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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2024

Or

☐ 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: 001-36333

Bio-Path Holdings, Inc.

(Exact name of registrant as specified in its charter)

Delaware	87-0652870
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4710 Bellaire Boulevard, Suite 210, Bellaire, Texas	77401
(Address of principal executive offices)	(Zip Code)

(832) 742-1357
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.001 per share	BPTH	The Nasdaq Capital Market

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 (§232.405 of this chapter) during the preceding 12 months (or for 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 ☐
Non-accelerated filer ☒

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 ☒

At August 8, 2024, the Company had 2,552,190 outstanding shares of common stock, par value $0.001 per share.

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "our," "us," "the Company" and "Bio-Path" refer to Bio-Path Holdings, Inc. and its subsidiary. Bio-Path Holdings, Inc.'s wholly-owned subsidiary, Bio-Path, Inc., is sometimes referred to herein as "Bio-Path Subsidiary."

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements can be identified by words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," "project," "goal," "strategy," "future," "likely," "may," "should," "will" and variations of these words and similar references to future periods, although not all forward-looking statements contain these identifying words. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent risks, uncertainties and changes in circumstances, including those discussed in "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and in other reports or documents we file with the U.S. Securities and Exchange Commission ("SEC"). As a result, our actual results and financial condition may differ materially from those expressed or forecasted in the forward-looking statements, and you should not rely on such forward-looking statements. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following:

- our lack of significant revenue to date, our history of recurring operating losses and our expectation of future operating losses;
- our need for substantial additional capital and our need to delay, reduce or eliminate our drug development and commercialization efforts if we are unable to raise additional capital;
- the highly-competitive nature of the pharmaceutical and biotechnology industry and our ability to compete effectively;
- the success of our plans to use collaboration arrangements to leverage our capabilities;
- our ability to retain and attract key personnel;
- the risk of misconduct of our employees, agents, consultants and commercial partners;
- disruptions to our operations due to expansions of our operations;
- the costs we would incur if we acquire or license technologies, resources or drug candidates;
- risks associated with product liability claims;
- our reliance on information technology systems and the liability or interruption associated with cyber-attacks or other breaches of our systems;
- our ability to use net operating loss carryforwards;
- provisions in our charter documents and state law that may prevent a change in control;
- work slowdown or stoppage at government agencies could negatively impact our business;
- the impact, risks and uncertainties related to global pandemics, including the COVID-19 pandemic, and actions taken by governmental authorities or others in connection therewith;
- our need to complete extensive clinical trials and the risk that we may not be able to demonstrate the safety and efficacy of our drug candidates;
- risks that our clinical trials may be delayed or terminated;
- our ability to obtain domestic and/or foreign regulatory approval for our drug candidates;
- changes in existing laws and regulations affecting the healthcare industry;
- our reliance on third parties to conduct clinical trials for our drug candidates;
- our ability to maintain orphan drug exclusivity for our drug candidates;
- our reliance on third parties for manufacturing our clinical drug supplies;
- risks associated with the manufacture of our drug candidates;
- our ability to establish sales and marketing capabilities relating to our drug candidates;
- market acceptance of our drug candidates;
- third-party payor reimbursement practices;

- our ability to adequately protect the intellectual property of our drug candidates;
- infringement on the intellectual property rights of third parties;
- costs and time relating to litigation regarding intellectual property rights;
- our ability to adequately prevent disclosure by our employees or others of trade secrets and other proprietary information;
- our need to raise additional capital;
- the volatility of the trading price of our common stock;
- our common stock being thinly traded;
- our ability to issue shares of common or preferred stock without approval from our stockholders;
- our ability to pay cash dividends;
- costs and expenses associated with being a public company;
- our ability to maintain effective internal controls over financial reporting; and
- our ability to regain and maintain compliance with the listing standards of the Nasdaq Capital Market.

Please also refer to "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of the fiscal year ended December 31, 2023, "Item 1A. Risk Factors" to Part II of this Quarterly Report on Form 10-Q and other reports or documents we file with the SEC for a discussion of risks and factors that could cause our actual results and financial condition to differ materially from those expressed or forecasted in this Quarterly Report on Form 10-Q.

Any forward-looking statement made by us in this Quarterly Report on Form 10-Q is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise. However, you should carefully review the risk factors set forth in other reports or documents we file from time to time with the SEC.

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PART I – FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

	As of June 30, 2024 (unaudited)	As of December 31, 2023
Assets		
Current assets		
Cash	$ 4,006	$ 1,052
Prepaid drug product	274	632
Other current assets	739	1,358
Total current assets	5,019	3,042
Fixed assets		
Furniture, fixtures & equipment	1,120	1,120
Less accumulated depreciation	(1,072)	(1,044)
	48	76
Right of use operating assets	51	102
Total Assets	$ 5,118	$ 3,220
Liabilities & Shareholders' Equity		
Current liabilities		
Accounts payable	$ 766	$ 457
Accrued expenses	2,189	1,346
Current portion of lease liabilities	55	103
Total current liabilities	3,010	1,906
Warrant liability	817	863
Noncurrent lease liabilities	—	10
Total Liabilities	3,827	2,779
Shareholders' equity		
Preferred stock, $.001 par value; 10,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $.001 par value; 200,000 shares authorized; 2,283 and 618 shares issued and outstanding, respectively	2	1
Additional paid in capital	113,922	108,047
Accumulated deficit	(112,633)	(107,607)
Total shareholders' equity	1,291	441
Total Liabilities & Shareholders' Equity	$ 5,118	$ 3,220

SEE ACCOMPANYING NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses				
Research and development	$ 1,873	$ 3,051	$ 4,161	$ 7,040
General and administrative	1,165	1,191	2,572	2,494
Total operating expenses	3,038	4,242	6,733	9,534
Net operating loss	$ (3,038)	$ (4,242)	$ (6,733)	$ (9,534)
Other income				
Change in fair value of warrant liability	1,163	—	1,701	—
Interest income	6	8	6	27
Total other income	1,169	8	1,707	27
Net loss	$ (1,869)	$ (4,234)	$ (5,026)	$ (9,507)
Net loss per share, basic and diluted	$ (1.16)	$ (10.64)	$ (4.45)	$ (23.89)
Basic and diluted weighted average number of common shares outstanding	1,612	398	1,130	398

SEE ACCOMPANYING NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2024	**2023**
Cash flow from operating activities		
Net loss	$ (5,026)	$ (9,507)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	311	376
Amortization of right of use assets	51	47
Depreciation	28	44
Change in fair value of warrant liability	(1,701)	—
(Increase) decrease in operating assets		
Prepaid drug product	358	2,518
Other current assets	619	(102)
Increase (decrease) in operating liabilities		
Accounts payable and accrued expenses	1,152	(263)
Lease liabilities	(58)	(53)
Net cash used in operating activities	(4,266)	(6,940)
Cash flow from financing activities		
Net proceeds from sale of common stock	7,220	—
Net cash provided by financing activities	7,220	—
Net increase (decrease) in cash	**2,954**	**(6,940)**
Cash, beginning of period	1,052	10,384
Cash, end of period	$ 4,006	$ 3,444

SEE ACCOMPANYING NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(in thousands)
(Unaudited)

Description	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total
Balance at March 31, 2023	**398**	**$ 1**	**$ 105,908**	**$ (96,802)**	**$ 9,107**
Stock-based compensation	—	—	170	—	170
Net loss	—	—	—	(4,234)	(4,234)
Balance at June 30, 2023	**398**	**$ 1**	**$ 106,078**	**$ (101,036)**	**$ 5,043**
Balance at March 31, 2024	**754**	**$ 1**	**$ 108,138**	**$ (110,764)**	**$ (2,625)**
Issuance of common stock and warrants, net of fees and warrant liability	1,529	1	5,643	—	5,644
Stock-based compensation	—	—	141	—	141
Net loss	—	—	—	(1,869)	(1,869)
Balance at June 30, 2024	**2,283**	**$ 2**	**$ 113,922**	**$ (112,633)**	**$ 1,291**

Description	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total
Balance at December 31, 2022	**398**	**$ 1**	**$ 105,702**	**$ (91,529)**	**$ 14,174**
Stock-based compensation	—	—	376	—	376
Net loss	—	—	—	(9,507)	(9,507)
Balance at June 30, 2023	**398**	$ **1**	**$ 106,078**	**$ (101,036)**	**$ 5,043**
Balance at December 31, 2023	**618**	**$ 1**	**$ 108,047**	**$ (107,607)**	**$ 441**
Issuance of common stock and warrants, net of fees and warrant liability	1,665	1	5,564	—	5,565
Stock-based compensation	—	—	311	—	311
Net loss	—	—	—	(5,026)	(5,026)
Balance at June 30, 2024	**2,283**	$ **2**	**$ 113,922**	**$ (112,633)**	**$ 1,291**

SEE ACCOMPANYING NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.
Notes to the Unaudited Condensed Consolidated Financial Statements

Unless the context requires otherwise, references in these Notes to the Condensed Consolidated Financial Statements to "we," "our," "us," "the Company" and "Bio-Path" refer to Bio-Path Holdings, Inc. and its subsidiary. Bio-Path Holdings, Inc.'s wholly-owned subsidiary, Bio-Path, Inc., is sometimes referred to herein as "Bio-Path Subsidiary."

