

Infant Bacterial Therapeutics AB (publ)

Year-end report January 1 – December 31, 2024

Fourth quarter (October-December) 2024

- Net sales KSEK 0 (0)
- Operating income KSEK -37,445* (-45,652)
- Earnings per share before and after dilution SEK -2.51 (-3.04)

Reporting period (January-December) 2024

- Net sales KSEK 0 (0)
- Operating income KSEK -145,343* (-134,617)
- Earnings per share before and after dilution SEK -10.16 (-9.95)

Significant events during the fourth quarter (October-December)

- In October, IBT was invited to present at a workshop with the title "Live Biotherapeutic Products to prevent Necrotizing Enterocolitis in Very Low Birth Weight Infants", organized by the FDA in the US.
- Following further analysis of the study results and dialogue with the FDA, IBT announced in December that the company is continuing to prepare a "Biologicals License Application (BLA) to obtain drug approval.

Significant events during the reporting period (January - September)

- On April 4, 2024, IBT announced that the last patient out of a total of 2,158 premature infants had been enrolled in the global Phase 3 clinical program ("The Connection Study") for the development of IBP-9414.
- July 8, 2024, IBT announced that the last patient in the global Phase 3 clinical program "The Connection Study" had completed treatment. This meant that the clinical development program was completed.
- On August 15, 2024, IBT announced they had received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for the drug candidate IBP-9414.
- On August 30, 2024, IBT announced that the phase III study did not show significant effects on the primary endpoints but did show a significant reduction in the secondary endpoint, allcause mortality.

^{*} Operational income includes exchange rate effects on foreign currency deposits to secure future outflows during the fourth quarter amounting to KSEK 5,552 (-9,387) and during the reporting period amounting to SEK 5,445 (-2,074)



Summary of selected financial data

000's	2024	2023	2024	2023
	Oct-Dec	Oct-Dec	Jan-dec	Jan-Dec
Net Sales	-	-	-	-
Other income	-	-	4	77
Operating profit / loss	-37,445	-45,652	-145,343	-134,617
Result after tax	-33,765	40,891	-136,905	-123,068
Total assets	239,566	351,334	239,566	351,334
Cash flow for the period	-8,360	-28,757	-111,120	-4,704
Cash flow per share for the period (SEK)	-0.62	-2.13	-8.25	-0.38
Cash	223,388	329,064	223,388	329,064
Earnings per share before and after dilution (SEK)	-2.51	-3.04	-10.16	-9.95
Equity per share (SEK)	12.64	22.65	12.64	22.65
Equity ratio (%)	71%	87%	71%	87%

Message from the CEO

The scientific literature suggests that benign bacteria of the type found in IBT's drug product IBP-9414 can positively affect the health of premature infants. In 2024, we received the results of "The Connection Study", our phase 3 study, the largest randomized clinical trial ever conducted in premature infants. The size of the study and the way it was conducted provides a unique opportunity to answer the question; whether the mechanisms that were already known could improve the health situation for premature infants. The short answer is yes, the health of the infants improves and they survive to a significantly higher degree after IBP-9414 has been administered.

Of course, it is not enough for IBT to claim that we have a good product. In order to sell our product, it must be approved by the pharmaceutical authorities. During the fall, IBT has therefore discussed our conclusions of the study results, which concern, for example, reduced mortality, but also NEC with the FDA. During the period October to the end of December, we have communicated intensively with the FDA, which led to a formal meeting on December 19th 2024. IBT has received several good suggestions from the FDA and it is from that perspective and with the support of relevant guidelines that IBT plans to submit all our clinical data to the FDA as soon as possible in the spring of 2025. At the same time, work is progressing to finalize the validation of the production in accordance with our previous plan. At present, we have much of the documentation required for a drug approval available, but the last parts of the validation are expected to be available in the second half of 2025. Assuming that the FDA wants 6-9 months to review the clinical material and that during that time we can add the final pieces of the required information, then an optimistic scenario is that IBP-9414 could receive an approval this year.

IBT will therefore intensify preparations for a launch of IBP-9414. We plan to conduct market research. The results from these will guide future distribution and sales activities for IBP-9414. In addition, the commercial production needs will be influenced by how the market receives our product and how quickly we reach expected peak sales. It is about building stocks of IBP-9414 in a balanced way for a launch.

Our strategy for distribution partners of IBP-9414 remains unchanged. IBT wishes to be responsible for sales and marketing in the USA, while we intend to find the best possible partners for areas outside the USA. We plan to become more active in partnering during the year and will therefore also approach authorities in regions other than the USA in 2025.



Finally, I would like to thank everyone at IBT, all consultants and Key Opinion Leaders who have done a fantastic job during the fall to find alternative paths that will hopefully lead to a quick registration of our drug that saves the lives of premature infants.

