UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2024

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 001-41705

Azitra, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**46-4478536**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

21 Business Park Drive
Branford, CT 06405
(Address of principal executive offices and zip code)

(203)-646-6446
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock: Par value $0.0001	AZTR	NYSE American, LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares of the registrant's common stock outstanding as of November 12, 2024 was 7,626,056.

AZITRA, INC.

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PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements.

AZITRA, INC.

CONDENSED BALANCE SHEETS

	September 30, 2024	December 31, 2023
ASSETS	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 7,260,234	$ 1,795,989
Accounts receivable	—	8,255
Accounts receivable - related party	—	90,000
Tax credits receivable	9,923	118,383
Income tax receivable	—	6,836
Deferred offering costs	—	67,859
Prepaid expenses	364,673	448,257
Total current assets	7,634,830	2,535,579
Property and equipment, net	638,107	710,075
Financing lease right-of-use asset	28,392	40,002
Operating lease right-of-use asset	606,033	828,960
Intangible assets, net	248,739	210,881
Deferred patent costs	536,390	742,229
Deferred issuance costs	37,477	—
Other assets	47,531	47,760
Total assets	$ 9,777,499	$ 5,115,486
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	588,460	897,272
Current financing lease liability	15,687	14,600
Current operating lease liability	276,839	307,655
Accrued expenses	486,981	383,668
Total current liabilities	1,367,967	1,603,195
Long-term financing lease liability	14,266	26,169
Long-term operating lease liability	336,556	537,523
Warrant liability	457	35,453
Total liabilities	1,719,246	2,202,340
Commitments and contingencies (Note 12)		

The accompanying notes are an integral part of these unaudited condensed financial statements.

ITEM 1. Financial Statements.

AZITRA, INC.

CONDENSED BALANCE SHEETS

Stockholders' equity		
Preferred stock; $0.0001 par value; 10,000,000 shares authorized at September 30, 2024 and December 31, 2023; 0 shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock; $0.0001 par value, 100,000,000 shares authorized at September 30, 2024 and December 31, 2023, 7,626,056 and 403,246 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	763	40
Additional paid-in capital	63,230,182	51,510,269
Accumulated deficit	(55,172,692)	(48,597,163)
Total stockholders' equity	8,058,253	2,913,146
Total liabilities and stockholders' equity	$ 9,777,499	$ 5,115,486

The accompanying notes are an integral part of these unaudited condensed financial statements.

AZITRA, INC.

CONDENSED STATEMENTS OF OPERATIONS

(unaudited)

	For the Three Months September 30, 2024	For the Three Months September 30, 2023	For the Nine Months September 30, 2024	For the Nine Months September 30, 2023
Service revenue - related party	$ —	$ 310,700	$ 7,500	$ 596,000
Total revenue	—	310,700	7,500	596,000
Operating expenses:				
General and administrative	1,913,400	1,755,908	4,951,155	3,443,559
Research and development	1,015,807	548,524	3,607,329	2,132,510
Total operating expenses	2,929,207	2,304,432	8,558,484	5,576,069
Loss from operations	(2,929,207)	(1,993,732)	(8,550,984)	(4,980,069)
Other income (expense):				
Interest income	47,389	634	71,266	1,184
Interest expense	(3,851)	(710)	(6,548)	(166,729)
Change in fair value of convertible note	—	—	—	(3,630,100)
Change in fair value of warrants	4,001,469	98,061	4,033,996	9,450
Loss on issuance of common stock	(2,132,800)	—	(2,132,800)	—
Other income (expense)	7,509	(47,542)	10,711	(54,017)
Total other income (expense)	1,919,716	50,443	1,976,625	(3,840,212)
Loss before income taxes	(1,009,491)	(1,943,289)	(6,574,359)	(8,820,281)
Income tax expense	—	—	—	(9,715)
Net loss	(1,009,491)	(1,943,289)	(6,574,359)	(8,829,996)
Dividends on preferred stock	—	—	—	(1,355,347)
Net loss attributable to common shareholders	$ (1,009,491)	$ (1,943,289)	$ (6,574,359)	$ (10,185,343)
Net loss per share, basic and diluted	$ (0.17)	$ (4.82)	$ (2.64)	$ (58.98)
Weighted average common stock outstanding, basic and diluted	5,814,350	403,255	2,494,577	172,704

The accompanying notes are an integral part of these unaudited condensed financial statements.

AZITRA, INC.

CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

(unaudited)

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in-Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance - December 31, 2022	**205,385**	**$3,272,944**	**380,657**	**$14,100,533**	**391,303**	**$16,321,065**	**34,800**	**$ 3**	**$ 1,054,239**	**$(37,314,552)**	**$ (36,260,310)**
Issuance of Series B Convertible Preferred Stock	—	—	—	—	23,432	1,124,759	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	38,794	—	38,794
Net loss	—	—	—	—	—	—	—	—	—	(2,457,180)	(2,457,180)
Balance, March 31, 2023	205,385	$3,272,944	380,657	$14,100,533	414,735	$17,445,824	34,800	$ 3	$ 1,093,033	$(39,771,732)	$ (38,678,696)
Stock-based compensation	—	—	—	—	—	—	—	—	38,794	—	38,794
Conversion of convertible notes payable							61,534	6	9,495,066	—	9,495,072
Conversion of preferred stock	(205,385)	(3,272,944)	(380,657)	(14,100,533)	(414,735)	(17,445,824)	256,921	26	34,819,275	—	34,819,301
Initial public offering, net of issuance costs of $1,508,641							50,000	5	5,991,354	—	5,991,359
Net loss	—	—	—	—	—	—	—	—	—	(4,429,528)	(4,429,528)
Balance, June 30, 2023	—	—	—	—	—	—	403,255	$ 40	$51,437,522	$(44,201,260)	$ 7,236,302
Stock-based compensation	—	—	—	—	—	—	—	—	39,073	—	39,073
Net loss	—	—	—	—	—	—	—	—	—	(1,943,289)	(1,943,289)
Balance - September 30, 2023	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**403,255**	**$ 40**	**$51,476,595**	**$(46,144,549)**	**$ 5,332,086**

The accompanying notes are an integral part of these unaudited condensed financial statements.

AZITRA, INC.

CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

(unaudited)

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in-Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance - December 31, 2023	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**403,246**	**$ 40**	**$51,511,439**	**$(48,598,333)**	**$ 2,913,146**
Follow-on public offering, net of issuance costs of $709,426	—	—	—	—	—	—	555,567	56	4,290,618	—	4,290,674
Stock-based compensation	—	—	—	—	—	—	—	—	34,171	—	34,171
Exercise of stock options	—	—	—	—	—	—	1,333	—	19,100	—	19,100
Net loss	—	—	—	—	—	—	—	—	—	(2,932,875)	(2,932,875)
Balance, March 31, 2024	—	$ —	—	$ —	—	$ —	960,146	$ 96	$55,855,328	$(51,531,208)	$ 4,324,216
Follow-on public offering issuance costs adjustment	—	—	—	—	—	—	—	—	(227)	—	(227)
Stock-based compensation	—	—	—	—	—	—	—	—	34,170	—	34,170
Net loss	—	—	—	—	—	—		—		(2,631,993)	(2,631,993)
Balance, June 30, 2024	—	—	—	—	—	—	960,146	$ 96	$55,889,271	$(54,163,201)	$ 1,726,166
Follow-on public offering, net of issuance costs of $933,960	—	—	—	—	—	—	6,665,000	667	9,062,873	—	9,063,540
Reclass of warrant liability	—	—	—	—	—	—	—	—	(1,866,200)	—	(1,866,200)
Exercise of Warrants	—	—	—	—	—	—	1,000	—	704	—	704
Partial Share Cancellation Reverse Stock Split	—	—	—	—	—	—	(90)	—	—	—	—
Stock based compensation expense	—	—	—	—	—	—	—	—	143,534	—	143,534
Net loss	—	—	—	—	—	—	—	—	—	(1,009,491)	(1,009,491)
Balance - September 30, 2024	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**7,626,056**	**$ 763**	**$63,230,182**	**$(55,172,692)**	**$ 8,058,253**

The accompanying notes are an integral part of these unaudited condensed financial statements.

AZITRA, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

	For the Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (6,574,359)	$ (8,829,996)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	97,950	97,390
Amortization of debt discount	—	
Amortization of right-of-use assets	234,537	219,658
Change in foreign currency rates on remeasurement of Canadian fixed assets	(14,199)	—
Accrued interest on convertible notes	—	165,939
Stock based compensation	211,875	116,661
Change in fair value of warrant liability	(4,033,996)	(9,350)
Loss on issuance of common stock	2,132,800	—
Change in fair value of convertible notes	—	3,630,100
Forgiveness of accounts payable	—	(56,285)
Loss on disposal of property and equipment	4,859	41,417
Impairment of intangible assets and deferred patent costs	442,793	351,360
Changes in operating assets and liabilities:		
Accounts receivable	98,255	182,820
Prepaid expenses	83,584	(249,037)
Other assets	229	(39)
Tax credits receivable	108,460	29,141
Income tax receivable	6,836	—
Accounts payable and accrued expenses	(165,380)	(143,662)
Financing lease liability	—	—
Operating lease liability	(231,783)	(213,285)
Contract liabilities	—	(156,000)
Net cash used in operating activities	(7,597,539)	(4,823,168)
Cash flows from investing activities:		
Purchases of property and equipment	(8,569)	(22,882)
Proceeds from sale of property and equipment	—	—
Deferred patent costs	(255,145)	(208,723)
Capitalization of licenses	—	(13,096)
Capitalization of patent and trademark costs	—	(13,573)
Net cash used in investing activities	(263,714)	(258,274)
Cash flows from financing activities		
Proceeds from convertible notes, net of issuance costs	—	—
Payment of deferred issuance costs	(37,477)	—
Principal payments on finance leases	(10,816)	(2,246)
Proceeds from public offerings, net	13,354,691	5,991,359
Proceeds from exercise of stock options	19,100	—

The accompanying notes are an integral part of these unaudited condensed financial statements.