The accompanying unaudited condensed interim financial statements have been prepared in conformity with the authoritative U.S. generally accepted accounting principles (GAAP) for interim financial information and in accordance with the instructions to Form 10-Q pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") and, therefore, do not include all information and footnotes required by GAAP for complete consolidated financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation of the results of operations and financial position have been included and all such adjustments are of a normal recurring nature. The unaudited quarterly financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Annual Report on Form 10-K of the Company as of and for the fiscal year ended December 31, 2023. The results of operations for the period ended June 30, 2024 are not necessarily indicative of the results for a full-year period.

1. Organization and Business

The Company is a clinical and preclinical stage oncology-focused RNAi nanoparticle drug development company utilizing a novel technology that achieves systemic delivery for target-specific protein inhibition for any gene product that is over-expressed in disease. The Company's drug delivery and antisense technology, called DNAbilize®, is a platform that uses P-ethoxy, which is a deoxyribonucleic acid (DNA) backbone modification that is intended to protect the DNA from destruction by the body's enzymes when circulating *in vivo,* incorporated inside of a lipid bilayer having neutral charge. The Company believes this combination allows for high efficiency loading of antisense DNA into non-toxic, cell-membrane-like structures for delivery of the antisense drug substance into cells. *In vivo,* the DNAbilize® delivered antisense drug substances are systemically distributed throughout the body to allow for reduction or elimination of target proteins in blood diseases and solid tumors. Through testing in numerous animal studies and dosing in clinical trials, the Company's DNAbilize® drug candidates have demonstrated an excellent safety profile. DNAbilize® is a registered trademark of the Company. Using DNAbilize® as a platform for drug development and manufacturing, the Company currently has four antisense drug candidates in development to treat at least five different cancer disease indications.

The Company was incorporated in May 2000 as a Utah corporation. In February 2008, Bio-Path Subsidiary completed a reverse merger with the Company, which at the time was traded over the counter and had no current operations. The prior name of the Company was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path Subsidiary became the directors and officers of Bio-Path Holdings, Inc. Effective December 31, 2014, the Company changed its state of incorporation from Utah to Delaware through a statutory conversion pursuant to the Utah Revised Business Corporation Act and the Delaware General Corporation Law.

The Company's operations to date have been limited to organizing and staffing the Company, acquiring, developing and securing its technology and undertaking product development for a limited number of product candidates. As the Company has not begun its planned principal operations of commercializing a product candidate, the Company's activities are subject to significant risks and uncertainties, including the potential requirement to secure additional funding, the outcome of the Company's clinical trials and failing to operationalize the Company's current drug candidates before another company develops similar products.

2. Significant Accounting Policies

Net Loss Per Share – Basic net loss per common share is computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding during the period. Although there were warrants and stock options outstanding as of June 30, 2024 and 2023, no potential common shares are included in the computation of any diluted per share amount, as they would be antidilutive. Consequently, diluted net loss per share as presented in the condensed consolidated financial statements is equal to basic net loss per share for the three and six months ended June 30, 2024 and 2023. The calculation of diluted earnings per share for 2024 did not include 43,393 shares and 5,848,679 shares issuable pursuant to the exercise of outstanding common stock options and warrants, respectively, as of June 30, 2024 as the effect would be antidilutive. The calculation of diluted earnings per share for 2023

did not include 878,408 shares and 1,200,531 shares issuable pursuant to the exercise of outstanding common stock options and warrants, respectively, as of June 30, 2023 as the effect would be antidilutive.

Liquidity - The Company's available cash and cash equivalents of $4.0 million at June 30, 2024 will not be sufficient to fund liquidity and capital expenditure requirements for the next 12 months from the date of issuance of these consolidated financial statements. Therefore, substantial doubt exists about the Company's ability to continue as a going concern. The Company expects to continue to incur significant operating expenses for the foreseeable future in connection with its ongoing activities, including conducting clinical trials, manufacturing development and seeking regulatory approval of its drug candidates, prexigebersen, BP1002, BP1003 and BP-1001A. Accordingly, the Company will continue to require substantial additional capital to fund its projected operating requirements. Such additional capital may not be available when needed or on terms favorable to the Company. In addition, the Company may seek additional capital due to favorable market conditions or strategic considerations, even if it believes it has sufficient funds for its current and future operating plan. There can be no assurance that the Company will be able to continue to raise additional capital through the sale of securities in the future. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations, financial condition and future prospects.

Warrants - The Company determines whether warrants should be classified as a liability or equity. For warrants classified as liabilities, the Company estimates the fair value of the warrants at each reporting period using Level 3 inputs with changes in fair value recorded in the Condensed Consolidated Statement of Operations as change in fair value of warrant liability. The estimates in valuation models are based, in part, on subjective assumptions, including but not limited to stock price volatility, the expected life of the warrants, the risk-free interest rate and the fair value of the common stock underlying the warrants, and could differ materially in the future. The Company will continue to adjust the fair value of the warrant liability at the end of each reporting period for changes in fair value from the prior period until the earlier of the exercise or expiration of the applicable warrant.

Fair Value - The fair values of cash and cash equivalents, accounts payable and accrued liabilities approximate their carrying values because of the short-term maturities of these instruments.

3. Prepaid Drug Product

Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future clinical development activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. The Company recognized certain expenses and incurred installment costs for its contract drug manufacturing and raw material suppliers with prepayments totaling $0.6 million as of December 31, 2023 pursuant to drug supply contracts for the manufacture and delivery of prexigebersen for testing in a Phase 2 clinical trial. The Company recognized certain expenses during the first six months of 2024, with advanced payments remaining to be expensed totaling $0.3 million as of June 30, 2024.

4. Other Current Assets

As of June 30, 2024, other current assets included prepaid expenses of $0.7 million, comprised primarily of prepayments of $0.7 million made for the Company's clinical trial for BP1001-A in solid tumors. As of December 31, 2023, other current assets included prepaid expenses of $1.4 million, comprised primarily of prepayments of $0.9 million made for the Company's clinical trials for BP1002 in AML and lymphoma and BP1001-A in solid tumors as well as prepaid insurance of $0.3 million, prepaid Delaware franchise tax of $0.1 million and other prepaid expenses of $0.1 million.

5. Accounts Payable

As of June 30, 2024, current liabilities included accounts payable of $0.8 million, comprised primarily of expenses related to clinical trial expenses of $0.6 million, legal and patent fees of $0.1 million and other accounts payables of $0.1 million. As of December 31, 2023, current liabilities included accounts payable of $0.5 million, comprised primarily of expenses related to clinical trial expenses of $0.3 million, legal and patent fees of $0.1 million and other accounts payables of $0.1 million.

6. Accrued Expense

As of June 30, 2024, current liabilities included accrued expenses of $2.2 million, comprised primarily of accrued clinical trial expenses of $1.5 million, employee vacation and bonus expenses of $0.3 million, expenses related to the Company's recent financing activity of $0.2 million, legal and patent fees of $0.1 million and other accrued expenses of $0.1 million. As of December 31, 2023, current liabilities included accrued expenses of $1.3 million, comprised primarily of expenses related to the Company's clinical trial for prexigebersen in AML of $0.8 million, accrued employee vacation and bonus expenses of $0.2 million, professional and consulting fees of $0.1 million, legal and patent fees of $0.1 million and other accrued expenses of $0.1 million.

7. Warrant Liability

In connection with the 2023 Public Offering, the 2024 March Registered Direct Offering and the 2024 April Registered Direct Offering (each as defined below), the Company issued the 2023 Warrants, the March 2024 Private Placement warrants and the April 2024 Private Placement warrants (each as defined below, collectively, the "Warrants"). The Warrants contain a provision applicable in the event of a fundamental transaction whereby the volatility used to calculate the warrant exercise terms is fixed and meets the definition of a derivative.

Due to this provision and in accordance with ASC 815 Derivatives and Hedging, the Warrants were classified as a liability and recorded at fair value using the Black-Scholes valuation model. The estimated fair value of the warrant liability for the 2023 Warrants as of December 31, 2023, was $0.9 million. The estimated fair value of the warrant liability for the March 2024 Private Placement warrants on the closing date of the March 2024 Registered Direct Offering, March 27, 2024, was $0.3 million. The estimated fair value of the warrant liability for the April 2024 Private Placement warrants on the closing date of the April 2024 Registered Direct Offering, April 19, 2024, was $1.4 million. As of June 30, 2024, the fair value of the total warrant liability was $0.8 million. The net change in fair value for the three and six months ended, June 30, 2024 was $1.2 million and $1.7 million, respectively, and are shown as other income on the Company's Condensed Consolidated Statements of Operations. The Company will continue to measure the fair value of the Warrants each quarter until they are exercised or expire, and any change will be adjusted accordingly on the Company's financial statements.

