INFANT BACTERIAL THERAPEUTICS

Infant Bacterial Therapeutics AB (publ)

Interim report January 1 – March 31, 2024

First quarter (Jan-Mar) 2024

- Net sales KSEK 0 (0)
- Operating income KSEK -29 798* (-24 296)
- Earnings per share before and after dilution SEK -2.06 (-2.00)

* Operational income includes exchange rate effects on foreign currency deposits to secure future outflows during the first quarter amounting to KSEK 5 323 (-652).

Significant events during the reporting period (Jan-Mar)

- No significant events during the first quarter

Significant events after the reporting period

- On April 4th 2024, IBT announced that the last patient of a total of 2 158 premature babies has been enrolled in the global phase 3 clinical program ("The Connection Study" for the development of IBP-9414. The results from the study are anticipated during Q3 2024.

Selected financial data

000´s	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Net Sales	-	-	-
Other income	5	13	77
Operating profit / loss	-29 798	-24 296	-134 617
Result after tax	-27 815	-22 468	-123 068
Total assets	348 878	333 694	351 334
Cash flow for the period	-24 768	-28 509	-4 704
Cash flow per share for the period (SEK)	-1.84	-2.54	-0.38
Cash	309 618	306 680	329 064
Earnings per share before and after dilution (SEK)	-2.06	-2.00	-9.95
Equity per share (SEK)	20.59	27.55	22.65
Equity ratio (%)	79%	93%	87%

Message from the CEO

IBT has successfully completed the recruitment of infants for our Phase III study (The Connection Study), which is the final clinical trial planned according to the IBP-9414 development program. It all began with defining the clinical development plan for IBP-9414 with the FDA and the European equivalent, EMA, over 10 years ago. Once the plan was established, we built a small and highly efficient organization tasked with converting this plan into action. It is fantastic to note that we have succeeded. From a small office in the heart of Stockholm, we have managed to conduct the largest study ever in premature infants. Some companies choose to out-license their development projects in early stages to avoid responsibility for implementation or funding of the laborious development work and to reduce project risk. IBT has chosen to perform this work and decline early out-licensing opportunities, as we believe we will create greater long-term value for shareholders. We retain control and decide how and what should be done while maintaining good cost control. That is why reaching this milestone is truly extraordinary; 100% recruitment of 2158 infants. I also want to take this opportunity to thank the individuals behind this achievement, our team in Stockholm as well as those in the USA and Europe.

The last patient participating in "The Connection Study" will leave the study no later than July 2024. We expect to receive the results sometime during Q3 2024. IBT has initiated the demanding work to compile regulatory documentation and validation of the production process in order to submit the application for market approval (BLA) to the FDA as soon as possible. During the first quarter, we have also started preparing for the next stage. We have conducted several expert panel meetings with Key Opinion Leaders in the USA as well as in the EU. It is very stimulating to discuss IBP-9414, and there is no doubt that we will meet a clear medical need where treatments are currently lacking. We are convinced that if our study results show the expected effect, our product will contribute to less suffering and death. The medical experts share the same expectations.

During this quarter, the Canadian regulatory authority warned against using probiotic supplements as a treatment for premature infants. Therefore, Canada is choosing to follow the FDA's stance on the issue. The warning concerns several infants who have died after treatment with non-regulated products. IBT expects that EU regulatory authorities will act similarly and warn or prohibit the inappropriate use of available supplements when an approved medication is available.

Finally, I want to mention that we are now conducting something called PPQ (Product Process Qualification), which means we are documenting our manufacturing of IBP-9414 in a way that authorities can obtain the necessary documentation for approval of a medicinal product. IBT has also strengthened during the quarter by expanding our staff with more talented individuals, including a Head of Regulatory and a Supply Chain Director based in our Stockholm office to tackle the future challenges awaiting IBT.

We have entered a new stage at IBT, and we look forward to an exciting near future.

Stockholm May 7, 2024

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 since September 10, 2018, listed on Nasdaq Stockholm (IBTB).

IBT is a pharmaceutical company whose purpose is to develop and commercialize drugs for diseases affecting premature babies. During the 12 years of drug development IBT has gained unique expertise in the field of drugs using live bacteria as active substances, this is a key competitive factor for our development programs.