AZITRA, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

Net cash provided by financing activities	13,325,498	5,989,113
Net change in cash and cash equivalents	5,464,245	907,671
Cash and cash equivalents at beginning of period	1,795,989	3,492,656
Cash and cash equivalents at end of period	$ 7,260,234	$ 4,400,327
Supplemental disclosure of non-cash investing and financing information:		
Obtaining a right-of-use asset in exchange for financing lease liability	$ —	$ 46,452
Conversion of note to common stock	$ —	$ 9,495,152
Conversion of note to Series B Convertible Preferred Stock	$ —	$ 1,124,759

The accompanying notes are an integral part of these unaudited condensed financial statements.

1. Organization and Nature of Operations

Azitra, Inc. (the "Company") was founded on January 2, 2014. It is a synthetic biology company focused on screening and genetically engineering microbes of the skin. The mission is to discover and develop novel therapeutics to create a new paradigm for treating skin disease. The Company's discovery platform is screened for naturally occurring bacterial cells with beneficial effects. These microbes are then genomically sequenced and engineered to make cellular therapies, recombinant therapeutic proteins, peptides and small molecules for precision treatment of dermatology diseases. On May 17, 2023, the Company changed its name to from "Azitra Inc" to "Azitra, Inc."

The Company maintains a location in Montreal, Canada for certain research activities. The Company also opened a manufacturing and laboratory space in Groton, Connecticut during 2021.

Stock Splits, Change in Par Value, and Initial and Follow-on Public Offerings

In June 2023, the Company completed its initial public offering (IPO) in which it issued and sold 50,000 shares of its common stock at a price to the public of $150.00 per share. The shares began trading on the NYSE American on June 16, 2023 under the symbol "AZTR". The net proceeds received by the Company from the offering were $6.0 million, after deducting underwriting discounts, commissions and other offering expenses.

Immediately prior to the effectiveness of the Company's registration statement, the Company effected a 7.1-for-1 forward stock split (the "Forward Stock Split") of its issued and outstanding shares of common stock (the Forward Stock Split). On May 17, 2023, the Company changed the par value of its capital stock from $0.01 to $0.0001. Accordingly, all share and per share amounts for all periods presented in the accompanying unaudited condensed financial statements and notes thereto have been adjusted retroactively, unless otherwise noted, to reflect the effect of the Forward Stock Split. Refer to Note 7 for additional details relating to the Forward Stock Split.

In February 2024, the Company completed a follow-on public offering in which it issued and sold 555,567 shares of its common stock at a price to the public of $9.00 per share. The net proceeds received by the Company from the follow-on public offering were $4.3 million, after deducting underwriting discounts, commissions and other offering expenses.

On July 1, 2024, the Company effected a 30-for-1 reverse stock split of its issued and outstanding shares of common stock (the "Reverse Stock Split") and began trading on a split-adjusted basis the same day. There was no change in par value. Accordingly, all share and per share amounts for all periods presented in the accompanying unaudited condensed financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the effect of the Reverse Stock Split. Refer to Note 7 for additional details relating to the Reverse Stock Split.

In July 2024, the Company completed a follow-on public offering in which it issued and sold 6,665,000 shares of its common stock at a price of $1.50 per share and Class A Warrants exercisable for an aggregate 13,330,000 shares of common stock. The net proceeds received by the Company from the follow-on public offering were $9.1 million, after deducting underwriting discounts, commissions and other offering expenses. The Class A Warrants had an initial exercise price of $1.50 that was adjusted to $0.7043 in accordance with a reset price provision determined 30 days following the issuance date. Refer to Note 7 for additional details relating to the follow-on offering.

Going Concern Matters

The unaudited condensed financial statements have been prepared on the going concern basis, which assumes that the Company will continue in operation for the foreseeable future, and which contemplates the realization of assets and liquidation of liabilities in the normal course of business. However, management has identified the following conditions and events that created an uncertainty about the ability of the Company to continue as a going concern. As of and for the nine months ended September 30, 2024, the Company has an accumulated deficit of $55.2 million, a loss from operations of $8.6 million, used $7.6 million to fund operations and had

approximately $6.3 million of working capital. These factors among others raise substantial doubt about the Company's ability to continue as a going concern.

The Company will require a significant amount of additional funds to complete the development of its product and to fund additional losses which the Company expects to incur over the next few years. The Company is still in its pre-commercialization phase and therefore does not yet have product revenue. Management plans to continue to raise funds through equity and debt financing to fund operating and working capital needs, however, there can be no assurance that the Company will be successful in securing additional financing, if needed, to meet its operating needs.

These conditions and events create substantial doubt about the ability of the Company to continue as a going concern for twelve months from the date that the financial statements are available to be issued. The financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

Reclassification

Certain prior period amounts and disclosures have been reclassified to conform to the current period's financial presentation.

2. Summary of Significant Accounting Policies

Basis of Accounting

The financial statements of the Company are prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP").

Unaudited Interim Financial Information

The unaudited interim condensed financial statements and related notes have been prepared in accordance with U.S. GAAP for interim financial information, within the rules and regulations of the United States Securities and Exchange Commission (the "SEC"). Certain information and disclosures normally included in the annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. The interim unaudited condensed financial statements have been prepared on a basis consistent with the audited financial statements and in the opinion of management, reflect all adjustments, consisting of only normal recurring adjustments, necessary for the fair presentation of the results for the interim periods presented and of the financial condition as of the date of the interim balance sheet. The financial data and the other information disclosed in these notes to the interim unaudited condensed financial statements related to the three months and nine months ended are unaudited. Unaudited interim results are not necessarily indicative of the results for the full fiscal year. These interim unaudited condensed financial statements should be read in conjunction with the financial statements of the Company for the year ended December 31, 2023, and notes thereto that are included in the Company's Annual Report on Form 10-K, as filed with the SEC on March 15, 2024.

Revision of Prior Period Financial Statements

During the quarter ended September 30, 2024, the Company identified an immaterial error in the Statements of Operations for the periods ended September 30, 2023, and December 31, 2023 relating to a misclassification between Other income (expense) and Research and development expenses resulting from the forgiveness of accounts payable in the amount of $56,285. The Company determined the error was not material to any previously issued financial statements; however, the Company decided to revise the prior periods impacted. The prior period revisions had no impact on our previously reported net loss; however, the revision decreased our Research and development expenses and Total operating expenses, and increased our Other income (expense).

Deferred Offering Costs

The Company capitalized deferred offering costs, which primarily consisted of direct, incremental legal, professional, accounting, and other third-party fees relating to the Company's initial public offering and follow-on offerings. In June 2023 the Company consummated its IPO. In February and July 2024, the Company consummated its follow-on offerings. The Company recorded these amounts against the gross proceeds of these offerings within the statements of stockholders' equity during the periods ended September 30, 2024, March 31, 2024 and December 31, 2023.

In July 2024, the Company also filed a Form S-3 Registration Statement and recorded deferred issuance costs as a long-term asset and will reclass a portion of these costs against gross proceeds upon such time the proceeds are raised.

Deferred Patent Costs

Deferred patent costs represent legal and filing expenses incurred related to the submission of patent applications for patents pending approval. These deferred costs will be reclassed to intangible assets and begin to be amortized over their estimated useful lives upon the formal approval of the patent. If the patent is not issued, the costs associated with the patent will be expensed in the year the patent was rejected. Deferred patent costs are reviewed for impairment at each reporting period. The costs associated with any impairment are expensed in the period the deferred patent costs are determined to be impaired. In connection with its review of the third quarter financial statements, the Company recorded impairment expenses of $442,793 during the three and nine months ended September 30, 2024, respectively. The Company recorded impairment expenses of $351,360 during the three and nine months ended September 30, 2023, respectively.

Leases

The Company elected to account for non-lease components as part of the lease component to which they relate. Lease accounting involves significant judgments, including making estimates related to the lease term, lease payments, and discount rate. In accordance with the guidance, the Company recognized ROU assets and lease liabilities for all leases with a term greater than 12 months. Leases are classified as either operating or financing leases based on the economic substance of the agreement.

The Company has operating leases for buildings. The Company has 3 operating leases with a ROU asset and lease liability totaling $1,418,502 as of January 1, 2022. The basis, terms and conditions of the leases are determined by the individual agreements. The Company's option to extend certain leases ranges from 36 – 52 months. All options to extend have been included in the calculation of the ROU asset and lease liability. The leases do not contain residual value guarantees, restrictions, or covenants that could incur additional financial obligations to the Company. There are no subleases, sale-leaseback, or related party transactions.

At September 30, 2024, the Company had operating right-of-use assets with a net value of $606,033 and current and long-term operating lease liabilities of $276,839 and $336,556, respectively.

In 2023, the Company entered into a lease for the use of certain equipment that is classified as a finance lease. The finance lease has a term of 36 months. At September 30, 2024, the Company had financing right-of-use assets with a net value of $28,392 and current and long-term operating lease liabilities of $15,687 and $14,266, respectively.

Research and Development

The Company accounts for research and development costs in accordance with Accounting Standards Codification (ASC) subtopic 730-10, *Research and Development*. Accordingly, internal research and development costs are expensed as incurred. Research and development costs consist of costs related to labor, materials and supplies. Research and development costs incurred were $1,015,807 and $3,607,329 during the three and nine months ended September 30, 2024, respectively.