8. Fair Value Measurements

In accordance with ASC 820, the Company uses various inputs to measure the Warrants on a recurring basis to determine the fair value of the liability. ASC 820 also establishes a hierarchy categorizing inputs into three levels used to measure and disclose fair value. The hierarchy gives the highest priority to quoted prices available in active markets and the lowest priority to unobservable inputs. An explanation of each level in the hierarchy is described below:

Level 1 – Unadjusted quoted prices in active markets for identical instruments that are accessible by the Company on the measurement date

Level 2 – Quoted prices in markets that are not active or inputs which are either directly or indirectly observable

Level 3 – Unobservable inputs for the instrument requiring the development of assumptions by the Company

The following table summarizes the Company's Warrants measured at fair value within the hierarchy on a recurring basis as of June 30, 2024:

	Fair Value Measurements at June 30, 2024 (in thousands)			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities:				
Warrant liability	$ —	$ —	$ 817	$ 817

The following table summarizes the Company's 2023 Warrants measured at fair value within the hierarchy on a recurring basis as of December 31, 2023:

	Fair Value Measurements at December 31, 2023 (in thousands)			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Warrant liability	$ —	$ —	$ 863	$ 863

The following table summarizes changes to the fair value of the Level 3 Warrants for the six months ended June 30, 2024:

	Fair Value of Warrant Liability (in thousands)
Balance at December 31, 2023	$ 863
Issuance	1,655
Change in fair value	(1,701)
Balance at June 30, 2024	$ 817

The Company utilized the Black-Scholes valuation model for estimating the fair value of the Warrants using the following assumptions as of June 30, 2024:

	As of June 30, 2024
Risk-free interest rate	4.35 %
Expected volatility	108 %
Expected term in years	4.6
Dividend yield	— %

9. Stockholders' Equity

Issuances of Common Stock - On August 3, 2023, the Company entered into a placement agency agreement with Roth Capital Partners, LLC relating to a best efforts public offering of an aggregate of 3,500,000 shares of its common stock, together with warrants to purchase up to 3,500,000 shares of its common stock (the "2023 Warrants"), for gross proceeds of approximately $2.1 million (the "2023 Public Offering"). The 2023 Public Offering was made pursuant to a registration statement on Form S-1, as amended (File No. 333-272879), which was declared effective by the SEC on August 2, 2023. The 2023 Public Offering closed on August 7, 2023. The net proceeds from the offering, after deducting the placement agent's fees and expenses and the Company's offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offering, were approximately $1.7 million.

On March 25, 2024, the Company entered into a securities purchase agreement with a certain institutional and accredited investor pursuant to which the Company agreed to sell, in a registered direct offering, an aggregate of 75,000 shares of its common stock for gross proceeds of approximately $0.3 million under the base prospectus contained in the 2022 Shelf Registration Statement and a

related prospectus supplement filed with the SEC on March 27, 2024 (the "March 2024 Registered Direct Offering"). In a concurrent private placement, the Company also agreed pursuant to the securities purchase agreement to issue to such investor warrants to purchase up to 75,000 shares of its common stock at an exercise price of $3.865 per share (the "March 2024 Private Placement"). The March 2024 Registered Direct Offering and the March 2024 Private Placement closed on March 27, 2024. The net proceeds from the offerings, after deducting the placement agent's fees and expenses and the Company's offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $0.2 million.

On April 4, 2024, the Company entered into the At The Market Offering Agreement with Wainwright, as sales agent, pursuant to which the Company may offer and sell, from time to time, through Wainwright, shares of its common stock. Under the At The Market Offering Agreement, Wainwright may sell shares by any method deemed to be an "at the market" offering as defined in Rule 415 under the Securities Act, as amended, or any other method permitted by law, including in privately negotiated transactions. The Company or Wainwright may suspend or terminate the offering of shares upon notice to the other party and subject to other conditions. The Company will pay Wainwright a commission of 3.0% of the aggregate gross proceeds from each sale of shares under the At The Market Offering Agreement and have agreed to provide Wainwright with customary indemnification and contribution rights. The Company has also agreed to reimburse Wainwright for certain specified expenses. The Company is subject to certain restrictions on its ability to offer and sell shares of its common stock under the At The Market Offering Agreement. On April 4, 2024, in connection with the execution of the At The Market Offering Agreement, the Company filed with the SEC a prospectus supplement (the "Initial ATM Prospectus Supplement") to the base prospectus contained in the 2022 Shelf Registration Statement, which Initial ATM Prospectus Supplement related to the offering of up to $2.0 million of shares of the Company's common stock under the At The Market Offering Agreement. Subsequent to entering into the Offering Agreement, the Company offered and sold 436,511 shares of common stock for gross proceeds of approximately $2.0 million and terminated the offering under the Initial ATM Prospectus Supplement on April 19, 2024. The net proceeds from such offering, after deducting commissions and its offering expenses, were approximately $1.8 million.

On April 18, 2024, the Company entered into a securities purchase agreement with certain institutional and accredited investors pursuant to which the Company agreed to sell, in a registered direct offering, an aggregate of 375,000 shares of its common stock for gross proceeds of approximately $1.2 million under the base prospectus contained in the 2022 Shelf Registration Statement and a related prospectus supplement filed with the SEC on April 19, 2024 (the "April 2024 Registered Direct Offering"). In a concurrent private placement, the Company also agreed pursuant to the securities purchase agreement to issue to such investors warrants to purchase up to 375,000 shares of its common stock at an exercise price of $3.10 per share (the "April 2024 Private Placement"). The April 2024 Registered Direct Offering and the April 2024 Private Placement closed on April 19, 2024. The net proceeds from the offerings, after deducting the placement agent's fees and expenses and the Company's offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $0.9 million.

On April 19, 2024, the Company determined to increase the number of shares available for sale under the At The Market Offering Agreement, up to an additional aggregate offering price of approximately $1.1 million, which shares are being offered and sold pursuant to the 2022 Shelf Registration Statement and a prospectus supplement and accompanying prospectus filed with the SEC on April 19, 2024 (the "Subsequent ATM Prospectus Supplement"). As of June 30, 2024, the Company has offered and sold 334,929 shares of common stock under the Subsequent ATM Prospectus Supplement for gross proceeds of approximately $1.1 million. The net proceeds from such offering, after deducting commissions and the Company's offering expenses, were approximately $1.0 million.

On June 3, 2024, the Company entered into a securities purchase agreement with a certain institutional and accredited investor pursuant to which the Company agreed to sell, in a private placement, an aggregate of (i) 180,000 shares of its common stock, (ii) pre-funded warrants to purchase up to 1,629,955 shares of its common stock at an exercise price of $0.001 per share, (iii) series A warrants to purchase up to 1,809,955 shares of its common stock at an exercise price of $2.00 per share and (iv) series B warrants to purchase up to 1,809,955 shares of its common stock at an exercise price of $2.00 per share for gross proceeds of approximately $4.0 million (the "June 2024 PIPE"). The June 2024 PIPE closed on June 5, 2024. The net proceeds from the offering, after deducting the placement agent's fees and expenses and the Company's offering expenses, and excluding the proceeds, if any, from the exercises of the warrants issued in the offering, were approximately $3.3 million.

Stockholders' Equity totaled $1.3 million as of June 30, 2024 compared to $0.4 million as of December 31, 2023. There were 2,283,190 shares of common stock issued and outstanding as of June 30, 2024. There were no shares of preferred stock issued and outstanding as of June 30, 2024.

10. Stock-Based Compensation Plan

The 2022 Plan – On December 15, 2022, the Company's stockholders approved the Bio-Path Holdings, Inc. 2022 Stock Incentive Plan (the "2022 Plan"), which replaced the 2017 Stock Incentive Plan, as amended (the "2017 Plan," and together with the 2022 Plan, the "Plans"). As of stockholder approval of the 2022 Plan on December 15, 2022, no further awards will be made under the 2017 Plan. The 2022 Plan provides for the grant of Incentive Stock Options, Non-Qualified Stock Options, Restricted Shares, Restricted Share Units, Stock Appreciation Rights and other stock-based awards, or any combination of the foregoing, to the Company's employees, non-employee directors and consultants. As of December 31, 2023, there were 65,000 shares of common stock reserved for future issuance of awards under the 2022 Plan. Under the 2022 Plan, the exercise price of awards is determined by the Board of Directors or the compensation committee of the Board of Directors, and for options, may not be less than the fair market value as determined by the closing stock price at the date of the grant. Each option and award under the 2022 Plan shall vest and expire as determined by the Board of Directors or the compensation committee. Options expire no later than ten years from the date of grant. All grants provide for accelerated vesting if there is a change in control, as defined in the 2022 Plan.