IBT's main focus is the drug candidate IBP-9414, a formulated bacterial strain naturally found in human breast milk. The development program is designed to show a reduced incidence of necrotizing enterocolitis ("NEC") and improved gastrointestinal function ("SFT"). IBP-9414, is expected to be the first product in the new class of biologics called "Live Biotherapeutic Products" for premature infants. Upon approval, it would be the first product to prevent NEC and improve Sustained Feeding Tolerance (“SFT”) in newborns. The drug development of IBP-9414 is currently in its final stages and IBT expects to receive regulatory approval in 2025 for this important product for premature babies.

The portfolio also includes additional drug candidates, IBP-1016, IBP-1118 and IBP-1122. IBP-1016, for the treatment of gastroschisis, a life-threatening and rare disorder in which children are born with externalized gastrointestinal organs. IBP-1118 to prevent retinopathy of prematurity (ROP), one of the leading causes of blindness in premature babies, and IBP-1122 to eliminate vancomycin-resistant enterococci (VRE), which cause antibiotic-resistant hospital infections.

Through the development of these drugs, IBT can address medical needs where no sufficient treatments are 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 and is ongoing.

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 and demonstrated that IBP-9414 was safe and well 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 aims to demonstrate and document the effect of IBP-9414 compared to placebo with regard to two primary endpoints: prevention of NEC and improvement of sustained feeding tolerance (SFT) in preterm infants with birth weights of 1 500 grams or less. This study will also encompass safety evaluations.

Given the urgent need for an effective preventive treatment for NEC, IBT plans to utilize the accelerated procedures provided by the FDA and EMA to expedite the process of obtaining market authorization as quickly as possible.

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

The majority of IBT's development costs are incurred in foreign currency. If the SEK declines in value against the currency in question, it can have a significant impact on the company's position and earnings. The currencies to which IBT has the greatest exposure are USD and EUR.

The company has investments in foreign currencies and a strengthening of the SEK has a negative currency effect (see notes 1, 2 and 3). The company's equity and cash are considered sufficient for the implementation of the ongoing phase III study, and the company's operations until the application for market approval.

For further information on risks and uncertainties, please refer to IBT's Annual Report for 2023 and IBT's prospectus dated June 13, 2023 on the company's website www.ibtherapeutics.com.

Financial calendar

Interim report April – June 2024	August 28, 2024, 08:30 CET
Interim report July – September 2024	November 14, 2024, 08:30 CET
Financial Statement January – December 2024	February 13, 2025

The Annual General Meeting will be held May 8, 2024 at 16:00 – 18:00 CET in Stockholm

Contact person

Staffan Strömberg, CEO

Maria Ekdahl, CFO

Contact information

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Financial development – first quarter (Jan-Mar) 2024

Amounts are reported in KSEK (SEK in thousands). Amounts in parenthesis refer to the 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 first quarter 2024 amounted to KSEK 5 323 (-652). (Note 1,2).

Operational costs amounted to KSEK 35 125 (23 657) prior to exchange rate effects on foreign currency deposits and after exchange rate effects to KSEK 29 802 (24 308).

Costs for the ongoing IBP-9414 clinical trial amounted to KSEK 28 047 (18 630) prior to exchange rate effects.

Personnel costs amounted to KSEK 4 260 (3 510).

Other external costs amounted to KSEK 2 819 (1 516).

Result and financial position

Operational result amounted to KSEK -29 798 (-24 296) and result after financial items amounted to KSEK -27 815 (-22 468).

Result after tax amounted to KSEK -27 815 (-22 468)

Result per share prior to and after dilution amounted to SEK -2.06 (-2.00).

Cash flow for the period amounted to KSEK -24 768 (-28 509). Cash flow per share amounted to SEK -1.84 (-2.54).

Other

Prepaid expenses amounted to approximately KSEK 27 897 (11 575) and relates mainly to contractual prepayments to the company's CRO, advance payment for production of IBP-9414, rentals and insurance.

Accrued expenses amounted to approximately MSEK 29 625 (17 056) are mainly driven by research- and development cost, personnel, and consultant costs.