Stockholm February 12, 2025

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 Nasdag Stockholm (IBTB).

IBT is a pharmaceutical company whose purpose is to develop and commercialize drugs for diseases affecting premature babies. During the 13 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 IBT's development programs.

IBT's main focus is the drug candidate IBP-9414, a formulated bacterial strain naturally found in human breast milk. IBP-9414 is expected to be the first product in a new class of biologics called 'Live Biotherapeutic Products' for premature infants. The drug development of IBP-9414 is currently in its final stages for this important product for premature infants.

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 infants, 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 consisted of two clinical studies: safety and tolerability study and pivotal Phase III study, "The Connection Study". The safety and tolerability study was completed as planned in the fourth quarter of 2017. The subsequent pivotal Phase III study, "The Connection Study", commenced in the second half of 2019 and completed in July 2024. The results of the study were received in Q3 2024.

The first study was a randomized, double blind, parallel-group, dose escalation placebo-controlled multicenter study to investigate the safety and tolerability of IBP-9414 in premature infants. The study was completed as planned in the fourth quarter of 2017 and showed that IBP-9414 was safe and well tolerated in preterm infants with birth weights between 500 - 2,000 grams.

The completed pivotal Phase III study aimed to prove and document the efficacy of IBP-9414 compared to placebo on the two primary endpoints of preventing NEC and improving sustained feeding tolerance (SFT) in preterm infants with a birth weight of 1,500 grams or less. This study also included a safety evaluation. The study showed no significant effects on the primary endpoints but a significant difference in the secondary endpoint, the number of infant deaths.

In light of the results of the study and the urgent need for effective treatment of preterm infants, IBT will continue to move the drug toward registration in 2025.



Risks and uncertainties

IBT's value is to a very large extent dependent on the success of the company's development project IBP-9414 and the granting of marketing authorization by the US Food and Drug Administration ("FDA") and/or the European Medicines Agency ("EMA"). If a marketing authorization for IBP-9414 is not granted, IBT may focus on other projects, but there is a risk that such projects will not succeed.

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 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

Annual Report 2024 Interim report January – March 2025 Interim report April – June 2025 Interim report July – September 2025 March 27, 2025 May 7, 2025, at 14:30 CET August 20, 2025, at 08:30 CET November 13, 2025, at 08:30 CET

The annual General Meeting will be held May 8, 2025, at 16:00-18:00 in Stockholm

Contact persons

Staffan Strömberg, CEO Maria Ekdahl, CFO

Contact information

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Financial development - fourth quarter (October - December) 2024

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

Costs

Operational costs amounted to KSEK 42,998 (36,265) prior to exchange rate effects on foreign currency deposits and after exchange rate effects to KSEK 37,445 (45,652).

Costs related to the completed clinical study IBP-9414 amounted to KSEK 32,526 (28,604) prior exchange rate effects. The higher cost is mainly due to increased costs for reports and other compilation of data. Personnel costs amounted to KSEK 4,998 (5,063). Other external costs amounted to KSEK 5,474 (2,598). The increase in other costs compared with the same period last year is mainly linked to consultancy and legal fees.

Costs are reported net of exchange rate effects on foreign currency deposits. Exchange rate effects during the fourth quarter 2024 amounted to KSEK 5,552 (-9,387). (Note 1,2).

Result and financial position

Operational result amounted to KSEK -37,445 (-45,652) and result after financial items amounted to KSEK -33,765 (-40,891).

Result after tax amounted to KSEK -33,765 (-40,891)

Result per share prior to and after dilution amounted to SEK -2.51 (-3.04).

Cash flow for the period amounted to KSEK -8,360 (-28,757). The lower cash flow in the period compared to the same period last year is mainly due to increase in current liabilities. Cash flow per share amounted to SEK -0.62 (-2.13).

Financial development – reporting period (January - December) 2024

Costs

Operational costs amounted to KSEK 150,792 (132,619) prior exchange rate effects on foreign currency deposits, and after exchange rate effects to KSEK 145,347 (134,693).

Costs related to the completed clinical study IBP-9414 amounted to KSEK 112,544 (106,450) prior exchange rate effects. This is mainly due to increased manufacturing costs and the work to finalize the study and prepare for applying for market approval. Personnel costs amounted to KSEK 23,321 (17,779), mainly due to higher bonus payments in connection with the 2024/2027 warrant program. Other external costs amounted to KSEK 14,927 (8,390). The increase is mainly due to increased costs for consultants, lawyers and marketing costs.

Costs are reported net of exchange rate effects on foreign currency deposits. Exchange rate effects during the reporting period amounted to KSEK 5,445 (-2,074). (Note 1, 2).

Result and financial position

Operational result amounted to KSEK -145,343 (-134,617) and result after financial items amounted to KSEK -136,905 (-123,068).