Stock-based compensation expense for the three months ended June 30, 2024 and 2023 was $0.1 million and $0.2 million, respectively. Of these amounts, stock-based compensation expense for personnel involved in the Company's general and administrative activities for each of the three months ended June 30, 2024 and 2023 was $0.1 million. Stock-based compensation expense for personnel involved in the Company's research and development activities for the three months ended June 30, 2024 and 2023 was $40,000 and $43,000, respectively.

Stock-based compensation expense for the six months ended June 30, 2024 and 2023 was $0.3 million and $0.4 million, respectively. Of these amounts, stock-based compensation expense for personnel involved in the Company's general and administrative activities for the six months ended June 30, 2024 and 2023 was $0.2 million and $0.3 million, respectively. Stock-based compensation expense for personnel involved in the Company's research and development activities for each of the six months ended June 30, 2024 and 2023 was $0.1 million.

The Company utilized the Black-Scholes valuation model for estimating the fair value of the stock options granted. There were no options granted in the six months ended June 30, 2024 and 2023.

The following summary represents option activity under the Company's stock-based compensation plans for the six months ended June 30, 2024:

	Options (in thousands)	Weighted-Average Exercise Price
Outstanding at December 31, 2023	43	$ 161.20
Outstanding at June 30, 2024	43	$ 157.54
Vested and expected to vest June 30, 2024	43	$ 158.50
Exercisable at June 30, 2024	31	$ 196.82

As of June 30, 2024, outstanding stock options did not have any aggregate intrinsic value. The aggregate intrinsic value represents the total pretax intrinsic value (the difference between the Company's closing stock price on June 30, 2024 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on June 30, 2024. This amount changes based on the fair value of the Company's stock.

As of June 30, 2024, unamortized stock-based compensation expense for all outstanding options was $0.6 million, which is expected to be recognized over a weighted average vesting period of 1.5 years.

11. Commitments and Contingencies

Drug Supplier Project Plan – Total commitments for the Company's drug supplier project plan were $0.2 million as of June 30, 2024, comprised of $0.1 million for testing services and $0.1 million for manufacturing development. The Company expects to incur $0.1 million of these commitments over the next 12 months.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

When you read this Item of this Quarterly Report on Form 10-Q, it is important that you also read the unaudited financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto included in our Annual Report on Form 10-K as of the fiscal year ended December 31, 2023. This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. We use words such as "anticipate," "estimate," "plan," "project," "continuing," "ongoing," "expect," "believe," "intend," "may," "will," "should," "could," and similar expressions to identify forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the matters discussed in "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of the fiscal year ended December 31, 2023, the matters discussed in "Item 1A. Risk Factors" to Part II of this Quarterly Report on Form 10-Q and other risks and uncertainties discussed in filings made with the SEC. See "Cautionary Note Regarding Forward-Looking Statements" in this Quarterly Report on Form 10-Q for additional discussion regarding risks associated with forward-looking statements.

Overview

We are a clinical and preclinical stage oncology-focused RNAi nanoparticle drug development company utilizing a novel technology that achieves systemic delivery for target-specific protein inhibition for any gene product that is over-expressed in disease. Our drug delivery and antisense technology, called DNAbilize®, is a platform that uses P-ethoxy, which is a deoxyribonucleic acid (DNA) backbone modification that is intended to protect the DNA from destruction by the body's enzymes when circulating in vivo, incorporated inside of a lipid bilayer having neutral charge. We believe this combination allows for high efficiency loading of antisense DNA into non-toxic, cell-membrane-like structures for delivery of the antisense drug substance into cells. In vivo, the DNAbilize® delivered antisense drug substances are systemically distributed throughout the body to allow for reduction or elimination of target proteins in blood diseases and solid tumors. Through testing in numerous animal studies and dosing in clinical trials, our DNAbilize® drug candidates have demonstrated an excellent safety profile. DNAbilize® is a registered trademark of the Company.

Using DNAbilize® as a platform for drug development and manufacturing, we currently have four drug candidates in development to treat at least five different cancer disease indications. Our lead drug candidate, prexigebersen (pronounced prex" i je ber' sen), which targets growth factor receptor-bound protein 2 ("Grb2"), initially started the efficacy portion of a Phase 2 clinical trial for untreated acute myeloid leukemia ("AML") patients in combination with low-dose cytarabine ("LDAC"). The interim data presented in the 2018 American Society of Hematology ("ASH") Annual Meeting showed that 11 (65%) of the 17 evaluable patients had a response, including five (29%) who achieved complete remission ("CR"), inclusive of one CR with incomplete hematologic recovery ("CRi") and one morphologic leukemia-free state, and six (35%) stable disease responses, including two patients who had greater than a 50% reduction in bone marrow blasts. However, DNA hypomethylating agents are now the most frequently used agents in the treatment of elderly AML patients in the U.S. and Europe. As a result, Stage 2 of the Phase 2 trial in AML was amended to remove the combination treatment of prexigebersen and LDAC and replace it with the combination treatment of prexigebersen and decitabine, a DNA hypomethylating agent, for treatment of a second cohort of untreated AML patients. Since decitabine is also used as a treatment for relapsed/refractory AML patients, a cohort of relapsed/refractory AML patients was also added to the study.

The U.S. Food and Drug Administration ("FDA") granted approval of venetoclax in combination with LDAC, decitabine or azacytidine (the latter two drugs are DNA hypomethylating agents) as frontline therapy for newly diagnosed AML in adults who are 75 years or older, or who have comorbidities precluding intensive induction chemotherapy. We believe this approval of the frontline venetoclax and decitabine combination therapy provides an opportunity for combining prexigebersen with the combination therapy for the treatment of newly diagnosed AML patients. Preclinical efficacy studies for the triple combination treatment of prexigebersen, decitabine and venetoclax in AML have been successfully completed. In the preclinical efficacy studies, four AML cancer cell lines were treated with three different combinations of decitabine, venetoclax and prexigebersen. Decrease in AML cell viability was the primary measure of efficacy. The triple combination of decitabine, venetoclax and prexigebersen showed significant improvement in efficacy in three of the four AML cell lines. Based on these results, we believe that adding prexigebersen to the treatment combination of decitabine and venetoclax could lead to improved efficacy in AML patients. Accordingly, we further amended Stage 2 of this Phase 2 clinical trial to add the triple combination treatment comprised of prexigebersen, decitabine and venetoclax.

Our approved amended Stage 2 for this Phase 2 clinical trial currently has three cohorts of patients. The first two cohorts will treat patients with the triple combination of prexigebersen, decitabine and venetoclax. The first cohort will include newly diagnosed

AML patients, and the second cohort will include relapsed/refractory AML patients. Finally, the third cohort will treat relapsed/refractory AML patients, who are venetoclax-resistant or -intolerant, with the two-drug combination of prexigebersen and decitabine. The full trial design plans have approximately 98 evaluable patients for the first cohort having newly diagnosed AML patients with a preliminary review performed after 19 evaluable patients and a formal interim analysis after 38 evaluable patients. The full trial design plans have approximately 54 evaluable patients for each of the second cohort, having relapsed/refractory AML patients, and the third cohort, having AML patients who are venetoclax-resistant or -intolerant, in each case with a review performed after 19 evaluable patients. The study is anticipated to be conducted at up to ten clinical sites in the U.S., and Gail J. Roboz, MD, is the national coordinating Principal Investigator for the Phase 2 trial. Dr. Roboz is a professor of medicine and director of the Clinical and Translational Leukemia Program at the Weill Medical College of Cornell University (the "Weill Medical College") and the New York-Presbyterian Hospital in New York City. On August 13, 2020, we announced the enrollment and dosing of the first patient in this approved amended Stage 2 of the Phase 2 clinical trial.

The safety run-in of Stage 2 of the Phase 2 clinical study was successfully completed, and the preliminary data was presented at the 2021 ASH Annual Meeting. In the safety run-in of the triple combination, six evaluable patients were treated with the combination of prexigebersen, decitabine and venetoclax. These patients included four relapsed/refractory AML patients, and two newly diagnosed AML patients. Five patients (83%) responded to treatment, including four (67%) achieving CR/CRi/MLFS and one (17%) achieving partial remission ("PR"). Recent publications provide that response (CR + CRi) rates to combination treatment with decitabine and venetoclax (but without prexigebersen) are 12 to 52% for relapsed/refractory AML patients, depending on the length of treatment (12% for patients treated with venetoclax in combination with decitabine for five days and 42% to 52% for patients treated with venetoclax in combination with decitabine for 10 days), and 0 to 39% for relapsed/refractory secondary AML patients. Response rates to frontline treatment with decitabine and venetoclax (but without prexigebersen) are 54 to 74% for newly diagnosed AML patients. These preliminary data showed the treatment was well-tolerated and there were no dose limiting toxicities attributed to prexigebersen. Three patients remained on treatment for more than one cycle.