At September 30, 2024 and December 31, 2023, the Company has a state tax credit receivable of $0 and 86,778 for pending refunds related to the selling of research and development tax credits back to the State of Connecticut. At September 30, 2024 and December 31, 2023, the Company has $0 and $20,040, respectively for pending refunds related to Canadian Scientific Research and Experimental Development (SRED) credits. At September 30, 2024 and December 31, 2023, the Company has also recorded $9,923 and $11,565, respectively, related to refunds of Canadian Goods and Services Tax (GST) and Quebec Sales Tax (QST). Receipts of refunds are recorded in research and development on the statements of operations.

Certain Risks and Uncertainties

The Company's activities are subject to significant risks and uncertainties including the risk of failure to secure additional funding to properly execute the Company's business plan. The Company is subject to risks that are common to companies in the pharmaceutical industry, including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, reliance on third party manufacturers, protection of proprietary technology, and compliance with regulatory requirements.

Recent Accounting Pronouncements

Management does not believe that any other recently issued, but not yet effective, accounting standards could have a material effect on the accompanying financial statements. As new accounting pronouncements are issued, the Company will adopt those that are applicable under the circumstances.

3. Property and Equipment

Property and equipment consisted of the following at:

	September 30, 2024	December 31, 2023
Laboratory equipment	$ 1,024,033	$ 1,013,134
Computers and office equipment	30,825	30,825
Furniture and fixtures	24,316	24,316
Leasehold improvements	28,855	28,855
Building equipment	14,932	14,932
Total property and equipment	1,122,961	1,112,062
Less accumulated depreciation & amortization	(484,854)	(401,987)
Total property and equipment, net	$ 638,107	$ 710,075

Depreciation and amortization expense was $30,007 and $89,877 for the three and nine months ended September 30, 2024, respectively. Depreciation and amortization expense was $30,571 and $92,000 for the three and nine months ended September 30, 2023, respectively. Fixed assets are reviewed for impairment each reporting period. The Company recorded losses on disposal of assets of $4,859 for the three and nine months ended September 30, 2024 respectively. The Company recorded losses on disposal of assets of $41,417 for the three and nine months ended September 30, 2023, respectively.

4. Intangible Assets

Intangible assets consisted of the following at:

September 30, 2024:

	Estimated Useful Life	Gross Amount	Accumulated Amortization	Impairment	Net Amount
Trademarks	Indefinite	$ 59,474	$ —	$ —	$ 59,474
Patents	17 years	213,122	23,857	—	189,265
Intangible assets		$ 272,596	$ 23,857	$ —	$ 248,739

December 31, 2023:

	Estimated Useful Life	Gross Amount	Accumulated Amortization	Impairment	Net Amount
Trademarks	Indefinite	$ 57,474	$ —	$ —	$ 57,474
Patents	17 years	169,190	15,783	—	153,407
Intangible assets		$ 226,664	$ 15,783	$ —	$ 210,881

During the three and nine months ended September 30, 2024, amortization expense related to intangible assets was $2,990 and $8,073, respectively. During the three and nine months ended September 30, 2023, amortization expense related to intangible assets was $2,013 and $5,390, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following at:

	September 30, 2024	December 31, 2023
Employee payroll and bonuses	$ 318,619	$ 207,556
Vacation	71,361	31,074
Research and development projects	46,474	85,767
Professional fees	48,550	35,624
Other	1,977	23,647
Total accrued expenses	$ 486,981	$ 383,668

The Company accrues expenses related to development activities performed by third parties based on an evaluation of services received and efforts expended pursuant to the terms of the contractual arrangements. Payments under some of these contracts depend on research and non-clinical trial milestones. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of expense. In accruing service fees, the Company estimates the period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual or prepaid expense accordingly. The Company has not experienced any material differences between accrued costs and actual costs incurred since its inception.

6. Convertible Debt

Effective January 5, 2021, the Company entered into a Note Purchase Agreement to issue up to $2,000,000 of convertible promissory notes. On the same date, the Company entered into a convertible promissory note (2021 Convertible Note) with one investor for $1,000,000. The 2021 Convertible Note bears interest at a rate of 6% per annum and is due and payable in full on January 5, 2023. The 2021 Convertible Note automatically converts upon a qualified equity financing, as defined in the note agreement to the number of preferred shares equal to all principal and accrued interest divided by the conversion price of $48.00 on a basis unadjusted for the Forward Stock Split and the Reverse Stock Split, which is subject to adjustment as defined in the note agreement. The 2021 Convertible Note is also optionally convertible as defined in the note agreement for certain non-qualified financing, a change in control, or upon the maturity date of the 2021 Convertible Note. The Company incurred issuance costs of $15,613 related to the 2021 Convertible Note, which has been recorded as a debt discount and will be amortized over the term of the 2021 Convertible Note.

In September 2022, the Company entered into a Convertible Note Purchase Agreement (the Agreement) to issue up to $4,500,000 convertible promissory notes. On the same day, the Company entered into convertible promissory notes (2022 Convertible Notes) with three investors totaling $4,350,000. The 2022 Convertible Notes mature on January 13, 2023 or the occurrence of an Event of Default (as defined) and bear interest at a rate of 8% per annum which shall accrue but is not due and payable until conversion or full repayment of outstanding principal. The principal and interest outstanding under the 2022 Convertible Notes is automatically converted a) upon the closing of a Qualified Financing resulting in gross proceeds to the Company of at least $20 million into securities issued in connection with the Qualified Financing, at a discount of 30% per share; b) upon the closing of a Change of Control event into shares of capital stock of the Company or Series B preferred stock; and c) upon the closing of a Public Company Event, into shares of capital stock being issued to investors equal to two-times (2x) the amount of the outstanding principal and accrued interest then outstanding divided by the public offering price per share. The principal and interest outstanding under the 2022 Convertible Notes is convertible, at the option of the holders, at the maturity date into a new class of Company's Preferred Stock (Series C Preferred) equal to the quotient of the outstanding principal amount plus interest divided by the Capped Price, which is defined as the price per share equal to the Valuation Cap of $30 million divided by the Company Capitalization, as defined in the Agreement.

In January 2023, the Company elected to convert the 2021 Convertible Note, including interest accrued but not yet paid of $124,759 at a conversion price of $48.00 into 23,432 shares of its Series B Preferred Stock on a basis unadjusted for the Forward Stock Split and the Reverse Stock Split in accordance with the terms outlined in the Note Purchase Agreement.

In February 2023, the 2022 Convertible Notes were amended to extend the maturity date to March 31, 2023 and to change the conversion price upon a Qualified Financing or Change in Control event to $30 million divided by the number of shares of the Company's common stock issued and outstanding, on a fully diluted basis, immediately prior to the close of the Qualified Financing or Change in Control event.

During April and June 2023, the 2022 Convertible Notes were further amended to extend the maturity date to September 30, 2023 and allow for the sale of additional notes of $500,000 for a total aggregate principal of $4,850,000.

Effective June 21, 2023, the 2022 Convertible Notes were converted to 61,534 shares of the Company's common stock equal to $9,495,072. During the three and nine months ended September 30, 2023, the Company recorded a loss on the change in the fair value of $0 and $3,630,100, respectively.

Interest expense was $0 and $166,019 during the nine months ended September 30, 2024 and September 30, 2023, respectively.

7. Stockholders' Equity

On May 17, 2023, the Company effected a 7.1-for-1 Forward Stock Split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's preferred stock. The par value of the common stock was adjusted as a result of the Forward Stock Split from $0.01 to $0.0001 and the authorized shares were increased to 100,000,000 shares of common stock in connection with the Forward Stock Split. In lieu of any fractional shares issued as a result of the split the Company paid a cash amount to the holder of such fractional share. The accompanying financial statements and notes to the financial statements give retroactive effect to the Forward Stock Split for all periods presented. Shares of common stock underlying outstanding stock-based awards and other equity instruments were proportionately increased and the respective per share value and exercise prices, if applicable, were proportionately decreased in accordance with the terms of the agreements governing such securities.

On July 1, 2024, the Company effected a 30-for-1 Reverse Stock Split of its issued and outstanding shares of common stock and began trading on a split-adjusted basis the same day. There was no change to the par value of the common stock. In lieu of any fractional shares issued as a result of the split the Company paid a cash amount to the holder of such fractional share. The accompanying financial statements and notes to the financial statements give retroactive effect to the Reverse Stock Split for all periods presented unless otherwise noted. Shares of common stock underlying outstanding stock-based awards and other equity instruments were proportionately decreased and the respective per share value and exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities.

On July 25, 2024, the Company completed a follow-on offering of an aggregate of 6,665,000 shares of its common stock and Class A warrants to purchase 13,330,000 shares of common stock, at a combined public offering price of $1.50. The Class A warrant had an initial exercise price of $1.50 per share, are exercisable immediately upon issuance, and will expire on the fifth anniversary of the original issuance date. However, if on the date that was 30 calendar days immediately following the date of issuance of the Class A Warrants, or August 24, 2024 (the "Reset Date"), the Reset Price, as defined below, was less than the exercise price at such time, the exercise price would be decreased to the Reset Price. "Reset Price" is defined as 100% of the trailing five-day VWAP immediately preceding the Reset Date, provided, that in no event would the Reset Price be less than $0.32 (subject to adjustment for reverse and forward stock splits, recapitalizations and similar transactions), which represented 20% of the most recent closing price for the Common Stock at the time of execution of the placement agent agreement with respect to the offering. The Reset Price of the Class A Warrants as calculated on the Reset Date was $0.7043 The number of shares of Common Stock issuable upon exercise of the Class A Warrants has not been proportionately adjusted due to the reset of the exercise price.

