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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, 2023

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

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

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

At August 8, 2023, the Company had 11,460,164 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 as of the fiscal year ended December 31, 2022 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 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, 2022, "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, 2023 (unaudited)	As of December 31, 2022
Assets		
Current assets		
Cash	$ 3,444	$ 10,384
Prepaid drug product	1,069	3,587
Other current assets	1,746	1,644
Total current assets	6,259	15,615
Fixed assets		
Furniture, fixtures & equipment	1,120	1,120
Less accumulated depreciation	(1,006)	(962)
	114	158
Right of use operating assets	151	198
Total Assets	$ 6,524	$ 15,971
Liabilities & Shareholders' Equity		
Current liabilities		
Accounts payable	$ 638	$ 667
Accrued expenses	675	909
Current portion of lease liabilities	113	108
Total current liabilities	1,426	1,684
Noncurrent lease liabilities	55	113
Total Liabilities	1,481	1,797
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; 7,960 and 7,960 shares issued and outstanding, respectively	8	8
Additional paid in capital	106,071	105,695
Accumulated deficit	(101,036)	(91,529)
Total shareholders' equity	5,043	14,174
Total Liabilities & Shareholders' Equity	$ 6,524	$ 15,971

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,	
	2023	**2022**	**2023**	**2022**
Operating expenses				
Research and development	$ 3,051	$ 1,851	$ 7,040	$ 3,949
General and administrative	1,191	1,159	2,494	2,420
Total operating expenses	4,242	3,010	9,534	6,369
Net operating loss	$ (4,242)	$ (3,010)	$ (9,534)	$ (6,369)
Other income				
Interest income	8	2	27	2
Total other income	8	2	27	2
Net loss	$ (4,234)	$ (3,008)	$ (9,507)	$ (6,367)
Net loss per share, basic and diluted	$ (0.53)	$ (0.42)	$ (1.19)	$ (0.89)
Basic and diluted weighted average number of common shares outstanding	7,960	7,160	7,960	7,160

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,	
	2023	**2022**
Cash flow from operating activities		
Net loss	$ (9,507)	$ (6,367)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	376	430
Amortization of right of use assets	47	45
Depreciation	44	43
(Increase) decrease in operating assets		
Prepaid drug product	2,518	(1,624)
Other current assets	(102)	451
Increase (decrease) in operating liabilities		
Accounts payable and accrued expenses	(263)	343
Lease liabilities	(53)	(50)
Net cash used in operating activities	(6,940)	(6,729)
Cash flow from investing activities		
Purchases of furniture, fixtures & equipment	—	(21)
Net cash used in investing activities	—	(21)
Net decrease in cash	**(6,940)**	**(6,750)**
Cash, beginning of period	10,384	23,774
Cash, end of period	$ 3,444	$ 17,024
Supplemental disclosure of non-cash activities		
Non-cash operating activities		
Right of use asset recognized in exchange for lease obligation	$ —	$ 85

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, 2022	**7,160**	**$ 7**	**$ 103,328**	**$ (81,020)**	**$ 22,315**
Stock-based compensation	—	—	213	—	213
Net loss	—	—	—	(3,008)	(3,008)
Balance at June 30, 2022	**7,160**	**$ 7**	**$ 103,541**	**$ (84,028)**	**$ 19,520**
Balance at March 31, 2023	**7,960**	**$ 8**	**$ 105,901**	**$ (96,802)**	**$ 9,107**
Stock-based compensation	—	—	170	—	170
Net loss	—	—	—	(4,234)	(4,234)
Balance at June 30, 2023	**7,960**	**$ 8**	**$ 106,071**	**$ (101,036)**	**$ 5,043**

Description	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total
Balance at December 31, 2021	**7,160**	**$ 7**	**$ 103,111**	**$ (77,661)**	**$ 25,457**
Stock-based compensation	—	—	430	—	430
Net loss	—	—	—	(6,367)	(6,367)
Balance at June 30, 2022	**7,160**	**$ 7**	**$ 103,541**	**$ (84,028)**	**$ 19,520**
Balance at December 31, 2022	**7,960**	**$ 8**	**$ 105,695**	**$ (91,529)**	**$ 14,174**
Stock-based compensation	—	—	376	—	376
Net loss	—	—	—	(9,507)	(9,507)
Balance at June 30, 2023	**7,960**	**$ 8**	**$ 106,071**	**$ (101,036)**	**$ 5,043**