On August 1, 2023, we announced interim data for the first two cohorts of the amended Stage 2 of the Phase 2 clinical trial. Fourteen newly diagnosed patients were evaluable in the first cohort and treated with at least one cycle of the prexigebersen, decitabine and venetoclax combination therapy. All patients in the first cohort (median age 75) were adverse risk by 2017 European LeukemiaNet ("ELN") guidelines (n=10) or secondary AML (n=4). Prexigebersen was well-tolerated, and adverse events ("AEs") were generally consistent with decitabine and venetoclax treatment and/or for AML. Twelve of the 14 evaluable patients (86%) achieved CR/CRi and two (14%) achieved PR. In total, 100% of the evaluable patients had a response to treatment. The CR/CRi rate of 86% for the evaluable patients in the first cohort is significantly higher than the range of CR/CRi rates of 54 to 74% for newly diagnosed patients treated with the frontline combination treatment of decitabine and venetoclax from the publications described above. Fourteen refractory/relapsed evaluable AML patients in the second cohort were treated with at least one cycle of the prexigebersen, decitabine and venetoclax combination therapy. Substantially all of the patients in the second cohort (median age 56.5) were adverse risk by 2017 ELN guidelines (n=11) or secondary AML (n=2). Prexigebersen was well-tolerated, and AEs were generally consistent with decitabine and venetoclax treatment and/or for AML. Eight of the 14 evaluable refractory/relapsed patients (57%) achieved CR/CRi, two (14%) achieved PR and two (22%) achieved stable disease. In total, 93% of the evaluable patients in the second cohort had a response to treatment. The CR/CRi rate of 57% for the evaluable refractory and relapsed patients in the second cohort is significantly higher than the range of CR/CRi rates of 12 to 52% for refractory/relapsed patients treated with the combination treatment of decitabine and venetoclax from the publications described above.

On June 3, 2024, we announced additional interim data for the first two cohorts of the amended Stage 2 of the Phase 2 clinical trial. In Cohort 1, 31 newly diagnosed patients were enrolled; 20 evaluable patients with a median age of 75 years, treated with at least one cycle of prexigebersen, decitabine and venetoclax, had adverse-risk or secondary AML evolved from myelodysplastic syndromes, chronic myelomonocytic leukemia or treatment-related AML. Fifteen patients (75%) achieved complete remission, CR with partial recovery of peripheral blood counts ("CRh"), or CRi. Two patients achieved PR and two patients achieved stable disease. In Cohort 2, 38 relapsed/refractory patients were enrolled; 23 evaluable patients with a median age of 63 years, treated with at least one cycle of prexigebersen, decitabine and venetoclax, had adverse-risk or secondary AML. Twelve patients (55%) achieved CR/CRi/CRh, one patient achieved PR, eight patients achieved stable disease and one patient had treatment failure. Among the evaluable patients of both cohorts, adverse events were consistent with those expected with decitabine and venetoclax and/or AML, including fatigue (72%), anemia (60%) and neutropenia (49%), while the most frequent severe adverse events were febrile neutropenia (26%) and sepsis (5%). The interim analysis data was selected as an oral presentation in the 2024 American Society of Clinical Oncology ("ASCO") Annual Meeting and as a poster presentation in the 2024 European Hematology Association ("EHA") Annual Meeting. Based on this interim data, we expect to continue enrollment of up to 98 and 54 evaluable patients for Cohorts 1 and

2, respectively and plan to pursue FDA expedited programs for Fast Track designation. We are evaluating whether to seek to expand Stage 2 of the Phase 2 clinical trial in Europe.

On July 8, 2024, we announced that the study is currently paused for an interim analysis, amendment preparation and FDA review. We expect to complete enrollment in cohorts 1 and 2 of the study over the next eighteen months.

Grb2 is involved in activating the RAS/ERK pathway for cell growth. By blocking the cell's ability to produce Grb2, prexigebersen treatment may limit cell growth. In obesity, two such pathways are related to leptin and insulin. Activation of leptin or insulin receptors can stimulate the RAS/ERK pathway via Grb2. We believe development of prexigebersen for the treatment for obesity and obesity-related cancers could be accelerated given the large amount of safety data from prexigebersen treatment of leukemia patients and the continued unmet medical need. The Company is preparing for preclinical development evaluating prexigebersen for the treatment of obesity and will continue thereafter to conduct additional IND-enabling studies with an aim to advance prexigebersen into first-in-human studies in this indication.

Our second drug candidate, Liposomal Bcl-2 ("BP1002"), targets the protein Bcl-2, which is responsible for driving cell survival in up to 60% of all cancers. A Phase 1 clinical trial to evaluate the ability of BP1002 to treat refractory/relapsed lymphoma and refractory/relapsed chronic lymphocytic leukemia ("CLL") patients has been initiated. The Phase 1 clinical trial is being conducted at the Georgia Cancer Center, The University of Texas Southwestern and New York Medical College. On January 10, 2024, we announced the successful completion of the first dose cohort in the Phase 1 clinical trial. A total of six evaluable patients are scheduled to be treated over two dose levels with BP1002 monotherapy in a standard 3+3 design, unless there is a dose limiting toxicity which would require an additional three patients to be tested. There were no dose limiting toxicities in the first dose cohort (20 mg/m^2). Enrollment has continued for patients in the second BP1002 dose cohort of 40 mg/m^2 and we expect to complete enrollment and to review this data by year-end

Additionally, preclinical studies suggest that the combination of BP1002 with decitabine is efficacious in venetoclax-resistant leukemia and lymphoma cells. An abstract of the preclinical study was presented at the 2021 American Association for Cancer Research ("AACR") Annual Meeting. A Phase 1/1b clinical trial to investigate the ability of BP1002 to treat refractory/relapsed AML patients, including venetoclax-resistant patients, is being studied. A recent study found that AML patients who had relapsed from frontline venetoclax-based treatment had a very poor prognosis, with a median survival of less than three months. Since venetoclax and BP1002 utilize different mechanisms of action, we believe that BP1002 may be a potential treatment for venetoclax-relapsed AML patients. The Phase 1/1b clinical trial is being conducted at several leading cancer centers in the United States, including the Weill Medical College, The University of Texas MD Anderson Cancer Center ("MD Anderson"), Scripps Health and The University of California at Los Angeles Cancer Center. On December 14, 2023, we announced the successful completion of the first dose cohort of the dose escalation portion of the Phase 1/1b clinical trial of BP1002; and on April 18, 2024, we announced the successful completion of the second dose cohort. The testing of these two dose levels is now complete and the clinical trial has paused for a brief data review by the FDA. We are completing an analysis of PK/PD data to be submitted to the FDA in order to advance to the next dose level. Upon submission of data and approval from the FDA, we expect to advance to the next planned higher dose of 60 mg/m^2 in the fourth quarter of 2024. The approved treatment cycle is two doses per week over four weeks, resulting in eight doses administered over twenty-eight days. The Phase 1b portion of the study is expected to commence after completion of BP1002 monotherapy cohorts and will assess the safety and efficacy of BP1002 in combination with decitabine in refractory/relapsed AML patients.

Our third drug candidate, Liposomal STAT3 ("BP1003"), targets the STAT3 protein and is currently in IND enabling studies as a potential treatment of pancreatic cancer, non-small cell lung cancer ("NSCLC") and AML. Preclinical models have shown BP1003 to inhibit cell viability and STAT3 protein expression in NSCLC and AML cell lines. Further, BP1003 successfully penetrated pancreatic tumors ex vivo and significantly enhanced the efficacy of gemcitabine, a treatment for patients with advanced pancreatic cancer, in a pancreatic cancer patient derived tumor model. An abstract of the preclinical study was presented at the 2019 AACR Annual Meeting. Our lead indication for BP1003 is pancreatic cancer due to the severity of this disease and the lack of effective, life-extending treatments. For example, pancreatic adenocarcinoma is projected to be the second most lethal cancer behind lung cancer by 2030. Typical survival for a metastatic pancreatic cancer patient is about three to six months from diagnosis. Additionally, an abstract of the preclinical study demonstrating that BP1003 enhanced the sensitivity of breast and ovarian cancer cells to chemotherapy was presented at the 2022 AACR Annual Meeting. We have successfully completed several IND enabling studies of BP1003 and have one additional IND enabling study to complete. Once the additional study is successfully completed, our goal is to file an IND application and initiate the first-in-humans Phase 1 study of BP1003 in patients with refractory, metastatic solid tumors, including pancreatic cancer and NSCLC.

In addition, a modified product named BP1001-A, our fourth drug candidate, has shown to enhance chemotherapy efficacy in preclinical solid tumor models. Results of the preclinical study were published in the scientific journal Oncotarget in July 2020. BP1001-A incorporates the same drug substance as prexigebersen but has a slightly modified formulation designed to enhance nanoparticle properties. A BP1001-A Phase 1/1b clinical trial in patients with advanced or recurrent solid tumors has been initiated. The Phase 1/1b clinical trial is being conducted at several leading cancer centers in the United States, including MD Anderson, Karmanos Cancer Institute, Mary Crowley Cancer Research and Holy Cross Hospital, Maryland. On July 17, 2023, we announced completion of the first cohort of the dose escalation portion of the Phase 1/1b clinical trial. A total of nine evaluable patients are scheduled to be treated with BP1001-A monotherapy over three dose levels in a standard 3+3 dose escalation design. The first dose cohort consisted of a starting dose of 60 mg/m^2, and there were no dose limiting toxicities. Enrollment is now open for patients for the second dose cohort of 90 mg/m^2 which we expect to be complete by the end of 2024 in order to advance to dose level 3. The Phase 1b portion of the study is expected to commence after successful completion of BP1001-A monotherapy cohorts and is intended to assess the safety and efficacy of BP1001-A in combination with paclitaxel in patients with recurrent ovarian or endometrial tumors. Phase 1b studies are also expected to be opened in combination with gemcitabine in Stage 4 pancreatic cancer and combination therapy in breast cancer.