In consideration for Maxim Group LLC serving as the placement agent of the offering (the "Placement Agent"), the Company paid the Placement Agent a cash fee equal to 7% of the aggregate gross proceeds of the Offering and reimbursed the Placement Agent for certain expenses and legal fees for a total of $809,825. The Company also issued warrants to designees of the Placement Agent (the "Placement Agent Warrants") exercisable for an aggregate of 266,600 shares of Common Stock (the "Placement Agent Warrant Shares"). The Placement Agent Warrants have substantially the same terms as the Class A Warrants, except that the Placement Agent Warrants have an exercise price equal to $1.875 per share (125% of the $1.50 offering price of the Common Share and accompanying Class A Warrants), have an initial exercise date of January 23, 2025 and expire on July 23, 2029.

The gross proceeds from the offering, before deducting the placement agent's fees and other offering expenses, were approximately $10.0 million.

Common Stock

At September 30, 2024 and December 31, 2023, per the Company's amended and restated Certificate of Incorporation, the Company was authorized to issue 100,000,000 shares of $0.0001 par value common stock.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders.

The Company currently has 13,670,222 shares of common stock reserved for future issuance for the potential exercise of stock options and warrants outstanding at September 30, 2024.

Preferred Stock

At September 30, 2024 and December 31, 2023, per the Company's amended and restated Certificate of Incorporation, the Company has authorized 10,000,000 shares of $0.0001 par value preferred stock.

Upon the close of the Company's IPO in June 2023, all of the then outstanding preferred stock converted to common stock, resulting in the issuance of shares of common stock in exchange for outstanding Series A (48,608 shares), Series A-1 (98,828 shares), and Series B Preferred Stock (109,485 shares), respectively. There was no gain or loss upon conversion.

8. Warrants

The Company issued warrants to purchase 1,596 shares of common stock in 2018 in conjunction with convertible debt financing that have a redemption provision providing the holder the right to have the Company redeem all or any portion of the warrant (or shares it has converted into) at a purchase price equal to the fair market value of the shares as determined by the board of directors or an independent appraiser. As a result of this redemption provision, the warrants have been classified as a liability in the financial statements based on ASC 480 – Distinguishing Liabilities from Equity. These warrants have an exercise price of $14.40 per share and a term of 10 years. The warrants are marked to market each reporting period. The fair value was $457 and $35,453 at September 30, 2024 and December 31, 2023, respectively.

The Company issued 2,000 warrants to its underwriters as part of our initial public offering in fiscal 2023. In fiscal 2024, the Company issued an additional 22,223 warrants in February, and 266,600 warrants in July to its underwriters as part of our follow-on offerings in fiscal 2024. The underwriter warrants have a term of 5 years.

The Company also issued warrants in fiscal years 2019, 2023, and 2024 which did not meet the criteria under ASC 480 to be classified as a liability, and instead meet the equity classification criteria.

Additionally, the Company issued 13,330,000 Class A Warrants to shareholders who participated in the Company's July 2024 follow-on public offering. The Class A Warrants had an initial exercise price of $1.50 per share of Common Stock, however on August 24, 2024 the exercise price was reset to $0.7043. See, Note 7. The number of shares of Common Stock issuable upon exercise of the Class A Warrants were not proportionately adjusted in connection with the reset of the exercise price.

The Class A Warrants are exercisable upon issuance and expire five years from the date of issuance. The Class A Warrants contain ownership limitations pursuant to which a holder does not have the right to exercise any portion of their warrants if it would result in the holder (together with its affiliates) beneficially owning more than 4.99% (or, at the election of the holder, 9.99%) of the Company's outstanding Common Stock. The Class A Warrants are issued pursuant to a Warrant Agent Agreement dated July 25, 2024 ("Warrant Agent Agreement") between the Company and VStock Transfer LLC, as warrant agent.

In connection with the July 2024 follow-on public offering, the Company evaluated the Class A Warrants and determined they met the criteria for liability classification as they met the criteria in ASC 815 - Derivatives and Hedging due to the reset provision. The Class A Warrants had an initial fair value of $12.1 million. The gross proceeds of $10.0 million from the July 2024 follow-on public offering was allocated to the Class A Warrants resulting in a loss on issuance of common stock of approximately $2.1 million recorded in Other income (expenses). Upon the reset of the Class A Warrant exercise price, the Class A Warrants no longer met the criteria for liability classification pursuant to ASC 815; at which time the Company recorded a gain in Other income (expenses) - Change in fair value of Class A warrants of $4.0 million, and reclassified $(1.9) million to equity representing the difference between the change in the fair value, and the loss upon issuance of our common stock.

The Class A Warrants were valued utilizing a probability weighted scenario method with a Monte Carlo simulation model and Black-Scholes Model. The significant assumptions in the Monte Carlo simulation model include a stay public assumption of 90%, and a fundamental transaction assumption of 10%. The significant assumptions utilized in estimating the fair value of the Class A Warrants at issuance include (i) a per share price of common stock range of $1.14 - $1.40; (ii) a dividend yield of 0%; (iii) a risk-free rate range of 4.13% - 4.14%; (iv) expected volatility of 119%; (v) projected stock price and volume weighted average price as of the Reset Date of $1.14; (vi) a strike price range of $1.50 - $1.40; and (vii) expected term range of 5.00 - 4.92.

The following table summarizes information about warrants outstanding at September 30, 2024:

		Warrants Outstanding			Warrant Exercisable		
Year Granted	Exercise Price	Number of Warrants at 09/30/2024	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Warrants at 09/30/2024	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
2018	$ 14.40	1,596	3.5 years	$ 14.40	1,596	3.5 years	$ 14.40
2019	$ 158.40	7,195	1.4 years	$ 158.40	7,195	1.4 years	$ 158.40
2023	$ 187.50	2,000	3.7 years	$ 187.50	2,000	3.7 years	$ 187.50
2024	$ 11.40	22,223	4.4 years	$ 11.40	22,223	4.4 years	$ 11.40
2024	$ 0.70	13,329,000	4.8 years	$ 0.70	13,329,000	4.8 years	$ 0.70
2024	$ 1.88	266,600	4.8 years	$ —	—	0 years	$ —
		13,628,614		$ 0.85	—		$ 0.83

9. Stock Options

In March 2023, the Company's Board of Directors and stockholders approved the 2023 Stock Incentive Plan ("2023 Plan"). The 2023 Plan allows the Compensation Committee to grant up to 66,667 shares of Common Stock in the form of incentive and non-statutory stock options, restricted stock awards, restricted stock units, and other stock-based awards to employees, directors, and non-employees. As of September 30, 2024, options to purchase 1,333 shares of common stock had been granted and were outstanding under the 2023 Plan and 65,334 shares of common stock were available for grant under the plan. On October 3, 2024, the Company's Board of Directors approved amendments to the 2023 Plan that, subject to stockholder approval, would (i) increase the number of shares of Common Stock that may be issued under the 2023 Plan by 1,144,401 shares and (ii) adopt an evergreen provision to the 2023 Plan providing for an automatic 5% annual increase in the shares of Common Stock available for issuance under the 2023 Plan over the next 10 years. Both amendments are subject to the approval of the Company's stockholders and will be submitted for approval at the Company's annual stockholder meeting to be held on November 20, 2024.

During 2016, the Company established the Azitra Inc. 2016 Stock Incentive Plan ("2016 Plan") which provides for the grant up to 49,687 shares of Common Stock in the form of stock options and restricted shares to the Company's employees, officers, directors, advisors and consultants. As of September 30, 2024, options to purchase 40,275 shares of common stock had been granted and 7,457 shares of common stock were available for grant under the 2016 Plan.

During the three and nine months ended September 30, 2024 and 2023, the Company did not grant any equity awards under the 2016 or 2023 Plans. During the three and nine months ended September 30, 2024, the Company recognized stock compensation expense of $143,534 and $211,875, respectively, relating to the issuance of service-based and performance-based stock options. During the three and nine months ended September 30, 2023, the Company recognized stock compensation expense of $39,073 and $116,660, respectively, relating to the issuance of service-based stock options. At September 30, 2024, there was $114,564 of unamortized compensation expense that will be amortized over the remaining vesting period. At September 30, 2024 and 2023, there were 0 and 3,105 performance-based options outstanding, respectively with fair values of $0 and $109,551, respectively. During the three and nine months ended September 30, 2024, the Company recognized compensation expense for performance-based options. The Company determined the options qualified as plain vanilla under the provisions of SAB 107 and the simplified method was used to estimate the expected option life.

The following table summarizes information about options outstanding and exercisable at September 30, 2024:

	Options Outstanding			Options Exercisable		
Exercise Price	Number of Options at September 30, 2024	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Options at September 30, 2024	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
$ 14.32	6,871	1.3 years	$ 14.32	6,871	1.3 years	$ 14.32
$ 27.80	6,735	1.3 years	$ 27.80	6,735	1.3 years	$ 27.80
$ 51.08	26,669	6.5 years	$ 51.08	24,748	6.4 years	$ 51.08
$ 62.10	1,333	8.9 years	$ 62.10	389	8.9 years	$ 62.10
	41,608			38,743		

Total stock option activity for the nine months ended September 30, 2024, is summarized as follows:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2023	42,941	$ 41.10
Granted	—	—
Exercised	(1,333)	14.32
Forfeited	—	—
Outstanding at September 30, 2024	41,608	$ 41.60

10. Fair Value Measurements

The following tables summarize the fair values and levels within the fair value hierarchy in which the fair value measurements fall for assets and liabilities measured on a recurring basis as of:

September 30, 2024

Description	Level 1	Level 2	Level 3	Total
Liabilities				
Common stock warrants	$ —	$ —	$ 457	$ 457
Total	$ —	$ —	$ 457	$ 457

December 31, 2023

Description	Level 1	Level 2	Level 3	Total
Liabilities				
Common stock warrants	$ —	$ —	$ 35,453	$ 35,453
Total	$ —	$ —	$ 35,453	$ 35,453

The following table presents the changes in Level 3 instruments measured on a recurring basis for the period ended September 30, 2024:

Balance at December 31, 2023	$	35,453
Changes in fair value of warrants		(28,155)
Balance at March 31, 2024	$	7,298
Changes in fair value of warrants		(4,372)
Balance at June 30, 2024	$	2,926
Changes in fair value of warrants		(2,469)
Balance at September 30, 2024	$	457

At September 30, 2024 and December 31, 2023, the Company estimated the fair value of the warrants using the Black-Scholes option pricing model with the following assumptions:

	September 30, 2024	December 31, 2023
Underlying common stock value	$ 0.54	$ 27.60
Expected term (years)	3.54	4.29
Expected volatility	156 %	99 %
Risk free interest rate	4 %	4 %
Dividend yield	— %	— %

Fluctuations in the fair value of the Company's common stock is the primary driver for the change in the common stock warrant liability valuation during each year. As the fair value of the common stock increases the value to the holder of the instrument generally increases.