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, 2022. The results of operations for the period ended June 30, 2023 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, 2023 and 2022, 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, 2023 and 2022. 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. The calculation of diluted earnings per share for 2022

did not include 657,408 shares and 400,531 shares issuable pursuant to the exercise of outstanding common stock options and warrants, respectively, as of June 30, 2022 as the effect would be antidilutive.

Liquidity - The Company's available cash and cash equivalents of $3.4 million at June 30, 2023 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 BP1001-A. 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.

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 $3.6 million as of December 31, 2022 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 and incurred additional installment costs during the first six months of 2023, with advanced payments remaining to be expensed totaling $1.1 million as of June 30, 2023.

4. Other Current Assets

As of June 30, 2023, other current assets included prepaid expenses of $1.7 million, comprised primarily of prepayments of $1.7 million made for the Company's clinical trials for BP1002 in separate clinical trials for lymphoma and AML, prexigebersen in AML as well as BP1001-A in solid tumors. As of December 31, 2022, other current assets included prepaid expenses of $1.6 million, comprised primarily of prepayments of $1.3 million made for the Company's clinical trials for BP1002 in AML and lymphoma, BP1001-A in solid tumors and prexigebersen in AML as well as prepaid insurance of $0.3 million.

5. Accounts Payable

As of June 30, 2023, current liabilities included accounts payable of $0.6 million, comprised primarily of expenses related to drug manufacturing, development and testing services of $0.4 million and clinical trial expenses of $0.2 million. As of December 31, 2022, current liabilities included accounts payable of $0.7 million, comprised primarily of expenses related to drug manufacturing, development and testing services of $0.6 million and legal and patent fees of $0.1 million.

6. Accrued Expense

As of June 30, 2023, current liabilities included accrued expenses of $0.7 million, comprised primarily of accrued employee vacation and bonus expenses of $0.4 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. As of December 31, 2022, current liabilities included accrued expenses of $0.9 million, comprised primarily of accrued employee vacation and bonus expenses of $0.4 million, drug manufacturing development and testing services 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. Stockholders' Equity

Issuances of Common Stock - On November 6, 2022, the Company entered into a placement agency agreement with Roth Capital Partners, LLC relating to the 2022 Registered Direct Offering and the 2022 Private Placement. In addition, on November 6, 2022, the Company entered into securities purchase agreements with several institutional and accredited investors pursuant to which the Company agreed to sell, in a registered direct offering, an aggregate of 800,000 shares of our common stock for gross proceeds of approximately $2.0 million under the base prospectus contained in the Company's shelf registration statement on Form S-3 filed with the SEC, which was declared effective by the SEC on June 14, 2022 (File No. 333-265282) (the "2022 Shelf Registration Statement"), and a related prospectus supplement filed with the SEC on November 9, 2022 (the "2022 Registered Direct Offering"). In a concurrent private placement, the Company also agreed pursuant to the securities purchase agreements to issue to such investors warrants to purchase up to 800,000 shares of its common stock (the "2022 Private Placement"). The 2022 Registered Direct Offering and the 2022 Private Placement closed on November 9, 2022. 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 $1.7 million.

Stockholders' Equity totaled $5.0 million as of June 30, 2023 compared to $14.2 million as of December 31, 2022. There were 7,960,164 shares of common stock issued and outstanding as of June 30, 2023. There were no shares of preferred stock issued and outstanding as of June 30, 2023.

8. 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, 2022, there were 1,300,000 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 each of the three months ended June 30, 2023 and 2022 was $0.2 million. Of these amounts, stock-based compensation expense for personnel involved in the Company's general and administrative activities for the three months ended June 30, 2023 and 2022 was $0.2 million and $0.1 million, respectively. Stock-based compensation expense for personnel involved in the Company's research and development activities for the three months ended June 30, 2023 and 2022 was $43,000 and $50,000, respectively.