The company´s cash balance on March 31, 2024, amounted to KSEK 309 618 compared to KSEK 329 064 on December 31, 2023.

The company´s shareholders equity on March 31, 2024, amounted to KSEK 277 339 compared to KSEK 305 154 on December 31, 2023. Shareholders´ equity per share on March 31, 2024, amounted to SEK 20.59 compared to 22.65 on December 31, 2023.

The company´s equity ratio on March 31, 2024, amounted to 79% compared to 87% on December 31, 2023.

Operational costs in total before exchange rate gains increased during the reporting period compared to the previous year. The biggest increase is in costs related to the ongoing clinical study, mainly due to increased costs for CMC and Clinical, which is due to a higher rate of patient recruitment than the previous year and preparations for the completion of the study. Personnel costs and other costs also increased slightly during the reporting period compared with the previous year.

On a rolling twelve-month period, the company had 8 (8) fulltime equivalent employees, and 9 (8) headcount. The company had 9 (8) fulltime equivalent employees and 11 (9) headcount on the balance date.

During 2017 and 2018, IBT has carried out new issues amounting to approximately MSEK 528 after transaction costs. During June-July 2023, a rights issue was carried out amounting to approximately SEK 100 million before issue costs. The capital is considered sufficient for the ongoing Phase III study and the company's operations until the application for marketing approval.

Tax position

IBT has accumulated operational losses since the company was established in 2012 and until the year-end of 2023 amounting to approximately MSEK 506 (371). 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.

Macroeconomic situation

The general macroeconomic situation regarding inflation and cost increases contributes to some uncertainty and it cannot be excluded that IBT will be affected by this in the future. So far, IBT has countered cost increases by buying USD and EUR in the past when the exchange rate was more favorable.

Shares

On January 1, 2024, and March 31, 2024, respectively, the total number of shares amounted to 13,471,420 shares of which 453,283 class A-shares carried ten votes and 13,018,137 class B-shares carried one vote.

IBT´s class B share was listed on Nasdaq Stockholm on September 10, 2018.

IBT´s closing share price on March 31, 2024, amounted to SEK 80.00.

Analysts covering IBT:

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

Ownership March 31, 2024

Name	Class A-shares	Class B-shares	Share capital %	Votes %
ANNWALL & ROTHSCHILD INVESTMENT AB	453,283	721,351	8.72	29.93
SIX SIS AG W8IMY		1 498,679	11.12	8.54
FJÄRDE AP-FONDEN		1 344,000	9.98	7.66
NORTHERN TRUST COMPANY		1 266,065	9.40	7.21
AMF AKTIEFOND		601,902	4.47	3.43
UNIONEN		532,023	3.95	3.03
TREDJE AP-FONDEN		523,367	3.89	2.98
ÅLANDSBANKEN ABP		409,524	3.04	2.33
DANGOOR, DAVID		367,705	2.73	2,10
P.R BANQUE PIXTET & CIE SA		311,169	2.31	1,77
Total 10 largest shareholders	453,283	7 575,785	59.61	68.98
Other Shareholder		5 442,352	40.39	31.02
Totalt	**453,283**	**13 018,137**	**100**	**100**

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 7, 2024

Peter Rothschild Chairman	Anthon Jahreskog Director	Margareta Hagman 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	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Net Sales	-	-	-
Other income	5	13	77
Research-and development costs	-27 892	-21 530	-121 183
Administration cost	-1 910	-2 779	-13 511
Operating result	**-29 798**	**-24 296**	**-134 617**
Result from financial items			
Interest income and similar profit/loss items	1 983	1 827	11 549
Interest expense and similar profit/loss items	-	-	-
Result after financial items	**-27 815**	**-22 468**	**-123 068**
RESULT FOR THE PERIOD*	**-27 815**	**-22 468**	**-123 068**
*Result for the period equals total			
Result per share			
before and after dilution*	-2.06	-2.00	-9.95
Number of shares at begining of period**	13 471 420	11 226 184	11 226 184
Number of shares, weighted average	13 471 420	11 226 184	12 364 614
Number of shares at end of period***	13 471 420	11 226 184	13 471 420

* Through a new share issue, the number of shares in the company was increased on July 4, 2023, with 75 547 shares of class A and 2 169 689 shares c

** As of January 1, 2024, the distribution of issued shares was 377,736 of class A shares with voting rights of 10 and 10,848,448 of class B shares with a voting value of 1.