11. Net Loss Per Share

Basic and diluted net loss per share were calculated as follows:

The denominator for each respective period is as follows:

	Three Months Ended		Nine Months Ended	
	2024	2023	2024	2023
Weighted average common stock outstanding, basic and diluted	5,814,350	403,255	2,494,577	172,464
$0.01 warrants	—	—	—	239
Total	5,814,350	403,255	2,494,577	172,704

The following potential common stock equivalents, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	September 30,	
	2024	2023
Options to purchase shares of common stock	41,608	42,942
Warrants outstanding	13,628,614	10,791
Total	13,670,222	53,733

12. Commitments and Contingencies

Legal

The Company is subject to legal proceedings or claims which arise in the ordinary course of its business. Although occasional adverse decisions or settlements may occur, the Company believes that the final disposition of such matters should not have a material adverse effect on its financial position, results of operations or liquidity.

License Agreement

Effective January 26, 2022, the Company entered into an Exclusive License Agreement (the License Agreement) with an unrelated third party. Under the License Agreement, the Company is granted an exclusive license for certain patents and a non-exclusive license for certain know-how. The License Agreement continues until the later of the expiration of the last to expire licensed patent or ten years after the first commercial sale of the first licensed therapeutic or non-therapeutic product. The Company may terminate the License Agreement at any time by providing at least 30 days written notice to the third party. The License Agreement is also terminated upon breach of a material obligation under the agreement or bankruptcy. Upon any termination of the License Agreement, neither party is relieved of obligations incurred prior to the termination.

During the three and nine months ended September 30, 2024 the Company did not capitalize any payments made under this license agreement. During the three and nine months ended September 30, 2023, the Company capitalized payments made under this license agreement in the amount of $0 and $15,263, respectively.

Operating Leases

The Company leases office and lab space in Branford, CT, Groton, CT, and Montreal, Quebec. The Company's leases expire at various dates through May 31, 2027. Most leases are for a fixed term and for a fixed amount.

During 2019, the Company entered into a new lease agreement for office and laboratory space in Montreal, Quebec. The Montreal lease required monthly payments of $6,906, CAD which increases approximately 4% in each of the following years. The Montreal lease was increased to $8,130 CAD in 2021 upon leasing additional space. The Montreal lease was initially for a one-year term, renewable annually. The Montreal lease also requires the Company to pay additional common area maintenance.

During 2020, the Company entered into a new lease agreement for the Company's primary office and laboratory space in Branford, CT. The Branford lease requires monthly payments of $13,033 for the first year of the lease, which increases approximately 2% in each of the following years. The Branford lease also requires the Company to pay a pro-rata share of common area maintenance.

During May 2021, the Company entered into a new lease for office and laboratory space in Groton, CT. The Groton lease required monthly payments of $4,234, which was increased to $6,824 in September 2021 upon leasing additional space. In August 2024, the Company reassessed its needs and released certain lab space resulting in a decrease to the monthly payment to $5,216. The Groton lease is initially for a one-year term, renewable annually for up to three additional years.

Future minimum payments under non-cancelable operating leases with initial or remaining terms in excess of one year during each of the next five years follow:

2024 (Remaining 3 months)	$	73,307
2025		281,259
2026		199,713
2027		89,146
2028		—
Thereafter		—
Total future undiscounted lease payments		643,425
Less interest		(30,030)
Present value of minimum lease payments	$	613,395

Rent expense for all operating leases was $254,142 and $254,142 for the nine months ended September 30, 2024 and September 30, 2023, respectively. The weighted average lease term for all operating leases is 2.3 years. The weighted average discount rate for all operating leases is 4.25%.

Finance Leases

During 2023, the Company entered into an agreement with Hewlett Packard to lease equipment. The lease requires monthly payments of $1,478, including tax. The lease is for a 3 years term with option of purchase or extension at term end. The remaining lease term is 1.8 years and the discount rate is 9.60%.

The following is a schedule showing the future minimum lease payments under finance leases by years and the present value of the minimum payments as of September 30, 2024.

2024 (Remaining 3 months)	$	4,435
2025		17,001
2026		11,090
2027		—
Thereafter		—
Total future undiscounted lease payments		32,526
Less interest		(2,573)
Present value of minimum lease payments	$	29,953

Lease expense for the finance lease was $11,610 and $2,580 for the nine months ended September 30, 2024 and September 30, 2023, respectively. Interest expense for the finance lease was $2,486 and $710 for the nine months ended September 30, 2024 and September 30, 2023, respectively.

13. Retirement Plan

Effective January 1, 2019, the Company sponsors a 401(k) plan that covers substantially all employees. In order to be eligible to participate, an employee must complete two consecutive months of service and work a minimum of two hundred fifty hours or work 1,000 hours in their first year of service. Employees may make pre-tax deferrals upon meeting the Plan eligibility requirements. Effective January 1, 2020, the Plan was transitioned to a safe harbor plan in which highly compensated employees are not eligible for matching contributions and non-highly compensated employees earn 100% match on first 3% contributed and 50% on the next 2% contributed. Total employer matching contributions were $3,381 and $11,029 for the three and nine months ended September 30, 2024, respectively. Total employer matching contributions were $2,809 and $7,633 for the three and nine months ended September 30, 2023, respectively.

14. Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist principally of cash and accounts receivable.

For the three and nine months ended September 30, 2024 and 2023, all service revenue was from one customer.

The cash balance identified in the balance sheet is held in an account with a financial institution and insured by the Federal Deposit Insurance Corporation (FDIC) up to $250,000. At times, cash maintained on deposit may be in excess of FDIC limits.

15. Related Parties

Total related party revenue was $0 and $7,500 for the three and nine months ended September 30, 2024, respectively. Total related party revenue was $310,700 and $596,000 for the three and nine months ended September 30, 2023, respectively. Accounts receivable due from the related party was $0 and $90,000 at September 30, 2024 and December 31, 2023, respectively.

In September 2022, the Company entered into a convertible promissory note totaling $4,350,000 of which $4,000,000 was attributable to an entity who was also an investor in the Company's Series A, A-1, and B Preferred Stock financing (See Note 6). This entity received 1,697,490 shares of common stock on a basis unadjusted for a Forward Stock Split and a Reverse Stock Split, upon conversion of the promissory notes for principal and interest of $4,243,726.

In July 2024, Bayer was no longer considered a related party as their holdings in the Company no longer exceeded 5% of the total outstanding common stock, and the amounts disclosed above are accordingly presented while they were considered a related party.

16. Subsequent Events

The Company has evaluated events subsequent to the balance sheet date through November 12, 2024, the date these condensed financial statements are issued.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Cautionary Statement

The following discussion and analysis should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto contained elsewhere in this report. The information contained in this quarterly report on Form 10-Q is not a complete description of our business or the risks associated with an investment in our common stock. We urge you to carefully review and consider the various disclosures made by us in this report and in our other filings with the Securities and Exchange Commission, or SEC, including our Form 10-K for the year ended December 31, 2023 and filed with the SEC on March 15, 2024.

In this report we make statements, and from time to time we otherwise make written and oral statements regarding our business and prospects, such as projections of future performance, statements of management's plans and objectives, forecasts of market trends, and other matters that are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements containing the words or phrases "will likely result," "are expected to," "will continue," "is anticipated," "estimates," "projects," "believes," "expects," "anticipates," "intends," "target," "goal," "plans," "objective," "should" or similar expressions identify forward-looking statements, which may appear in our documents, reports, filings with the SEC, and news releases, and in written or oral presentations made by officers or other representatives to analysts, stockholders, investors, news organizations and others, and in discussions with management and other of our representatives.

Our future results, including results related to forward-looking statements, involve a number of risks and uncertainties, including those risks included in the "Risk Factors" section in our Form 10-K for the year ended December 31, 2023 and filed with the SEC on March 15, 2024. No assurance can be given that the results reflected in any forward-looking statements will be achieved. Any forward-looking statement speaks only as of the date on which such statement is made. Our forward-looking statements are based upon assumptions that are sometimes based upon estimates, data, communications and other information from suppliers, government agencies and other sources that may be subject to revision. Except as required by law, we do not undertake any obligation to update or keep current either (i) any forward-looking statement to reflect events or circumstances arising after the date of such statement or (ii) the important factors that could cause our future results to differ materially from historical results or trends, results anticipated or planned by us, or which are reflected from time to time in any forward-looking statement.

General

We were formed in January 2014 as a biopharmaceutical company focused on developing innovative therapies for precision dermatology using engineered proteins and live biotherapeutic products. We are an early-stage clinical biopharmaceutical company and have not commenced commercial operations.