Stock-based compensation expense for each of the six months ended June 30, 2023 and 2022 was $0.4 million. Of these amounts, stock-based compensation expense for personnel involved in the Company's general and administrative activities for each of the six months ended June 30, 2023 and 2022 was $0.3 million. Stock-based compensation expense for personnel involved in the Company's research and development activities for each of the six months ended June 30, 2023 and 2022 was $0.1 million.

The Company utilized the Black-Scholes valuation model for estimating the fair value of the stock options granted, with the following weighted-average assumptions for options granted in the six months ended June 30, 2023 and 2022, respectively:

	2023	2022
Risk-free interest rate	3.42 %	2.43 %
Expected volatility	129 %	127 %
Expected term in years	6.0	6.0
Dividend yield	— %	— %

The following summary represents option activity under the Company's stock-based compensation plans for the six months ended June 30, 2023:

	Options (in thousands)	Weighted-Average Exercise Price
Outstanding at December 31, 2022	658	$ 11.67
Granted	221	1.39
Outstanding at June 30, 2023	879	$ 9.09
Vested and expected to vest June 30, 2023	822	$ 9.23
Exercisable at June 30, 2023	428	$ 15.18

As of June 30, 2023, the aggregate intrinsic value of outstanding stock options was $0.1 million. The aggregate intrinsic value represents the total pretax intrinsic value (the difference between the Company's closing stock price on June 30, 2023 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, 2023. This amount changes based on the fair value of the Company's stock.

As of June 30, 2023, unamortized stock-based compensation expense for all outstanding options was $1.2 million, which is expected to be recognized over a weighted average vesting period of 2.1 years.

9. Commitments and Contingencies

Drug Supplier Project Plan – Total commitments for the Company's drug supplier project plan were $1.9 million as of June 30, 2023, comprised of $1.4 million for manufacture of the Company's Grb2 drug substance, $0.3 million for testing services and $0.2 million for the manufacture of prexigebersen drug product. The Company expects to incur $1.7 million of these commitments over the next 12 months.

10. Subsequent Events

2023 Public Offering – 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, 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. In connection with the 2023 Public Offering, the Company agreed to amend the existing warrants to purchase up to an aggregate of 800,000 shares of its common stock that were previously issued in the 2022 Private Placement at an exercise price of $2.85 per share, such that as of the closing of the 2023 Public Offering, the amended warrants have a reduced exercise price equal to $0.7593 per share.

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, 2022. 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, 2022, 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 released on March 6, 2019 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 *de novo* 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 untreated 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 untreated 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.

On April 5, 2021, we announced the successful completion of the safety run-in of Stage 2 of the Phase 2 clinical study. 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. In the preliminary safety data review, five of the patients (83%) responded to treatment, including four (67%) achieving CR and one (17%) achieving CRi. Recent publications provide that response (CR + CRi) rates to combination treatment with decitabine and venetoclax (but without prexigebersen) are 42 to 52% for relapsed/refractory AML patients and 0 to 39% for relapsed/refractory secondary AML patients. Response rates to frontline treatment with decitabine and venetoclax (but without prexigebersen) are 62 to 71% for newly diagnosed AML patients. These preliminary data, presented at the 2021 American Society of Hematology Annual Meeting, 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 partial remission ("PR"). In total, 100% of the evaluable patients had a response to treatment. The complete remission rate (CR/CRi) of 86% for the evaluable patients in the first cohort is significantly higher than complete remission (CR/CRi) rates of 62% for newly diagnosed patients treated with the frontline combination treatment of decitabine and venetoclax. 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. All 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 patients (57%) achieved CR/CRi, two (14%) achieved PR and three (22%) achieved stable disease. In total, 93% of the evaluable patients in the second cohort had a response to treatment. The complete remission rate (CR/CRi) of (57%) for the evaluable refractory and relapsed patients in the second cohort is significantly higher than complete remission (CR/CRi) rates (21%) for refractory/relapsed patients treated with the combination treatment of decitabine and venetoclax. Based on this interim data, we currently plan to pursue FDA expedited programs for Fast Track and Breakthrough Therapy designations, and we are evaluating whether to seek to expand Stage 2 of the Phase 2 clinical trial in Europe.