Our DNAbilize® technology-based products are available for out-licensing or partnering. We intend to apply our drug technology template to new disease-causing protein targets to develop new liposomal antisense drug candidates for inclusion in our pipeline that meet scientific, preclinical and commercial criteria and file new patents on these targets. We expect that these efforts will include collaboration with key scientific opinion leaders in the field of study and include developing drug candidates for diseases other than cancer. As we expand our drug development programs, we will look at indications where a systemic delivery is needed and antisense RNAi nanoparticles can be used to slow, reverse or cure a disease, either alone or in combination with another drug.

We are developing a molecular biomarker package to accompany prexigebersen treatment, the goal of which is to identify patients with a genetic profile more likely to respond to treatment thereby improving probability of success for this program. The emerging role of biomarkers has been enhancing cancer development over the past decade and has become a more common companion to many cancer development programs. We expect to develop molecular biomarker packages to accompany our new programs.

We have certain intellectual property as the basis for our current drug products in clinical development, prexigebersen, BP1002, BP1003 and BP1001-A. We are developing RNAi antisense nanoparticle drug candidates based on our own patented technology to treat cancer and autoimmune disorders where targeting a single protein may be advantageous and result in reduced patient adverse effects as compared to small molecule inhibitors with off-target and non-specific effects. We have composition of matter and method of use intellectual property for the design and manufacture of antisense RNAi nanoparticle drug products. As of June 30, 2024, we had an accumulated deficit of $112.6 million. Our net loss was $1.9 million and $4.2 million for the three months ended June 30, 2024 and 2023, respectively. Our net loss was $5.0 million and $9.5 million for the six months ended June 30, 2024 and 2023, respectively. We expect to continue to incur significant operating losses, and we anticipate that our losses may increase substantially as we expand our drug development programs and commercialization efforts. To achieve profitability, we must enter into license or development agreements with third parties or successfully develop and obtain regulatory approval for one or more of our drug candidates and effectively commercialize any drug candidates we develop. In addition, if we obtain regulatory approval of one or more of our drug candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Even if we succeed in developing and commercializing one or more of our drug candidates, we may not be able to generate sufficient revenue and we may never be able to achieve or sustain profitability. We expect to finance our foreseeable cash requirements through cash on hand, cash from operations, debt financings and public or private equity offerings. We may seek to access the public or private equity markets whenever conditions are favorable; however, there can be no assurance that we will be able to raise additional capital when needed or on terms that are favorable to us, if at all. Additionally, we may seek collaborations and license arrangements for our drug candidates. We currently have no lines of credit or other arranged access to debt financing.

Company History and Available Information

The Company was incorporated in May 2000 as a Utah corporation. In February 2008, Bio-Path Subsidiary completed a reverse merger with the Company, which at the time was traded over the counter and had no current operations. The prior name of the Company was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path Subsidiary became the directors and officers of Bio-Path Holdings, Inc. On March 10, 2014, our common stock ceased trading on the OTCQX and commenced trading on

the Nasdaq Capital Market under the ticker symbol “BPTH.” Effective December 31, 2014, we changed our state of incorporation from Utah to Delaware through a statutory conversion pursuant to the Utah Revised Business Corporation Act and the Delaware General Corporation Law. Our principal executive offices are located at 4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401, and our telephone number is (832) 742-1357.

On February 22, 2024, we effected a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-20, and our common stock began trading on the spilt-adjusted basis on the Nasdaq Capital Market at the commencement of trading on February 23, 2024. As a result of the reverse stock split, approximately 61,000 shares were added to our total shares outstanding due to rounding fractional shares of common stock up to a whole share of common stock. All common stock share and per share amounts in this Quarterly Report on Form 10-Q have been adjusted to give effect to the 1-for-20 reverse stock split.

Recent Accounting Pronouncements

There are no recent accounting pronouncements that have a material impact on our condensed consolidated financial statements.

Financial Operations Overview

Revenue

We have not generated significant revenues to date. Our ability to generate revenues from our drug candidates, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our drug candidates.

In the future, we may generate revenue from a combination of product sales, third-party grants, service agreements, strategic alliances and licensing arrangements. We expect that any revenue we generate will fluctuate due to the timing and amount of services performed, milestones achieved, license fees earned and payments received upon the eventual sales of our drug candidates, in the event any are successfully commercialized. If we fail to complete the development of any of our drug candidates or obtain regulatory approval for them, our ability to generate future revenue will be adversely affected.

Research and development expenses

Research and development expenses consist of costs associated with our research activities, including the development of our drug candidates. Our research and development expenses consist of:

- expenses related to research and development personnel, including salaries and benefits, travel and stock-based compensation;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, clinical investigative sites, laboratories, manufacturing organizations and consultants; and
- costs of materials used during research and development activities.

Costs and expenses that can be clearly identified as research and development are charged to expense as incurred. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense.

We expect research and development expenses associated with the completion of the associated clinical trials to be substantial and to increase over time. The successful development of our drug candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete development of

our drug candidates or the period, if any, in which material net cash inflows from our drug candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the rate of progress, results and costs of completion of ongoing clinical trials of our drug candidates;
- the size, scope, rate of progress, results and costs of completion of any potential future clinical trials and preclinical tests of our drug candidates that we may initiate;
- competing technological and market developments;
- the performance of third-party manufacturers and suppliers;
- the ability of our drug candidates, if they receive regulatory approval, to achieve market success;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our drug candidates; and
- the impact, risks and uncertainties related to global pandemics and actions taken by governmental authorities or others in connection therewith.

A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a drug candidate or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and administrative expenses

Our general and administrative expenses consist primarily of salaries and benefits for management and administrative personnel, professional fees for legal, accounting and other services, travel costs and facility-related costs such as rent, utilities and other general office expenses.

Results of Operations

Comparisons of the Three Months Ended June 30, 2024 to the Three Months Ended June 30, 2023

Revenue. We had no revenue for each of the three months ended June 30, 2024 and 2023.

Research and Development Expense. Our research and development expense for the three months ended June 30, 2024 was $1.9 million, a decrease of $1.2 million compared to the three months ended June 30, 2023. The decrease in research and development expense was primarily due to decreased manufacturing expenses related to drug product releases partially offset by an increase in expense related to our clinical trial for BP1002 in lymphoma due to increased patient enrollment in 2024. The following table sets forth our research and development expenses (in thousands):

	Three Months Ended June 30,	
	2024	2023
Research and development expense	$ 1,833	$ 3,008
Non-cash stock-based compensation expense	40	43
Total research and development expense	$ 1,873	$ 3,051

General and Administrative Expense. Our general and administrative expense for each of the three months ended June 30, 2024 and 2023 was $1.2 million. The following table sets forth our general and administrative expenses (in thousands):

	Three Months Ended June 30,	
	2024	2023
General and administrative expense	$ 1,064	$ 1,064
Non-cash stock-based compensation expense	101	127
Total general and administrative expense	$ 1,165	$ 1,191

Net Operating Loss. Our net loss from operations for the three months ended June 30, 2024 was $3.0 million, a decrease of $1.2 million compared to the three months ended June 30, 2023.

Change in Fair Value of Warrant Liability: The change in fair value of the warrant liability for the three months ended June 30, 2024 resulted in non-cash income of $1.2 million.

Net Loss. Our net loss for the three months ended June 30, 2024 was $1.9 million, a decrease of $2.4 million compared to the three months ended June 30, 2023.

Net Loss per Share. Net loss per share, both basic and diluted, for the three months ended June 30, 2024 was $1.16, compared to $10.64 for the three months ended June 30, 2023. Net loss per share is calculated using the weighted average number of shares of common stock outstanding during the applicable periods and excludes stock options and warrants because they are antidilutive.

Comparisons of the Six Months Ended June 30, 2024 to the Six Months Ended June 30, 2023

Revenue. We had no revenue for each of the six months ended June 30, 2024 and 2023.