To date, we have capitalized our operations primarily through a series of private placements of our convertible preferred stock and convertible promissory notes and our initial public offering, IPO, of common stock which closed on June 21, 2023. In connection with our IPO, we issued 50,000 shares of our common stock at a public offering price of $150 per share. Concurrent with the close of our IPO, all of our outstanding shares of convertible preferred stock and convertible promissory notes converted into a total of 298,384 shares of our common stock. In February 2024, we completed a follow-on public offering in which we issued and sold 555,567 shares of our common stock at a price to the public of $9.00 per share. On July 25, 2024, the Company completed a follow-on offering of an aggregate of 6,665,000 shares of its common stock, and Class A warrants to purchase up to 13,330,000 shares of common stock, at a combined public offering price of $1.50 per share and accompanying warrants.

As of November 12, 2024, we had 7,626,056 shares of our common stock issued and outstanding. Except as otherwise indicated, all share and share price this report gives effect to a reverse stock split effected on July 1, 2024 at a ratio of 30-for-1.

Overview

We focus on developing innovative therapies for precision dermatology using engineered proteins and topical live biotherapeutic products. We have built a proprietary platform that includes a microbial library comprised of approximately 1,500 unique bacterial strains that can be screened for unique therapeutic characteristics. The platform is augmented by an artificial intelligence and machine learning technology that analyzes, predicts and helps screen our library of strains for drug like molecules. The platform also utilizes a licensed genetic engineering technology, which can enable the transformation of previously genetically intractable strains. Our initial focus is on the development of genetically engineered strains of *Staphylococcus epidermidis, or S.*

epidermidis, which we consider to be an optimal therapeutic candidate species for engineering of dermatologic therapies. The particular species demonstrates a number of well-described properties in the skin. As of the date of this report, we have identified among our microbial library over 60 distinct bacterial species that we believe are capable of being engineered to create living organisms or engineered proteins with significant therapeutic effect.

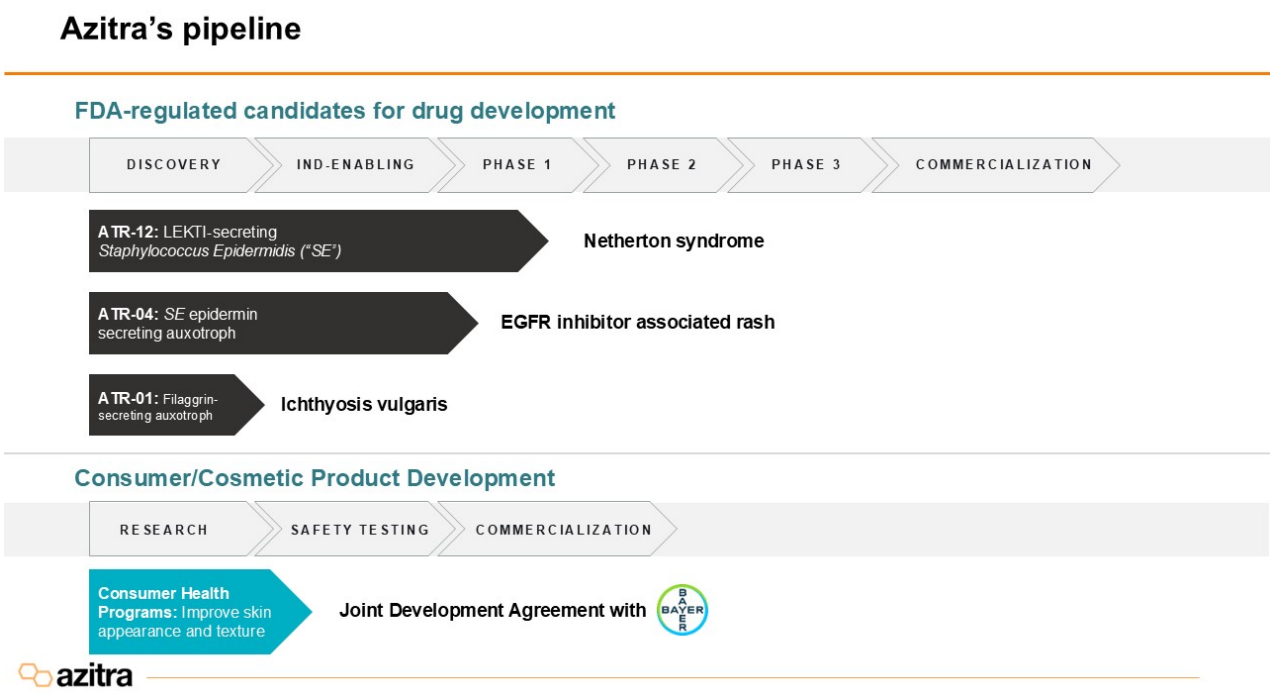
We are a pioneer in genetically engineered bacteria for therapeutic use in dermatology. Our goal is to leverage our platforms and internal microbial library bacterial strains to create new therapeutics that are either engineered living organisms or engineered proteins or peptides to treat skin diseases. Our initial focus is on the development of our current product candidates, including:

- **ATR-12**, a genetically modified strain of *S. epidermidis* for treating the orphan disease, Netherton syndrome, a chronic and sometimes fatal disease of the skin estimated to affect approximately one in every 100,000, but its prevalence may be underestimated due to misdiagnosis caused by similarities to other skin diseases. We received Pediatric Rare Disease Designation for ATR-12 by the United States Food and Drug Administration, or FDA, in 2019. In December 2022, we submitted an investigational new drug application, or IND, for a Phase 1b clinical trial of ATR-12 in Netherton syndrome patients, and on January 27, 2023 we received notification from the FDA that the "study may proceed" with respect to the proposed Phase 1b clinical trial. After submitting post-IND manufacturing reports, we have commenced operating activities for our Phase 1b clinical trial in December 2023, and we dosed our first patient in August 2024. We expect to report initial clinical safety results in the first quarter of 2025.

- **ATR-04**, a genetically modified strain of *S. epidermidis* for treating the papulopustular rash experienced by cancer patients undergoing epidermal growth factor receptor inhibitor, or EGFRi, targeted therapy. In August 2024, we obtained IND clearance from the FDA to commence a Phase 1/2 clinical trial in certain cancer patients undergoing EGFRi targeted therapy. In September 2024, we obtained Fast Track designation by the FDA in this indication. We expect to commence our Phase 1b clinical trial in the fourth quarter of 2024 and dose the first patient in the first quarter of 2025.

- **ATR-01**, a genetically modified strain of S. epidermidis that expresses an engineered recombinant human filaggrin protein for treating ichthyosis vulgaris, a chronic, xerotic (abnormally dry), scaly skin disease with an estimated incidence and prevalence of 1 in 250, which suggests a total patient population of 1.3 million in the United States. We are planning to perform lead optimization and IND-enabling studies in 2024 to support an IND filing targeted for early 2026.

- Two separate strains of bacterial microbes being investigated and developed by us and Bayer Consumer Care AG, the consumer products division of Bayer AG, or Bayer, the international life science company. We entered into a Joint Development Agreement, or JDA, with Bayer in December 2019. Under the terms of the JDA, we are responsible for testing our library of bacterial strains and their natural products for key preclinical properties. After screening through hundreds of strains, we and Bayer have selected two particular strains to move forward into further development. Bayer holds the exclusive option to license the patent rights to these strains. In December 2020, Bayer purchased $8 million of our Series B preferred stock, which converted into 48,324 shares of our common stock.



We also have established partnerships with teams from Carnegie Mellon University and the Fred Hutchinson Cancer Center, or Fred Hutch, two of the premier academic centers in the United States. Our collaboration with the Carnegie Mellon based team also takes advantage of the power of whole genome sequencing. This partnership is mining our proprietary library of bacterial strains for novel, drug like peptides and proteins. The artificial intelligence/machine learning technology developed by this team predicts the molecules made by microbes from their genetic sequences. The system then compares the predictions to the products actually made through tandem mass spectroscopy and/or nuclear magnetic resonance imaging to refine future predictions. The predictions can be compared to publicly available 2D and 3D protein databases to select drug like structures.

We hold an exclusive, worldwide license from Fred Hutch regarding the use of its patented SyngenicDNA Minicircle Plasmid, or SyMPL, technologies for all fields of genetic engineering, including to discover, develop and commercialize engineered microbial therapies and microbial-derived peptides and proteins for skin diseases. We are utilizing our licensed patent rights to build plasmids in order to make genetic transformations that have never been previously achieved. To date, our team has successfully engineered our lead therapeutic candidates without the SyMPL technology. However, we believe that SyMPL will open up the ability to make genetic transformations of an expanded universe of microbial species, and we expect that some or all of our future product candidates will incorporate the SyMPL technology.

Our Strategy

Beyond our three lead product candidates and collaboration with Bayer, our goal is to develop a broad portfolio of product candidates focused on expanding the application of our platforms for precision dermatology. We believe that we have established a unique position in advancing the development of biologics for precision dermatology.

We intend to create a broad portfolio of product candidates for precision dermatology through our development of genetically engineered proteins selected from our proprietary microbial library of approximately 1,500 unique bacterial strains. Our strategy is as follows:

- ***Build a sustainable precision dermatology company.*** Our goal is to build a leading precision dermatology company with a sustainable pipeline of product candidates. To that end, we are focused on rapidly advancing our current pipeline of live biotherapeutic candidates while actively developing additional product candidates. Each of our current product candidates are proprietary and subject to pending patent applications. We expect that most, if not all, genetically engineered product candidates we develop will be eligible for patent protection.