Result after tax amounted to KSEK -136,905 (-123,068).

The result per share prior to and after dilution amounted to SEK -10.16 (-9.95).



Cash flow for the period amounted to KSEK -111,120 (-4,704). Cash flow per share amounted to SEK -8.25 (-0.38). The lower cash flow in 2023 was due to the rights issue that took place in June 2023.

Other

Prepaid expenses amounted to approximately KSEK 3,224 (9,533) and relates mainly to manufacturing of IBP-9414, rents, insurance and IT systems.

Accrued expenses amounted to approximately MSEK 21,890 (15,334) are mainly driven by researchand development, personnel, and consultant costs.

The company's cash balance on December 31, 2024, amounted to KSEK 223,388 compared to KSEK 329,064 on December 31, 2023.

The company's shareholders equity on December 31, 2024, amounted to KSEK 170,263 compared to KSEK 305,154 on December 31, 2023. Shareholders' equity per share on December 31, 2024, amounted to SEK 12.64 compared to 22.65 on December 31, 2023.

The company's equity ratio on December 31, 2024, amounted to 71% compared to 87% on December 31, 2023.

During 2017 and 2018, IBT has carried out new issues amounting to approximately MSEK 528 after transaction costs. During July 2023, a rights issue was carried out amounting to approximately SEK 100 million before issue costs. The capital is deemed sufficient until the application for marketing authorization.

Tax position

IBT has accumulated operational losses since the company was established in 2012 and until the year-end of 2024 amounting to approximately MSEK 643 (506). 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 December 31, 2024, respectively, the total number of shares amounted to 13,471,420 shares of which 453,283 class A-shares carried 10 votes and 13,018,137 class B-shares carried 1 vote.

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

IBT's closing share price on December 31, 2024, amounted to SEK 53.60.

Analysts covering IBT:

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



Ownership December 31, 2024

	Class	Class	Share capital	Votes
Name	A-shares	B-shares	%	%
ANNWALL & ROTHSCHILD INVESTMENT AB	453,283	721,351	8.72	29.94
SIX SIS AG W8IMY		1 515,579	11.25	8.64
NORTHERN TRUST COMPANY		1 497,162	11.11	8.53
FJÄRDE AP-FONDEN		1 344,000	9.98	7.66
ÅLANDSBANKEN ABP		436,172	3.24	2.49
AVANZA PENSION		372,309	2.76	2.12
DANGOOR, DAVID		370,455	2.75	2.11
IBKR FINANCIAL SERVICES AG		343,432	2.55	1.96
P.R BANQUE PIXTET & CIE SA		311,169	2.31	1.77
NORDNET PENSIONSFÖRSÄKRING AB		243,315	1.81	1.39
Total 10 largest shareholders	453,283	7 154,944	56.48	66.61
Other Shareholder		5 863,193	43.52	33.39
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.

Certification

CEO hereby certifies 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, February 12, 2025

Staffan Strömberg CEO

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



Income statement

SEK 000	2024	2023	2024	2023
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Net Sales	-	-	-	-
Other income	-	-	4	77
Research-and development costs	-33,964	-38,495	-126,051	-121,183
Administration cost	-3,481	-7,157	-19,296	-13,511
Operating result	-37,445	-45,652	-145,343	-134,617
Result from financial items				
Interest income and similar profit/loss item	3,681	4,760	8,438	11,549
Interest expense and similar profit/loss iten	-	-	-	-
Result after financial items	-33,765	-40,891	-136,905	-123,068
RESULT FOR THE PERIOD*	-33,765	-40,891	-136,905	-123,068
*Result for the period equals total				
Result per share				
before and after dilution*	-2.51	-3.04	-10.16	-9.95
Number of shares at begining of period**	13,471,420	13,471,420	13,471,420	11,226,184
Number of shares, weighted average	13,471,420	13,471,420	13,471,420	12,364,614
Number of shares at end of period***	13,471,420	13,471,420	13,471,420	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 of cla

^{**} As of January 1, 2023, 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 Dec 30, 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	2024-12-31	2023-12-31
Assets		
Non-current assets		
Intangible non-current assets		
Activated development costs	8,886	9,702
Shares in subsidiary	70	70
Total non-current assets	8,956	9,772
Current assets		
Current receivables		
Other receivable	3,997	2,966
Prepaid expenses and accrued income	3,224	
Total current assets	7,221	12,499
Cash and cash equivalents 2,3	223,388	329,064
Total current assets	230,610	341,563
TOTAL ASSETS	239,566	351,334
Equity and Liabilities		
Equity		
Restricted equity		
Share capital	3,672	3,672
Unrestricted equity		
Share premium reserve	768,842	766,829
Accumulated losses	-465,346	-342,280
Net loss for the year	-136,905	-123,068
Total equity	170,263	305,154
Liabilities		
Current liabilities		
Accounts payable	46,993	30,067
Other current liabilities	421	779
Accrued expenses and prepaid income	21,890	15,334
Total current liabilities	69,303	46,180
TOTAL EQUITY AND LIABILITIES	239,566	351,334