*** As of March 31, 2024, the distribution of issued shares is 453,283 of class A shares with voting rights of 10 and 13,018,137 of class B shares with a voting value of 1.

Balance sheet

SEK 000	Not	2024-03-31	2023-03-31	2023-12-31
Assets				
Non-current assets				
Intangible non-current assets				
Activated development costs		9 498	10 314	9 702
Shares in subsidiary		70	70	70
Total non-current assets		**9 568**	**10 384**	**9 772**
Current assets				
Current receivables				
Other receivable		1 795	5 055	2 966
Prepaid expenses and accrued income		27 897	11 575	9 533
Total current assets		**29 692**	**16 631**	**12 499**
Cash and cash equivalents	2,3	309 618	306 680	329 064
Total current assets		**339 310**	**323 310**	**341 563**
TOTAL ASSETS		**348 878**	**333 694**	**351 334**
Equity and Liabilities				
Equity				
Restricted equity				
Share capital		3 672	3 060	3 672
Unrestricted equity				
Share premium reserve		766 829	670 926	766 829
Accumulated losses		-465 346	-342 280	-342 280
Net loss for the year		-27 815	-22 468	-123 067
Total equity		**277 339**	**309 237**	**305 154**
Liabilities				
Current liabilities				
Accounts payable		41 364	7 145	30 067
Other current liabilities		550	256	779
Accrued expenses and prepaid income		29 625	17 056	15 334
Total current liabilities		**71 539**	**24 457**	**46 180**
TOTAL EQUITY AND LIABILITIES		**348 878**	**333 694**	**351 334**

Statement of changes in equity

SEK 000	Restricted equity	Unrestricted equity		
	Share capital	Share premium reserve	Accumulated losses inkl. loss for the period	Total equty
Opening equity on Jan 1, 2023	**3 060**	**670 926**	**-342 279**	**331 705**
Result for the period			-22 468	-22 468
Total comprehensive income			**-22 468**	**-22 468**
Closing equity on Mar 31, 2023	**3 060**	**670 926**	**-364 747**	**309 237**
Opening equity on Jan 1, 2023	**3 060**	**670 926**	**-342 279**	**331 705**
Result for the period			-123 068	-123 068
Total comprehensive income			**-123 068**	**-123 068**
Shareholder transactions				
New Issue	612	100 424		101 036
Issuing cost		-5 030		-5 030
Warrants		510		510
Closing equity on Dec 31, 2023	**3 672**	**766 829**	**-465 347**	**305 154**
Opening equity on Jan 1, 2024	**3 672**	**766 829**	**-465 347**	**305 154**
Result for the period			-27 815	-27 815
Total comprehensive income			**-27 815**	**-27 815**
Closing equity on Mar 31, 2024	**3 672**	**766 829**	**-493 162**	**277 339**

Statement of cash flow

SEK 000	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Operating activities			
Operating profit / loss	-29 798	-24 296	-134 617
Interest income received	1 983	1 827	11 549
Paid interest cost	-	-	-
Adjustment for non - cash flow affecting items:			
depreciation produktion process	204	204	816
Value variance currency accounts	-5 323	652	2 074
Cash flow from operating activities before changes in working capital	**-32 933**	**-21 612**	**-120 178**
Cash flow fron changes in working capital			
Increase(-)/Decrease(+) in operating receivables	-17 193	-13 440	-9 308
Increase(+)/Decrease(-) in operating liabilities	25 359	6 544	28 267
Cash flow from operating activities	**-24 768**	**-28 509**	**-101 219**
Financing activities			
New issue	-	-	101 036
Issuing cost	-	-	-5 030
Warrants	-	-	510
Cash flow from financing activities	**0**	**0**	**96 515**
Cash flow for the period	**-24 768**	**-28 509**	**-4 704**
Unrealized exchange rate difference in cash	5 323	-652	-2 074
Cash and cash equivalents at the beginning of the period	329 064	335 840	335 840
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	**309 618**	**306 680**	**329 064**

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 per IAS 34 are presented in Notes and in other sections in the interim report.