Research and Development Expense. Our research and development expense for the six months ended June 30, 2024 was $4.2 million, a decrease of $2.9 million compared to the six months ended June 30, 2023. The decrease in research and development expense was primarily due to decreased manufacturing expenses related to drug product releases partially offset by an increase in expense related to our clinical trial for BP1002 in lymphoma due to increased patient enrollment in 2024. The following table sets forth our research and development expenses (in thousands):

	Six Months Ended June 30,	
	2024	2023
Research and development expense	$ 4,081	$ 6,948
Non-cash stock-based compensation expense	80	92
Total research and development expense	$ 4,161	$ 7,040

General and Administrative Expense. Our general and administrative expense for the six months ended June 30, 2024 was $2.6 million, an increase of $0.1 million compared to the six months ended June 30, 2023. The increase in general and administrative expense was primarily due to increased legal fees. The following table sets forth our general and administrative expenses (in thousands):

	Six Months Ended June 30,	
	2024	2023
General and administrative expense	$ 2,341	$ 2,210
Non-cash stock-based compensation expense	231	284
Total general and administrative expense	$ 2,572	$ 2,494

Net Operating Loss. Our net loss from operations for the six months ended June 30, 2024 was $6.7 million, a decrease of $2.8 million compared to the six months ended June 30, 2023.

Change in Fair Value of Warrant Liability: The change in fair value of the warrant liability for the six months ended June 30, 2024 resulted in non-cash income of $1.7 million.

Net Loss. Our net loss for the six months ended June 30, 2024 was $5.0 million, a decrease of $4.5 million compared to the six months ended June 30, 2023.

Net Loss per Share. Net loss per share, both basic and diluted, for the six months ended June 30, 2024 was $4.45, compared to $23.89 for the six months ended June 30, 2023. Net loss per share is calculated using the weighted average number of shares of common stock outstanding during the applicable periods and excludes stock options and warrants because they are antidilutive.

Liquidity and Capital Resources

Overview

We have not generated significant revenues to date. Since our inception, we have funded our operations primarily through public and private offerings of our capital stock and other securities. We expect to finance our foreseeable cash requirements through cash on hand, cash from operations, debt financings and public or private equity offerings. We may seek to access the public or private equity markets whenever conditions are favorable; however, there can be no assurance that we will be able to raise additional capital when needed or on terms that are favorable to us, if at all. Additionally, we may seek collaborations and license arrangements for our drug candidates. We currently have no lines of credit or other arranged access to debt financing.

We had a cash balance of $4.0 million as of June 30, 2024, an increase of $3.0 million compared to December 31, 2023. We do not believe that our available cash at June 30, 2024 will be sufficient to meet obligations and fund our liquidity and capital expenditure requirements for the next 12 months from the date of this Quarterly Report on Form 10-Q. The Company's ability to continue as a going concern is dependent upon obtaining funding through one or more sources as described above to meet its planned obligations and pay its liabilities.

Cash Flows

Operating Activities. Net cash used in operating activities for the six months ended June 30, 2024 was $4.3 million. Excluding non-cash change in fair value of the warrant liability of $1.7 million, stock-based compensation expense of $0.3 million and depreciation and amortization expenses of $0.1 million, net cash used in operating activities for the six months ended June 30, 2024 consisted primarily of the net loss for the period of $5.0 million and a decrease in lease liabilities of $0.1 million. These are partially offset by an increase in accounts payable and accrued expenses of $1.2 million and a decrease of $1.0 million in other current assets. Net cash used in operating activities for the six months ended June 30, 2023 was $6.9 million. Excluding non-cash stock-based compensation expense of $0.4 million and depreciation and amortization expenses of $0.1 million, net cash used in operating activities for the six months ended June 30, 2023 consisted primarily of the net loss for the period of $9.5 million, a decrease in operating liabilities of $0.3 million and an increase in other current assets of $0.1 million. These are partially offset by a decrease in prepaid drug product of $2.5 million.

Financing Activities. Net cash provided by financing activities for the six months ended June 30, 2024 was $7.2 million from the March 2024 Registered Direct Offering, the April 2024 Registered Direct Offering, the At The Market Offering Agreement and the June 2024 PIPE (each as defined below). There were no financing activities for the six months ended June 30, 2023.

2022 Shelf Registration Statement

On May 27, 2022, we filed a shelf registration statement on Form S-3 with the SEC, which was declared effective by the SEC on June 14, 2022 (File No. 333-265282) (the "2022 Shelf Registration Statement"), at which time the offering of unsold securities under a previous shelf registration statement on Form S-3 filed with the SEC, which was declared effective by the SEC on June 5, 2019 (File No. 333-231537) (the "2019 Shelf Registration Statement"), was deemed terminated pursuant to Rule 415(a)(6) under the Securities Act. The 2022 Shelf Registration Statement was filed to register the offering, issuance and sale of (i) up to $110.0 million of our common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination thereof, either individually or in units, (ii) up to $9.0 million of our common stock under our At The Market Offering Agreement (the "Offering Agreement"), dated as of July 13, 2020, with H. C. Wainwright & Co., LLC ("Wainwright"), pursuant to which we could offer and sell, from time to time, through or to Wainwright, shares of our common stock, which $9.0 million was subsequently reduced to $3.0 million pursuant to a prospectus supplement filed with the SEC on July 29, 2022, and (iii) up to 11,895 shares of our common stock pursuant to the exercise of warrants outstanding on May 27, 2022. The $3.0 million of our common stock that could

previously be offered, issued and sold under the Offering Agreement was included in the $110.0 million of our securities that may be offered, issued and sold. On December 7, 2022, we received written notice from Wainwright that Wainwright had elected, pursuant to Section 8(b) of to terminate the Offering Agreement effective as of December 7, 2022, at which time all $3.0 million of shares of our common stock remained available for sale thereunder. As a result of the termination of the Offering Agreement, we will not offer or sell any additional shares of our common stock thereunder, and the entire $3.0 million of shares of our common stock previously available for sale under the Offering Agreement will be available for sale in other offerings pursuant to the 2022 Shelf Registration Statement. Because our public float is less than $75.0 million, our ability to offer and sell any securities under the 2022 Shelf Registration Statement is currently limited pursuant to Instruction I.B.6 to Form S-3. For so long as our public float is less than $75.0 million, the aggregate market value of securities we sell pursuant to Instruction I.B.6 to Form S-3 during any 12 consecutive months may not exceed one-third of our public float. The foregoing does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

2023 Public Offering

On August 3, 2023, we entered into a placement agency agreement with Roth Capital Partners, LLC relating to a best efforts public offering of an aggregate of 3,500,000 shares of our common stock, together with warrants to purchase up to 3,500,000 shares of our common stock, for gross proceeds of approximately $2.1 million (the "2023 Public Offering"). The 2023 Public Offering was made pursuant to a registration statement on Form S-1, as amended (File No. 333-272879), which was declared effective by the SEC on August 2, 2023. The 2023 Public Offering closed on August 7, 2023. The net proceeds from the offering, after deducting the placement agent's fees and expenses and our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offering, were approximately $1.7 million.

March 2024 Registered Direct Offering and March 2024 Private Placement

On March 25, 2024, we entered into a securities purchase agreement with a certain institutional and accredited investor pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 75,000 shares of our common stock for gross proceeds of approximately $0.3 million under the base prospectus contained in the 2022 Shelf Registration Statement and a related prospectus supplement filed with the SEC on March 27, 2024 (the "March 2024 Registered Direct Offering"). In a concurrent private placement, we also agreed pursuant to the securities purchase agreement to issue to such investor warrants to purchase up to 75,000 shares of our common stock at an exercise price of $3.865 per share (the "March 2024 Private Placement"). The March 2024 Registered Direct Offering and the March 2024 Private Placement closed on March 27, 2024. The net proceeds from the offerings, after deducting the placement agent's fees and expenses and our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $0.2 million.

At the Market Offering

On April 4, 2024, we entered into the At The Market Offering Agreement with Wainwright, as sales agent, pursuant to which we may offer and sell, from time to time, through Wainwright, shares of our common stock. Under the At The Market Offering Agreement, Wainwright may sell shares by any method deemed to be an "at the market" offering as defined in Rule 415 under the Securities Act, as amended, or any other method permitted by law, including in privately negotiated transactions. We or Wainwright may suspend or terminate the offering of shares upon notice to the other party and subject to other conditions. We will pay Wainwright a commission of 3.0% of the aggregate gross proceeds from each sale of shares under the At The Market Offering Agreement and have agreed to provide Wainwright with customary indemnification and contribution rights. We have also agreed to reimburse Wainwright for certain specified expenses. We are subject to certain restrictions on our ability to offer and sell shares of our common stock under the At The Market Offering Agreement. On April 4, 2024, in connection with the execution of the At The Market Offering Agreement, we filed with the SEC a prospectus supplement (the "Initial ATM Prospectus Supplement") to the base prospectus contained in the 2022 Shelf Registration Statement, which Initial ATM Prospectus Supplement related to the offering of up to $2.0 million of shares of the Company's common stock under the At The Market Offering Agreement. Subsequent to entering into the Offering Agreement, we offered and sold 436,511 shares of common stock for gross proceeds of approximately $2.0 million and terminated the offering under the Initial ATM Prospectus Supplement on April 19, 2024. The net proceeds from such offering, after deducting commissions and our offering expenses, were approximately $1.8 million.

