equity				
Share capital		3 060	3 060	3 060
Unrestricted equity				
Share premium reserve		669 022	669 018	669 022
Accumulated losses		-276 828	-231 837	-231 837
Net loss for the year		-19 201	451	-44 991
Total equity		**376 053**	**440 692**	**395 254**
Liabilities				
Current liabilities				
Accounts payable		19 843	3 400	4 797
Other current liabilities		291	337	779
Accrued expenses and prepaid income		13 780	6 709	7 648
Total current liabilities		**33 914**	**10 446**	**13 224**
TOTAL EQUITY AND LIABILITIES		**409 967**	**451 138**	**408 478**

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, 2021	**3 060**	**668 931**	**-231 837**	**440 154**
Net loss for the year			451	451
Total comprehensive income			**451**	**451**
Shareholder transactions				
Warrants		87		87
Closing equity on Mar 31, 2021	**3 060**	**669 018**	**-231 386**	**440 692**
Opening equity on Jan 1, 2021	**3 060**	**668 931**	**-231 837**	**440 154**
Net income for the period			-44 991	-44 991
Total comprehensive income			**-44 991**	**-44 991**
Shareholder transactions				
Warrants		91		91
Closing equity on Dec 31, 2021	**3 060**	**669 022**	**-276 828**	**395 254**
Opening equity on Jan 1, 2022	**3 060**	**669 022**	**-276 828**	**395 254**
Net income for the period			-19 201	-19 201
Total comprehensive income			**-19 201**	**-19 201**
Closing equity on Mar 31, 2022	**3 060**	**669 022**	**-296 029**	**376 053**

Statement of cash flows

SEK 000	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Operating activities			
Operating profit/loss	-19 063	452	-44 578
Interest income received	-	-	-
Paid interest costs	-138	-1	-413
Adjustment for non - cash flow affecting items:			
Depreciation production process	204	204	816
Value variance currency accounts	-6 252	-12 114	-18 846
Cash flow from operating activities before changes in working capital	**-25 249**	**-11 459**	**-63 021**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in operating receivables	-6 246	1 296	4 338
Increase (+)/Decrease (-) in operating liabilities	20 690	282	3 060
Cash flow from operating activities	**-10 805**	**-9 881**	**-55 623**
Investment activities			
Acquisition of non-current assets	-20	-	-
Cash flow from investment activities	**-20**	**-**	**-**
Financing activities			
Warrants	-	87	91
Cash flow from financing activities	**0**	**87**	**91**
Cash flow for the period	**-10 825**	**-9 794**	**-55 532**
Unrealized exchange rate difference in cash	6 252	12 114	18 846
Cash and cash equivalents at the beginning of the period	386 752	423 438	423 438
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	**382 179**	**425 758**	**386 752**

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 2021 annual report. New principles are not expected to impact the company's financial reports.

IBT has no transactions to report under other comprehensive income and thus presents information thereon under the income statement.
IBT has deposits in foreign currencies. Effects of foreign currency exchange rates are reported in the company's financial statements at market value in the income statements item research-and development costs (Notes 2 and 3).
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 hierarchy 1 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, 2022, amounted to MSEK 382.2 (425.8) of which USD amounted to MSEK 203.9 (218.0) and EUR amounted to MSEK 42.0 (54.3).

Note 4 Share based incentive program 2017/2022

Warrant holders had the right until May 3, 2022, for each warrant to subscribe for one-and one tenth (1.1) new share in the company at a subscription price per share of SEK 272.41. Total number of warrants amounted to 260,000. The warrants have expired with no subscriptions as the subscription price was in excess of the current market share price.

Further information regarding the company's incentive programs is available in the company's annual report 2021.

Note 5 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 2021.

Deduction of certain key figures

	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Cash flow per share			
Cash flow for the period, 000's	-10 825	-9 794	-55 532
Average number of shares	11 226 184	11 226 184	11 226 184
Cash flow per share (SEK)	**-0.96**	**-0.87**	**-4.95**
Equity per share			
Equity, 000's	376 053	440 692	395 254
Number of shares at end of period	11 226 184	11 226 184	11 226 184
Equity per share (SEK)	**33.50**	**39.26**	**35.21**
Equity ratio			
Equity, 000's	376 053	440 692	395 254
Total equity and liabilities, 000's	409 967	451 138	408 478
Equity ratio %	**92%**	**98%**	**97%**