Statement of changes in equity

SEK 000	Restricted equity	Unrestricted equity			
	Share capital	Share	Accumulated	Total	
		premium	losses inkl.	equty	
		reserve	loss for the		
			period		
Opening equity on Jan 1, 2023	3,060	670,926	-342,280	331,705	
Result for the period			-123,068	-123,068	
Total comprehensive income			-123,068	-123,068	
New Issue	612	100,424		101,036	
Issuing cost		-5,030		-5,030	
Warrants		510		510	
Closing equity on Dec 31, 2023	3,672	766,830	-465,348	305,154	
Opening equity on Jan 1, 2024	3,672	766,830	-465,348	305,154	
Result for the period			-136,905	-136,905	
Total comprehensive income			-136,905	-136,905	
Warrants		2,013		2,013	
Closing equity on Dec 31, 2024	3,672	768,843	-602,252	170,263	



Statement of cash flow

SEK 000	2024	2023	2024	2023
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Operating activities				
Operating profit / loss	-37,445	-45,652	-145,343	-134,617
Interest income received	3,681	4,760	8,438	11,549
Paid interest cost	-	-	-	-
Adjustment for non - cash flow affecting items:				
depreciation produktion process	204	204	816	816
Value variance currency accounts	-5,552	9,387	-5,445	2,074
Cash flow from operating activities	-39,113	-31,301	-141,533	-120,178
before changes in working capital				
Cash flow fron changes in working capital				
Increase(-)/Decrease(+) in operating receivables	-3,274	-2,967	5,277	-9,308
Increase(+)/Decrease(-) in operating liabilities	34,027	5,511	23,123	28,267
Cash flow from operating activities	-8,360	-28,757	-113,133	-101,219
, -				
Financing activities				
New issue	-	-	-	101,036
Issuing cost	-	-	-	-5,030
Warrants	-	-	2,013	510
Cash flow from financing activities	0	0	2,013	96,515
•				
Cash flow for the period	-8,360	-28,757	-111,120	-4,704
Unrealized exchange rate difference in cash	5,552	-9,387	5,445	-2,074
Cash and cash equivalents at the beginning of the period	226,196	367,207	329,064	335,840
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	223,388	329,064	223,388	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 December 31, 2024 amounted to MSEK 223,4 (329).

Note 4 Share based incentive programs

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

Warrants 2022/2025

As below and as described in the 2023 annual report

Warrant holders 2022/2025	Number allotted 2024-12-31	Number issued 2024-12-31	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 2024-12-31	Number issued 2024-12-31	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



Warrants 2024/2027

As below and as described in the minutes of the 2024 AGM.

Warrant holders 2024/2027	Number allotted 2024-12-31	Number issued 2024-12-31	Number allotted 2023-12-31	Number allotted 2023-12-31
Staffan Strömberg, VD	50 000	50 000	0	0
Anders Kronström, COO	25 000	25 000	0	0
Maria Ekdahl, CFO	25 000	25 000	0	0
Övriga anställda	65 000	65 000	0	0
Totalt	165 000	165 000	0	0

IBT's three outstanding warrant programs in summary:

Issued Warrants, Year	Number allotted	Strikeprice	Value per allotted warrant	R Volatilitet, ii % * %		Expiry, year
2022 (2022/2025)	272 000	128,77	7	39	1,32	2025
2023 (2023/2026)	155 000	100,05	3,29	39	2,76	2026
2024 (2024/2027)	165 000	176,83	12,20	40	2,55	2027
	592 000	-	-	-	-	-

^{*}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

During the quarter, Eva Idén, through her company Better & Beyond AB, invoiced the company KSEK 52 for consulting assignments within CMC. Otherwise, there is no significant change in transactions with related parties in relation to the information provided in the annual report 2023.

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	2023	2024	2023
	Oct-Dec	Oct-Dec	Jan-dec	Jan-Dec
Cash flow per share				
Cash flow for the period, 000's	-8,360	-28,757	-111,120	-4,704
Average number of shares	13,471,420	13,471,420	13,471,420	12,364,614
Cash flow per share (SEK)	-0.62	-2.13	-8.25	-0.38
Equity per share				
Equity, 000's	170,263	305,154	170,263	305,154
Number of shares at end of period	13,471,420	13,471,420	13,471,420	13,471,420
Equity per share (SEK)	12.64	22.65	12.64	22.65
Equity ratio				
Equity, 000's	170,263	305,154	170,263	305,154
Total equity and liabilities, 000's	239,566	351,334	239,566	351,334
Equity ratio %	71%	87%	71%	87%