On April 19, 2024, we determined to increase the number of shares available for sale under the At The Market Offering Agreement, up to an additional aggregate offering price of approximately $1.1 million, which shares are being offered and sold pursuant to the 2022 Shelf Registration Statement and a prospectus supplement and accompanying prospectus filed with the SEC on April 19, 2024 (the "Subsequent ATM Prospectus Supplement"). During the quarter ended June 30, 2024, we offered and sold 334,929 shares of common stock under the Subsequent ATM Prospectus Supplement for gross proceeds of approximately $1.1 million and after deducting commissions and the Company's offering expenses, the net proceeds from such offering were approximately $1.0 million.

April 2024 Registered Direct Offering and April 2024 Private Placement

On April 18, 2024, we entered into a securities purchase agreement with certain institutional and accredited investors pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 375,000 shares of our common stock for gross proceeds of approximately $1.2 million under the base prospectus contained in the 2022 Shelf Registration Statement and a related prospectus supplement filed with the SEC on April 19, 2024 (the "April 2024 Registered Direct Offering"). In a concurrent private placement, we also agreed pursuant to the securities purchase agreement to issue to such investors warrants to purchase up to 375,000 shares of our common stock at an exercise price of $3.10 per share (the "April 2024 Private Placement"). The April 2024 Registered Direct Offering and the April 2024 Private Placement closed on April 19, 2024. The net proceeds from the offerings, after deducting the placement agent's fees and expenses and our offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the offerings, were approximately $0.9 million.

June 2024 PIPE

On June 3, 2024, we entered into a securities purchase agreement with a certain institutional and accredited investor pursuant to which we agreed to sell, in a private placement, an aggregate of (i) 180,000 shares of our common stock, (ii) pre-funded warrants to purchase up to 1,629,955 shares of our common stock at an exercise price of $0.001 per share, (iii) series A warrants to purchase up to 1,809,955 shares of our common stock at an exercise price of $2.00 per share and (iv) series B warrants to purchase up to 1,809,955 shares of our common stock at an exercise price of $2.00 per share for gross proceeds of approximately $4.0 million (the "June 2024 PIPE"). The June 2024 PIPE closed on June 5, 2024. The net proceeds from the offering, after deducting the placement agent's fees and expenses and our offering expenses, and excluding the proceeds, if any, from the exercises of the warrants issued in the offering, were approximately $3.3 million.

Future Capital Requirements

We expect to continue to incur significant operating expenses in connection with our ongoing activities, including conducting clinical trials, manufacturing and seeking regulatory approval of our drug candidates, prexigebersen, BP1002, BP1003 and BP1001-A. Accordingly, we will continue to require substantial additional capital to fund our projected operating requirements. Such additional capital may not be available when needed or on terms favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current and future operating plan. There can be no assurance that we will be able to continue to raise additional capital through the sale of our securities in the future. Our future capital requirements may change and will depend on numerous factors, which are discussed in detail in "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of the fiscal year ended December 31, 2023. For more information, see Note 1 to the Unaudited Condensed Consolidated Financial Statements included herein.

Off-Balance Sheet Arrangements

As of June 30, 2024, we did not have any material off-balance sheet arrangements.

Critical Accounting Policies

The preparation of financial statements in conformity with generally accepted accounting principles in the United States has required our management to make assumptions, estimates and judgments that affect the amounts reported in the financial statements, including the notes thereto, and related disclosures of commitments and contingencies, if any. We consider our critical accounting policies to be those that require the more significant judgments and estimates in the preparation of financial statements. There have

been no significant changes to our critical accounting policies from those disclosed in Note 2 to our Consolidated Financial Statements included in our Annual Report on Form 10-K as of the year ended December 31, 2023.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

It is management's responsibility to establish and maintain adequate disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including the company's principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Our management, including our Chief Executive Officer (who is also our Chief Financial Officer), has reviewed and evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q. Following this review and evaluation, our management determined that as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

Failure to meet Nasdaq's continued listing requirements could result in the delisting of our common stock, negatively impact the price of our common stock and negatively impact our ability to raise additional capital.

On March 12, 2024, we received a deficiency letter from the Listing Qualifications Department of Nasdaq ("Nasdaq") notifying the Company that it is not in compliance with the minimum stockholders' equity requirement of at least $2,500,000 for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(1) (the "Stockholders' Equity Requirement"). On April 26, 2024, in accordance with Nasdaq Listing Rule 5810(c)(2)(A), the Company submitted a plan to Nasdaq to regain compliance (the "Compliance Plan") with the Stockholders' Equity Requirement. On June 12, 2024, the Company received a letter from Nasdaq granting an extension (the "Extension Letter") until September 8, 2024 to demonstrate compliance with the Stockholders' Equity Requirement in accordance with the terms of the Extension Letter.

If the Company does not demonstrate compliance in accordance with the Extension Letter, the Company may be subject to delisting. At that time, the Company may appeal Nasdaq's delisting determination to a Nasdaq Hearings Panel (the "Panel"). If the Company timely appeals, it would remain listed pending the Panel's decision. The Company intends to continue making efforts to implement the Compliance Plan to regain compliance with the Stockholders' Equity Requirement. However, there can be no assurance that the Company will be able to regain compliance with the Stockholders' Equity Requirement within the allotted extension period. If the Company is unsuccessful in regaining compliance within the allotted extension period and appeals the delisting determination by Nasdaq to the Panel, there can be no assurance that such appeal will be successful.

If our common stock is delisted, it could reduce the price of our common stock and the levels of liquidity available to our stockholders. In addition, the delisting of our common stock could materially adversely affect our access to the capital markets and any limitation on liquidity or reduction in the price of our common stock could materially adversely affect our ability to raise capital. Delisting from The Nasdaq Capital Market could also result in other negative consequences, including the potential loss of confidence by suppliers, customers and employees, the loss of institutional investor interest and fewer business development opportunities.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

Insider Adoption or Termination of Trading Arrangements

During the last fiscal quarter, none of our directors or officers adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408.

ITEM 6. EXHIBITS

Exhibit No.	Description of Exhibit
2.1	Agreement and Plan of Merger and Reorganization dated September 27, 2007, by and among the Company, Biopath Acquisition Corp., a Utah corporation and wholly owned subsidiary of the registrant, and Bio-Path, Inc., a Utah corporation (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on September 27, 2007).
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed on January 6, 2015).
3.2	Certificate of Amendment to the Certificate of Incorporation of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 9, 2018).
3.3	Certificate of Amendment to the Certificate of Incorporation of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 16, 2019).
3.4	Certificate of Amendment to the Certificate of Incorporation of Bio-Path Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 23, 2024).
3.5	First Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 7, 2017).
3.6	Amendment No. 1 to the First Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 8, 2023).
4.1	Form of Common Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on April 19, 2024).
4.2	Form of Placement Agent Common Stock Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on April 19, 2024).
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 5, 2024).
4.4	Form of Series A Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on June 5, 2024).
4.5	Form of Series B Warrant (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on June 5, 2024).
4.6	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed on June 5, 2024).
10.1	At The Market Offering Agreement, dated as of April 4, 2024, by and between the Company and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 4, 2024).
10.2	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 19, 2024).
10.3	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 5, 2024).
10.4	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on June 5, 2024).
31*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 Sarbanes Oxley Act of 2002.
32**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
101*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, formatted in Inline XBRL: (i) Condensed Consolidated Balance Sheets (Unaudited); (ii) Condensed Consolidated Statements of Operations (Unaudited); (iii) Condensed Consolidated Statements of Cash Flows (Unaudited); (iv) Condensed Consolidated Statements of Shareholders' Equity (Unaudited); and (v) Notes to the Unaudited Condensed Consolidated Financial Statements, tagged as blocks of text and including detailed tags.
104*	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, formatted in Inline XBRL (included as Exhibit 101).

* Filed herewith.

** Furnished herewith.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: August 14, 2024

BIO-PATH HOLDINGS, INC.

By: /s/ Peter H. Nielsen
Peter H. Nielsen
President
Chief Executive Officer
(Principal Executive Officer)
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31

CERTIFICATION OF
PRINCIPAL EXECUTIVE OFFICER AND
PRINCIPAL FINANCIAL OFFICER

I, Peter H. Nielsen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Bio-Path Holdings, Inc.;

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 registrant as of, and for, the periods presented in this report;

4. I am 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 registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

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 registrant'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 registrant's internal control over financial reporting.

Dated: August 14, 2024

By: /s/ Peter H. Nielsen
Peter H. Nielsen
Chief Executive Officer
(Principal Executive Officer)
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

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

In connection with the Quarterly Report on Form 10-Q of Bio-Path Holdings, Inc. (the "Company") for the quarter ended June 30, 2024 as filed with the Securities and Exchange Commission (the "Report"), I, Peter H. Nielsen, Chief Executive Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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.

Dated: August 14, 2024

By: /s/ Peter H. Nielsen
Peter H. Nielsen
Chief Executive Officer
Chief Financial Officer