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. On November 21, 2019, we announced that the FDA cleared an Investigational New Drug ("IND") application for BP1002 for an initial Phase 1 clinical trial to evaluate the ability of BP1002 to treat refractory/relapsed lymphoma and chronic lymphocytic leukemia patients. The Phase 1 clinical trial is being conducted at the Georgia Cancer Center while two additional clinical trial sites are currently being processed for inclusion in the study, The University of Texas Southwestern and New York Medical College.

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. On August 24, 2021, we announced that the FDA cleared an IND application for BP1002 for an initial Phase 1/1b clinical trial to evaluate the ability of BP1002 to treat refractory/relapsed AML patients, including venetoclax-

resistant 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. Gail J. Roboz, MD, will serve as the national coordinating Principal Investigator for the Phase 1/1b trial. On October 24, 2022, we announced the enrollment and dosing of the first patient in the Phase 1/1b clinical trial.

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. On October 27, 2021, we announced that the FDA cleared an IND application for BP1001-A for an initial Phase 1/1b clinical trial in patients with advanced or recurrent solid tumors, and on December 7, 2022, we announced the enrollment and dosing of the first patient in the Phase 1/1b clinical trial. On July 17, 2023, we announced completion of the first cohort of the dose escalation portion of the Phase 1/1b clinical trial. 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.

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 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, 2023, we had an accumulated deficit of $101.0 million. Our net loss was $4.2 million and $3.0 million for the three months ended June 30, 2023 and 2022, respectively. Our net loss was $9.5 million and $6.4 million for the six months ended June 30, 2023 and 2022, 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.

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, 2023 to the Three Months Ended June 30, 2022

Revenue. We had no revenue for each of the three months ended June 30, 2023 and 2022.

Research and Development Expense. Our research and development expense for the three months ended June 30, 2023 was $3.1 million, an increase of $1.2 million compared to the three months ended June 30, 2022. The increase in research and development expense was primarily due to manufacturing expenses related to drug product releases in the second quarter of 2023 and increased

patient enrollment related to our Phase 2 clinical trial for prexigebersen in AML. The following table sets forth our research and development expenses (in thousands):

	Three Months Ended June 30,	
	2023	2022
Research and development expense	$ 3,008	$ 1,801
Non-cash stock-based compensation expense	43	50
Total research and development expense	$ 3,051	$ 1,851

General and Administrative Expense. Our general and administrative expense for each of the three months ended June 30, 2023 and 2022 was $1.2 million. The following table sets forth our general and administrative expenses (in thousands):

	Three Months Ended June 30,	
	2023	2022
General and administrative expense	$ 1,064	$ 996
Non-cash stock-based compensation expense	127	163
Total general and administrative expense	$ 1,191	$ 1,159

Net Operating Loss. Our net loss from operations for the three months ended June 30, 2023 was $4.2 million, an increase of $1.2 million compared to the three months ended June 30, 2022.

Net Loss. Our net loss for the three months ended June 30, 2023 was $4.2 million, an increase of $1.2 million compared to the three months ended June 30, 2022.

Net Loss per Share. Net loss per share, both basic and diluted, for the three months ended June 30, 2023 was $0.53, compared to $0.42 for the three months ended June 30, 2022. 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, 2023 to the Six Months Ended June 30, 2022

Revenue. We had no revenue for each of the six months ended June 30, 2023 and 2022.