- ***Advance our lead product candidates, ATR-12 and ATR-04, through clinical trials.*** In December 2022, we filed an IND for a first-in-human trial of ATR-12 in Netherton syndrome patients. On January 27, 2023, we received notification from the FDA that the "study may proceed" with respect to the proposed Phase 1b clinical trial, and in August 2024 we initiated dosing the first patient in its Phase 1b clinical trial evaluating ATR-12. In April 2024, we held a pre-IND meeting with the FDA to discuss an IND filing for a first-in-human Phase 1b/2a clinical trial in patients with EGFRi-associated rash, and in September 2024 the FDA granted Fast Track designation for ATR-04. We expect to report initial safety results of the first patients dosed in our Phase 1b clinical trial for our ATR-12 in Netherton syndrome patients in early 2025 with full results anticipated in the second half of 2025, and are currently planning to commence a Phase 1b trial of our ATR-04 in certain cancer patients undergoing EGFRi therapy in the fourth quarter of 2024.

- ***Broaden our platform by selectively exploring strategic partnerships that maximize the potential of our precision dermatology programs.*** We intend to maintain significant rights to all of our core technologies and product candidates. However, we will continue to evaluate partnering opportunities in which a strategic partner could help us to accelerate development of our technologies and product candidates, provide access to synergistic combinations, or provide expertise that could allow us to expand into the treatment of different types of skin diseases. We may also broaden the reach of our platform by selectively in-licensing technologies or product candidates. In addition, we will consider potentially out-licensing certain of our proprietary technologies for indications and industries that we are not ourselves pursuing. We believe our genetic engineering techniques and technologies have applicability outside of the field of medicine, including cosmetics and in the generation of clean fuels and bioremediation.

- ***Leverage our academic partnerships.*** We currently have partnerships with investigators at the Fred Hutchinson Cancer Center, Yale University, Jackson Laboratory for Genomic Medicine, and Carnegie Mellon University. We expect to leverage these partnerships and potentially expand them or form other academic partnerships to bolster our engineering platforms and expand our research and development pipeline.

- ***Expand on our other potential product candidates.*** Beyond our three lead product candidates, our goal is to develop a broad portfolio of product candidates focused on expanding the application of our platforms for precision dermatology. We have a proprietary platform for discovering and developing therapeutic products for precision dermatology. Our platform is built around a microbial library comprised of approximately 1,500 unique bacterial strains to allow screening for unique therapeutic characteristics and utilizes a microbial genetic technology that analyzes, predicts and engineers the proteins, peptides and molecules made by skin microbes. Our ability to genetically engineer intractable microbial species is uniquely leveraged by our exclusive license to the SyMPL technology.

Results of Operations

We are an early-stage clinical biopharmaceutical company, formed in January 2014, and have limited operating history. We have not commenced revenue-producing operations apart from limited service revenue derived through our JDA with Bayer. Under the terms of the JDA, we are responsible for testing our library of microbial strains and their natural products for key preclinical properties and Bayer reimburses us for our development costs. To date, our operations have consisted of the development of our proprietary microbial library, the identification, characterization and testing of certain bacterial species from our microbial library that we believe are capable of being engineered to provide significant therapeutic effect and the development of our initial product candidates.

Three Months Ended September 30, 2024 Compared to Three Months Ended September 30, 2023

The following table summarizes our results of operations with respect to the items set forth below for the three months ended September 30, 2024 and 2023, together with the percentage change for those items.

	Three Months Ended September 30,			
	2024	2023	$ Change	% Change
Service revenue - related party	$ —	$ 310,700	$ (310,700)	(100)%
Total revenue	—	310,700	(310,700)	(100)%
Operating expenses:				
General and administrative	1,913,400	1,755,908	157,492	9 %
Research and development	1,015,807	548,524	467,283	85 %
Total operating expenses	2,929,207	2,304,432	624,775	27 %
Loss from operations	(2,929,207)	(1,993,732)	(935,475)	47 %
Other income (expense):				
Interest income	47,389	634	46,755	7,375 %
Interest expense	(3,851)	(710)	(3,141)	442 %
Change in fair value of warrants	4,001,469	98,061	3,903,408	3981 %
Loss on issuance of common stock	(2,132,800)	—	(2,132,800)	100 %
Other income (expense)	7,509	(47,542)	55,051	(116)%
Total other income (expense)	1,919,716	50,443	1,869,273	3,706 %
Loss before income taxes	(1,009,491)	(1,943,289)	933,798	(48)%
Net loss	(1,009,491)	(1,943,289)	933,798	(48)%
Dividends on preferred stock	—	—	—	— %
Net loss attributable to common shareholders	$ (1,009,491)	$ (1,943,289)	$ 933,798	(48)%

Service Revenue - Related Party

We generated $0 of service revenue under the Bayer JDA during the third quarter of fiscal 2024 compared to service revenue of $310,700 under the JDA for the comparable period in fiscal 2023. The decrease of $310,700 in service revenue is attributable to a decrease in the amount of reimbursable development costs incurred in 2024. In the future, we expect to generate minimal service revenue, if any, under the Bayer JDA.

General and Administrative

General and administrative costs during the third quarter of fiscal 2024 increased by $157,492, or 9%, to $1,913,400 from the comparable prior period. The increase was primarily related to the costs incurred following, and as a result of, our emergence as a public company in June 2023, including $165,000 of salaries and benefits, an increase of $168,000 primarily related to the hiring of our CFO, an increase of $110,000 primarily related to the achievement of a milestone for our CEO's performance based options, an increase of $47,000 in public relations costs offset by a decrease of $159,000 primarily related to the reduction in financing costs, a decrease of $190,000 in legal expenditures, and a net increase of $16,492 in other overhead expenses.

Research and Development

Research and development expenses include salaries and benefits of all research personnel, payments to contract research organizations, payments to research consultants, and the purchase of lab supplies. These expenses are offset by development tax credits.

During the third quarter of fiscal 2024, research and development expenses increased by $467,283, or 85%, to $1,015,807 from the comparable prior period. The increase was primarily related to an increase of $180,000 in salaries and benefits, an increase of $130,000 in research and development related costs attributable to our efforts in moving our ATR-12 program forward into the clinic, an increase of $116,000 attributable to the use of clinical consultants, an increase of $59,000 attributable to moving our ATR-04 program forward and a net decrease of $17,717 in other costs. There was no government and nonprofit grant revenue received by us during the third quarter of fiscal 2024 and 2023. There were no refundable tax credits for the three-month periods ended September 30, 2024 and 2023.

We expect our research and development expenses to significantly increase in the future due primarily to our planned clinical trial activity and continued development of product candidates.

Other Income (Expense)

Our other income (expense) consists of interest income, changes in the valuation of warrants, loss on foreign currency translation, loss on issuance of stock, loss on disposal of equipment and interest expense. During the third quarter of fiscal 2024, other income (expense) increased by $1,869,273, or 3,706%, compared to the comparable period in fiscal 2023. The increase was primarily related to an increase of $3,903,408 in warrant value, a net decrease of $98,665 attributable to other income and expense, offset by a increase of $2,132,800 attributable to the loss on issuance of stock.

Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

The following table summarizes our results of operations with respect to the items set forth below for the for the nine months ended September 30, 2024 and 2023 together with the percentage change for those items.

	Nine Months Ended September 30,			
	2024	2023	$ Change	% Change
Service revenue - related party				
Total revenue	$ 7,500	$ 596,000	$ (588,500)	(99)%
	7,500	596,000	(588,500)	(99)%
Operating expenses:				
General and administrative	4,951,155	3,443,559	1,507,596	44 %
Research and development	3,607,329	2,132,510	1,474,819	69 %
Total operating expenses	8,558,484	5,576,069	2,982,415	53 %
Loss from operations	(8,550,984)	(4,980,069)	(3,570,915)	72 %
Other income (expense):				
Interest income	71,266	1,184	70,082	5919 %
Interest expense	(6,548)	(166,729)	160,181	(96)%
Change in fair value of convertible note	—	(3,630,100)	3,630,100	(100)%
Change in fair value of warrants	4,033,996	9,450	4,024,546	(100)%
Loss on issuance of common stock	(2,132,800)	—	(2,132,800)	(100)%
Other income (expense)	10,711	(54,017)	64,728	(120)%
Total other income (expense)	1,976,625	(3,840,212)	5,816,837	(151)%
Loss before income taxes	(6,574,359)	(8,820,281)	2,245,922	(25)%
Income tax expense	—	(9,715)	9,715	(100)%
Net loss	(6,574,359)	(8,829,996)	2,255,637	(26)%
Dividends on preferred stock	—	(1,355,347)	1,355,347	(100)%
Net loss attributable to common shareholders	$ (6,574,359)	$ (10,185,343)	$ 3,610,984	(35)%

Service Revenue - Related Party

We generated $7,500 of service revenue under the Bayer JDA during the first nine months of fiscal 2024 compared to service revenue of $596,000 under the JDA for the comparable period in fiscal 2023. The decrease of $588,500 in service revenue is attributable to a decrease in the amount of reimbursable development costs in 2024. In the future, we expect to generate minimal service revenue, if any, under the Bayer JDA.

General and Administrative

General and administrative costs during the first nine months of fiscal 2024 increased by $1,507,596, or 44%, to $4,951,155 from the prior year period. The increase was primarily related to the costs incurred following, and as a result of, our emergence as a public company in June 2023, including an increase of $462,000 of salaries and benefits, an increase of $429,000 primarily related to the hiring of our CFO, an increase of $112,000 primarily related to the achievement of a milestone for our CEO's performance based options, an increase of $183,000 primarily related to costs associated with listing on the NYSE, an increase of $191,000 primarily related to the cost of directors and officers insurance, an increase of $170,000 in public relations expenditures, an increase of $59,000 in Board member costs, an increase of $32,000 in conference expense offset by a decrease of $25,000 in legal costs, a decrease of $141,000 in accounting and audit expenses and a net increase of $35,596 in other overhead expenses.