IBT has adopted the same accounting principles and calculation methods as those described in the 2023 annual report. New principles are not expected to impact the company´s financial reports.

IBT has no transaction to report under other comprehensive income and thus presents information thereon under the income statement.

IBT has deposits in foreign currencies. The company's expenses are allocated to the functions Research and development and administration costs. The effects of changes in exchange rates are recognized in the company's financial statements at market value through the functions. (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.

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 on March 31, 2024 amounted to MSEK 310 (307).

Note 4 Share based incentive programs

IBT had on the balance sheet date, March 31, 2024, three outstanding warrant programs.

Warrants 2020/2024

As below and as described in the 2023 annual report

Warrant holders 2020/2024	Number allotted 2024-03-31	Number issued 2024-03-31	Number allotted 2023-12-31	Number issued 2023-12-31
Staffan Strömberg, VD	50 000	50 000	50 000	50 000
Anders Kronström, COO	40 000	40 000	40 000	40 000
Other employees	154 073	154 073	154 073	154 073
Total	**244 073**	**244 073**	**244 073**	**244 073**

Warrants 2022/2025

As below and as described in the 2023 annual report

Warrant holders 2022/2025	Number allotted 2024-03-31	Number issued 2024-03-31	Number allotted 2023-12-31	Number issued 2023-12-31
Staffan Strömberg, VD	120 000	120 000	120 000	120 000
Anders Kronström, COO	75 000	75 000	75 000	75 000
Other employees	77 000	77 000	77 000	77 000
Total	**272 000**	**272 000**	**272 000**	**272 000**

Warrants 2023/2026

As below and as described in the 2023 annual report

Warrant holders 2023/2026	Number allotted 2024-03-31	Number issued 2024-03-31	Number allotted 2023-12-31	Number allotted 2023-12-31
Staffan Strömberg, VD	50 000	50 000	50 000	50 000
Anders Kronström, COO	25 000	25 000	25 000	25 000
Maria Ekdahl, CFO	25 000	25 000	25 000	25 000
Övriga anställda	55 000	55 000	55 000	55 000
Totalt	**155 000**	**155 000**	**155 000**	**155 000**

IBT´s three outstanding warrant programs in summary:

Issued Warrants, Year	Number allotted	Strikeprice	Value per allotted warrant	Volatilitet, % *	Risk free interest, %	Value per share, weighted average	Expiry, year
2020 (2020/2024)	87 543	397,56	14,24	40	-0,3	170	2024
2020 (2020/2024)	97 484	397,56	4,86	40	-0,3	125	2024
2021 (2020/2024)	49 046	397,56	1,78	40	-0,3	105	2024
2021 (2020/2024)	10 000	397,56	0,29	40	-0,3	81	2024
2022 (2022/2025)	272 000	128,77	7	39	1,32	66,90	2025
2023 (2023/2026)	155 000	100,05	3,29	39	2,76	43,40	2026
Totalt	**671 073**	-	-	-	-	-	-

*Expected future volatility is ascertained by comparison of historical average and median values for comparable listed companies in the same sector as IBT based on analysis in S&P Capital IQ.

Note 5 Related party transactions

Compensations 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 312 per annum, and KSEK 400 annually as operational Chairman, and KSEK 20 for his work in the remuneration committee.

Otherwise, there have been no material transactions with related parties.

Note 6 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 performance. 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 2023.

Deduction of certain key figures

	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Cash flow per share			
Cash flow for the period, 000´s	-24 768	-28 509	-4 704
Average number of shares	13 471 420	11 226 185	12 364 614
Cash flow per share (SEK)	-1.84	-2.54	-0.38
Equity per share			
Equity, 000´s	277 339	309 237	305 154
Number of shares at end of period	13 471 420	11 226 185	13 471 420
Equity per share (SEK)	20.59	27.55	22.65
Equity ratio			
Equity, 000´s	277 339	309 237	305 154
Total equity and liabilities, 000´s	348 878	333 694	351 334
Equity ratio %	79%	93%	87%