Research and Development Expense. Our research and development expense for the six months ended June 30, 2023 was $7.0 million, an increase of $3.1 million compared to the six months ended June 30, 2022. The increase in research and development expense was primarily due to manufacturing expenses related to drug product releases in 2023. The following table sets forth our research and development expenses (in thousands):

	Six Months Ended June 30,	
	2023	2022
Research and development expense	$ 6,948	$ 3,852
Non-cash stock-based compensation expense	92	97
Total research and development expense	$ 7,040	$ 3,949

General and Administrative Expense. Our general and administrative expense for the six months ended June 30, 2023 was $2.5 million, an increase of $0.1 million compared to the six months ended June 30, 2022. The increase in general and administrative

expense was primarily due to an increase in audit fees. The following table sets forth our general and administrative expenses (in thousands):

	Six Months Ended June 30,	
	2023	2022
General and administrative expense	$ 2,210	$ 2,087
Non-cash stock-based compensation expense	284	333
Total general and administrative expense	$ 2,494	$ 2,420

Net Operating Loss. Our net loss from operations for the six months ended June 30, 2023 was $9.5 million, an increase of $3.2 million compared to the six months ended June 30, 2022.

Net Loss. Our net loss for the six months ended June 30, 2023 was $9.5 million, an increase of $3.1 million compared to the six months ended June 30, 2022.

Net Loss per Share. Net loss per share, both basic and diluted, for the six months ended June 30, 2023 was $1.19, compared to $0.89 for the six months ended June 30, 2022. 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 $3.4 million as of June 30, 2023, a decrease of $6.9 million compared to December 31, 2022. We do not believe that our available cash at June 30, 2023, together with the net proceeds received from the 2023 Public Offering, as described below, 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 within the next 12 months 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, 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. Net cash used in operating activities for the six months ended June 30, 2022 was $6.7 million. Excluding non-cash stock-based compensation expense of $0.4 and depreciation and amortization expenses of $0.1 million, net cash used in operating activities consisted primarily of the net loss for the period of $6.4 million and an increase in prepaid drug product of $1.6 million partially offset by a decrease in other current assets of $0.5 million and an increase in operating liabilities of $0.3 million.

Investing Activities. There were no investing activities for the six months ended June 30, 2023. Net cash used in investing activities for the six months ended June 30, 2022 consisted of a capital expenditure totaling $21,000 which was related to a research and development equipment purchase.

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 237,890 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. The Offering Agreement was terminated 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.

2022 Registered Direct Offering and 2022 Private Placement

On November 6, 2022, we entered into a placement agency agreement with Roth Capital Partners, LLC relating to the 2022 Registered Direct Offering and the 2022 Private Placement. In addition, on November 6, 2022, we entered into securities purchase agreements with several institutional and accredited investors pursuant to which we agreed to sell, in a registered direct offering, an aggregate of 800,000 shares of our common stock for gross proceeds of approximately $2.0 million under the base prospectus contained in the 2022 Shelf Registration Statement and a related prospectus supplement filed with the SEC on November 9, 2022 (the "2022 Registered Direct Offering"). In a concurrent private placement, we also agreed pursuant to the securities purchase agreements to issue to such investors warrants to purchase up to 800,000 shares of our common stock (the "2022 Private Placement"). The 2022 Registered Direct Offering and the 2022 Private Placement closed on November 9, 2022. 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 $1.7 million.

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.

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, 2022. For more information, see Note 1 to the Unaudited Condensed Consolidated Financial Statements included herein.

Off-Balance Sheet Arrangements

As of June 30, 2023, 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, 2022.

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

There were no material changes from the risk factors previously disclosed under “Item 1A. Risk Factors” to Part I of our Annual Report on Form 10-K as of the fiscal year ended December 31, 2022.

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

None.

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	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).
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 August 7, 2023).
4.2	Warrant Agency Agreement, dated as of August 7, 2023, by and between the Company and Equiniti Trust Company, LLC (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on August 7, 2023).
10.1	Placement Agency Agreement, dated as of August 3, 2023, by and between the Company and Roth Capital Partners, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 7, 2023).
10.2	Form of Securities Purchase Agreement, dated as of August 3, 2023, by and between the Company and certain purchasers (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on August 7, 2023).
10.3	Form of Warrant Amendment Agreement, dated as of August 3, 2023, by and between the Company and certain warrant holders (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on August 7, 2023).
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, 2023, 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, 2023, 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, 2023

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, 2023

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, 2023 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, 2023

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