Research and Development

Research and development expenses include salaries and benefits of all research personnel, payments to contract research organizations, payments to research consultants, and the purchase of lab supplies. These expenses are offset by income earned from government grant payments. We generate grant revenue on contracts with various federal agencies and nonprofit research institutions for general research conducted by us. These grant arrangements also do not meet the criteria for revenue recognition and amounts earned under these grant contracts are recorded as a negative research and development expense.

During the first nine months of fiscal 2024, research and development expenses increased by $1,474,819, or 69%, to $3,607,329 from the prior year period. The increase was primarily related to an increase of $205,000 in salaries and benefits, an increase of $267,000 in research and development related costs attributable to our efforts in moving our ATR-12 program forward into the clinic, an increase of $388,000 attributable to the use of clinical consultants, an increase of $633,000 attributable to moving our ATR-04 program forward offset by a net decrease of $18,181 in other costs. There was $0 and $1,145 in government and nonprofit grant funds received by us during the first nine months of fiscal 2024 and 2023, respectively, and we do not anticipate any significant grants in the near term.

We expect our research and development expenses to significantly increase in the future due primarily to our planned clinical trial activity and continued development of product candidates.

Other Income (Expense)

Our other income (expense) consists of interest income, loss on foreign currency translation, change in fair value of the convertible note, change in fair value of warrants, loss on the issuance of our common stock, and interest expense. During the first nine months of fiscal 2024, other income (expense) decreased by $5,816,837, or 151%, compared to the comparable period in fiscal 2023. The decrease was primarily related to a decrease of $3,630,100 attributable to the change in fair value of the convertible note, an decrease of $160,181 attributable to interest expense, a decrease of $4,024,546 in warrant value, an increase in loss on issuance of common stock of $2,132,800 and a net decrease of $134,810 attributable to other income and expense.

Financial Condition

As of September 30, 2024, we had total assets of approximately $9.8 million and working capital of approximately $6.3 million. As of September 30, 2024, our liquidity included approximately $7.3 million of cash and cash equivalents. We believe that our cash on-hand as of the date of this report may not be sufficient to cover our proposed plan of operations over the next twelve months. We intend to seek additional funds through various financing sources, including the sale of our equity and debt securities, federal grants, licensing fees for our technology and joint ventures with industry partners. In addition, we will consider alternatives to our current business plan that may enable us to achieve revenue producing operations and meaningful commercial success with a smaller amount of capital. However, there can be no guarantees that such funds will be available on commercially reasonable terms, if at all. If such financing is not available on satisfactory terms, we may be unable to further pursue our business plan and we may be unable to continue operations.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, our common stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

As of the date of this filing, management has determined there is substantial doubt about our ability to continue as a going concern based on our lack of revenue from commercial operations, significant losses, and the need to raise additional capital to support ongoing operations.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

	Nine Months Ended September 30,	
	2024	**2023**
Net cash used in operating activities	$ (7,597,539)	$ (4,823,168)
Net cash used in investing activities	$ (263,714)	$ (258,274)
Net cash provided by financing activities	$ 13,325,498	$ 5,989,113
Net increase in cash	$ 5,464,245	$ 907,671

Operating Activities

During the first nine months of fiscal 2024, operating activities used $7.6 million of cash primarily driven by our net loss of $6.6 million, and non-cash items of $1.0 million. During the comparable period of fiscal 2023, operating activities used $4.8 million of cash primarily driven by our net loss of $8.8 offset by non-cash items of $4.0 million.

Investing Activities

During the first nine months of fiscal 2024, investing activities used $263,714 of cash driven by $255,145 trademark and deferred patent costs. During the comparable period of fiscal 2023, investing activities used $258,274 of cash driven by $208,723 of trademark and deferred patent costs, $22,882 for the purchase of furniture and equipment, and $26,669 of patent, trademark, and license costs.

Financing Activities

During the first nine months of fiscal 2024, financing activities provided $13.3 million in cash primarily driven by proceeds from our February and July 2024 follow-on public offerings. During the comparable period of fiscal 2023, financing activities provided $6.0 million in cash primarily driven by proceeds from our June 2023 IPO.

Critical Accounting Policies

During the nine months ended September 30, 2024, there were no material changes to our critical accounting policies previously disclosed in our Form 10-K dated December 31, 2023 and filed with the SEC on March 15, 2024.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these condensed financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our condensed financial statements. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, will be reflected in the condensed financial statements prospectively from the date of change in estimates. There were no material changes to our critical accounting estimates as reported in our Form 10-K for the year ended December 31, 2023 and filed with the SEC on March 15, 2024.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures, pursuant to Rule 13a-15 of the Securities Exchange Act of 1934, as of September 30, 2024. In the course of that evaluation, we identified a material weakness as it relates to a lack of adequate segregation of accounting functions. We intend to increase staffing within our accounting infrastructure sufficient to facilitate proper segregation of accounting functions and to enable appropriate review of our internally prepared financial statements. Based upon the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were not effective as of September 30, 2024.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Those forward-looking statements include our expectations, beliefs, intentions and strategies regarding the future. You should carefully consider the risk factors discussed in the "Risk Factors" section in our Form 10-K for the year ended December 31, 2023 as, in light of those risks, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in our forward-looking statements. Other than as set forth below, there have been no material changes in the risk factors included in our 2023 Form 10-K. The risk factors described in our 2023 Form 10-K are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results.

In December 2019, we entered into a Joint Development Agreement, or JDA, with Bayer pursuant to which we agreed to the joint development of certain strains selected from our proprietary microbial library. We have granted Bayer an option to acquire an exclusive royalty bearing license for up to six strains subject to development activities under the JDA, including an exclusive royalty bearing license to any related patent rights. We continue to conduct joint development work with Bayer and discuss the proposed royalty bearing license. While we remain optimistic concerning the successful completion of a royalty bearing license agreement with Bayer, there can be no assurance we will be able to conclude a licensing agreement or, if we are, that the terms of such license agreement will be favorable to us. Assuming our joint development work is successful, our ability to convert the successful development work into a commercial license with Bayer is dependent on a number of risks and factors, many of which are outside our control, including:

- Bayer's internal evaluation of the economic benefits of marketing a dermatological product that may be competitive with other products currently in development or commercial sale by Bayer regardless of the perceived benefits or advantages of the microbial strain;
- Pharmaceutical regulations vary by country and, depending on Bayer's marketing plans for the product based on our microbial strain, the pharmaceutical regulations in countries to be targeted by Bayer may render the clinical development of the product to be too expensive, time consuming or at risk for regulatory approval;
- Bayer's internal budgetary and product development issues, including their ability to commit the capital and human resources towards the development and commercialization of our microbial strain; and
- Bayer's willingness to accept our requirements for upfront fees and ongoing royalties.

In addition, we believe that in many cases our potential partners or licensee, including Bayer, may engage with us in the early-stage feasibility testing as part of their evaluation of multiple drug and drug delivery options and prior to making any decision or commitment to the development of a new drug product. Consequently, even if our joint development activities with Bayer are successful, for reasons unrelated to the performance of our technology, we may not be able to conclude a licensing agreement with Bayer.

Item 6. Exhibits

Exhibit Number	Description	Method of Filing
1.1	Placement Agency Agreement dated July 23, 2024 between the Registrant and Maxim Group LLC	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on July 26, 2024
3.1	Amended and Restated Certificate of Incorporation of the Registrant	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on June 21, 2023
3.2	Second Amended and Restated Bylaws of the Registrant	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on June 21, 2023
3.3	Amendment to Second Amended and Restated Bylaws of the Registrant	Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q filed on August 12, 2024
4.1	Form of Class A Warrant	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on July 26, 2024
4.2	Form of Placement Agent Warrant	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on July 26, 2024
4.3	Warrant Agent Agreement dated July 25, 2024 between the Registrant and VStock Transfer LLC	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on July 26, 2024
10.1	Form of Securities Purchase Agreement between the Registrant	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on July 26, 2024
31.1	Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed electronically herewith
31.2	Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed electronically herewith
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).	Filed electronically herewith
101 INS	Inline XBRL Instance Document.	Filed electronically herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	Filed electronically herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	Filed electronically herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	Filed electronically herewith

101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	Filed electronically herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	Filed electronically herewith
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	Filed electronically herewith

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AZITRA, INC.

Date: November 12, 2024

By: /s/ Francisco D. Salva

Francisco D. Salva,
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2024

By: /s/ Norman Staskey

Norman Staskey
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATIONS

I, Francisco D. Salva, certify that:

(1) I have reviewed this Form 10-Q of Azitra, Inc. (the "Company");

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

(4) The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d- 15(f)) for the company and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; And

(5) The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

AZITRA, INC.

November 12, 2024

By: */s/ Francisco D. Salva*

Francisco D. Salva, Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Norman Staskey, certify that:

(1) I have reviewed this Form 10-Q of Azitra, Inc. (the "Company");

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

(4) The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d- 15(f)) for the company and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; And

(5) The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

AZITRA, INC.

November 12, 2024

By: */s/ Norman Staskey*

Norman Staskey, Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Azitra, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Francisco D. Salva, the Chief Executive Officer, and Norman Staskey, the Chief Financial Officer, of the Company, respectively, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: */s/ Francisco D. Salva* November 12, 2024
Francisco D. Salva,
Title: President and Chief Executive Officer

By: */s/ Norman Staskey* November 12, 2024
Norman Staskey,
Title: Chief Financial Officer

This certification is made solely for the purposes of 18 U.S.C. Section 1350, subject to the knowledge standard contained therein, and not for any other purpose.